Proposal Subject: Procedure for the Approval of Analytical Methods for the NSSP

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: PROCEDURE XVI. Procedure for the Approval of Analytical Methods for the NSSP

Section 1. Prior to NSSP adoption, all laboratory methods shall be ~~Systematic~~ evaluat~~ion~~ed by the ISSC ~~of the analytical method~~ using the validation criteria developed ~~by the ISSC~~ as detailed in the Single Laboratory Validation Protocol;

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

Subdivision a. Proposals shall include a ~~Submission of the Proposal~~ completed Single Laboratory Validation Method Application and Checklist.~~;~~

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

Section 3. Review by Laboratory Methods Review Committee;

Subdivision a. The Laboratory Methods Review Committee shall conduct an ~~review and~~ evaluation of the data ~~submitted~~ which describe~~sing~~ the performance characteristics of the 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. ~~Possible Actions by t~~The Laboratory Methods Review Committee shall submit one of the following recommendations to Task Force I:~~;~~

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

Subdivision b. Accept as an Approved NSSP ~~Type IV~~ Method;

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

Subdivision d. Accept as an Emergency Use NSSP ~~Type III~~ Method~~, and recommend adoption as Type II or Type I Method;~~

~~Subdivision e. Rescind acceptance for cause (the need no longer exists, poor performance, equipment or reagents no longer available, etc.)~~

Section 5. 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.~~Task Force recommendation (or non-recommendation) for adoption by ISSC;~~

Section 6. ~~Section 6. Adoption (or non-adoption) by ISSC General Assembly;~~ 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 .10 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 .10 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:

Subdivision i. Name of Method;

Sudivision 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, reagents 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.

~~Section 7. Review and Acceptance by FDA Office of Food Safety in the Summary of Actions;~~

~~Section 8. Addition to/removal from the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods.~~

~~Section 9. Types of NSSP analytical methods.~~

~~Subdivision a. Type I Methods. Type I methods are methods accepted for use in the NSSP and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that 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; and/or,~~

~~Subdivision v. Long used as an accepted method in the NSSP. Examples: APHA MPNs for total and fecal coliforms, Modified A-1 MPN (MA-1), and the mouse bioassay for saxitoxins (PSP).~~

~~Subdivision b. Type II Methods. Type II methods are methods accepted for use in the NSSP and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that 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. Long used and accepted for use in the NSSP. Examples: Elevated temperature coliform pour plate method (ETCP) and the mouse bioassay for brevetoxins (NSP).~~

~~Subdivision c. Type III Methods. Type III methods include those methods accepted by unanimous vote of the Laboratory Methods Review Committee for use on an interim basis and cited in the NSSP *Guide for the Control of Molluscan Shellfish*,~~

~~Guidance Documents, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that 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. Selected to fulfill a continuing need;~~

~~Subdivision v. Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation or deletion.~~

~~Subdivision d. Type IV Methods. Type IV methods include those methods accepted by majority vote of the Laboratory Methods Review Committee for use on an interim basis and cited in the NSSP *Guide for the Control of Molluscan Shellfish*, Guidance Documents, Chapter II, Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods that 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. Selected to fulfill an immediate need;~~

~~Subdivision v. Designated for review and assessment by the Laboratory Methods Review Committee for continued use, re-designation or deletion.~~

Public Health Significance:

Cost Information (if available):

Action by 2011 Task Force III Recommended adoption of Proposal 11-307 as submitted.

Action by 2011 General Assembly Adopted the recommendation of Task Force III on Proposal 11-307.

Action by FDA February 26, 2012 Concurred with Conference action on Proposal 11-307.