

**Proposal Subject:** Revision of Procedure XVI of the ISSC's Constitution, Bylaws and Procedures

**Specific NSSP Guide Reference:** ISSC Constitution, Bylaws and Procedures Procedure XVI. Procedure for Acceptance and Approval of Analytical Methods for the NSSP (Section 3, subdivision b, b i, b ii, b iii, Section 4, subdivision a, subdivision b, subdivision c, subdivision d, subdivision e, subdivision f and subdivision g, Section 5, Section 6, Section 7, Section 8, Section 9, subdivision a, a ii, a iii, a iv, Subdivision b, b ii, b iii, b iv, Subdivision c, c ii, c iii, c iv, c v, Subdivision d, d ii, d iii, d iv, d v.)

**Text of Proposal/ Requested Action** Revise Procedure XVI ISSC Constitution, Bylaws and Procedures as follows.

Section 3 Review by Laboratory Methods Review Committee;

Subdivision a. Committee review .....

Subdivision i. These performance .....

- 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.....

Subdivision ii. Method documentation including: .....

- Subdivision (a) Method title.....
- Subdivision (b) Equipment and.....
- Subdivision (c) Sample collection .....
- Subdivision (d) Safety requirements;
- Subdivision (e) Step by step procedure;
- Subdivision (f) Specific quality.....
- Subdivision (g) Cost of the method;
- Subdivision (h) Sample turnaround time.

Subdivision iii. Specific application(s);

Subdivision b. Review of the need for the method;

Subdivision i. ~~Method~~ Meets ~~an immediate or continuing a~~ critical need for a method of analysis where there is no existing NSSP method available;

Subdivision ii. Improves turnaround time, cost effectiveness or develops analytical capacity beyond existing NSSP methods; ~~capability under the NSSP as an alternative to an accepted~~

~~method(s);~~

Subdivision iii. Replaces an obsolete NSSP method of analysis, other approved or accepted method(s).

Section 4. Possible Actions by the Laboratory Methods Review Committee;

Subdivision a. Recommend non-adoption as the proposed method does not meet a critical need; does not replace an obsolete NSSP method or improve turnaround time, cost-effectiveness or develop analytical capacity beyond existing NSSP methods;

Subdivision b. Recommend non-adoption ~~Non-acceptance~~ pending further information as ~~defined~~ required by the Committee;

Subdivision c. Recommend adoption ~~Accept~~ as a Type IV Method;

Subdivision d. Recommend adoption ~~Accept~~ as a Type III Method;

Subdivision e. Accept as a Type III Method and Recommend adoption as a Type II or Type I Method;

Subdivision f. Recommend adoption as a Type I Method;

Subdivision g. Rescind acceptance Recommend rescinding the method for cause (the need no longer exists, poor performance, equipment or reagents no longer available, little or unused etc.).

Subdivision h. Recommend no action as there has been no response to the Committee's request for further information or additional data.

Section 5. Task force Recommendation (or non-recommendation) for adoption by the ISSC;

Section 6. Adoption (or non-adoption) by the ISSC General Assembly;

Section 7. Review and concurrence (or non-concurrence) ~~Acceptance~~ by FDA Office of Food Safety in the Summary of Actions;

Section 8. If the Task Force's action is adopted by the Conference and concurred with by FDA, the method is added ~~Addition~~ ~~to/removal~~ ~~removed~~ from the Table of Approved National Shellfish Sanitation Program Laboratory Tests 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.~~

Section 9. Types of NSSP analytical methods.

Subdivision a. Type I Methods. Core Methods. ~~Type I~~ Core methods are methods accepted for use in the NSSP and ~~etted~~ 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:  
~~Microbiological and Biotxin Analytical Methods~~ that have been:

- Subdivision i. Described in a scientific or other peer-reviewed professional publication;
- Subdivision ii. Used successfully throughout the NSSP to detect or quantify;
- Subdivision iii. Evaluated, and the performance characteristics for specific applications in the NSSP 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~~ the “gold standard” ~~throughout in~~ the NSSP to meet established Program requirements. Examples of ~~Type I methods~~ the: the APHA MPNs methods for both total and fecal coliforms, ~~Modified A-1 MPN- (MA-1)~~ and the mouse bioassays for ~~saxitoxin~~ Paralytic shellfish toxins (PSP) and brevetoxins (NSP).

Subdivision b. Type II Methods. Permanent Methods. ~~Type II Permanent~~ methods are methods accepted for use in the NSSP and ~~cited~~ 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: ~~Microbiological and Biotxin Analytical Methods~~ that have been:

- Subdivision i. Described in a scientific or other peer-reviewed professional publication;
- Subdivision ii. Used successfully within the NSSP to detect or quantify;
- Subdivision iii. ~~Evaluated~~ NSSP validated and the performance characteristics for specific applications within the NSSP have been determined and found fit for purpose;
- Subdivision iv. Long Widely used and accepted for use within the NSSP as alternative methods to improve turnaround time, cost effectiveness or to develop analytical capacity beyond what is achieved by the core methods. Examples of

Type II methods: the Elevated temperature coliform pour plate method (ETCP) for fecal coliform analysis and the mouse bioassay for brevetoxins (NSP) mTEC membrane filtration method for fecal coliforms.

Subdivision c. Type III Methods.

Interim Methods. Type III Interim methods ~~are include those~~ methods accepted ~~by unanimous vote of the Laboratory Methods Review Committee~~ for use in the NSSP on an interim basis and ~~listed~~ 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 within the NSSP to detect or quantify;

Subdivision iii. ~~Evaluated~~ NSSP validated and the Performance characteristics for specific applications within the NSSP have been determined and found fit for purpose;

Subdivision iv. Selected to fill ~~fulfill~~ an ongoing NSSP Program continuing need;

Subdivision v. Used effectively outside the laboratory in which the method was developed and/or validated;

Subdivision vi. Designated for periodic review and assessment by the Laboratory Methods Review Committee as to the feasibility for continued use, re-designation or deletion of the method. Examples of Type III methods: the Jellett Rapid Test (JRT) for PSP and the mEndo-LES membrane filtration method for UV treated process water.

Subdivision d. Type IV Methods. Provisional Methods. Type iv Provisional methods ~~are include those~~ methods accepted ~~by majority vote of the Laboratory Methods Review Committee~~ for use in the NSSP on an interim basis and ~~cited~~ 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: ~~Microbiological and Biotoxin Analytical Methods~~ that: ~~have been:~~

Subdivision i. Have been described in a scientific or other

peer-reviewed professional publication;

Subdivision ii. Can be used ~~successfully~~ within the NSSP to detect or quantify;

Subdivision iii. ~~Evaluated,~~ Have been NSSP validated and the performance characteristics for specific applications within the NSSP have been determined and found fit for purpose;

Subdivision iv. Have been selected to ~~fulfill~~ fill an ongoing NSSP Program ~~immediate~~ need;

Subdivision v. Have been Newly accepted for use and/or not yet used for Program support outside the laboratory in which the method was developed and/or validated;

Subdivision vi. Designated for periodic review and assessment by the Laboratory Methods Review Committee as to the feasibility for ~~continued~~ use, redesignation or deletion of the method. Examples of Type IV methods: the HPLC post column oxidation (PCOX) method for paralytic shellfish toxins and the Male Specific Coliphage (MSC) method for soft shell clams and American Oysters.

**Public Health Significance:** The revision of Procedure XVI is meant to clarify the overall process of analytical method acceptance into the NSSP and ensure that only proven methods of analysis are available for use to support NSSP Program requirements.

**Cost Information (if available):** None

**Action by 2011 Task Force III** Recommended no action on Proposal 11-308.

Rationale: Proposal 11-308 was resolved by Task Force action on Proposal 11-307.

**Action by 2011 General Assembly** Adopted the recommendation of Task Force III on Proposal 11-308.

**Action by FDA February 26, 2012** Concurred with Conference action on Proposal 11-308.