ISSC

Interstate Shellfish Sanitation Conference

Task Force III Proposals for Consideration At the 2027 Biennial Meeting

Newport, Rhode Island
January March 24-29, 2027

ISSC Task Force III
2027 Proposal Inventory

Proposal Number	Proposal Subject	Page
11-310	Internal Authority Self-Assessment Using a National Program Standards Manual	3
13-301	Growing Area Classification Criteria	7
17-204	Add in-field Compliance Criteria for Control of Harvest Element	11
19-312	Plant and Shipping Element Evaluation Criteria	15
23-301	Guidance Documents	16
23-303	Revision of Standing Committee List	19
23-304	Remove Proposal Review Committee	21
23-305	Biotoxin Management Plan Criteria	23
27-300	ISSC Membership	35
27-301	Constitution, Bylaws and Procedures Update	37
27-302	States Forum	80
27-303	Definition of Shellfish	82
27-304	Definition of Certification Number	83
27-305	New State in the NSSP Process	85
27-306	Changes to the Patrol Evaluation Section	87
27-307	Quantitative risk assessment of individual oyster harvests using real-time observations can expand Vibrio risk management options	90
27-308	Add new Section X, Notes, to the Guide as well as endnote reference numbers within the Guide, referring Guide readers to specific proposal number(s) that created/altered Guide language	92

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	Julie Henderson
Affiliation	Virginia Department of Health Division of Shellfish Sanitation
Proposal Subject	Internal Authority Self-Assessment Using a National Program Standards Manual
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority
Text of Proposal/ Requested Action	**@.01 Administration** A. Scope… B. State Law and Regulations… C. Records… D. Shared Responsibilities… E. Administrative Procedures… F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness… G. Commingling… H. Program Evaluation. The Authority shall conduct a self-assessment using the National Program Standards Manual and report annually to the U.S. Food and Drug Administration the results of the assessment.
Public Health Significance	The purpose of this proposal is to begin discussions on how a self-assessment can be used by Authorities to conduct a comprehensive evaluation of their ability to promote the protection of public health. An assessment conducted by an Authority may encourage continuous improvement and innovation and can assure that individual program activities provide comparability among other domestic and international shellfish programs. The evaluation can be used to assist both the FDA and shellfish Authorities in fulfilling regulatory obligations and ensuring the implementation of the requirements set forth in the NSSP Model Ordinance
Cost Information	N/A
Action by 2011 Task Force III	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-310.

Action by 2013 NSSP Evaluation Criteria Committee	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions. Establish a workgroup to evaluate the Manufactured Food Standards and determine the applicability of and/or use of these Manufactured Standards to the National Shellfish Sanitation Model Ordinance requirements and report their findings and recommendations to the NSSP Evaluation Criteria Committee at the next ISSC Meeting. The Committee further recommended that self-assessments should be voluntary and that the word "shall" should be replaced with the word "may".
Action by 2013 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 11-310.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-310.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended that draft standards be developed for each program element. These draft standards will be developed using the stnadards from other programs and the FDA draft. It is further recommended that the ISSC identify volunteer states to ilot the standards once developed. The committee will review results from the pilot and submit a proposal for conference
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-210.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-310.
Action by 2017 NSSP Evaluation Committee	Recommended: 1. The full committee be allowed to review the Voluntary National Shellfish Regulatory Program Standards Plant Sanitation draft report. 2. This review should take place as soon as possible so that a decision can be made in January by the NSSP Evaluation Committee via a conference call. 3. If the full committee concurs, 2-4 state can move forward with a pilot study for the program standards as determined by the sub-

	committee chair.
Action by 2017 Task Force III	Recommended referral of Proposal 11-310 back to the NSSP Evaluation Criteria Committee with instructions to review the Plant Sanitation Standards developed by the Standards Subcommittee. The Committee is instructed to complete the review by January 31, 2018 and present recommendations to the ISSC Executive Board for interim approval and pilot testing.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 11-310.
Action by 2019 Standards Committee	The Committee recommended Task Force III adopt the draft Voluntary National Shellfish Regulatory Program Standards (attached) for the Plant Sanitation element into Section IV Guidance Documents of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish.
Action by 2019 Task Force III	Recommended adoption of the Standards Committee recommendation on Proposal 11-310 as follows: 1) Adopt the draft Voluntary National Shellfish Regulatory Program Standards for the Plant Sanitation element into Section IV Guidance Documents of the National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish. 2) The committee complete the piloting and recommend any needed changes to the Conference at the 2021 Bienninal Meeting. The committee begin the development of Program Standards for the Growing Area Classification Element for Conference consideration.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 11-310.
Action by 2023 Standards Committee	Recommended continued development of the voluntary program standards.
Action by 2023 Task Force III	Recommended adoption of the Standards Committee recommendation on Proposal 11-310.

Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 11-310.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	ISSC Executive Office
Affiliation	ISSC
Email	issc@issc.org
Proposal Subject	Growing Area Classification Criteria
Specific NSSP Guide Reference	To Be Determined
Text of Proposal/ Requested Action	The ISSC has adopted evaluation criteria for several program elements within the NSSP. These include laboratories, plant sanitation, and patrol. The development of these criteria has seemed to provide a better understanding of expectations, improve uniformity in State evaluations and enhance compliance. The ISSC should expand its evaluation criteria efforts to include growing area classification. Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification. Although more complex, this element of the program could benefit from the development of evaluation criteria. The purpose of this proposal is to request the Evaluation Criteria Committee be charged with the task of developing evaluation criteria for the growing area element.
Public Health Significance	Growing area classification criteria will enhance State classification efforts and ensure a high level of uniformity and effectiveness in FDA evaluations.
Cost Information	
Action by 2013 Task Force III	The submitter of Proposal 13-301 requested that the following sentence be deleted from the proposal. ~~Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification.~~ The Task Force recommended adoption of Proposal 13-301 with the amendment as requested by the submitter.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-301.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-301.
Action by 2015 NSSP Evaluation Criteria Committee	**Recommended:** 1) The following criteria be used in evaluating the State Growing Area classification element 1. Written Sanitary Survey

	(A) Is there a written Sanitary Survey for each growing area that is classified other than prohibited? (B) Is the Sanitary Survey complete? A. Executive Summary B. Description of Growing Area C. Pollution Source Survey D. Hydrographic and Meteorological Characteristics E. Water Quality Studies F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following: G. Conclusions (C) Is the Sanitary Survey current? A. Annual B. Triennial C. 12 Year) 2. Shoreline Survey (A) Does Shoreline Survey include identification and evaluation of all actual and potential sources of pollution (B) Does Shoreline Survey include boundaries? (C) Does Shoreline Survey include unique designation? (D) Does Shoreline Survey include required maps? (E) Does Shoreline Survey include a summary of survey findings? 3. Adequate Sampling (A) Are the number and location of sampling stations adequate to effectively evaluate all pollution sources. (B) Were adequate samples collected for each area consistent with the classification and type of sampling approach used (i.e. Remote, Adverse Pollution, Systematic Random Sampling)? (C) Were samples collected under appropriate conditions consistent with the type of sampling approach? 4. Data to support Classification (A) The assigned classifications are based on data/information supporting the classification and performance standards? (B) Is appropriate data/information available to support the classification within each designated growing area? 5. Proper Classification (A) Are all growing areas properly classified? (B) Does SSCA have appropriate MOU(s) with appropriate parties for each area classified as conditional? 2) The subcommittee will develop a scoring system which assigns appropriate significance to the criteria and establishes compliance standards which can be used to assign compliance designations as outlined in the other NSS elements. 3) Field testing of the complete evaluation criteria including compliance designation will be field tested in one state in each ISSC region. The results

	will be reviewed by the NSSP Evaluation Committee, modified as appropriate and presented to the ISSC as a proposal.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendations on Proposal 13-301.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-301.
Action by 2017 NSSP Evaluation Criteria Committee	Recommended: 1. The full committee is allowed to review the FDA proposed growing area evaluation criteria immediately. Concurrence with FDA not to initiate a full pilot until the committee completes a review of the FDA proposed criteria.
Action by 2017 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 back to the NSSP Evaluation Criteria Committee with the following charge: Review the evaluation criteria provided to the NSSP Evaluation Criteria Committee and provide recommendation for interim approval by the ISSC Executive Board at the Spring Board meeting. The Executive Board is requested to coordinate the piloting of the criteria with FDA as soon as possible.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 13-301.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-301.
Action by 2019 NSSP Evaluation Criteria Committee	Recommended Proposal 13-301 be referred to an appropriate committee as determined by the Conference Chairperson to continue the development of the growing area classification evaluation criteria and make recommendations to the conference on proposal 13-301. The committee will work with FDA to assure consistency and uniformity of evaluation criteria for all program elements. The committee requests the Conference Chairperson to instruct the committee to start deliberation as soon as possible.
Action by 2019 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 to the NSSP Evaluation Criteria Committee.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.

Action by FDA February 21, 2020	Concurred with Conference action on Proposal 13-301.
Action by Growing Area Evaluation Criteria Committee	Recommended referral of Proposal 13-301 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Growing Area Evaluation Criteria Committee recommendation on Proposal 13-301.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 13-301.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	US Food & Drug Administration (FDA)
Affiliation	FDA
Email	Melissa.Abbott@fda.hhs.gov
Proposal Subject	Add in-field Compliance Criteria for Control of Harvest Element
Specific NSSP Guide Reference	Section II. Model Ordinance - Chapter I@03B.3
Text of Proposal/ Requested Action	1. ~~Patrol~~ Control of Harvest (Change "Patrol Element" to "Control of Harvest Element" in Chapter I@03B.3 Section.) a. Requirements for evaluation …. (new) i. In-field (Harvester) Compliance Criteria i. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities. **95% of harvesters have valid license Critical** ii. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education. **A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing. At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training. The harvester shall maintain record of the completed training.** **100% of licensed harvesters have required training within specified time.Critical** iii. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall: Be a dealer; or Pack shellstock for a dealer. **95% of harvesters engaging in shellfish packing meet this requirementCritical** iv. Non-Vessel Harvesting. Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination,

deterioration, and decomposition.

95% of the non-vessel harvesters meet this requirement Key

v. Vessels. The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.

95% of the harvest vessels meet this requirement Key

Cats, dogs, and other animals shall not be allowed on vessels.

95% of the harvest vessels meet this requirement Key

Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

100% of harvest vessels meet this requirement

Critical

As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.

95% of the harvest vessels meet this requirement Critical

~~i.~~**vi. Shellstock Washing. The harvester shall be primarily responsible for washing shellstock.**

If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility. Water used for shellstock washing shall be obtained from: A potable water source; or a growing area in the: Approved classification; or in the open status of the conditionally approved classification.

If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI. 02 A. (3) and Chapter XIII. 02 A. (3).

95% of the harvesters meet this requirement

Critical

v. Shellstock Identification. Each harvester shall affix a tag that meets Chapter

	VIII.02.F to each container of shellstock which shall be in place while the shellstock is being transported to a dealer. **95% of the harvesters meet this requirement** **Critical** vi. Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities meets the requirements of Chapter VIII02.F(7). **95% of the harvesters utilizing bulk tagging meet this requirementCritical** **Shellstock Temperature Control. All harvesters shall comply with the applicable time to temperature requirements of a State *V.v.* and *V.p.* Control Plans outlined in Chapter II. @.06 and @.07; or Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3). All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements.** **95% of the harvesters meet these requirements** **Critical** **ji. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above ~~patrol~~ Control of Harvest evaluation criteria.** i. The overall ~~Patrol Program~~ Control of Harvest element will be assigned one of the following designations: (a) **Conformance:** The program is in compliance with all of the criteria listed above. (b) **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item. (c) **Non-Conformance:** The program has: i. at least one (1) critical deficiency; ii. ~~two (2)~~ four (4) or more key deficiencies; or iii. a repeat **[Key]** deficiency from the previous evaluation. (d) **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.
Public Health Significance	Adds in-field compliance criteria to address Control of Harvest Element evaluation activities related to NSSP MO Chapter VIII Requirements for Harvesters. Proposal will bring in the in-field compliance criteria which is similar to plant compliance criteria which have administrative and in-field components.
Cost Information	N/A

Action by 2017 Task Force II	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chair with instructions that this proposal be assigned to the appropriate multiple committees.
Action by 2017 General Assembly	Adopted the recommendation of Task Force II on Proposal 17-204.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-204.
Action by 2019 NSSP Evaluation Criteria	Recommends the Conference Chairperson establish a workgroup including members from the NSSP Evaluation Criteria Committee and the Patrol Committee to review and make recommendations to the conference on proposal 17-204 working with FDA to consider consistency and uniformity of evaluation criteria for all program elements.
Action by 2019 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-204.
Action by 2023 Control of Harvest Evaluation Criteria	Recommended referral of Proposal 17-204 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force III	Recommended adoption of the Control of Harvest Evaluation Criteria Committee recommendation on Proposal 17-204.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 17-204.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-204.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X☐ Administrative

Submitter	US Food & Drug Administration (FDA)
Affiliation	FDA
Email	Melissa.abbott@fda.gov
Proposal Subject	Plant and Shipping Element Evaluation Criteria
Specific NSSP Guide Reference	Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 B. 4.
Text of Proposal/ Requested Action	We have been using the plant and shipping evaluation criteria for approximately 10 years and have identified some areas that need review. FDA requests that the NSSP Evaluation Criteria Committee be charged with reviewing the criteria, especially with respect to these areas of concern: (1) In-field Plant Criteria (2) Compliance Schedules (3) Follow-Up for Compliance Schedules (4) Conformance Designations
Public Health Significance	Many states have expressed concerns to FDA and the ISSC Executive Office surrounding the Plant and Shipping evaluation criteria. In addition, FDA has identified its own concerns with the implementation of the criteria.
Cost Information	No additional cost
Action by 2019 Task Force III	Recommended referral of Proposal 19-312 to the NSSP Evaluation Criteria Committee
Action by 2019 General Assembly	Adopted recommendation of Task Force III on Proposal 19-312.
Action by Plant Evaluation Criteria Committee	Recommended referral of Proposal 19-312 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Recommended adoption of the Plant Evaluation Criteria Committee recommendation on proposal 19-312
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-312

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
Submitter	Eric Hickey, MA Department of Public Health Kathy Brohawn, MD Department of the Environment Jeff Kennedy, MA Division of Marine Fisheries Michael Bott, DE Department of Natural Resources and Environmental Control Bryant Lewis, ME Department of Marine Resources Chris Nash, NH Department of Environmental Services Danielle Schools, VA Department of Health, Division of Shellfish Safety
Email	Eric.hickey@mass.gov
Proposal Subject	Guidance Documents
Specific NSSP Guide Reference	ISSC Constitution and Bylaws Section I. Purpose & Definitions Section II Model Ordinance, Chapter I. Shellfish Sanitation Program Requirements for the Authority @03 A. (1) (c) and (3) Section IV. Guidance Documents
Text of Proposal/ Requested Action	**Section I. Purpose & Definitions** (50) **Guidance Document** means a document that provides ISSC current thinking and/or general applicability suggestions on a NSSP provision. Guidance documents do not create or confer any rights or requirements for or on any person that are beyond those outlined in the NSSP Model Ordinance and do not operate to bind FDA, the Authority, or the public. Guidance documents do not preclude the use of alternative approaches for the implementation of NSSP Model Ordinance requirements. ~~(50)~~(51) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992). ~~(51)~~(52) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 Code of Federal Regulations (CFR) 123.6 as adopted by the Interstate Shellfish Sanitation Conference. Section II. Model Ordinance **Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements** **A. The goal of shellfish program evaluation shall be to monitor program implementation and work with States to determine where problems may exist and how to address them.** 1. Shellfish program evaluation

methodologies shall:

a. Monitor State program implementation;

b. Assess State program effectiveness;

c. Evaluate the validity of the elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance.

Ch. I @.03 Evaluation of Shellfish Sanitation Program Elements

A. 3. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP ~~Guide to the Control of Molluscan Shellfish~~ Model Ordinance.

ISSC Constitution Bylaws and Procedures Procedure IV Responsibilities of the FDA

~~1.~~ The FDA should prepare an annual evaluation of the shellfish program of each state in accordance with the Procedures of the NSSP Model Ordinance. This evaluation should consider the program as a whole and should also specifically address the legal authority, the classification of shellfish growing waters, the shellfish sanitation control and certification, personnel training, patrol, relaying, depuration and laboratory phases of the program, and the status of state authorities Memorandums of Understanding. The state evaluation prepared by the Regional Shellfish Specialist should be reviewed and discussed with the appropriate state shellfish officials prior to submission to FDA headquarters. A PEER deficiency item can only be found based on the Model Ordinance requirements (not guidance).

INTRODUCTORY STATEMENT TO BE PLACED AT THE BEGINNING OF SECTION IV:

Guidance documents are intended to provide supporting information on how to implement the criteria set forth in the Model Ordinance or the current thinking on topics referenced in the Model Ordinance. Alternative approaches that satisfy requirements of the Model Ordinance may be used. Guidance documents are not intended to be solely used by FDA as a reference to cite NSSP deficiencies in a

	PEER or determine program conformance with the requirements of the NSSP Model Ordinance.
Public Health Significance	The purpose of this proposal is to address concerns of state control authorities and to clarify areas of confusion which include, but are not limited to, guidance concerning marinas and moorings, biotoxin management strategies, and shellfish program element evaluations. Under 21 CFR Part 123 FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidance describes ISSC current thinking on relevant topics and should be viewed only as supporting information, recommendations, and NSSP implementation aids unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidance means that something is suggested or recommended, but not required. Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. The Authority can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. The same definition of guidance and how it is applied should be adopted in the NSSP MO to be consistent with FDA policy and definitions.
Cost Information	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-301 to an appropriate Committee or Committees as determined by the Conference Chair. Further recommends that the committee(s) review NSSP Guidance to identify requirements that need to be moved from guidance into the Model Ordinance with completion of the review by the next ISSC Biennial meeting.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-301.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-301.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	ISSC Executive Office
Email	issc@issc.or
Proposal Subject	Revision of Standing Committee List
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 10
Text of Proposal/ Requested Action	**ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES** 1. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: • ~~Audit Committee;~~ • Credentials Committee; • ~~Education Committee;~~ • ~~Foreign Relations Committee;~~ • Laboratory Committee • Model Ordinance Effectiveness Review Committee; • Pathogen Review Committee; • ~~Patrol Committee;~~ • Proposal Review Committee; • ~~Research Guidance Committee;~~ • ~~Research Management Committee;~~ • Resolutions Committee; • ~~Shellfish Restoration Committee;~~ • Study Design Guidance Committee; • ~~Training Committee;~~ • Unresolved Issues Committee; • ~~Vibrio~~Vibrio vulnificus Illness Review Committee; and • *Vibrio* Management Committee. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting.
Public Health Significance	Standing committees are committees that have been assigned charges by the ISSC Constitution, By-laws & Procedures. These committees are appointed either every Biennial Meeting cycle for ongoing charges or as needed as defined in the ISSC

	Constitution By- laws & Procedures. Committees should not be included in the standing committee list unless a purpose for the committee has been defined by the ISSC Constitution, By-laws & Procedures. The revisions to the standing committee list will remove committees that have not been defined by the ISSC Constitution, By-laws & Procedures and will add committees that are defined in the ISSC Constitution, By-laws & Procedures.
Cost Information	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-303 to an appropriate Committee or Committees as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-303.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-303.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
Submitter	ISSC Executive Office
Email	issc@issc.or
Proposal Subject	Remove Proposal Review Committee
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures, Article IV 10. & 13., Article XIII. 3.

Text of Proposal/ Requested Action

ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES

1. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference:
   - Audit Committee;
   - Education Committee;
   - Foreign Relations Committee;
   - Laboratory Committee
   - Model Ordinance Effectiveness Review Committee;
   - Patrol Committee;
   - ~~Proposal Review Committee;~~
   - Research Guidance Committee;
   - Research Management Committee;
   - Resolutions Committee;
   - Shellfish Restoration Committee;
   - Study Design Guidance Committee;
   - Training Committee;
   - Vibrio Illness Review Committee; and
   - *Vibrio* Management Committee.

   The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting.
2. A quorum for…
3. The Nine-member…

~~The Executive Board Chairperson shall appoint a 12-member Proposal Review Committee. The Committee will be comprised of a Chairperson, four (4) regulatory members, four (4) industry members, and a representative from the~~

	~~FDA, NOAA, and EPA. The Committee will review and link proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.~~ ARTICLE XIII. PROCEDURE FOR THE SUBMISSION OF PROPOSALS Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force. Proposals that lack required information will be deemed incomplete and returned to the submitter for completion. ~~The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.~~
Public Health Significance	The Proposal Review Committee is not necessary as the charge of linking proposals has not proved to be effective. There has also been no need to ask the committee for consultation with Task Force Assignment or invalidating a proposal during the last decade of Biennial Meeting cycles.
Cost Information	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-304 to an appropriate Committee or Committees as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-304.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-304.

Proposal No. 2 3 - 3 0 5

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative

Submitter	ISSC Executive Office
Email	issc@issc.org
Proposal Subject	Biotoxin Management Plan Criteria
Specific NSSP Guide Reference	Section II Model Ordinance; Chapter IV. Shellstock Growing Areas @.04.B
Text of Proposal/ Requested Action	Section II Model Ordinance; Chapter IV. Shellstock Growing Areas @.04.B. B. Marine Biotoxin Management Plan. In those areas that have been implicated in an illness outbreak or where toxin- producing phytoplankton have been documented to occur, the toxins are prone to accumulate in shellfish and during times when marine biotoxins are likely to occur, representative samples of water and/or shellfish shall be collected during harvest periods in accordance with one (1) or a combination of the marine biotoxin management strategies listed below in (4). and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. (1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP and/or AZP; if toxin-producing phytoplankton have been documented to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur. (2) The plan shall define the administrative procedures and resources necessary to accomplish the following: (a) Maintain a toxin-producing phytoplankton and/or shellfish sampling program as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in ~~Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans~~Section 4 Marine Biotoxin Management Strategies. (b) Close growing areas and embargo shellfish; (c) Prevent harvesting of contaminated species; (d) Provide for product recall; (e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent States, shellfish industry, and local health agencies; (f) Coordinate control actions taken by Authorities and Federal agencies;

(g) Establish reopening criteria; and

Ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status meets all conditions of harvest restrictions prior to being placed in distribution. This would include all sampling, testing or product holds.

(3) The Authority may use precautionary closures based on shellfish toxicity screening or phytoplankton sample results as defined in their marine biotoxin management plan. Precautionary closures may be lifted immediately:

(a) if confirmatory testing using an approved method shows the level of biotoxin present in shellfish meats is not equal to or above established criteria as described below in C; or

(b) when shellfish toxicity screening or phytoplankton sample results indicate that the precautionary closure was not necessary.

(4) Marine biotoxin management strategies are as follows:

(a) Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species known or suspected to produce marine biotoxins. This is a complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish and must be used in combination with other management strategies. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

The phytoplankton monitoring strategy shall be used together with one (1) or more of the other biotoxin management strategies. If it were used as the sole management strategy, phytoplankton monitoring would likely misrepresent the actual risk of marine biotoxins. Cell counts, as measured per liter of water, are often used to trigger additional testing of shellfish in biotoxin monitoring programs. These cell count criteria can only be established with a robust dataset; therefore, new monitoring programs should employ low cell count criteria to trigger shellfish toxicity samples to establish or refine the cell concentrations responsible for toxins accumulating in shellfish.

(b) Routine shellfish toxicity onitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. nless species specific shellfish

testing is conducted, the highest risk species shall be used. This strategy may be used in combination with other management strategies. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~
The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sample locations (stations),
- appropriate sampling frequency; and
- a sufficient dataset to support management decisions.

Analytical methods used in this strategy shall be in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14 or Section II. Chapter III.@02C.

(c) Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvest. This strategy, if used independent of any other strategy, shall permit harvest for a short period of time following testing. This strategy may be used in combination with other management strategies. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~
This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin

monitoring plan may be modified. Without at least 36 samples per harvest area over the span of at least three (3) years, the short duration of permitted harvest shall not exceed three (3) days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify the duration of permitted harvest.

This management strategy can be applied to harvest areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. If toxicity in excess of the established threshold in Section II. Chapter IV. @.04 C. is detected, the growing area must be either be placed in the closed or controlled access status.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- appropriate duration for permitted harvesting subsequent to sampling.

This strategy is specifically for permitting harvest following shellfish testing. The duration of permitted harvesting will depend on the species being tested, the risk of increasing toxicity and the timing of additional sampling. Samples must be representative of the harvest area.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14 or Section II. Chapter III. @.02 C.

(d) Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~ Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled

Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified.
The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency, and;
- representative number of samples per lot.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.

(e) Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial dealer. ~~Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine BiotoxinPlans. (5)~~ The marine biotoxin management plan shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in a growing area that is placed in the controlled access status. Such harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4).
This strategy shall permit harvest from intended harvest areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the intended harvest area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.

The marine biotoxin management plan that incorporates this strategy must establish:

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),
- an appropriate sampling plan,
- appropriate sampling frequency,
- a defined harvest area, and;
- representative number of samples.

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.

Section IV Guidance Documents; Chapter II Growing Areas .02

Marine Biotoxin Management Strategies

It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. The Authority initiating biotoxin management plans should employ sampling in accordance with the strategies below until a baseline dataset of at least 36 samples per growing area or hydrographically linked waterbodies is developed. These samples should cover representative environmental conditions and a time span of at least three (3) years. Once this dataset is developed, the Authority may consider modifying sample numbers and frequency in the marine biotoxin management plan in accordance with the strategies below.

A. Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species documented or suspected to produce marine biotoxins. This complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish must be used in combination with other management strategies. The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of toxin-producing phytoplankton may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies for a time span of at least three (3) years of phytoplankton counts, comparing with the onset of shellfish toxicity when toxic phytoplankton are present, should be developed before the biotoxin monitoring plan may be modified.

Phytoplankton monitoring can be applied to all growing areas where collecting, transporting and processing water samples is logistically feasible, taking into consideration effects of zooplankton grazing and durability of various cell types to temperature and transport. This

management strategy may be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible wild harvest areas and aquaculture sites in state waters or aquaculture sites in federal waters.

~~The marine biotoxin management plan that incorporates this strategy must establish:~~

- ~~appropriate screening levels,~~
- ~~appropriate methods,~~
- ~~appropriate laboratory(s)/analyst(s),~~
- ~~an appropriate sampling plan,~~
- ~~appropriate sample locations (stations),~~
- ~~appropriate sampling frequency; and~~
- ~~a sufficient dataset to support management decisions.~~

- ~~The phytoplankton monitoring strategy shall be used together with one (1) or more of the other biotoxin management strategies. If it were used as the sole management strategy, phytoplankton monitoring would likely misrepresent the actual risk of marine biotoxins. Cell counts, as measured per liter of water, are often used to trigger additional testing of shellfish in biotoxin monitoring programs. These cell count criteria can only be established with a robust dataset; therefore, new monitoring programs should employ low cell count criteria to trigger shellfish toxicity samples to establish or refine the cell concentrations responsible for toxins accumulating in shellfish.~~

When an early warning system such as phytoplankton monitoring detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program. If a plan consists of water sampling for phytoplankton cell counts as surveillance, the Authority should identify its plan to be able to initiate shellfish sampling.

Considerations should be made for how sampling is conducted such as phytoplankton net tows, filtered surface water, or whole water samples. The depth of water sampled should also be considered and evaluated for all species of phytoplankton being targeted. Some species of phytoplankton are known to display diurnal, vertical migration patterns within the water column, while other species are known to occur in dense patches.

Laboratory and field methods may include, but are not limited to light microscopy, flowcytometry, DNA fingerprinting, rapid toxin detection tests, and PCR assays. Analysts should be trained in each method employed and consideration should be given to complimentary methods of analysis such as light microscopy with phytoplankton identification confirmed by a rapid test at least in the initial phases of the monitoring program.

An appropriate sampling plan, station location, and sampling frequency

should all factor in the location and type of the resource being monitored, the species of phytoplankton anticipated or observed, and the environmental conditions that might result in a rapid bloom or trigger the production of toxicity in an existing population. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxic phytoplankton are most likely to first appear, based either on experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are also significant. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom, or a hurricane may drive an offshore phytoplankton bloom onshore. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites.

B. Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species-specific shellfish testing is conducted, the highest risk species (e.g. species that metabolizes toxin most quickly) occurring in the growing area shall be used. Many biotoxin monitoring programs have found mussels to be the best sentinel species. This strategy may be used alone or in combination with other management strategies.
~~The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year.~~

This management strategy can be applied to all growing areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to, easily accessible wild harvest areas and aquaculture sites in state waters or wild harvest areas and aquaculture sites in federal waters.

~~The marine biotoxin management plan that incorporates this strategy must establish:~~
- ~~appropriate screening levels,~~
- ~~appropriate methods,~~

	~~• appropriate laboratory(s)/analyst(s),~~ ~~• an appropriate sampling plan,~~ ~~• appropriate sample locations (stations),~~ ~~• appropriate sampling frequency; and~~ ~~• a sufficient dataset to support management decisions.~~ • The routine shellfish toxicity monitoring strategy may be used independently or together with one (1) or more of the other biotoxin management strategies. If used as the sole management strategy, predicting future toxicity levels in shellfish and the appropriate sampling frequency can be difficult. Long-term databases can provide valuable historic information on the timing of toxicity occurring in shellfish as well as toxicity elimination from shellfish. Shellfish toxin levels that are below the regulatory levels may trigger emergency or expanded testing, or precautionary closures. Growing areas should be placed in the closed status at a level that provides an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be considered. Precautionary closures can be made to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed. Consideration should be given to the different species of shellfish present in a growing area, the intensity and duration of harmful algal blooms and the uptake and elimination rates of specific toxins from all species of shellfish harvested from the growing areas (e.g., sea scallops). Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C. Additionally, the Authority should identify laboratories that can perform approved methods for marine biotoxins and identify laboratory capacity. An appropriate sampling plan, station location and sampling frequency should factor in the location and type of the resource being monitored, the species of shellfish harvested in the growing area and environmental conditions that might affect toxin uptake, such as water temperatures. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxin is most likely to first appear, based either on past experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Sample collection, sample transportation, and sample analysis procedures should be developed, and predictable timeframes established between collection and results. The Authority should ensure that in an emergency, such as a suspected biotoxin illness, the normal timeframe can be compressed, and sample results known as quickly as possible. It is important to consider emergency coverage schedules for staff and lab availability outside of normal office hours during harmful algal bloom events.

When an early warning system detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program.

C. Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvesting. This strategy, if used independent of any other strategy, shall permit harvest in specific geographic locations and for short durations. This strategy may also be used in combination with other management strategies and should be considered as a complementary strategy while developing datasets for alternative management strategies (e.g. pre-harvest shellfish toxicity testing in combination with phytoplankton monitoring which can evolve into a robust shellfish toxicity monitoring strategy).

~~This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin monitoring plan may be modified. Without at least 36 samples per harvest area over the span of at least three (3) years, the short duration of permitted harvest shall not exceed three (3) days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify the duration of permitted harvest.~~

~~This management strategy can be applied to harvest areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. If toxicity in excess of the established threshold in Section II. Chapter IV. @.04 C. is detected, the growing area must be either be placed in the closed or controlled access status.~~

~~The marine biotoxin management plan that incorporates this strategy must establish:~~

- ~~appropriate screening levels,~~
- ~~appropriate methods,~~
- ~~appropriate laboratory(s)/analyst(s),~~
- ~~an appropriate sampling plan,~~
- ~~appropriate sampling frequency,~~
- ~~a defined harvest area, and;~~
- ~~appropriate duration for permitted harvesting subsequent to sampling.~~

~~This strategy is specifically for permitting harvest following shellfish~~

~~testing. The duration of permitted harvesting will depend on the species being tested, the risk of increasing toxicity and the timing of additional sampling. Samples must be representative of the harvest area.~~

~~Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14 or Section II. Chapter III. @.02 C.~~

D. Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

~~This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three (3) years shall be developed before the biotoxin monitoring plan may be modified.~~

This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.

~~The marine biotoxin management plan that incorporates this strategy must establish:~~

- ~~appropriate screening levels,~~
- ~~appropriate methods,~~
- ~~appropriate laboratory(s)/analyst(s),~~
- ~~an appropriate sampling plan,~~
- ~~appropriate sampling frequency, and;~~
- ~~representative number of samples per lot.~~

~~Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.~~

E. Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial certified dealer.

~~This strategy shall permit harvest from intended harvest areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the~~

	~~harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three (3) years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the intended harvest area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.~~ This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters. ~~The marine biotoxin management plan that incorporates this strategy must establish:~~ • ~~appropriate screening levels,~~ • ~~appropriate methods,~~ • ~~appropriate laboratory(s)/analyst(s),~~ • ~~an appropriate sampling plan,~~ • ~~appropriate sampling frequency,~~ • ~~a defined harvest area, and;~~ ~~representative number of samples.~~ ~~Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14 or Section II. Chapter III. @.02 C.~~
Public Health Significance	Several sections of Chapter IV of the Model Ordinance refer to language in Section IV Guidance Documents that indicate that the guidance is mandatory. This proposal moves these criteria and strategies for Biotoxin Management from Guidance to Chapter IV of the Model Ordinance to clarify what are minimum requirements for NSSP compliance versus suggested options.
Cost Information	N/A
Action by 2023 Task Force III	Recommended referral of Proposal 23-305 to an appropriate Committee or Committees as determined by the Conference Chair.
Action by 2023 General Assembly	Adopted recommendation of Task Force III on Proposal 23-305.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-305.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	4801 Hermitage Road
5. Address Line 2	Suite 102
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	ISSC Membership
10. Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures. Article III, Section 2
11. Text of Proposal/ Requested Action	**ARTICLE III. MEMBERSHIP AND REGISTRATION** 1. The membership and registration fees shall be set by the Executive Board as necessary to defray the costs of the Biennial Meeting and the operating costs of the Conference. 2. Membership Fees a. The fee for each category of membership and the membership period shall be set by the Executive Board. State membership fees will be established as necessary to provide, at a minimum, ten percent (10%) of the operating budget of the Conference. The Executive Board will follow the guidelines of Procedure XIX. in establishing membership fees b. There shall be ~~two (2)~~ five (5) categories of membership: i. State Authority (a) Shellfish producing states (b) Non-producing states ii. Agency membership: Individuals employed by agencies that are responsible for NSSP oversight and law enforcement activities at state, federal or local levels. iii. Industry Membership: Individuals employed by or representing the shellfish industry. iv. Academia membership: Individuals employed by a two- or four- year college or university involved in education or research involving foods, drugs, cosmetics, devices, or product safety. v. Individual Membership: Individuals interested in the objectives of the ISSC, but do not fall under any of the other categories.

<table>
<tr><td></td><td>
c. Group Membership: Organizations interested in having multiple members from their organization may be eligible for group membership at a reduced rate. To be eligible for group membership, a list of all members of the group must be submitted together to issc@issc.org indicating who the group contact will be. The following group membership discounts will apply:
<table>
<tr><th># Memberships</th><th>Discount rate</th></tr>
<tr><td>3 - 5</td><td>5%</td></tr>
<tr><td>6 - 10</td><td>10%</td></tr>
<tr><td>11 - 15</td><td>15%</td></tr>
<tr><td>> 15</td><td>20%</td></tr>
</table>
d. The membership fees may be paid annually or biennially.
e. The State authority membership fees shall include one membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee.
f. The membership period shall coincide with the calendar year. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.
</td></tr>
<tr><td>12. Public Health Significance</td><td></td></tr>
<tr><td>13. Cost Information</td><td></td></tr>
<tr><td>14. Changes Needed to Guidance (if proposed change is adopted)</td><td></td></tr>
</table>

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Constitution, Bylaws and Procedures Update
10. Specific NSSP Guide Reference	N/A
11. Text of Proposal/ Requested Action	See attached supplemental documentation
12. Public Health Significance	Updates to the Constitution, Bylaws and Procedure are needed to reflect current organizational structure and processes at the FDA.
13. Cost Information	No cost
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Interstate Shellfish Sanitation Conference



Constitution, Bylaws, and Procedures

Updated July 22, 2024

4801 Hermitage Rd, Suite 102
Richmond, VA 23227
Telephone 804-330-6380
Email: issc@issc.org
Website: www.issc.org

Table of Contents

PREFACE ..... !
DEFINITIONS 3
CONSTITUTION OF THE INTERSTATE SHELLFISH SANITATION CONFERENCE 5
ARTICLE I. ORGANIZATION 5
AR1'ICLE II. OBJECTIVES 5
ARTICLE III. MEMBERSHIP AND REGISTRATION 5
ARTICLE IV. EXECUTfVE BOARD, OFFICERS, COMMITTEES 7
ARTICLE V. DUTIES OF 'fHE BOARD 10
ARTICLE VI. DUTIES OF THE BOARD CHAIRPERSON 11
ARTICLE VII. DUTIES OF THE VICE-CHAIRPERSON 11
ARTICLE VIII. DUTIES OF THE EXECUTIVE DIRECTOR 12
ARTICLE IX. RULES OF BIENNIAL CONFERENCE MEETINGS 13
ARTICLE X. AMENDMEN1'S 15
ARTICLE XI. PROCEDURE FOR THE SUBMISSION OF PROPOSALS 15
BY-LAWS OF THE INTERSTATE SHELLFISH SANITATION CONFERENCE 17
ARTICLE I. TASK FORCES 17
ARTICLE II. TASK FORCE CONSULTANTS 18
AR1'ICLE III. AMENDMENTS 18
PROCEDURES OF THE INTERSTATE SHELLFISH SANITATION CONFERENCE 19
PROCEDURE I. PURPOSE 19
PROCEDURE II. PROGRAM 19
PROCEDURE III. RESPONSIBILITIES OF THE STATE 19
PROCEDURE IV. RESPONSIBILITIES OF THE FDA 20
PROCEDURE V. GUIDELINES 21
PROCEDURE VI. GROWING WATERS CLASSIFICATION 21
PROCEDURE VII. SHIPPER CERTIFICATION 21
PROCEDURE VIII. BILL OF LADING AND LABELING 21
PROCEDURE IX. PROCEDURES FOR HANDLING COMPLAINTS AND CHALLENGES REGARDING THE ADEQUACY OF CERTIFICATION CONTROLS 22
PROCEDURE X. PROCEDURE FOR HANDLING ISSC SUMMARY OF ACTIONS 24
PROCEDURE XI. PROCEDURE FOR HANDLING RESOLUTIONS 25
PROCEDURE XII. PROCEDURE FOR HANDLING AND DISSEMINATING INTERPRETATIONS OF THE NSSP GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH BY FDA 26
PROCEDURE XIII. PROCEDURE FOR INCORPORATION OF APPENDICES INTO THE NSSP MODEL ORDINANCE 27
PROCEDURE XIV. PROCEDURE FOR ADDRESSING PATHOGENS AND DELETERIOUS SUBSTANCES NEWLY RECOGNIZED IN SHELLFISH 27
PROCEDURE XV. PROCEDURE FOR THE APPROVAL OF ANALYTICAL METHODS FOR THE NSSP 28

PROCEDURE XVI. PROCEDURE FOR *Vibn<J vulnificus (V, v.)* **ILLNESS REVIEW COMMI17'EE PROCEDURES** 31

PROCEDURE XVII. RECIPROCITY 35

PROCEDURE XVIII. EXECUTIVE BOARD PROCEDURES FOR ESTABLISHING MEMBERSHIP FEES 36

PROCEDURE XIV. PROCEDURE FOR DISSOLUTION 36

PREFACE

The sanitary quality of shellfish shipped interstate as well as intrastate has been a matter of concern to receiving areas for many years. The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wide use. In 1658, the Dutch Council of New Amsterdam passed an ordinance regulating the taking of oysters from the East River. Other early legislation (1715, 1730, and 1734) was designed to regulate harvesting, presumably as conservative measures to guarantee a continuing supply.

The public health problems which were associated with shellfish in the United States in the first two decades of the twentieth century brought a new dimension to natural resource utilization; i.e., shellfish could not be used as food unless of acceptable sanitary quality. The concept was clearly recognized in a Public Health Service sponsored conference in 1925. All parties seemed to recognize and accept as fact, the premises that: (1) shellfish represented a valuable natural food resource; (2) the cultivation, harvesting, and marketing of this food resource were valuable to the economy of many coastal communities; (3) a state/federal program was necessary to permit the safe use of this resource; and (4) the transmission of disease by shellfish was preventable and, therefore, not to be tolerated. Founders of the shellfish program held that instead of prohibiting use of this resource, beneficial use of the estuaries was in the best public interest, and that sanitary controls should be developed and maintained which would allow safe use.

In 1954, the Surgeon General of the United States Public Health Service called a second national conference to discuss shellfish sanitation problems. There was general agreement that, despite the profusion of technical problems, the basic concepts were sound and that it was in the public interest to maintain the program. The 1964 National Shellfish Sanitation workshop stated that survival of the shellfish industry was in the best public interest and that application of the established principles on a state-by-state basis would allow shellfish to continue to be used safely as food.

In the ensuing years, changes in the state and federal governmental organizations participating in the shellfish program and challenges to portions of the federal part of the program made participation in the program by state regulatory officials and the shellfish industry less effective. Various state programs began to diverge from established standards and the federal arm of the program appeared to be unable to retain control or re-establish uniform program application necessary to ensure the safety of shellfish for use as food. As a result, representatives of fifteen shellfish producing states met in Ocean City, Maryland, in October 1979 to investigate the problem.

This meeting established a committee to explore the alternative types of organizations that could deal with the problems and continue to ensure a viable, uniform national program. The committee, after two years of serious deliberations and numerous meetings, developed a proposal for an organization of state shellfish regulatory and industry representatives interfacing with the United States Food and Drug Administration to establish uniform basic guidelines that could be used for sanitary control of the shellfish industry. The recommended program of this proposed organization would provide regulatory authorities with reliable data on sources of high quality shellfish. The

recommended program could also be used to advantage by states and municipalities in developing sound, uniform programs to secure better shellfish supplies for their people.

In the following year the committee held meetings with representatives of the FDA, industry, and various states and further refined the proposal. A final draft was prepared and notice of a national meeting to present the proposal to Authorities for adoption was mailed.

A national meeting was convened in Annapolis, Maryland, on September 20, 1982. Representatives attended the meeting from twenty-two states, shellfish industry representatives from several east and Gulf Coast states, the United States Food and Drug Administration, and the National Marine Fisheries Service. Consideration and amendment of the Committee Proposal resulted in adoption of a Constitution, By-Laws, and Procedures on September 21, 1982, establishing a viable organization with the stated purpose of fostering and improving the sanitation of shellfish through interstate cooperation and through uniformity of state shellfish programs.

DEFINITIONS

The following definitions apply to the Constitution, By-Laws, and Procedures of the Interstate Shellfish Sanitation Conference.

(1) AUTHORITY - the State or local shellfish control authority or authorities or its designated agents which are responsible for the enforcement of this Code.

(2) INDUSTRY - any commercial operation routinely dealing in the harvesting, processing, packaging, storage, or distribution of shellfish.

(3) **INTERPRETATION** - a written request for a clarification of a part of the National Shellfish Sanitation Program from the FDA ~~Regional Office~~Shellfish Specialist to FDA Headquarters, and the written response to that request from FDA Headquarters.

(4) **ISSC REGION** - geographical grouping of shellfish producing states with similar characteristics and interests, established to provide for fairly distributed representation. The ISSC Regions shall be:

Region 1:	Maine, New Hampshire, Massachusetts, Rhode Island
Region 2:	Connecticut, New York, New Jersey
Region 3:	Maryland, Delaware, Virginia
Region 4:	North Carolina, South Carolina, Georgia, Florida
Region 5:	Alabama, Mississippi, Louisiana, Texas
Region 6:	Alaska, Washington, Oregon, California, Hawaii

(5) NATIONAL SHELLFISH SANITATION PROGRAM (NSSP)-the cooperative State-FDA-Industry program for the sanitary control of shellfish. Cooperative partners may include States, the FDA, industry, tribes, other nations, and other federal agencies. The Guide for the Control of Molluscan Shellfish, including the Model Ordinance as adopted by the Interstate Shellfish Sanitation Conference replaced the NSSP Manual of Operations [effective January 1, 1998] and contains the same requirements in ordinance language.

(6) **NON-PRODUCING STATE** - any state that does not qualify as a producing state.

(7) **PARTICIPATING MEMBER** - any individual wishing to participate or receive correspondence from the Conference.

(8) PRODUCING STATE - a state having shellfish growing waters in its jurisdiction and having certified shellfish plants for the initial processing of shellfish.

(9) REGISTERED VOTE - (as used in Article IX Section 3.b.) the maximum possible vote during the current Conference meeting, determined by counting the votes or portions of votes of all registered voting delegates.

(10) SHELLFISH - means all species of:

(i) Oysters, clams or mussels, whether:
(ii) Shucked or in the shell;
(iii) Raw, including post-harvest processed;
(iv) Frozen or unfrozen;
(v) Whole or in part; and
(vi) Scallops in any form, except when the final product form is the adductor muscle only.

(11) STATE - a shellfish producing or rece1vmg state that participates and votes in the Conference General Assembly.

(12) UNRESOLVED ISSUE - a disagreement or continued failure to achieve satisfactory compliance with the NSSP Model Ordinance. Unresolved issues may be between FDA and a state or between states or non-state parties.

(13) VOTING DELEGATE - the person designated by an Authority to cast the agency's portion of the state vote in Conference meetings.

CONSTITUTION OF THE INTERSTATE SHELLFISH SANITATION CONFERENCE

ARTICLE I. ORGANIZATION

1. The name of the organization shall be the "Interstate Shellfish Sanitation Conference", hereinafter referred to as the Conference.

2. The Conference shall be directed by and shall be under the control of the various states, federal agencies and shellfish industry that join together to form the Conference.

ARTICLE II. OBJECTIVES

1. The objective of the Conference shall be to foster and improve the sanitation of shellfish in this country and to encourage restoration of shellfish growing areas.

2. The objective of the Conference shall be accomplished by:
   a. Adopting sound, uniform methods into a National Shellfish Sanitation Program that is accepted by participating shellfish control authorities.
   b. Promoting mutual respect and trust among shellfish control authorities, the shellfish industry, and consumers of shellfish.
   c. Acquainting control authorities, producers, processors, and consumers with the purpose of the Conference through the media of meetings, press releases, and publications, and by utilization of facilities and personnel of educational institutions, trade associations, shellfish control authorities, and other groups that are willing to assist in the dissemination of such information.

ARTICLE III. MEMBERSHIP AND REGISTRATION

1. The membership and registration fees shall be set by the Executive Board as necessary to defray the costs of the Biennial Meeting and the operating costs of the Conference.

2. Membership Fees
   a. The fee for each category of membership and the membership period shall be set by the Executive Board. State membership fees will be established as necessary to provide, at a minimum, ten percent (10%) of the operating budget of the Conference. The Executive Board will follow the guidelines of Procedure XVIII. in establishing membership fees
   b. There shall be two (2) categories of membership:
      1. State
         (a) Shellfish producing states
         (b) Non-producing states
      ii. Individual member
   c. The membership fees may be paid annually or biennially.

d. The State authority membership fees shall include one membership for one Voting Delegate. Persons other than Voting Delegates shall be considered members by payment of the membership fee.
e. The membership period shall coincide with the calendar year.
f. Applications for membership shall be mailed at least thirty (30) days prior to the beginning of the membership period to the two (2) previous years' membership rolls.

3. Registration Fees
   a. Registration fees shall include those amounts required by Article V. Section 9. of this Constitution.
   b. Any person who is interested in promoting the availability of safe, wholesome shellfish may register at the Conference meeting.
   c. Persons attending and participating in a Conference meeting must first register their name, address, and affiliation with the Executive Director and pay the appropriate registration fee.

4. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative. The Consumer Advisor shall serve a two (2) year term. The initial Consumer Advisory term shall be one (1) year to coincide with the Biennial meeting schedule.

5. Each Board member and alternate must be a member when elected. For producing state and non-producing state elections, each state may cast one (1) vote by the authorized ISSC Voting Delegates (or alternates). For industry elections, industry registrants within each state may cast one (1) collective vote. Industry may caucus among its registrants in order to determine the voting member.

6. Elected Board members shall serve four-year terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Biennial Conference meeting.

7. The Board shall elect a Chairperson and Vice-Chairperson for a two, (2) year term at the Executive Board meeting following the voting General Assembly of the regular Biennial Conference meeting. New officers shall take office at the beginning of the Spring Executive Board meeting.

8. The Board shall direct the Executive Director to collect membership and registration fees. The Executive Director shall pay all bills approved by the Board. The Board shall cause an audit to be made of the Executive Director's financial report annually.

9. The Board shall direct the Executive Director to prepare annually a written financial report listing all receipts, expenditures, and financial balance of the ISSC for the previous year. A copy of the financial report shall be distributed to the membership at each Biennial Meeting.

10. The Board shall authorize the form used to tally and record votes in Board meetings and Conference meetings.

11. The Board shall direct the Executive Director to prepare written minutes of all Board meetings and make copies of such minutes for the previous two years available to the ISSC membership on the ISSC website at www.issc.org.

ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES

1. The Conference shall elect its Executive Board, hereinafter called the Board, in accordance with Article IV. Sections 2., 6., and 7. of this Constitution.

2. The Board shall be comprised of eighteen (18) voting members selected as follows: (a) six (6) Authority members elected from the producing states, one (1) from each of the ISSC Regions; (b) three (3) Authority members elected at large from the non-producing states; (c) six (6) members elected from industry, one (1) from each of the ISSC Regions; (d) one (1) member designated by the United States Food and Drug Administration; (e) one (1) member designated by the National Marine Fisheries Service; and (f) one (1) member designated by the United States Environmental Protection Agency.

3. The immediate past Chairperson, the three (3) Task Force Chairpersons, and the Executive Director, except as otherwise provided, shall serve as non-voting members of the Board.

4. The Treaty Tribes of Western Washington, signatory to the Consent Decree regarding shellfish sanitation with the State of Washington, shall have a non-voting member on the Executive Board designated by the tribal parties to the Consent Decree, whose name shall be submitted by the Northwest Indian Fisheries Commission.

5. The Board Chairperson, with the approval of the Board, shall appoint a non-voting Consumer Advisory representative, a non-voting Retail Advisory representative, a non-voting CDC Liaison and a non-voting FDA ~~Office of Regulatory Affairs~~Operations Liaison. The Consumer Advisory representative, the Retail Advisory representative, the CDC Liaison and the FDA ~~Office of Regulatory Affairs~~Operations Liaison shall serve a two (2) year term. The two- year term shall coincide with the Biennial meeting schedule.

6. Each Board member and alternate must be a member when elected. For producing state and non-producing state elections, each state may cast one (1) vote by the authorized ISSC Voting Delegates (or alternates). For industry elections, industry registrants within each state may cast one (1) collective vote. Industry may caucus among its registrants in order to determine the voting member.

7. Elected Board members shall serve four-year terms. Terms of the elected Board members shall expire at the end of the voting General Assembly of the regular Biennial Conference meeting.

8. The Board shall elect a Chairperson and Vice-Chairperson for a two, (2) year term at the Executive Board meeting following the voting General Assembly of the regular Biennial Conference meeting. New officers shall take office at the beginning of the Spring Executive Board meeting.

9. The Executive Committee, at a minimum, shall consist of the Board Chairperson, Vice Chairperson, Executive Director, one Industry Executive Board member, and the immediate past Board Chairperson. The function of the Executive Committee is to provide administrative guidance to the Executive Office of the ISSC for management of daily activities. Industry representation on the Executive Committee shall be appointed by the Chairperson of the Executive Board, at each Biennial Meeting, with recommendation from the industry members of the Board.

10. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference:
    - Audit Committee;
    - Education Committee;
    - Foreign Relations Committee;
    - Laboratory Committee
    - Model Ordinance Effectiveness Review Committee;
    - Patrol Committee;
    - Proposal Review Committee;
    - Research Guidance Committee;
    - Research Management Committee;
    - Resolutions Committee;
    - Shellfish Restoration Committee;
    - Study Design Guidance Committee;
    - Training Committee;
    - Vibrio Illness Review Committee; and
    - *Vibrio* Management Committee.

    The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting.

11. A quorum for conducting Board business shall consist of ten (10) voting members.

12. The nine-member Unresolved Issues Committee shall be comprised of a state regulatory representative from each of the six (6) regions, one (1) state regulatory representative from a non-producing state, and two (2) industry representatives at large. Should a state regulatory committee member be a representative from a state affected by an unresolved issue, the ISSC Board Chairperson shall appoint a substitute representative from another state within the same region or another non-producing state. Should an industry committee

member be a representative from a state affected by an unresolved issue, the ISSC Board Chairperson shall appoint a substitute at-large industry representative. The committee Chairperson shall be a non-voting member except in the event of a tie.

13. The Executive Board Chairperson shall appoint a 12-member Proposal Review Committee. The Committee will be comprised of a Chairperson, four (4) regulatory members, four (4) industry members, and a representative from the FDA, NOAA, and EPA. The Committee will review and link proposals for Conference consideration. The Committee will also provide consultation as needed to the Executive Director in assigning proposals to Task Forces.

14. The Executive Board Chairperson shall appoint a sixteen (16) member *Vibrio* Management Committee. The Committee will be comprised of a Chairperson with at least two (2) industry members from the East, Gulf and West coasts and at least one (1) state regulatory from each of the ISSC regions. The Committee will also include one voting member from NOAA, one voting member from FDA, one voting member from EPA and one voting member from CDC. The Federal entities will appoint these members. Non-voting advisors will be appointed as appropriate. The Committee will assess if additional changes are needed in the NSSP Guide for the Control of Molluscan Shellfish Model Ordinance to reduce the risk of *Vibrio* illnesses. The Committee will annually review trends in *Vibrio* illnesses.

15. The Executive Board Chairperson shall appoint a thirteen (13) member Model Ordinance Effectiveness Review Committee. The Committee will be comprised of a Chairperson with at least one (1) industry member from the East, Gulf, and West coasts; at least one (1) State regulatory person from each of the ISSC regions; and at least one (1) State regulatory person from a non-producing State. The Committee will also include one (1) voting member from NOAA; one (1) voting member from FDA; and one (1) voting member from EPA. The federal entities will appoint these members. This Committee will review the requirements of the NSSP Model Ordinance and identify requirements that are deemed to be ineffective. The Committee will present recommendations in proposal form to the appropriate Task Force for the deletion or modification of ineffective requirements. New requirements will not be reviewed until after the second (2nd) ISSC Biennial Meeting following the implementation date. A four (4) year waiting period will provide adequate time to determine effectiveness of new controls.

16. The Executive Board Chairperson shall appoint a Laboratory Committee. The Committee will review and make recommendations on laboratory methods that are presented to the ISSC for approval. Additionally, the Committee will be requested to provide recommendations regarding laboratory related matters.

17. The Executive Board shall appoint a Study Design Guidance Committee. The Committee will develop guidance to assist States and the industry in establishing target levels and developing protocols for studies to determine the effectiveness of post-harvest processes.

ARTICLE V. DUTIES OF THE BOARD

1. The Board shall manage the affairs of the Conference. The Board may act on behalf of the Voting Delegates between voting Conference meetings, in keeping with the spirit and intent of the delegates. Any decision or action taken by the Board which would require Voting Delegate approval in accordance with the remainder of this Constitution, By-Laws, or Procedures, shall be submitted as a proposal to the next voting meeting for concurrence or correction.

2. The Board shall meet during each Conference meeting and after the voting General Assembly of the regular Biennial Conference meeting. The Board Chairperson shall call special meetings of the Board at any time at the request of two-thirds (2/3) of its members. The Board Chairperson may call special meetings of the Board at any time, as the need arises, with the concurrence of two-thirds (2/3) of the Board members.

3. The Board may retain the services of an Executive Director who shall serve as chief administrator of the Conference.

4. The Board shall direct the Executive Director in the preparation of programs for each General Assembly of the Biennial Conference meeting.

5. The Board shall set the time and place of each required Biennial Meeting of the Conference. Special meetings of the Conference may be called as the need arises.

6. In the event a vacancy occurs in its membership between elections, the Board may fill such vacancy with a qualified Conference member from the area represented to serve the unexpired term.

7. If a member of the Board is unable to attend a meeting, he/she may send an elected alternate. The member shall notify the Executive Director of the substitution prior to the meeting and provide the substitute with a letter of proxy. In the event time or circumstances prevent prior notification of the alternate to the Executive Director, the letter of proxy presented to the Executive Director at the meeting shall be sufficient.

8. A Board member who fails to attend two (2) consecutive Board meetings shall show cause why he/she should not resign and his/her position be declared vacant by the Executive Director. The Board meeting during each Conference meeting and the Board meeting immediately after the voting general assembly of the regular Biennial Conference meeting shall be considered as one meeting for the purposes of this Section.

9. The Board shall direct the Executive Director to collect membership and registration fees. The Executive Director shall pay all bills approved by the Board. The Board shall cause an audit to be made of the Executive Director's financial report annually. The Board shall

direct the Executive Director to prepare annually a written financial report listing all receipts, expenditures, and financial balance of the ISSC for the previous year. A copy of the financial report shall be distributed to the membership at each Biennial Meeting.

10. The Board shall authorize the form used to tally and record votes in Board meetings and Conference meetings.

11. The Board shall direct the Executive Director to prepare written minutes of all Board meetings and make copies of such minutes for the previous two years available to the ISSC membership on the ISSC website at www.issc.org.

ARTICLE VI. DUTIES OF THE BOARD CHAIRPERSON

1. The Board Chairperson shall preside at all meetings of the Board and during Conference meetings, except as provided for in Article VII. of this Constitution.

2. The Board Chairperson, with the approval of the Board, shall appoint committees as directed by the Conference, the Board, the Constitution, or the By-Laws.

3. The Board Chairperson, with the approval of the Board, shall appoint the Task Force Chairpersons, Vice-Chairpersons, and Members as outlined in Article I., 2. and 3. of the By-Laws of the Conference.

4. The Board Chairperson, with the approval of the Board, shall appoint Task Force consultants as outlined in Article II. 1. of the By-Laws of the Conference.

5. The Board Chairperson, with the approval of the Board, shall appoint an Unresolved Issues Committee.

6. The Board Chairperson, with the approval of the Board, shall appoint Executive Board advisors.

ARTICLE VII. DUTIES OF THE VICE-CHAIRPERSON

1. In the event the Board Chairperson is unable to attend any meeting of the Board or Conference, the Board Vice-Chairperson shall act as Board Chairperson at the meeting.

2. When acting as Board Chairperson as provided in Section 1. of this Article, the Vice-Chairperson shall perform all the necessary duties for the Conference as outlined in Article VI. of this Constitution.

ARTICLE VIII. DUTIES OF THE EXECUTIVE DIRECTOR

1. The Executive Director shall serve as chief administrator of the Conference and shall serve as a non-voting member of the Executive Board and the Executive Committee. The Executive Director shall conduct the affairs of the Conference and shall implement the decisions and policies of the Board and voting delegates.

2. The duties of the Executive Director shall be:
   a. Coordination oflSSC external affairs, specifically interacting with other designated organizations, federal and State government agencies, Congressional committees and staff, State legislative bodies, shellfish and other food-related industries, and other entities whose work or interests affect public health issues relating to the consumption of molluscan shellfish;
   b. Advisement of the Board concerning prioritization of external areas requiring ISSC involvement. Assistance in development of long-range goals and strategies;
   c. Preparation and oversight of position papers or other public policy documents for approval by the Board. Preparation of routine ISSC correspondence;
   d. Spokesperson for ISSC providing or arranging testimony or dialogue on ISSC issues and positions;
   e. Management of the Executive Office and supervision of Executive Office staff;
   f. Management of the fiscal affairs of ISSC in cooperation with the Executive Committee.

3. The Executive Director shall plan and arrange all Conference meetings.

4. The Executive Director may retain the services of a parliamentarian to rule on matters of parliamentary procedure at Board meetings and during Conference meetings.

5. The Executive Director, with the approval of the Board, may retain clerical assistance as needed.

6. The Executive Director shall record the minutes of each meeting of the Board and the Conference.

7. The Executive Director shall tally and record all voting of the Board and of the Conference on a form authorized by the Board.

8. The Executive Director shall pay bills as directed by the Board. A receipt shall be obtained for all disbursements and shall be made a part of Board records.

9. The Executive Director shall accomplish the requirements outlined in Article IX. 3. d., e., f., and g. of this Constitution.

10. The Executive Director shall mail a copy of the tentative program sixty (60) days prior to the Conference meeting to each registrant of the previous Conference meeting and to any

State authority or shellfish industry member or representative who so requests and shall prepare and distribute programs at each Conference meeting.

11. The Executive Director shall notify the appropriate shellfish control authorities in each state, at least ninety (90) days prior to each Conference meeting, of the time and place of the meeting and what proposals are to be voted on under the heading of unfinished business.

12. The Executive Director shall notify the United States Food and Drug Administration, National Marine Fisheries Service, and the United States Environmental Protection Agency at least one hundred twenty (120) days prior to each Conference meeting of the time and place of the meeting so that FDA can publish this information in the Interstate Shellfish Shippers List (ICSSL) at least ninety (90) days prior to the meeting.

ARTICLE IX RULES OF BIENNIAL CONFERENCE MEETINGS

1. Except for special meetings, as provided for in Article V.5. of this Constitution, the Conference will convene a meeting biennially and will rotate the meeting location among the different ISSC Regions of the country.

2. Conference meetings shall include the following:
   a. Registration - all attendees must register;
   b. Call to order by the Board Chairperson;
   c. Roll call of the states and announcement of the name of the delegates who will vote for each state in General Assembly;
   d. Audit report;
   e. Unfinished business;
   f. Subcommittee and Committee meeting;
   g. Task Force meetings;
   h. Election of Board members;
   1. Program, new business, and committee reports;
   J. Installation of new Board members;

3. Business Rules of Conference Meetings

a. Robert's Rules of Order shall prevail, unless specific rules are established by the Conference.

b. Each shellfish producing state shall be entitled to one (1) full vote in the Conference meeting general assembly and each non-producing state shall be entitled to one (1) vote in the Conference meeting general assembly with the exception of issues involving Task Force I recommendations. Non-producing states shall be entitled to one-half (1/2) vote on proposals involving Task Force I recommendations. In states where elements of the NSSP are administered by different shellfish control agencies, each agency shall have an appropriate portion of the vote, or at the option of the state, the vote may be combined and cast by the voting delegate of the single shellfish control agency selected by the state. Membership fees must be paid by the participating state in order to exercise voting privileges.

c. Only a registrant at the Conference meeting who is a representative of an Authority is entitled to be a voting delegate. Each voting delegate at the meeting may cast a vote only for his/her own state agency, except when the state vote has been combined in accordance with Article IX. Section 3.b. of this Constitution and assigned to his/her agency.

d. Ninety (90) days prior to a meeting, the Executive Director shall send to the office or offices of all appropriate shellfish control authorities in each participating state notice of the forthcoming meeting. Each notice shall include a copy of Article IX. Section 3.b., Section 3.c., and Section 3.d. of this Constitution. Each authority shall report in writing on forms provided within thirty (30) days to the Executive Director the following: (1) its official designated responsibility, (2) the name of the delegate and alternate or alternates and the agency represented, and (3) the portion of the vote the delegate is to cast

e. In the event the sum total of the portions of the vote designated for an individual state's delegates exceeds the amount authorized for that state, the Executive Director shall reject, void, and return the reports to the authorities for correction so that they are in compliance with Article IX. Section 3.b. of this Constitution. Such revision shall be submitted at least thirty (30) days before the meeting.

f. A qualified Voting Delegate who must leave the meeting may transfer his/her voting privileges to another qualified registrant from his/her state. The transfer must be presented in writing to the Credentials Committee signed by the departing voting delegate. Upon approval, the Credentials Committee Chairperson shall notify the Executive Director of the transfer of voting privilege.

g. Each state Voting Delegate shall record his/her name with the Executive Director and shall cast his/her vote in the Conference meeting General Assembly when the state's name is called by announcing "yes" or "no" for the delegate's appropriate portion of the vote.

h. Voting in the Conference meeting General Assembly shall be recorded as "yes" or "no".

1. In case of a roll call vote, if a state's representative wishes to caucus, the delegates may pass for the purpose of caucusing when the state's name is called and then shall vote when the second roll is called.

J. To adopt in Conference meeting general assembly:
   1. A quorum must be present.
   11. A quorum shall consist of two-thirds (2/3) of the registered vote at the Conference meeting.
   111. In order to adopt a new Procedure, a simple majority vote is required for passage. In order to change an existing Procedure in any way, a two-thirds (2/3) majority vote is required for passage.

k. Recommendations from a Task Force can be adopted as written, editorially amended to be correct, or consistent with other language in the NSSP Model Ordinance, Constitution, By-Laws, or Procedures, rejected by voting "No Action", or referred back to a Task Force or Committee. The Executive Director will determine whether it is referred to a Task Force or Committee.

ARTICLE X. AMENDMENTS

1. This Constitution may be amended at a duly called Conference meeting, the delegates having had sixty (60) days' notice from the Executive Director of proposed amendments. Adoption of an amendment to the Constitution shall require at least a two-thirds (2/3) majority vote.

2. Amendments to the Constitution will become effective at the close of the Conference meeting at which they are adopted.

ARTICLE XI. PROCEDURE FOR THE SUBMISSION OF PROPOSALS

iv. The Executive Director shall provide each registrant of the preceding Conference meeting at least one hundred sixty-five (165) days prior to the next Conference meeting with forms on which proposal for problems are to be submitted to the Executive Director for assignment to the appropriate Task Force.

v. All proposals must be submitted to the Executive Office no later than one hundred twenty (120) days prior to the Conference meeting.

vi. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force. Proposals that lack required information will be deemed incomplete and returned to the submitter for completion. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.

vii. The Executive Director shall review and assign all problems or proposals received for Task Force and Conference deliberation. Problem or proposal assignment shall be made according to subject matter and in accordance with Article XI. Section 5., Section 6., and Section 7. of the Constitution of the Conference.

viii. Task Force I - Growing Areas: all proposals submitted to the Conference dealing with the classification or patrol of shellfish growing waters, relaying, training and research, or

similar items concerning growing areas shall be assigned to Task Force I by the Executive Director.

ix. Task Force II - Harvesting, Handling, and Distribution: all proposals submitted to the Conference dealing with the sanitation of harvesting, depuration, processing, labeling, transporting, storage, fill or content, training and research, or similar items concerning processing and distribution shall be assigned to Task Force II by the Executive Director.

x. Task Force III - Administration: all proposals submitted to the Conference dealing with Conference agreements, memorandums of understanding, complaints and challenges of reciprocity and program evaluations, or similar items, or items not specifically relating to Task Force I or II shall be assigned to Task Force III by the Executive Director.

xi. Proposals that are deemed technical in nature may be submitted to a committee for review. The committee will provide a recommendation to the appropriate Task Force(s).

xii. The Executive Director shall provide the appropriate shellfish control authorities in each state and all members, at least ninety (90) days prior to each Conference meeting, with the proposals to be discussed under the heading of Unfinished Business or New Business.

xiii. Proposals submitted after the deadline, established in Article XI Section 2. of the Constitution, will be reviewed and may be accepted by the Executive Board for Task Force Consideration. The Executive Board will use the following criteria in accepting late proposals.

a. Why is the proposal being submitted after the deadline?
b. Was the information available prior to the deadline?
c. What is the criticality of the proposal to the safety of molluscan shellfish or the future of the ISSC?
d. Does the proposal involve an NSSP Guide for the Control of Molluscan Shellfish change or an ISSC administrative change?

BY-LAWS OF THE INTERSTATE SHELLFISH SANITATION CONFERENCE

ARTICLE I. TASK FORCES

1. There shall exist three (3) Task Forces in the Conference to provide for continuity of action in carrying out the objectives of the Conference. The Task Forces shall be known as Task Force I, Task Force II, and Task Force III.

2. Each Task Force shall have a total voting membership of eight (8) members to be appointed by the Board Chairperson with the approval of the Board.
   a. Four (4) of the voting members shall be selected from Authorities and four (4) shall be selected from industry providing that each ISSC Region shall be represented by at least one (1) Task Force member, either industry or regulatory. The Chairperson (the ninth voting member who will vote only in case of a tie vote) shall alternately be selected from an Authority and from industry as outlined in Article I., Section 3. of the By-Laws.
   b. Three (3) of the Authority members shall be from producing states and one (1) shall be from a non-producing state, except for Task Force I where at least four (4) authority members shall be from producing states. Prior to the March Board meeting, the industry and regulatory Board member from each region may submit a list of Task Force nominees ofup to three (3) candidates each per Task Force to the Board Chairperson. The Board Chairperson shall appoint a member from each ISSC Region to each Task Force from the list of candidates submitted. The Board shall approve the candidates selected. In the absence of any nominees submitted from a region, the Board Chairperson, with Board approval, shall appoint the Task Force member.

3. The Board Chairperson, with approval of the Board, shall appoint a Chairperson and Vice-Chairperson for each Task Force.
   a. If the Task Force Chairperson represents an authority, the Vice-Chairperson shall be an industry representative.
   b. At the end of the Task Force Chairperson's term of office, the Vice-Chairperson will become Chairperson and a new Vice-Chairperson will be appointed who represents the same segment of the Conference as the outgoing Task Force Chairperson.

4. The Task Force Chairperson and Vice-Chairperson shall serve for a four (4) year period, i.e., through two (2) consecutive Conference Biennial meetings. Task Force members may not serve more than two (2) consecutive Biennial Meetings on the same Task Force.

5. A quorum for conducting Task Force business shall consist of five (5) voting members.

6. Each Task Force shall deliberate all proposals during the times specified at the Conference meeting. Each Task Force Chairperson shall report the actions recommended by his/her respective Task Force to the voting delegates at the Conference under the heading of New

Business for final Conference consideration. Any "No Action" recommended by a Task Force shall contain the reasons for the "No Action" recommendation.

7. If a Task Force member is unable to attend the Biennial Meeting, he/she shall notify the Executive Director prior to the first Executive Board meeting. The Board Chairperson, with approval of the Board, shall appoint a replacement that represents the same segment of the Conference as the member who is unable to attend to serve the remainder of the unexpired term. The Board Chairperson will confer with Board members from the affected region before appointing a replacement.

ARTICLE II. TASK FORCE CONSULTANTS

1. The Board Chairperson shall appoint a consultant for each Task Force from the Board.

2. FDA, EPA, and NMFS may provide a consultant for each Task Force.

3. Consultants will have no voting rights in Task Force action but will attend Task Force deliberations to offer advice as needed.

ARTICLE III. AMENDMENTS

Section 1. These By-Laws may be amended at a duly called Conference meeting, the Delegates having had sixty (60) days' notice from the Executive Director of proposed amendments. Adoption of an amendment to the By-Laws shall require at least a two-thirds (2/3) majority vote.

Section 2. Amendments to the By-Laws will become effective at the close of the Conference meeting at which they are adopted.

PROCEDURES OF THE INTERSTATE SHELLFISH SANITATION CONFERENCE

PROCEDURE I. PURPOSE

The Interstate Shellfish Sanitation Conference (ISSC) is intended to foster and improve the sanitation of shellfish through cooperation and through uniformity of state shellfish programs.

PROCEDURE II. PROGRAM

1. To achieve its goal, the ISSC will adopt a NSSP Guide for the Control of Molluscan Shellfish for sanitary control of shellfish that is adequate to ensure that the shellfish produced in a state that complies with these guidelines will be safe and sanitary. This NSSP Guide for the Control of Molluscan Shellfish shall be called the National Shellfish Sanitation Program (NSSP).

2. The ISSC shall adopt an NSSP Guide for the Control of Molluscan Shellfish as the NSSP, effective January 1998.

PROCEDURE III. RESPONSIBILITIES OF THE STATE

1. The state shall have adequate laws and regulations to provide a legal basis for sanitary control of all interstate phases of the shellfish industry.

2. The state shellfish growing area classification authority shall forward the classification of shellfish growing waters in the state to the appropriate Food and Drug Administration (FDA) ~~Regional Office~~Shellfish Specialist. The most recent classification shall be reported. When the classification of growing waters changes, the most recent classification shall apply and shall be submitted to FDA. The state shellfish growing area classification authority shall keep current the classification of all growing waters within its state.

3. The Authority of the shipping state shall certify the results of inspections of each interstate shellfish shipper meeting NSSP requirements to the FDA ~~headquarters office~~Shellfish and Aquaculture Policy Branch (SAPB) for inclusion in the Interstate Certified Shellfish Shippers List (ICSSL)~~, with copies to the appropriate FDA Regional Office~~. The certification ~~inspection report, together with other pertinent~~ information~~,~~ shall be ~~forwarded with~~submitted through a registered user account ~~the appropriate~~on FDA's electronic Interstate Shellfish Shippers information system (form number FDA 3038~~b~~). The most recent certification status of a shipper shall be reported. When the sanitation compliance status of a listed shipper changes, as a result of a new inspection made with the twelve (12) month eligibility period, the most recent status shall apply and shall be submitted to FDA. When a certified interstate shellfish shipper changes status because of certificate revocation, the shipping state shall immediately notify the FDA ~~headquarters office~~SAPB, all known receiving states, the ISSC, and the appropriate FDA ~~Regional Office~~Operations Branch. Receiving states shall immediately notify shipping states in writing with a copy of irregularities in shellfish received, which may raise questions concerning the source or quality of the product.

4. The Authorities shall accept responsibility for having trained personnel to implement the state programs. Methods should be developed so that personnel who have completed the training can demonstrate proficiency at appropriate intervals.

5. Shellfish growing area patrol activities shall be carried out by an enforcement authority designated by the state in any productive shellfish growing areas failing to meet the approved area criteria of the NSSP.

6. All phases associated with the relaying of shellfish from closed areas to approved areas shall be under the immediate supervision of the appropriate responsible Authority.

7. Depuration may be permitted only under the effective supervision of the Authority(ies).

8. Laboratories shall be provided and staffed to effectively support the state shellfish program. Sample analysis shall be performed in accordance with the latest approved edition of the APHA, AOAC, or ISSC approved methods.

PROCEDURE IV. RESPONSIBILITIES OF THE FDA

1. The FDA should promote uniformity among FDA personnel through a national shellfish-training program, which will be conducted at least every three (3) years. Methods should be developed so that personnel who have completed the course can demonstrate proficiency in lieu of attending the course at subsequent intervals. The FDA should administer an ISSC approved training course at least every three (3) years for Authority personnel. The FDA should evaluate and ensure the uniformity of methods of state shellfish laboratory personnel who are responsible for the operation of the state laboratories. The FDA annual state program evaluation should include: a listing and the date of most recent training of the Authority personnel who have completed the appropriate training, a list of FDA personnel who have completed the appropriate training, and a list of state shellfish laboratory personnel whose competence in interpreting and evaluating shellfish laboratory methods has been demonstrated to and evaluated by the FDA.

2. The FDA should publish the ICSSL monthly. The ICSSL should include certification of shellfish shippers as submitted by the states.

3. The FDA should prepare an annual evaluation of the shellfish program of each state in accordance with the Procedures of the NSSP. This evaluation should consider the program as a whole and should also specifically address the legal authority, the classification of shellfish growing waters, the shellfish sanitation control and certification, personnel training, patrol, relaying, depuration and laboratory phases of the program, and the status of state authorities Memorandums of Understanding. The state evaluation prepared by the ~~Regional~~ Shellfish Specialist should be reviewed and discussed with the appropriate state shellfish officials prior to submission to FDA ~~headquarters~~SAPB.

4. Interpretations of the FDA recommended National Shellfish Sanitation Program and FDA evaluation procedures should be furnished periodically to the Authorities. Administrative

procedures developed by the FDA should be drafted and forwarded to the ISSC for review and comment prior to their adoption. The ISSC should stand ready to deal with such problems on a continuing basis.

PROCEDURE V. GUIDELINES

The NSSP as adopted by the ISSC and the FDA, without footnotes except as the Conference may adopt, shall be used as the basic guidelines for the classification of shellfish growing waters and the basic sanitation guidelines in making shellfish sanitation certification inspections of interstate shellfish shippers. The Conference discourages the use of separate guidelines for intrastate shellfish shippers. Shellfish from any state participating in the ISSC should be accepted for sale in any other member state under the principles of reciprocity, provided the state's program is in compliance with the NSSP. Such states shall be indicated on the ICSSL. For the purpose of the NSSP and ISSC in total, the District of Columbia shall be considered as a state with all the rights, duties, responsibilities, and privileges of a state.

PROCEDURE VI. GROWING WATERS CLASSIFICATION

The state shellfish classification authority shall survey and classify the shellfish growing waters of the state in accordance with the methods outlined in the NSSP. Classification of shellfish growing waters shall be made by qualified state shellfish classification personnel who have successfully completed training. Classification shall be reappraised at least every twelve (12) months, a complete resurvey shall be completed at least every three (3) years, and a comprehensive sanitary survey at least every twelve (12) years.

PROCEDURE VII. SHIPPER CERTIFICATION

A shipper desiring classification of his plant for the purpose of interstate shipment of shellfish shall submit a request to the state shellfish sanitation control authority in his own state. Shellfish sanitation certification inspections shall be made by qualified state shellfish sanitation control personnel who have completed the appropriate training. State shellfish sanitation certification inspections shall be made at least annually. The names, certification numbers, and locations of all certified interstate shippers shall be published monthly in the ICSSL, with more frequent updates at the dynamic online listing.

PROCEDURE VIII. BILL OF LADING AND LABELING

1. All interstate shipments of shellfish must be accompanied by copies of a bill of lading which includes the following information: (a) shipper's name, address and certification number; (b) point of origin of shipment; (c) quantity of product; (d) type of product; (e) date of shipment. All entries on bills of lading shall be legible. When the interstate shipment is derived from more than one shipper, separate bills of lading for each of the sources shall accompany the shipment.

2. All individual containers of shellfish in interstate shipment shall be labeled in accordance with applicable FDA and NSSP requirements.

PROCEDURE IX. PROCEDURES FOR HANDLING COMPLAINTS AND CHALLENGES REGARDING THE ADEQUACY OF CERTIFICATION CONTROLS

1. Complaints from any state or non-state party regarding possible non-conformities in a producing and/or shipping state shall be handled as follows:
   a. Only complaints regarding the sanitary quality and effectiveness of public health controls shall be covered under this procedure.
   b. Complaints shall be made in writing to the Authority as listed in the ICSSL, with a copy to the appropriate FDA ~~Regional Office~~Operations Branch.
   c. The complaint shall provide specific and complete factual information concerning all items not in conformity and shall specifically verify that all sampling and testing has been conducted in accordance with the NSSP.
   d. The Authority shall make an investigation of the complaint within twenty (20) working days of receipt, promptly notify the complainant in writing of the findings and any actions being taken, and provide a copy to the appropriate FDA ~~Regional Office~~Operations Branch.
   e. Upon receipt of the response or upon the failure to receive a response within thirty (30) days, the complainant may request in writing to the ISSC Board Chairperson that further investigation by FDA be conducted. FDA may also undertake further investigation at their own initiative.
   f. FDA shall provide a written report of its findings or the status of the complainant within thirty (30) days to the parties involved and the ISSC Board Chairperson.
   g. If FDA's investigation does not lead to a satisfactory resolution of the problem, the problem shall be handled as an unresolved issue according to Procedure IX. Section 3.

2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken:
   a. FDA shall provide written notification to the Authority of the item(s) requiring action with supporting documentation and recommendations as appropriate.
   b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days.
   c. When a state does not disagree with FDA observations, but disagrees with an FDA report or FDA findings in the report regarding the state's NSSP compliance status, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days.

d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary.

e. If the state and FDA are unable to find a mutually agreeable resolution to the disagreement, or FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), FDA shall notify the state and the ISSC Executive Director of an unresolved issue. In response to the FDA notice, the State may pursue one of the following actions:

1. The State may request consultation from the Consultation Subcommittee of the ISSC Unresolved Issues Committee. The purpose of this consultation will allow the State the opportunity to seek guidance from the Consultation Subcommittee regarding program requirements and FDA findings; or

ii. The State shall notify the ISSC Executive Director of an unresolved issued.

f. Upon notification from both FDA and the state of an unresolved issue, the ISSC Executive Director shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.

3. After receipt of an unresolved issue, the Executive Director shall immediately send the unresolved issue to the Executive Board. Within thirty (30) days of receipt of the unresolved issue by the Executive Director, the Executive Board shall take one (1) of the following actions:

a. Resolve the issue on their own initiative.

b. Refer the matter to the Unresolved Issues Committee.

4. When an issue has been referred, the Unresolved Issues Committee shall convene a meeting, giving all involved parties an opportunity to participate. The Committee shall review the issue, and considering input from involved parties, submit its recommendations to the Executive Board.

5. The following list of deficiencies and sanctions shall serve as a guide for actions should the Executive Board confirm the findings of the FDA evaluation.

a. State program deficiencies, which may result in ISSC sanctions, are as follows:

i. Administrative - Inadequate State Laws/Regulations to Enforce the Program

ii. Growing Areas

a. Failure to properly classify.

b. Failure to close in an emergency situation.

c. Repeated failure to comply with conditional management plans.

d. Lack of sanitary survey and supporting documentation justifying classifications.

e. Lack of Biotoxin contingency plan.

f. Failure to comply with contingency plans.

iii. Plant Sanitation

a. Failure to have a standardization officer.

b. Certification of plants by non-standardized inspector.
c. Failure to take action on critical deficiencies.
d. Significant differences between state vs. state/FDA inspections.
e. Repeated Critical and Key items at significant number of firms.
f. Inadequate state laws/regulations to enforce program.

iv. Other Program Areas
a. Inadequate tagging and records by shellfish dealers.
b. Refusal to participate/provide cooperation in FDA program evaluations.
c. Failure to control relaying.

b. The following actions shall be taken by the Executive Board as appropriate:
i. Meeting(s) with responsible state officials to express ISSC concern about the unresolved issue and to develop an acceptable action plan.
ii. A letter to top state program administrators, including the governor, expressing ISSC concern regarding state program deficiencies.
iii. Notification to ISSC members of the unresolved issue for their information.
iv. Recommendation to FDA to include a notice in the ICSSL regarding the unresolved issue.
v. Recommendation to the Authority to remove affected dealers from the ICSSL.
vi. Recommendation to FDA to remove all certified dealers from future ICSSL publications.
vii. Notification to all states and other appropriate authorities describing the unresolved issue and that action against products from a state with significant control problems may be appropriate for their consideration.
viii. A letter to FDA expressing ISSC concern regarding the position of FDA.

PROCEDURE X. PROCEDURE FOR HANDLING ISSC SUMMARY OF ACTIONS

Unless explicitly specified otherwise by a vote of the voting delegates, recommended changes in the NSSP or Procedures shall be implemented in accordance with the following schedule:

1. The Summary of Actions for the Biennial meeting shall be forwarded to FDA within sixty (60) days of the close of the Biennial meeting.

2. FDA will review the actions of the ISSC and within sixty (60) days of the receipt will notify the Board Chairperson of the ISSC of which actions conflict with existing federal laws, regulations or policies. NSSP changes, with which FDA concurs, will be effective upon posting on the FDA website unless otherwise stated in the Summary of Actions or in the NSSP Model Ordinance. The Task Force may recommend a specific implementation date.

3. For those actions which FDA feels conflict with existing federal laws, regulations or written policies or when a federal law, regulation or written policy does not address the issue, a written decision made by the Director, FDA ~~Office of Food~~Division of Seafood Safety, along with supporting rationale, will be provided to the ISSC Chairperson within sixty (60) days ofreceipt of the Summary of Actions.

4. The ISSC Chairperson will refer those actions which FDA feels conflict with existing federal laws, regulations, or written policies with FDA's rationale, to the Executive Board for further discussion or referral to the next Biennial meeting for reconsideration.

PROCEDURE XL PROCEDURE FOR HANDLING RESOLUTIONS

1. The Board Chairperson, with approval of the Board, shall appoint a four-member Resolutions Committee. Membership shall consist of one member from regulatory, one member from industry, one representative from FDA, and one member from NMFS. The appointment of the Committee and the duties of the Committee will be as outlined in the ISSC Constitution, By-Laws, and Procedures.

2. The objective of the Resolutions Committee shall be to review all proposed resolutions with respect to criteria for content and format and for adherence to time frames for submission and posting to permit adequate review by all Conference participants prior to the final Voting General Assembly. Depending on circumstances and timing, resolutions may be submitted by any Conference member for consideration by the General Assembly or by the Board at interim meetings.

3. For the purpose of resolution procedures, there shall be two types of resolutions.
   a. Housekeeping resolutions are routine resolutions for acknowledging accomplishments or recognition of services, such as hotel staff and volunteers, for activities performed. Housekeeping resolutions may be submitted at any time prior to the voting of the General Assembly.
   b. Substantive resolutions are relevant to the objectives to the ISSC. Substantive resolutions shall be submitted to the Resolutions Committee Chairperson no later than two days prior to the issuance of the final Task Force Reports. Copies of the resolutions, including Resolution Committee recommendations, shall be included with the Task Force Reports when they are distributed for membership consideration.

4. There are two prescribed criteria for resolutions.
   a. Resolutions shall not propose changes in major ISSC policies, the Constitution, By-Laws, or Procedures or the NSSP. These changes are considered Proposals and must be submitted as outlined in Article XI. of the Constitution for consideration by Task Forces.
   b. Resolutions shall be submitted uniformly using a standard ISSC Resolution Form.

5. The Resolutions Committee, in reviewing the submitted resolution, may:
   a. Make editorial changes (grammatical, spelling, or format only); and
   b. Make substantive changes (must discuss with submitter).

6. The Resolutions Committee shall make recommendations that may include:
   a. Referral to the General Assembly and/or the Board for consideration; and
   b. Referral to the Board for assignment to a Task Force for appropriate action.

   The Committee must provide in writing its reason for the action it has taken.

PROCEDURE XII. PROCEDURE FOR HANDLING AND DISSEMINATING INTERPRETATIONS OF THE NSSP GUIDE FOR THE CONTROL OF MOLLUSCAN SHELLFISH BY FDA.

1. A request for Interpretation must be submitted to FDA ~~Headquarters (Office of Food Safety)~~SAPB through either an FDA ~~Regional Office~~Shellfish Specialist or the ISSC Executive Director according to the following routes:
   a. The interpretation request is submitted to the ~~Office of Food Safety~~FDA SAPB following the administrative chain of communication from industry to the State and, to the FDA ~~Regional Office~~Shellfish Specialist; or
   b. The interpretation request is submitted to the ISSC Executive Director by industry, a State, or the general public. The ISSC forwards the interpretation request to ~~Office of Food Safety~~the FDA SAPB for a response.
2. The interpretation request submitted to ~~Office of Food Safety~~the FDA SAPB must be written and include the following:
   a. The question to be interpreted. Clearly state what the issue(s) is and include the NSSP Guide for the Control of Molluscan Shellfish reference(s) that is unclear and requires interpretation. Include any NSSP Guide for the Control of Molluscan Shellfish references related to the question.
   b. Who is requesting the interpretation? Give the name, state, area of interest (i.e., an industry person who operates an oyster shucker/packer operation, a State Shellfish Standardization Officer, etc.) and his/her address and phone number.
   c. The background surrounding the interpretation request. It is very important to understand the circumstances, motivation, and purpose for an interpretation to put it into context.
   d. An opinion on resolving the problem. Include ideas on what the Interpretation should be. This includes what the NSSP Guide for the Control of Molluscan Shellfish means, the intent of the NSSP Guide for the Control of Molluscan Shellfish, how appropriate reference (CFR, EPA Guidance Document, etc.) should be interpreted.
3. Within seven (7) days, the ~~Office of Food Safety~~FDA SAPB will acknowledge receipt of the letter to the requestor and the FDA Operations Branches ~~FDA's Division of Federal and State Relations (DFSR)~~.
4. All requests for interpretations must be sent to the ~~Office of Food Safety~~FDA SAPB.
   a. Within sixty (60) days of acknowledgment of the letter, the ~~Office of Food Safety~~FDA SAPB will provide a draft proposal to the FDA ~~Regional Offices~~Operations Branches~~,~~ and the ISSC Executive Director~~, and DFSR~~ for comment. The ISSC Executive Director shall distribute the draft proposal to the requestor and ISSC members from states, industry, and the general public.
   b. An additional thirty (30) days may be permitted for draft development if circumstances warrant. The requestor must be notified of the additional development time.
5. Comments on the Draft Interpretation.
   a. The FDA ~~Regional Offices~~Operations Branches~~,~~ and ISSC Executive Director~~, and DFSR~~ have thirty (30) days from receipt to comment on the draft proposal to the ~~Office of Food Safety~~FDA SAPB.

The ISSC Executive Director is responsible for receiving, consolidating, and forwarding to the ~~Office of Food Safety~~FDA SAPB comments from ISSC members from states, industry, and the general public.

b. The FDA ~~Regional Offices~~Operations Branches~~,~~ and ISSC Executive Director~~, and DFSR~~ may request, in writing to the ~~Office of Food Safety~~FDA SAPB, an additional thirty (30) days to comment on the draft proposal.

6. Action on Draft Interpretation Comments.

a. The ~~Office of Food Safety~~FDA SAPB has thirty (30) days from receipt of comments to complete the final interpretation by:

i. Incorporating the comments and issuing a final interpretation; or

ii. Issuing the final interpretation without revision.

b. FDA may request an additional thirty (30) days for issuance of the final interpretation if circumstances warrant. The requestor and ISSC Executive Director must be notified of the additional development time.

7. The ~~Office of Food Safety~~FDA SAPB shall disseminate final interpretations to the ISSC and ~~DFSR~~ the FDA Operations Branches for dissemination as follows:

a. Upon receipt of the final interpretation, the ISSC Executive Director shall distribute it to the requestor and ISSC members from states, industry, and the general public.

b. Upon receipt of the final interpretation, ~~DFSR~~ the FDA Operations Branches shall distribute it to the FDA ~~Regional Offices and the Office of Food Safety~~Shellfish Specialists.

c. Final interpretation shall be incorporated into the NSSP Guide for the Control of Molluscan Shellfish.

PROCEDURE XIII. PROCEDURE FOR INCORPORATION OF APPENDICES INTO THE NSSP MODEL ORDINANCE.

Reference materials related to Satisfactory Compliance will be included in the NSSP Model Ordinance. All other reference materials will be referenced by title only.

PROCEDURE XIV. PROCEDURE FOR ADDRESSING PATHOGENS AND DELETERIOUS SUBSTANCES NEWLY RECOGNIZED IN SHELLFISH.

1. Issues or concerns regarding pathogen(s) or deleterious substances newly recognized in shellfish, which may not be presently addressed in the NSSP submitted to the Conference for action, shall be immediately referred to the Pathogen Review Committee. The committee shall review the issue or concern, gather information, and provide a written report and recommendation to the Executive Board or Task Force for appropriate action. The intent of this procedure is to provide a base of knowledge in an expeditious manner for effective action by the ISSC. The written report shall include:

a. Characterization of the pathogen or deleterious substance. Characterization shall address, as a minimum, the following:

i. The illness and symptoms

ii. Dose/response relationship

iii. Route of transmission

iv. Incidence of illness

v. Population affected

vi. Source of pathogen
vii. Pollution level association
viii. Geographic scope
ix. Type of shellfish implicated

b. A detailed summary of the literature search conducted by the committee. The search shall include, as a minimum, the following:
i. Published literature
ii. Grey literature
iii. White papers
iv. Personal communication

b. Recommendation on the adequacy of present NSSP or other controls in addressing the pathogen or deleterious substance.

c. Recommendation of additional NSSP controls or alternative controls if appropriate.

d. Recommendation of additional data or information needs critical to development of effective controls.

ii. The Pathogen Review Committee shall include representatives from FDA, NMFS, EPA; Authorities, the shellfish industry, and academia with knowledge of the pathogen(s) or deleterious substances of concern and risk analysis and risk management.

iii. The ISSC Executive Board shall set a date for completion of the report to ensure that the ISSC membership is informed. The written committee report shall be presented to the Executive Board or appropriate Task Force for use in its deliberation of the issue.

PROCEDURE XV. PROCEDURE FOR THE APPROVAL OF ANALYTICAL METHODS FOR THENSSP

iv. Prior to NSSP adoption, all laboratory methods shall be evaluated by the ISSC. 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; and
c. Time Table for SLV

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

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

vii. The full proposal shall be submitted to the ISSC in proposal form requesting approval of the analytical method for use in the NSSP.
a. All proposals shall include a completed ISSC Method Application and Single Laboratory Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP. AOAC approved methods that have undergone the AOAC Official Methods of Analysis (OMA) or FDA ~~Office of~~ Foods Program 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 an ISSC Method Application and Single Laboratory

Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP, along with the AOAC OMA or FDA ~~Office of~~ Foods Program Level 3 or 4 validations.

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

viii. Within six (6) months of receipt, the Laboratory 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.

ix. Review by Laboratory Committee:

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

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

ii. Method documentation including:
   (a) Method title, scope and references;
   (b) Equipment and reagents required;
   (c) Sample collection, preservation and storage requirements;
   (d) Safety requirements;
   (e) Step by step procedure;
   (f) Specific quality control measures associated with the method;
   (g) Laboratory Evaluation Checklist for use during evaluations of proper method implementation;
   (h) Cost of the method;
   (i) Sample turnaround time.

iii. Specific application(s);

b. Review of need for the method;

i. Method meets an immediate or continuing need;

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

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

x. The Laboratory 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:

a. Non-acceptance (no action) pending further information as defined by the

Committee. The method submitter has eighteen (18) months from the date of the written request from the ISSC to provide the information/data necessary to complete the evaluation of the method. If there is no response from the submitter within this timeframe, the Laboratory Committee will recommend no action on the Proposal;

b. Accept as an Approved NSSP Method;

c. Accept as an Approved Limited Use NSSP Method;

d. Accept as an Emergency Use NSSP Method.

xi. 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.

xii. Types of NSSP Analytical Methods.

a. Approved NSSP Methods.

Approved NSSP Methods are the primary/core methods used in the NSSP and cited in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests. These methods have been described in scientific or other peer-reviewed professional publications; have been used historically or are used throughout the NSSP and elsewhere to effectively detect or quantify and have been extensively evaluated and the performance characteristics for specific applications in the NSSP determined as fit for purpose through long use in the NSSP and/or Single Laboratory Validation (SLY) testing and/or collaborative study.

b. Approved Limited Use Methods.

Approved Limited Use Methods are permanent 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 include new methods, alternative methods or screening methods within the NSSP that meet an immediate need of the NSSP, improve turnaround time, cost effectiveness, and/or increase analytical capacity. These methods have been evaluated and the performance characteristics for specific applications in the NSSP have been determined through the Single Laboratory Validation Method Protocol (SLV) to be fit for purpose within the NSSP. These methods are referred to as being oflimited use within the NSSP either because of their status as newly adopted methods with little corroborating data beyond the SLV or because the application for which the method can be or is used within the NSSP is limited in scope with little laboratory participation within the NSSP and little to no subsequent corroborating data or because of the nature of the test method itself and/or restrictions that have been placed on its use that limit its usefulness within the NSSP.

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 criteria in Procedure XV. of the ISSC Constitution, Bylaws, and Procedures are provided.

xiii. Matrix Extensions.

For methods already adopted into the NSSP, additional work must be done in order to expand

the use of that method to a new molluscan shellfish matrix. To determine if a Matrix Extension is needed, please refer to the guidance provided in the NSSP Guide for the Control of Molluscan Shellfish, Section IV. Guidance Documents, Chapter II. Growing Areas .21 - Guidance for Laboratory Method Matrix Extensions. If a matrix extension is needed, the necessary information, studies, and data to be provided to the Laboratory Committee for consideration are summarized on the "ISSC Method Application Format for Biotoxin Methods Matrix Extension" and the "ISSC Method Application Format for Microbiology Methods Matrix Extension" documents available on the Laboratory tab of the ISSC website. This simplified, reduced approach to method validation for expanding an NSSP method to a new molluscan shellfish matrix is visually represented in the "Matrix Extension Guidelines" schematic, also available on the ISSC website.

PROCEDURE XVI. PROCEDURE FOR *Vibrio vulnificus (V v.)* ILLNESS REVIEW COMMITTEE PROCEDURES

1. Committee Charge
   On at least an annual basis, FDA and the Centers for Disease Control and Prevention (CDC) shall complete and reconcile all reported *V.v.* cases involving the consumption of shellfish. The *V v.* Illness Review Committee will review all *V v.* cases submitted by FDA and CDC . The Committee will determine which cases meet the case definition of a National Shellfish Sanitation Program (NSSP) *V v.* case as outlined in Model Ordinance Section IL Chapter IL @.06. All cases meeting the NSSP definition will be included in an annual report which will be presented to the Interstate Shellfish Sanitation Conference (ISSC) Executive Board and the Vibrio Management Committee. Following ISSC Executive Board approval the report will be made available to the ISSC membership and posted on the ISSC website. This data is expected to be used by USFDA, State Authorities, and the ISSC for the following purposes:
   a. Conducting annual *V v.* Risk Evaluations;
   b. Risk per serving determinations;
   c. *V v.* Control Plan Evaluations;
   d. *V v.* Contingency Plan Evaluations; and
   e. Reviewing illness trends.
2. Procedures.
   a. The Committee will only consider cases that are reported on a CDC and Prevention Cholera Vibrio Illness Surveillance Report (COVIS) Form CDC 52.79 or other electronic means.
   b. FDA will coordinate the collection of cases and COVIS forms, and other information and after redacting identifying information will make this information available to the ISSC Executive Office .
   c. The information from the COVIS forms will be shared with the *V v.* Illness Review Committee for review.
   d. The *V v.* Illness Review Committee will review the cases and- apply the criteria and guidelines in Section 3. 2016 is the first full year to which these criteria will be applied. The Committee will incorporate the appropriate information into a chart

which will serve as the Committee report.

e. The report will be presented to the ISSC Executive Board for approval and then forwarded to the Vibrio Management Committee.

f. The availability of the report will be announced to the ISSC membership.

A copy of the report will be posted on the ISSC website.

3. Criteria and Guidelines.

The Committee will use the following criteria and guidelines in reviewing reported cases:

a. Was the illness etiologically confirmed? In this context "etiologically confirmed "shall man laboratory confirmation by wound, stool or blood culture. Confirmation may be by a laboratory other than a State laboratory."

b. Was the illness epidemiologically linked to shellfish? Epidemiologically linked will mean "associated with" the consumption of oysters. Consumption means ingested; eaten within 7 days of onset of symptoms. Date of onset may be before hospitalization. Further information may be warranted; discretion may be exercised.

c. Were the shellfish commercially harvested? Commercially harvested shall mean the shellfish were intended for sale or distribution in commerce. Commercial harvest will include those cases involving a foreign state.

d. From what State was the shellfish harvested?

e. A case of severe *V.v.* is defined as illness in a person who had *V. vulnificus* infection confirmed by bacterial culture and either of the following:

i. *V. vulnificus* was isolated from blood or a site that likely indicates invasive disease (see specimen source table).

ii. For patients with no report on the COVIS form of wound exposure to a body of water or drippings from raw or live seafood during the 7 days before illness began any of the following were indicated on the COVIS case report form:

(a) Septic Shock
(b) Death
(c) Any of the following: necrosis; or invasive procedure, such as surgery, amputation, skin graft, would debridement, fasciotomy, or incision and drainage

iii.

4. Challenges to Committee Findings.

Persons wishing to challenge the information included in the report must notify the ISSC Executive Director within sixty (60) days of the posting of the report on the ISSC website. The ISSC Executive Board will review all challenges at the next scheduled Executive Board meeting.

5. *V v.* Case Appeal Procedure

a. Appropriate V.v. information will be provided to the reporting and source States at least 60 days prior to committee review. The States will be given 30 days from the date of receipt to respond.

b. Following V.v. Illness Review Committee review, each source State with a countable case will be notified.

c. Should a source State disagree with the Committee determination on a specific case,

the source State will be provided thirty (30) days to file an appeal.

d. Should the Committee, based on the information provided by the appellant, conclude that the original determination should be reversed, the appellant will be notified.

e. Should the Committee, based on the information provided by the appellant, conclude that the original determination was appropriate; the Committee will provide the appellant an opportunity to state their position. This opportunity will be either by telephone conference call or in person. The choice of venue will be determined by the Committee and will not exceed fifteen (15) minutes.

f. The Committee will consider information presented by the appellant in the oral presentation. The appellant will be notified of the final decision of the Committee.

g. The appellant will receive a final decision from the Committee no more than 30 days after the date the appeal is submitted; if a decision can NOT be made after 30 days, then an appeal extension must be granted by the committee, or the appeal will be considered denied.

Table: Specimen sources that likely reflect invasive disease

Blood: Includes plasma and blood components
Vascular: Includes heart, heart valves, aorta, blood vessels
Lymphatic: Includes lymph, lymph nodes, thymus
Spleen: Includes spleen, splenic abscesses
Bone: Includes bone, bone marrow
Placenta and products of conception: Includes fetus, cord blood
Nervous System Cerebrospinal fluid (CSF) Other nervous tissue: Includes brain abscess
Pleural fluid
Peritoneal fluid
Joint: Includes synovial/joint fluid
Hepatobiliary: Gallbladder, bile, liver (includes abscesses)
Pancreas: Includes pancreas, pancreatic cysts and abscesses
Reproductive: Ovary, fallopian tube, uterus (includes cysts and abscesses in these sites), pelvic abscesses, amniotic fluid
Kidney: Includes renal and perinephric abscesses

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

Case Identifier/Number:	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed			
2. Epidemiologically Linked?			
3. Severe Illness?			
4. Reporting State?			
5. Commercial Harvest?			
6. Were shellfish consumed?			
a. Specify shellfish consumed:	**Oysters**	**Clams**	**Specify Other**
b. Date of consumption: _____			
c. Is onset consistent with consumption of shellfish? Date of onset _____			
7. **Trace-back Information**			
a. Were shipping tags available? If other trace-back information reported, list:			
b. State of harvest, harvest area (s), and harvest date (list all reported).			

Harvest Area	Harvest State	Harvest Date	Species	Comment

ISSC *V v.* Illness Review Form (06/28/2013)

PROCEDURE XVII. RECIPROCITY

Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. The intent of this procedure is to ensure that state actions do not unnecessarily restrict interstate shipment of shellfish conforming to the reciprocity of the NSSP. The ISSC recognizes that States should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish. Procedure XVII. Section 1. Notification and Consultation provides adequate opportunity for communication between interested parties that could include State and Federal regulatory agencies and the industry.

1. Notification and Consultation.
A State, prior to taking an action that may fail to meet the definition of "reciprocity," must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC prior to a decision to take the action. The State should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that State;
- The potential effect on the public health in other States;
- The potential economic impact on States;
- The necessity for the action within the proposed timeframe; and
- How the proposed actions are consistent with Procedure I. requirements relating to uniformity and the importance of operating within a collective framework.

A State may also notify the ISSC Executive Board upon learning of another State's intention to take action that may violate Procedure V.

2. Consideration.
If, after fully considering the State's rationale for the proposed actions, the Executive Board determines that the State's actions are unwarranted and contrary to the interests of the collective membership, the Executive Board shall so advise the State. If the State takes the proposed action after being so advised, or fails to follow Procedure V., the Executive Board will commence a formal Procedure V. process.

3. Formal Procedure V. Process.
The process will include written notification to all States involved (initiating and affected States), to present findings on the scientific and public health issues raised, which support their respective views or actions on the issue, along with identification of the formal procedural process and timeline.

All affected States (initiating and affected States), shall present the following information to the ISSC Executive Board:

- Scientific and related public health issues.

- Economic issues.
- Other relevant issues.
- Rationale why Procedure V. has/has not been violated.
- Alternate Actions for consideration.

The Executive Board determination will include Findings of Facts and Conclusions.

4. Censure.
If the State takes the proposed action after being so advised, or fails to follow Procedure V., the Executive Board may place the State under censure until such time as removed from the censure by the Executive Board and so inform the Governor of that State in writing. A State under censure may attend all functions and otherwise exercise rights as a member of the ISSC, but may not vote, either in committees, task forces, or in the General Assembly. The Executive Board reserves the right to take additional actions against the non-compliant State.

PROCEDURE XVIII. EXECUTIVE BOARD PROCEDURES FOR ESTABLISHING MEMBERSHIP FEES

The ISSC Executive Board will follow these guidelines in establishing membership fees for State and individual members.

1. Membership fees will be established as necessary to provide at a minimum ten percent (10%) of the operating costs of the ISSC.
2. The Executive Board will consider appropriate changes to the minimum of ten percent (10%) should decreases in other funding sources occur.
3. The Executive Board will allocate travel assistance to member States when the revenue acquired from membership fees is not critical to support the Conference operating budget.

PROCEDURE XIX. PROCEDURE FOR DISSOLUTION

Upon the dissolution of the corporation, assets shall be distributed for one or more exempt purposes within the meaning of section 501(c)(3) of the Internal Revenue Code, or corresponding section of any future federal tax code, or shall be distributed to the federal government, or a state or local government, for a public purpose. Any such assets not so disposed of by a Court of Competent Jurisdiction of the county in which the principal office of the corporation is then located, exclusively for such purposes or to such organization or organizations, as said Court shall determine, which are organized and operated exclusively for such purposes.

ISSC *Vibrio vulnificus* Illness Review Criteria Table

Review Date: _____

Case Identifier/Number:	**Criteria Status Determination**		
Criteria	**Yes**	**No**	**Unknown**
1. Etiologically Confirmed			
2. Epidemiologically Linked?			
3. Severe Illness?			
4. Reporting State?			
5. Commercial Harvest?			
6. Were shellfish consumed?			
a. Specify shellfish consumed:	**Oysters**	**Clams**	**Specify Other**
b. Date of consumption: _____			
c. Is onset consistent with consumption of shellfish? Date of onset _____			
7. **Trace-back Information**			
a. Were shipping tags available? If other trace-back information reported, list:			
b. State of harvest, harvest area (s), and harvest date (list all reported).			

Harvest Area	Harvest State	Harvest Date	Species	Comment

ISSC *V v.* Illness Review Form (06/28/2013)

PROCEDURE XVII. RECIPROCITY

Reciprocity for the purpose of ISSC agreements shall mean that no action or requirements on the part of any regulatory authority will cause or require any action in excess of the requirements of the NSSP or the ISSC agreements. The intent of this procedure is to ensure that state actions do not unnecessarily restrict interstate shipment of shellfish conforming to the reciprocity of the NSSP. The ISSC recognizes that States should be allowed to appropriately respond to public health emergencies that could restrict interstate shipment of shellfish. Procedure XVII. Section 1. Notification and Consultation provides adequate opportunity for communication between interested parties that could include State and Federal regulatory agencies and the industry.

1. Notification and Consultation.
A State, prior to taking an action that may fail to meet the definition of "reciprocity," must first notify and consult with the Executive Board. Notification should be as far in advance as is reasonably possible in order to take into account the views of the ISSC prior to a decision to take the action. The State should provide the rationale for the proposed action by describing, at a minimum:

- The potential effect on the public health within that State;
- The potential effect on the public health in other States;
- The potential economic impact on States;
- The necessity for the action within the proposed timeframe; and
- How the proposed actions are consistent with Procedure I. requirements relating to uniformity and the importance of operating within a collective framework.

A State may also notify the ISSC Executive Board upon learning of another State's intention to take action that may violate Procedure V.

2. Consideration.
If, after fully considering the State's rationale for the proposed actions, the Executive Board determines that the State's actions are unwarranted and contrary to the interests of the collective membership, the Executive Board shall so advise the State. If the State takes the proposed action after being so advised, or fails to follow Procedure V., the Executive Board will commence a formal Procedure V. process.

3. Formal Procedure V. Process.
The process will include written notification to all States involved (initiating and affected States), to present findings on the scientific and public health issues raised, which support their respective views or actions on the issue, along with identification of the formal procedural process and timeline.

All affected States (initiating and affected States), shall present the following information to the ISSC Executive Board:

- Scientific and related public health issues.

- Economic issues.
- Other relevant issues.
- Rationale why Procedure V. has/has not been violated.
- Alternate Actions for consideration.

The Executive Board determination will include Findings of Facts and Conclusions.

4. Censure.
If the State takes the proposed action after being so advised, or fails to follow Procedure V., the Executive Board may place the State under censure until such time as removed from the censure by the Executive Board and so inform the Governor of that State in writing. A State under censure may attend all functions and otherwise exercise rights as a member of the ISSC, but may not vote, either in committees, task forces, or in the General Assembly. The Executive Board reserves the right to take additional actions against the non-compliant State.

PROCEDURE XVIII. EXECUTIVE BOARD PROCEDURES FOR ESTABLISHING MEMBERSHIP FEES

The ISSC Executive Board will follow these guidelines in establishing membership fees for State and individual members.

1. Membership fees will be established as necessary to provide at a minimum ten percent (10%) of the operating costs of the ISSC.
2. The Executive Board will consider appropriate changes to the minimum of ten percent (10%) should decreases in other funding sources occur.
3. The Executive Board will allocate travel assistance to member States when the revenue acquired from membership fees is not critical to support the Conference operating budget.

PROCEDURE XIX. PROCEDURE FOR DISSOLUTION

Upon the dissolution of the corporation, assets shall be distributed for one or more exempt purposes within the meaning of section 501(c)(3) of the Internal Revenue Code, or corresponding section of any future federal tax code, or shall be distributed to the federal government, or a state or local government, for a public purpose. Any such assets not so disposed of by a Court of Competent Jurisdiction of the county in which the principal office of the corporation is then located, exclusively for such purposes or to such organization or organizations, as said Court shall determine, which are organized and operated exclusively for such purposes.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. X Administrative
2. Submitter	Andrew Bell
3. Affiliation	State of Delaware, Department of Natural Resources & Environmental Control
4. Address Line 1	285 Beiser Boulevard
5. Address Line 2	Suite 102
6. City, State, Zip	Dover, DE 19904
7. Phone	302-608-5511
8. Email	andrew.bell@delaware.gov
9. Proposal Subject	States Forum
10. Specific NSSP Guide Reference	Constitution of the Interstate Shellfish Sanitation Conference Article VIII. Duties of the Executive Director
11. Text of Proposal/ Requested Action	Article VIII. Duties of the Executive Director 13. The Executive Director shall arrange two virtual forums of ISSC states on a semi-annual basis for the purpose of facilitating communication and resource sharing between states. One semi-annual forum shall be for topics and questions relating to growing area classification, patrol, and laboratory matters. The other semi-annual forum shall be for topics and questions relating to aquaculture and processing and shipping matters. Sixty (60) days prior to the forums, the Executive Director shall send the date and other pertinent details, and solicit questions and topics for discussion, to all ISSC members of producing states for the forum relating to growing area classification, patrol, aquaculture, Vibrio control plan, and laboratory matters, and to all ISSC members of all states for the forum relating to processing and shipping matters. State attendance at these virtual forums is optional.
12. Public Health Significance	Consumer safety is strengthened when public health authorities have the opportunity to have discussions and share resources. It would be beneficial if Authorities met occasionally to discuss emerging topics and ask questions amongst ourselves. The intent is an opportunity for informal dialogue, to provide state representatives with a place to ask questions and obtain resources, so that shellfish sanitation can be improved and standardized at the national level. Examples of questions and topics that a state may wish to bring to these forums might be "At what rainfall level do other states issue an emergency closure?" or "Are any states requiring shading on harvest boats outside Vibrio Control Plan months?" or "Does anyone have a template for a cooler process study that they could share?" There is an observation that Authorities generally don't communicate much outside Biennial Meetings, and this proposal is an attempt to provide them with an optional opportunity for increased communication. This proposal adds to the duties of the Executive Director to hold two semi-annual virtual forums for ISSC state members, one for growing area, patrol, aquaculture, Vibrio control plan, and laboratory topics, and the other for processing and shipping topics (the idea is that the first type of forum would be relevant for producing states, while the second type of forum would be relevant for all states). Both these forums would be held every six months to facilitate state communication.

13. Cost Information	None or minimal
14. Changes Needed to Guidance (if proposed change is adopted)	None

Proposal No. 27-303
~~Date~~

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	4801 Hermitage Road
5. Address Line 2	Suite 102
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	Definition of Shellfish
10. Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures. Definitions
11. Text of Proposal/ Requested Action	(10) SHELLFISH – means all species of: (a) Oysters, clams or mussels, whether: ~~(ii)~~(i) Shucked or in the shell; ~~(iii)~~(ii) Raw, including post-harvest processed; ~~(iv)~~(iii) Frozen or unfrozen; ~~(v)~~(iv) Whole or in part; and (b) Scallops in any form, except when the final product form is the adductor muscle only~~.~~, attached or unattached to the shell.
12. Public Health Significance	Proposal 23-101 was adopted at the 2023 Biennial Meeting which amended the definition of shellfish in the NSSP Model Ordinance. The new language aligns the definition in the ISSC Constitution, Bylaws and Procedures with the new definition in the NSSP Model Ordinance.
13. Cost Information	
14. Changes Needed to Guidance (if proposed change is adopted)	

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	4801 Hermitage Road
5. Address Line 2	Suite 102
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	Definition of Certification Number
10. Specific NSSP Guide Reference	
11. Text of Proposal/ Requested Action	**(17) Certification Number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one (1) to five (5) digit Arabic number preceded by the two letter State abbreviation and followed by a two (2) letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with Chapter X. .04 B. ~~The certification type will be followed by applicable permit designation as indicated in Chapter I. @.02 E.1.~~
12. Public Health Significance	This language is submitted to address an unintended consequence related to the adoption of proposals 19-201 and 19-204 at the 2019 Biennial Meeting. The two related proposals addressed the information that is required to be submitted to FDA by states when a dealer is certified. Proposal 19-204 amended language to clarify that any permit designations held by the dealer being certified must be submitted along with the certification number so that the information can be included in the ICSSL. Proposal 19-201 amended the definition of "certification number" to add a reference to the appropriate section of Chapter X related to certification types instead of repeating the section. In addition, a phrase was added stating that "the certification type will be followed by the applicable permit designation as indicated in Chapter I. @.02.E.1." Although Chapter I @.02.E.1. refers only to information that is to be listed in the ICSSL, the inclusion of the statement added to the definition by the

	adoption of 19-201 arguably created a new requirement that permit designations must be added anywhere that a dealer certification number is required which includes shellstock tags as well as all packages of shucked shellfish and in-shell product. This issue was discussed by the ISSC Executive Board, many of whom were not aware that the new language may have created a significant new labeling requirement. A motion was adopted that directed the ISSC Executive Office to submit a proposal for discussion of the issue at the next Biennial Meeting.
13. Cost Information	
14. Changes Needed to Guidance (if proposed change is adopted)	

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-26-1
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	New State in the NSSP Process
10. Specific NSSP Guide Reference	Guide for the Control of Molluscan Shellfish, 2023 Revision Section IV. Guidance Documents Chapter I. @.01 .02
11. Text of Proposal/ Requested Action	.02 Procedures for Initiating a New State Program Under the National Shellfish Sanitation Program The requirements of the NSSP are contained in its Model Ordinance. Implementation of the Model Ordinance ….. The ISSC provides the formal structure …. To ensure uniformity in the administration and implementation of the requirements of the NSSP Model Ordinance at the State and tribal regulatory agency level, the FDA reviews their programs on an annual basis. New State or tribal regulatory programs under the NSSP are required to have their proposed program reviewed prior to its initiation to assure that any shellstock produced, stored or shipped under the State or tribal program for movement in interstate commerce meets the requirements of the Model Ordinance. *New State or Tribal Program* The Authority must apply to the FDA for evaluation and be found in conformity or compliance with the NSSP before initiating a State or tribal shellfish sanitation program or a new program element within an existing State or tribal program. The application should consist of a letter of intent to participate in the NSSP with a description of the shellfish sanitation program the State or tribal authority will initiate. The letter of intent should be on letterhead of the agency or department that will serve as the Authority. The FDA will ~~act on~~ acknowledge receipt of the ~~any~~ application submitted by the Authority and begin the review and evaluation process of the proposed shellfish sanitation program. ~~If the FDA has not acted within thirty (30) days, the Authority may proceed with the new shellfish sanitation program.~~

	When two (2) or more State or tribal agencies will be involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed. States and tribes are responsible for maintaining shellfish programs that conform to or comply with the requirements contained in the most current revision of the Model Ordinance. These requirements ~~should~~ shall be mandatory within each State program.
12. Public Health Significance	This guidance section provides instructions for a state or tribal authority to initiate the process of participating in the NSSP. This process does not apply to foreign governments seeking arrangements with the FDA to export bivalve molluscan shellfish to the U.S. Eliminating the statement that states or tribal authorities can initiate their shellfish sanitation program if the FDA fails to act within 30 days takes away the possibility of proceeding with a non-compliant program potentially risking public health. With that statement removed, the timeframe for initiating the process by FDA is not needed. There is no public health significance of these arbitrary timeframes and removing them provides more flexibility in beginning and completing the initial program review and evaluation process.
13. Cost Information	No cost to industry or the Authority
14. Changes Needed to Guidance (if proposed change is adopted)	This proposal is a change to guidance Chapter I. @.1 .02

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	
6. City, State, Zip	College Park, MD 20740
7. Phone	301-436-2601
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Changes to the Patrol Evaluation Section
10. Specific NSSP Guide Reference	NSSP Model Ordinance, Chapter I. @.03 3, i.
11. Text of Proposal/ Requested Action	**i.** The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above patrol evaluation criteria. i. The overall Patrol Program element will be assigned one (1) of the following designations: (a) **Conformance:** The program is in compliance with all of the criteria listed above. (b) **Conformance with Deficiencies**: The program only has minor deficiencies associated with a key compliance item. (c) **Nonconformance:** The program has: i. at least one (1) critical deficiency; ii. two (2) or more key deficiencies; or iii. a repeat **[Key]** deficiency from the previous evaluation. (d) **Major Nonconformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters. ii. During the closeout meeting for patrol evaluation, the Shellfish Specialists shall ~~identify~~ discuss any observations that may become a ~~patrol~~ deficiency ~~to~~ with the State patrol agency; iii. ~~Within thirty (30) days of~~ After the closeout meeting, the Shellfish Specialist shall provide a draft written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency; ~~iv. Within thirty (30) days of receiving the~~

	~~PEER,~~ The State patrol agency shall have the opportunity to review, comment and provide a written response to the draft PEER. ~~provide a written response that indicates:~~ ~~(a) The item(s) was corrected;~~ ~~(b) A correction plan has been developed with a completion date; or,~~ ~~(c) The reasons why the State disagrees with FDA's finding(s).~~ v. ~~Within fifteen (15) days of receipt FDA shall review the State response, and respond to the State;~~ For any deficiency that cannot be corrected prior to issuance of the final PEER, the State patrol agency will submit a corrective action plan including steps they will take to correct the deficiency and a timeframe for correction. vi. ~~Any CRITICAL item deficiency shall be corrected within thirty (30) days of acceptance by FDA of the correction plan;~~ The FDA will monitor the state's actions to complete the corrective action plan to correct the deficiency. ~~vii. Any KEY item deficiency shall be corrected within one (1) year of acceptance by FDA of the correction plan.~~ ~~viii. FDA shellfish specialists shall be responsible for monitoring the progress of State action plans.~~ ~~ix. Patrol Program recommendations addressing improvements not associated with the criteria included in Section I or recommendations addressing improvements beyond the requirements of the Model Ordinance should be submitted to the Authority in correspondence.~~
12. Public Health Significance	This section contains very specific timeframes for steps in the Program Element Evaluation Report process and for correcting reported deficiencies. Chapter I. @.03 does not have specific process timeframes for the growing area classification, plant processing and shipping and risk assessment and risk management program element evaluations. It places requirements on the FDA that do not belong in a section for requirements of the authority. It is often difficult for the FDA or the state patrol agency to meet the timeframes specified for a variety of reasons and there is no allowance for extensions. The FDA includes timeframes for completing the field portion of evaluations, for providing a draft PEER, for the state to review the PEER, for providing a corrective action plan if needed and for completing the corrective action plan in Compliance Program 7328.004 Molluscan Shellfish as policy, not an MO requirement. This is a public document and provided to the Authority. The timeframes in this section are not aligned with

	timeframes in the compliance program. Removing the specific timeframes allows for more flexibility for the state authority and FDA to effectively conduct the PEER process. Having uniform timeframes across all program area evaluations adds to consistency in expectations. There is no public health significance to the specific timeframes outlined in this section and they are better included in the FDA Compliance Program than in the MO.
13. Cost Information	There is no cost to the industry or Authority.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	ISSC
4. Address Line 1	4801 Hermitage Rd
5. Address Line 2	
6. City, State, Zip	Richmond, VA 23227
7. Phone	(804) 330-6380
8. Email	issc@issc.org
9. Proposal Subject	Quantitative risk assessment of individual oyster harvests using real-time observations can expand Vibrio risk management options
10. Specific NSSP Guide Reference	TBD
11. Text of Proposal/ Requested Action	Develop guidance through the Vibrio Management Committee to assist implementation of existing quantitative risk assessment models by state authorities and industry to manage vibrio risk of individual oyster harvests using real-time observed water and oyster temperatures as an alternative to historical monthly mean maximum water temperatures to achieve an equivalent level of consumer protection.
12. Public Health Significance	Quantitative risk assessment (QRA) for *V. vulnificus (*Vv) in raw oysters was released by the Food and Agriculture Organization/World Health Organization in 2005. Water temperature determined Vv levels in oyster at harvest and post-harvest growth on ambient air temperature and cooldown time to minimum growth temperature (<13°C). The US Food and Drug Administration developed an Excel risk calculator based on this QRA to facilitate scenario analysis by state authorities. The National Shellfish Sanitation Program (NSSP) adopted a Vv Control Plan based on this risk calculator in 2009. State can use average monthly maximum water temperature in the previous five years to implement controls that will minimize risk to: (<3/100,000 when >80°F; <2.5/100,000 when 75-80°F; and <1.75/100,000 when 70-75°F). The NSSP allows states other risk management options: "may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above". States have generally adopted plans based on a single scenario analysis with rigid maximum harvest and cooling times. This "one size fits all" policy can result in excessive risk during heat anomalies and also restricts industry risk

	management options that could extent harvest periods by harvesting at cooler times or rapid cooling. A paradigm shift using observed harvest condition instead or relying on average historical temperatures is a more granular alternative control that improves QRA accuracy and expands compliance options. QRA models are available for *V. parahaemolyticus* and are amenable to real-time inputs by stakeholders to improve risk management using scenario analysis for emerging industry practices such as serving oysters during farm tours or to support a variance from re-mergence requirements.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
4. Address Line 1	5001 Campus Drive
5. Address Line 2	CPK1, HFS-325
6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Add new Section X, Notes, to the Guide as well as endnote reference numbers within the Guide, referring Guide readers to specific proposal number(s) that created/altered Guide language
10. Specific NSSP Guide Reference	Create new Section X.
11. Text of Proposal/ Requested Action	Currently, there is no reference mechanism within the Guide to allow readers to easily reference the proposal(s) that created/altered specific Guide language. Creating a reference mechanism linking Guide language to the proposals that created/altered that language would aid the reader in researching specific proposal(s) and the 'intent' of those changes. Currently the only way to research why Guide language was created or altered is to compare current Guide language to previous Guide versions to find the specific Guide version where that language changed, and then research that conference year's Task Force reports to find the specific proposal, a cumbersome process. This proposal would add a new Section X, *Notes*, to the Guide, as well as require that a superscript reference number be added to any new adopted language (or at a minimum any new adopted language of significance). The superscript reference number would refer the reader to the appropriate endnote in the *Notes* section, and that would include a brief description of that language/change, the related proposal number(s), and the conference year(s) adopted. Additionally, as sometimes Guide language is altered outside of the traditional Conference process by ISSC Executive Board action, this proposed referencing system would also capture those Board actions. As an example, in Section II Chapter VI. @.02 Seed Shellstock, subsection A., there is a relatively new 120 day minimum grow-out requirement for shellfish seed grown in Prohibited waters. This proposal would insert a superscript endnote reference number in that subsection as follows, '…a minimum of 120 days[1] of growing… The new Section X, *Notes* (organized in the same manner as the Guide), would read, Section II. Chp. VI. @.02 Seed Shellstock 1. 120 day grow-out requirement – Previously 6 months, See Proposal 13-107, adopted 2017.

12. Public Health Significance	A reference mechanism linking Guide language to the proposal(s) that created that language would increase the understanding of the reader as to why particular Guide language was adopted.
13. Cost Information	No cost to States/Industry. If adopted, this proposal would increase the administrative burden of the ISSC office when publishing a new Guide, going forward.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD