ISSC

Interstate Shellfish Sanitation Conference

Task Force I Proposals for Consideration At the 2027 Biennial Meeting

Newport, Rhode Island
January March 24-29, 2027

ISSC Task Force I
2027 Proposal Inventory

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

Submitter	Alison Sirois and Jackie Knue
Affiliation	Department of marine Resources and Alaska State Environmental Health Laboratory
Email	Alison.Sirois@maine.gov and Jacqueline.Knue@alaska.gov
Proposal Subject	PSP HPLC-PCOX Species Expansion
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	4. Approved Limited Use Methods for Marine Biotoxin Testing PCOX This submission presents data to support the use of PCOX method for Quahogs (M. mercenaria and A. icelandica), Surf Clams (S. solidissima), Geoducks (P. generosa), Butter Clams (S. giganteus), Little Neck Clams (P. stamineais), and Razor Clams (S. patula) for regulatory paralytic shellfish toxin (PST) testing. Results of the 2009 Interstate Shellfish Sanitation Conference (ISSC) proposal 09- 104 concluded the PCOX method approved for official use as a Type IV method; subsequently after single laboratory validation (SLV) and collaborative studies, ISSC proposal 13-309 accepted PCOX method as an AOAC official method of analysis (OMA) in 2013. Currently PCOX is an "Approved for Limited Use" method for mussel, clam, oyster and scallop. SLV work will be presented for quahogs, surf clams, geoducks, butter clams, little neck clams, and razor clams that demonstrates comparable performance characteristics for these species as with mussels, clams, oysters, and scallops using the PCOX method. The cost and challenges associated with maintaining both the MBA and PCOX methods for these species are high; differing laboratory skill sets are required and state laboratories have limited budgets and staff resources. Additionally, the recent shortage of the NIST saxitoxin standard used for MBA proficiencies is of concern if laboratories are expected to maintain MBA for verification purposes for these species. The requested action is being made and data presented for the purpose of inclusion of quahogs, surf clams, geoducks, butter clams, little neck clams, and razor clams as approved species (by addition to the footnote that includes mussels, clams, oysters, and scallops or as the ISSC deems appropriate) within the NSSP Guide Section IV Guidance Documents Chapter II. Growing Areas .11 Laboratory Tests Methods Table, Methods for Marine Biotoxin Testing with Biotoxin Type: Paralytic Shellfish Poisoning (PSP), Application: Growing Area Survey & Classification Sample Type: Shellfish And Application: Controlled Relaying Sample Type: Shellfish.
Public Health Significance	The PCOX method was developed to provide a rapid, high throughput chemical assay that would eliminate the need to sacrifice animals, AOAC mouse bioassay (MBA), for toxin detection. There is a worldwide move to replace assays that use live animals as test subjects. Laboratories currently using PCOX for regulatory

	PST testing have found that the lower detection limits of the PCOX method allow for better early warning therefore better management of PST closures and significantly improved public health decision-making. The addition of the proposed species will allow regulatory laboratories to move away from the costliness of maintaining MBA and eliminate the need to sacrifice animals as well as improve management of species specific closure decision–making.
Cost Information	Total consumable costs for the analysis is estimated at $10/sample. A chemistry laboratory will usually be equipped with an LC system and a post column reactor to carry out the analysis. Total capital costs for the instrumentation required for the analysis is approximately $120,000. Although the upfront investment for instrumentation is high, the removal of care, maintenance, and cost of mice quickly offsets this expenditure.
Action by 2015 Laboratory Method Review Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair for evaluation of data and until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Method Review Committee recommendation on Proposal 15-109.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-109.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-109.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 15- 109.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 15-109.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-109.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 15-109.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 15-109.

Action by FDA February 21, 2020	Concurred with Conference action on Proposal 15-109.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 15-109 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force	Recommended adoption of the Laboratory Committee recommendation for Proposal 15-109.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 15-109.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 15-109.

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

Submitter	US Food & Drug Administration (FDA)
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Proposal Subject	Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Method for the Determination of Diarrhetic Shellfish Poisoning (DSP) Toxins in Shellfish.
Specific NSSP Guide Reference	Section IV. (Guidance Documents), Chapter II. (Growing Areas), Section .14 (Approved Laboratory Tests), Table 2 (Approved Methods for Biotoxin Testing) and Table 4 (Approved Limited Use Methods for Marine Biotoxin Testing)
Text of Proposal/ Requested Action	The intention is for this method to be an Approved Method for Marine Biotoxin Testing for clams and that it should appear in Section IV. (Guidance Documents), Chapter II. (Growing Areas), Section .14 (Approved Laboratory Tests), Table 2 (Approved Methods for Marine Biotoxin Testing) under the new heading: Biotoxin Type: Diarrhetic Shellfish Poisoning (DSP), and the applications should be (1) Growing Area Survey and Classification and (2) Controlled Relaying with the sample type of Shellfish for both. In addition, the method should also be included in Table 4 (Approved Limited Use Methods for Biotoxin Testing) for mussels and oysters. Additional validation will be submitted later in order to move mussels and oysters also to Table 2.
Public Health Significance	Method will be used to control hazard from Diarrhetic Shellfish Poisoning (DSP) in shellfish. No methods for DSP are currently listed in the NSSP yet shellfish harvesting closures have occurred due to these toxins in Texas since 2008, in the Pacific Northwest since 2011, and in the New England region since 2015. Regulatory laboratories in these regions are currently using best available science of LC-MS/MS according to the EU reference SOP for LC-MS/MS determination of lipophilic shellfish toxins
Cost Information	Capital equipment purchases: $500,000. Consumable cost per sample: $10.00

Research Needs Information

a. Proposed specific research need/ problem to be addressed	No methods are currently approved for use to control DSP hazard under the NSSP. The EU has adopted LC-MS/MS as the reference method for all of the lipophilic shellfish toxins, including DSP. This method is a modified version of the EU LC-MS/MS method optimized specifically for DSP.
b. Explain the relationship between proposed research need and program change recommended in the proposal	The proposal will provide full SLV data for the detection of DSP toxins in clams. Therefore it would be considered an Approved Method for clams (Table 2). Based on the immediate need for this method, it was felt that the submission should be made with the available data for clam with the intention of subsequent validation for mussels and oysters, for which only preliminary data is provided here. Therefore, the method should be considered for Approved Limited Use at this time for mussel and oyster and be included in Table 4 for these matrices.
c. Estimated cost	$10,000
d. Proposed sources of funding	FDA Internal Funding
e. Time frame anticipated	Submission of all materials I order to

	be reviewed prior to the 2017 bi-annual ISSC meeting
Action by 2017 Laboratory Committee	Recommended the following: 1) Adoption of Proposal 17-103 as an Approved Method for clams 2) Referral of Proposal 17-103 to an appropriate committee as determined by the Conference Chair to determine the appropriateness of the method for mussels and oysters
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendations on Proposal 17-103
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-103.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-103.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 17-103 to an appropriate committee as determined by the Conference Chair
Action by 2019 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-103.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 17-103
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-103
Action by the 2023 Laboratory Committee	Recommended referral of Proposal 17-103 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 17-103
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-103
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-103

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

Submitter	Pacific Rim Shellfish Sanitation Association
Affiliation	Sitka Tribe of Alaska
Email	michael,jamros@sitkatribe-nsn.gov
Proposal Subject	Matrix Expansion for the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity **Determination to Allow Use with Geoduck**
Specific NSSP Guide Reference	Section IV, Chapter II.14 -- NSSP Approved Laboratory Tests (p. 261 Table 2. Approved Methods for Marine Biotoxin Testing -- footnote 2, and/or p. 263 Table 4. Limited Use Methods for Marine Biotoxin Testing -- footnote 5)
Text of Proposal/ Requested Action	This submission presents the 'Matrix Expansion for the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination to Allow Use with Geoduck' for consideration as an NSSP Approved Method for Marine Biotoxin Testing for PSP in Geoduck. The RBA is a competition-based assay that employs radiolabeled saxitoxin (3H-STX) to compete with PSP toxins present in standards/samples for binding sites on natural receptors in the assay. Following incubation with the receptors, unbound 3H-STX is removed and the remaining labeled toxin is measured with a scintillation counter. The amount of remaining 3H-STX is inversely proportional to standard/sample toxicity. The RBA offers a high-throughput, sensitive, and quantitative alternative to the mouse bioassay (MBA), which has been the long-standing reference method for PSP toxicity. Further, the RBA eliminates the use of live animals for detection of these toxins. While the RBA still uses receptors prepared from animals, the number of animals required for analysis is significantly reduced. Using native receptors as the analytical recognition elements for the assay allows for a composite measure of overall toxicity, as opposed to toxin concentrations measured by liquid chromatographic methods that require conversion factors of equivalent toxicity to calculate the overall toxicity. The RBA has undergone AOAC single and multi-laboratory validation and is designated through AOAC as an Official Method of Analysis (OMA 2011.27). The RBA is currently an NSSP Approved Method for Marine Biotoxin Testing for PSP in mussels as well as a NSSP approved for Limited Use Method for clams and scallops for the purpose of screening and precautionary closure for PSP (ISSC 2015 Summary of Actions Proposal 13-114). Here we provided results from a single laboratory validation study for use of RBA with the matrix geoduck (*Panopea*) viscera for submission for the RBA to be considered for approval as an NSSP Approved Method for Marine Biotoxin Testing for PSP.

Public Health Significance	Paralytic shellfish poisoning intoxications result from the consumption of seafood (primarily bivalve molluscs) contaminated with neurotoxins known as paralytic shellfish toxins (PSTs). This suite of toxins binds to voltage-gated sodium channels and may result in paralysis if enough toxin is consumed. In extreme cases when respiratory support is not available to the patient, the intoxication may prove fatal. Since the toxins cannot be destroyed during cooking and there is no way to remove the toxins from seafood, the best control strategy is to ensure that contaminated product never reaches the market. To protect public health, harvesting closures are implemented when toxicity exceeds the guidance level of 80 micrograms saxitoxin equivalents per 100 grams of shellfish tissue. As such, accurate analytical methods are needed to monitor shellfish toxicity for making decisions regarding opening and closing shellfish growing areas accordingly. Acceptance of the RBA as an NSSP Approved Method for Marine Biotoxin Testing for PSP toxicity determination in geoduck (*Panopea*) would provide monitoring and management programs with an additional tool that can be used for monitoring toxin levels and making regulatory decisions. Not only does the RBA eliminate the need for live animals for PSP testing, it is also more sensitive than the MBA, thereby providing an early warning system for monitoring programs as toxin levels begin to rise.
Cost Information	For the assay: The estimated cost per 96-well plate assay is ~$95.00. Including standards and samples with triplicate measurements (as well as three dilutions per sample[ranging from 3.5-600 µg STX eq 100 g-1] to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitation would be ~$13.60. If running multiple plates or in screening mode, sample costs would be reduced. (Van Dolah 2013) For proposal: The cost of RBA work for geoduck matrix expansion is covered by and existing grant awarded to the Sitka Tribe of Alaska. Naturally contaminated samples from Washington and Alaska are pulled from regular samples tested by the respective state agencies that are part of routine shellfish testing. Therefore, there is no additional cost or funding necessary for the proposal.
Research Needs Information a. Proposed specific research need/ problem to be addressed	Paralytic shellfish poisoning (PSP) is a foodborne illness caused by ingestion of contaminated shellfish. The paralytic shellfish toxin, saxitoxin (STX), and its analogs are potent neurotoxins responsible for PSP. Marine dinoflagellates and freshwater cyanobacteria produce STX. The STX can accumulate in filter-feeding bivalve mollusks to levels that are toxic to humans. Symptoms of PSP include: tingling and numbness of the perioral area and extremities, drowsiness, incoherence, loss of motor control, and following high dose consumption, respiratory paralysis. In 1965 the mouse bioassay (MBA) was adopted as an official AOAC method for STX determination. The MBA has been the only method available for PSP testing for the last five decades. Both North American and European regulatory agencies have expressed the desire to transition to a more humane PSP testing method that does not require the use of live animals and is not subject to the matrix effects documented for the MBA

	(Turner 2012). Recently, the NSSP approved a post- column oxidation liquid chromatographic (PCOX) method and a receptor binding assay (RBA) as alternatives to the MBA. The PCOX method is approved for full use; whereas, the RBA is approved for limited use (the RBA is only approved for shellfish matrices evaluated in the single lab and multi-lab validation studies). Both the PCOX and RBA are sensitive quantitative assays for STX detection, and they do not require the use of live animals. The RBA is approved for regulatory testing of mussels as an alternative to the MBA and is approved for limited use as a screening tool for clams and scallops, but is not yet approved for use with geoduck (*Panopea*) due to a lack of data. Geoduck are a major commercial product, with large dive fisheries in Southeast Alaska and the Puget Sound that require STX testing. This proposal requests consideration for the NSSP RBA approval to be expanded to include geoduck. The proposal provides data from a single laboratory validation (SLV) of the RBA for geoduck testing as support for this request.
b. Explain the relationship between proposed research need and program change recommended in the proposal	This method is intended for use as an NSSP Approved Limited Use Method for screening for PSP toxicity in shellfish. The RBA serves as an alternative to the MBA in these applications, offering a measure of composite toxicity with high throughput and the elimination of live animal testing. (Van Dolah 2013) This application is for the addition of geoduck to the list of matrices approved for use with the RBA. There is an acknowledged need for this method in NSSP. A significant portion of the Washington and Alaska state shellfish industries are comprised of the harvest of geoduck. Approval of the RBA for use with geoduck would provide an alternative to (1) the MBA, which uses live animals, and (2) the PCOX HPLC method, which requires costly equipment and skilled personnel and offers low throughput. Acceptance of the RBA as an NSSP Approved Method for Marine Biotoxin Testing for PSP toxicity determination in geoduck would provide monitoring and management programs with an additional tool that can be used for monitoring toxin levels and making regulatory decisions. Not only does the RBA eliminate the need for live animals for PSP testing, it is also more sensitive than the MBA. References: Van Dolah 2013. ISSC application: Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP)Toxicity Determination. Van Dolah et al. 2012. Determination of paralytic shellfish toxins in shellfish by receptor binding assay: collaborative study. J AOAC Int. May-Jun;95(3):795-812. Van Dolah et al. 2009. Single-laboratory validation of the microplate receptor binding assay for paralytic shellfish toxins in shellfish. J AOAC Int. Nov- Dec;92(6):1705-13.

	Ruberu et al. 2012. Evaluation of variability and quality control procedures for a receptor-binding assay for paralytic shellfish poisoning toxins. Food Addit Contam Part A Chem Anal Control Expo Risk Assess.29(11):1770-9. Turner et al. 2012. Investigations into matrix components affecting the performance of the official bioassay reference method for quantitation of paralytic shellfish poisoning toxins in oysters. Toxicon : official journal of the International Society on Toxicology 59, 215-230. OMA 2011.27. AOAC Official Method 2011.27 Paralytic shellfish toxins (PSTs) in shellfish, receptor binding assay. In Official Methods of Analysis of AOAC International. http://www.eoma.aoac.org.
c. Estimated cost	
d. Proposed sources of funding	Thid research was performed by the Sitka Tribe of Alaska using funds from an ANA ERE grant.
e. Time frame anticipated	
Action By 2017 Laboratory Committee	Recommended referral to an appropriate committee as determined by the Conference Chair.
Action By 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-106
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-106
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-106
Action By 2019 Laboratory Committee	Recommended referral to an appropriate committee as determined by the Conference Chair.
Action By 2019 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-106
Action by 2019 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-106
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-106
Action By 2023 Laboratory Committee	Recommended referral to an appropriate committee as determined by the Conference Chair.
Action By 2023 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-106
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-106
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-106

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

Submitter	Titan Fan, Ph.D
Affiliation	Beacon Analytical Systems, Inc
Email	titan@beaconkits.com, holly@beaconkits.com
Proposal Subject	Detection of ASP biotoxins in *Mytilus edulis* (Blue Mussel) shellfish by ELISA for Domoic Acid
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas, Table 2.
Text of Proposal/ Requested Action	SLV Proposal supporting the use of Beacon Domoic Acid Plate Kit as fit for purpose as an Approved NSSP Method for quantification of ASP toxins in Marine Biotoxin Monitoring Programs
Public Health Significance	Shellfish consumption can pose a mammal and bird health risk (1) when toxins produced by cyanobacteria present in water and shellfish growing areas, concentrate in shellfish meat due to their filter feeding system. A Closed Status for any growing areas with shellfish tissue levels of ASP of 2 mg/100 g (20 ppm) or more have been established to protect the consumer from exposure (2). The most common clinical signs of acute toxicity are gastrointestinal distress, confusion and neurological symptoms, disorientation, memory loss, coma and death (3). (1). M.Fernanda, F, Mazzillo, C. Pomeroy, J.Kuo, P. Ramondi,R. Prado, M.Silver. 2010. Aquatic Biol. 9:1-12. (2). NSSP Guide for the Control of Molluscan Shellfish: 2015 Rev. Sec.IV Chp. II., p 231. (3). Kathi A. Lefebvre, Alison Robertson, Toxicon, Vol. 56, Issue 2, 15 Aug. 2010, p. 218-230.
Cost Information	The price per sample is eight to nine dollars dependent upon the number of samples tested during one ELISA run, and/or the volume of kits purchased. There is an ELISA Plate Reader requirement. They can range in price from a low cost unit at approximately $2,600 to a higher cost of $15,000 USD unit depending upon complexity.
Action By 2017 Laboratory Committee	Recommended referral of Proposal 17-108 to an appropriate committee as determined by the Conference Chair.
Action By 2017 Task Force I	Recommended adoption of the Laboratory Committee on Proposal 17-108
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-108.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-108.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 17-108 to an appropriate committee as determined by the Conference Chair.

Action by 2019 Task Force I	Recommended adoption of the Laboratory Committee on Proposal 17-108
Action by 2019 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-108.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 17-108.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 17-108 to an appropriate committee as determined by the Conference Chair.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee on Proposal 17-108
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-108.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 17-108.

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Michael Hickey, Jeff Kennedy, Diane Regan
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7. Phone	(508) 990-2860
8. Fax	(508) 990-0449
9. Email	Michael.hickey@mass.gov
10. Proposal Subject	Conditionally Conforming Laboratory Status
11. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 B. 1. b. Section II. Model Ordinance Chapter III. Laboratory @.01 Section II. Model Ordinance Chapter XV. Depuration .03 J. (4)
12. Text of Proposal/ Requested Action	The requested action is to create a NSSP laboratory status of conditionally conforming. This status is based on a demonstrated proficiency of laboratory method performance. Laboratories that are found to conditionally conform for a laboratory analysis may support the NSSP. **MO Chapter 1.@.03 B. 1. b.** v. Performance Evaluation: Conditionally Conforms. Tto be deemed conditionally conforming under the NSSP, a laboratory must meet one of the following laboratory performance criteria: (a) Complete an appropriate ISSC Accepted SLV; or (b) Complete a Method Verification Study, Section IV. Chapter II. .20 that successfully transfers; or (c). Successfully complete a proficiency and/or inter-laboratory study approved by the FDA Shellfish LEO or State certified Shellfish LEO. (d) This laboratory status will remain in effect until an technical FDA Shellfish LEO or FDA certified State Shellfish LEO Evaluation occurs as in @.03 B. **MO Chapter III. @.01 Quality Assurance** A. NSSP Conformance Required for all laboratories supporting the NSSP. All laboratory analyses shall be performed by a laboratory found to conform, conditionally conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under the NSSP. **MO Chapter XV. .03 J. (4)** (a) Are analyzed by a laboratory which has been evaluated and found to conform or conditionally conform to the NSSP pursuant to the requirements in Chapter III, using an NSSP-Approved Method;
13. Public Health Significance	A technical Laboratory evaluation, as outlined in MO Chapter 1.@.03B.1.b.ii, is conducted to verify that conditions are present *in the laboratory* which **should**

	result in the accurate outcome of method data. A performance evaluation **verifies** that the method data produced *by the laboratory and for all analysts* is accurate. A technical evaluation does not examine the quality of a laboratory's method data for validity, standardization or for individual analysts. If a laboratory has successfully passed a proficiency study, SLV or MV, and statistically confirmed method data results, the laboratory can be assumed to have technically performed the method correctly. Under current interpretation a laboratory may have completed and had accepted by the conference a method SLV with accompanying checklist yet not be able to support the NSSP with data until a FDA Shellfish LEO or FDA certified State Shellfish LEO conducts a technical inspection at their laboratory using the laboratory's own checklist. If a laboratory has proven its ability to perform a method, then the laboratory should be able to conditionally support the NSSP with data. A cooperative goal of the NSSP, FDA and the SSCA is to assure that a laboratory's data is accurate, verified and standardized. Method based performance evaluations confirm data which results in standardization across laboratories. Method based performance evaluations statistically verify data accuracy. Performance Evaluations therefore support the legal defensibility of the laboratory's Laboratory Quality Management System.
14. Cost Information	Cost of conducting SLV, MV or Proficiency Participation
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-101. Rationale: This issue is addressed by Proposal 19-301.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-101 as submitted.
Action by 2019 General Assembly	Recommended referral of Proposal 19-101 to an appropriate committee as determined by the Conference Chair.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-101.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 19-101 to an appropriate committee as determined by the Conference Chairperson
Action by 2023 Task Force I	Recommended referral of Proposal 19-101 as amended to the Laboratory Committee with the provision that a recommendation for interim approval be provided at the 2023 Fall Executive Board Meeting. **MO Chapter 1.@.03 B. 1. b.** v. Performance Evaluation: Conditionally Conforms. Tto be deemed conditionally conforming under the NSSP, a laboratory must meet one of the following laboratory performance criteria: (a) Complete an appropriate ISSC Accepted SLV; or (b) Complete a Method Verification Study, Section IV. Chapter II. .20 that successfully transfers; or ~~(c). Successfully complete a proficiency and/or inter-laboratory study approved by the FDA Shellfish LEO or State certified Shellfish LEO.~~ (c~~d~~)

	This laboratory status will remain in effect until an technical FDAShellfish LEO or FDA certified State Shellfish LEO Evaluation occurs as in @.03 B. **MO Chapter III. @.01 Quality Assurance** A. NSSP Conformance Required for all laboratories supporting the NSSP. All laboratory analyses shall be performed by a laboratory found to conform, conditionally conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under the NSSP. **MO Chapter XV. .03 J. (4)** (a) Are analyzed by a laboratory which has been evaluated and found to conform or conditionally conform to the NSSP pursuant to the requirements in Chapter III, using an NSSP-Approved Method;
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-101.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-101.
Action by 2024 Laboratory Committee	Recommended Proposal 19-101 as substituted and submit to the 2024 Executive Board for interim approval. **Chapter III** **@.01 Quality Assurance** C. FDA Responsibilities. The FDA will ensure that all laboratories generating data in support of the NSSP will be evaluated at a minimum frequency of once every three (3) years. (1) Evaluations will be conducted by either an FDA Shellfish LEO or an FDA certified State Shellfish LEO as appropriate. Normally the initial evaluation of a laboratory will be conducted by FDA. (2) Evaluations are ~~generally~~ conducted onsite; however, evaluations may be conducted ~~but can under certain circumstances~~ be ~~by~~ desk/virtual audit when scheduling or extenuating circumstances will not permit a timely onsite evaluation. ~~(evaluation follow-up,~~ action ~~plan monitoring, nonconformity corrections, major changes in personnel, workload or facilities, etc.).~~ (3) When there is an immediate and critical need, and: (a) no NSSP conforming or provisionally conforming laboratory exists to perform a specific Approved NSSP Method, or (b) no NSSP conforming or provisionally conforming laboratory is accessible (i.e. due to distance, etc.) to perform specific Approved NSSP method, or (c) following a request for emergency consideration as defined in Section II, Ch. 1 @.01 I. The following alternative laboratories may implement that Approved ISSC Method in support of the NSSP:

	(a) A laboratory that has not been evaluated or assigned an NSSP operational status, provided that: i. the ISSC Executive Board is notified within a reasonable period of time regarding the laboratory used; and, ii. the appropriate FDA Office is notified within a reasonable period of time regarding the laboratory used; and, iii. the laboratory meets the following laboratory performance criteria: 1. completed the SLV study which resulted in the Approved NSSP method; or 2. maintains a recognized laboratory accreditation status (e.g., ISO 17025:2017, LAAF, etc.), with documentation of accreditation provided to the FDA prior to method implementation; and 3. successfully completed a Method Verification Study, as outlined in Section IV, Chapter II, .20, and the method verification data package has been approved by an FDA Shellfish LEO. If an FDA Shellfish LEO is unavailable to review the method verification data package in a timely manner, an FDA certified State Shellfish LEO may review and approve the data package instead. State Shellfish LEOs will only review method verification data packages pertaining to methods for which they have documented proficiency and evaluation standardization. (b) An existing NSSP conforming or provisionally conforming laboratory that has not been evaluated for the specific Approved NSSP method to be used, provided that: i. the ISSC Executive Board is notified within a reasonable period of time regarding the laboratory used; and, ii. the appropriate FDA Office is notified within a reasonable period of time regarding the laboratory used; and, iii. the laboratory has successfully completed a Method Verification Study, as outlined in Section IV, Chapter II, .20, and the method verification data package has been approved by an FDA Shellfish LEO. If an FDA Shellfish LEO is unavailable to review the method verification data package in a timely manner, an FDA certified State Shellfish LEO may review and approve the data package instead. State Shellfish LEOs will only review method verification data packages pertaining to methods for which they have documented proficiency and evaluation standardization. If the immediate and critical need for analysis becomes an ongoing or recurring need, the laboratory implementing the method will work with the FDA

	Shellfish LEOs to promptly initiate the evaluation process. D. Wet Storage and Post-Harvest Processors. For any laboratory providing analytical testing services for depuration, wet storage or PHP, initial and subsequent triennial evaluations will be required and conducted in accordance with @.01 and @.02 of this Chapter by an FDA Shellfish LEO or an FDA certified State Shellfish LEO ~~as appropriate~~. It is understood that academic laboratories involved in PHP Validation or Verification have special circumstances such as extended periods of inactivity resulting from university schedules or funding constraints; however, written documentation of Quality Control practices will be required for time periods in which they are preparing for or actively participating in a PHP Validation or Verification. Times in which the lab is inactive can be explained with a not applicable notation.
Action by 2023 Executive Board	Adopted the recommendation of 2024 Laboratory Committee. Interim Approval on October 30, 2024.

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

Submitter	Robert Rheault
Affiliation	ECSGA
Email	bob@ecsga.org
Proposal Subject	Aquaculture Seed Shellstock
Specific NSSP Guide Reference	Section II Model Ordinance, Chapter VI. Shellfish Aquaculture, Requirements of the Authority @.02
Text of Proposal/ Requested Action	**@ .02 Seed Shellstock** A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 60~~120~~ days of growing with water temperatures over 50 degrees F to reach market size. B. For states that have not established a minimum market size, the Authority shall establish record-keeping protocols to track seed sourced from prohibited waters to ensure seed have at least 60 days of growing with water temperatures above 50 degrees F before sale for human consumption. C. ~~B.~~ The Authority shall establish appropriate corrective actions for ~~when~~ seed that exceeds the maximum seed size when it is being cultured in ~~has been~~ ~~produced in~~ waters classified as prohibited. ~~C.~~ All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority
Public Health Significance	Existing language does not describe how the Authority should establish maximum seed size in states that have no minimum market size. Further the existing language does not require that shellfish from prohibited waters are held in waters above 50 degrees to ensure that the animals are metabolically active. Shellfish seed collected or cultured in prohibited waters have been shown through repeated sampling not to accumulate heavy metals at levels that exceed EPA alert levels. (John Mullen RI DOH, unpub. Data, Rheault unpubl. Data, Rice unpub. Data, Leavitt unpub. Data). A period of one month is typically adequate to purge bacterial contaminants provided water temperatures are high enough to maintain active metabolic activity (above 50 degrees F or 10 degrees C) (Richards 1988). Several studies have demonstrated that viral contamination in relayed or depurated shellfish is reduced to non-detect levels in 30-40 days (McLeod et. Al. 2017 and Choi and Kingsley 2016). The Authority has the option to deny seed culture in any area, or to require additional testing for deleterious substances, or to require longer purge periods as they deem necessary based on potential sources of

	contaminants. References Cited: Richards, G. (1988), Microbial Purification of Shellfish: A Review of Depuration and Relaying, J. Food Protection 51(3)218-251. A. McLeod et. Al. (2017) Depuration and Relaying: A Review on Potential Removal of Norovirus from Oysters. Comprehensive Reviews in Food Science and Food Safety, Vol.16, pp. 692-706 Choi, C. and D. H. Kingsley. Temperature-Dependent Persistence of Human Norovirus within Oysters (Crassostrea virginica). Food and Environmental Virology, 8:141-147. 2016 Supporting Information: RI DOH metals data, (oyster seed grown in Billington Cove Marina) Unpublished data from Rd. Dale Leavitt: (clam seed grown in Warwick Cove Marina)
Cost Information	Proposal would not impact the enforcement costs for the authority and would simplify management for growers.
Action by 2019 Task Force I	Recommended referral of Proposal 19-108 to an appropriate committee as determined by the Conference Chairperson.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-108
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-108
Action by 2023 Aquaculture Committee	Recommended no action on Proposal 19-108. Rationale: There is not sufficient data or need for action
Action by 2023 Task Force I	Recommended referral of Proposal 19-108 to an appropriate committee as determined by the Conference Chairperson
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-108.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-108.

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

Submitter	Gina Olson
Affiliation	Washington Dept of Health
Email	Gina.olson.wa.gov
Proposal Subject	Laboratory Method for *Vibrio parahaemolyticus* and *Vibrio vulnificus* Enumeration and Detection Through MPN and Real-Time PCR
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II Growing Areas .14 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	1. Approved Methods fir Vibrio Enumeration

	Vibrio Type:	**Application : PHP Sample Type:**	**Application : Reopening**
		X	
EIA[1]	***Vibrio vulnificus (V.v.)***	X	
MPN[2]	***Vibrio vulnificus (V.v.)***	X	
SYBR Green 1 QPCR-MPN[5]	***Vibrio vulnificus (V.v.)***	X	
MPN[3]	***Vibrio parahaemolyticus (V.p.)***	X	
PCR[4]	***Vibrio parahaemolyticus (V.p.)***	X	
MPN-Real Time PCR[6]	***tdh+ and trh+ Vibrio parahaemolyticus (V.p.)***	X X	X
MPN-Real Time PCR[7]	***Vibrio parahaemolyticus (V.p.)***	x	X
MPN-Real Time PCR[9]	***Vibrio parahaemolyticus (V.p.)* and *Vibrio vulnificus (V.v.)***		X
Direct Plating Method[8]	***Vibrio parahaemolyticus (V.p.)***		X

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.

MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or by the DNA - alkaline phosphatase gene probe for vvhA as described by Wright et al., or a method that a State can demonstrate is equivalent.

[2] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, followed by confirmation using biochemical analyses or the DNA-alkaline phosphatase gene probe for tlh as described by McCarthy et al., or a method that a State can demonstrate is equivalent.

[3] MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, and as described in the "Direct Plating Procedure for the Enumeration of Total and Pathogenic *Vibrio parahaemolyticus* in Oyster Meats" developed by FDA, Gulf Coast Seafood Laboratory, or a method that a State can demonstrate is equivalent.

[5] *Vibrio vulnificus*, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.

[6] MPN-Real Time PCR Method for the tdh and trh Genes for Total *V. parahaemolyticus* as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15-111, Page 397.

[7] MPN-Real Time PCR Method for the *tlh* gene for total *V. parahaemolyticus* as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15- 113, Page 418

[8] Direct Plating Procedure in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, and as described in the 'Direct Plating Procedure for the Enumeration of Total and Pathogenic *Vibrio parahaemolyticus* in Oyster Meats' developed by FDA, Gulf Coast Seafood Laboratory.

[9] MPN-Real Time PCR Method for *Vibrio parahaemolyticus* and *Vibrio vulnificus*. Washington State Department of Health, Food and Shellfish Bacteriology Laboratory.

Public Health Significance	The purpose of this method is to provide laboratories supporting the NSSP the ability to rapidly quantify *Vibrio parahaemolyticus (Vp)* and *Vibrio vulnificus (Vv)* from oysters using a high throughput real-time PCR assay. Rapid and early detection of these pathogens, complying with the required quantitative detection guidelines suggested by the ISSC, will help the shellfish industry market oysters for consumption that are within regulatory limits for these pathogens. This method once approved would add a testing method of MPN Real-Time PCR for *Vibrio vulnificus* and it would be an alternative to the *Vibrio parahaemolyticus* MPN Real-Time PCR methods already approved in the 2017 Model Ordinance.
Cost Information	The cost for this method is approx. $155 per sample. This estimate is based on recurring costs of consumables, reagents, and supplies needed for routine testing. It does not include indirect materials considered to be standard microbiology equipment such as analytical balance, PCR workstation, DNA purification system, refrigerator, pipettes, etc.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-128 to an appropriate committee as determined by the Conference Chair
Action by 2019 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-128
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-128.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-128.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 19-128 to an appropriate committee as determined by the Conference Chair
Action by 2023 Task Force I	Recommended the adoption of Laboratory Committee recommendation on Proposal 19-128
Action by 2023 General Assembly	Adopted recommendation of Task Force I on Proposal 19-128.
Action by FDA July 7,2023	Concurred with Conference action on Proposal 19-128.
Action by 2025 Executive Board	Adopted the recommendation of 2025 Laboratory Committee Committee. Interim Approval on October 15,2025

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

Submitter	Thomas Howell
Affiliation	Spinney Creek Shellfish Inc.
Email	tlhowell@spinneycreek.com
Proposal Subject	Guidance for Assessing the Viral Impact from Waste Water Treatment Plant Outfall on Adjacent Growing Areas using the Male-specific Coliphage Method on Effluent Samples.
Specific NSSP Guide Reference	Section IV Guidance Documents - Chapter II. Growing Areas - .19 Classification of the Shellfish Growing Waters Adjacent to Waste Water Treatment Plants
Text of Proposal/ Requested Action	The requested action is that an ISSC committee be formed to draft guidance language describing how to best use MSC effluent sampling techniques to assess the viral impact on adjacent growing areas. This proposed action is the result of recent collaborative work funded by New Hampshire Sea Grant. The PI's and project participants on this project included University of New Hampshire Sea Grant, Connecticut Sea Grant, Spinney Creek Shellfish, Connecticut Department of Agriculture, New Hampshire Department of Environmental Services, US Food and Drug Administration Center for Food Safety and Applied Nutrition, and US Food and Drug Administration Gulf Coast Seafood Laboratory. An optimized method to determine MSC in effluent samples, both pre-treatment (disinfection) and final effluent has been submitted to the Lab Committee for approval. Two years of field studies were recently completed which looked closely at 2 plants in CT and 4 plants in NH. Results of these field studies were reported at the 2019 NESSA meeting in Plymouth MA. By taking effluent samples from WTP's two to three times per week over an extended period, a database can be assembled including Geomean and P95 values in a strategy consistent with NSSP practices. Plotting the effluent time-series data can be used to identify times when plant performance is degraded by predictable, challenging, conditions whether they are operational or environmental. By informing dye study work with WWTF effluent analysis, much more informed decisions can be made with respect to classification of adjacent growing waters. Simply multiplying the P95 results from final effluent statistical analysis by the dilution line in question, an upper level of MSC concentration MSC in the growing waters can be estimated. An interpretation matrix for final effluent MSC time- series analysis to interpret results in a relative way is proposed.
Public Health Significance	The Public Health Significance of this proposal is substantial. Dye studies alone are protective of public health using the 1000:1 dilution line for classification purposes. However, MSC assessment of effluent samples gives a much more informed picture of how appropriate the 1000:1 line is in a particular situation. If an under-designed, problematic WWTP is not adequately deactivating viruses, a higher dilution may be required. This is an important consideration when

	dealing with a WWTP that does not perform to typical standards of secondary treatment with effective disinfection. However, the study has shown that many modern and advanced WWTPs can be reliably operated at sufficient performance levels to justify the 300:1 dilution line for the establishment of a prohibited classification around the WWTP outfall. As time continues and WWTPs are upgraded, this method and technique may permit increased utility of the growing area between the 300:1 and 1000:1 dilution line. In conclusion, public health can be informed and optimized while maximum commercial utilization of growing areas can be achieved.
Cost Information	The MSC method for WWTP effluent samples is inexpensive and easy to perform. Costs become more significant when one considers the personnel and travel time needed to sample the WWTP's. The state control agency can optimize this work by focusing field work during the winter months when the WWTP are likely more challenged and personnel resources are more available.
Action by 2019 Task force I	Recommended referral of Proposal 19-144 to an appropriate committee as determined by the Conference Chairman.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-144.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-144.
Action by 2023 Male Specific Coliphage Committee	Recommended referral of Proposal 19-144 to an appropriate committee as determined by the Conference Chairman.
Action by 2023 Task Force I	Recommended adoption of the Male Specific Coliphage Committee recommendation for Proposal 19-144.
Action by 2023 General Assembly	Adopted recommendation of Task Force I on Proposal 19-144.
Action by FDA July 7,2023	Concurred with Conference action on Proposal 19-144.

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

Submitter	US Food & Drug Administration (FDA)
Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	Guidance on Cleansing Studies
Specific NSSP Guide Reference	NSSP Section IV Chapter II .19 VI B.
Text of Proposal/ Requested Action	A. Guidance for a Conditional Area Management Plan The management plan for a growing area in the conditionally approved or conditionally restricted classification must meet certain minimum requirements to ensure that the safety of the shellfish for human consumption is maintained. The use and success of the conditional classification depends upon a thorough and accurate management plan. Therefore, it is important that all aspects of the management plan be fully considered and implemented. The minimum requirements to be addressed are: (1) An understanding of and an agreement to the conditions of the management plan by the one (1) or more Authorities involved, other local, State and Federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; (2) A written management plan for the growing area being placed in the conditional classification, which includes a general description of the growing area with a map showing the area's boundaries, and which addresses all items in C. through H. (3) A sanitary survey that shows the growing area will be in the open status of its conditional classification for reasonable periods of time. The survey must provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted, and the supporting information and data. (4) A description of the predictable pollution event or events that are being managed and the performance standards established for each pollution source contributing to the pollution event including: (a) For a wastewater treatment facility, the performance standard should be

based on:
(i) Peak effluent flow
(ii) Bacteriological quality of the effluent
(iii) Physical and chemical quality of the effluent
(iv) Bypasses from the treatment plant or its collection system
(v) Design, construction, and maintenance to minimize mechanical failure or overloading (i.e., the reliability of the treatment system and collection system components)

(vi) Provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment.
(vii) Identification of conditions that lead to WWTP failure, a lapse in WWTP treatment leading to untreated or partially treated sewage discharge, and closure of the conditionally approved area.

(b) For meteorological or hydrological events, the performance standard should be based on:
(i) Identification of the specific meteorological and/or hydrologic event that will cause the growing area to be placed in the closed status;
(ii) Discussion and data analyses concluding that effects on water quality from these specific meteorological and/or hydrologic events are predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for the growing area placed in the conditional classification; and
(iii) The predicted number of times, based on historical findings, that the pollution event will occur within one (1) year.

(c) For seasonal events, such as marina operation, seasonal rainfall, and waterfowl migration, the performance

	standard should be based on: (i) Identification of the seasonal event that will cause the growing area to be placed in the closed status, including its estimated duration; and (ii) Discussion and data concluding that the seasonal event is predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for a growing area placed in the conditional classification; (5) A description of the plan for monitoring water quality including numbers and frequency; (6) A description of how the closed status for the conditional classification will be implemented, which must include: (a) A clear statement that when the performance standards are not met, the growing area will immediately be placed in the closed status; (b) A requirement to notify the Authority or Authorities that the management plan performance standards have not been met, including: (i) The name of the agency or other party responsible for notifying the Authority; (ii) The anticipated response time between the performance standards not being met and notification of the Authority; and (iii) The procedures for prompt notification including contingencies such as night, weekend and absences of key personnel; (c) A description of the implementation and enforcement, including: (a) The response time between the notification to the Authority of the failure to meet performance standards and activation of the legal closure of the growing area by the Authority; (b) The procedures and methods to be used to notify the shellfish industry; and

(c) The procedures and methods to be used to notify the patrol agency (enforcement agency) including:
- The name of the responsible patrol agency;
- The anticipated response time between the Authority's legal closure of the growing area and notification of closure to the patrol agency; and
- A description of the patrol agencies anticipated activities to enforce the closed status.

(7) A description of the criteria that must be met prior to reopening a growing area in the closed status, including the need to determine that:
(a) The performance standards established in the management plan are again fully met;
(b) The flushing time for pollution dissipation is adequate;
(c) A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock; . Studies shall be conducted to document the time interval necessary for the reduction of coliform levels in the shellstock to pre- closure levels. The Authority shall develop and implement a study design that includes:
(i) The utilization of NSSP-conforming laboratories and NSSP-approved methods to analyze coliform in shellstock and water.
(ii) Establishing a pre-closure coliform baseline in shellstock for each species under consideration in the conditional area management plan.
(iii) If re-opening is to be based on coliform levels in the water, identify and describe an association between coliform levels in shellstock for each species under consideration in the conditional area management plan and coliform levels in growing area water.

(iv) Defining conditions under the conditional area management plan which considers various factors including water temperature, salinity, seasonality,and other environmental conditions that may affect the pumping

activity of each species of shellstock under consideration.

(i)(v) A study design and data analysis approach providing statistical reliability. At a minimum, this should include consideration of:

- variability of measurements of indicator levels in replicate samples
- the likelihood or probability that a significant difference in indicator levels will be identified based on the sample outcomes if a substantial difference exists between the populations being sampled.

Irrespective of the type of study design, these considerations apply and should be used to ensure that the number of samples collected is adequate. The number of samples needed increases with increasing variability of the measurements. When there is a substantial difference between indicator levels in the populations being sampled, the study should have at least an 80% probability of identifying this as such.

(ii)(vi) Determining the time interval for post- closure coliform levels in shellstock and water to return to the pre-closure established baseline.

(d) When utilizing MSC in shellstock in growing areas subjected to suspected human sewage to reopen a closed growing area, studies (utilizing the same format as (c) above) establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. The utilization of NSSP- conforming laboratories and NSSP-approved methods to analyze MSC in shellstock. Analytical shellstock sample results shall not exceed a level of 50 MSC per 100 grams or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in the shellfish meats or the area must be in the closed status until the event is over and twenty-one (21) days have passed;

(d)(e) Where necessary, the bacteriological quality of the water must be verified; and

(e)(f) Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.

(8) A commitment to a reevaluation of the management plan at least annually using, at a minimum, the reevaluation requirements in the NSSP Model Ordinance.

Public Health Significance	This language will provide state shellfish Authorities with guidance regarding establishing the elapsed time to reopen closed conditional management areas and assure that shellstock are not adulterated. The public health significance of the proposed guidance for statistical reliability of studies used to establish an elapsed time to reopen is evident by considering an example of the effect of application of these criteria. While several different types of study designs are suitable to identify a minimum elapsed time for pathogen reduction, a common approach is to compare mean log concentrations of fecal indicators in a group of samples collected pre-closure, and representative of baseline, to that in a group of samples collected at the candidate elapsed time post-closure. For this type of study, a two-sample one-sided t-test is typically applied to test the null hypothesis that mean log concentrations are equal. If the test statistic is statistically significant (i.e., $p<0.05$), the null hypothesis is rejected; otherwise, mean concentrations are considered equivalent and the candidate elapsed time sufficient for pathogen reduction. To satisfy the proposed criteria of statistical reliability the sample size of the study will need to be large enough to achieve, based on expected variability of sample measurements about mean levels, an 80% probability of rejecting the null hypothesis when a minimally consequential difference in means exists. This determination of the sample size is made based on what is called the power function of the test statistic. Explicit formula and/or software to calculate sample sizes based on power functions are widely available for most commonly used hypothesis tests and test statistics. Using such calculations, it can be determined that, when the expected standard deviation of log sample measurements about mean levels is 0.5 logs, the example study design requires 13 samples per group to achieve 80% power (probability) to reject the null hypothesis when a true difference in means of 0.5 logs exists. Consequently, when a difference in means of 0.5 logs is considered consequential, a study of this type with fewer than 13 samples per group would not be considered sufficiently reliable. With an expected standard deviation of 0.5 logs, a sample size of 3 per group would have only a 27% probability of rejecting the null hypothesis when a consequential difference in means of 0.5 logs exists and an 80% probability of rejecting the null hypothesis would be achieved only when the true difference in means is equal to or greater than 1.25 logs
Cost Information	No additional cost. This is simply providing guidance for a requirement already in place
Action by 2019 Task Force I	Recommended referral of Proposal 19-145 to an appropriate committee as determined by the Conference Chairperson with the following instructions to develop guidance for cleansing studies and to assess scenarios where water quality sampling could be used in place of cleansing studies
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-145.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-145.

Action by 2023 Cleansing Study Committee	**Recommended:** 1) The committee recommended adoption of Proposal 19-145 as substituted. Guidance on Studies Used in the Reopening of an Area Temporarily Placed in the Closed Status Due to an Emergency Condition, a Discharge of Raw Sewage, or when Conditional Area Management Plan (CAMP) Performance Standards are not Met *Note: Similar contaminant reduction studies associated with shellstock relaying and validation studies associated with the depuration process are not covered in this g uidance document. Instead, each has their own specific requirements which are covered in Chapter V. and Chapter XV., as well as Guidance Documents Chapter II .10 and .19, respectively.* A. When Are Studies Required? Per Chapter IV. @.03 A.(5)(d) and C.(2)(c), studies are required for reopening a closed area to establish the environmental conditions and time required for pathogens (as measured by microbiological indicators) in shellstock and water to return to acceptable levels following the impact from an emergency condition, discharge of raw sewage, or when conditional area management plan (CAMP) performance standards are not met. Listed below is a summary of scenarios for reopening options: *1) Scenarios where studies are required to reopen once the emergency situation or condition has returned to normal, or CAMP performance standards are fully met, and sufficient time has elapsed to allow the shellstock to reduce pathogens and for the growing area water quality to return to acceptable levels:* (a) Chapter IV. @.03A.(5)(d): • Reopening due to closures resulting from an emergency condition or situation when pathogens are of concern (other than raw untreated sewage discharged from a sewage collection system or WWSD), studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studies may establish criteria for reopening based on coliform levels in the water. • Reopening due to emergency closures caused by the occurrence of raw untreated sewage discharged from a sewage collection system or WWSD, when the closure duration is less than 21 days or when analytical shellstock samples are utilized for comparison to the levels established in the Chapter IV. @.02 E. (4). The authority may use studies to establish pre-determined male-specific coliphage (MSC) levels in shellfish samples that are conducted no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area

potentially impacted.

(b) Chapter IV. @.03 C.(2)(c)(iii):
For management plans based on WWSD function or pollution sources other than WWSD criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status.

- Reopening due to closures impacted by pathogens (other than raw untreated sewage discharged from a sewage collection system or WWSD) from a failure to comply with its conditional management plan, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. These studies may establish criteria for reopening based on coliform levels in the water.

- Reopening due to temporary closures impacted by sewage from a failure to comply with the conditional management plan based on the WWSD performance standards, studies may be conducted to establish sufficient elapsed time and shall document the interval necessary for reduction of viral levels in the shellstock. These studies may establish pre-determined levels based on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in shellfish meats.

2) Scenarios where sampling is required to reopen when a study is not conducted, include:

(a) Chapter IV. @.03A.(5)(d):

- Reopening due to emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a sewage collection system or WWSD, when the closure duration is intended to be less than 21 days, the analytical sample results shall not exceed the levels established in Chapter IV. @.02 E. (4).

- Reopening due to emergency closures of harvest areas when poisonous or deleterious substances are the concern, sampling shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances, guidance levels, and levels that are deemed unsafe through risk evaluation.

(b) Chapter IV. @.03C.(2)(c)(iii):

- Reopening due to temporary closures impacted by sewage from a failure to comply with the conditional management

	plan based on the WWSD performance standards, analytical sample results shall not exceed the MSC level established in Chapter IV. @.02 E. (4). • Water quality sampling can be used to reopen an area following temporary closures resulting from a failure to comply with conditional management plan performance standards based on the effects of non- point sources of pollution such as rain events and/or stormwater runoff. *3) Scenarios where no studies or sampling are required to reopen, include:* (a) Chapter IV. @.03A.(5)(d)(ii) and C.(2)(c)(iii): • Reopening due to the temporary closure from a discharge of raw untreated sewage or exceedance of management plan performance standards relating to WWTP function. If no studies or analytical samples are collected and compared to the levels established in Chapter IV. @.02 E. (4), the area must be in the closed status until the event is over and twenty-one (21) days have passed. 2) proposal be referred back to an appropriate committee as determined by the conference chair to allow for further development of additional sections of the Guidance Document. 3) expanding the charge of the committee to include reviewing Model Ordinance language relating to cleansing studies for reopening.
Action by 2023 Task Force I	Recommended adoption of the Cleansing Study Committee recommendation for Proposal 19-145
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-145.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-145

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

Submitter	Brooke Roman
Affiliation	Neogen Corporation
Email	broman@neogen.com
Proposal Subject	Neogen's 'Reveal 2.0 for PSP' for detection of PSP
Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	The intention is for this method to be an Approved Limited Use Method for Biotoxin testing for PSP toxins under the NSSP (for mussels and oysters) and that it should appear in Section IV (Guidance Documents), Table 4 (Approved Limited Use Methods for Biotoxin Testing). Full SLV validation data is provided for mussels and oysters.
Public Health Significance	PSP is a serious intoxication which still occurs in the USA and elsewhere. The USFDA and the European Union (EU) have established action levels for PSP toxins at 800 ppb (800 µg/kg) STX equivalents in shellfish. PCOX, has been accepted as a quantitative reference method in the USA and some other countries, although Pre- COX is also accepted by regulatory agencies in other areas of the world such as the UK, various EU countries, AU and NZ. Shellfish need to be more easily screened for toxins that cause paralytic shellfish poisoning (PSP), and they need to be screened closer to growing/harvesting areas to better protect public health. A reliable and simple screening tool for end product testing (EPT) by industry, for community- based and remote surveillance, and for screening out negative samples from the regulatory sample stream. Implementation of these approaches would broaden the food safety net and reduce outbreaks of PSP intoxication. Neogen is the only antibody-based test to detect both the STX and NEO parts of the PSP family of toxins at similar levels. No other antibody-based rapid test for PSP can detect NEO to any significant degree. Other ISSC approved "rapid" methods for PSP screening are largely limited to laboratory settings because of complexity which limits their use in EPT and community-based and remote surveillance of shellfish resources. The only ISSC-approved LFA rapid method, the Scotia LFI, has had many issues with reliability that have limited its applicability in screening for PSP, and concerns about the stability of the method have also been published [1,2,3,4,5]. The Neogen Reveal 2.0 for PSP is an

	excellent candidate for rapid screening of shellfish for PSP toxins in both laboratory and field situations, and is an extension of a platform used by Neogen for many reliable rapid tests in the meat, dairy and food sectors, many of which are approved for use by FDA, USFDA and/or EPA. The test has undergone SLV and ILV evaluations [5,6]and has been shown to be an accurate and reliable candidate for approval for use in the NSSP. [1] Cefas 2006 [2] Turner et al. 2015 [3] Harrison et al. 2016 [4] Dorantes-Aranda et al.2017a [5] Jawaid et al. 2015 [6] Dorantes-Aranda et al. 2017b
Cost Information	Approximately $20 per test. Reader based assay – approximate cost of reader is $2,700.00 USD
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-150 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force	Recommended adoption of Laboratory Committee recommendation on Proposal 19-150.
Action by 2019 General Assembly	Adopted recommendation of Task Force I on Proposal 19-150.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-150.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 19-150 to an appropriate committee as determined by the Conference Chairperson
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation for Proposal 19-150.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19- 150
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-150.

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

Submitter	Robert Rheault
Affiliation	ECSGA
Email	Bob@ecsga.org
Proposal Subject	Data evaluation when the nonpoint sources impacting a growing area are not from a human sewage source
Specific NSSP Guide Reference	Section II. Model Ordinance; Chapter IV Growing Areas; Section @.02 Microbiological Standards F.1.
Text of Proposal/ Requested Action	F. Standard for the Approved Classification of Growing Areas when Evaluated for Nonpoint Sources. (1) Exception. (a) If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area. (b) If the Authority has documentation supporting that the nonpoint sources impacting the growing area are not from a human sewage origin they may exclude up to two outlier datapoints from the dataset being evaluated. (2) Pollution Sources. Growing areas shall be impacted only by randomly occurring, intermittent events. (3) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (4). (4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of: (a) 43 MPN per 100 ml for a five-tube decimal dilution test; (b) 49 MPN per 100 ml for a three-tube decimal dilution test; or (c) 31 CFU per 100 ml for a MF (mTEC) test. (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by: (a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10); (b) Multiplying the standard deviation in (a) by 1.28; (c) Adding the product from (b) to the arithmetic mean; (d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and (e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number. (6) Required Sample Collection (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity

	and frequency as described in Section E.(3) for application of the standard under Section E. (2). (b) Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when: (i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution; (ii)Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical; (iii) A minimum of six (6) random samples shall be collected annually from each sample station in the growing area; (iv) A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6)(b) (iii) must resume at least six (6) months before an area is reactivated; and (v) A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard. (c) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority: (i) Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and (ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

Public Health Significance	It is recognized that on occasion water quality may be impacted by non-human sources such as birds. Scientific literature also indicates that the presence of human enteric pathogens in wild birds is overestimated with the use of the coliform indicator (Smith et al. 2021) https://doi.org/10.1111%2Fbrv.12581 If a few aberrant samples can be reliably attributed to birds it is likely that the closure of the harvest area is an unwarranted response
Cost Information	
Research Needs Information (Optional) a. Proposed specific research need/ problem to be addressed	At this time we do not have an estimate of the correlation of human enteric pathogens with coliforms in wild bird waste. Our growing area classification has been entirely built on the correlation between pathogens and coliforms in wastewater. Using the coliform standard to close harvest areas impacted by birds assumes the relationship is similar, when scientific literature indicates that the risk is being overestimated. Research is needed to describe the persistence of bird-sourced pathogens in the marine environment, and how long these pathogens persist in the shellfish if they are taken up by filter feeding bivalves
b. Explain the relationship between proposed research need and program change recommended in the proposal	Research to elucidate the relationship between human enteric pathogens and coliforms will help define the risk of illness associated with consumption of shellfish that may have been impacted by birds. Studies evaluating how these pathogens survive in the marine environment will further inform this relationship. Studies evaluating the purge rates of these pathogens will help growers devise management approaches to ensure potentially impacted product is held away for contaminated sites and is safe for consumption
Action by 2023 Task Force I	Recommended referral of Proposal 23-107 as amended to an appropriate committee as determined by the Conference Chair F. Standard for the Approved Classification of Growing Areas when Evaluated for Nonpoint Sources. (7) Exception. (a)If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area. (b) ~~If the Authority has documentation supporting that the nonpoint sources impacting the growing area are not from a human sewage origin they may exclude up to two outlier datapoints from the dataset being evaluated.~~ (8)Pollution Sources. Growing areas shall be impacted only by randomly occurring, intermittent events. (9)Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (4). (10) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF

	(mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of: (a) 43 MPN per 100 ml for a five-tube decimal dilution test; (b) 49 MPN per 100 ml for a three-tube decimal dilution test; or (c) 31 CFU per 100 ml for a MF (mTEC) test. (11) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by: (a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10); (b) Multiplying the standard deviation in (a) by 1.28; (c) Adding the product from (b) to the arithmetic mean; (d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and (e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number. Required Sample Collection. (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section E. (2). Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when: (i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution; (ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical; (iii) A minimum of six (6) random samples shall be collected annually from each sample station in the growing area; (iv) A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6)(b) (iii) must resume at least six (6) months before an area is reactivated; and (v) A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.

	(d) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority: (i) Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and (ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1)
Action by 2023 General Assembly	Adopted the recommendations of Task Force I on Proposal 23-107.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-107

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

Submitter	Adam Wood
Affiliation	Virginia Department of Health
Email	Adam.wood@vdh.virginia.gov
Proposal Subject	Relay Timeframe
Specific NSSP Guide Reference	Section II Model Ordinance, Ch. V Shellshock Relaying @.02 Contaminant Reduction C(3)
Text of Proposal/ Requested Action	(1) The Authority may waive the requirements for a contaminant reduction study if: (1) Only microbial contaminants need to be reduced; and (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and (3) The treatment period exceeds ~~sixty~~fourteen (~~60~~14) days. D. The time period shall be at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequa
Public Health Significance	The change to 14 days is consistent with the literature available and already cited in the NSSP. The Guidance documents already have established 14 days as the ideal acceptable time for elimination of microbial contaminants. 60 days is not in any literature nor in any other already voted on sections of the NSSP for relaying. 21 days is the agreed upon value for harvesting waters adulterated with raw sewage, which is likely the worst-case scenario, relay from areas only impacted by microbial contamination should surely be less than those contaminated by raw sewage
Cost Information	N/A
Action by 2023 Task Force I	Recommended referral of Proposal 23-111 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-111.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-111.

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

Submitter	Jackie Knue
Affiliation	State of Alaska Environmental Health Laboratory
Email	Jacqueline.knue@alaska.gov
Proposal Subject	Domoic Acid (Amnesic Shellfish Poisoning) HPLC Method Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklist
Text of Proposal/ Requested Action	The requested action is to edit the text of the attached checklist for the HPLC method for detecting domoic acid and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Public Health Significance	The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing the HPLC method for domoic acid to support the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined
Cost Information	None
Action by 2023 Laboratory Committee	Recommended referral of Proposal 23-114 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23- 114
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-114.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-114

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

Submitter	Jackie Knue
Affiliation	State of Alaska Environmental Health Laboratory
Email	Jacqueline.knue@alaska.gov
Proposal Subject	Paralytic Shellfish Poisoning (PSP HPLC-PCOX) HPLC Method Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklist
Text of Proposal/ Requested Action	The requested action is to edit the text of the attached checklist for the HPLC method for detecting domoic acid and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Public Health Significance	The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing the HPLC method for domoic acid to support the NSSP. The checklist documents the number of critical, key or other nonconformities and how overall laboratory status for the method is determined
Cost Information	None
Action by 2023 Laboratory Committee	Recommended referral of Proposal 23-115 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 Task Force I	Recommended adoption of the Laboratory Committee recommendation on Proposal 23- 115
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-115.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-115

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

Submitter	George Trevelyan
Affiliation	Grassy Bar Oyster Company, Inc.
Email	gboysterco@gmail.com
Proposal Subject	**Guidance for calculating the 90th percentile for end-product depurated shellfish**
Specific NSSP Guide Reference	**Section IV Guidance Documents; Chapter II Growing Areas; Section .17 Calculating the 90th percentile for end-product depurated shellfish**
Text of Proposal/ Requested Action	Process verification in depuration is performed continuously to ensure that the microbial contaminant load is being effectively reduced. Two (2) indices of performance, the geometric mean and the ninetieth (90th) percentile have been developed to describe the effectiveness of the depuration process. Critical limits for these parameters have been established empirically by shellfish species. For soft clams (*Mya arenaria*), a geometric mean of fifty (50) and a ninetieth (90th) percentile of 130 have been set. For hard clams, oysters, manila clams and mussels, a geometric mean of twenty (20) and a ninetieth (90th) percentile of seventy (70) have been adopted. Geometric means and ninetieth (90th) percentiles are determined daily or as end- product results become available from the analysis of the most recent ten (10) consecutive harvest lots per species, per restricted harvest area used. If the critical limits for either the geometric mean and/or the ninetieth (90th) percentile are exceeded, the process is considered to be unverified; and, additional sampling requirements must be instituted to ensure effective process control. End-product depurated shellfish samples are analyzed using two (2) different methods of recovery, a pour plate procedure and a single dilution MPN test. Calculation of the ninetieth (90th) percentile for these samples is complicated by the fact that fecal coliforms recovered by the MPN and ETCP methods follow different statistical distributions. To accommodate these differences and maintain a high likelihood for detecting an unacceptable amount of process variability without having to change or alter the formula used requires the use of nonparametric or "distribution free statistics." Using "distribution free statistics," the position of the ninetieth (90th) percentile for end-product depurated shellfish samples is calculated by arraying the fecal coliform count data in ascending order and applying the formula (n + 1)P/100.

	As an example of the use of this formula, the Model Ordinance requires that the ninetieth (90th) percentile of the fecal coliform analytical data be calculated from the most recent ten (10) consecutive harvest lots for each shellfish species depurated from each restricted harvest area. Fecal coliform count data, whether from the ETCP or MPN procedure for these ten (10) lots must be arrayed from the smallest to the largest value using the arithmetic (not logarithmically transformed) count data. Applying the formula, n would be greater than or equal to ten (10) for the ten (10) most recent consecutive harvest lots required by the Model Ordinance. P, the percentile of interest would be ninety (90). Using the minimum sample set of n=10, ~~Multiplying~~ multiplying the formula out gives the position of the ninetieth (90th) percentile in the arrayed data. Performing these calculations, 10 + 1 = 11, 11 x 90 = 990/100 = 9.9. Thus, the ninetieth (90th) percentile for end-product depurated shellfish data when n=10 is the value of the 9.9th sample in the ten (10) sample array. Using ~~the~~ ten (10) samples ~~as required by the Model Ordinance~~, the ninetieth (90th) percentile for end- product depurated shellfish samples would always be the value of the 9.9th sample in the ascending array of the arithmetic count data. To calculate this value from the arrayed data, interpolation between samples nineand ten (10) is necessary. This is best illustrated using several samples. Example 1… Example 2… Example 3… In cases where more than ten samples have been analyzed in the most recent ten consecutive harvest lots for each species depurated or for each harvest area used, the geometric mean and estimated 90th percentiles may be calculated using the methodologies below in examples 4 and 5. Example 4 (attached) Example 5 (attached)
Public Health Significance	Incorrectly calculating the 90th percentile can lead to erroneous decisions that could affect public health. For instance, both the California Dept of Public Health and the FDA mis-calculated the 90th percentile for a data set in which n=36. They insisted, based on the examples given in the NSSP Guide, that the 90th percentile was **always found between the 2 largest numbers** in the data set, even when n is large, which is incorrect.
Cost Information	This clarification to the NSSP Guide, with additional examples, will make it easier to correctly calculate this depuration performance index and should reduce confusion and disagreements, which could save time and money.
Action by 2023 Task Force I	Recommended referral of Proposal 23-123 to an appropriate committee as determined by the Conference Chairperson.

Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-123.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-123

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

Submitter	US Food & Drug Administration (FDA)
Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	Updated Marina and Mooring Area Guidanc
Specific NSSP Guide Reference	Section IV. Guidance (Mooring Area)
Text of Proposal/ Requested Action	MARINA and MOORING AREA GUIDANCE - **DRAFT** The following guidance is provided to ensure the uniform application of the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO) criteria, as adopted by the Interstate Shellfish Sanitation Conference (ISSC), for the evaluation and classification of shellfish growing waters in and around docks, marinas, and boat mooring areas. BACKGROUND A marina policy was developed at the ISSC conference held in August of 1986. It was recognized that a marina is a potential pollution source in a shellfish growing area, and that a closure zone is required to prevent the harvest of shellfish for human consumption in and around occupied marinas and mooring areas. The purpose of the policy was to establish a uniform national approach to marina and mooring area closures. At the July 1988 ISSC conference, approval was given to incorporate the marina policy into the definition and growing area classification sections of the NSSP MO. The 1989 "*Evaluation of Marinas by State Shellfish Sanitation Control Officials*", better known as the **1989 Marina Guideline,** was released in order to further clarify the new marina policy adopted into the 1990 NSSP Manual of Operations Part I Sanitation of Shellfish Growing Areas. The 1989 Marina Guideline was originally intended for the U.S. Food and Drug Administration (FDA) and State Shellfish Control Authorities (Authority) to use as guidance when classifying growing areas in and around marina facilities. The 1989 Marina Guideline has been used in all the FDA growing area training courses since inception as a reference on implementation of the NSSP MO marina criteria. As a result of actions taken at the 2019 biennial conference, "marina" and "mooring area" were separated into two (2) definitions (NSSP MO Section I. B.). In addition, the NSSP MO Section II. Chapter IV. @.06 was created to allow for mooring areas to be classified as conditionally approved and conditionally restricted in the open status if a detailed pollution assessment

	is conducted at the frequencies required by the NSSP MO Section II. Chapter IV. @.01 A. (2.), C., and D. indicating a significant reduced risk from pollution sources and if there is a Conditional Area Management Plan (CAMP) in place with sufficient controls to protect human health. The justification for this change suggests that there may be a different level of human health risk associated with how a mooring area, as a pollution source, may be managed compared to a marina. Boats are considered a potential pollution source due to the capability to discharge human sewage into a growing area. As technology has improved and the management of mooring areas have evolved with the implementation of the Federal No Discharge Zone (NDZ) program and availability of boat waste pump out boats and facilities, there is the potential, with enough oversight and management controls in place, to limit the capacity for overnight occupancy and sewage discharge from boats in a mooring area compared to a marina. This updated marina and mooring area guidance document is intended to serve as guidance for the FDA when evaluating state growing area classification programs and as guidance for authorities regarding the classification and management of marinas and mooring areas in accordance with the NSSP MO requirements. GUIDANCE This guidance will provide clarification for the pollution assessment, classification, dilution calculation, and conditional area classification management of marinas and mooring areas, in and adjacent to, shellfish growing areas. Boats congregated into a marina or mooring area are operated and inherently occupied by people at some time and therefore, have the potential to discharge human sewage and graywater into associated shellfish growing areas. As a result, every public or private watercraft, barge, houseboat, or boat, that has the potential to produce an overboard discharge from a marine toilet or discharge graywater, should be considered a potential pollution source in the evaluation of shellfish growing areas. Since marine toilets may provide only limited or no treatment, human sewage discharges from boats may contain bacteria and viruses attributed to human sewage and graywater. For this reason, discharges of graywater and marine toilets represent a greater public health risk than other discharges

	of sanitary waste, and since these discharges can be sporadic, it may represent a greater public health risk than the FC sources typically detected by routine bacteriological monitoring. Since many marina facilities and mooring areas are in or adjacent to shellfish growing areas, and waste discharges are not uniformly distributed in the water column, detection of low levels of coliforms from waste discharges by current pollution monitoring methods may not provide sufficient information to properly classify the waters in or adjacent to a marina or mooring area. Therefore, each marina and mooring area pollution assessment, dilution analysis, classification, and closure zone should be considered on a site-by-site basis, given the potential significant public health risk combined with the unique characteristics of each site. As a result, a classification other than approved or restricted is required for the area within a marina or mooring area. This requirement is based on the public health requisite that waters receiving sporadic waste discharges from marine toilets or discharge of graywater are not suitable for the direct harvest of shellfish destined for human consumption or for relay or depuration. A pollution assessment and dilution determination must be used for classifying and making status determinations for marinas and mooring areas and adjacent shellfish growing areas. MARINAS Per the 2019 Revision of the NSSP MO Section I. B.: **Definition: Marina -** *any water area with a structure (docks, basin, floating docks, etc.) which is used for docking and constructed to provide temporary or permanent docking space for more than ten (10) boats.* MARINA PROPER Per the NSSP MO Section II. Chapter IV. @.05 A, the marina proper shall be classified as: conditionally approved, conditionally restricted, or prohibited. A *pollution assessment* shall also be conducted in order to support the conditionally approved or conditionally restricted classification. The FDA's interpretation is that the marina pollution assessment is not intended to allow direct harvesting in the marina proper while more than 10 boats are present, but to document the seasonality

and the presence of boats for the development of a Conditional Area Management Plan (CAMP) and to assess the marina proper as a pollution source, gather information for the dilution analysis, and provide documentation in the sanitary survey.

If more than 10 boats are not present during certain seasons (as in some geographical areas) the marina proper may be reclassified or changed to the open status if already classified as conditionally approved or conditionally restricted to permit harvest. During such periods the Authority must document that the area meets the specific NSSP MO criteria for the classification allowing harvest in the CAMP.

ADJACENT WATERS

Per the NSSP MO Section II. Chapter IV. @.05 B., waters adjacent to a marina proper may be impacted by pollution associated with the marina. Therefore, when more than 10 boats are present, a dilution analysis shall be used to determine if there is any impact to the adjacent growing area waters. The dilution analysis shall be based on the volume of water in the vicinity of the marina proper.

If the dilution analysis predicts a theoretical fecal coliform (FC) loading greater than (>) 14 FC/100 ml, the waters adjacent to the marina shall be classified as: conditionally approved, restricted, conditionally restricted, or prohibited. If the dilution analysis predicts a theoretical FC loading less than (<) 14 FC/100 ml, the waters adjacent to the marina may be classified as: approved or conditionally approved.

In reference to NSSP MO Section II. Chapter IV. @.05 B. (3), the dilution analysis around a marina proper shall incorporate the following factors. The recommendations provided represent guidance for how the authority may meet the intent of each requirement:

(a) Slip occupancy rate for the marina:

This is the quantity of waste potentially originating in a marina and depends on the number of people who are present in the marina. The fewer boats that are found to be occupied, the smaller the expected impact from the marina proper. The NSSP MO provides for establishing an occupancy rate for each marina. The slip occupancy rate of the marina should be documented by actual observation of

marina operations during the time of highest usage such as weekends or holidays. Document the overall number of boats in a marina proper and the number of boats being occupied as well as the number of people on each boat. Document the number of slips in the marina proper.

(b) **An actual or assumed rate of boats which will discharge untreated waste**:
Document the number of boats with a marine sanitation device (MSD) type used (i.e., MSD Type I, II, or III) in the marina. If the authority uses an assumed rate of discharge, that rate should be supported by data gathered during the pollution assessment of the marina.

(c) An occupancy per boat (number of ersons per boat):
If the authority chooses not to determine a specific occupancy per boat rate by investigation, the authority shall assume a minimum occupancy rate of two (2) persons per boat (NSSP MO Section II. Chapter IV. @.05 B. (6)).

Document the number of boats with liveaboard capability as well as the number of people on liveaboard boats in the marina. This inventory should be taken during the expected high usage times such as weekends and holidays. The inventory should have continuity so that changes in population during high occupancy times will be documented. Regional differences in boat usage, and the percent of high usage, will vary.

(d) A fecal coliform discharge rate of 2 x 10^9 for the theoretical fecal coliform contribution per person per day.

(e) Assume that the wastes are completely mixed in the volume of water in and around the marina.

(f) **Documentation, verification and enforcement of Federal No Discharge Zones and locally well enforced no discharge and occupancy by-laws and regulations**:
Provide documentation of the NDZ: enforcement records, vessel inspection records, marina use agreements, available educational material, and graywater regulations.

Document in the management plan how vessels are inspected to ensure that boats equipped with an MSD that is not properly sealed to prevent discharge of sewage into the water is documented and enforced. Document Memorandums of Understanding or Agreements with local towns, municipalities, and patrol enforcement agencies defining each agency's responsibility in administering and enforcing the NDZ.

(g) Availability and documented use of pump out boats or facilities:

Document the availability and number of pump out facilities and boats available to the marina. Document use and maintenance records, operation procedures, ease of use, hours of operation, pump out log, previous spills, and the individual responsible for pump out operations. The pump out log should include: date, boat name and length, approximate number of gallons pumped, and initials of the operator.

Document enforcement records and boat inspection records. Document the procedures used if there is a waste spill. Document the frequency of when inspections are conducted to ensure pump-out stations are properly maintained and compliant with Clean Vessel Act (CVA) grant requirements. The records of inspections must be maintained and available for review.

MOORING AREAS

Per the 2019 Revision of the NSSP MO Section I. B.:

Definition: Mooring Areas - *any water area that is used to provide temporary or permanent anchorage for more than twenty (20) boats. Mooring areas do not include any structures for docking boats.*

MOORING AREA PROPER

Per the NSSP MO Section II. Chapter IV. @.06, a designated mooring area, where there is anchoring or mooring of boats, which is in or adjacent to a shellstock growing area shall be classified as: conditionally approved, restricted, conditionally restricted, or prohibited.

Prior to the Authority establishing a classification of conditionally

approved, conditionally restricted, or restricted in the mooring area proper, a *pollution assessment* supporting the classification will need to be conducted by the authority. The NSSP MO provides flexibility so that if the *pollution assessment* determines that the mooring area has controls in place and is not considered a pollution source and it is thoroughly documented in the CAMP, the area may be classified as conditionally approved or conditionally restricted and placed in the open status with boats present.

The following factors shall be considered and documented when conducting a *pollution assessment* to determine the classification of the mooring area and adjacent waters in accordance with the NSSP MO requirements.

POLLUTION ASSESSMENT

The NSSP MO Section II. Chapter IV. @.06 A. (1) requires that a *pollution assessment* supporting the classification of mooring areas be conducted by the authority. In accordance with the 1986 ISSC Marina Policy and the 1989 Marina Guidance, the basis for occupancy and discharge rates should reflect worst case conditions and the inventory should be taken during the expected high usage times such as weekends and holidays.

The *pollution assessment* shall include the following factors according to the NSSP MO Section II. Chapter IV. @.06 A. (1). The recommendations provided for each factor represents suggested guidance for how the authority may meet the intent of each required component of the *pollution assessment*:

(a) **Boat Type and Usage**:

- Documentation of the boat type and usage should be considered from a public health perspective and the risk of the potential for overboard discharge from both treated and untreated sewage as well as graywater.
  - Document the type and size of boats in the mooring or anchorage area such as cabin cruiser, houseboat, cuddy cabin, runabout, commercial fishing vessel, skiff, daysailer, etc.
  - Document the number of boats in

each type and size category.

- Document the usage of boats such as overnight, weekend, day use, as well as commercial, or recreational.
- The boat type and usage information may be used in a mooring area management strategy to separate out boats that might pose more of a human health risk into a different conditionally managed area using separate performance standards.

(b) **Density of Boats**:

- Document the geographic location of the mooring area and include a map defining the mooring area boundaries.
- If boats are geographically managed by type and use, document this management strategy using a map that defines the mooring area management areas.
- Document the density of boats as the number of boats per a unit of area (For example: 100 boats per 1 sq. mile).
- Each individual mooring or anchorage area in a growing area should be accounted for and evaluated and where multiple mooring areas are present in a growing area, the authority should evaluate the impact of those individual mooring areas on the growing area from a holistic or cumulative impact. As an example, using best human health protection management practices, it may not be appropriate to separate a single group of multiple mooring boats (greater than 20 boats) into numerous separate mooring areas of 20 or less boats.

(d) **Accessibility to boats which could reduce likelihood of overnight occupancy**:

- In reference to the term "parking lot" mooring area, such as a location where boats are temporarily moored for short periods of

	time, but not occupied overnight, document the factors which could reduce or increase the likelihood of overnight occupancy in the mooring area proper. • Provide a detailed justification explaining how accessibility to boats in the mooring area increases or decreases the likelihood of overnight occupancy. This may include how the access of the boats in the mooring area are managed and how accessible boats are to overnight occupancy. • Document the municipal mooring area regulation(s), town charter(s), municipal regulation(s), and records documenting enforcement of said regulation(s) and charter(s) that limits or mandates no overnight occupancy. • Document how boat owners access their vessels, such as through launch service (hours of operation), personal dinghy, etc. • Provide and maintain records from the municipal or state enforcement agencies when overnight occupancy regulations are enforced or violated. (d) **Occupancy Rates**: • Document the number of mooring balls/buoys and the number of boats allowed on each. • Document the overall number of boats in a mooring area and the number of boats being occupied as well as the number of people on each boat. If the mooring area is considered a "parking lot", such as a location where boats are temporarily moored for short periods of time but not occupied overnight, provide documentation to that effect, including justification for use. • Document any transient mooring areas

	and their boat capacity. (e) **Seasonal Use Pattern**: • Document if there is a seasonal boat use pattern. • Document what the seasonal boat use pattern is including the seasonal dates as to when more than 20 boats are present in the mooring area. (f) **An actual or assumed rate of boats which will discharge untreated waste**: • Conduct and document an onsite assessment of the mooring area and document the type and number of boats that have the potential for discharging treated or untreated sewage including graywater. • Document boats with marine heads and include the number and location of boats with each type of MSD (Type: I, II, or III). (g) **Documentation, verification, and enforcement of Federal No Discharge Zones (NDZ), and locally well enforced no discharge and occupancy regulations or by-laws:** • Provide documentation of the NDZ: enforcement records, boat inspection records, mooring area use agreements, available educational material, graywater discharge regulations, and occupancy records during high-use times. • Document how boats equipped with a MSD, not properly sealed to prevent discharge of sewage into the water, are inspected. • Provide any Memoranda of Understandings or Agreements with local towns, municipalities, and patrol enforcement agencies. Define each agency's responsibility in administering and enforcing the NDZ; including references to the statue, regulation, or charter that confers authority to enforce the NDZ. (e) Document the CAMP communication

requirements (contact tree) in case an emergency closure is warranted.

(h) **Availability and documented use of shore-based pump out facilities and pump out boats**:

- Document the availability and number of pump out facilities and pump out boats available to the boats in the mooring area proper.
- Document pump out practices, pump out procedures, educational information, and employee/operator training.
- Document the use and maintenance records, operation procedures, ease of use, hours of operation, pump out log, previous spills, and who is responsible for the pump out operations. The pump out log should include date, boat name and length, approximate number of gallons pumped, and initials of the operator.
- Document enforcement records and boat inspection records.
- Document the procedures if there is a waste spill.
- Document the frequency as to when inspections are conducted to ensure pump-out stations are properly maintained and compliant with Clean Vessel Act grant requirements; with records of past inspections maintained and available for review.

The NDZ is only one factor to consider when conducting a *pollution assessment* to classify a growing area with a mooring area(s) as conditionally approved or conditionally restricted in the open status with boats present. The FDA does not consider the NDZ designation to be a standalone *pollution assessment*, control mechanism, or justification for classifying a mooring area(s) as conditionally approved or conditionally restricted in the open status. As stated in the NSSP MO language, documentation, verification, and enforcement of the NDZ and locally well enforced no discharge and occupancy regulations or by-laws will be necessary for the *pollution assessment* and for review during FDA growing area program

	evaluations. In addition, Section 312 of the Clean Water Act (CWA) contains the principal framework for domestically regulating sewage discharges from boats and is implemented jointly by the U.S. Environmental Protection Agency (EPA) and the U.S. Coast Guard (USCG). Sewage, treated or untreated, is prohibited in an NDZ. The NSSP utilizes the CWA definition of sewage. **Definition: Sewage - human body wastes and the waste from toilets and other receptacles intended to receive or retain body wastes.** Graywater is not defined as "sewage" and is not prohibited under the NDZ requirements. Graywater may contain high levels of human bacteria and viruses and poses a significant human health risk when present and this should also be considered in the *pollution assessment*. CONDITIONAL AREA MANAGEMENT PLAN (CAMP) FOR THE MOORING AREA PROPER CLASSIFIED AS CONDITIONALLY APPROVED OR CONDITIONALLY RESTRICTED IN THE OPEN STATUS Per the NSSP MO Section II. Chapter IV. @.06 A. (1), a *pollution assessment* of the mooring area proper is required to determine if the mooring area can be classified as conditionally approved or conditionally restricted. Per the NSSP MO Section II. Chapter IV. @.06 A. (2), after the mooring area proper pollution assessment determines that the mooring area proper is not a pollution source and it is documented in the CAMP, the growing area may be placed in the open status. The CAMP for each mooring area placed in a conditional classification is based on the information gathered during the *pollution assessment*. The CAMP will establish a strict set of criteria or performance standards, which must be met for the growing area to remain in the open status. Failure to meet the criteria or performance standards automatically places the growing area in the closed status, with immediate notice to the CAMP participants, affected industry, and the public. Performance Standards for a Mooring Area CAMP should include:

	• Establishment of a Memorandum of Understanding and/or an agreement to the conditions of the CAMP by the one (1) or more authorities involved including: mooring area management organizations, local municipalities, other local, State and Federal agencies, enforcement, harbor master, or other organizations which may be involved in the management and enforcement of the mooring area proper, pump out operations, and NDZ management and enforcement. • A written CAMP for the mooring area(s) and associated growing area being placed in the conditional classification, which includes a description of the mooring area(s) with a map showing the mooring area(s) boundaries. • A sanitary survey that shows the growing area will be in the open status of its conditional classification and provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted with supporting information and data. • A description of the *pollution assessment* for the mooring area documenting how the reduction of an illicit human sewage (treated or untreated) and graywater discharge will be prevented and what management strategies are in place including, documenting boat types and uses, inspection of boat MSDs, documentation of pump out boats and facilities, NDZ regulations, education, management, and enforcement. • A description of the plan for monitoring water quality including what will be sampled and the location of sample stations on a map, numbers of sample stations, and frequency monitored. • A description of how the closed status for the conditional classification will be implemented which must include:

	○ A clear statement indicating when the performance standards are not met, the growing area will immediately be placed in the closed status; ○ A requirement to notify the authority or authorities that management plan performance standards have not been met, including: ▪ The name of the agency or other party responsible for notifying the authority; ▪ The anticipated response time between the performance standards not being met and notification of the authority; and ▪ The procedures for prompt notification including contingencies such as night, weekend, and absences of key personnel; • A description of implementation and enforcement, including: ▪ The response time between the notification to the authority of the failure to meet performance standards and activation of the legal closure of the growing area by the authority; ▪ The procedures and methods to be used to notify the shellfish industry; and ▪ The procedures and methods to be used to notify the patrol agency (enforcement agency) including: ▪ The name of the responsible patrol agency; ▪ The anticipated response time between the Aathority's legal closure of the growing area and notification of closure to the patrol agency; and ▪ A description of the patrol agencies anticipated activities to enforce the closed status of an area.

- A description of the criteria that must be met prior to reopening a mooring area or growing area in the closed status, including the need to determine that:
    - The performance standards established in the management plan are again compliant;
    - The flushing time for pollution dissipation is adequate;
    - A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock;
    - Where necessary, the bacteriological quality of the water must be verified; and
    - Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.

- A commitment to a reevaluation of the management plan, at least annually, using the reevaluation requirements in the NSSP MO, or other regulations/rules required as necessary.
- A designation in the CAMP whether the shellstock may be harvested for relaying or depuration in a conditionally approved (closed status) or whether the harvested shellstock are to be relayed or depurated in a conditionally restricted area (open status).

ADJACENT WATERS
Per the NSSP MO Section II. Chapter IV. @.06 B., waters adjacent to a mooring area proper may be impacted by pollution associated as a result. Based on the pollution assessment conducted in NSSP MO Section II. Chapter IV. @.06 A., if the authority determines that the mooring area proper is a pollution source, a dilution analysis shall be used to determine if there is any impact to the adjacent waters. The dilution analysis shall be based on the volume of water in the vicinity of the mooring area proper.

If the dilution analysis predicts a theoretical FC loading greater than (>) 14 FC/100 ml, the waters adjacent to the mooring area shall be classified as: conditionally approved, restricted, conditionally restricted, or prohibited. It the dilution analysis predicts a theoretical FC loading less than (<) 14 FC/100 ml, the waters adjacent to the marina may be classified as: approved or conditionally approved.

	The dilution analysis shall include the following factors according to the NSSP MO Section II. Chapter IV. @.06 B. The recommendations provided, represents guidance for how the authority may meet the intent of each requirement: (a) **An occupancy rate for the mooring area**: Consider that the quantity of waste potentially originating in a mooring area depends on the number of people who are present in the mooring area. The fewer boats that are found to be occupied, the smaller the expected impact from the mooring area. The occupancy rate of the mooring area should be documented by actual observation of mooring area operations during the time of highest usage such as weekends or holidays. Document the overall number of boats in a mooring area and the number of boats being occupied as well as the number of people on each boat. Document the number of mooring balls and buoys in the mooring area. (b) **An actual of assumed rate of boats which will discharge untreated waste**: Document the number of boats with installed toilets and document the MSD type used (MSD Type I, II, or III) in the mooring area having the capability to discharge to the environment. If the authority uses an assumed rate of discharge, that rate should be supported by data gathered during the pollution assessment of the mooring area. **(c) An occupancy per boat (i.e., number of persons per boat):** If the authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the authority shall assume a minimum occupancy rate of two (2) persons per boat (NSSP MO Section II. Chapter IV. @.06 B. (6)). Document the number of people on liveaboard boats in the mooring area. This inventory should be taken during the expected high usage times such as weekends and holidays. The inventory should have continuity so that changes in population during high occupancy times can be documented. Regional differences exist regarding boat usage; therefore, the percent of high usage will vary. **(d) A fecal coliform discharge rate of 2 x 10^9 for the**

theoretical fecal coliform contribution per person per day.

(e) Assume that the wastes are completely mixed in the volume of water in and around the marina. Document the average depth of the area based on bathymetry charts and the volume of dilution water needed if complete mixing is assumed.

DILUTION ANALYSIS

The NSSP MO Section II. Chapter IV. @.05 and @.06 states that a dilution analysis will be used for making classification and closure determinations for waters adjacent to each marina proper and mooring area proper (if a pollution assessment determines the mooring area may be a pollution source). The information collected from a pollution assessment will help in determining the potential pollution impact and classification and size of the classification area or closure zone.

This dilution analysis requirement is based on the public health requisite that waters receiving waste discharges from marine toilets from marinas and mooring areas are not suitable for the direct harvest of shellfish destined for human consumption.

The intentional or unintentional direct discharge of treated or untreated human sewage and graywater discharge from a boat into a marina or mooring area is considered a point source and a high human health risk and therefore, pursuant to the NSSP MO Section II. Chapter IV. @.03 E. (5) (a), "An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance."

The estimated per capita discharge of fecal coliforms, coupled with the estimated population in the marina or mooring area, can be used to determine the classification and estimate a closure zone. Closures for existing or proposed marinas and mooring areas should be developed assuming two (2) persons per boat, and a 2×10^9 fecal coliform (FC) contribution per person per day, unless actual persons per boat or occupancy and discharge rates are documented by surveys conducted for individual marinas or mooring areas on a case-by-case basis. The authority should assume 100% boat slip and mooring ball occupancy unless the actual occupancy rate is documented through observation or credibly estimated. This documentation shall be maintained as specified by the NSSP MO,

Chapter I, for reevaluation of sanitary survey information.

Similarly, any expansion, modification, or change to the operation of a marina or mooring area will necessitate the reevaluation of the marina or mooring area occupancy rate.

In determining the above loading rates, a minimum factor should be considered to provide protection against intentional or unintentional waste discharges from boats in the marina or mooring area.

The theoretical waste discharge based on the occupancy and discharge rate, will be completely mixed in and around the marina or mooring area. The marina or mooring area closure zone shall be calculated to reduce the assumed bacterial load to 14 FC/100 ml, in the volume of water in the vicinity of the marina or mooring area. If the results of hydrographic studies are used, the estimated fecal coliform contribution can be distributed throughout the volume of water calculated to flow by the site in 24 hours.

Dilution hydrographic studies may be used to determine the water volume available for dilution and limits of travel of discharges from a marina. The area to be closed shall provide sufficient water volume for calculations to show that theoretical discharges from the marina or mooring area are diluted to 14 FC/100 ml of water. In situations where there are no hydrographic studies, the closed or prohibited area is to be established on a volumetric basis as though the wastes are completely mixed and uniformly distributed in and around the marina or mooring area. The closed area volume is typically based on average water depth and shall be sufficient to dilute the assumed waste load to a value of 14 FC/100 ml.

EXAMPLE CALCULATIONS

The following examples show how various factors are to be considered in closure area determinations around marinas or mooring areas:

CASE 1: No Documentation of Occupancy or Discharge Rates

Number of Boat Slips **50**

Number of People **2 x 50 =100**

Number of Fecal Coliforms (FC) **100 x 2 x 10^9 = 200 x 10^9 Dilution**

Volume Required **200 x 10^9 FC**

(14 FC/100 mL) x (1000 mL/liter)

Volume = 1.4 x 10^9 liters (5.0 x 10^7 cu ft)

Average Depth in Vicinity of Marina **3 meters (10ft)**

Closed Area Required **1.4 x 10^9 liters**

(3 meters) x (1000 liters/cubic meter)

A = 4.7 x 10^5 square meters (5.0 x 10^6 sq ft)

Radius of Half Circle Prohibited/Closed Area

2/ (4.7 10^5)

R = 550 meters (1800 ft)

CASE 2: Boat Slip Occupancy, Population, Holding Tanks and Pumpout Facilities Documented	
Number of Boat Slips	50
Slip Occupancy- Holiday Weekends	40 (80%)
Boats with No Holding Tanks*	16 (16/40 = 40%)
Average People per Boat	1.5
Number of People	1.5 x .40 x .80 x 50 =24
Number of Fecal Coliform (FC)	24 x 2 x 10^9 = 48 x 10^9
Dilution Volume Required	48 x 10^9 FC (14 FC/100 mL) x (1000 mL/liter) V = 3.4 x 10^8 liters (1.2 x 10^7 cu ft)
Average Depth in Vicinity of Marina	3 meters (10ft)
Closed Area Required	3.4 x 10^8 liters (3 meters) x (1000 liters/cubic meter) A = 1.1 x 10^5 square meters (1.2 x 10^6 sq ft)
Radius of Half Circle Closed Area	2/ππππ (1.1 xxxx 105) R = 265 meters (870ft)

	• Assumes pumpout facilities are consistently used, increase percentage if otherwise **REFERENCES** 1. Interstate Shellfish Sanitation Conference Marina Policy. August 1986. 2. Evaluation of Marinas by State Shellfish Sanitation Control Officials. Guideline 1.0. June 1989. 3. National Shellfish Sanitation Program Manual of Operations, Part I. 1988 revision. 4. Department of Health and Human Services NE Technical Unit. 1986. Hydrographic Studies of the Great Salt Pond, Block Island, Rhode Island. 5. Geldreich, Edwin, et al. Bacteria in the Feces of 295 (March). 1962. The distribution of Coliform Bacteria in the Feces of Warm-Blooded Animals. JWPCF 34(3), 6. U.S. Environmental Protection Agency (EPA), Region IV. 1985. Coastal Marina Assessment Handbook. 7. U.S. Department of Health and Human Services, Northeast Technical Services Unit. 1983. Hydrographic Studies of the Kiawah River, South Carolina. 8. Title 33 Code of Federal Regulations, Section 159.7 https://www.govregs.com/regulations/expand/title33_chapterI_part159_subpartA_section159.7#title33_chapterI_part159_subpartA_sectio n159.1 9. National Shellfish Sanitation Program (NSSP), Model Ordinance (MO). 2019 Revision 10. U.S. Environmental Protection Agency (EPA), Office of Waste Management. 2011. Graywater Discharges from Vessels. U.S. Environmental Protection Agency (EPA), Federal No Discharge Zone (NDZ) Link: https://www.epa.gov/vessels-marinas-and- ports/vessel-sewage-no-discharge-zones
Public Health Significance	The 2019 NSSP MO included new language separating out marinas and mooring areas. The adopted language does not have descriptive details as to how the new mooring area language will be evaluated by the FDA. Given that marinas and mooring areas may be considered a potential pollution source and high risk if mooring areas are not assessed correctly, the proposed updated marina and mooring area guidance is presented to help provide the guidance on how to meet those new requirements

Cost Information	N/A
Action by 2023 Task Force I	Recommended referral of Proposal 23-124 to an appropriate committee as determined by the Conference Chairperson.
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 23-124,
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 23-124

Proposal No. 27-100
Date Received:

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 Laboratory Committee
3. Affiliation	
4. Address Line 1	4801 Hermitage Rd. Ste 102
5. Address Line 2	
6. City, State, Zip	Richmond, VA 23227
7. Phone	804-330-6380
8. Fax	
9. Email	issc@issc.org
10. Proposal Subject	Modify Approved Laboratory Methods Table In Guidance Documents
11. Specific NSSP Guide Reference	Section IV – Guidance Documents, Ch. III – Laboratory, @.02 Methods, .01 Approved NSSP Laboratory Tests
12. Text of Proposal/ Requested Action	See Attached
13. Public Health Significance	The ISSC Laboratory Committee (LC) circulated a questionnaire to ISSC Membership in 2022 requesting feedback on the existing Approved Laboratory Methods Table included in the Guidance Documents section of the NSSP Guide. Based on the responses to that questionnaire, the LC has been working since that time to update and improve the Lab Methods Table to make it more accurate and user friendly. The updated Methods Table has been reorganized by method application, as most questionnaire responses indicated that determining the application/approved uses of laboratory methods was the primary reason why this table was utilized. Additionally, the following changes were made to the table in response to feedback received: 1) Method names were updated for consistency purposes and to match the terminology used in the Laboratory Evaluation Checklists. 2) The associated indicators and approved matrix categories were updated and corrected to match original approvals. 3) Limitations and conditions of use for each method have been more clearly spelled out in the updated table. 4) Method references have been corrected and refined, and additional details have been added to make them easier to access. 5) An introduction was added providing information on how to use the table, where to access pertinent program documentation, and how to access original copies of the method reference documents via the ISSC website. 6) Method applications for biotoxin methods were updated to match the Biotoxin Management Strategies described in the Model Ordinance text. 7) The market shellfish application was removed, as there are no longer any market shellfish standards included in the Model Ordinance. 8) The *Vibrio cholera* method (qPCR for CTX Gene) was removed from the table, as it was never officially adopted by the ISSC.
14. Cost Information	N/A

Action by 2025 Executive Board	Adopted the recommendation of 2025 Laboratory. Interim Approval on October 15, 2025

Proposal No. 27-101
Date Received:

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 Laboratory Committee
3. Affiliation	
4. Address Line 1	4801 Hermitage Rd. Ste 102
5. Address Line 2	
6. City, State, Zip	Richmond, VA 23227
7. Phone	804-330-6380
8. Fax	
9. Email	issc@issc.org
10. Proposal Subject	Request to rescind the Reveal 2.0 for ASP Method
11. Specific NSSP Guide Reference	Section IV, Chapter III, @.02 Methods, .01 Approved NSSP Laboratory Tests

12. Text of Proposal/ Requested Action

4. Approved Limited Use Methods for Marine Biotoxin Testing

	Biotoxin Type: Amnesic Shellfish Poisoning (ASP)	Biotoxin Type: Paralytic Shellfish Poisoning (PSP)	Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP)	Application: Growing Area Survey & Classification Sample Type: Shellfish	Application: Onboard Testing Program Sample Type: Shellfish	Application: Controlled Relaying Sample Type: Shellfish	Application: Controlled Harvest End Product Testing
Abraxis Shipboard ELISA[2]		X			X		
SRT[1]		X		X	X	X	
~~Reveal 2.0 ASP[3]~~	~~X~~			~~X~~	~~X~~	~~X~~	
~~RBA[4]~~RBA[3]		X		X	X	X	
MARBIONC Brevetoxin ~~ELISA[5]~~ELISA[4]			X	X	X	X	X

Footnotes:

1. Scotia Rapid Test for PSP, formerly Jellett Rapid Testing Ltd.
   a. Method can be used to determine when to perform a mouse bioassay in a previously closed area.
   b. A negative result can be substituted for a mouse bioassay to maintain an area in the open status.
   c. A positive result shall be used for a precautionary closure.
2. Saxitoxin (PSP) ELISA Kit. Method can be used in conjunction with rapid extraction method using 70% isopropanol (rubbing alcohol): 5% acetic acid (white vinegar) 2.5:1. ISSC Summary of actions, Proposal 05.111 (page 15) and 09-107 (page 140).

~~3. Reveal 2.0 ASP. Neogen Corporation. Screening Method for Qualitative Determination of Domoic Acid Shellfish. ISSC 201 Summary of Actions Proposal 13-112.~~

~~4.~~3. Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination. Dr. Fran Van Dolah. Method for Clams and Scallops for the Purpose of Screening and Precautionary Closure for PSP. ISSC 2013 Summary of Actions Proposal 13-114.

~~5.~~4. MARBIONC Brevetoxin ELISA, MARBIONC Development Group, LLC. Method can be used in place of an Approved Method for oysters, hard clams, and sunray venus clams within this parameters:
   a. A negative result (≤ 1.6 ppm in hard clams and sunray venus clams and ≤ 1.80 ppm in oysters) can substitute for testing by an Approved Method for the purposes of controlled relaying, controlled harvest end-product testing, or to re-open a previously closed area.
   b. A positive result (> 1.6 ppm in hard clams and sunray venus clams and > 1.8 ppm in oysters) requires additional testing by an Approved Method or could support the same management actions as samples failing by an Approved Method. ISSC 2017 Proposals for Consideration, Proposal 17-107 (page 466).

13. Public Health Significance

The Neogen Corporation has discontinued production on all biotoxin test kits, and the last of the Reveal 2.0 for ASP kits that were produced prior to that discontinuation have all passed their expiration date. There are no plans for

	Neogen or any other corporation to resume production of these kits. With this discontinuation, the only remaining laboratory method available within the NSSP for testing for ASP is the HPLC method cited in this same method table in Section 2. Approved Methods for Marine Biotoxin Testing.
14. Cost Information	N/A
Action by 2024 Executive Board	Adopted the recommendation of 2024 Laboratory Committee. Interim Approval on April 16, 2025

Proposal No. 27-102
Date Received:

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 Laboratory Committee
3. Affiliation	
4. Address Line 1	4801 Hermitage Rd. Ste 102
5. Address Line 2	
6. City, State, Zip	Richmond, VA 23227
7. Phone	804-330-6380
8. Fax	
9. Email	issc@issc.org
10. Proposal Subject	Request to rescind the Scotia Rapid Test for PSP Method
11. Specific NSSP Guide Reference	Section IV, Chapter III, @.02 Methods, .01 Approved NSSP Laboratory Tests

12. Text of Proposal/ Requested Action

4. Approved Limited Use Methods for Marine Biotoxin Testing

	Biotoxin Type: Amnesic Shellfish Poisoning (ASP)	Biotoxin Type: Paralytic Shellfish Poisoning (PSP)	Biotoxin Type: Neurotoxic Shellfish Poisoning (NSP)	Application: Growing Area Survey & Classification Sample Type: Shellfish	Application: Onboard Testing Program Sample Type: Shellfish	Application: Controlled Relaying Sample Type: Shellfish	Application: Controlled Harvest End Product Testing
Abraxis Shipboard ~~ELISA[2]~~ ELISA[1]		X			X		
~~SRT[1]~~		~~X~~		~~X~~	~~X~~	~~X~~	
Reveal 2.0 ~~ASP[3]~~ ASP[2]	X			X	X	X	
~~RBA[4]~~RBA[3]		X		X	X	X	
MARBIONC Brevetoxin ~~ELISA[5]~~ELISA[4]			X	X	X	X	X

Footnotes:

~~1. Scotia Rapid Test for PSP, formerly Jellett Rapid Testing Ltd.~~
~~a. Method can be used to determine when to perform a mouse bioassay in a previously closed area. A negative result can be substituted for a mouse bioassay to maintain an area in the open status.~~
~~b. A positive result shall be used for a precautionary closure.~~

~~2.~~1. Saxitoxin (PSP) ELISA Kit. Method can be used in conjunction with rapid extraction method using 70% isopropanol (rubbing alcohol): 5% acetic acid (white vinegar) 2.5:1. ISSC Summary of actions, Proposal 05.111 (page 15) and 09-107 (page 140).

~~3.~~2. Reveal 2.0 ASP. Neogen Corporation. Screening Method for Qualitative Determination of Domoic Acid Shellfish. ISSC 201 Summary of Actions Proposal 13-112.

~~4.~~3. Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination. Dr. Fran Van Dolah. Method for Clams and Scallops for the Purpose of Screening and Precautionary Closure for PSP. ISSC 2013 Summary of Actions Proposal 13-114.

~~5.~~4. MARBIONC Brevetoxin ELISA, MARBIONC Development Group, LLC. Method can be used in place of an Approved Method for oysters, hard clams, and sunray venus clams within these parameters:

a. A negative result (≤ 1.6 ppm in hard clams and sunray venus clams and ≤ 1.80 ppm in oysters) can substitute for testing by an Approved Method for the purposes of controlled relaying, controlled harvest end-product testing, or to re-open a previously closed area.

b. A positive result (> 1.6 ppm in hard clams and sunray venus clams and > 1.8 ppm in oysters) requires additional testing by an Approved Method or could support the same management actions as samples failing by an Approved Method. ISSC 2017 Proposals for Consideration, Proposal 17-107 (page 466).

13. Public Health Significance

The Scotia Rapid Testing company has gone out of business and is no longer producing these test kits. There are still several options available for PSP testing

	within the NSSP, but the discontinuation of this particular test kit eliminates one rapid, easy-to-use option from the list of approved limited use methods.
14. Cost Information	N/A
Action by 2025 Executive Board	Adopted the recommendation of 2024 laboratory Committee. Interim Approval on April 16, 2025

Proposal No. 2 7 - 1 0 3

Add Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

2. Submitter	ISSC Laboratory Committee
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	Checklist – RBA PSP
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	Corrections to Receptor Binding Assay for Paralytic Shellfish Poisoning (RBA PSP) Checklist
12. Public Health Significance	N/A
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A
Action by 2024 Executive Board	Adopted the recommendation of 2024 Laboratory Committee. Interim Approval on October 30, 2024

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	New Federal Waters Definitions
10. Specific NSSP Guide Reference	**Section I. Purposes & Definitions** Definitions
11. Text of Proposal/ Requested Action	**Definitions** A. General. The definitions provided below are consistent in intent with the NSSP. B. Definition of Terms. **(1) Adequately Iced …** **…** **(23) Container …** **(24) Contract Harvester List** refers to a list of harvesters holding an approved NOAA SIP contract for harvesting shellstock from federal waters. (~~24~~25) **Corrosion Resistant Materials …** **…** (~~81~~82) **National Shellfish Sanitation Program (NSSP) …** **(83) NOAA** means the National Oceanic and Atmospheric Administration. **…** (~~116~~118) **Shellfish Gardening …** **(119) Seafood Inspection Program (SIP)** is a NOAA program established to ensure the safety and quality of seafood by providing inspection services to the seafood industry for fish, shellfish, and fishery products. **…** (~~117~~120) **Shellfish Standardization Inspector …** **…** (~~124~~127) **Standardization …** **(128) State of Landing Authority** means the NSSP member state where product harvested in federal waters lands and is received by the primary processor. **…** (~~125~~129) **Swing Deficiency …** **…** (~~131~~135) **Wet Storage …**

12. Public Health Significance	The proposed update to develop a federal waters chapter introduces new terms to the Model Ordinance that need defined for clarification.
13. Cost Information	No cost.
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	Definition of mooring areas
10. Specific NSSP Guide Reference	Section I Purposes & Definitions
11. Text of Proposal/ Requested Action	**(74) Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is used for docking and constructed to provide temporary or permanent docking space for more than ten (10) boats. **(79) Mooring Area** means any water area that is used to provide temporary or permanent anchorage for more than ten ~~twenty~~ (2~~1~~0) boats ~~with marine sanitation devices~~. Mooring areas do not include any structures for docking boats.
12. Public Health Significance	**Background** The current NSSP Model Ordinance (2023) defines a **mooring area** as: *"any water area that is used to provide temporary or permanent anchorage for **more than twenty (20) boats with marine sanitation devices**. Mooring areas do not include any structures for docking boats."* By contrast, a **marina** is defined as: *"any water area with a structure (docks, basin, floating docks, etc.) which is used for docking and constructed to provide temporary or permanent docking space for **more than ten (10) boats**."* FDA proposes reverting the mooring area threshold to **>10 boats** and **eliminating the MSD qualifier**. The following provides the science-based public health rationale. The 10-boat threshold proposed for mooring areas is grounded in established Federal science. EPA's *Guidance Specifying Management Measures for Sources of Nonpoint Pollution in Coastal Waters* (EPA-840-B-92-002, January 1993), issued under Coastal Zone Act Reauthorization Amendments (CZARA), explicitly applies management measures to "any mooring field where 10 or more boats are moored"

	— the same scientific baseline from which the NSSP's marina definition derives. The 2023 NSSP amendment, which doubled the threshold to >20 boats and added an MSD qualifier, departed from this Federal standard without a supporting public health rationale. Restoring the >10-boat threshold eliminates an irrational public health regulatory disparity: marinas and mooring areas concentrate equivalent numbers of boats in fixed water areas and generate equivalent per-boat fecal coliform loading. The only difference between them is the presence of docking structures — a factor with no established relationship to pathogen risk. The public health consequences of the current definition are direct and documentable. The NSSP's own dilution analysis methodology calculates fecal coliform loading based on boat count and occupancy — not MSD presence — at a rate of 2×10^9 fecal coliforms per person per day. A cluster of 11–20 boats at an unqualified mooring area generates loading sufficient to shift adjacent shellfish growing area classifications, yet the current definition excludes this range from required sanitary survey consideration entirely. EPA CZARA guidance identified boating activities as a contributing source in the closure of millions of acres of East Coast shellfish-growing waters. Shellfish bioaccumulate fecal pathogens — including norovirus and hepatitis A virus — at concentrations far exceeding surrounding waters, creating direct, foreseeable risk of foodborne illness when growing area classifications do not account for all proximate pollution sources. This proposal closes that gap.
13. Cost Information	No cost.
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	Model Ordinance Effectiveness Review Committee
3. Affiliation	ISSC
4. Address Line 1	4801 Hermitage Rd
5. Address Line 2	
6. City, State, Zip	Richmond,VA
7. Phone	804-330-6380
8. Email	issc@issc.org
9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter I. Shellfish Sanitation Program Requirements for the Authority
11. Text of Proposal/ Requested Action	**@.01 Administration** A. **Scope.** (1) **The Authority shall establish a statewide shellfish safety and sanitation program to regulate:** (a) **The classification of shellfish growing areas;** (b) **The harvesting of shellfish;** (c) **Shellfish processing procedures and facilities;** (d) **Product labeling;** (e) **Storage, handling and packing;** (f) **Shellfish shipment in interstate commerce;** (g) **Shellfish dealers; and** (h) **Bivalve aquaculture.** (2) **All foreign countries shipping shellfish into the United States will have a memorandum of understanding or an equivalency agreement with the United States.** (3) **The regulatory responsibility for growing area and harvest control in federal waters will be the responsibility of the FDA and NOAA.** B. **State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A. Federal Agencies shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of growing areas and harvest control.** C. **Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be made available~~maintained in a central file and made available physically and/or electronically~~ to any interested person upon request, consistent with appropriate State and Federal law.** D. **Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation**

program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities. In the case of Federal Waters, if more than one agency is involved in the administration of the shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.

E. Administrative Procedures.

(1) The Authority shall have administrative procedures sufficient to:

(a) Regulate shellfish harvesting, sale, processing and shipment;

(b) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the State from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its State to purchase the shellstock;

(c) Detain, condemn, seize, and embargo shellfish; and

(d) Assure compliance with Shellfish Plant Inspection Standardization.

(2) In the case of Federal Waters, the FDA and NOAA shall have administrative procedures sufficient to regulate growing areas and harvest control.

F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness.

The Authority shall:

(1) Have a written protocol with the appropriate State agencies responsible for collecting epidemiological information related to reported foodborne illnesses. The protocol shall outline the procedure to ensure that all shellfish related illnesses are reported to the shellfish Authority(s); and

(2) Have written procedures for investigating incidents of ~~shellfish~~ foodborne illness~~disease~~.

G. Commingling.

(1) Except for any shellfish included in the Authority's commingling plan, the Authority shall not permit the commingling of shellfish.

(2) If the Authority permits shellfish product commingling, the Authority shall develop a commingling management plan. The plan shall:

(a) Minimize the commingling dates of harvest and growing areas;

(b) Define a primary dealer;

(c) Limit the practice of commingling to primary dealers;

(d) Limit commingling to shellfish harvested from specific growing areas within the State as identified by the Authority and purchased directly from harvesters; and

(e) Define how the commingled shellfish will be identified.

H. **Personnel training requirements for implementing the NSSP**

(1) **Shellfish Dealer Inspections**

(a) **Shellfish Standardization Officer (SSO) shall successfully complete:**

(i) the FDA standardization training course;

(ii) seafood HACCP; and

(iii) the field evaluation by a FDA standardization officer.

(b) **Shellfish Standardization Inspector (SSI) shall successfully complete:**

(i) the FDA standardization training course;

(ii) seafood HACCP; and

(iii) the field evaluation by a FDA standardization officer or the SSO.

(2) **Growing Area Classification**

(a) **Sanitary Survey Officer shall successfully complete:**

(i) the FDA growing area course; and

(ii) have a minimum of one (1) year of on the job experience in a NSSP growing area classification program within the shellfish sanitation program.

(3) **Patrol Enforcement**

(a) **Officers responsible for the patrol of shellfish growing areas shall obtain the following training:**

(i) basic law enforcement before assuming patrol duties;

(ii) shellfish control regulations before assuming independent patrol duties; and

(iii) updated shellfish control regulations at an interval deemed appropriate by the Authority.

(4) **Laboratory**

(a) **Laboratory Evaluation Officer (LEO) shall successfully complete:**

(i) the FDA Laboratory Evaluation Officer training course;

(ii) field standardization by a FDA LEO; and

(iii) have a minimum of two (2) years of shellfish laboratory experience or a laboratory background with a minimum of three (3) years of bench level experience with the method types that will be evaluated.

I. **Request for Emergency Consideration. In the event of a declared public health emergency or natural or man-made disaster, including activation of the State Emergency Response Plan, if the Authority is not in a position to operate the program in full compliance with NSSP program requirements, the Authority shall immediately notify the ISSC and the FDA. The FDA shall immediately conduct discussions with the Authority to reach a mutually acceptable resolution.**

Additional Guidance: Section IV Guidance Documents Chapter III. Section.02

@.02 Dealer Certification

A. **General**

(1) **A person requesting certification shall be subject to a comprehensive, onsite inspection and meet the criteria in Section B. or Section C., as appropriate. The plant inspection shall be conducted by the SSO or SSI, using the appropriate inspection form, within the 120-day period immediately prior to the issuance or renewal of the certification.**

(2) **Certification shall be given only to persons who meet the established requirements established for certification.**

(3) **All certifications shall expire annually. The month selected for certification expiration shall be at the discretion of the Authority.**

(4) **The Authority shall issue only a unique~~one~~ certification number to a dealer for a location. A person or dealer may obtain more than one certification if each business is maintained as a separate entity.~~:~~**

~~(a) Maintained as a separate entity; and~~

~~(5) Is not found at the same location.~~

~~(6)~~(5) **The Authority may permit separate certified dealers to share a facility.**

~~(7) The certification number issued to each dealer by the Authority shall be unique.~~

~~(8)~~(6) **Adequate records documenting each dealer's compliance with certification requirements shall be maintained for at least three (3) years. These records shall include:**

(a) **Inspection reports of dealers;**

(b) **Notification letters and enforcement actions;**

(c) **Shellfish sample results and follow-up actions taken;**

(d) **Records of complaints or inquiries and follow-up actions taken; and**

(e) **Administrative hearing transcripts and records.**

B. **Initial Certification.**

(1) **Initial certification shall be given only to persons who meet the following requirements:**

(a) **HACCP requirements:**

(i) **A HACCP plan accepted by the Authority;**

(ii) **No critical deficiencies;**

(iii) **Not more than two (2) key deficiencies; and**

(iv) **Not more than two (2) other deficiencies.**

(b) **Sanitation and additional Model Ordinance Requirements**

(i) **No critical deficiencies;**

(ii) **Not more than two (2) key deficiencies; and**

(iii) **Not more than three (3) other deficiencies.**

(2) **The initial certification shall include a compliance schedule to correct any deficiencies not corrected by the**

dealer during the inspection.

~~(2)~~**(3) Provide proof of training for employees in accordance with Chapter X .04A 2.(c).**

C. **Renewal of Certification.**

(1) **A dealer shall make application for certification renewal annually at the time specified by the Authority. The Authority shall not renew the certification for any dealer until the dealer:**

(a) **Meets the requirements of Section B. 1. (a) and Section B. 1. (b). The number of deficiencies allowed under Section B. 1. (a) and Section B. 1. (b) shall include carry over deficiencies from an existing compliance schedule approved by the Authority and new deficiencies identified during the certification renewal inspection; and**

(b) Agrees to a compliance schedule to address any new deficiencies not corrected by the dealer during the inspection.

~~(b)~~**(c) Provides proof of training for employees in accordance with Chapter X .04A 2.(c).**

D. **Revocation or Suspension of Certification.**

(1) **The Authority shall not allow any dealer whose certification has been suspended or revoked under Section H. to deal in shellfish.**

(2) **The Authority shall not issue certification to a dealer whose certification has been suspended or revoked to deal in shellfish until the dealer meets the requirements for initial certification.**

E. **Interstate Certified Shellfish Shippers List (ICSSL).**

(1) **When the Authority certifies a person to become a dealer, the Authority shall notify the FDA for the purpose of having the dealer listed in the ICSSL. The Authority shall include the certification type and any permit designation to be included in the ICSSL. The notice shall be in the format of FDA Form 3038.**

Designations:

Certification	Permit
SP – Shucker Packer	PHP – Post-Harvest Proce
RP – Repacker	AQ – Aquaculture
SS – Shellstock Shipper	WS – Wet Storage
RS – Reshipper	
DP – Depuration	

(2) **The Authority shall notify the FDA by updating Form 3038 for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is suspended, revoked or cancelled.~~:~~**

~~**(a) Suspended; or**~~

~~**F. Revoked.**~~

~~**G.**~~**F. Inspections.**

	(1) **After any person is certified, the Authority ~~shall~~should make unannounced inspections of the dealer's facilities:** (a) **During periods of activity; and** (b) **At the following minimum frequencies during the period of certification:** (i) **Within thirty (30) days of beginning activities if the dealer was certified on the basis of a pre-operational inspection;** (ii) **At least monthly for dealer facilities certified as depuration processors;** (iii) **At least triannually for dealer's activities certified as shucker-packer or repacker; and** (iv) **At least semiannually for other dealer activities or annually for seasonal other dealer activities that are certified for six (6) months or less.** (2) **The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation within a reasonable time of completing the inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Ordinance.** ~~H.~~G. **Performance Based Inspection Program (PIP).** (1) **A PIP may be instituted by the Authority for any dealer who meets the requirements of this section.** (2) **The minimum frequency of inspection under a PIP shall be no less than one (1) inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.** (3) **To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three (3) year period. The three (3) year demonstration shall include:** (a) **Full compliance with the minimum inspection frequency shown under Section F.;** (b) **Recertification of the dealer by the Authority;** (c) **Verification that no critical deficiencies, no more than one (1) key deficiency and no more than two (2) other deficiencies have occurred in any one (1) inspection;** (d) **Correction of all identified deficiencies in accordance with the compliance schedule approved by the Authority; and** (e) **No repetition of the identified deficiencies.** ~~I.~~H. **Enforcement.** (1) **General.** (a) **The Authority shall use any combination of administrative hearings, fines, certification cancellations, temporary suspension of operating licenses, embargoes, product condemnations or product**

seizures to accomplish the implementation of this Ordinance.

(b) When a dealer has failed to meet the compliance schedule, the Authority shall:

(i) Consider whether it is appropriate to revise the compliance schedule, suspend or revoke the dealer's certification, or seek other administrative remedies; and

(ii) Document why an option was selected.

(2) Actions Triggered by Inspections.

(a) When any inspection detects a critical deficiency:

(i) The deficiency shall be corrected during that inspection; or

(ii) The dealer must cease production affected by the deficiency.

(b) When the dealer fails to comply with (a) above, the Authority shall immediately begin actions to suspend or revoke the dealer's certification.

(c) Product affected by a critical deficiency shall be controlled to prevent contaminated or adulterated product from reaching consumers. When necessary the Authority shall:

(i) Detain or seize any undistributed lots of shellfish that may have been adulterated;

(ii) Initiate a recall of any distributed shellfish; and

(iii) Immediately notify the enforcement officials for FDA and any other Authorities where the product was distributed.

(d) When any inspection detects any key or other deficiencies not already covered in a compliance schedule, the Authority, working with the dealer, shall develop a compliance schedule to correct the new key or other deficiencies.

(e) When any inspection detects four (4) or more new key deficiencies, the Authority shall consider at least one of the following options and document the reasons for the selection of a particular option:

(i) Revise the existing compliance schedule;

(ii) Suspend or revoke the dealer's certification; or

(iii) Seek other administrative remedies.

@.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; and

c. Evaluate the effectiveness~~validity~~ of the elements of

the NSSP Guide for the Control of Molluscan Shellfish.

2. **The minimum components of shellfish program evaluation shall include:**
   a. **A description of the program activity;**
   b. **A comparison of FDA observations with State observations; and**
   c. **A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.**
3. **The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish.**
4. **The types of data collected shall include the following:**
   a. **Program records;**
   b. **Direct observation made by the evaluator; and**
   c. **Data and information from the Authority or other pertinent sources.**

B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:

1. **Laboratory**
   a. **Requirements for evaluation of shellfish laboratories shall include at a minimum:**
      i. **Records audit of laboratory operations both Quality Systems and Technical methods;**
      ii. **Direct observation of current laboratory operating conditions; and**
      iii. **~~Information collection from the Authority and other pertinent sources concerning laboratory operations.~~Other relevant information collected from the Authority.**
   b. **Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists found in Section IV Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.**
      i. **Quality System Evaluation.**

      This checklist includes a conforming and nonconforming status only. All nonconformities must be reconciled prior to scheduling an onsite evaluation of technical methods in NSSP laboratories. As this part of the evaluation specifically refers to the Quality manual and SOPs and other documentation considered the basis for data defensibility, this documentation must be in order prior to further Laboratory Evaluation Officer (LEO) scheduling. The

	Quality Systems evaluation is performed as a desk audit and is in accordance with the checklist found in Section IV Chapter II. ii. **Technical Evaluation: Shellfish Laboratory will be technically evaluated and will be assigned the designation of conforms, provisionally conforms or non-conformance. The criteria used in determining the evaluation designations are included in the NSSP Shellfish Laboratory Evaluation Checklist designated for the specific type of laboratory evaluation being performed. (For more information see Section IV. Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.)** c. **Corrective Actions for Conforming Status. A laboratory found to be in conforming status for technical checklists, other than the Quality Systems checklist, has up to ninety (90) days to successfully correct all nonconformities noted in each component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory's status will be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component in question.** d. **Corrective Actions for Provisionally Conforming Status. A laboratory found to be in provisionally conforming status for technical methods checklists has up to sixty (60) days to successfully correct all nonconformities found in each provisionally conforming component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory will be assigned the following status for the laboratory component(s) in question:** i. **Conforms if all the critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated; or** ii. **Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluated or if the lab is not able to be evaluated because of a nonconforming Quality System. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component**

in question.

e. **Nonconformance.**

i. **Upon a determination of nonconforming status in any of the technical method components, the laboratory has up to thirty (30) days to demonstrate successful correction of all nonconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming for the laboratory component(s) in question. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory components will continue to be unacceptable for use in support of the NSSP.**

ii. **Upon a determination of nonconformance for the Quality Systems component, the laboratory will have to successfully implement a quality system prior to the onsite technical evaluation. Once all nonconformities are reconciled successfully, a technical evaluation for NSSP methods using the appropriate method specific NSSP Shellfish Laboratory Evaluation Checklist will be scheduled with the laboratory.**

iii. **When a laboratory is found to be nonconforming in either the technical or quality component or in both components for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority will ensure that an action plan is developed to correct the situation in an acceptable and expeditious manner or discontinue use of the laboratory to support the NSSP.**

iv. **For each laboratory component evaluated, the laboratory will be reevaluated either on-site or through a thorough desk audit as determined by the FDA Shellfish LEO and the FDA certified State Shellfish LEO if one is utilized by the State. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP for the laboratory components in question.**

2. **Growing Areas**

Requirements for evaluation of the shellfish growing area program element shall include at a minimum:

a. **Records audit of sanitary survey;**

b. **Bacteriological standards;**
c. **Growing area classification;**
d. **Marine biotoxin control; and**
e. **Marinas.**

3. **Patrol**

a. **Requirements for evaluation of shellfish growing area patrol elements shall include at a minimum:**
   i. **Records audit of past patrol activities;**
   ii. **Direct observation of current patrol activities; and**
   iii. **Information collection from the Authority and other pertinent sources.**

b. **Legal Penalties – Chapter VIII. @.01 A. (2) (c) Are there penalties in place to address illegal harvest?**
Compliance Criteria: The patrol element will be deemed in compliance if laws and regulations exist that provide penalties for controlling harvest from harvest restricted areas. [Critical]

c. **Notification of Harvest Restricted Areas – Chapter VIII. @.01 A. (2) (d)**
Is the industry notified of the boundaries of Harvest Restricted Areas? – Chapter VIII. @.01 A. (3) (b)
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the appropriate Authority demonstrates that the industry has been notified of the boundaries. [Critical]

d. **Comprehensive Listing of Harvest Restricted Areas – Chapter VIII. @.01 A. (3) (b)**
Does the Patrol Agency have a comprehensive listing of Harvest Restricted areas?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the Authority has a comprehensive listing of all Harvest Restricted areas. [Critical]

e. **Patrol Policy Document – Chapter VIII. @.01 B. (6).**
   i. **Does the Patrol Agency have a patrol policy document?**
   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Authority provides a patrol policy document. [Key]
   ii. **Is the patrol policy document complete?**
   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the patrol policy document includes all items in Chapter VIII. @.01 B. (7) listed below. [Key]
      (a) **Citation of the law providing the legal basis for enforcement authority**
      (b) **Citation of the laws and regulations, including**

	penalties, which are directly related to effective control of illegal harvest activities; (c) **The organizational structure of the unit responsible for patrol activities, including:** (1) **Patrol unit(s) name, address, and phone number;** (2) **The roster and chain of command;** (3) **Area assignments that support the frequencies of patrol delineated in B. (2); and** (4) **A listing of specific vessels, vehicles, and equipment that support the frequencies of patrol delineated in @.01 B. (2);** (d) **Summaries of training in shellfish patrol techniques;** (e) **The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;** (f) **A listing of growing areas where patrol is required;** (g) **An identification of any patrol problems;** (h) **The type and frequency of reporting by patrol personnel;** (i) **Copy of agreements with other agencies responsible for shellfish control activities; and** (j) **Citations/summons for the past year. If available, this information may include:** (1) **The number of convictions or dismissals;** (2) **Fines in dollar amount;** (3) **Equipment or property confiscations and forfeitures;** (4) **License suspensions or revocations; and** (5) **Jail sentences; and** (6) **Written warnings.** iii. **Is the patrol policy document updated annually?** **Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Authority can demonstrate that the patrol policy document is updated every calendar year. [Key]** f. **Officer Training – Chapter I. @.01 H. (3) (a) (i-iii)** **Has the Patrol Agency met the NSSP patrol training requirements?** **Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Agency can demonstrate that all officers have met or are scheduled for the training requirements of Chapter VIII. @.01 B. (6) before assuming their patrol duties [Key].** g. **Patrol Frequency – Chapter VIII. @.01 B. (2).** i. **Has the agency determined risk categories for all**

harvest restricted areas? – Chapter VIII. @.01 B. (4)?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Authority assigns risk categories for each harvest restricted area and provides a listing of those categories. [Critical]

ii. **Does a risk management plan exist if required? – Chapter VIII. @.01. B. (3) (c) and (d)**
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Authority has conducted a Risk Management Plan for all areas that are not patrolled at the frequency required in Chapter VIII.
@.01 B. (2). [Critical]

iii. **Has the patrol frequency requirement been met in all areas? – Chapter VIII.**
@.01 B. (3) (b), (c), and (d)
Compliance Criteria: The patrol element will be deemed in compliance as follows:

(a) **When the Authority achieved 95-100% of required patrols in all harvest restricted areas the program is considered to be in conformance with NSSP patrol frequency requirements.**

(b) **When the Authority achieved 80 – 94% of required patrols in all harvest restricted areas the program is considered to be in nonconformance with NSSP patrol frequency requirements. [Key]**

(c) **When the Authority achieved <80% of required patrols in all harvest restricted areas the program is considered to be in major non-conformance with NSSP patrol frequency requirements. [Critical]**

h. **Memorandum of Understanding/Agreements - Chapter VIII. @.01 B. (5). If enforcement of shellfish regulations is shared with another agency(s), is there a formalized MOU/MOA with the other agency(s)?**
Compliance Criteria: The patrol element will be deemed in compliance when the authority has developed a Memorandum of Understanding/Agreement with all Authorities which have delegated patrol responsibilities. [Key]

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 any patrol deficiency to the State patrol agency;**
iii. **Within thirty (30) days of the closeout meeting, the Shellfish Specialist shall provide a 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 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;**
vi. **Any CRITICAL item deficiency shall be corrected within thirty (30) days of acceptance by FDA of the correction plan;**
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.**

4. Plants

Requirements for evaluation of the shellfish plant inspection program elements shall include at a minimum:

a. **Records audit of past shellfish processing facility**

inspections;

b. **Direct observation of current shellfish processing facility conditions;**

c. **Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.**

d. **Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:**

i. **All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.**

ii. **95% of the certified dealers evaluated must have been inspected by the State at the frequency required by the current Guide for the Control of Molluscan Shellfish.**

iii. **Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.**

iv. **States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.**

v. **All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.**

e. **Plant Evaluation Criteria**

i. **Legal Authority – Chapter I @ .01 B.**
The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ 02. [Critical]

ii. **Initial Certification – Chapter I @ .02 B and C.**
The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below:

(a) **HACCP requirements:**

(i) **A HACCP plan accepted by the Authority**

(ii) **No critical deficiencies;**

(iii) **Not more than two (2) key deficiencies;**

(iv) **Not more than two (2) other deficiencies.**

(b) **Sanitation and additional Model Ordinance**

Requirements:
(i) **No critical deficiencies;**
(ii) **Not more than two (2) key deficiencies;**
(iii) **Not more than three (3) other deficiencies.**

iii. **Inspection frequency – Chapter I @ .02 F. and G.**
The Plant Sanitation Element will be deemed in compliance with this requirement when one (1) or less plants inspected doesn't meet the required inspection frequency.

iv. **Compliance schedules.**
The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the inspection reports~~the certified dealers~~ evaluated are found to be without schedules.

v. **Follow-Up.**
The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates that they have performed proper follow-up for compliance schedules for 90% of inspection reports~~dealers evaluated~~ and if the compliance schedules were not met that administrative action was taken.

vi. **Deficiency Follow-up.**
The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates that all critical deficiencies have been addressed.

vii. **In-Field Plant Criteria.**
Certified plants will be evaluated to determine compliance with the criteria listed below:
(a) **Shucker/packers and repackers HACCP requirements:**
(i) **A HACCP plan accepted by the Authority;**
(ii) **No critical deficiencies; and**
(iii) **Not more than four (4) key deficiencies.**
(b) **Shucker/packers and repackers sanitation and additional Model Ordinance requirements:**
(i) **No critical deficiencies; and**
(ii) **Not more than four (4) key deficiencies.**
(c) **Shellstock shippers and reshippers HACCP requirements:**
(i) **A HACCP plan accepted by the authority;**
(ii) **No critical deficiencies; and**
(iii) **Not more than three (3) key deficiencies.**
(d) **Shellstock shippers and reshippers**

sanitation and additional Model Ordinance requirements

(i) **No critical deficiencies; and**

(ii) **Not more than three (3) key deficiencies.**

viii.

f. **Conformance Designations**

i. **The overall Plant Sanitation Program element will be assigned one (1) of the following conformance designations based on compliance with the criteria listed in Chapter I. @.03 B. 4.:**

(a) **Conformance: The program is in compliance with all of the criteria listed in Chapter I. @.03 B. 4. e. i.-vi. and has 25% or fewer of plants with deficiencies as outlined in Chapter I. @.03 B. 4. e. vii.**

(b) **Provisional Conformance: The program is in compliance with Chapter I. @.03 B. 4. e. i - vi. and has 26% to 42% of plants with deficiencies as outlined in Chapter I. @ .03 B. 4. e. vii. For plant sanitation programs that have 26-42% deficiencies, the Authority can achieve a designation of conformance by successful completion of the actions listed in Chapter I. @.03 B. 4. f. ii. (b).**

(c) **Nonconformance: The program is in compliance with Chapter I. @.03 B. 4. e. i., but does not meet the criteria in Chapter I. @.03 B. 4. e. ii. or iii. or iv. or v. or vi. or has greater than 42% of plants with deficiencies as outlined in Chapter I. @.03 B. 4. e. vii.. Two consecutive FDA audits of Provisional Conformance will result in a conformance designation of Non-Conformance. This conformance designation requires an action plan as outlined in Chapter I. @.03 B, 4. f. ii. (c). the program has been deemed in Provisional Conformance on two consecutive FDA audits.**

(d) **Major Nonconformance: The program has multiple deficiencies. It is non-compliant with Chapter I. @.03 B. 4. e. i., or two (2) or more of Chapter I. @.03 B. 4. e. ii., or iii., or iv., or v., or vi., The failure of a state to develop and implement an acceptable and effective action plan.**

ii. **Each conformance designation will require the actions listed below:**

(a) **Conformance: The Authority will work cooperatively with the individual firms to correct deficiencies or develop deficiency-**

specific compliance schedules in plants audited by FDA.

(b) **Provisional Conformance: For plant sanitation programs that have 26-42% deficiencies, the Authority can achieve a designation of Conformance by successful completion of the actions listed below:**

(i) **Correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA within 30 days of the in-field closeout meeting. If there are any disagreements between the Authority and FDA an additional 15 days will be allowed to resolve differences.**

(ii) **The State must take one of the following actions.**

- **Within 30 days, the SSO will conduct an audit of the same number of plants as the original FDA evaluation to determine compliance with Chapter I. @.03 B. 4. e. vii., (The Authority will work with FDA to select the plants.); or**
- **Conduct inspections of all certified dealers within 120 days to identify and correct deficiencies. Within 30 days of completion of the inspections, the SSO will conduct an audit of the same number of plants to determine compliance with Chapter I. @.03 B. 4. e. vii. (The Authority will work with FDA to select the plants.)**

(iii) **Conduct a file review for the purpose of comparing FDA and SSO findings to previous inspections**

(iv) **Determine if inspector re-standardization or additional training is needed.**

(v) **Re-standardize and provide additional training for inspectors as needed.**

Should the SSO audit outlined in Chapter I. @.03 B. 4. f. ii. (b) (ii) above determine that compliance with Chapter I.@.03 B. 4. f. i. (a) the program will be reassigned a conformance designation of Conformance. This reassignment will be

acknowledged in FDA correspondence to the Authority.

Should the SSO audit outlined in Chapter I. @.03 B. 4. f. ii. (b) (ii) determine that the program is not in compliance with Chapter I. @.03 B. 4. f. i. (a), the program will be reassigned a designation of Nonconformance. This reassignment will be acknowledged in FDA correspondence to the Authority.

(c) **Nonconformance: The Authority must develop and complete an action plan that includes a plan to specifically address any deficiencies associated with Chapter I. @.03 B. 4. e. ii-vi. Should the designation of Nonconformance be the result of deficiencies associated with Chapter I. @.03 B. 4. e. vii the action plan shall include the following:**

- **(i) Correct deficiencies or develop deficiency-specific compliance schedules in plants audited by FDA within 30 days of the in-field closeout meeting. Should the state disagree with FDA regarding an identified deficiency(s), an additional 15 days will be allowed for resolution and/or correction of those specific deficiencies.**
- **(ii) Within 10 days of correcting the deficiencies identified in the FDA audit, the Authority shall request re-standardization of state SSO(s) by FDA.**
- **(iii) Within 60 days of SSO re-standardization by FDA, the SSO will conduct an abbreviated re-standardization of all inspectors using a minimum of 3 plants for the purpose of evaluating staff competency.**
- **(iv) Provide additional inspector training as determined by the Authority.**
- **(v) Following re-standardization, the state will conduct a state-wide compliance inspection of all plants (excluding plants audited by FDA). This activity must be completed within 120 days or another timeframe mutually agreed upon by the Authority and FDA.**
- **(vi) Within 30 days of completion of the state-wide compliance effort, the SSO will conduct an audit of the same number of plants to determine**

	compliance with Chapter I. @.03 B. 4. e. (The Authority will work with FDA to select the plants) **(vii) The state SSO will conduct a file review for the purpose of comparing FDA and SSO findings to previous inspections** **Failure to complete an effective action plan will result in a Conformance designation of major Non-Conformance.** **If Non-Conformance is the result of Provisional Conformance failure, an action plan would be required consistent with a conformance designation of Non-Conformance.** (d) **Major Non-Conformance: All determinations of Major Non-Conformance and the identification of deficiencies that pose imminent health concerns will be immediately reported to the ISSC Executive Board for consideration for appropriate action.** g. **FDA will follow the current compliance program for communication with the State agencies.** h. **All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Chapter I. @.03 B. 4. e.ii.** a.
12. Public Health Significance	N/A
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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	New Federal Waters Chapter
10. Specific NSSP Guide Reference	**Table of Contents** **Section II. Model Ordinance**: Chapter I. @.01; Chapter IV. @.01; Chapter IV. @.03; Chapter VI. @.03; Chapter VI. .07; Chapter VIII. .03; Chapter X. .09; **Section IV. Chapter XVII. .01 Federal Waters Guidance**
11. Text of Proposal/ Requested Action	**Table of Contents** **Section II. Model Ordinance…** Chapter VI. Shellfish Aquaculture Requirements for the Authority …~~@.03 Aquaculture in Federal Waters……64~~ Requirements for the Harvester/Dealer …~~.07 Requirements for the Harvester in Aquaculture in Federal Waters……67~~ Chapter VIII. Control of Shellfish Harvesting Requirements for Harvesters …~~.03 Shellstock Harvesting in Federal Waters……84~~ Chapter X. General Requirements for Dealers …~~.09 Shellfish Harvested from Federal Waters……98~~ Chapter XVIII. Federal Waters Federal Agencies .01 Requirements for the Harvester in Federal Waters .02 Requirements for Shellfish Aquaculture in Federal Waters

.03 Requirements for the Dealer Receiving Shellstock Harvested from Federal Waters

Section II. Model Ordinance

Chapter I. @.01 Administration

A. Scope…

(3) The regulatory responsibility for growing area and harvest control in federal waters will be the responsibility of the FDA and NOAA, in accordance with Section II, Chapter XVIII.

B. State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A. ~~Federal Agencies shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of growing areas and harvest control.~~

…

D. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities. In the case of federal waters where the state shellfish control Authority, in consultation with FDA and NOAA, chooses to be responsible for all or a portion of the marine biotoxin control of shellfish harvested from federal waters and landed at the associated state of landing certified shellfish dealer, a written agreement shall be developed between FDA, NOAA, and the state of landing Authority defining each agency's roles and responsibilities. ~~if more than one agency is involved in the administration of the shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.~~

E. Administrative Procedures.

…

~~(2) In the case of Federal Waters, the FDA and NOAA shall have administrative procedures sufficient to regulate growing areas and harvest control.~~

Chapter IV. Shellstock Growing Areas

@.01 Sanitary Survey

…

~~E. Sanitary surveys for Federal waters will be the responsibility of FDA. Sanitary surveys will be conducted in accordance with Chapter IV @.01, as applicable.~~

@.03 Growing Area Classification

…

~~F. FDA is responsible for the classification of growing areas in Federal waters. Federal waters are classified as Approved for shellfish harvesting unless such areas are known to be polluted (i.e., microbiological, chemical, or marine biotoxin hazards) and involve commercial shellfish resources. Should FDA allow harvesting in Federal waters with known marine biotoxin hazards, the FDA will classify the~~

~~harvest area in a manner equivalent to the requirements of Model Ordinance Chapter IV.~~

Chapter VI. Shellfish Aquaculture

Requirements for the Authority…

~~.@.03 Aquaculture in Federal Waters~~
~~A. Federal Agency Responsibilities. Once the appropriate permits for the construction of the aquaculture facility have been obtained,~~
~~(1) NOAA is responsible for establishing a contract, in consultation with FDA, with the aquaculture facility describing requirements of the NSSP including:~~
~~(a) the frequency with which NOAA will audit the aquaculture facility and vessels;~~
~~(b) testing requirements of the aquaculture facility; and~~
~~(c) the generation of product identification for traceability (i.e., tag numbers); and~~
~~(2) FDA is responsible for reviewing the aquaculture facility operational plan prior to the start of operations, as well as the annual inspection of records, to ensure adherence to NSSP requirements. FDA is also responsible for the classification of the growing area(s) associated with the aquaculture facility.~~

Requirements for the Harvester/Dealer
~~….07 Requirements for the Harvester in Aquaculture in Federal Waters~~
~~A. Prior to beginning any aquaculture activities, the person who performs aquaculture or operates an aquaculture facility to raise shellfish in Federal waters for human consumption shall obtain the appropriate permission(s) from Federal agencies as described in @.03.~~
~~B. Operational Plan. Each aquaculture facility shall have a written operational plan as described for Land Based Aquaculture in Section II Chapter VI .05(A). The operational plan shall also include:~~
~~(1)Description of harvest, tagging, handling, storage, transportation, and landing procedures;~~
~~(2)Description of a marine biotoxin management and contingency plan (Section II Chapter IV @.04) to include marine biotoxin sampling consistent with Section II Chapter IV @.04(B)(6) and ensure product segregation and control until biotoxin results confirm the shellfish do not contain biotoxins equal to or exceeding criteria established in Section IV Chapter II .08.;~~
~~(3)Description of a contingency in the event of an emergency situation or condition (e.g., sewage or oil spills); and~~
~~(4)Procedures for implementing product recalls.~~
~~C. Each aquaculture facility shall obtain a review from the FDA to ensure adherence to NSSP requirements prior to its implementation. If the aquaculture facility makes changes to the operational plan, they shall obtain a new review from the FDA to ensure adherence to the NSSP requirements.~~

Chapter VIII. Control of Shellfish Harvesting

…
Requirements for Harvesters

~~.03 Shellstock Harvesting in Federal Waters~~
~~A. The harvester shall obtain a NOAA contract to land commercial shellfish harvested from Federal waters at a state certified dealer. In addition, if applicable, obtain the required NOAA NMFS managed fisheries harvester license(s) and/or permit(s)~~
~~B. Prior to harvesting shellfish in Federal waters from an area in the controlled access status, the harvester shall:~~
~~(1) Enter into agreements or memoranda of understanding between the landing state~~
~~Authority, NOAA and the shellfish dealers receiving the shellfish as necessary to comply with the requirements outlined in NSSP MO, Chapter IV. @.04 B. and in accordance with Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.~~

Chapter X. General Requirements for Dealers
…
~~.09 Shellfish Harvested from Federal Waters~~
~~A. The dealer shall:~~
~~(1) If receiving shellstock harvested from Federal waters in the controlled access status, be party to agreement or memoranda of understanding between the Authority, NOAA and the individual harvesters as necessary to comply with the biotoxin controls outlined in the NSSP Chapter IV. @.04 B. and in accordance with Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.~~

Chapter XVIII. Federal Waters

Federal Agencies

Landing shellfish harvested from federal waters (those waters that fall outside of state and local jurisdiction but within U.S. sovereignty and are typically 3 to 200 nautical miles offshore) at a state certified shellfish dealer is considered “interstate commerce” under the Federal Food and Drug Cosmetic Act Sec. 201(b). As such, the regulatory responsibility for shellfish growing area and harvest control in federal waters is the responsibility of the FDA and NOAA.

Per Section II, Chapter I. @.01 D., in consultation with the FDA and NOAA, through a written agreement, a state shellfish control Authority may choose to be responsible for all or a portion of the marine biotoxin control of shellfish harvested from federal waters that is landed at an associated state of landing certified shellfish dealer. In this case, the FDA will evaluate the Authority’s role in federal waters marine biotoxin control during the state program evaluation process.

The NOAA Seafood Inspection Program (SIP) is the primary contact for all commercial shellfish harvesting activities in federal waters. This does not

	supersede the harvester's responsibilities to contact other federal agencies related to federal fisheries permits and aquaculture siting permits. To ensure the safety and quality of seafood, NOAA SIP provides a contract as the mechanism for the control of harvest and traceability for all commercial shellfish grown and harvested from federal waters. It is the responsibility of each shellfish harvester to contact NOAA SIP to apply for and obtain a contract to land shellfish harvested from federal waters at a state certified shellfish dealer. The NOAA SIP contract also provides the unique identifier number that will be used on federal waters shellfish harvester tags. The NOAA SIP will generate and maintain a NOAA SIP Contract Harvester List which can be accessed through the Interstate Shellfish Sanitation Conference (ISSC) website. The FDA is responsible for the classification and status of growing areas in federal waters. The FDA will coordinate with the NOAA SIP to notify harvesters of any microbiological water or shellfish tissue sampling requirements in federal waters through the NOAA SIP contract application process. The FDA is responsible for overseeing marine biotoxin control in federal waters. The FDA will coordinate with the NOAA SIP to notify harvesters of any marine biotoxin management requirements in federal waters through the NOAA SIP contract application process. The FDA, in coordination with the NOAA SIP, will provide a marine biotoxin contingency plan template for all federal waters growing and harvest areas addressing the management of PSP, ASP, NSP, DSP and AZP in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred, or an illness outbreak caused by marine biotoxins, per Section II, Chapter IV. @.04 A. The FDA, in coordination with the NOAA SIP, will determine and delineate shellfish growing and harvest areas in federal waters that meet the criteria and requirement for a marine biotoxin management plan in Section II, Chapter IV. @.04 B. The FDA, in coordination with the NOAA SIP, will provide a marine biotoxin management plan template to each harvester harvesting in an area in federal waters where biotoxins are required to be managed and a marine biotoxin management plan is required. Within the marine biotoxin management plan template, in consultation with the FDA and the NOAA SIP, the harvester will choose which marine biotoxin management strategy to use and which laboratory to use for biotoxin sample analyses. Per Section II, Chapter IV. @.04 B.(4)(d) & (e) and (5), as part of the marine biotoxin management plan, the use of the marine biotoxin management strategy, lot testing or pre-harvest shellfish toxicity screening coupled with lot testing, requires a written agreement or MOU between the state of landing Authority, NOAA SIP, shellfish dealer(s), and the harvester. The written agreement will be reviewed by

	the FDA and the NOAA SIP before implementation of the marine biotoxin management plan. **.01 Requirements for the Harvester in Federal Waters** A. The harvester shall: (1) Obtain a NOAA contract to land commercial shellfish harvested from federal waters at a state certified dealer. In addition, if applicable, obtain the required NOAA NMFS managed fisheries harvester license(s) and/or permit(s). (2) Prior to harvesting shellfish in federal waters from an area in the controlled access status, the harvester shall enter into agreements or memoranda of understanding between the landing state Authority, NOAA, and the shellfish dealers receiving the shellfish as necessary to comply with the requirements outlined in Section II, Chapter IV. @.04 B. (3) Shellstock harvested from growing areas in the controlled access status shall be tagged with restricted shellstock tags (Section II, Chapter IV. @.04 C. (7)). (4) Meet the requirements for Section II, Chapter VIII .02 Shellstock Harvesting and Handling (5) In the event that federal waters shellfish harvesters are required to collect microbiological or marine biotoxin samples, to meet the laboratory requirements for the analysis of regulatory samples from federal waters, the harvester will be responsible for identifying and using a laboratory with an operational status of conforming or provisionally conforming to the requirements set forth by the NSSP and implement NSSP approved and/or approved limited use method for fecal coliform and marine biotoxin analysis (Section II, Chapter I @.03 B. 1.). **.02 Requirements for Shellfish Aquaculture in Federal Waters** A. The aquaculturist shall contact NOAA SIP to apply for and obtain a NOAA SIP contract to land commercial shellfish grown and harvested from federal waters at a state certified shellfish dealer. B. Each shellfish aquaculture facility shall have and implement a written site-specific operational plan ~~as described for Land Based Aquaculture in Section II, Chapter VI .05(A). The operational plan shall also~~ that includes: (1) A description of the design and activities of the culture facility; (2) The specific site and boundaries in which shellfish culture activities will be conducted; (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters; (4) The species of shellfish to be cultured and harvested; (5) The source of seed. All sources of seed produced or collected in prohibited waters shall be sanctioned by the FDA and NOAA SIP. (6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities; (7) A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;

(8) Description of harvest, tagging, handling, storage, transportation, and landing procedures;
(9) Description of a marine biotoxin contingency plan and, if required, a marine biotoxin management plan (Section II, Chapter IV. @.04) to include marine biotoxin sampling consistent with Section II, Chapter IV. @.04(B);
(10) Description of a contingency plan in the event of an emergency situation or condition (such as sewage or oil spills);
(11) If it is determined that the aquaculture site attracts sufficient birds and/or marine mammals that their waste presents a human health risk, include a description of the mitigation or deterrent measures to minimize the potential pollution impact of birds and/or mammals; and
(12) Procedures for implementing product recalls.
(13) Maintenance of the required records.

C. Each aquaculture facility shall obtain a review of the operational plan from the FDA and NOAA SIP prior to its implementation. If the aquaculture facility makes changes to the operational plan, they shall obtain a new review from the FDA and NOAA SIP.

.03 Requirements for the Dealer Receiving Shellstock Harvested from Federal Waters

A. The dealer shall:
(1) Only receive shellstock from harvesters in federal waters that have a NOAA contract and are on the Harvester Contract List.
(2) If receiving shellstock harvested from federal waters in the controlled access status with restricted tags, be party to agreement or memoranda of understanding between the Authority, NOAA, and the individual harvesters as necessary to comply with the biotoxin controls outlined in the Section II, Chapter IV. @.04 B.

GUIDANCE

Chapter XVII. Federal Waters

.01 Federal Waters Guidance

A. Introduction

~~Requirements for Federal waters shellfish harvesters, dealers, the State of Landing Authority and FDA and NOAA are listed in multiple sections throughout the NSSP Model Ordinance.~~ The following guidance provides additional information to assist in meeting the~~se~~ requirements for federal waters shellfish harvesters, dealers, the state of landing Authority, FDA, and NOAA.

B. Harvester Requirements

(1) HARVESTER LICENSING AND TRACEABILITY

	The ~~Food and Drug Administration (~~FDA~~)~~ and ~~the National Oceanographic Atmospheric Administration (~~NOAA~~)~~ are the federal agencies responsible for shellfish growing areas and harvest control in federal waters. The state of landing Authority, through written agreements and in coordination with the FDA and NOAA, may also ~~take the lead and/or take~~ choose ~~agree~~ to be ~~have~~ responsible~~ilities~~ for ~~the management, control of harvest, and/or~~ marine biotoxin control associated with commercial shellfish harvested from federal waters and landed in their state. The NOAA Seafood Inspection Program (SIP) is the primary contact for all commercial shellfish harvesting activities in federal waters. This does not supersede the harvester's responsibilities to contact other federal agencies related to federal fisheries permits and aquaculture siting permits. ~~To meet the requirement in the NSSP MO, Chapter VIII .03A. for Federal waters,~~ The NOAA SIP utilizes the NOAA SIP contract that serves as the mechanism for the control of harvest and traceability for all commercial shellfish grown and harvested from federal waters. It is the responsibility of shellfish harvesters to contact the NOAA SIP to obtain a NOAA SIP contract, which is the identified mechanism for authorizing harvesters to land shellfish harvested from federal waters at a state certified dealer. The NOAA SIP contract also provides the unique identifier number that will be used on federal waters shellfish harvester tags. The NOAA SIP contract application process requires that the harvester provide their contact information as well as the intended federal waters harvest and/or aquaculture site location information to the NOAA SIP. Harvester contact information will be used to contact each harvester in the event of an emergency closure (e.g., oil spill, hurricane, severe storm, chemical spill, WWTP spill, or ship discharge) and reopening, status change, classification change, and/or product recall. The NOAA SIP will generate and maintain a NOAA SIP Contract Harvester List which can be accessed through the Interstate Shellfish Sanitation Conference (ISSC) website for reference. The NOAA SIP will coordinate with the FDA regarding meeting the requirements related to the growing area classification, control of harvest, and marine biotoxin control of the intended area of harvest as well as shellfish aquaculture operation and initial siting evaluation. (2) Federal Waters Shellfish Classification

The FDA is responsible for the classification of federal waters shellfish growing areas. ~~(NSSP MO, Section II, Chapter IV @.03 F.). Federal waters are considered generally free from bacterial and chemical pollution and are therefore classified as approved for shellfish harvesting unless such areas are known to be polluted and involve commercial shellfish resources (Verber, 1977).~~ Areas known to be polluted or are considered potential sources of pollution in federal waters may include but are not limited to ocean dump sites designated for the disposal of contaminated wastes, areas where major estuarine complexes discharge large quantities of sewage effluents or other contaminants, wastewater treatment plant effluent pipes, commercial shipping channels and anchorages, and oil platforms.

When applying for the NOAA SIP contract, the harvester will provide the intended harvest location(s) to the NOAA SIP using either the 10-minute latitude and longitude grid number(s), the NOAA National Marine Fisheries Statistical grid, or the latitude(s) and longitude(s). The NOAA SIP will coordinate and provide the FDA with the intended harvest site location(s).

For shellfish harvest areas of concern, the FDA will conduct a site-specific sanitary survey in accordance with NSSP MO, Chapter IV. @.01, as applicable. Once the sanitary survey is completed, the FDA will coordinate with the NOAA SIP to notify the harvester of the sanitary survey findings, any growing area classification and/or status change, and if warranted, any microbiological and/or biotoxin monitoring requirements.

(3) Marine Biotoxins

To meet the NSSP MO, Chapter IV. @.04 requirements, once the harvester notifies the NOAA SIP of the intended harvest location(s) in federal waters, through coordination with the NOAA SIP, the FDA will review available data and determine if marine biotoxins are of concern and which marine biotoxin requirements apply to the harvester for the intended harvest and/or aquaculture site locations. The harvester will then be notified by the NOAA SIP of any marine biotoxin requirements.

If the harvester is harvesting from a location in federal waters where the associated ~~S~~state of ~~L~~landing Authority has agreed to be responsible for marine biotoxin control, the harvester must abide by the ~~S~~state of ~~L~~landing Authority marine biotoxin contingency plan and if applicable, marine biotoxin management plan.

i. MARINE BIOTOXIN CONTINGENCY PLAN

To meet the NSSP MO, Chapter IV. @.04 A. requirements, as a default, each harvester will abide by the FDA/NOAA SIP Marine Biotoxin Contingency Plan that addresses the management of paralytic shellfish poisoning (PSP), amnesic shellfish poisoning (ASP), neurotoxic shellfish poisoning (NSP), diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred, or an illness outbreak caused by marine biotoxins.

If applicable, in the case where the ~~S~~state of ~~L~~landing Authority chooses to be responsible for the control of marine biotoxins in federal waters, the harvester will follow the ~~S~~state of ~~L~~landing marine biotoxin contingency plan. The FDA will review the federal waters component in the ~~S~~state of ~~L~~landing Authority's marine biotoxin contingency plan during the state program growing area evaluation process.

ii. MARINE BIOTOXIN MANAGEMENT PLAN

To meet the NSSP MO, Chapter IV. @.04 B. requirements ~~(and in accordance with Section IV. Guidance Documents- Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans)~~, the FDA and NOAA SIP will work with other federal and associated state agencies as well as the shellfish industry to collect and review all available data to assist in identifying and delineating shellfish growing areas in federal waters that meet(s) the criteria and requirement for a marine biotoxin management plan. If harvesting in these designated areas, each harvester must utilize the FDA/NOAA SIP Marine Biotoxin Management Plan template and specify and abide by the marine biotoxin management strategy(ies) of choice, intended state of landing, and the laboratory to be used for marine biotoxin sample analysis.

In the case where the ~~S~~state of ~~L~~landing Authority has agreed to be responsible for the management of biotoxins and/or has an established a biotoxin management strategy(ies) for shellfish landed in their state from federal waters, each harvester must coordinate with the ~~S~~state of ~~L~~landing Authority to meet the marine biotoxin management plan requirements.

	In coordination with the NOAA SIP, the FDA will review all harvester marine biotoxin management plans for compliance with NSSP MO, Chapter IV. @.04 B. For marine biotoxin management plans associated with federal waters managed by the ~~S~~state of ~~L~~landing Authority, the FDA will evaluate these management plans during the state of landing growing area program evaluation. In addition, to meet the requirements for marine biotoxin management strategies that include shellfish lot testing or pre-harvest shellfish toxicity screening coupled with lot testing [NSSP MO, Chapter IV. @.04 B.(4)(d) & (e) and (5)] and allow the landing of shellfish harvested in a growing area that is placed in the controlled access status, the harvester will be required to enter into ~~an~~ a written agreement or memoranda of understanding (MOU) between the ~~S~~state of ~~L~~landing Authority, individual growers, individual shellfish dealers, and NOAA SIP. At a minimum, the agreement or MOU- should reference the marine biotoxin management plan and include language indicating that all parties~~signatories~~ agree with and will abide by the marine biotoxin management plan. The FDA and NOAA SIP will review the agreement or MOU for NSSP compliance. To meet the restricted tag requirement of the NSSP MO, Chapter IV. @.04 C. (7), all shellstock harvested from growing areas in the controlled access status shall be tagged with restricted shellstock tags. Information included on the restricted shellstock tag should include specific details defining the restriction. iii. LABORATORY REQUIREMENTS FOR SAMPLE ANALYSES To meet the laboratory requirements for the analysis of regulatory samples from federal waters, the harvester will be responsible for identifying and using a laboratory with an operational status of conforming or provisionally conforming to the requirements set forth by the NSSP and implement NSSP approved and/or approved limited use method for fecal coliform and marine biotoxin analysis. For guidance on available laboratories, the harvester may refer to the Interstate Shellfish Sanitation Conference (ISSC) website for the Domestic NSSP Laboratory List. (4) Vibrio Risk Assessment & Time/Temperature Control The harvester is responsible for meeting the requirements in the NSSP MO, Chapter VIII. @.02 & Chapter II. @.06 &

@.07. To meet this requirement, the harvester must meet the time to temperature matrix found in the NSSP MO, Chapter VIII. @.02 A. (3) or if the risk of *Vibrio parahaemolyticus* or *Vibrio vulnificus* illness has been determined to be reasonably likely to occur, then they must meet the defined Vibrio Control Plan for the area.

(5) Harvester Training

To meet the NSSP MO, Chapter VIII. .01 B. harvester training requirement, each harvester will ~~be provided an electronic harvester training document~~ be provided with training during the application process for the NOAA SIP contract.

(6) Shellfish Aquaculture Operational Plan

~~Per the NSSP MO, Chapter VI .07 B., e~~Each federal waters shellfish aquaculture harvester ~~site~~ is required to develop and maintain a farm site-specific Operational Plan. During the NOAA SIP contract application process, each Operational Plan will be provided to the NOAA SIP by the harvester for review by the FDA and NOAA SIP to ensure that it meets the NSSP requirements. The Operational Plan must at a minimum, include all items from the NSSP MO, ~~Chapter VI. .05 A. and~~ Chapter XVIII .02~~VI. .07 B~~.

(7) Finalize NOAA SIP Contract

Once all the harvester requirements have been reviewed and found to conform with the NSSP MO by the FDA and NOAA SIP, the NOAA SIP contract may be finalized with signatures, an effective date, and the contract number assigned by NOAA SIP to be used as the shellfish harvester's tag number. The finalized NOAA SIP contract will be added to the NOAA SIP Contract Harvester List located on the ISSC website.

C. Dealer Requirements

To meet the requirement for state shellfish dealers listed on the Interstate Certified Shellfish Shippers List (ICSSL) to only accept shellfish harvested from federal waters from a harvester with a NOAA SIP contract, the dealer may go to the ISSC website and review the NOAA SIP Contract Harvester List to verify that a federal waters harvester has a valid NOAA SIP contract.

When receiving shellstock harvested from federal waters in the controlled access status, the dealer must agree to be a party to a written ~~to be a signatory to an~~ agreement or MOU ~~to~~ and abide by the marine biotoxin management plan. In addition, the marine biotoxin management plan will include specific language detailing the use of the

	restricted shellstock tag(s) as well as restrictions that require further processing and testing prior to the distribution of the shellstock into commerce. References ~~1. Verber, 1977, Classification of Offshore Waters, James L. Verber~~ ~~2~~1. NOAA SIP Contract a. NOAA SIP Contract information (click here) b. Harvester Contract List (click here) ~~3~~2. ~~State of landing shellfish contacts (click here)~~ ~~4~~3. ~~FDA/NOAA SIP Marine Biotoxin Contingency and Management Plan (click here)~~ ~~5~~2. NSSP Conforming Laboratories (click here)
12. Public Health Significance	The Model Ordinance was organized by state shellfish control Authority (Authority), harvester, and dealer requirements. The Authority requirements are identified by using the "@" symbol. Federal waters shellfish control requirements are the responsibility of federal agencies (FDA and NOAA) and have over time been inserted throughout the Model Ordinance and under various sections designated as requirements for the Authority. The FDA and NOAA do not fall under that category so, this proposal consolidates the federal waters requirements into one chapter in the Model Ordinance.
13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	Chapter XVII. Federal Waters .01 Federal Waters Guidance

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	David Borkman[1], Bryant Lewis[2], Matt Richards[3], Christian M. Petitpas[4]
3. Affiliation	Rhode Island Department of Environmental Management[1]; Maine Department of Marine Resources[2] ; New York Department of Environmental Conservation[3]; Massachusetts Division of Marine Fisheries[4]
4. Address Line 1	235 Promenade Street1; 194 McKnown Point Road[2]; 123 Kings Park Blvd[3]; 706 South Rodney French Boulevard[4]
5. Address Line 2	
6. City, State, Zip	Providence, RI 02908[1]; West Boothbay Harbor, ME 04575[2]; Kings Park, NY 11754[3]; New Bedford, MA 02744[4]
7. Phone	401-537-4203[1] 207-633-4700[2]; 631-444-0491[3]; (508) 742-9766[4]
8. Email	david.borkman@dem.ri.gov [1]; Bryant.j.lewis@maine.gov [2]; matt.richards@dec.ny.gov[3]; christian.petitpas@mass.gov[4]
9. Proposal Subject	Clarification of illness investigation timing and precautionary growing area closure during illness investigation
10. Specific NSSP Guide Reference	Section II, Chapter II, @.01 B (2) and @.01 E (1-3)
11. Text of Proposal/ Requested Action	Section II, Chapter II, @.01 B (2) B. When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption, the appropriate Authorities shall: (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) Within twenty-four (24) hours initiate the investigation to determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source state. (3) When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall: (a) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status. Should the Authorities later determine that the illnesses are related to post-harvest contamination, or mishandling, or harvested from a closed area, the suspected growing area can be reopened. (b) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate. (c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective. AND Section II, Chapter II, @.01 E (1-3) ~~(3) When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall: (1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status. Should the Authorities later determine that the illnesses are related to post harvest contamination, or mishandling, or harvested from a closed area, the suspected growing area can be reopened.~~ ~~(2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate.~~ ~~(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective.~~

12. Public Health Significance	The proposed change clarifies the distinction between precautionary growing area closure and growing area closures during the initial phase of an illness investigation and does not reduce public health protection. Existing language in the 2023 MO requires determination of the cause(s) of shellfish-related illness within 24-hours ("…Authorities shall: Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting…" (Section II, Chapter II, @.01 B (2)); and then in Section II, Chapter II, @.01 C requires that, lacking initial evidence of post-harvest contamination, etc., implicated growing areas be immediately placed in the closed status, with a series of actions required to reopen the closed area(s) outlined in Section II, Chapter II, @.01 F. However, in Section II, Chapter II, @.01 E current MO language allows implicated growing area(s) to immediately placed in the precautionary closed status *if the Authority can not make an illness determination within 24 hours* (Section II, Chapter II, @.01 E(1)). The proposed language would require that the Authorities initiate illness investigation within 24 hours and place implicated growing area(s) into the precautionary closed status during that investigation. If subsequent investigation identifies non-growing area causes of contamination (post-harvest handling, illegal harvest, etc.) then precautionarily closed areas can be reopened immediately, the same as stipulated in existing 2023 MO language in Section II, Chapter II, @.01 E (1). If the investigation identifies the growing area as the cause of illness, then the implicated growing area(s) will be changed from the precautionary closed to the closed status immediately upon that determination, with the reopening criteria in Section II, Chapter II, @.01 F applied prior to reopening the implicated closed area(s). The proposal also seeks to move unmodified language of Section II, Chapter II, @.01 E forward so that it becomes Section II, Chapter II, @.01 B (3) (a-c) to clarify the timing of precautionary closure of implicated growing area(s) during the investigatory period. No language changes are proposed for Section II, Chapter II, @.01 E of the current MO; only the above-described relocation of that text for clarity is proposed.
13. Cost Information	No additional costs are associated with the proposed changes.
14. Changes Needed to Guidance (if proposed change is adopted)	Guidance in Section IV. Guidance Documents – Chapter II Risk Assessment and Risk may need minor revision to reflect the distinction between a precautionary closure during the period of investigation versus a growing area closure if the investigation identifies the growing area is responsible for the illness.

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	Model Ordinance Effectiveness Review Committee
3. Affiliation	ISSC
4. Address Line 1	4801 Hermitage Rd
5. Address Line 2	
6. City, State, Zip	Richmond,VA
7. Phone	804-330-6380
8. Email	issc@issc.org
9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter II. Risk Assessment and Risk Management
11. Text of Proposal/ Requested Action	**@.01 Outbreaks of Shellfish-Related Illness** A. **When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the determination of whether an epidemiological association exists between the illness and the shellfish consumption will be made by the state or local epidemiologist in the state in which the outbreak occurs. The determination will be made by reviewing:** (1) **Food history;** (2) **Whether the disease has the potential or is known to be transmitted by shellfish; and** (3) **Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.** **NOTE: For additional guidance refer to the International Association for Food Protection *Procedures to Investigate Food Borne Illness*.** B. **When the state or local epidemiologist in the state in which the outbreak occurs has determined an epidemiological association between an illness outbreak meeting the definition of the NSSP and shellfish consumption, the appropriate Authorities shall:** (1) **Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred.** (2) **Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting from a closed area. The determination of post-harvest contamination may involve multiple authorities in multiple states. The determination of the illness being growing area related will be conducted by the source**

state.

C. **When the Authorities determine that the outbreak is not the result of a post-harvest contamination problem or illegal harvesting from a closed area, the Authority shall determine if the outbreak is from a single source or multiple sources.**

(1) **When the Authority determines that a single source outbreak has occurred, the Authority shall:**

(a) **Immediately place the implicated portion(s) of the harvest area(s) in the closed status;**

(b) **Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;**

(c) **Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when a recall is deemed appropriate by the Authority. The recall shall include all implicated products.**

(d) **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.**

(e) **The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.**

(2) **When the Authority determines that a multiple source outbreak has occurred, the Authority shall immediately place the implicated portion(s) of the harvest area(s) in a precautionary closure. A specific growing area placed in a precautionary closed status under this section can be immediately re- opened when one (1) or more of the following conditions are met:**

(a) When the investigation, conducted in consultation with epidemiologist(s) in the state(s) in which the outbreak occurs, determines that the shellfish which caused the outbreak did not come from one (1) or more of the implicated growing areas in question based on consumption data provided by victims or other relevant data provided by state investigators. This would include an additional illness(es) that matches one (1) or more of the implicated areas and allows for a more precise identification of the growing area(s) which caused the outbreak.

(b) When an investigation, in accordance with Chapter II @ .01 H, of an implicated growing area identifies an actual or potential pollution source(s) in a specific growing area and no source(s) are identified in other implicated

growing areas, the precautionary closures in other implicated growing areas can be reopened. The reopening can only occur in a growing area after the investigation referenced above does not indicate an actual or potential pollution source that could be the cause of the outbreak.

(c) When the investigation, conducted in consultation with the epidemiologists in the state(s) in which the illnesses occur and the Authorities in the state from which the shellfish were harvested, provides information that may include but shall not be limited to:

(i) Volume or distribution information which would implicate a specific growing area;

(ii) Illness reporting from immediately adjacent growing areas;

(iii) Pollution source investigation in conjunction with growing area evaluation does not identify a pollution source.

(iv) Epidemiological tools that would link cases based on genetic similarity.

(3) When precautionary closures are established to address an illness outbreak involving multiple sources, Authorities will not be required to initiate voluntary recalls until the investigations indicate a single source.

D. **When the appropriate Authorities determine that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority in the state where the post-harvest contamination, mishandling or illegal harvesting from a closed area occurred shall:**

(1) **Notify the ISSC and the FDA Shellfish Specialist of the problem; and**

(2) **Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 when a recall is deemed appropriate by the Authority . The recall shall include all implicated products.**

(3) **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.**

(4) **The ISSC will notify States and FDA Shellfish Specialists of ~~growing area closures and~~ recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. ~~Closure and r~~Recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of ~~closure and~~ recall information.**

E. **When the Authority can not complete the determination outlined in Chapter II. @.01 B. within 24 hours, the Authority in the source state shall:**

(1) **Immediately place the implicated portion(s) of the**

harvest area(s) in a precautionary closed status. Should the Authorities later determine that the illnesses are related to post-harvest contamination, or mishandling, or harvested from a closed area, the suspected growing area can be reopened.

(2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority deems appropriate.

(3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, when the authority can document a rationale that a recall would be effective.

F. **Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:**

(1) Shall follow an existing marine biotoxin contingency/management plan, if appropriate.

(2) Shall collect and analyze samples relevant to the investigation, if appropriate.

(3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.

(4) Shall follow the procedure outlined in Chapter II @ .02 A. (10)(a) or (b) for closures resulting from *V.p.* illnesses.

(5) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

G. **When the growing area is determined the problem, the Authority shall:**

(1) Place the growing area in the closed status until:

(a) The Authority verifies that the area is properly classified by conducting a review of the growing area to include:

i. current data, in compliance with the NSSP Model Ordinance;

ii. A field review of existing pollution sources;

iii. A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems. If a previously unknown pollution source can be corrected, the closure period shall be extended to allow for natural depuration following correction of the pollution source; and

iv. Examination of water quality subsequent to the illness outbreak.

(b) It has been determined that the event which caused the contamination no longer exists and sufficient time has elapsed for natural depuration;

(2) Keep the area closed until at least 21 days have passed from the last date of harvest of the implicated shellstock if the illness is consistent with viral etiology; and

(3) Develop a written report summarizing the findings of the

investigation and actions taken.

H. **Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, ISSC and the Authorities in other States involved in the recall. The Authority shall submit periodic recall status reports to the FDA Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 CFR Part 7, Subpart C, Section 7.53 (b) (1- 6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the State of product origin regarding recall efforts within their State until such time that the Authority in the State of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any State involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.**

I. **Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v., V.p.* or Norovirus may be reconditioned.**

(1) **Validated reconditioning processes for *V.v.* and *V.p.* include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.**

(2) **Product associated with a Norovirus outbreak may be reconditioned by returning the product, within ten (10) days of harvest, to the area from which it was harvested for an appropriate period of time. Environmental conditions in the harvest area must be conducive for pumping and feeding. The period of time shall not be less than sixty (60) days. The Authority shall ensure appropriate controls and provide documentation of the activity**

@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*

A. **When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically**

associated with the implicated area. States will not be expected to close growing areas based on *V.p.* cases that are reported more than thirty (30) days after harvest or when environmental parameters have changed or monitoring indicates the *V.p.* risk is reduced. Actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) **When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.**

(2) **When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall:**

- (a) **Determine the extent of the implicated area; and**
- (b) **Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and**
- (c) **As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.**

(3) **When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall:**

- (a) **Determine the extent of the implicated area; and**
- (b) **Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and**
- (c) **Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.**
- (d) **Issue a consumer advisory for all shellfish (or species implicated in the illness).**

(4) **When the number of cases and the span of time reach the thresholds outlined above, prior to implementing the controls above, the Authority shall conduct an investigation of the illnesses within seventy-two (72) hours of reaching any one (1) of the thresholds of Chapter II @.02 A. (1), (2) or (3) to determine whether**

	the illness is growing area related or is the result of post-harvest abuse or mishandling such as time temperature abuse. (a) **If the conditions in Chapter II @.02 A. (2) or (3) are met and the investigation cannot be completed within 72 hours, immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status.** (b) **Should the Authority later determine that the illnesses are related to post harvest abuse or mishandling the implicated harvest area(s) can be immediately reopened.** **(5) When the investigation outlined in Model Ordinance Chapter II. @.02 A. (4) demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:** (a) **Notify the ISSC and the FDA Shellfish Specialist of the problem; and** (b) **Determine the appropriateness of initiating a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.** (c) **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish; Should closures and recalls be necessary the ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.** (6) **When the investigation outlined in Model Ordinance Chapter II. @.02 A.(4) does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:** (a) **Follow the procedures outlined in Chapter II @.02 A. (1), (2) and (3).** (b) **Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;** (c) **If a recall is required by Chapter II @.02 A. (3)** i. **Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.**

ii. **The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.**

(7) **When the State Authority investigating the laboratory confirmed *V.p.* cases does not provide information to identify a single growing area and multiple growing areas are implicated, the State Authorities in the states with implicated growing areas shall evaluate to determine if the illness should be attributed to the implicated area(s). Evaluations may include but are not limited to:**

(a) Vibrio levels in the growing area around the time and date of harvest

(b) Comparison of other single source illnesses attributed to a growing area(s) involved in a multiple source outbreak. The purpose of this comparison would be to determine if a common growing area can be identified.

(c) Environmental conditions which could increase the risk of *V.p.* at the time of harvest. This could include conditions such as water temperature, air temperature and tidal stage.

(d) Genetic typing of clinical isolates implicates a common growing area or rules out implicated growing areas

(8) **If the evaluation in (7) provides sufficient information to implicate a single area, then the Shellfish Authority shall take actions outlined in A. (6), above.**

(9) **When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:**

(a) **The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area.**

(b) **The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area**

(10) **Prior to reopening an area closed as a result of @.02 A. (9)(a) or (b), the Authority shall:**

(a) **Collect and analyze samples to ensure that tdh does**

not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies.

(i) **Samples shall be collected to be representative of the area and shellfish types.; and**

(ii) **Multiple sample collection events shall span the closure time period in @.02 A. (9)(a) or (b) and be collected at intervals necessary to determine trends in the implicated area.**

;or

(b) **Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.**

(11) **Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls:**

(a) **PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;**

(b) **Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;**

(c) **Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.**

@. 03 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production

A. **The Authority shall assess annually *Vibrio vulnificus (V.v.)* and *Vibrio parahaemolyticus (V.p.)* CIDT cases or culture confirmed illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V.v.* and *V.p.* shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.**

B. **The Authority shall collect by month and report annually to the ISSC the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species. Where available the volume breakdown of the production data will be reported by utilization type (raw, shucked, PHP, etc.).**

@.04 Presence of Human Pathogens in Shellfish Meats

A. **Finding. Upon determination that human pathogens are present in shellfish meats, the Authority shall investigate the harvesting, the distribution, and the processing of the shellfish.**

B. **Growing Area Investigation.**

(1) **The Authority shall review the following factors:**

(a) **The documentation to trace the shellfish to its source;**

(b) **The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and**

(c) **The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.**

(2) **The Authority shall not be required to~~shall~~ take ~~no~~ further action when the Authority determines that:**

(a) **The growing area is properly classified;**

(b) **No evidence that illegal harvesting is taking place; and**

(c) **There is an absence of evidence~~no reason to believe~~ that the growing area is the source of the pathogens.**

(3) **When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:**

(a) **Change the existing classification to the correct classification; or**

(b) **Close the growing area until the correct classification can be determined; and**

(c) **Determine whether to initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.**

(4) **When the Authority determines that the growing area may be the source of pathogens and the pathogens exceed tolerance levels, the Authority shall request a voluntary recall by firms. The firms will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.**

(5) **When the Authority determines that illegal harvesting is taking place, the Authority shall determine whether to initiate a voluntary recall by firms. The firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.**

C. **Distribution and Processing Investigation.**

(1) **The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.**

(2) **The Authority shall not be required to take ~~no~~ further**

action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.

(3) **When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem and determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.**

D. **Risk Management and Tolerance Levels.**

(1) **Pathogen Present. When a growing area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification for an area.**

(2) **Established Tolerance Levels.**

(a) **When the established tolerance level for a particular pathogen isolate is not exceeded, the Authority:**

(i) **Shall maintain a written summary of its finding and the data supporting its finding in its central file; and**

(ii) **May leave the growing area in its present classification.**

(b) **When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of shellfish associated disease caused by that pathogen in a particular growing area, the Authority shall:**

(i) **Leave the area in the open status of its classification when the tolerance level is not exceeded; and**

(ii) **Place the area in the closed status of its classification when the tolerance level is exceeded.**

(c) **When the tolerance level is exceeded, the Authority may:**

(i) **Maintain the growing area in the closed status of its current classification;**

(ii) **Reclassify the growing area to the restricted or prohibited classification; or**

(iii) **Reclassify the growing area to the conditionally restricted classification and establish a management plan.**

(d) **Any management plan based on shellstock exceeding established tolerance levels shall:**

(i) **Meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification;**

(ii) **Specify the additional criteria associated with the particular pathogen isolate that the growing area must meet to be in the open status of its classification;**

(iii) **Document the scientific basis for the additional criteria;**

(iv) **Provide for periodic retesting of the shellfish meats; and**

(v) **Provide for the growing area to be placed in the closed status if the criteria are exceeded.**

(3) **Established Tolerance Levels Not Known.**

(a) **When an established tolerance level does not exist for the particular pathogen isolated, the Authority shall assess the public health significance of the levels of the pathogen found in the growing area shellfish meats. The Authority may consider FDA recommended action levels or levels of concern in this determination. When the Authority determines that:**

(i) **The levels are acceptable, the growing area ~~shall~~ may remain in the open status of its classification; or**

(ii) **The levels are unacceptable; the growing area shall be placed in the closed status of its classification.**

(b) **If a growing area is placed in the closed status, the Authority may elect to**

(i) **Maintain that status indefinitely;**

(ii) **Reclassify the area to the restricted or prohibited classification; or**

(iii) **Reclassify the area to the conditionally restricted classification and establish a management plan. The management plan shall meet the requirements of Section D. (2) (d).**

@.05 Presence of Toxic Substances in Shellfish Meats

A. **Upon determination that toxic substances, including but not limited to heavy metals, chlorinated hydrocarbons, and natural toxins are present in levels of public health significance in shellfish meats, the Authority shall investigate the harvesting, distribution, and processing of shellfish and take necessary corrective action in accordance with the procedures described in Section @.04.**

B. **When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification of the area. The risk assessment and subsequent risk management shall follow the procedures outlined in Section @.04 D., Risk Management and Tolerance Levels.**

@.06 *Vibrio vulnificus* Control Plan

A. **Risk Evaluation**

Each shellfish producing State that is not currently implementing

	a *V.v.* Control Plan shall conduct a *V.v.* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining the risk of *V.v.* infection from the consumption of shellfish harvested from the State's growing waters. **(1) In conducting the risk evaluation, the Authority will at a minimum consider the following:** **(a) The number of *V.v.* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and** **(b) Levels of *V.v.* in the growing waters and in shellfish, to the extent that such data exists; and** **(c) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.** **B. States which have previously met the illness threshold requiring a *V.v.* Control Plan will continue to maintain and implement a *V.v.* Control Plan.** **C. All States not currently implementing a *V.v.* Control Plan shall develop and implement a *V.v.* Control Plan if the risk evaluation indicates two (2) or more etiologically confirmed, and epidemiologically linked *V.v.* illnesses from consumption of commercially harvested oysters that originated from the growing waters of that State within the previous ten (10) years** **D. The Authority shall develop a *V.v.* Contingency Plan should the risk evaluation indicate any etiologically confirmed shellfish-borne *V.v.* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.06 C.** **E. Control Plan** **(1) The *V.v.* Control Plan shall include the following:** **(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One (1) or more of the following triggers will be used:** **(i) The water temperatures in the area;** **(ii) The air temperatures in the area;** **(iii) Salinity in the area;** **(iv) Harvesting techniques in the area; and** **(v) Other factors which affect risk which can be used as a basis for reducing risk.** **(b) Implementation of one (1) or more of the following control measures to reduce the risk of *V.v.* illness:** **(i) Labeling oysters as being for shucking by a certified dealer or for approved post-harvest processing to control the *Vibrio vulnificus* hazard when the Average Monthly Maximum Water Temperature exceeds 70 °F.** **(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved PHP when the Average Monthly Maximum Water Temperature exceeds 70 °F.**

(iii) **Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *V.v.* plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Water Temperature exceeds 80 °F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70 °F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70 °F but is less than or equal to 75 °F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75 °F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *V.v.* calculator. A State is in compliance with the NSSP when it effectively implements the controls established in its plan using the FDA calculator to determine the risk per serving for the established water temperatures.**

(iv) **The State Authority may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.06 E. (1) (b) (iii) when water temperatures exceed 70 °F.**

(c) **A state has the option to implement a *Vibrio vulnificus* Control Plan that includes time-temperature harvesting controls when Average Monthly Maximum water temperatures are below 70ºF. If the state implements this option, shellstock intended for raw consumption shall comply with the matrix below:**

Action Level	Water Temperature	Max Expos

Level 1	**<65ºF**	**36 hours**
Level 2	**65ºF - 70ºF (18ºC - 23ºC)**	**14 hours**

(d) All shellstock harvested according to a *Vibrio vulnificus* control plan shall be cooled to an internal temperature of 55ºF (12.7ºC) or less within 10 hours of being placed into temperature control.

(e) When pre-harvest culture practices have the potential to elevate Vibrio levels in market size product intended for immediate harvest, the Authority shall establish Vibrio control measures and include the measures in the State Vibrio Control Plan. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.

(2) Control Plan Evaluation

(a) The State Authority will conduct annual evaluations of the plan. At a minimum the Authority will consider:

(i) The annual number of *Vibrio vulnificus* cases associated with the State's growing waters and the amount of shellstock sold for half shell consumption to determine risk per servings for each temperature period.

(ii) Environmental changes which could affect total *V.v.* in shellfish pre and post-harvest.

(iii) Industry compliance with existing controls.

(iv) The Authorities enforcement of industries' implementation of the controls.

(b) For the purposes of determining Authority compliance the FDA will conduct an annual Vibrio evaluation of the Authority to determine the following:

(i) Authority compliance with *V.v.* Risk Evaluation as required in Chapter II. @.06 A.

(ii) For States requiring the development of *V.v.* Plans, compliance with Control Plan requirements of Chapter II. @.06 E. (1). The evaluation should determine:

(a) Appropriate identification of triggers to determine when control measures are needed.

(b) **Did the Authority implement one (1) or more of the control measures required in Chapter II. @.06 E. (1) (b).**

(c) **For Authorities implementing Chapter II. @.06 E. (1) (b) (i) and (ii), were the controls implemented adequately.**

(d) **For Authorities implementing Chapter II. @.06 E. (1) (b) (iii) (time and temperature control), did the Authority establish controls consistent with water temperature and was the FDA developed *V.v.* calculator used correctly.**

(iii) **For Authorities required to develop *V.v.* Contingency Plans the evaluation should determine:**

a. **Did the risk evaluation indicate the need for a Contingency Plan.**

b. **For States requiring the development of a Contingency Plan, does the plan include the regulatory steps to be implemented should the number of illnesses reach the threshold for a *V.v.* Plan**

(c) **Should the findings of the State evaluation indicate that the Authority was in compliance with the items audited in (2) (b) and the observed risk per servings exceeded established risk per serving for one (1) or more water temperature, the Authority will be deemed in compliance with the NSSP Model Ordinance. The FDA will include this finding in a report to the ISSC.**

(d) **The results of the State and FDA risk per serving evaluations will be shared with the ISSC Vibrio Management Committee for use in conducting trend evaluations as stated in the ISSC Constitution, Bylaws, and Procedures.**

F. **Contingency Plan**

(1) **The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *V.v.* Control Plan.**

(2) **Contingency Plan Evaluation**
In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

@.07 *Vibrio parahaemolyticus* Control Plan

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio parahaemolyticus* (*V.p.*) illness during periods that have been historically associated with annual illnesses. The Plan is to be

implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. **Independent Species Specific Risk Evaluation.**
Every State from which oysters or hard clams (*Mercenaria mercenaria*) are harvested shall conduct a *V.p.* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *V.p.* infection from the consumption of oysters or hard clams harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)
(1) **The number of *V.p.* cases epidemiologically linked to the consumption of oysters or hard clams commercially harvested from the State;**
(2) **Levels of total and tdh+ *V.p.* in the area, to the extent that such data exists;**
(3) **The water temperatures in the area;**
(4) **The air temperatures in the area;**
(5) **Salinity in the area;**
(6) **Harvesting techniques in the area; and**
(7) **The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.**

B. **Independent Species Specific Control Plan**
(1) **If a State's *V.p.* risk evaluation determines that the risk of *V.p.* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *V.p.* Control Plan.**
(2) **If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *V.p.* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:**
(a) **Waters bordering the Pacific Ocean: 60 °F.**
(b) **Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81 °F.**
(c) **Waters bordering the Atlantic Ocean (NY and north): 60 °F.**
(d) **However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *V.p.* illness will occur from the consumption of oysters or hard clams harvested from those areas.**
(i) **In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during**

	periods when the temperatures exceed those listed in this section; (ii) **In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the State and adjoining States that have been the source of shellfish that have been epidemiologically linked to cases of *V.p.* illness; or** (3) **If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *V.p.* within the prior five (5) years, the State shall develop and implement a *V.p.* Control Plan for the area.** (4) **For States required to implement *V.p.* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:** (a) **Establish one (1) or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.** (b) **Implement one (1) or more control measures to reduce the risk of *V.p.* illness at times when it is reasonably likely to occur. The control measures may include:** (i) **PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;** (ii) **Closing the area to oyster and/or hard clam harvest;** (iii) **Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;** (iv) **Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;** (v) **Limiting time from harvest to refrigeration such that the levels of total *V.p.* after the completion of initial cooling to 60 °F (internal temperature of the oysters or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;** (vi) **Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.** (c) **Require the original dealer to cool oysters and/or hard clams to an internal temperature of 50 °F (10 °C) or below within ten (10) hours or less as determined by the**

	Authority after placement into refrigeration during periods when the risk of *V.p.* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Oysters and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled as being for shucking by a certified dealer or for approved post-harvest processing to control the *Vibrio parahaemolyticus* hazard. **(d) Evaluate the effectiveness of the Plan.** **(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.** **(f) Optional cost benefit analysis of the *V.p.* Control Plan.** **(5) When pre-harvest culture practices have the potential to elevate *V.p.* levels in market size product intended for immediate harvest, the Authority shall establish *V.p.* control measures and include the measures in the State Vibrio Control Plan. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.** **C. The Time When Harvest Begins** **For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.**
12. Public Health Significance	N/A
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Chris Schillaci
3. Affiliation	East Coast Shellfish Growers Association (ECSGA)
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6. City, State, Zip	New Bedford, MA 02740
7. Phone	(401) 783-3360
8. Email	chris@ecsga.org
9. Proposal Subject	Consideration of Illnesses Among Non-Consumers of Shellfish in Outbreak Investigations
10. Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish, 2023 Revision. Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.01 Outbreaks of Shellfish-Related Illness, B. (new (3) and (4)), C. (2) (new (d)), and E. (1).
11. Text of Proposal/ Requested Action	Amend Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.01 Outbreaks of Shellfish-Related Illness, as follows. New language is shown in red double underline. Deleted language is shown in blue strikethrough. Existing text not shown is unchanged (indicated by ellipses). **1. Add new paragraphs B.(3) and B.(4):** B. When the state or local epidemiologist ... the appropriate Authorities shall: (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred. (2) Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling or illegal harvesting from a closed area. ... (3) The Authority, in consultation with the epidemiologist(s) in the state(s) in which the outbreak occurs, may determine that the outbreak is not attributable to shellfish when the investigation documents that: (a) Cases within the same illness cluster (the same event, establishment, or common exposure setting and time period) include one (1) or more persons who did not consume shellfish; (b) The illnesses among persons who did not consume shellfish are caused by, or are clinically consistent with, the same etiologic agent as the illnesses among persons who consumed shellfish and, where laboratory data are available, share the same genotype, strain, or sequence type; (c) The onset dates of the illnesses among persons who did not consume shellfish are consistent with exposure to a common source during the same exposure period and are not consistent with secondary (person-to-person) transmission from persons who consumed shellfish; and (d) The epidemiological evidence, including food histories and, where

	available, food-specific attack rates, identifies a source other than shellfish (such as an ill food worker, another food item, or environmental contamination) or does not support an association between illness and shellfish consumption. (4) When the Authority makes the determination described in B.(3): (a) Growing area closure and recall of shellfish are not required; (b) Any precautionary closure placed under Section C.(2) or Section E.(1) may be immediately lifted; (c) The Authority shall notify the FDA Shellfish Specialist and the ISSC of the determination and provide the supporting basis; (d) The Authority shall document the determination and supporting information in a written record in the central file; and (e) If additional information becomes available (e.g., additional cases, trace-back results, or laboratory results) that implicates shellfish, the Authority shall take the actions required in Sections C. through H. **2. Amend C.(2) by adding new item (d):** A specific growing area placed in a precautionary closed status under this section can be immediately re-opened when one (1) or more of the following conditions are met: (a) ... (b) ... (c) ... (d) The Authority has determined, in accordance with Section B.(3), that the outbreak is not attributable to shellfish. **3. Amend E.(1):** (1) Immediately place the implicated portion(s) of the harvest area(s) in a precautionary closed status. Should the Authorities later determine that the illnesses are related to post-harvest contamination, ~~or~~ mishandling, ~~or~~ harvested from a closed area, or are not attributable to shellfish in accordance with Section B.(3), the suspected growing area can be reopened.
12. Public Health Significance	Section II, Chapter II @.01 establishes the actions an Authority must take once shellfish are epidemiologically associated with an outbreak, and Section E requires a precautionary closure whenever the growing-area determination cannot be completed within 24 hours. The Model Ordinance provides explicit off-ramps for outbreaks traced to post-harvest contamination, mishandling, or illegal harvest (Section D) and for multiple-source outbreaks (Section C.(2)), but it does not explicitly recognize one of the most informative findings in an outbreak investigation: persons in the same illness cluster who became ill but did not eat shellfish. Norovirus and other enteric outbreaks at events, restaurants, and catered functions frequently involve multiple menu items and ill food workers. When shellfish were served, early food histories can create an apparent association with shellfish even though non-consumers in the same cluster became ill with the same agent at the same time. Such cases point to a common source other than shellfish. Without clear authority in the Model Ordinance to act on this evidence, Authorities may feel

	obligated to close growing areas and initiate recalls that do not protect public health, while investigative resources are drawn away from identifying and controlling the actual source. The proposed language gives the Authority discretion, in consultation with the epidemiologist, to conclude that an outbreak is not attributable to shellfish, while building in safeguards that protect public health: Timing of onset: non-consumer cases must be consistent with a common-source exposure and not with secondary person-to-person spread, which commonly follows shellfish-borne norovirus outbreaks and would otherwise be misread as evidence against shellfish. Same agent: cases must share the same etiologic agent, and the same genotype or strain where laboratory data exist. Supporting epidemiology: food histories and attack rates must identify another source or fail to support a shellfish association. Transparency and reversibility: the determination must be documented and reported to the FDA Shellfish Specialist and the ISSC, and the Authority must resume closure and recall actions if new evidence implicates shellfish. This approach is consistent with the epidemiological principles already referenced in @.01 A (International Association for Food Protection, Procedures to Investigate Foodborne Illness) and with the existing reopening criteria in C.(2), which allow reopening based on consumption data and other relevant information provided by state investigators. It aligns shellfish control actions with the weight of the epidemiological evidence, reduces unnecessary closures and recalls, and helps focus outbreak response on the true source of illness.
13. Cost Information	No additional cost to Authorities is anticipated; the proposal uses information already collected during routine outbreak investigations. The proposal is expected to reduce costs to Authorities, harvesters, and dealers by avoiding closures, recalls, and associated sampling and reopening activities in outbreaks not caused by shellfish.
14. Changes Needed to Guidance (if proposed change is adopted)	No changes to the Guidance Documents (Section IV) are required.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Chris Schillaci
3. Affiliation	East Coast Shellfish Growers Association (ECSGA)
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7. Phone	(401) 783-3360
8. Email	chris@ecsga.org
9. Proposal Subject	Risk-Based Response to Shellfish-Related Illnesses Associated with Campylobacter spp.
10. Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish, 2023 Revision. Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.01 Outbreaks of Shellfish-Related Illness (new paragraph J); new @.08 Shellfish-Related Illnesses Associated with Campylobacter spp.
11. Text of Proposal/ Requested Action	This proposal adds a new Model Ordinance section, Chapter II @.08, that sets out a risk-based, tiered response to shellfish-associated Campylobacter illnesses, patterned on the existing Chapter II @.02 for Vibrio parahaemolyticus. The new section (1) accounts for the time between harvest, illness onset, and case reporting; (2) distinguishes sporadic cases from clusters and outbreaks, using genetic relatedness where available; (3) uses risk per serving together with case counts so that a single sporadic case does not by itself trigger closure of a small production area; and (4) sets closure durations, reopening criteria, and harvest controls based on available purge and survival data. A conforming amendment to Chapter II @.01 routes these illnesses to the new section. New language is shown in red double underline. Deleted language is shown in blue strikethrough. The Executive Office is requested to adjust section and paragraph numbering as needed, including if the companion Salmonella proposal is also adopted. **1. Amend Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.01 Outbreaks of Shellfish-Related Illness, by adding a new paragraph J:** J. When the investigation outlined in Chapter II @.01 A. indicates that the illness(es) are associated with Campylobacter spp., the Authority shall follow the requirements of Chapter II @.08 in lieu of Chapter II @.01 B. through G., except as referenced in Chapter II @.08. **2. Add the following new section to Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management:** @.08 Shellfish-Related Illnesses Associated with Campylobacter spp. A. Applicability and Definitions. (1) This section applies when the investigation outlined in Chapter II @.01 A. indicates that the illness(es) are associated with thermotolerant Campylobacter spp. (Campylobacter jejuni, Campylobacter coli, or

	Campylobacter lari) and the consumption of molluscan shellfish. (2) For the purposes of this section: (a) Case means a laboratory-confirmed Campylobacter infection, identified by culture or by a culture-independent diagnostic test (CIDT), that the state or local epidemiologist has determined is epidemiologically associated with the consumption of shellfish from the implicated area. In making this determination the epidemiologist should consider whether the interval between shellfish consumption and illness onset is consistent with the incubation period (typically two (2) to five (5) days) and whether other exposures documented in the food and exposure history (e.g., poultry, unpasteurized dairy products, untreated water, animal contact, or travel) provide a more likely source of infection. (b) Sporadic cases means cases from an implicated area in which no two (2) cases are associated with a single harvest date and clinical isolates, where characterized, are not genetically related. (c) Genetically related means that clinical isolates (and shellfish or environmental isolates, where available) have been determined to be closely related by whole genome sequencing (WGS) or another subtyping method used by PulseNet, as determined by the state public health laboratory or the Centers for Disease Control and Prevention (CDC). (d) Harvest date means the date of harvest shown on the shellstock tag or, where tags are unavailable, the harvest date determined through traceback. (e) Implicated area means the growing area, portion of a growing area, or aquaculture site from which the shellfish associated with the case(s) were harvested. (f) Contributing condition means an identified or suspected source of Campylobacter contamination of the implicated area that the investigation associates with the case(s) or that exceeds conditions normally present in the growing area, including but not limited to congregations of birds and/or mammals on or around aquaculture gear or other structures, failing on-site sewage disposal systems, wastewater discharges, livestock, or agricultural runoff. The presence of birds or other wildlife at levels normally found in the growing area is not by itself a contributing condition. (g) Risk per serving means the number of cases associated with shellfish harvested from the implicated area within a thirty (30) day period, divided by the number of servings harvested from the implicated area during the same period, expressed as illnesses per 100,000 servings. For this calculation one (1) serving equals twelve (12) oysters or hard clams, or the equivalent shucked meat weight, unless the Authority documents an alternative conversion consistent with that used for Vibrio risk-per-serving calculations.

B. Time Between Harvest and Case Reporting.

(1) Cases shall be attributed to the thirty (30) day period in which the implicated shellfish were harvested, regardless of the date the cases are reported to the Authority.

(2) States will not be expected to close growing areas based on cases reported more than thirty (30) days after the last implicated harvest date, unless the investigation in C. indicates that a contributing condition present at the time of harvest persists. When closure is not required under this subsection, the Authority shall complete the investigation in C., require correction of any contributing condition identified, and document its findings.

C. Investigation.

(1) Within seventy-two (72) hours of notification of a case, the Authority shall initiate an investigation to determine:

(a) The extent of the implicated area and the harvest date(s) of the implicated shellfish;

(b) Whether the illness(es) are growing area related or are the result of post-harvest contamination or mishandling, including cross-contamination during storage, preparation, or service (e.g., contact with raw poultry), or illegal harvesting from a closed area;

(c) Whether a contributing condition exists, including a review of bird and/or mammal congregations on or near aquaculture gear and of compliance with any operational plan required under Chapter VI. .04;

(d) Whether the growing area is properly classified, including a review of current water quality data and the sanitary survey; and

(e) The volume of shellfish harvested from the implicated area during the relevant thirty (30) day period, for the purpose of calculating risk per serving.

(2) If the conditions in D. (2) or D. (3) are met and the investigation cannot be completed within seventy-two (72) hours, the Authority shall immediately place the implicated area in the precautionary closed status. Should the Authority later determine that the illnesses are related to post-harvest contamination or mishandling, the implicated area may be immediately reopened.

(3) When the investigation demonstrates that the illnesses are related to post-harvest contamination or mishandling, growing area closure is not required and the Authority shall follow the requirements of Chapter II @.01 D.

(4) When the investigation identifies a human sewage source or an improperly classified growing area, the Authority shall also follow the requirements of Chapter II @.01 G.

D. Risk Management Actions. When the investigation in C. does not indicate post-harvest contamination, mishandling, or illegal harvesting from a closed area, the actions taken by the Authority shall be based on the number of cases,

their relationship to one another, and the span of time, as follows:

(1) Sporadic Cases. When a single case occurs within a thirty (30) day period from the implicated area, or when two (2) or three (3) sporadic cases occur within a thirty (30) day period and the risk does not exceed one (1) illness per 100,000 servings, the Authority shall:

(a) Determine the extent of the implicated area;

(b) Evaluate the implicated area for contributing conditions and, when a contributing condition is identified, require corrective action, which may include development or revision of an operational plan and mitigation or deterrent measures for birds and/or mammals under Chapter VI. .04;

(c) Notify the FDA Shellfish Specialist and the Authorities in receiving States of the case(s) and the actions taken; and

(d) Coordinate with the state epidemiologist to enhance surveillance for additional cases associated with the implicated area.

Closure of the implicated area is not required under this subsection.

(2) Clusters. When (i) two (2) or three (3) cases are associated with a single harvest date; (ii) two (2) or more cases are genetically related; (iii) two (2) or three (3) sporadic cases occur within a thirty (30) day period and the risk exceeds one (1) illness per 100,000 servings; or (iv) four (4) to six (6) cases occur within a thirty (30) day period from the implicated area, the Authority shall:

(a) Determine the extent of the implicated area;

(b) Immediately place the implicated area in the closed status. The closure may be limited to the implicated aquaculture site(s) and/or shellfish species when the investigation identifies a site-specific contributing condition;

(c) As soon as determined by the Authority, transmit to the ISSC, the FDA, and receiving States information identifying the dealers shipping the implicated shellfish;

(d) Determine the appropriateness of a voluntary recall by firms consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. A recall is not required when the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses; and

(e) Require correction of any contributing condition identified.

(3) Outbreaks. When four (4) or more cases are associated with a single harvest date, or more than six (6) cases occur within a thirty (30) day period from the implicated area, the Authority shall:

(a) Take the actions in D. (2) (a) through (c) and (e);

(b) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7, unless the Authority determines that the implicated product is no longer available on the

market or that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products; and

(c) Issue a consumer advisory for the shellfish species implicated in the illnesses.

(4) The ISSC will notify States and FDA Shellfish Specialists of closures and recalls under D. (2) and D. (3), consistent with Chapter II @.01 C. (1) (e).

E. Multiple Implicated Areas. When the investigation does not identify a single implicated area, the Authorities in the States with implicated areas shall evaluate whether the illness(es) should be attributed to one (1) or more of the areas. Evaluations may include but are not limited to:

(1) Contributing conditions in each area at the time of harvest, including bird and/or mammal observations recorded by operators, enforcement staff, or sampling staff;

(2) Comparison with other cases attributed to the areas;

(3) Genetic comparison of clinical, shellfish, and environmental isolates; and

(4) Volume and distribution information.

If the evaluation implicates a single area, the Authority shall take the actions in D. Precautionary closures of multiple implicated areas are not required under D. (1). For D. (2) and D. (3), Chapter II @.01 C. (2) and (3) shall apply.

F. Closure Duration and Reopening.

(1) An area closed under D. (2) shall remain closed for a minimum of seven (7) days, and an area closed under D. (3) for a minimum of fourteen (14) days, from the date the Authority verifies that the contributing condition has been corrected or no longer exists or, when no contributing condition is identified, from the date of closure. When water temperatures in the implicated area are below 10 °C (50 °F), at which shellfish feeding is greatly reduced, the Authority should consider extending the closure period.

(2) Prior to reopening an area closed under this section, the Authority shall:

(a) Verify that the contributing condition has been corrected or no longer exists, including, for aquaculture sites, that required mitigation or deterrent measures are in place and functioning;

(b) Verify that the growing area meets the microbiological standards for its classification under Chapter IV. @.02; and

(c) When determined appropriate by the Authority, collect shellstock samples representative of the implicated area and shellfish types and analyze them for C. jejuni, C. coli, and C. lari using a method acceptable to the Authority until a method is adopted under Chapter III. Isolates recovered shall be submitted for whole genome sequencing or another subtyping method for comparison with the clinical isolates.

	Because Campylobacter spp. may be present in shellfish from growing areas not associated with illness, detection alone shall not be the basis for continued closure. If the outbreak strain is detected, the Authority shall continue the closure and re-evaluate the contributing condition. (3) The Authority shall develop a written report summarizing the findings of the investigation and the actions taken. G. Harvest from Closed Areas and Reconditioning. (1) Shellfish harvesting may occur in an area closed under this section, and shellfish recalled under this section may be reconditioned, when the Authority implements one (1) or more of the following controls: (a) Relaying the shellstock under Chapter V., or placing it in an approved or conditionally approved growing area in the open status where the contributing condition is absent, for not less than seven (7) days, with appropriate controls and documentation determined by the Authority; (b) Depuration in a certified depuration facility using a process the Authority determines, based on appropriate scientific studies, reduces Campylobacter to levels not reasonably likely to cause illness; (c) Post-harvest processing (PHP) using a process validated to reduce Campylobacter to levels not reasonably likely to cause illness; or (d) Other control measures that, based on appropriate scientific studies, are designed to ensure that the risk of Campylobacter illness is no longer reasonably likely to occur, as approved by the Authority.
12. Public Health Significance	**Campylobacter is a common foodborne pathogen but a rare shellfish hazard.** CDC estimates about 1.5 million Campylobacter infections in the United States each year, most of them linked to poultry, unpasteurized dairy, and produce. From 2000 to 2024, CDC outbreak surveillance recorded 11 Campylobacter outbreaks (66 illnesses) linked to oysters, compared with 190 Vibrio and 143 norovirus outbreaks linked to oysters over the same period (ISSC Aquatic Bird Risk Assessment Committee, draft final report). Source attribution using U.S. surveillance isolates attributes only about 3% of human campylobacteriosis to wild birds, compared with about 68% to poultry and 28% to cattle (Pascoe et al. 2024). Most Campylobacter strains, including many carried by birds, are not associated with human illness, and C. jejuni accounts for most human cases. **Background presence in growing areas.** Campylobacter spp. are commonly carried by gulls, waterfowl, and other wildlife and occur in estuarine waters and shellfish from growing areas that are not linked to illness (Carter et al. 1987). Much of what is found in these settings is C. lari or bird-adapted strains that are rarely associated with human illness (Smith et al. 2020). Detection in shellfish or water therefore does not by itself show that a growing area caused a case, and non-detection does not show that an area is free of risk. For this reason the proposal bases actions on case patterns, genetic relatedness, and risk per serving, and ties reopening to correcting the contributing condition rather than to non-detection. **Recent shellfish-associated events and a gap in the Model Ordinance.** Shellfish-associated Campylobacter outbreaks have been linked to birds congregating on

	floating aquaculture gear, including an October 2021 Rhode Island outbreak of C. jejuni (eight ill) (Caron et al. 2023; NSSP Guide Section IV, Chapter VI). In August 2025, Massachusetts closed Katama Bay (Edgartown) to oyster harvest after five confirmed Campylobacter illnesses linked to oysters harvested July 7–17 and eaten July 12–21. The closure took effect August 1, 15 days after the last implicated harvest date, and was to remain in place "until examined by the Division." The Model Ordinance currently addresses these illnesses only through the general outbreak provisions of Chapter II @.01. Under @.01, two illnesses in different households count as an outbreak and require immediate closure and consideration of recall. However, @.01 provides no guidance on sporadic cases, on the lag between harvest and case reporting, on risk relative to production volume, or on closure duration and reopening criteria suited to a bacterial pathogen that shellfish purge quickly. The result can be inconsistent responses between States and open-ended closures of small aquaculture operations. **Time from illness to reporting.** Campylobacter incubation is typically 2–5 days (CDC). For enteric bacterial pathogens, the time from exposure to confirmation that a case is part of an outbreak is typically 2–4 weeks, reflecting care-seeking, laboratory testing, isolate shipping, and subtyping (CDC, Timeline for Reporting Cases of Salmonella Infection). By the time a shellfish Authority is notified, the implicated lots may be beyond their market life, and a short-lived contamination event (e.g., a seasonal bird congregation) may have ended. The 30-day reporting window in the proposed @.08 B. matches the one in @.02 for V.p. It keeps closure authority when a contributing condition persists and still requires investigation and correction in every case. **Sporadic cases vs. outbreaks, and risk per serving.** Because Campylobacter is a common infection with many non-shellfish sources, a single reported case with a history of shellfish consumption does not show that the growing area is the source. The proposal therefore requires investigation and correction of contributing conditions for sporadic cases, and reserves closure for (i) multiple cases from a single harvest date, (ii) genetically related cases, (iii) sporadic cases that exceed the risk-per-serving benchmark already used in @.02 (one illness per 100,000 servings), or (iv) larger case counts. To keep a single case from triggering closure at low-volume sites, the risk-per-serving trigger applies only when two or more cases occur. WGS through PulseNet is now routine and lets investigators tell linked from unrelated cases. **Closure duration and reopening.** Preliminary results from an ISSC-funded study found that Eastern oysters exposed to C. jejuni, C. coli, and C. lari cleared all three species to below molecular (ddPCR) detection in tissue within two days (Richards, Noble and Smith, in prep.). A two-day depuration period was also effective for Sydney rock oysters (Arumugaswamy et al. 1988). Campylobacter can, however, survive in harvested shellfish for up to 22 days at 4 °C (Abeyta et al. 1993; Arumugaswamy et al. 1988), so recall stays relevant when product is still in commerce. The proposed minimum closures (7 and 14 days after the contributing condition is corrected) give a wide margin over observed purge times. The added caution at water temperatures below 10 °C reflects reduced oyster feeding. Fecal indicator bacteria correlate poorly with Campylobacter (Carter et al. 1987; Hellein et al. 2011; Caron et al. 2023). For that reason, reopening is tied to verified correction of the contributing condition, along with the classification standards.

	Optional shellstock testing is used to check whether the outbreak strain persists, not to require non-detection, because these organisms can be present in areas not associated with illness. **Consistency with ISSC work.** The proposal follows the direction of the Aquatic Bird Risk Assessment Committee, which recommends species-specific, risk-based management of C. jejuni, C. coli, C. lari, and Salmonella enterica rather than genus-level responses. It also follows the Committee's recommendation that shellfish Authorities work with epidemiologists to weigh other exposures when attributing illness to shellfish. It builds on the existing requirements for aquaculture sites that attract birds or mammals (Chapter VI. .04) and gives a proportionate, consistent response while research continues. **Supporting References** 1. Abeyta, C., et al. 1993. Campylobacter jejuni in a Washington state shellfish growing bed associated with illness. J Food Prot. 56:323-325. 2. Arumugaswamy, R., R. Proudford, and M. Eyles. 1988. The response of Campylobacter jejuni and Campylobacter coli in the Sydney Rock Oyster during depuration and storage. Int J Food Microbiol. 7:173-183. 3. Caron, G., et al. 2023. Campylobacter jejuni outbreak linked to raw oysters in Rhode Island, 2021. J Food Prot. 86:1-7. 4. Carter, A. M., et al. 1987. Seasonal occurrence of Campylobacter spp. in surface waters and their correlation with standard indicator bacteria. Appl Environ Microbiol. 53:523-526. 5. CDC. Clinical Overview of Campylobacter. https://www.cdc.gov/campylobacter/hcp/clinical-overview/index.html 6. CDC. Timeline for Reporting Cases of Salmonella Infection. https://stacks.cdc.gov/view/cdc/22424 7. CDC. BEAM (Bacteria, Enterics, Ameba, and Mycotics) Dashboard / NORS, 2000–2024, as summarized in the ISSC Aquatic Bird Risk Assessment Committee draft final report. 8. Hellein, K. N., et al. 2011. Culture-based indicators of fecal contamination and molecular microbial indicators rarely correlate with Campylobacter spp. in recreational waters. J Water Health. 9:695-707. 9. ISSC Aquatic Bird Risk Assessment Committee. Final Report: Aquatic Bird Risk Assessment Committee Literature Review (draft). 10. Massachusetts Division of Marine Fisheries. August 1, 2025. Oysters closure due to Campylobacter sp. outbreak in Edgartown (V20). https://www.mass.gov/doc/8125-oysters-closure-due-to-campylobacter-sp-outbreak-in-edgartown-v20/download 11. NSSP Guide for the Control of Molluscan Shellfish, 2023 Revision. Section II, Chapter II @.01–@.02; Section IV, Chapter VI. 12. Pascoe, B., et al. 2024. Machine learning to attribute the source of Campylobacter infections in the United States: A retrospective analysis of national surveillance data. J Infect. 89:1-10.

	13. Richards, G. P., R. Noble, and Smith. In prep. Campylobacter purge rates in Eastern oysters (Appendix 1, ISSC Aquatic Bird Risk Assessment Committee draft report). 14. Smith, O. M., W. E. Snyder, and J. P. Owen. 2020. Are we overestimating risk of enteric pathogen spillover from wild birds to humans? Biol Rev. 95:652-679.
13. Cost Information	No significant new costs are expected. WGS of clinical isolates is already performed routinely through PulseNet. Investigation requirements are similar to those already carried out under Chapter II @.01. Shellstock testing for reopening is optional and at the Authority's discretion. The proposal is expected to reduce economic losses to growers, especially small aquaculture operations, by avoiding closures and recalls that do not reduce risk, while keeping protective actions for clusters and outbreaks.
14. Changes Needed to Guidance (if proposed change is adopted)	No changes to the Guidance Documents (Section IV) are required for adoption. If adopted, the Executive Office is requested to make conforming cross-reference updates to Section IV guidance that refers to Chapter II @.01 outbreak response and to Chapter VI aquaculture bird and mammal requirements, so that it also references new Chapter II @.08.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Chris Schillaci
3. Affiliation	East Coast Shellfish Growers Association (ECSGA)
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6. City, State, Zip	New Bedford, MA 02740
7. Phone	(401) 783-3360
8. Email	chris@ecsga.org
9. Proposal Subject	Annual Assessment of Shellfish-Related Campylobacter and Salmonella Illnesses
10. Specific NSSP Guide Reference	NSSP Guide for the Control of Molluscan Shellfish, 2023 Revision. Section II. Model Ordinance, Chapter II. Risk Assessment and Risk Management, @.03 Annual Assessment of Vibrio vulnificus and Vibrio parahaemolyticus Illnesses and Shellfish Production, A. and B.; new paragraph C.
11. Text of Proposal/ Requested Action	This proposal amends Chapter II @.03 so that the Authority's annual assessment also covers shellfish-associated Campylobacter spp. and non-typhoidal Salmonella enterica illnesses. It adds the case details needed to evaluate reporting lag, sporadic versus outbreak-associated cases, contributing conditions, and risk per serving. This proposal can stand alone or support the companion Campylobacter proposal, which sets a response framework for that pathogen. For Salmonella, it builds the case data needed before a pathogen-specific response framework is proposed. New language is shown in red double underline. Deleted language is shown in blue strikethrough.

Amend Section II. Model Ordinance, Chapter II. @.03 as follows:

@.03 Annual Assessment of Vibrio vulnificus ~~and~~, Vibrio parahaemolyticus, Campylobacter spp., and Non-typhoidal Salmonella enterica Illnesses and Shellfish Production

A. The Authority shall assess annually Vibrio vulnificus (V.v.) ~~and~~, Vibrio parahaemolyticus (V.p.), Campylobacter spp., and non-typhoidal Salmonella enterica illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all V.v. ~~and~~, V.p., Campylobacter, and Salmonella shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.

(1) For Campylobacter and Salmonella illnesses, the record shall also include, where available:

(a) The harvest date(s) and implicated growing area or aquaculture site;

(b) The dates of illness onset and of notification to the Authority;

(c) Whether the cases were sporadic or associated with a cluster or outbreak, and any species, serotype, or whole genome sequencing results;

(d) Any contributing condition identified, including bird and/or mammal congregations on or near aquaculture gear; and

	(e) The risk per serving, when calculated. B. The Authority shall collect by month and report annually to the ISSC the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species. Where available the volume breakdown of the production data will be reported by utilization type (raw, shucked, PHP, etc.). C. The ISSC will compile the Campylobacter and Salmonella information reported under A. and make it available to the appropriate ISSC committee(s) for trend evaluation and for evaluating risk-based management thresholds for these pathogens.
12. Public Health Significance	Shellfish-associated Campylobacter and Salmonella illnesses are rare but have become more visible with the growth of floating and off-bottom aquaculture and documented bird-associated outbreaks (e.g., Rhode Island 2021; Massachusetts 2025). The ISSC Aquatic Bird Risk Assessment Committee found that limited outbreak data and an incomplete picture of underreporting and misattribution are critical knowledge gaps. It recommended developing a risk assessment framework for C. jejuni, C. coli, C. lari, and Salmonella enterica. Without consistent, production-normalized illness data, the Conference cannot evaluate risk per serving, reporting lag, or how well mitigation such as bird deterrents works. The annual Vibrio assessment under @.03 already provides this kind of data for V.v. and V.p. Extending it to Campylobacter and Salmonella builds the dataset needed to set and review science-based thresholds. For Salmonella, shellfish-associated outbreaks are fewer, sources are more varied (including human sewage, livestock, and wildlife), and depuration and survival data are more variable than for Campylobacter. Consistent annual case data are therefore a necessary first step before the Conference evaluates a Salmonella-specific response framework.
13. Cost Information	Minimal. Authorities already record shellfish-associated illnesses and report production volumes under @.03. The added fields are collected during illness investigations and add only modest recordkeeping.
14. Changes Needed to Guidance (if proposed change is adopted)	No changes to the Guidance Documents (Section IV) are required. If the ISSC maintains a reporting template for the annual @.03 assessment, it should be updated to add the Campylobacter and Salmonella fields listed in proposed @.03 A. (1).

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	Jenifer Yeadon and Alissa Dragan
3. Affiliation	CT Department of Agriculture
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6. City, State, Zip	Milford, CT, 06460
7. Phone	203-874-0696
8. Email	Jenifer.Yeadon@ct.gov
9. Proposal Subject	Request to add the use of MSC testing for illness investigations when the illness is known to be transmitted person to person.
10. Specific NSSP Guide Reference	Section II, Chapter II, @.01 A (2), B, G (1) (a), and G (2)
11. Text of Proposal/ Requested Action	@.01 A (2) Whether the disease has the potential or is known to be transmitted by shellfish and/or person to person; and @.01 B (3) If the disease is known to be transmitted person to person, the source state may conduct an investigation to determine if the growing area is implicated. The investigation shall include a review as outlined in Chapter II @01. G. and MSC sample data. In the event the producing state's review determines the source of the contamination is not from the growing area, the supporting data used to make the determination shall be forwarded to the Regional FDA Specialist. In coordination with the FDA Specialist, the Authority may reopen the growing area and no recall is required. G (1) (a) i. (a) If the disease is known to be transmitted person to person, the Authority may include MSC analytical sample results from shellfish in the implicated growing area in accordance with the MSC levels established in Chapter IV @.02E (4) or pre-determined MSC levels in shellfish established by the Authority based on studies conducted on regional species under regional conditions not impacted by sewage closures; iv. Examination of water quality during and subsequent to the illness outbreak; v. If the disease is known to be transmitted person to person, the Authority may review the extent of distribution of the implicated product: total harvest amount of the suspected product, total amount in distribution chain, and time frame from harvest to notification. This information will help inform the Authority if the outbreak is isolated to one distribution area, indicating post harvest contamination, or widespread indicating the illness is growing area related. G (2) Keep the area closed until at least 21 days have passed from the last date of harvest of the implicated shellstock if the illness is consistent with viral etiology unless the Authority can collect MSC samples in accordance with Chapter IV @03. A. (5) (d) (iv) a-c; and

12. Public Health Significance	MSC testing is permitted for reopening following a raw sewage discharge prior to 21 days. An Authority implementing MSC background monitoring and sampling of shellstock produces sufficient data to demonstrate that the area is not impacted by viral contaminants. In instances where the producing state can provide sufficient data and make a determination in coordination with their FDA Specialist that a shellfish growing area was unlikely to be the source of the outbreak, the investigation should be directed to other potential sources like person to person transmission.
13. Cost Information	The use of MSC sampling is not a requirement; therefore, if a state does not have the laboratory capability, they do not need to use this strategy.
14. Changes Needed to Guidance (if proposed change is adopted)	Relevant Chapter II guidance.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
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6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Conformance status and scope of technical laboratory evaluations
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter 1 Shellfish Sanitation Program Requirements for the Authority, @.03 Evaluation of Shellfish Sanitation Program Elements, B. 1. b.
11. Text of Proposal/ Requested Action	Chapter I @.03 B. Criteria for evaluation of shellfish sanitation program elements shall be as follows: 1. Laboratory a. Requirements for evaluation of shellfish laboratories shall include… b. Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the ~~FDA~~ NSSP Shellfish Laboratory Evaluation Checklists found in Section IV Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists. i. Quality System Evaluation... ii. Technical Evaluation: Shellfish Laboratory will be technically evaluated and will be assigned the designation of conforms, provisionally conforms or non-conformance for the specific NSSP Approved methods included in the evaluation scope. The criteria used in determining the evaluation designations are included in the NSSP Shellfish Laboratory Evaluation Checklist designated for the specific type of laboratory evaluation being performed.
12. Public Health Significance	The proposed modifications are to clarify that Laboratory Evaluation Checklists are NSSP documents, not FDA documents, and to clarify that NSSP laboratory conformance status is assigned based on the method(s) being evaluated.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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)
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6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Clarification of proficiency test participation in NSSP laboratories
10. Specific NSSP Guide Reference	Section II Model Ordinance, Chapter III Laboratory, @.01 Quality Assurance, B. (1) (f)
11. Text of Proposal/ Requested Action	Chapter III @.01 A… B. State Program Responsibilities. The Authority shall ensure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. Accordingly, the Authority shall: (1) Require laboratories to develop a written quality assurance plan that: (a) Describes the organization and management structure of the laboratory; (b) Describes the laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised; (c) Describes all procedures and methods used to analyze samples; (d) Describes quality control measures, their frequency and tolerance limits, for determining equipment performance; (e) Requires maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration; (f) Includes an internal assessment and participation in a recognized annual proficiency test program, as applicable. For microbiology, potential providers include (FDA FoodSHIELD, and Northeast Laboratory Examination Officers and Managers (NELEOM), etc.); and (g) Requires corrective action for any deficiencies found in the laboratory quality assurance program.
12. Public Health Significance	Proficiency test programs are not available for all NSSP Approved methods. The proposed wording provides clarification that participation in annual proficiency test programs is only required when such programs are available.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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)
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4. Address Line 1	5001 Campus Drive
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6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	NSSP Sample Collection and Transportation
10. Specific NSSP Guide Reference	Chapter III. @.01 B. (1), Chapter IV. @.02 A., Chapter IV. @.04 A. (2), Chapter IV. @.04 B. (2)
11. Text of Proposal/ Requested Action	Chapter III. @.01 B. State Program Responsibilities. The Authority shall ~~ensure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. Accordingly, the Authority shall~~: (1) Ensure all wastewater, seawater and shellfish samples are collected, maintained, transported, and analyzed in accordance with NSSP Laboratory Evaluation Checklist requirements, as applicable. (2~~1~~) Require laboratories to develop a written quality assurance plan that… Chapter IV. @.02 A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The Authority may utilize MSC data in conjunction with bacteriological data to evaluate WWSD impacts on shellfish growing areas. The Authority shall ensure requirements of Chapter III @.01. B. (1) are met. Chapter IV. @.04 A. *Contingency Plan*…. (1)… (2) The plan shall…accomplish the following: (a) Ensure the requirements of Chapter III @.01. B. (1) are met; (b~~a~~) Initiate an emergency shellfish sampling program… Chapter IV. @.04 B. *Management Plan* (1)… (2) The plan shall define the administrative procedures and resources necessary to accomplish the following: (a) Ensure the requirements of Chapter III @.01. B. (1) are met;

	(b~~a~~) Maintain….
12. Public Health Significance	The responsibility for ensuring sample integrity and data defensibility is shared among NSSP laboratories and program staff. NSSP Laboratory Evaluation Checklists contain Sample Collection and Transportation requirements that are evaluated by Laboratory Evaluation Officers. The program staff members responsible for sample collection and transportation are sometimes not aware of the requirements. Adding clarifying language to the MO for the Authority the requirements being in the NSSP Guide and not only having them in the NSSP Laboratory Evaluation Checklists will minimize sample rejection at the laboratory, which will maximize collector and laboratory efficiency.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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)
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6. City, State, Zip	College Park, MD 20740
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9. Proposal Subject	CAMP Reopening Criteria
10. Specific NSSP Guide Reference	Chapter IV. @.03 C. (2) (c)
11. Text of Proposal/ Requested Action	Chapter IV. @.03 C. (2) (c) For management plans based on WWSD function or pollution sources other than WWSD criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum reopening criteria for conditional management plans are: (i) Performance standards of the plan are fully met; (ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels; (iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. (iv) Shellstock feeding activity is sufficient to achieve pathogen reduction. (v) If (i-iv) are met and if the conditional management plan closure performance standard(s) is(are) based on effects of non-point sources of pollution such as ~~rain events and/or~~ storm water runoff due to rain events, an area may be reopened when the water quality meets classification criteria without a shellstock cleansing study. (vi) If (i-iv) are met and if the ~~For~~ conditional~~ly~~ management~~d~~ plan closure performance standard(s) is(are) ~~areas~~ based on WWSD function~~performance standards~~, the Authority may utilize MSC levels in shellstock to establish that sufficient time has elapsed to allow ~~water quality and~~ shellstock to return to acceptable levels in growing areas adjacent to WWSD. a. Analytical shellstock tissue sample results shall not exceed the MSC levels established in Chapter IV@.02 E.(4); or b. Pre-determined MSC shellstock tissue levels established by the Authority based on studies conducted on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in the shellfish meats; or c. The area must be in the closed status until the event is over, and ~~twenty one (~~21~~)~~ days have passed.
12. Public Health Significance	Conditional management plans (CAMPs) based on wastewater system

	discharge (WWSD) performance standards present a distinct public health risk profile compared to those based on non-point source pollution. Shellfish harvested from growing areas adjacent to WWSD outfalls may accumulate human enteric pathogens, including norovirus and hepatitis A virus, at levels that cannot be adequately characterized by fecal coliform (FC) water quality indicators alone. Requirements (i) through (iv), must be met for reopening a closed area based on both, (v) non-point pollution source performance standards and (vi) WWSD performance standards. The proposed changes address any confusion, including language requiring that items (i) through (iv) also be met if reopening a closed area based on WWSD performance standards. These revisions make both reopening scenarios consistent and will reduce any confusion, thereby, protecting public health and maintaining consumer confidence in the safety of commercially harvested shellfish.
13. Cost Information	No cost.
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	Model Ordinance Effectiveness Review Committee
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8. Email	issc@issc.org
9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter IV. Shellstock Growing Areas
11. Text of Proposal/ Requested Action	**@.01 Sanitary Survey** A. **General.** (1) **The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:** (a) **A shoreline survey;** (b) **A survey of the microbiological quality of the water. In growing areas adjacent to waste water system discharge (WWSD)s the Authority may utilize male specific coliphage (MSC) results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report;** (c) **An evaluation of the effect of any meteorological, hydrographic~~dynamic~~, and geographic characteristics on the growing area; and** (d) **A determination of the appropriate growing area classification.** (2) **The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with Section C. to assure that data are current and that conditions are unchanged.** (3) **The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the ~~central~~Authority's file system shall include all data, results, and analyses from:** (a) **The sanitary survey reviewed and signed by the Sanitary Survey Officer;** (b) **The triennial reevaluation; and** (c) **The annual review.**

(4) **The Authority shall maintain a current ~~comprehensive, itemized~~ list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.**

B. **Sanitary Survey Required.**

(1) **A sanitary survey shall not be required to classify growing areas as prohibited. The findings of a sanitary survey, however, may result in a growing area being classified as prohibited.**

(2) **A sanitary survey, including the triennial reevaluation, when available, of each growing area shall be required prior to:**

(a) **The harvest of shellstock for human consumption; and**

(b) **The classification of a growing area as approved, conditionally approved, restricted, or conditionally restricted.**

C. **Sanitary Survey Performance.**

(1) **A sanitary survey of each growing area shall be performed at least once every twelve (12) years and shall include the components in Section A. (1).**

(2) **When a written sanitary survey report is not completed within the twelve (12) year time frame, the area shall be immediately placed in the closed status.**

(3) **The growing area classification and the supporting data from the sanitary survey shall be reviewed at least every three (3) years.**

(a) **This triennial reevaluation shall include:**

(i) **A water quality review in accordance with Section C. (5)(b)**

(ii) **Documentation of any new pollution sources and an evaluation of their effect on the growing area;**

(iii) **Reevaluation of all pollution sources~~, including the sources previously identified in the sanitary survey, as necessary~~ to ~~fully~~ evaluate any changes in the sanitary conditions of the growing area. The reevaluation may or may not include a site visit;**

(iv) **A comprehensive report which analyzes the sanitary survey data and makes a determination that the existing growing area classification is correct or needs to be revised; and**

(v) **If the triennial reevaluation determines that conditions have changed based on the information and data collected during the triennial review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.**

(b) **When a written triennial reevaluation report is not completed, the Authority shall place the growing area in the closed status.**

(4) **The triennial reevaluation may include:**

	(a) **Inspection of WWSD or collection of additional effluent samples to determine their impact on the growing area;** (b) **Hydrodynamic studies;** (c) **Additional field work to determine the actual impact of pollution sources; and** (d) **Collection of additional water samples.** (5) **On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include:** (a) **A field observation of the pollution sources which may include:** (i) **A drive-through survey;** (ii) **Observations made during sample collection; and** (iii) **Information from other sources.** (b) **Review, at a minimum, of the past year's microbiological results by adding the year's sample results to the data base collected in accordance with the requirements for the microbiological standards and sample collection required in Section @.02;** (c) **Review of available inspection reports and effluent samples collected from pollution sources;** (d) **Review of available performance standards for various types of discharges that impact the growing area; and** (e) **A brief report which documents the findings of the annual reevaluation.** (f) **The Authority may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of WWSD impacts on shellfish growing areas. If MSC meat and/or water data are being used, the Authority shall conduct annual sample collection and analysis in determining performance standards.** (6) **If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.** D. **Shoreline Survey Requirements.** (1) **In the shoreline survey for each growing area, the Authority shall:** (a) **Identify and evaluate all actual and potential sources of pollution which may affect the growing area;** (b) **Determine the distance from the pollution sources to the growing area and the impact of each source on the growing area;** (c) **Assess the reliability and effectiveness of sewage or other waste treatment systems.;** (d) **Determine if poisonous or deleterious substances adversely affect the growing area;**

(e) **Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas; and**

(f) Conduct an assessment of pollution sources which may include:

(i) A drive-through survey;

(ii) Observations made during sample collection;

(iii) Other in-field assessments; and/or

(iv) Information from other sources.

(2) **The Authority shall assure that the shoreline survey meets the following minimum requirements:**

(a) **The boundaries, based on the area topography, of each shoreline survey area are determined by an investigation which identifies the properties with the potential to impact the shellfish waters;**

(b) **Each shoreline survey area is identified by a unique designation which results in identification of all data associated with each shoreline survey by the unique designation;**

(c) **Each shoreline survey area is investigated and pollution sources evaluated by qualified, trained personnel;**

(d) **Documentation for each pollution source identified by the Authority as affecting a growing area includes:**

(i) **The location of the site on a comprehensive map of the survey area; and**

(ii) **The determination that the pollution source has a direct or indirect impact on shellfish waters: and**

(e) **A written ~~summary~~ report of the survey findings.**

E. **Sanitary surveys for Federal waters will be the responsibility of FDA. Sanitary surveys will be conducted in accordance with Chapter IV @.01, as applicable.**

@.02 Microbiological Standards

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the State. The NSSP also allows for two (2) sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two (2) ways: a total coliform strategy and a fecal coliform strategy so that the State may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, an Authority may wish to adopt the use of both standards and both sampling strategies for

each standard. This codification represents the fecal coliform standards. Additionally, the Authority may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by WWSD.

A. **General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The Authority may utilize MSC data in conjunction with bacteriological data to evaluate WWSD impacts on shellfish growing areas.**

B. **Water Sample Stations. The Authority shall enassure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources.**

C. **Exceptions.**

(1) **Except for growing areas classified as prohibited, in growing areas where there are pollution sources having an impact on the water quality, a minimum of thirty (30) samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under Section @.03.**

(2) **Except for growing areas classified as prohibited or when the systematic random sampling standard is applied, in growing areas where there are no pollution sources having an impact on the water quality, a minimum of fifteen (15) samples shall be required to classify any growing area not previously classified under Section @.03.**

(3) **Except for offshore state waters greater than three (3) nautical miles from shore where a sanitary survey shows that there are no pollution sources that will impact the microbiological quality of the water. Offshore state waters greater than three (3) nautical miles from shore may be classified as approved.**

D. **Standard for the Approved Classification of Growing Areas in the Remote Status.**

(1) **Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard below.**

(2) **Fecal Coliform Standard for the Remote Status. The fecal coliform median or geometric mean most probable number (MPN) or membrane filter (MF) (membrane-Thermotolerant *Escherichia coli* [mTEC]) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:**

(a) **43 MPN per 100 ml for a five-tube decimal dilution test;**

(b) **49 MPN per 100 ml for a three-tube decimal dilution test;**

(c) **28 MPN per 100 ml for a twelve-tube single dilution test; or**

(d) **31 colony-forming units (CFU) per 100 ml for a MF (mTEC) test.**

(3) **Required Sample Collection.**

(a) **A minimum of two (2) samples shall be collected annually.**

(b) **A minimum of the most recent fifteen (15) samples**

	collected shall be used to calculate the median or geometric mean and percentage to determine compliance with the standard established for the approved classification of remote growing areas. E. **Standard for the Approved Classification of Growing Areas when Evaluated for Adverse Pollution Conditions.** (1) **Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2).** (2) **Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:** (a) **43 MPN per 100 ml for a five-tube decimal dilution test;** (b) **49 MPN per 100 ml for a three-tube decimal dilution test;** (c) **28 MPN per 100 ml for a twelve-tube single dilution test; or** (d) **31 CFU per 100 ml for a MF (mTEC) test.** (3) **Required Sample Collection.** (a) **A minimum of five (5) samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.** (b) **A minimum of the most recent fifteen (15) samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric mean and percentage to determine compliance with this standard.** (c) **Sample station locations shall be adjacent to actual or potential sources of pollution.** (4) **For Authorities utilizing MSC data in conjunction with bacteriological data to evaluate WWSD impacts, the MSC level shall not exceed fifty (50) MSC per hundred (100) grams.** F. **Standard for the Approved Classification of Growing Areas when Evaluated for Nonpoint Sources.** (1) **Exception. If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area.** (2) **Pollution Sources. Growing areas shall be impacted only by randomly occurring, intermittent events.** (3) **Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (4).** (4) **Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:** (a) **43 MPN per 100 ml for a five-tube decimal dilution test;**

	(b) **49 MPN per 100 ml for a three-tube decimal dilution test; or** (c) **31 CFU per 100 ml for a MF (mTEC) test.** (5) **Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:** (a) **Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10);** (b) **Multiplying the standard deviation in (a) by 1.28;** (c) **Adding the product from (b) to the arithmetic mean;** (d) **Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and** (e) **The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number.** (6) **Required Sample Collection.** (a) **Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section E. (2).** (b) **Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when:** (i) **Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;** (ii) **Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical;** (iii) **A minimum of six (6) random samples shall be collected annually from each sample station in the growing area;** (iv) **A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6)** (b) **(iii) must resume at least six (6) months before an area is reactivated; and** (v) **A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.** (c) **Transition from Adverse Pollution Condition Standard**

	to Systematic Random Sampling Standard. If the Authority: (i) **Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and** (ii) **Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).** G. **Standard for the Restricted Classification of Growing Areas when Evaluated for Adverse Pollution Conditions and Used as a Shellstock Source for Shellstock Depuration.** (1) **Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section G. (2).** (2) **Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:** (a) **260 MPN per 100 ml for a five-tube decimal dilution test;** (b) **300 MPN per 100 ml for a three-tube decimal dilution test;** (c) **173 MPN per 100 ml for a twelve-tube single dilution test; or** (d) **163 CFU per 100 ml for a MF (mTEC) test.** (3) **Required Sample Collection. Samples shall be collected in accordance with Section E. (3).** H. **Standard for the Restricted Classification of Growing Areas when Evaluated for Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.** (1) **Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.** (2) **Pollution Sources. Growing areas shall meet the requirements in Section F. (2).** (3) **Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Section G. (2) or Section H. (4).** (4) **Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:** (a) **260 MPN per 100 ml for a five-tube decimal dilution test;** (b) **300 MPN per 100 ml for a three-tube decimal dilution test; or** (c) **163 CFU per 100 ml for a MF (mTEC) test.**

(5) **Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in Section F. (5).**

(6) **Required Sample Collection.**

(a) **Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section G. (2).**

(b) **Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in Section F. (6) for the application of the standard under Section H. (4).**

@.03 Growing Area Classification

A. **General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.**

(1) **Emergency Conditions. A growing area or a portion of a growing area (harvest area) shall be placed in the closed status under Section @.03 A. (5) when pollution conditions exist which were not included in the data used to classify the area. If it is determined that an emergency condition or situation exists, then the growing area or harvest area will be immediately (within twenty-four (24) hours) placed in the closed status.**

(2) **Classification of Growing Areas. Each growing area which:**

(a) **Is not subjected to a sanitary survey every twelve (12) years shall be classified as prohibited or, if unclassified, shall be treated as prohibited for NSSP purposes; or;**

(b) **Is subjected to a sanitary survey shall be correctly classified based on the twelve (12) year sanitary survey, and its most recent triennial or annual reevaluation when available, as one (1) or more of the following:**

(i) **Approved;**

(ii) **Conditionally Approved;**

(iii) **Restricted;**

(iv) **Conditionally Restricted; and/or**

(v) **Prohibited.**

(3) **Boundaries. The boundaries of each classified growing area shall be delineated on charts which are:**

(a) **Of sufficient scale and detail so as to adequately describe the boundaries; and**

(b) **Maintained in the central file by the Authority.**

(4) **Revision of Classifications.**

(a) **Any upward revision of a growing area classification shall be supported by an adequate sanitary survey.**

(b) **The appropriate FDA office shall be notified of any revision in growing area classification.**

	(5) **Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open, closed, or inactive for the harvesting of shellstock. Supporting information for all changes in the status of growing areas shall be documented by a written record in the central file.** (a) **Open Status. Except for an area in the prohibited classification, any correctly classified growing area is normally open for the purposes of harvesting shellstock, subject to the limitations of its classification.** (b) **Closed Status. Any classified growing area or harvest area may be closed because of:** (i) **An emergency condition or situation;** (ii) **The presence of biotoxins in concentrations of public health significance;** (iii) **Conditions stipulated in the management plan of conditionally approved or conditionally restricted areas;** (iv) **Failure of the Authority to complete a written sanitary survey or triennial review evaluation report; or** (v) **The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met.** (c) **Controlled Access Status. This status can be applied to allow harvesting in areas with biotoxin concerns where routine monitoring or pre-harvest testing is not practical.** (d) **Reopened Status. A growing area or harvest area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:** (i) **The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels.** (ii)**When pathogens are of concern and the area is not impacted by human sewage, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studies may establish criteria for reopening based on coliform levels in the water.** (iii) **When poisonous or deleterious substances are the concern, sampling shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluation; or** (iv)**For emergency closures of harvest areas caused by the occurrence of raw untreated sewage or partially treated sewage discharged from a sewage collection system or WWSD:**

	a. The MSC analytical sample results in shellfish shall not exceed MSC levels established in Chapter IV @.02 E (4) or **b. Pre-determined MSC levels in shellfish established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted or** **c. Until the event is over and twenty-one (21) days have passed; or** (v) **The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met; and** (vi) **Supporting information is documented by a written record in the central file.** (e) **Inactive Status. The authority may place an approved or restricted growing area affected by non-point sources in the inactive status for up to five (5) years when shellstock harvest is suspended or no longer occurring. Shellstock harvesting shall be closed while an area is in the inactive status. The inactive status must continue for a minimum of one (1) year.** (i) **While in inactive status, the required bacteriological sample collection under @.02 F. (6) (b) (iii) may be reduced to two (2) water samples per station per year collected under the systematic random sample collection strategy. Sanitary survey reports, triennial reevaluations, and annual updates must be completed as required under @.01 C.** (ii) **The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6) (b) (iii) must resume at least six (6) months before an area is reactivated.** (iii) **Before an area is reactivated, the results of the most recent thirty (30) samples must be reviewed and comply with the requirements under @.02 F.** (f) **Remote Status. A growing area may be placed in the remote status if:** (i) **A sanitary survey determines that the area has no human habitation, and is not impacted by any actual or potential pollution sources; and** (ii) **The area is in the approved classification.** (g) **Seasonally Remote/Approved Status. A growing area may be placed in a seasonally remote/approved status requiring two (2) water samples per year if the following criteria are met:** (i) **The area is initially classified as approved;**

(ii) **The closure time period is defined; and**
(iii) **At least one (1) sample be taken upon reopening the area.**

B. **Approved Classification. Growing areas shall be classified as approved when the following criteria are met.**
(1) **Survey Required. A sanitary survey finds that the area is:**
(a) **Safe for the direct marketing of shellfish;**
(b) **Not subject to contamination from human or animal fecal matter at levels that, in the judgment of the Authority, presents an actual or potential public health hazard; and**
(c) **Not contaminated with:**
(i) **Pathogenic organisms;**
(ii) **Poisonous or deleterious substances;**
(iii) **Marine biotoxins; or**
(iv) **Bacteria concentrations exceeding the bacteriological standards for a growing area in this classification.**
(2) **Water Quality. The water quality in the growing area shall meet the bacteriological standards for an approved classification in Section @.02.**

C. **Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:**
(1) **Survey Required. The sanitary survey meets the following criteria:**
(a) **The factors determining the period the growing area is in open status are known and predictable and are not so complex as to preclude a reasonable management approach as determined by the Authority;**
(b) **Each potential source of pollution that may adversely affect the growing area is evaluated;**
(c) **When conditional management is based at least in part on predicted changes in microbiological water quality, microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and**
(d) **For Authorities utilizing MSC meat sample data, when conditional management is based at least in part on predicted changes in MSC levels, those data correlate with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.**
(2) **Management Plan Required. For each growing area, a written management plan shall be developed and shall include:**
(a) **For management plans based on wastewater treatment plant function, performance standards that include:**
(i) **Peak effluent flow, average flow, and infiltration flow;**
(ii) **Microbiological quality of the effluent;**
(iii) **Physical and chemical quality of the effluent;**
(iv) **Conditions which cause plant failure;**
(v) **Plant or collection system bypasses;**
(vi) **Design, construction, and maintenance to**

	minimize mechanical failure, or overloading; (vii) **Provisions for monitoring and inspecting the waste water treatment plant; and** (viii) **Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;** (b) **For management plans based on pollution sources other than waste water treatment plants:** (i) **Performance standards that reliably predict when criteria for conditional classification are met; and** (ii) **Discussion and data supporting the performance standards.** (c) **For management plans based on WWSD function or pollution sources other than WWSD criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum reopening criteria for conditional management plans are:** (i) **Performance standards of the plan are fully met;** (ii) **Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;** (iii) **Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels.** (iv) **Shellstock feeding activity is sufficient to achieve pathogen reduction.** (v) **If (i-iv) are met and if the conditional management plan closure performance standard(s) is(are) based on effects of non-point sources of pollution such as rain events and/or storm water runoff, an area may be reopened when the water quality meets classification criteria without a shellstock cleansing study.** (vi) **For conditionally managed areas based on WWSD performance standards, the Authority may utilize MSC levels in shellstock to establish that sufficient time has elapsed to allow water quality and shellstock to return to acceptable levels in growing areas adjacent to WWSD.** **a. Analytical shellstock tissue sample results shall not exceed the MSC levels established in Chapter IV@.02 E.(4); or** **b. Pre-determined MSC shellstock tissue levels established by the Authority based on studies conducted on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in the shellfish meats; or** **c. The area must be in the closed status until the**

event is over and twenty-one (21) days have passed.

(d) **For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;**

(e) **For management systems based on marine biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;**

(f) **Procedures for immediate notification to the Authority when performance standards or criteria are not met;**

(g) **Provisions for patrol to prevent illegal harvest; and**

(h) **Procedures to immediately place the growing area in the closed status in twenty-four (24) hours or less when the criteria established in the management plan are not met.**

(3) **Reevaluation of Conditional Classification.**

(a) **The classification shall be reevaluated at least once each year. The reevaluation shall include:**

(i) **Evaluation of compliance with the management plan;**

(ii) **Determination of adequacy of reporting of failure to meet performance standards;**

(iii) **Review of the cooperation of the persons involved;**

(iv) **Evaluation of water quality in the growing area with respect to the bacteriological standards for its classification;**

(v) **Field inspection of critical pollution sources, where necessary; and**

(vi) **Written findings, evaluations and recommendations.**

(b) **Water Sample Collection.**

(i) **When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three (3) of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.**

(ii) **When the conditional management plan is based on the operation and performance of a WWSD (s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification except when:**

(a) Hydrographic or dilution analysis has been completed to determine the impact of a WWSD performance failure and communication requirements are documented and the WWSD operator provides immediate notification to the Authority during a performance failure; or

(b) Mooring assessment determines the mooring area is not a pollution source.

(iii) **If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.**

(iv) **When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, storm water runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or six (6) sets of water samples (when the Systematic Random Sampling regimen is used) are required. The samples shall be collected when the growing area is in the open status.**

(v) **When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events or storm water runoff, and the area is in the open status for less than six (6) months a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). At least one (1) sample shall be collected each month the area is placed in the open status. This sample shall be collected while the area is open. If closed status samples are used to meet the minimum sample requirements only two (2) sets of samples may be utilized and they must have been taken within five (5) days of when the Authority anticipates that the area will be placed in the open status. For growing areas in the open status less than two (2) months, at least one (1) sample must be collected while the area is in the open status. Samples collected during the closed status to meet the minimum five (5) sets of water samples shall be applied to annual and triennial reevaluations of the area.**

(vi) **When the conditional management plan is based on the seasonal opening and closing of the area, and the area is in the open status for a predetermined period of less than six (6) months, a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). All samples shall be collected while the area is in the open status unless the Authority has historical water quality data to demonstrate that the area meets open status criteria while in the closed status. If closed status samples are used to meet the minimum sample requirements they must be collected within thirty (30) days prior to the area being placed in the open status.**

(4) **Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management**

Plan by All Parties Involved.

(a) **The management plan shall be developed by the Authority in coordination with:**

(i) **The local shellfish industry;**

(ii) **The individuals responsible for the operation of any WWSDs involved; and**

(iii) **Any local or State agencies; and**

(b) **Failure of any one party to agree shall constitute sufficient justification to deny the application of the conditional classification to a growing area.**

(5) **Conditional Area Types. There are two (2) types of conditional areas:**

(a) **Conditionally approved; and**

(b) **Conditionally restricted.**

(6) **Conditionally Approved Classification. Any growing area in the conditionally approved classification shall:**

(a) **Meet the requirements for:**

(i) **An approved area classification when the conditionally approved classification is in the open status; and**

(ii) **A restricted or prohibited classification when the conditionally approved classification is in the closed status; and**

(b) **If the closed status meets the criteria for the restricted classification, designate in its management plan whether the shellstock may be harvested for relaying or depuration.**

(7) **Conditionally Restricted Classification. Any growing area in the conditionally restricted classification shall:**

(a) **Meet the requirements for:**

(i) **A restricted classification when the conditionally restricted classification is in the open status; and**

(ii) **A prohibited classification when the conditionally restricted classification is in the closed status; and**

(b) **Designate in its management plan whether the harvested shellstock are to be relayed or depurated.**

D. **Restricted Classification.**

(1) **General**

(a) **A growing area may be classified as restricted when:**

(i) **A sanitary survey indicates a limited degree of pollution; and**

(ii) **Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.**

(b) **The Authority shall have effective controls to assure that shellfish are harvested from restricted areas only:**

(i) **By special license; and**

(ii) **Under the supervision of the Authority.**

(2) **Water Quality. Water quality in the growing area shall meet**

	the bacteriological standards in Section @.02 for a growing area in the restricted classification if the growing area is used for depuration. (3) **Shellstock Quality Criteria. The Authority shall establish shellstock quality criteria for use in placing an area in the restricted classification. Depending on the treatment process to be applied to the shellstock, the criteria shall be established in accordance with:** (a) **Chapter V. Shellstock Relaying; or** (b) **Chapter XV. Depuration.** E. **Prohibited Classification.** (1) **Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas. The Authority, however, may use the prohibited classification for these waters.** (2) **General. The Authority shall:** (a) **Not permit the harvest of shellstock from any area classified as prohibited, except for the gathering of seed or nursery culture for aquaculture or resource enhancement or the depletion of the areas classified as prohibited; and** (b) **Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it complies with the criteria in NSSP Model Ordinance Chapter VI. Shellfish Aquaculture @.02 Seed Shellstock.** (3) **Sanitary Survey. A growing area shall be classified as prohibited if:** (a) **No current sanitary survey exists;** (b) **A sanitary survey determines:** (i) **The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;** (ii) **Pollution sources may unpredictably contaminate the growing area;** (iii) **The growing area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms;** (iv) **The concentration of biotoxin is sufficient to cause a public health risk as identified in Section @ .04. or** (v) **The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.** (4) **Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II. Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption.** (5) **Wastewater Discharges.** (a) **An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.**

(b) **The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:**

(i) **The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent. The Authority may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant;**

(ii) **The decay rate of the contaminants of public health significance in the wastewater discharged;**

(iii) **The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and**

(iv) **The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.**

F. **FDA is responsible for the classification of growing areas in Federal waters. Federal waters are classified as Approved for shellfish harvesting unless such areas are known to be polluted (i.e., microbiological, chemical, or marine biotoxin hazards) and involve commercial shellfish resources. Should FDA allow harvesting in Federal waters with known marine biotoxin hazards, the FDA will classify the harvest area in a manner equivalent to the requirements of Model Ordinance Chapter IV.**

@.04 Marine Biotoxin Control

A. **Contingency Plan.**

(1) **The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas addressing the management of PSP, ASP, NSP, diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred or an illness outbreak caused by marine biotoxins.**

(2) **The plan shall define the administrative procedures and resources necessary to accomplish the following:**

(a) **Initiate an emergency shellfish sampling program;**

(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 and federal partners, shellfish industry, and local health agencies;**

(f) **Coordinate control actions taken by Authorities and Federal agencies; and**

(g) **Establish reopening criteria including the number of**

samples over what period of time.

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 IV. Growing Areas @.04 Marine Biotoxin Control .01 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 IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.
(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
(h) 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 IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans. (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 shall be used. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans. (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 IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.

(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 IV. Growing Areas @.04 Marine Biotoxin Control .01 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.

(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. Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.

(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).

C. **Closed or Controlled Access Status of Growing Areas.**

(1) **A growing area, or portion(s) thereof as provided in Section A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the number of toxin-forming organisms in the growing waters and/or the level of biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:**

(a) **PSP - 80 µg saxitoxin equivalents/100 grams**
(b) **NSP - 20 MU/100 grams (0.8 mg brevetoxin-2 equivalents/kg)**
(c) **AZP - 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)**
(d) **DSP – 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)**
(e) **ASP - 2 mg domoic acid/100 grams (20 ppm)**

	(2) **For any marine biotoxin for which criteria have not been established under this Ordinance, either cell counts of the toxin producing organism in the water column or biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.** (3) **When sufficient data exist to establish that certain shellfish species can be safely exempted , the closed status for harvesting may be applied selectively to some shellfish species and not others.** (4) **The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area.** (5) **The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.** (6) **The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.** (7) **A growing area, or portion(s) thereof, shall be placed in the controlled access status for the taking of shellstock when the Authority determines that additional requirements are necessary to ensure the safe harvest of product. Controlled access status is a designation of an approved area or a conditionally approved area in open status. Additional requirements shall be included in harvest permit conditions. All shellstock harvested from growing areas in the controlled access status shall be tagged with Restricted Shellstock tags.** D. **Heat Processing. If heat processing is practiced, a control procedure shall be developed. This procedure shall define the following:** (1) **Toxicity limits for processing;** (2) **Controls for harvesting and transporting the shellstock to processor;** (3) **Special marking for unprocessed shellstock;** (4) **Scheduled processes; and** (5) **End product controls on the processed shellfish.** E. **Records. The Authority shall maintain a copy of all of the following records.** (1) **All information, including monitoring data, relating to the levels of marine biotoxins in the shellfish growing areas;** (2) **Copies of notices placing growing areas in the closed status;** (3) **Evaluation reports; and** (4) **Copies of notices returning growing areas to the open status.** **@.05 Marinas** A. **Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as conditionally approved, conditionally restricted or prohibited.** (1) **Prior to the Authority establishing a classification of conditionally**

approved or conditionally restricted in the marina proper, a pollution assessment supporting the classification will be conducted by the authority.

(2) **The assignment of a prohibited classification within the marina proper does not require a pollution assessment by the Authority.**

B. **Adjacent Waters. Waters adjacent to marina waters classified under Section A. may be impacted by pollution associated with the marina.**

(1) **A dilution analysis shall be used to determine if there is any impact to adjacent waters.**

(2) **The dilution analysis shall be based on the volume of water in the vicinity of the marina.**

(3) **The dilution analysis shall incorporate the following:**

(a) **A slip occupancy rate for the marina;**

(b) **An actual or assumed rate of boats which will discharge untreated waste;**

(c) **An occupancy per boat rate (i.e., number of persons per boat);**

(d) **A fecal coliform discharge rate of 2 x 10^9 fecal coliforms per day; and**

(e) **The assumption that the wastes are completely mixed in the volume of water in and around the marina.**

(f) **Documentation, verification and enforcement of Federal No Discharge Zones and locally well enforced no discharge and occupancy by-laws and regulations.**

(g) **Availability and documented use of pump out boats or facilities.**

(4) **If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina shall be classified as:**

(a) **Conditionally approved;**

(b) **Restricted;**

(c) **Conditionally restricted; or**

(d) **Prohibited.**

(5) **If the dilution analyses predicts a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:**

(a) **Approved; or**

(b) **Conditionally approved.**

(6) **If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two (2) persons per boat.**

@.06 Mooring Areas

A. Mooring Area. The area within any designated mooring area, where there is anchoring of boats, which is in or adjacent to a shellstock growing area shall be classified as conditionally approved, conditionally restricted, restricted or prohibited.

(1) Prior to the Authority establishing a classification of conditionally approved or conditionally restricted or restricted in the mooring area proper, a pollution assessment supporting the classification will be conducted by the authority. The assessment shall include:

	(a) Boat type and usage (b) Density of boats (c) Accessibility to boats which could reduce likelihood of overnight occupancy. (d) Occupancy rates (e) Seasonal Use Pattern (f) An actual or assumed rate of boats which will discharge untreated waste (g) Documentation, verification and enforcement of federal No Discharge Zones, and locally well enforced no discharge and occupancy regulations or by-laws. (h) Availability and documented use of pump out boats. (2) After assessment determines that the mooring area is not a pollution source and it is documented in the Conditional Area Management Plan, the area can be placed in the open status. **(3) The assignment of a prohibited classification within the mooring area proper does not require a pollution assessment by the Authority.** B. Adjacent Waters. Waters adjacent to open water mooring areas classified under Section A. may be impacted by pollution associated with the mooring areas. If determined a pollution source: (1) A dilution analysis shall be used to determine if there is any impact to adjacent waters. (2) The dilution analysis shall be based on the volume of water in the vicinity of the mooring areas. (3) The dilution analysis shall incorporate the following: (a) An occupancy rate for the mooring areas; (b) An actual or assumed rate of boats which will discharge untreated waste; (c) An occupancy per boat rate (i.e., number of persons per boat); (d) A fecal coliform discharge rate of 2×10^9 fecal coliform per day; and (e) The assumption that the wastes are completely mixed in the volume of water in and around the open water mooring areas. (4) If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas shall be classified as: (a) Conditionally approved; (b) Restricted; (c) Conditionally restricted; or (d) Prohibited. (5) If the dilution analyses predict a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas may be classified as: (a) Approved; or (b) Conditionally approved.
12. Public Health Significance	N/A

13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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

2. Submitter	U.S. Food & Drug Administration (FDA)
3. Affiliation	U.S. Food & Drug Administration (FDA)
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6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Documentation requirements for no-discharge zones
10. Specific NSSP Guide Reference	NSSP MO, Section II, Chapter IV. @.05 B. (3) (f) and @.06 A. (1) (g)
11. Text of Proposal/ Requested Action	@.05 B. (3) (f) If the No Discharge Zone designation is utilized in the dilution analysis, provide ~~D~~documentation~~,~~ of ~~verification and~~vessel compliance or non-compliance with and enforcement of ~~Federal~~ statutory No Discharge Zones ~~and~~ including locally well enforced no discharge and occupancy by-laws and regulations. @.06 A. (1) (g) If the No Discharge Zone designation is utilized in the pollution assessment, provide ~~D~~documentation~~,~~ of ~~verification and~~ vessel compliance or non-compliance with and enforcement of ~~Federal~~statutory No Discharge Zones ~~and~~ including locally well enforced no discharge and occupancy by-laws and regulations.
12. Public Health Significance	This is a suggested change to Model Ordinance language to clarify the intent of the requirement to document the NDZ federal regulation (33 CFR 159.7(b)-(c) (PDF)) is being enforced in marinas and mooring areas. The documentation of enforcement is required where the NDZ is being used to justify reducing the impact of waters adjacent to marinas and areas classified as conditionally approved in the open status for mooring areas. The intent of this requirement is to protect public health by ensuring that the Authority provide documentation that the NDZ vessel requirements in marinas and mooring areas are being effectively enforced. NDZ federal regulation (33 CFR 159.7(b)-(c) (PDF)) requirements: Type I or II marine sanitation device (MSD): • Closing the seacock and removing the handle; • Padlocking the seacock in the closed position; • Using a non-releasable wire-tie to hold the seacock in the closed position; or • Locking the door to the space enclosing the toilets with a padlock or door handle key lock. Type III MSDs: • Closing valves leading to overboard discharge and removing the handle; • Padlocking any valves leading to overboard discharge in the closed position; or • Holding overboard discharge valves closed using a non-releasable wire-tie.

	Additionally, the Environmental Protection Agency (EPA) administers the Clean Water Act's (CWA) No Discharge Zone (NDZ) program; however, most existing NDZs were approved by EPA but designated by the state under CWA Section 312(f)(3). Only 4 NDZs are EPA/federal NDZs: the FL Keys National Marine Sanctuary, the Boundary Waters Canoe Area, California Marine Water, and part of the Hudson River in NY. No discharge zones in state waters are not Federal No Discharge Zones. Upon approval of the Environmental Protection Agency (EPA), no discharge zones become state no discharge zones and are subject to state enforcement capabilities. States are responsible for enforcing the statutory requirement and can delegate the responsibility to local entities. Reference: The Clean Water Act: Section 312 (f) (3). https://www.epa.gov/vessels-marinas-and-ports/vessel-sewage-no-discharge-zones
13. Cost Information	No cost.
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	Matt Richards, Scott Berbells – Washington State Department of Health, David Borkman – Rhode Island Department of Environmental Management, Bryant Lewis – Maine Department of Marine Resources
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8. Email	matt.richards@dec.ny.gov
9. Proposal Subject	No Discharge Zone (NDZ) enforcement and verification
10. Specific NSSP Guide Reference	Section II, Chapter IV, @.05 B (3) (f) and @.06 A (1) (g)
11. Text of Proposal/ Requested Action	(f) ~~Documentation, verification and enforcement~~ Documentation of ~~Federal~~ No Discharge Zones and ~~locally well enforced~~local no discharge and occupancy ~~by-laws and regulations.~~regulations or by-laws (g) ~~Documentation, verification and enforcement~~Documentation of ~~federal~~ No Discharge ~~Zones, and locally well enforced~~Zones and local no discharge and occupancy regulations or by-laws.
12. Public Health Significance	No change will occur to public health protection. Established No Discharge Zones (NDZ) and local regulations/by-laws (where used) already prohibit discharges from vessels. Verification of state and local NDZ enforcement efforts by the shellfish authority does not increase the amount of compliance with federal/state/local laws and regulations and will not decrease the amount of potential illicit discharges from vessels. The pollution assessment, dilution analysis, and sizing of necessary closures around marinas and mooring areas when boats are present already account for illicit discharges from vessels. No metrics to measure compliance with this portion of the requirements exist within the NSSP-MO. NDZ enforcement and verification creates unreasonable burdens on the shellfish authority to gather large amounts of information on a regular basis from every marina and mooring facility in the conditionally approved classification. Gathering this information also places additional burdens on state and local authorities by straining resources and relationships, encouraging violation of search and seizure laws, requiring large amounts of time, effort, and personnel by law enforcement agencies, and requiring the cooperation of vessel owners and facility owners/managers to conduct inspections.
13. Cost Information	No cost is associated with this proposal.
14. Changes Needed to Guidance (if proposed change is adopted)	The Marina and Mooring Committee is currently working on proposal 23-121 and proposal 23-124, proposed guidance for marinas and moorings. These proposed changes would need to be incorporated into the work product from that proposal.

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	Christian Petitpas[1], Matt Camisa[1], Wayne Castonguay[2]
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6. City, State, Zip	New Bedford, MA 02744[1]; Gloucester, MA 01930[2]
7. Phone	(508) 742-9766
8. Email	Christian.Petitpas@mass.gov
9. Proposal Subject	Clarification of re-opening criteria following emergency closure due to discharge of untreated or partially treated sewage
10. Specific NSSP Guide Reference	Section II, Chapter IV, @.03 A. (5) (d) (iv)
11. Text of Proposal/ Requested Action	(iv)For emergency closures of harvest areas caused by the occurrence of raw untreated sewage or partially treated sewage discharged from a sewage collection system or WWSD: a. Shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted may be tested for MSC. The MSC analytical sample results in shellfish shall not exceed ~~1.~~ MSC levels established in Chapter IV @.02 E (4) or 1. 2. Pre-determined MSC levels in shellfish established by the Authority based on studies conducted on regional species under regional conditions; ~~from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted~~ or ~~a.~~b. Until the event is over and twenty-one (21) days have passed; or
12. Public Health Significance	The proposed change clarifies that a growing area impacted by raw, untreated or partially treated sewage must be closed a minimum of 7 days prior to MSC testing whether the MSC standard of fifty (50) MSC per hundred (100) grams is used to re-open or a return to pre-determined baseline MSC levels in shellfish. As written in the 2023 MO, it can be interpreted that the 7-day closure only applies if the Authority is using pre-determined baseline MSC levels in shellfish as the standard for re-opening, and that if the Authority is using the MSC standard of 50 PFU/100 g shellfish for re-opening then shellfish could be tested on day 2 or 3 following an untreated sewage discharge and the growing area returned to the open status sooner than 7 days if results do not exceed 50 PFU/100 g. It is believed that the intent of the conference was for the 7-day closure to apply regardless of the MSC level used as the re-opening standard. This is supported by the following language in Guidance (p.312): "The regulatory level of 50 PFU/100 g is a conservative value used for re-opening approved growing areas (after 7 days) after a sewage spill…" AND in Section VIII FDA Manual of Interpretations (p.486): "under emergency conditions…such as a raw sewage discharge from an extreme event, and the SSCA closes the growing area as a result, reopening samples (such

	as assessing the levels of Male Specific Coliphage (MSC) in shellfish meats no sooner than seven (7) days after the event)". The proposed change moves the language "shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted" before the two options for MSC levels in shellfish and both options for MSC levels become sub bullets under bullet a. The default 21-day closure option becomes bullet b.
13. Cost Information	No additional costs are associated with the proposed changes.
14. Changes Needed to Guidance (if proposed change is adopted)	No changes to Guidance would be required.

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)
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6. City, State, Zip	College Park, MD 20740
7. Phone	240-402-1401
8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	WWTP minimum dilution zone
10. Specific NSSP Guide Reference	Section II Model Ordinance Chapter IV @.03 E.
11. Text of Proposal/ Requested Action	Chapter IV @.03 E. Prohibited Classification. (1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas. The Authority, however, may use the prohibited classification for these waters. (2) General. The Authority shall: (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the gathering of seed or nursery culture for aquaculture or resource enhancement or the depletion of the areas classified as prohibited; and (b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it complies with the criteria in NSSP Model Ordinance Chapter VI. Shellfish Aquaculture @.02 Seed Shellstock. (3) Sanitary Survey. A growing area shall be classified as prohibited if: (a) No current sanitary survey exists; (b) A sanitary survey determines: (i) The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance; (ii) Pollution sources may unpredictably contaminate the growing area; (iii) The growing area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms; (iv) The concentration of biotoxin is sufficient to cause a public health risk as identified in Section @ .04. or (v) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated. (4) Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II. Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption. (5) Wastewater Discharges.

(a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.
(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:

(i) The volume flow rate~~,~~ location of discharge~~, performance of the wastewater treatment plant and the microbiological quality of the effluent. The Authority may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant~~;

(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;

(iii) The wastewater's ~~dispersion and~~ dilution, ~~and the time of waste transport to the area where shellstock may be harvested; and~~ performance of the wastewater treatment plant, and the microbiological quality of the effluent prior to disinfection:

a. If wastewater samples are not collected from the WWTP to evaluate the MSC levels and microbiological quality of the effluent to establish the size of a prohibited area around a WWTP outfall, the following minimum dilutions for the boundary line between prohibited and other possible classifications, shall be based on an assumed worst-case fecal coliform value of 1.4×10^6 FC/100 ml:
   (1) Prohibited to Approved: Minimum 100,000:1 dilution that would be equivalent to an MPN of 14 FC/100 ml.
   (2) Prohibited to Conditionally Approved: Minimum 1,000:1 dilution.
   (3) Prohibited to Restricted or Conditionally Restricted (For depuration only**):** Minimum 16,000:1 dilution that would be equivalent to an MPN of 88 FC/100 ml.
   (4) Prohibited to Restricted or Conditionally Restricted (For relay only): Minimum 400:1 dilution. Based on WWTP performance standards.
b. If MSC samples collected from the WWTP to evaluate the microbiological quality of effluent are used to establish the size of a prohibited area around a WWTP outfall, the following minimum requirements shall be met:

	(1) MSC samples are collected from the influent and pre- and post-disinfection effluent from each WWTP to be evaluated: (i) MSC samples are collected to establish effluent quality and effectiveness of disinfection under normal operating conditions for the WWTP; and (ii) MSC samples are collected to establish effluent quality and effectiveness of disinfection under adverse conditions for the WWTP; and (2) The sample collection is conducted to account for environmental and high use period factors such as seasonality, rainfall, and high flows; and (3) The effluent quality and environmental data shall be used to establish the size of the prohibited area. For a prohibited area adjacent to an approved area, worst-case pre-disinfection levels and time of travel must be considered. (4) If (1) through (3) have been completed and the effluent quality and environmental data justifies a reduced prohibited area, the minimum size of the prohibited area shall be based on a minimum dilution of 400:1 using a hydrographic dye study or hydrodynamic dispersion modeling to account for the risk of enteric viruses. Additional sampling shall be required to account for the risk for poisonous or deleterious substances of public health concern present in the wastewater effluent. (iv) The wastewater's dispersion. (v) The wastewater effluent time of travel to the area where shellstock may be harvested; and (~~i~~vi) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.
12. Public Health	In sizing prohibited areas around a WWTP outfall, broad minimum criteria have been established in the Model Ordinance. Guidance is available that provides

Significance	additional information to assist in meeting the Model Ordinance requirements if microbiological quality samples are not collected. Authorities also have the option to collect microbiological samples to assess the WWTP effluent and justify an alternate prohibited area sizing strategy. Some advanced wastewater treatment plants have become very efficient at treating for and removing fecal coliforms from wastewater effluent. Depending on the disinfection process, fecal coliform may not be the most appropriate indicator of viruses and poisonous or deleterious contaminants of concern as you get closer to the WWTP effluent, creating a false sense of human health protection. This proposal is meant to establish more defined guidelines as well as, a minimum dilution zone requirement around all wastewater treatment plant outfall pipes to ensure protection from viral and other contaminants (poisonous or deleterious substances) that fecal coliforms may not represent. In addition, Section II. Chapter XV. .03 K. already sets precedence for a minimum prohibited area for depuration: "K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD) outside of a 300:1 dilution or the EPA Toxic Dilution Zone (whichever is greater) and within an area determined to be impacted by wastewater treatment system discharge. These requirements would allow harvesting in areas that would otherwise be classified as prohibited due to viral pollution concerns. The harvest area that could be considered would include the area between 300:1 dilution or the EPA Toxic Dilution Zone (whichever is greater) and the established boundary for depuration (Chapter IV @.02 G.)."
13. Cost Information	No cost.
14. Changes Needed to Guidance (if proposed change is adopted)	TBD

pProposal 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	Model Ordinance Effectiveness Review Committee
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6. City, State, Zip	Richmond,VA
7. Phone	804-330-6380
8. Email	issc@issc.org
9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter VI. Shellfish Aquaculture
11. Text of Proposal/ Requested Action	**@ .01 General** A. Aquaculture activities which may pose a ~~significant~~ public health concern and are regulated in this Chapter include, but are not limited to: (1) Seed production in waters classified as Prohibited or Unclassified; (2) Aquaculture structures that attract birds or mammals; and (3) Land based aquaculture. B. The Authority shall: (1) Approve the written operational plan for operations as outlined in @.01A above; (2) Inspect operations outlined in @.01A above at least annually; and (3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A (1). are being implemented. (4) Consistent with Chapter IV @ .01 D(1)(e) when aquaculture as defined in the Model Ordinance attracts birds or mammals, their presence should be considered for possible adverse effects on growing area water quality. **@ .02 Seed Shellstock** A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size. B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed size when it has been produced in waters classified as prohibited. C. All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.

@.03 Aquaculture in Federal Waters

A. Federal Agency Responsibilities. Once the ~~appropriate~~ permits for the construction of the aquaculture facility have been obtained,
   (1) NOAA is responsible for establishing a contract, in consultation with FDA, with the aquaculture facility describing requirements of the NSSP including:
      (a) the frequency with which NOAA will audit the aquaculture facility and vessels;
      (b) testing requirements of the aquaculture facility; and
      (c) the generation of product identification for traceability (i.e., tag numbers); and
   (2) FDA is responsible for reviewing the aquaculture facility operational plan prior to the start of operations, as well as the annual inspection of records, to ensure adherence to NSSP requirements. FDA is also responsible for the classification of the growing area(s) associated with the aquaculture facility.

Requirements for the Harvester/Dealer

.01 Exceptions

Hatcheries and nurseries rearing larvae and/or seed that are located in:
   A. Approved or conditionally approved growing areas are exempt from these requirements; or
   B. Restricted or Conditionally Restricted (in the open status) would be exempt from these requirements but subject to relay requirements in Ch V. or depuration requirements in Chapter XV for seed that exceeds the maximum seed size established by the Authority.

.02 General

   A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
      (1) A permit from the Authority for the activity and functioning of his facility;
      (2) A harvester's license; and
      (3) Certification as a dealer, where necessary.
   B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced ~~only~~ in ~~strict~~ compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.
   C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.

D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
   (1) The closed status of the conditionally approved classification;
   (2) The restricted classification; or
   (3) The open status of the conditionally restricted classification.

E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.

F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.

G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:
   (1) Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification; and
   (2) Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Production in Water Classified as Prohibited or Unclassified

Seed may come from any growing area, or from any growing area in any classification, provided that:

A. The source of the seed, if from waters classified as prohibited or unclassified, is sanctioned by the Authority; and

B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
   (1) A description of the design and activities of the culture facility;
   (2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
   (3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
   (4) The species of shellfish to be cultured and harvested;
   (5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities; and
   (6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.

.04 Aquaculture That Attracts Birds or Mammals

A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammalswhose ~~that their~~ waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:

(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
(5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities;
(6) A description of the mitigation or deterrent measures to minimize the potential pollution impact of birds and/or mammals; and
(7) Maintenance of the required records.

.05 Land Based Aquaculture

A. Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:
(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish culture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
~~(5) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;~~
~~(6)~~(5) A program of sanitation, maintenance, and supervision to prevent contamination or adulteration of the shellfish products;
~~(7)~~(6) A description of the water source, including the details of any water treatment process or method;
~~(8)~~(7) A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring (the bacterial indicator monitored shall be the same as used for monitoring growing areas);
~~(9)~~(8) If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and
~~(10)~~(9) Maintenance of the required records.
B. Each land-based facility conducting aquaculture as defined by the Model Ordinance shall maintain the following records while the aquaculture activity continues:
(1) Construction and remodeling plans for any permitted aquaculture facility;
(2) Aquaculture operational plans; and
(3) Aquaculture permits.
C. Water Systems.
If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the

open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.

D. Water Quality.

(1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and meets the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.

(2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) shall be relayed or depurated consistent with Chapters ~~I~~V and XV prior to direct marketing.

.06 Polyculture Systems

A polyculture system shall:

A. Meet all requirements in Section .05 Land Based Systems;

B. Provide information concerning all sources and species of all organisms to be cultivated, cultured, and harvested; and

C. Include in its operational plan requirements to:

(1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

(2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

.07 Requirements for the Harvester in Aquaculture in Federal Waters

A. Prior to beginning any aquaculture activities, the person who performs aquaculture or operates an aquaculture facility to raise shellfish in Federal waters for human consumption shall obtain the required ~~appropriate~~ permission(s) from Federal agencies as described in @.03.

B. Operational Plan. Each aquaculture facility shall have a written operational plan as described for Land Based Aquaculture in Section II Chapter VI .05(A). The operational plan shall also include:

(1) Description of harvest, tagging, handling, storage, transportation, and landing procedures;

(2) Description of a marine biotoxin management and contingency plan (Section II Chapter IV @.04) to include marine biotoxin sampling consistent with Section II Chapter IV @.04(B)(6) and ensure product segregation and control until biotoxin results confirm the shellfish do not contain biotoxins equal to or exceeding criteria established in Section IV Chapter II .08.;

	(3) Description of a contingency in the event of an emergency situation or condition (e.g., sewage or oil spills); and **(4) Procedures for implementing product recalls.** **Each aquaculture facility shall obtain a review from the FDA to ensure adherence to NSSP requirements prior to its implementation. If the aquaculture facility makes changes to the operational plan, they shall obtain a new review from the FDA to ensure adherence to the NSSP requirements.**
12. Public Health Significance	N/A
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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	Meredith L. Zahara, Leanne J. Flewelling
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9. Proposal Subject	NSSP PSP Bioassay Checklist: Part II 2.4 Calculation of toxicity for MBA
10. Specific NSSP Guide Reference	NSSP 2023 Revision: Section IV Guidance Documents – Chapter III Laboratory
11. Text of Proposal/ Requested Action	This proposal requests a revision to NSSP PSP Bioassay Checklist linked in the NSSP 2023 Revision: Part II 2.4 Calculation of toxicity for MBA. Current text: *Part II 2.4.5 The toxicity of each sample is calculated as follows:* *µg STX eq/100 g of sample = MCMU x CF x DF x 200 except when less than 100 grams of sample is used for analysis.* *In this case an adjustment for sample weight must be made such that the formula for calculating sample toxicity becomes:* *µg STX eq/100 grams of sample = MCMU x CF x DF x 200/Adjusted weight of the acidified sample x 200.* *Where:* *MCMU=Median Corrected Mouse Unit for the sample* *CF=Laboratory Conversion Factor* *DF=Dilution Factor (if additional dilution is required)* The calculation provided for cases when less than 100 grams of sample is used for analysis is incorrect. The PSP Bioassay Checklist requires a strict 1:1 ratio between sample weight (g) and acid volume (mL) added (2.2.3). The final weight (g) is adjusted as needed due to evaporative losses to the pre-boiling weight (2.2.10). In the primary equation, when 100 g of sample is used for analysis: µg STX eq/100 g of sample = MCMU x CF x DF x 200 • MCMU x CF x DF generates the µg STX eq. in a 1 mL injection (volume injected into each mouse). • The 200 multiplier extrapolates the STX eq in 1 mL (0.5g eq) of extract to 200 g (100g eq). When this proportional scaling is maintained, as required, the final calculation remains unchanged because the total extract weight divided by sample mass **will always reduce to 2.**

	However, to explicitly reflect using <100 g in the calculation, the formula could be corrected to µg STX eq/100 g of sample = MCMU x CF x DF x (Total Extract Weight (g) / Sample Mass (g)) × 100 grams
12. Public Health Significance	The calculation in its current form substantially overestimates the toxin level in samples and can prevent harvest. Although this does not pose a public health risk, it can cause significant negative impacts to the aquaculture industry and economic harm to local communities.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	Proposed revision to the PSP Bioassay Checklist: *Part II 2.4.5 The toxicity of each sample is calculated as follows:* *µg STX eq/100 g of sample = MCMU x CF x DF x 200* *except when less than 100 grams of sample is used for analysis.* ~~*In this case an adjustment for sample weight must be made such that the formula for calculating sample toxicity becomes:*~~ ~~*µg STX eq/100 grams of sample = MCMU x CF x DF x 200/Adjusted weight of the acidified sample x 200.*~~ *To document the use of less than 100 g, use the following calculation:* *µg STX eq/100 g of sample = MCMU x CF x DF x (Total Extract Weight (g) / Sample Mass (g)) × 100 grams* *Where:* *MCMU=Median Corrected Mouse Unit for the sample* *CF=Laboratory Conversion Factor* *DF=Dilution Factor (e.g. 1:1 dilution, DF=2)*

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Matrix Extensions for the Receptor Binding Assay for detecting Paralytic Shellfish Poisoning [SLV (2023;Proposal13-114)]
Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter IV. Growing Areas Paralytic Shellfish Poisoning (PSP) Shellfish Lab Methods page 351
Text of Proposal/ Requested Action	This submission presents the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination for consideration to upgrade its current limited use status to an NSSP Fully Approved Use Method from mussels (*Mytilus species*) to include Pacific geoduck clam (*Panopea generosa*) gutball, whole Pacific oysters (*Crassostrea gigas*), northern razor clam (*Siliqua patula*) meat only, and whole hard clams, comprising three species: butter clams (*Saxidomus gigantea*), Pacific littleneck clams (*Protothaca staminea*), and Japanese littleneck clams (also known as Manila clams; *Venerupis philippinarum).* The mouse bioassay (MBA) remains the most widely accepted method for detecting saxitoxins worldwide and has been demonstrated to adequately protect public health. The receptor binding assay (RBA) is a competitive assay in which radiolabeled saxitoxin competes with unlabeled saxitoxin for a finite number of available receptor sites. The resulting measurement provides an estimate of overall PSP toxicity in a shellfish sample (Van Dolah et al., 2009). The RBA was approved for use with mussels and approved for limited use with clams and scallops in 2014. To support full implementation of the RBA, Washington State conducted matrix extension studies to evaluate and expand the use of the method to additional species of molluscan shellfish. The validation and matrix extension study report is included with this proposal submission. The requested action is to expand the NSSP approved use of the RBA to include mussels, clams, geoduck clams (gutball), razor clam (meat), and oysters as a fully approved use method for PSP toxicity determination. **Paralytic Shellfish Poisoning (PSP) Toxins**

Shellfish Lab Methods	The mouse bioassay is still the most widely accepted detection method for the saxitoxins around the world and has been shown to adequately protect the public's health. In 2009, the Interstate Shellfish Sanitation Conference approved a post-column oxidation HPLC- PCOX method, making it the newest regulatory method available for PSP toxins in the U.S. The receptor binding assay (RBA), a competition assay whereby radiolabeled saxitoxin competes with unlabeled saxitoxin for a finite number of available receptor sites, provides a measure of

		overall PSP toxicity in a sample (Van Dolah et al., 2009). The RBA was approved for mussels in 2014, Pacific geoduck gutball, whole Pacific oysters, northern razor clam (meat only), and whole hard clams, comprising three species: butter clams, Pacific littleneck clams and Japanese littleneck clams in 2026 and approved limited use for ~~clams~~ and scallops in 2014.
Public Health Significance	**Public Health Significance:** Paralytic shellfish poisoning (PSP) is a serious public health concern because exposure to paralytic shellfish toxins can cause severe illness and, in some cases, death. The receptor binding assay (RBA) provides a more sensitive and efficient approach for detecting saxitoxin and related toxins in shellfish. The RBA can detect toxins at approximately five times lower concentrations than the mouse bioassay, providing an earlier warning of toxin accumulation. This increased sensitivity supports more timely public health actions, including increased sampling, harvest closures, and reopening decisions, helping reduce the potential for contaminated shellfish to reach consumers and recreational harvesters. The implementation of the RBA strengthens Washington's ability to protect public health while supporting efficient, sustainable shellfish monitoring.	
Cost Information	The estimated cost per 96-well plate assay is ~$300. Including standards and samples with triplicate measurements (as well as three dilutions per sample [ranging from 3.5-600 µg STX eq 100 g-1] to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitation would be ~$40. If running multiple plates or in screening mode (single dilutions), sample costs could be reduced significantly. A microplate scintillation counter is needed as a one-time purchase, and the cost is ~$70-250K for a new counter, depending on the brand and number of simultaneous detectors. However, used instruments can be purchased for ~$13K. In 2025, the Washington State Public Health Laboratories (WA PHL) analyzed approximately 3,000 paralytic shellfish poisoning (PSP) samples. Replacing the more costly Mouse Bioassay ($145 per sample) with the less expensive Receptor Binding Assay (RBA) ($40 per sample) could have resulted in an estimated savings of approximately $315,000 in a single year. Expanding the use of the RBA offers significant potential for long term cost savings while maintaining the capacity needed to support ongoing public health surveillance and shellfish safety testing.	

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative
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Proposal Subject	**Method Modification Request: Receptor Binding Assay for the Detection of Paralytic Shellfish Poisoning Toxins: porcine tissue option for use as a receptor source.**
Specific NSSP Guide Reference	**2023 NSSP Guide for the Control of Molluscan Shellfish** Section IV Guidance Documents – Chapter IV. Chapter III. Laboratory Page | 266 SHELLFISH LABORATORY EVALUATION CHECKLIST Receptor Binding Assay for Paralytic Shellfish Poisoning (RBA PSP) https://www.issc.org/sites/default/files/uploads/-2023/2023-guide-docs/11-rba-psp-checklist-with-comments.pdf Part I Quality Assurance 1.5 Reference Solution Reagent Storage, Preparation and Security 1.5.8 Commercial porcine brain homogenate is stored according to the manufactures specification and is properly labeled with received date and expiration date. 1.7 ~~Rat Brain~~ Membrane Tissue Preparation 1.7.1 The protein/receptor concentration of the rat or porcine membrane tissue preparation is determined for each new commercial lot or batch or using a Pierce Micro BCA Protein Assay Reagent Kit No. 23235 (micro plate method) or No. 23225 (tube method) or equivalent. 1.7.2 The dilution of the protein/receptor concentration of the rat or porcine brain membrane tissue preparation needed to obtain a working stock of 1 mg/mL is determined by either titration to meet the required 'top' value or by generating a tissue linearity curve. 1.7.3 Dilutions of the protein/receptor concentration of the rat or porcine brain membrane tissue preparation of less than 1:4 are not used as they may be too viscous

Text of Proposal/ Requested Action	This submission presents the Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination for consideration to offer an optional tissue type as a receptor source. We propose that the Interstate Shellfish Sanitation Conference (ISSC) approve a modification to the Receptor Binding Assay (RBA) method [SLV (2023;Proposal13-114] for the detection of Paralytic Shellfish Poisoning (PSP) toxins. The proposed modification would allow the use of porcine brain tissue as an alternative source of receptorsto rat brain tissue for the RBA. This modification would provide an additional tissue source for preparation of the receptor material while maintaining the established principles and intended analytical application of the RBA method. The proposed modification would be supported by appropriate method validation data demonstrating that the use of porcine brain tissue provides comparable analytical performance to the currently specified rat brain tissue.
Public Health Significance	The Receptor Binding Assay (RBA) provides a sensitive and efficient method for detecting Paralytic Shellfish Poisoning (PSP) toxins in shellfish and supports timely public health decisions related to shellfish safety and harvest closures. Maintaining reliable access to the tissue required for the assay is important to ensure continued laboratory capacity for routine monitoring and response to PSP events. Allowing the use of porcine brain tissue as an alternative to rat brain tissue would provide laboratories with a commercially accessible source of receptors, which reduces the cost associated with obtaining and preparing the receptor material. This modification could therefore reduce the overall cost and ease of performing the RBA while supporting the sustainability and availability of the method. The proposed modification would not change the intended use of the RBA for detection of PSP toxins. Use of porcine brain tissue would be supported by appropriate validation demonstrating comparable analytical performance to the established rat brain tissue source. Providing laboratories with an additional, readily available and cost effective receptor source would strengthen the long term sustainability of the RBA and support continued, timely public health monitoring of shellfish for PSP toxins.
Cost Information	The estimated cost per 96-well plate using porcine is ~$235. Including standards and samples with triplicate measurements (as well as three dilutions per sample [ranging from 3.5-600 µg STX eq 100 g-1] to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitation would be ~$35. In contrast, the estimated cost for a 96-well plate using rat brain is ~$300 with a cost per sample for quantitation of ~$40. For a potential savings of ~$5 per sample while using porcine. If running multiple plates or in screening mode, sample costs would be reduced for both receptor protein sources." In 2025, the Washington State Public Health Laboratories (WA PHL) analyzed approximately 3,000 PSP samples. The use of less expensive porcine tissue in the Receptor Binding Assay would have resulted in an estimated cost savings of approximately $15,000 that year.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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9. Proposal Subject	Provide Guidance on Performing Laboratory Method Platform Extensions
10. Specific NSSP Guide Reference	Section IV: Guidance Documents, Chapter III. Laboratory, @.02 Methods and Single Lab Validation For Laboratory Methods page in the Laboratory Section of the ISSC Website
11. Text of Proposal/ Requested Action	New guidance document attached.
12. Public Health Significance	Modifications to validated laboratory methods are sometimes necessary in order to improve accessibility, adapt to new equipment or technology, or adapt to changes in availability or suitability of materials utilized in the original method. Additional studies must be done to demonstrate that these modified methods perform equivalently to the approved method before they can be used within the NSSP. In some situations, the modifications to the method are significant enough that a full Single Lab Validation is necessary. In other situations, a smaller extension study may be appropriate. These documents provide guidance on how and when to conduct a platform extension study in order to validate certain modifications to laboratory methods.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Update Guidance on Analytical Method Verification
10. Specific NSSP Guide Reference	Section IV: Guidance Documents, Chapter III. Laboratory, @.02 Methods, .02
11. Text of Proposal/ Requested Action	New guidance attached.
12. Public Health Significance	Verification of method performance within a lab is a necessary step before a laboratory may begin to implement a method to support a state shellfish sanitation program. This proposal is intended to update the existing guidance documents section on method verification to provide clearer instruction on how to carry out a method verification, and to add in new information on how to verify a laboratory method that does not include original SLV data.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

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9. Proposal Subject	Update SOP for Quantitative Biotoxin Method Validation
10. Specific NSSP Guide Reference	ISSC Website – Laboratory – Single Laboratory Validation Protocol for Submission to the ISSC
11. Text of Proposal/ Requested Action	Procedure Attached
12. Public Health Significance	Laboratory method validation is a foundational component of the NSSP Laboratory Program, ensuring that laboratory methods are fit for their intended use within the program before they are approved for use. The existing SOPs providing guidance on how to conduct a single laboratory validation study were originally added to the program in the 1990s, and since that time, a lot has been learned as they have been applied to the many laboratory methods that have been submitted for adoption into the program. Using feedback from both method developers and method reviewers, an improved SOP for Quantitative Biotoxin Method Validation has been developed.
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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
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9. Proposal Subject	AOAC OMA 2005.06, Determination of Paralytic Shellfish Poisoning Toxins in Shellfish Using Prechromatographic Oxidation and Liquid Chromatography with Fluorescence Detection
10. Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter III. Laboratory @.02 Methods 0.1 Approved NSSP Laboratory Tests 2. Approved Methods for Marine Biotoxin Testing
11. Text of Proposal/ Requested Action	Adoption of AOAC Official Method 2005.06 (OMA 2005.06) as an Approved Method of PSP testing in mussels, clams, oysters, and scallops. In the ISSC Constitution Bylaws and Procedures, updated July 22, 2024, Procedure XV. Procedure for the approval of analytical methods for the NSSP, section vii(a) states that: *AOAC approved methods that have undergone the AOAC Official Methods of Analysis (OMA) or FDA Office of Foods Level 3 or 4 validations may be accepted as an NSSP method without Single Lab Validation providing the AOAC or FDA multi-laboratory validation was performed in the raw molluscan shellfish matrix for which the Conference intends it to be used and is deemed by ISSC as fit for purpose.* The European Union (EU) integrated OMA 2005.06 into its regulatory monitoring in 2006, and in 2019, officially adopted OMA 2005.06 as the EU Reference Method for the detection of PSP toxins in shellfish. This method has been rigorously vetted and validated and has been deemed to be fit for purpose across the EU. This proposal is for adoption of OMA 2005.06 as published. Subsequent refinements and improvements (including additional toxins), as adopted by the EU, will be submitted as method extensions in future submissions.
12. Public Health Significance	Paralytic Shellfish Poisoning (PSP) occurs worldwide and poses a serious threat to shellfish consumers. Currently approved methods in the NSSP include the APHA Mouse Bioassay (for all matrices covered by the NSSP), the Receptor Binding Assay (for mussels only), and the PCOX HPLC method (for mussels, clams, oysters, and scallops). Each method has its advantages and drawbacks, and NSSP laboratories benefit from choices that may be driven by access to equipment, the matrices of interest, or local PSP profiles.

13. Cost Information	$94,000 – $240,000 for equipment. $14 - $25 per sample for consumables, depending on the toxins present.
14. Changes Needed to Guidance (if proposed change is adopted)	Section IV Guidance Documents – Chapter III. Laboratory @.02 Methods 0.1 Approved NSSP Laboratory Tests Add to table: 2. Approved Methods for Marine Biotoxin Testing AOAC Official Method 2005.06[6] Indicate applicability to columns: Biotoxin Type Paralytic Shellfish Poisoning (PSP) Application: Growing Area Survey & Classification Sample Type: Shellfish Application: Dockside Testing Program Sample Type: Shellfish Application: Controlled Relaying Sample Type: Shellfish Add to Footnotes: 6. AOAC International. (2005). AOAC Official Method 2005.06: Paralytic Shellfish Poisoning Toxins in Shellfish: Prechromatographic Oxidation and Liquid Chromatography with Fluorescence Detection. In Official Methods of Analysis of AOAC International. Gaithersburg, MD: AOAC International. doi: 10.1093/9780197610145.003.4019. Applicable to the determination of STX; NEO; GTX2,3; GTX1,4; dcSTX; B-1/GTX5; C1,2; and C3,4 in mussels, clams, oysters, and scallops.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. **X** Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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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	@ .06 Vibrio vulnificus plan & @ .07 Vibrio parahaemolyticus plan
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)	Guidance for vibrio risk analysis using real time data for senario analysis

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
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9. Proposal Subject	Calibration and validation of hydrodynamic models used in shellfish growing area classification
10. Specific NSSP Guide Reference	Proposed changes are to Section IV Guidance Documents only (no change to the Model Ordinance): Section IV Guidance Documents – Chapter IV. Growing Areas @.01 Sanitary Survey .01 Sanitary Survey and the Classification of Growing Waters Components of a Sanitary Survey - (3) An evaluation of hydrographic factors that may affect distribution of pollutants throughout the area. (Pg 282) "Tracer dye studies provide site-specific dilution, dispersion and time of travel information, and can be used in calibration of site-specific hydrodynamic models." Section IV Guidance Documents – Chapter IV. Growing Areas @.03 Growing Area Classification .03 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants, IV. Prohibited Classification, Guidance for Dilution Ratios (pg. 314)
11. Text of Proposal/ Requested Action	The Model Ordinance requires every sanitary survey to evaluate hydrodynamic characteristics (@.01 A.(1)(c)), and the guidance notes that tracer dye studies can be used to calibrate hydrodynamic models, but the NSSP Guide sets no requirements for how models used in classification are developed, calibrated or validated. Hydrodynamic models have become a widely used tool for predicting hydrodynamic factors. By combining data such as tidal amplitude/type and water circulation patterns with water depths and stratification caused by density (salinity and temperature) differences, prevailing wind patterns, and other external physical inputs, models predict dilution and time of transport of deleterious materials, e.g. WWTP outflows. The hydrodynamic model output on dilution and time of transport can then be applied to describe boundaries for shellfish growing area classification using the dilution criteria defined in *Section IV Guidance Documents – Chapter IV. Growing Areas @.03 Growing Area Classification .03 Classification of Shellfish Growing Waters Adjacent to Wastewater Treatment Plants. IV. Prohibited Classification. I. Establishment of Boundaries for the Prohibited Area, Guidance for Dilution Ratios* (pg. 314). However, hydrodynamic modelling is an inexact science that requires an iterative process of development, calibration and validation before the model output can be used as a predictive tool for dilution and dispersion and subsequently used in a regulatory environment to set the classification status of shellfish harvest areas. Without adequate validation, e.g. a tracer dye study as referenced in *Section IV Guidance Documents – Chapter IV. Growing Areas. Components of a Sanitary*

	Survey - (3) An evaluation of hydrographic factors that may affect distribution of pollutants throughout the area, model output cannot be shown to represent the actual environment it is intended to describe, and classification boundaries based on it have no demonstrated basis. This proposal requests two actions. First, add the guidance language shown below so that any hydrodynamic model used in a sanitary survey, or to set growing area classification boundaries, is calibrated and validated with site-specific field data, documented, and independently reviewed. Second, refer the proposal to the appropriate ISSC committee to develop more detailed guidance establishing minimum standards for model development, calibration, validation and review. The guidance (guardrails) would ensure hydrodynamic models that are used for regulatory decisions, such as defining growing area classification, are properly developed, calibrated and validated so that the model output is reflective of the environment it proposes to describe and accurate in its predictive capacity. It would establish what valid data are to be used for constructing the model, confirm the data inputs are properly calibrated, and ensure that validation of the model has been adequately verified. As a final step prior to regulatory use, the model, its output and its application should be reviewed by qualified reviewers independent of the model developer to ascertain its validity for the proposed specific application before it is used for growing area classification purposes. As is true of all procedures and protocols listed in the NSSP Guide, the identification and application of standards for shellfish sanitation and guidelines to protect human health are based on information that is peer reviewed and accepted in the scientific community. A standard for the application of hydrodynamic models for the purpose of shellfish area classification needs to be well defined and evaluated for the specific locale and situation where it is being applied and the NSSP Guide must carefully establish a standard set of guidelines for the application of modelling in shellfish management. **Proposed changes to Section IV Guidance Documents (new language underlined):** **Section IV Guidance Documents – Chapter IV. Growing Areas, @.01 Sanitary Survey, .01 Sanitary Survey and the Classification of Growing Waters** *[Add as a new paragraph immediately following item (3), An evaluation of hydrographic factors that may affect distribution of pollutants throughout the area]* Use of hydrodynamic models. Hydrodynamic models (computer models that simulate water circulation and the transport of pollutants in a growing area) are increasingly used to evaluate hydrographic factors and to estimate dilution and time of transport. Model results are only as reliable as the data used to build and test them. When a hydrodynamic model is used in a sanitary survey, or to establish the boundary of any growing area classification, the Authority should: (a) Calibrate the model using site-specific field data from the growing area and adjacent waters, such as tidal elevation, current velocity and direction,

	salinity, temperature and bathymetry; (b) Validate the model's predictions of dilution and time of travel against independent site-specific field measurements not used in calibration, such as a dye or other tracer study; (c) Document in the sanitary survey the model used, the input data and their sources, the calibration and validation methods and results, and the limitations of the model; and (d) Have the model, its calibration and validation, and its application reviewed by qualified personnel independent of the model developer before its results are used to establish classification boundaries. These recommendations are not intended to apply to simple dilution calculations, such as tidal prism or mass-balance estimates. **Section IV Guidance Documents – Chapter IV. Growing Areas, @.03 Growing Area Classification, .03 Classification of Shellfish Growing Waters Adjacent to Waste Water Treatment Plants, IV. Prohibited Classification, Guidance for Dilution Ratios** *[Add at the end of the introductory paragraph, before item (1)]* When a hydrodynamic model is used to estimate the dilution or time of transport used to set the boundary of a prohibited area, the model should be calibrated, validated, documented and reviewed as described in @.01 .01, Use of hydrodynamic models.
12. Public Health Significance	Applying a non-validated hydrodynamic model for shellfish growing area classification can result in incorrectly sized Prohibited Areas and incorrectly placed classification boundaries. The pendulum of damage can swing in both directions, either not closing areas when needed leading to enhanced human health risks or closing areas when not needed leading to economic damage to businesses dependent on shellfish harvest area classification for conducting their business. Requiring calibration and validation against site-specific field data gives model-based boundaries the same evidentiary footing the NSSP already expects of other data used in classification.
13. Cost Information	The proposal does not require any Authority to use a model; it applies only where models are used for classification. Costs would fall mainly on Authorities, or on permittees or consultants modeling on their behalf, for the field data needed to calibrate and validate a model (e.g., current measurements and dye or tracer studies). Many Authorities already conduct dye studies at WWTP outfalls, which would serve this purpose. Committee work to develop the guidance would rely on volunteer time and regular ISSC meeting costs.
14. Changes Needed to Guidance (if proposed change is adopted)	Add the guidance language shown in Item 11 to Section IV Guidance Documents, Chapter IV, @.01 .01 and @.03 .03. No change to the Model Ordinance. In addition, guidelines need to be developed that provide detailed standards for the development, calibration and validation of hydrodynamic models prior to their application for shellfish area classification. These guidelines must be included in the NSSP Guide. At a minimum, the guidance should address acceptable input data and sources; calibration procedures and performance criteria; validation methods (including tracer studies) and acceptance criteria; documentation to be included in the sanitary survey; independent technical review; and when re-

	calibration or re-validation is required (e.g., changes to an outfall location, discharge volume or bathymetry).

Proposal No. 27-133

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Modification of NSSP Shellfish Laboratory Evaluation Checklist for Microbiology: Temperature Monitoring in the Laboratory
Specific NSSP Guide Reference	2023 NSSP Guide for the Control of Molluscan Shellfish NSSP Shellfish Section IV Guidance Documents – Chapter III. Laboratory Page | 265 Laboratory Evaluation Checklists Laboratory Evaluation Checklist for Microbiology PART 1 - QUALITY ASSURANCE 1.4 Laboratory Equipment
Text of Proposal/ Requested Action	1.4.9 Refrigerator temperature(s) are monitored at least once daily on workdays or when using continuous temperature monitoring systems daily active monitoring is not required so long as alarm thresholds can alert staff to temperature excursions affecting storage and sample integrity. Monitoring and alarm records are maintained. ~~Results are recorded and records maintained.~~
	1.4.11 The temperature of the incubator is maintained at 35 ± 0.5°C. When verified by continuous automated monitoring alarms triggered by excursions are investigated, with affected samples evaluated for validity. Monitoring and alarm records are maintained.
	1.4.14 Temperature of a working ~~the~~ waterbath is maintained at 44.5 ± 0.2°C ~~under all loading conditions.~~ When verified by continuous monitoring systems, alarms triggered by excursions are investigated, with affected samples evaluated for validity. Monitoring and alarm records are maintained.
	1.4.18 Air incubator/waterbath temperatures are taken twice daily on workdays or when using continuous temperature monitoring systems twice daily active monitoring is not required so long as alarm thresholds are addressed and samples are evaluated for validity for temperature excursions exceeding time/temperature limits for appropriate incubation periods. Monitoring and alarm records are maintained. ~~The results are recorded and records maintained.~~
1.4.23 New checklist item(s)	Temperature monitoring systems (wired/wireless) • Software must record temperature reading from each sensor/probe in the piece of equipment being monitored at the same or greater frequency as required by check list items.

	• When temperatures are out of acceptable temperature range and method specific time, event must be documented and corrective action taken. Monitoring and alarm records are maintained. Method specific time ranges:
	  ○ Methods using a 24 ± 2hr incubation period must not have temperature excursions exceeding 2 hours across all incubation steps
	  ○ Methods using a 48± 3hr incubation period must not have temperature excursions exceeding 3 hours across all incubation steps
	  ○ Methods with variable incubation times will not have temperature excursions greater than minimum of 2 hours scaled to total incubation period (ie 30-hour incubation period = 2 hours + 15 minutes, 18-hour incubation = 2 hours)
	• Temperature monitoring system records for each piece of equipment must be available for auditing.

Public Health Significance	Deviations from required waterbath and incubator temperatures are inevitable due to the nature of NSSP microbiology methods which require the transfer of cold samples and room temperature media into 35˚C incubators, and subsequently into 44.5˚C waterbaths (1.4.11 & 1.4.14). These fluctuations are not routinely captured in twice daily temperature monitoring as required by the NSSP checklist (1.4.9 & 1.4.18) but could greatly impact sample validity during equipment failure or malfunction. One solution to invalidating temperature deviations has been the implementation of electronic temperature sensing systems (i.e. data loggers). Data logging systems with built-in alarms and continuous monitoring close blind spots in temperature records that can occur over a workday or during times staff are away from the lab, allowing for close monitoring of storage and incubation steps which have temperature sensitive pieces. These systems, when set up correctly can quickly alert analysts to deviations that would invalidate samples as demonstrated by time/temperature laboratory assessments while liberating laboratory staff time from multiple audit points. Efforts to improve temperature monitoring during these procedures have run up against current NSSP guidance and checklist items due to the high-resolution data that is being produced by data logging systems and passive monitoring by staff. NSSP microbiology checklists should be updated to accommodate different temperature monitoring systems adopted by individual labs. Updated guidance on electronic temperature systems *Standard Methods for the Examination of Water and Wastewater* (24th Edition) 9-11: > Electronic temperature-sensing devices (i.e., data loggers) may be used so long as the laboratory's system for recording information from the devices also promptly notifies analysts of temperature violations so they can invalidate test samples, as appropriate, and request that new samples be collected. this system also must document the data such that time/temperature readings can be used to trace a sample and its testing conditions during laboratory assessments. Each data logger should be marked with any correction factor needed. Additionally, other areas overseen by FDA such as the National Conference on Interstate Dairy shipments Cultural procedures checklist contain language around temperature monitoring systems that allow for timed temperature excursions with documentation requirements for excursions specific to methods (Section 3: Temperature Measuring Devices). Guidance also includes requirements for software compatibility and records/auditing requirements. These, along with the updated

	Standard Methods for Examination of Water and Wastewater (24th Edition) provide updated guidance on temperature monitoring systems. In conclusion, laboratories that have implemented temperature monitoring systems have increased confidence in media productivity, sample integrity, and data confidence when appropriately implemented.
Cost Information	None- these changes include more appropriate practices for data logging devices for temperature monitoring. Laboratories would not be required to implement these systems unless desired.
References	American Public Health Association (APHA). 2022. *Standard Methods for the Examination of Water and Wastewater*, 24th Edition. APHA/AWWA/WEF, Washington, D.C. Standard Methods National Conference on Interstate Milk Shipments. Laboratory Form 2400 Cultural Procedures- General Requirements. March 2024

Proposed Task Force Consideration at the 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative
Submitter	Hosseinali Safavieh
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Proposal Subject	DSP Alert™: Qualitative Detection of Diarrhetic Shellfish Toxins in Mussels and Oysters
Specific NSSP Guide Reference	Section IV Guidance Documents, Chapter III. Laboratory, @.02 Methods, .01 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	Request for approving DSP Alert™ as a qualitative screening tool for the detection of diarrhetic shellfish toxins in mussels and oysters.
Public Health Significance	Diarrhetic shellfish toxins (DSTs) are a group of heat-stable, lipophilic marine biotoxins produced primarily by certain dinoflagellates, including species of *Dinophysis* and *Prorocentrum*. DSTs, which include okadaic acid (OA), dinophysistoxin-1 (DTX1), dinophysistoxin-2 (DTX2), and their esterified derivatives, can accumulate in filter-feeding bivalve molluscs such as mussels, oysters, clams, and scallops. Consumption of contaminated shellfish can cause Diarrhetic Shellfish Poisoning (DSP), characterized by symptoms including diarrhea, nausea, vomiting, abdominal pain, and cramping. The toxic effects of DSTs are primarily associated with their inhibition of protein phosphatases, particularly protein phosphatases 1 and 2A, which disrupts normal cellular processes and intestinal function. DST-producing harmful algal blooms occur in many shellfish-growing regions worldwide, including coastal areas of North America, and can result in rapid increases in toxin concentrations in mussels and oysters. Such events may lead to harvesting restrictions or closures and can present significant risks to public health and the shellfish industry. Rapid and reliable detection of DSTs in mussels and oysters is therefore important for supporting routine monitoring, identifying potentially unsafe harvesting areas, and enabling timely management decisions.
Cost Information	Refer to “ISSC Method Application and Single Lab Validation Checklist For Acceptance of a Method for Use in the NSSP” document attached for Sensoreal Inc.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Updating Glassware BTB Residue Testing Criteria to Follow Manufacturer Instructions.
10. Specific NSSP Guide Reference	Section IV. Guidance Documents – Chapter III. Laboratory @.01 Quality Assurance .01 (Laboratory Evaluation Checklist – Laboratory Quality Assurance Program) Specify Part I and line item 1.5.7 within that checklist.
11. Text of Proposal/ Requested Action	With each load of labware/glassware washed, ~~the contact surface of~~ several ~~dry~~ pieces from each load are tested for ~~residual~~ detergent residues (acid or alkali) with aqueous 0.04% bromothymol blue in accordance with manufacturer instructions. Results are recorded and records maintained.
12. Public Health Significance	Detergent residues remaining on laboratory glassware can inhibit microbial growth or interfere with chemical assays, potentially yielding false-negative or inaccurate analytical results in shellfish safety testing. Ensuring glassware is completely free of detergent residues is essential for public health
13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	No additional changes to the NSSP Guidance Documents are required. The proposed change in Field 11 directly updates line item 1.5.7 of the Laboratory Evaluation Checklist – Laboratory Quality Assurance Program in Section IV, Chapter III.

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)
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9. Proposal Subject	Growing Area Guidance Review and Update
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter IV. Growing Areas
11. Text of Proposal/ Requested Action	See supplemental document
12. Public Health Significance	Section IV. Chapter IV. Growing Area Guidance section has not been updated in some time. There are also sections of the guidance that are outdated and do not match the current NSSP MO. This proposal provides a suggested update for the Growing Area Guidance Chapter.
13. Cost Information	No change in cost.
14. Changes Needed to Guidance (if proposed change is adopted)	

Proposal No. 27-137

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	Modified Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) Method for the Determination of Diarrhetic Shellfish Poisoning (DSP) Toxins in Shellfish.
Specific NSSP Guide Reference	The intention is for this method to be an Approved Method for Biotoxin Testing for DSP toxins under the NSSP and that it should be added as a new listing in Section IV: Guidance Documents, Chapter III: Laboratory, @.02 Methods, .01 Approved NSSP Laboratory Tests, Table 2 Approved Methods for Marine Biotoxin Testing under the heading: Biotoxin Type: Diarrhetic Shellfish Poisoning (DSP) titled **Liquid Chromatography Tandem Mass Spectrometry (LC-MS/MS) – Matrix Matched (Mussels only)**, and the applications should be (1) Growing Area Survey and Classification, (2) Dockside Testing Program, and (3) Controlled Relaying.
Text of Proposal/ Requested Action	See full SLV report and specific edits to existing method checklist.
Public Health Significance	Shellfish contaminated with natural toxins can cause consumer illnesses. The Food and Drug Administration (FDA) has established guidance levels for five groups of natural toxins in shellfish responsible for the following illnesses: amnesic shellfish poisoning (ASP), azaspiracid shellfish poisoning (AZP), diarrhetic shellfish poisoning (DSP), neurotoxic shellfish poisoning (NSP), and paralytic shellfish poisoning (PSP). While management programs have existed in the United States for PSP, NSP, and ASP for many years, the need for management programs for lipophilic shellfish toxins, including DSP and AZP, are a relatively recent occurrence. The first shellfish harvesting closure due to DSP toxins (DSTs) in excess of the regulatory guidance level of 16 µg OA eq./100 g shellfish (0.16 ppm) occurred on the Texas Gulf Coast in 2008. The first harvesting closure, and illnesses, in the Puget Sound region occurred in 2011 and the first closure in the New England region occurred in 2015. In response to these events, a method for the detection and quantitation of DSTs based on liquid chromatography tandem mass spectrometry (LC-MS/MS) was validated and approved by the ISSC for use in clams in 2017 (Proposal #17-103). A checklist for the evaluation of this method in NSSP labs was approved in 2023 (Proposal #19-136). However, after subsequent failure of verification efforts in several NSSP labs, issues were noted with the method that were preventing its widespread use. This report describes the validation of a modified LC-MS/MS method for DSTs for use in the NSSP for the management of this toxin group in mussels. These modifications specifically address deficiencies in the original method for clams identified during method verification. If approved, this modified method will subsequently be extended to additional matrices, including clams and oysters.
Cost Information	**Capital equipment purchases:** 1. Ultra-high Performance Liquid chromatograph (UHPLC) or High-Performance Liquid Chromatograph (HPLC), capable of running in gradient mode [examples: Waters Corporation Acquity UPLC system (Manchester, UK) (approx. $60,000, new with government (GSA) discount), Shimadzu Corporation Nexera UHPLC system (Kyoto, Japan) (approx. $80,000, new with government (GSA) discount)]

	2. Mass Spectrometer, equipped with an electrospray ionization source and multiple reaction monitoring scan mode capabilities [example: Sciex QTrap 5500+ equipped with a Turbo V ionization source (Framingham, MA) (approx. $320,000, new with government (GSA) discount)] **Cost per sample (approx. for consumables):** $14/sample

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Proposal Subject	Vibrio MPN with Biochemical or PCR Confirmation Checklist
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to adopt the checklist in the attached supplemental documentation.
12. Public Health Significance	There is no checklist to evaluate the Vibrio MPN followed by biochemical or PCR confirmation of isolates, even though these methods are included as approved methods in the NSSP. The proposed checklist will provide Laboratory Evaluation Officers an appropriate and standardized tool by which to evaluate laboratories implementing these methods.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Proposal Subject	Revised Quality Systems Checklist
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to modify the NSSP Quality Systems checklist. Specific edits are reflected in the attached supporting documentation.
12. Public Health Significance	The proposed modification is to improve efficiency in the current NSSP Quality Systems Laboratory Evaluation checklist.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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)
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9. Proposal Subject	Rescind the SmartCycler Instrument from the MPN Real-Time PCR Methods for *Vibrio parahaemolyticus* and *Vibrio vulnificus*
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to rescind the Cepheid SmartCycler instrument from the Approved NSSP MPN Real-Time PCR Methods for *Vibrio parahaemolyticus* and *Vibrio vulnificus*. The proposal removes the Cepheid SmartCycler from the method name and also removes SmartCycler specific dyes in line 3.1.3. See supplemental documentation for specific edits.
12. Public Health Significance	There are no laboratories using this instrument in support of the Program. The manufacturer has discontinued the instrument and service to the instrument is no longer supported. In addition, consumables required to run the instrument are no longer produced. There are alternative methods in the Program for the detection and confirmation of Vibrios. Additionally, the ISSC Constitution, Bylaws, and Procedures states in Procedure XV, Section xi. that a method is subject to recantation when the equipment is no longer available. As such, there should be no impact to the Program and the protection of public health.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Proposal Subject	Rescind the Alkaline Phosphatase Vibrio Probe Method
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists Section IV. Chapter III. @.02 Methods .01 Approved Laboratory Tests
11. Text of Proposal/ Requested Action	Section IV. Chapter II @.02 Methods .01 Approved Laboratory Tests

	Vibrio Type:	**Application: PHP Sample Type: Shucked**	**Application: Reopening**
MPN[1]	***Vibrio vulnificus (V.v.)***	X	
MPN[2]	***Vibrio parahaemolyticus (V.p.)***	X	
~~**PCR[3]**~~	~~***Vibrio parahaemolyticus (V.p.)***~~	~~X~~	
MPN-Real Time PCR[43]	***tdh+ and trh+ Vibrio parahaemolyticus (V.p.)***	X	X
MPN-Real Time PCR[54]	***Vibrio parahaemolyticus (V.p.)***	X	X
~~**Direct Plating Method[6]**~~	~~***Vibrio parahaemolyticus (V.p.)***~~	~~-~~	~~X~~
MPN-Real Time PCR[75]	***Vibrio vulnificus (V.v.)***	X	

Footnotes:
1. MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual (BAM), 7th Edition, May 2004 revision, followed by confirmation using biochemical

	analyses or PCR method from the FDA BAM as described in Hill et al., 1991. ~~or by the DNA–alkaline phosphatase gene probe for vvhA as described by Wright et al., or a method that a State can demonstrate is equivalent.~~ 2. MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7 th Edition, May 2004 revision, followed by confirmation using biochemical analyses or PCR method from the FDA BAM as described in Bej et al., 1999. ~~or the DNA-alkaline phosphatase gene probe for tlh as described by McCarthy et al., or a method that a State can demonstrate is equivalent.~~ ~~3. MPN method in Chapter 9 of the FDA Bacteriological Analytical Manual, 7 th Edition, May 2004 revision, and as described in the "Direct Plating Procedure for the Enumeration of Total and Pathogenic Vibrio parahaemolyticus in Oyster Meats" developed by FDA, Gulf Coast Seafood Laboratoryfollowed by confirmation using conventional PCR, or a method that a State can demonstrate is equivalent.~~ ~~4~~3. MPN-Real Time PCR Method for the tdh and trh Genes for Total V. parahaemolyticus as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15-111, Page 397. ~~5~~4. MPN-Real Time PCR Method for the tlh gene for total V. parahaemolyticus as described in Kinsey et al., 2015. ISSC 2015 Summary of Actions Proposal 15-113, Page 418 ~~6. Direct Plating Procedure in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, and as described in the 'Direct Plating Procedure for the Enumeration of Total and Pathogenic Vibrio parahaemolyticus in Oyster Meats' developed by FDA, Gulf Coast Seafood Laboratory.~~ ~~7~~5. MPN-Real Time PCR Method for the vvh gene for total V. vulnificus as described in Kinsey et al., 2015. The Alkaline Phosphatase Probe Laboratory Evaluation Checklist will also be rescinded in its entirety.
12. Public Health Significance	The critical reagent required for the test method is not produced and is no longer supported by any manufacturer, indicating a lack of ability to perform the method. There are multiple alternative methods in the Program for the detection and confirmation of Vibrios, including BAM and Real-Time PCR Methods. Additionally, the ISSC Constitution, Bylaws, and Procedures states in Procedure XV, Section xi. that a method is subject to recantation when reagents are no longer available. As such, there should be no impact to the Program and the protection of public health and the table indicating Approved Methods for Vibrio Enumeration will reflect the available choices of analyses.
13. Cost Information	No direct cost to rescind the method. However, laboratories required to switch from the probe method due to its lack of availability may incur some additional costs, depending on the method implemented.
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Checklist Modifications - pH Meter Calibration
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to modify checklist line items in multiple NSSP Laboratory Evaluation Checklists related to calibration of laboratory pH meters. The proposed edits are applicable to the following NSSP Laboratory Evaluation Checklists: 1. Microbiology, line item 1.4.5 2. PCR Microbiology, line item 1.4.5 3. Mouse Bioassay and Scotia Rapid Test for Paralytic Shellfish Poisoning (PSP), line item 1.4.6 4. Probe Microbiology, line item 1.4.5 5. Marbionc Brevetoxin (Neurotoxic Shellfish Poisoning; NSP) ELISA, line item 1.4.5 6. Domoic Acid (Amnesic Shellfish Poisoning; ASP) HPLC-UV, line item 1.4.4 7. Paralytic Shellfish Poisoning (PSP PCOX-HPLC), line item 1.4.6 8. Receptor Binding Assay for Paralytic Shellfish Poisoning (RBA PSP), line item 1.4.6 Replacement Text for pH Meter Calibration Requirements: The pH meter manufacturer instructions are followed for calibration, or a minimum of two (2) standard buffer solutions are used to calibrate the pH meter. The calibration must include the pH 7 buffer and a second buffer near the expected sample pH (i.e., pH 4 or pH 10) in order to bracket the measurement range. Standard buffer solutions are used once and discarded. The specific checklists and text are in the accompanying document.
12. Public Health Significance	The proposed replacement language standardizes the language regarding calibration of pH meters for all mentioned checklists. This change reflects current laboratory equipment QC practices for pH meters.
13. Cost Information	None

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
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9. Proposal Subject	Checklist Modification - Quality Assurance Technical Requirement
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The proposal is to modify text for 1.1.2 checklist line items in the following NSSP Laboratory Evaluation Checklists: 1. Microbiology 2. PCR Microbiology 3. Probe Microbiology 4. RBA for PSP 5. PSP MBA and Scotia Rapid Test 6. Domoic Acid HPLC-UV 7. PSP PCOX HPLC 8. NSP MBA 9. DSP LC-MS/MS Specific edits are reflected in the attached supporting documentation.
12. Public Health Significance	The proposed modification is to improve efficiency in the current NSSP Laboratory Evaluation checklists.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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6. City, State, Zip	College Park, MD 20740
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8. Email	Melissa.Abbott@fda.hhs.gov
9. Proposal Subject	Checklist – Microbiology modifications for consistency
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to modify text in thirty-two (32) NSSP Microbiology Checklist items and to delete two (2) line items from the checklist. Modified checklist items are as follows: 1.2.4, 1.3.5, 1.4.1, 1.4.3, 1.4.4, 1.4.6, 1.4.7, 1.4.10, 1.4.23, 1.4.24, 1.4.25, 1.5.4, 1.5.10, 1.6.6, 1.6.8, 1.6.9, 1.6.13, 1.7.4, 1.7.6, 1.7.7, 1.7.8, 1.7.10, 1.7.11, 2.1.4, 3.1.2, 3.1.3, 3.2.1, 3.2.3, 3.2.9, 3.2.10, 3.2.11, and 3.7.2. The line items to be deleted are 3.11.6 and 4.3.6. After deletions, editorial renumbering of Sections 3.11 and 4.3 will be required. Specific edits are reflected in attached supporting documentation.
12. Public Health Significance	The proposed modifications are to improve consistency in the current NSSP Laboratory Evaluation checklist. Deletion of line items 3.11.6 and 4.3.6 remove the possibility of a laboratory receiving a double nonconformity during a technical evaluation.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal No. 2 7 - 1 4 5

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Proposal Subject	Checklist – Microbiology Single Dilution MPN Reporting and Unnecessary Requirements
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The proposal is to replace the text as follows for Microbiology Checklist items 2.4.2, 2.6.2, and 3.5.2: Results from a single dilution series are calculated using the appropriate MPN table. Additionally, propose removing the following line items from the Microbiology Checklist: 1.4.25, 1.5.3, 1.5.4, 1.5.5, 3.2.14. Editorial renumbering will be addressed, as applicable.
12. Public Health Significance	The proposed modifications to the Checklist clarify reporting for single dilution MPN tests and remove outdated line items. Public health and laboratory integrity will not be affected by proposed modifications.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Proposal Subject	PCR Microbiology Checklist –Updates for consistency
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to modify the PCR Microbiology checklist to improve consistency of NSSP requirements across multiple checklists. Specific edits are reflected in supporting documentation. Editorial renumbering of the checklist as required by edits.
12. Public Health Significance	The proposed modifications are to improve consistency in the current NSSP PCR Microbiology Laboratory Evaluation checklist. This action will help laboratories meet NSSP requirements when performing multiple methods.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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

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Proposal Subject	Checklist Modifications – Combined MBA for PSP and NSP Checklist
Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to combine the MBA for PSP and MBA for NSP Checklists. Proposal 27-102 which rescinds the Scotia Rapid Test (SRT) received interim approval by the Executive Board, so the SRT is not addressed in this proposal beyond deleting the relevant line items. Part I: Quality Assurance is combined for both methods as there is significant overlap in the checklist line items. Line items that remain specific to the individual methods are documented appropriately. Part II: Collection and Transportation of Samples and Sample Processing is combined for both methods; the requirements are identical. Part III: Analysis of Shellfish for PSP Toxins; the MBA for PSP method requirements are now located in Sections 3.1 – 3.3. There are no changes to the specific requirements for MBA for PSP. Part IV: Analysis of Shellfish for NSP Toxin; the MBA for NSP method requirements are located in Sections 4.1 – 4.4. Several line items were updated or removed to improve the checklist. The changes improve clarity of the line items and/or combine/remove line items to avoid repetition. See specific edits to all line items in the supporting documentation. Editorial re-numbering will be addressed, as applicable
Public Health Significance	The proposed changes improve the MBA for NSP by adding missing references and aligning the checklist requirements with the MBA for PSP method. In addition, for laboratories that run both methods this will reduce the amount of work that is done to ensure they are meeting the requirements for both methods.
Cost Information	None

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Checklist Modifications – Microbiology and PCR Sterility
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	PCR Checklist item 1.6.16 and Microbiology Checklist item 1.6.15: (Critical) The sterility of reusable items is determined with each load sterilized. Results are recorded and records maintained. Sterility is determined by an appropriate microbiological method, biological indicators and/or chemical integrators. Indicators and/or integrators appropriate for cycle and conditions are used and appropriately placed throughout the autoclave and/or product to verify the sterility of autoclave sterilized consumables. Autoclave sterilized materials are considered sterile as per manufacturer IFU of autoclave packages and/or indicators/integrators used. Upon expiration, the items may be re-packaged, autoclaved, and verified. Results are recorded and records maintained. PCR Checklist item 1.6.17 and Microbiology Checklist item 1.6.16: (Critical) The sterility of pre-sterilized consumables is determined with each lot received. Sterility is verified by an appropriate microbiological method, or a traceable certification of sterilization is obtained. Results are recorded and records maintained. Certificates are maintained in accordance with the records management plan. PCR Checklist item 1.6.18 and Microbiology Checklist items 1.6.19, 1.6.20, 1.6.22, 2.7.4, 2.11.2 will be deleted to avoid checklist redundancy. Editorial updates to items 2.7.10, 2.11.7, 3.10.3, 3.10.7, 4.2.3, and 4.2.7 are also proposed to reflect the sterility requirement. Editorial re-numbering will be addressed, as applicable.
12. Public Health Significance	Historically, pre-sterilized items required sterility verification testing by NSSP laboratories. This proposal is a paradigm shift; instead of testing all pre-sterilized items before use, NSSP laboratories will be allowed to retain the traceable certification of sterilization as proof of sterility. The proposed changes clarify the acceptable methods for sterility verification and remove redundancy in the checklists, as all pre-sterilized and autoclaved sterilized items share the same requirements.

13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Proposal Subject	Checklist Modifications - Collection and Transportation of Samples
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to modify text of temperature requirements for sample transport and receipt on the Microbiology and PCR Microbiology checklists. The proposal edits four (4) line items, updates criticality codes, and adds a line item on the NSSP Microbiology Checklist. On the PCR Microbiology checklist, the proposal edits one (1) line item, adds one (1) line item and one (1) reference, and updates criticality codes. Specific edits are reflected in attached supporting documentation. Editorial re-numbering will be addressed, as applicable.
12. Public Health Significance	The proposed modifications are to improve understanding and promote consistency in the current NSSP Microbiology and NSSP PCR Microbiology Laboratory Evaluation checklists. These proposed updates will simplify and clarify the sample receipt and temperature requirements for the collection and transportation of seawater and shellfish samples.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal No. 2 7 - 1 5 0 _____

_____ **Date**

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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9. Proposal Subject	Checklist – PCR Microbiology Technical Modifications
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The proposal is to modify the PCR Microbiology checklist to improve the accuracy and clarity of technical checklist requirements. In addition, some modifications correct incomplete and/or inaccurate checklist requirements. Specific edits are reflected in supporting documentation. Editorial renumbering of the checklist as required by edits.
12. Public Health Significance	The proposed modifications will clarify checklist line items which will help laboratories understand and meet NSSP requirements, thereby increasing likelihood to conform to requirements.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

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)
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9. Proposal Subject	NSSP Biotoxin-related Laboratory Evaluation Checklists: Collection and Transportation of Samples Contingency Plan Edits
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory @.01 Quality Assurance .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to modify the Collection and Transportation of Samples contingency plan checklist line items in multiple checklists. The proposed edits are applicable to the following NSSP Laboratory Evaluation Checklists: 1. Mouse Bioassay and Scotia Rapid Test for Paralytic Shellfish Poisoning (PSP), line item 1.6.4 2. Paralytic Shellfish Poisoning (PSP HPLC-PCOX), line item 1.6.4 3. Domoic Acid (Amnesic Shellfish Poisoning; ASP) HPLC-UV, line item 1.6.4 4. MARBIONC Brevetoxin (Neurotoxic Shellfish Poisoning; NSP) ELISA, line item 1.6.4 5. Diarrhetic Shellfish Poisoning Toxins (DSP) LC-MS/MS, line item 1.6.4 6. Receptor Binding Assay for Paralytic Shellfish Poisoning (RBA PSP), line item 2.1.5 Modified Text for Sample Collection and Transportation section: ~~Time from collection to initiation of the extraction should not exceed 24 hours. However, if significant delays are anticipated or if they occur~~ When ~~are anticipated~~ the time from collection to initiation of extraction is anticipated to exceed 24 hours, the sample submitter(s) and laboratory implement ~~has~~ an appropriate written contingency plan ~~in place~~ to handle these samples and protect sample integrity. ~~For samples shipped live in accordance with 1.6.3, the contingency plan ensures samples remain within allowable temperature tolerances and animals are alive upon receipt~~. The written contingency plan must ~~also~~ address~~es~~ field ~~and/or laboratory~~ practices and sample processing that ensures the sample and extract integrity ~~of the sample or extract~~ until initiation of the assay. For example, samples are washed, shucked, drained and processed as follows: a. refrigerated or frozen until extracted; b. homogenized and frozen until extracted; or c. extracted, the supernatant decanted, and refrigerated or frozen until assayed

	The specific checklists and text are in the accompanying documents.
12. Public Health Significance	The proposed modifications to the requirement line item will clarify the laboratory's sample contingency plan standard requirement and improve consistency in NSSP laboratories. The current requirement has been misinterpreted, and the proposed modifications provide direct language to define the requirement.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. X Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	US Food & Drug Administration (FDA)
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9. Proposal Subject	Checklist – Microbiology Update MSC (with MA DMF)
10. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
11. Text of Proposal/ Requested Action	The requested action is to consolidate the MSC sections (Shellfish, Part III; Wastewater, Part IV) into Part IV. The proposed section is titled "MSC Analysis for Shellfish Meats and Wastewater". The proposal addresses redundancy for laboratories performing analysis in shellfish and wastewater, and clarifies quality control line items. Summary of proposed changes: Removal of Parts 3.10 through 3.15; line items are incorporated into updated Part IV Part 4.1: Combined shellfish and wastewater sample collection, defined matrix specific line items; clarified use of sodium thiosulfate; addition of collection of temperature control for wastewater analysis Part 4.2: Defined matrix specific line items; updated balance requirement to align with application Part 4.3: No proposed changes Part 4.4: No proposed changes Part 4.5: Updated shellfish preparation for shellfish analysis; edited sterile growth broth dilution Part 4.6: Defined matrix specific line items; clarified wastewater plating, added reference; combined analysis QC line items; defined sample set Part 4.7: Defined plaques; updated variable to "supernatant extracted"; included full equation to account for less than 25 grams plated Part 4.8: Defined plaques; added language for calculating further dilutions See specific edits to all line items in the supporting documentation.

	Editorial re-numbering and formatting will be addressed, as applicable .
12. Public Health Significance	The proposed checklist removes duplicate line items between the shellfish and wastewater sections. Laboratories running both MSC methods for both will reduce the amount of potential nonconformities. The quality control line items will be better understood, increasing likelihood to conform to requirements.
13. Cost Information	None
14. Changes Needed to Guidance (if proposed change is adopted)	N/A

Proposal No. 27-153

Proposal for Task Force Consideration at the ISSC 2025 Biennial Meeting *(Tab to go to next field)*	1. a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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9. Email	issc@issc.org
10. Proposal Subject	Modify Laboratory Chapter of Model Ordinance to Add Clarity, To Account For New Lab Method, and To Correct For Changes In Guidance Documents
11. Specific NSSP Guide Reference	Section II, Chapter III
12. Text of Proposal/ Requested Action	Chapter III. Laboratory Requirements for the Authority [Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.] For the purposes of this chapter, "Regulatory Decision" is defined as: a. the determination of classification(s) within a growing area, with the exception of the Prohibited classification; or b. the determination of the open status when reopening a growing area or portion of a growing area previously placed in the closed status due to association with illnesses or hazardous substances, as described in Section II. Chapter II. @.01F and @.02A(10)(a); or c. when determining pathogen concentrations as part of an investigation or determining growing area status after finding human pathogens present in shellfish meats, as described in Section II. Chapter II. @.04; or d. the determination of the open status of a growing area or portion of a growing area, unless alternative processes for determining open status are defined within the Model Ordinance, as described in Section II. Chapter IV. @.03 and @.04; or e. the determination of controls for Vibrio management as described in Section II. Chapter II. @.06E(1)(b)(iv), @.06E(1)(e), @.07B(4)(b)(vi), and @.07B(5); or f. the release of restricted shellstock from an area in the controlled access status; or g. the determination of the microbiological suitability of water used in land-based aquaculture, wet storage, or depuration, as described in Section II. Chapter VI. .05, Chapter VII. .04C, and Chapter XV. .02A(4); or h. cleansing or contaminant reduction studies, as described in Section II. Chapter IV. @.03A(5)(d), @.03C(2)(c), or Chapter V.; or

	i. validation or verification of other processes for pathogen reduction, as described in Section II. Chapter XVI. .01A and .02D. @.01 Quality Assurance … @.02 Methods A. Microbiological. ~~Methods for~~Microbiological laboratory methods generating data to support regulatory decisions~~the analysis of shellfish and shellfish growing or harvest waters~~ shall be: (1) The Approved NSSP Methods validated for use in the NSSP under Procedure XV. of the Constitution, Bylaws, and Procedures of the ISSC and/or cited in the Guidance Documents ~~Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.~~Chapter III Laboratory @.02 Methods .01 Approved NSSP Laboratory Tests. (2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used: (a) A validated AOAC, Bacteriological Analytical Manual (BAM), or EPA method; (b) An Emergency Use Method pursuant to @.02 D. (1) and (2) below. B. Chemical and Physical. ~~Methods for~~Chemical and physical laboratory methods ~~the analysis of shellfish and shellfish growing or harvest waters~~generating data to support regulatory decisions shall be: (1) The Approved NSSP Methods validated for use in the NSSP under Procedure XV. of the Constitution, Bylaws, and Procedures of the ISSC and/or cited in the Guidance Documents Chapter III Laboratory @.02 Methods .01 Approved NSSP Laboratory Tests. ~~Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.~~ (2) Results shall be expressed for chemical and physical measurements in standard units and not instrument readings. (3) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used: (a) A validated AOAC, BAM, or EPA method; (b) An Emergency Use Method pursuant to @.02 D. (1) and (2) below. C. Biotoxin. ~~Methods~~ Biotoxin laboratory methods ~~for the analysis of shellfish and shellfish harvest waters~~generating data to support regulatory decisions shall be: (1) The Approved NSSP Methods validated for use in the NSSP under Procedure XV. of the Constitution, Bylaws, and Procedures of the ISSC and/or cited in the Guidance Documents Chapter III Laboratory @.02 Methods .01 Approved NSSP Laboratory Tests.~~Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.~~
13. Public Health Significance	The phrase "generating data to support regulatory decisions…" was introduced to the Laboratory Chapter of the Model Ordinance as part of amendments to @.01A adopted by the Conference at the 2023 Biennial Meeting. During followup discussions, it was pointed out that what constitutes a "regulatory decision" might not be clear to all users of the Model Ordinance, and especially Laboratory Method

	Developers or other users new to the NSSP. In order to add clarity to this Chapter, a definition for the term "Regulatory Decision" is proposed. This definition is intended to be applicable only to the Laboratory Chapter of the Model Ordinance, and is not intended to create any new requirements. Instead, it is intended to serve as a roadmap pointing the user towards all instances already defined within the Model Ordinance where an Approved or Approved Limited Use Laboratory Method is required to be used. Also at the 2023 Biennial Meeting, a new laboratory method, the Male-Specific Coliphage Enumeration in Wastewater by Direct Double-Agar Overlay Method, was adopted into the program. The current text of the Microbiological Lab Methods section in the Model Ordinance only includes language referencing the testing of shellfish and shellfish growing or harvest waters. Proposed modifications are intended to expand the language of these methods sections to include this method for wastewater analysis, and to allow for the analysis of other items besides shellfish and shellfish growing or harvest waters if/when other methods are adopted into the program. Lastly, the Guidance Documents were rearranged following the 2023 Biennial Meeting, and the references to the Methods Table need to be updated to point to the right location within the Guidance Documents.
14. Cost Information	N/A

Proposal No. 27-154

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	NSSP Receptor Binding Assay Paralytic Shellfish Poisoning Checklist
Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter III. Laboratory, .01 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists, 11. Receptor Binding Assay for Paralytic Shellfish Poisoning (RBA PSP) Checklist
Text of Proposal/ Requested Action	The requested action is to update the receptor binding assay (RBA) for paralytic shellfish poisoning (PSP) lab evaluation checklist.
Public Health Significance	A comprehensive review of the RBA for PSP checklist was conducted using data from both the RBA matrix extension study and workflow feedback from the Washington State Department of Health. Data from 107 assay runs were analyzed to identify procedural elements relevant to the existing checklist and provided the basis for targeted revisions to the checklist, including removing redundant requirements, clarifying evaluation criteria, and adding necessary procedural detail. The proposed revisions are based on AOAC Official Method 2011.27. In addition, supplemental validation data from the ISSC submitted matrix extension study which demonstrated the applicability of the RBA across multiple shellfish species, support updating the current NSSP RBA lab evaluation checklist to reflect current laboratory practices. Adoption of the revised checklist will improve the facilitate uniform implementation across participating laboratories while maintaining rigorous standards for analytical quality, regulatory oversight, and protection of public health.
Cost Information	N/A

Proposal No. 27-155

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative

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Proposal Subject	ASP Alert™: Qualitative Detection of Domoic Acid in Mussels and Scallops
Specific NSSP Guide Reference	Section IV Guidance Documents, Chapter III. Laboratory, @.02 Methods, .01 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	Request for approving ASP Alert™ as a qualitative screening tool for the detection of domoic acid in mussels and scallops
Public Health Significance	Domoic acid (DA) is a heat-stable marine biotoxin produced by certain species of diatoms, particularly those in the genus *Pseudo-nitzschia*. It can accumulate in various species of shellfish, especially filter-feeding bivalve molluscs. Domoic acid causes Amnesic Shellfish Poisoning (ASP), which is characterized by symptoms such as nausea, vomiting, diarrhea, abdominal cramps, headache, dizziness, confusion, and in severe cases, short-term memory loss, seizures, or death. These symptoms may occur in humans after consumption of contaminated shellfish such as mussels, clams, scallops, or oysters. The toxic effects of domoic acid are primarily associated with its action as an excitatory neurotoxin that binds to glutamate receptors and causes neuronal damage. Recently, elevated levels of domoic acid have been detected in North American coastlines leading to beach closures and intoxication of several marine mammals such as dolphins and sea lions.
Cost Information	Refer to "ISSC Method Application and Single Lab Validation Checklist For Acceptance of a Method for Use in the NSSP" document attached for Sensoreal Inc.

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting	☒ Growing Area ☐ Harvesting/Handling/Distribution ☐ Administrative
Submitter	Hosseinali Safavieh
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City, State, Zip	Montreal, QC H2V 4L5 Canada
Phone	438-728-1243
Fax	Not applicable
Email	roozbeh@sensoreal.com
Proposal Subject	PSP Alert™: Qualitative Detection of Paralytic Shellfish Toxins in Mussels
Specific NSSP Guide Reference	Section IV Guidance Documents, Chapter III. Laboratory, @.02 Methods, .01 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	Request for approving PSP Alert™ as a qualitative screening tool for the detection of paralytic shellfish toxins in mussels.
Public Health Significance	Paralytic shellfish toxins (PSTs) are a group of potent, heat-stable marine biotoxins produced primarily by certain dinoflagellates, including species of *Alexandrium*, *Gymnodinium*, and *Pyrodinium*. PSTs, which include saxitoxin (STX) and several structurally related analogues, can accumulate in filter-feeding bivalve molluscs such as mussels, clams, oysters, and scallops. Consumption of contaminated shellfish can cause Paralytic Shellfish Poisoning (PSP), characterized by symptoms including tingling or numbness of the lips and extremities, headache, dizziness, muscle weakness, loss of coordination, and, in severe cases, respiratory paralysis and death. The toxic effects of PSTs are primarily associated with their ability to block voltage-gated sodium channels, thereby interfering with normal nerve and muscle function. PST-producing harmful algal blooms occur in many shellfish-growing regions worldwide, including coastal areas of North America, and can result in rapid increases in toxin concentrations in shellfish. Such events may lead to harvesting restrictions or closures and can present significant risks to public health and the shellfish industry. Rapid and reliable detection of PSTs in shellfish is therefore important for supporting routine monitoring, identifying potentially unsafe harvesting areas, and enabling timely management decisions.
Cost Information	Refer to “ISSC Method Application and Single Lab Validation Checklist For Acceptance of a Method for Use in the NSSP” document attached for Sensoreal Inc.