Interstate Shellfish Sanitation Conference

2019 Biennial Meeting

Task Force I Report

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October 5 - 10, 2019
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Proposal No. **11-103**

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Proposal Subject	Alternative Male-specific Coliphage Meat Standard for Restricted Classification of Growing Areas Impacted by wastewater treatment plant outfall.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Area @ .02 Bacteriological Standards
Text of Proposal/ Requested Action	G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration. (4) Exception. If the Male-specific Coliphage indicator is used for supplemental process verification using an end-point meat standard of < 50PFU/100gm and existing fecal coliform testing requirements in Chapter XV .03 J. are used, then FC water quality monitoring is not required for the restricted classification of growing areas affected by point sources such as wastewater treatment plant outfall.
Public Health Significance	Under shellfish relay, water quality requirements are not needed for the restricted classification when a contaminant reduction study is conducted and a minimum time period of two weeks is used. For depuration, the restricted classification requires water quality monitoring and standards. The reason for these upper FC limits is that FC meat indicator does not adequately reflect the viral risk and/or viral depuration kinetics. Male-specific coliphage is a viral indicator organism to be used in growing areas impacted by point source sewage contamination. MSC demonstrates significant advantages over FC alone for both the assessment of viral contamination and assessment of viral depuration kinetics. Upper FC limits were put into the NSSP to prevent shellfish with higher levels of viruses from being depurated. Several studies clearly show that conventional depuration using FC for process validation is not adequate to protect public health with respect to virus contamination in growing areas with significant wastewater treatment plant and sewage impact. Studies have also shown that viral levels in shellfish impacted by sewage and partially treated sewage detected using MSC and molecular techniques are much lower in the summer months than the winter months. Additionally, the viral depuration rate is higher in the summer with process waters >18°C. Recent studies have also shown that MSC is an appropriate viral indicator to assess viral depuration. Therefore, seasonal viral depuration using male-specific coliphage as well as FC for process verification is a superior approach to taking water samples using FC in a growing area adjacent to wastewater treatment plant outfall. Combining the bacterial indicator of FC and the viral indicator MSC for mitigation strategies that use meat scores is far more direct and effective than water quality sampling in this context.
Cost Information	The Male-specific Coliphage (MSC) method is an inexpensive double-agar pour plate method that can be run in any state-certified microbiological laboratory. A refrigerated centrifuge capable of 9,000G is required which costs $10K to $12K (USD). Significant cost savings and a higher level of public health protection may be realized using strategies such as seasonal coliphage depuration process validated

	using MSC and seasonal coliphage relay using MSC in contaminant reduction studies than requiring water quality limits using FC.
Action by 2011 Task Force I	Recommend referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted recommendation of 2011 Task Force I on Proposal 11-103.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-103.
Action by 2013 Growing Area Classification Committee	Recommend referral of Proposal 11-103 to the appropriate committee as determined by the Conference Chairman. It was additionally recommended that a workgroup be formed to look at current MSC data and the science behind its potential use and applicability for use in the NSSP. The workgroup will organize a summit of outside experts, academia, and scientists to present current information and science on MSC. The group will meet at least quarterly and respond back to the Growing Area Classification Committee on its findings and recommendations. Recommended that the ISSC pursue funding to facilitate scheduling a summit to bring together experts to present the current science in the use of MSC.
Action by 2013 Task Force I	Recommended adoption of Growing Area Classification Committee action on Proposal 11-103.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 11-103.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-103.
Action by 2015 Growing Area Classification Committee	Recommended referral of Proposal 11-103 to appropriate committee as determined by the Conference Chair.
Action by 2015 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 11-103.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-103.
Action by 2017 Growing Area Committee	Recommended adoption of Proposal 11-103 as amended. Add a new section as follows: Chapter XV. Depuration .03 Other Model Ordinance requirements K. Supplemental Requirements for Depuration using MSC Viral Controls for Shellstock Harvested from Conditionally Restricted Growing Areas Impacted by Wastewater System Discharge (WWSD). If the conditionally restricted growing area from which the shellstock is being depurated is impacted by wastewater treatment system discharge (generally that section of the conditionally restriced growing area located within the 300:1 to 1000:1 dilution lines), then supplemental requirements for depuration using MSC viral controls may be required. Depuration using MSC viral controls may be seasonally limited and may be species and depuration facility specific. Contaminant reduction studies as described in (1) below are

	recommended unless the SSCA and the Depuration Facility Operator have significant experience with the depuration process using MSC viral controls. (1) Male-specific coliphage may be used in addition to fecal coliform for species-specific, growing area-specific, and depuration system-specific contaminant reduction studies. These contaminant reduction studies should demonstrate that; (a) Predictable periods of time exist when male-specific coliphage levels are less than 1,000 PFU/100gm in shellfish meats, (b) Male-specific coliphage and fecal coliform can be consistently reduced below end-point requirements, and (c) Critical limits of season, process water temperature and salinity, and system design and operation limitations can be assessed and determined (d) Species-specific operating protocols may be developed from the contaminant reduction studies for each conditionally restricted growing area that includes; (i) Calendar dates when depuration shall be permitted, (ii) Water temperature and salinity limitations, (iii) Minimum processing time, (iv) Sampling requirements and release criteria, and (v) Operating Protocol. (2) All requirements of Chapter XV shall be followed, (3) A single 0-day MSC shellfish meat sample is required. (4) The MSC end-point requirement for depuration is 50 PFU/100gm. If the single 0-day sample exceeds 50 PFU/100gm, then triplicate samples are required prior to release of product. (5) The geometric mean of the triplicate samples used for product release must not exceed 50PFU/100gm and no single sample over 100 PFU/100gm. (6) Extended depuration may be permitted to achieve end-point requirements. (7) Evaluation of male-specific coliphage samples shall be performed in an NSSP conforming laboratory,
Action of 2017 Task Force I	Recommended adoption of Growing Area Classification Committee recommendation on Proposal 11-103.
Action by FDA February 7, 2018	Did not concur with Conference action on proposal 11-103
Action by ISSC Executive Board	Referred Proposal 11-103 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Male-Specific Coliphage Committee	Committee recommended the adoption of 11-103 as amended. 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 are 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 (whichever is greter) and the established boundary for depuration (Chapter IV @.02 G.)

~~If the conditionally restricted growing area from which the shellstock is being depurated is impacted by wastewater treatment system discharge (generally that section of the conditionally restriced growing area located within the 300:1 to 1000:1 dilution lines), then supplemental requirements for depuration using MSC viral controls may be required. Depuration using MSC viral controls may be seasonally limited and may be species and depuration facility specific. C~~The suplemental requirements must be included in contaminant reduction studies as described in (1) below~~. are recommended unless the SSCA and the Depuration Facility Operator have significant experience with the depuration process using MSC viral controls.~~

(1) Male-specific coliphage ~~may~~ shall be used in addition to fecal coliform for species-specific, growing area-specific, and depuration system-specific contaminant reduction studies. These contaminant reduction studies should demonstrate that;

~~(a) Predictable periods of time exist when male-specific coliphage levels are less than 1,000 PFU/100gm in shellfish meats,~~

(~~b~~a) Male-specific coliphage and fecal coliform can be consistently reduced below end-point requirements, and

(~~c~~b) Critical limits of season, process water temperature and salinity, and system design and operation limitations can be assessed and determined

(~~d~~c) Species-specific operating protocols ~~may~~ shall be developed from the contaminant reduction studies for each conditionally restricted growing area that includes;

(i) Calendar dates when depuration shall be permitted,
(ii) Water temperature and salinity limitations,
(iii) Minimum processing time,
(iv) Sampling requirements and release criteria, and
(v) Operating Protocol.

(2) All requirements of Chapter XV shall be followed,

(3) A ~~single~~triplicate 0-day MSC shellfish meat sample is required.

~~(4) The MSC end-point requirement for depuration is 50 PFU/100gm. If the single 0-day sample exceeds 50 PFU/100gm, then triplicate samples are required prior to release of product.~~

	(~~5~~4) The geometric mean of the triplicate samples used for product release must not exceed 50PFU/100gm and no single sample over 100 PFU/100gm (~~6~~5) Extended depuration ~~may be permitted~~is allowable if necessary to achieve end-point requirements. (~~7~~6) Evaluation of male-specific coliphage samples shall be performed in an NSSP conforming laboratory,
Action by 2019 Task Force I	Recommends adoption of Male Specific Coliphage Committee recommendations on Proposal 11-103.

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Proposal Subject	Sources of Seed for Aquaculture
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VI. Shellfish Aquaculture
Text of Proposal/ Requested Action	TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT
Public Health Significance	Shellfish seed collected or cultured in certain growing areas that are in the prohibited classification have been shown through repeated sampling to be free of deleterious substances (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 viral and bacterial contaminants provided water temperatures are high enough to maintain active metabolic activity (above 60 degrees F or 15 degrees C) (Richards 1988). Once the Authority is satisfied that adequate sampling has demonstrated that the seed have "acceptable levels of deleterious substances", then a 30 day period of culture in open waters should be adequate to allow purging of bacterial and viral contaminants to ensure that public health is protected. The Authority retains the right to deny seed collection and culture in any area, or to require additional testing for deleterious substances, or to require longer periods to purge contaminants as necessary. The original intent of this section was to provide for purging of viral and bacterial contamination prior to harvest for consumption on the assumption that deleterious substances were at acceptable levels prior to moving the seed to grow out areas The six-month requirement was implemented as a short-hand way to ensure that seed were grown for at least one month when water temperatures exceeded 60 degrees F. It makes little sense to require relay times in excess of one month for seed that are typically more than six months from harvest size when shellstock relay times as short as two weeks are common. References Cited: Richards, G. (1988), Microbial Purification of Shellfish: A Review of Depuration and Relaying, J. Food Protection 51(3)218-251. 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	This change should facilitate record keeping and documentation efforts required to ensure that seed from prohibited waters do not get harvested until bacterial and viral contamination has been purged.

Action by 2013 Task Force I	Recommended referral of Proposal 13-107 to an appropriate committee as determined by the Conference Chairman.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-107.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-107.
Action by 2015 Aquaculture Facility Inspection Committee	Recommended the following: (1) Referral of Proposal 13-107 back to Committee as appointed by the Conference Chair. (2) The charge of the Committee be expanded to include updating and revising the Aquaculture Chapter of the Model Ordinance to reflect current practices and methods and submit proposals for the next Annual Meeting.
Action by 2015 Task Force I	Recommended adoption of Aquaculture Facility Inspection Committee recommendations on Proposal 13-107.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 13-107.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-107.
Action by 2017 Aquaculture Facilities Inspection Committee	Recommended adoption of Proposal 13-107 as substituted. TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT
Action by 2017 Task Force I	Recommended adoption of Aquaculture Committee recommendation on Proposal 13-107 as amended. TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-107.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-107.
Action by 2019 Aquaculture Committee	In 2017 the Conference adopted the new language of Proosal 13-107 to modify the requirements of Chapter VI. The Conference further directed the development of guidance for Chapter VI. The Aquaculture Committee was charged with the development of a Guidance Document. That work was not completed. The Chapter VI language that was adopted in 2017 is not included in the 2019 Task Force II report. The Aquaculture Committee recommended referral of the Guidance Document request included in Proposal 13-107 to an appropriate committee as determined by the Conference Chairperson with further instruction that the committee be convened before the Spring Executive Board meeting to begin development of a guidance document for the revised Aquaculture Chapter.
Action by 2019 Task Force I	Recommends adoption of the Aquaculture Committee recommendation on Proposal 13-107.

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Proposal Subject	DSP PPIA Kit for Determination of Okadaic Acid Toxins Group (OA, DTX1, DTX2) in Molluscan Shellfish
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests Marine Biotoxin Testing
Text of Proposal/ Requested Action	The DSP PPIA kit be approved as a Marine Biotoxin Laboratory Test Method.
Public Health Significance	Okadaic acid (OA) and its analogues, DTX1, DTX2, together with their ester forms are known as the group of OA-toxins. These toxins, lipophilic and heat stable, are produced by dinoflagellates and can be found in various species of shellfish, mainly in filter feeding bivalve molluscs. The OA-toxins group causes Diarrheic Shellfish Poisoning (DSP), which is characterized by symptoms such as diarrhea, nausea, vomiting and abdominal pain. These symptoms may occur in humans shortly after consumption of contaminated bivalve molluscs such as mussels, clams, scallops or oysters. Inhibition of serine/threonine phosphoprotein phosphatases is assumed to be responsible for these toxic effects. Recently in the Pacific Northwest harvest areas, outbreaks of DSP have occurred.
Cost Information	Refer to Para D.1. of the Checklist
Action by 2013 Laboratory Methods Review and Quality Assurance Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chairman and directed the Executive Office send a letter to the submitter requesting additional information as provided by the Laboratory Methods Review and Quality Assurance Committee.
Action by 2013 Task Force I	Recommended adoption of Laboratory Methods Review and Quality Assurance Committee recommendation on Proposal 13-111.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-111.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-111.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair until additional data are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-111.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-111.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-111.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-111.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task	Recommended adoption of Laboratory Committee recommendation on Proposal

Force I	13-111.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-111.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-111.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 13-111 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends adoption of the Laboratory Committee recommendation for Proposal 13-111.

Submitter	Darcie Couture
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Proposal Subject	Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination
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 This submission presents the 'Receptor Binding Assay (RBA) for Paralytic Shellfish Poisoning (PSP) Toxicity Determination' for consideration as an NSSP Approved Limited Use Method. 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). Results from those studies, and additional data, are included in this proposal submission for the RBA to be considered for approval as an NSSP Approved Limited Use Method for Marine Biotoxin Testing.
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 Limited Use Method for PSP toxicity determination 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	The estimated cost for a full 96-well plate assay is ~$95.00. Including standards and samples with triplicate measurements (as well as three dilutions per sample to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitative results would be ~$13.60. If running multiple plates or in screening mode, sample costs would be reduced. Further, the filter plates used in the RBA differ from ELISA plates in that all reagents are added to each well as needed rather than already being a component of the plate, making it more practical and cost-effective to analyze samples when there is less than a full plate.
Action by 2013 Laboratory Methods and Quality Assurance Review Committee	1. Recommended approval of this method as an alternative to the mouse bioassay for PSP in mussels. 2. Recommended approval of this method for Limited Use for clams and scallops for the purpose of screening and precautionary closure for PSP. 3. Recommended referral of this proposal to an appropriate committee as determined by the Conference Chairman to address this method in oysters. 4. Recommended Executive Office sends a letter to submitter to request a checklist for evaluation of labs using this method with said checklist to be submitted within three (3) months.
Action by 2013 Task Force I	Recommended adoption of Laboratory Method Review and Quality Assurance Committee recommendation on Proposal 13-114.
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-114.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-114.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair until additional data for oyster matrix are received.
Action by 2015 Task Force I	Recommended adoption of Laboratory Methods Review Committee recommendation on Proposal 13-114.
Action by 2015 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-114.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-114.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 13-114.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-114.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-114.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 13-114 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 13-114.

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Proposal Subject	Shellfish Quarantine Guidance Document
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control Section IV. Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans
Text of Proposal/ Requested Action	Model Ordinance Chapter IV. Shellstock Growing Areas @.04 Marine Biotoxin Control Section A. (4) describes agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting during marine Biotoxin closures under specific, controlled conditions. The State of Florida has successfully implemented such an agreement to address Neurotoxic Shellfish Poisoning (NSP) for over a decade. This pilot project, developed in consultation with FDA, has resulted in zero cases of NSP in commercially harvested shellfish from Florida waters. NSP may affect any Gulf or South Atlantic state and therefore Florida wishes to provide ISSC member states with a proven quarantine protocol template for incorporation into the Model Ordinance Section IV. Guidance Documents. Guidance Documents Chapter II. Growing Areas .02 Guidance for Developing Marine Biotoxin Contingency Plans. Text of the proposed guidance is as follows: Example Protocol for Quarantine Harvest of Shellfish from Aquaculture Leases During *Karenia brevis* Closures: A. Closure of an entire shellfish growing area due to *Karenia brevis* shall be in accordance with Model Ordinance Chapter IV. @.04 C. (1). B. When a shellfish growing area is closed due to *Karenia brevis*, the Authority may allow harvest of shellfish from selected aquaculture leases within a specific zone by authorized harvesters and subsequent controlled quarantine at a certified shucker packer or shellstock shipper. This option would not be available if any Authority collected water samples in the specific zone exceeded 200,000 cells per liter of *Karenia brevis*. Zone is defined as an Authority delineated geographic area within a Conditionally Approved or Approved classified shellfish growing area.

Controlled quarantine conditions:

The Authority will determine and plot the specific zones. Certified processors possessing a valid shellfish processing plant certification license must have written permission from the Authority to engage in this activity. To be eligible for participation in the quarantine program, the certified processor must:

(1) Provide the Authority with written and signed agreements the processor has with shellfish aquaculture leaseholders who would be supplying the shellfish and;

(2) Notate on their application letter which FDA-approved marine Biotoxin laboratory will be used to conduct the approved mouse bioassay and;

(3) Provide the Authority with the cooler capacity, physical address and current certification number of the facility to be used for controlled quarantine of shellfish. All quarantine coolers must be non-mobile, secure from unauthorized access and equipped with warning signs in a language readily understood by all employees.

Participation in each week's quarantine program is only possible for certified processors who:

(1) Have written permission on file with the Authority and are on an Authority-controlled document listing current approved quarantine program processors and;

(2) Possess emailed permission granted by the Authority the day before harvest for that one specific quarantine and;

(3) Propose harvesting a quantity of shellfish that meets the Authority established minimum number but does not exceed the maximum allowed number of shellfish of one specific species for that day.

Under no circumstances may any approved processor participate in any quarantine until they possess written (emailed) documentation sent by the Authority before each specific quarantine event.

- The authorization email sent by the Authority shall explicitly state the permissible species that may be harvested by that approved processor.
- The Authority will notify the appropriate law enforcement entity in charge of patrol of shellfish growing areas with a list of participants in that specific day's harvest.
- Persons harvesting a species not authorized for that day's harvest will be subject to seizure of that harvest by the Authority. In addition, the Authority will immediately seize and destroy product which is improperly tagged, violates any National Shellfish Sanitation Program (NSSP) Model Ordinance regulations, state laws or is from non-authorized participants.
- Co-mingling of species is not allowed to make up an individual lot.

Violation of the terms of this protocol may result in the termination of the participant's future eligibility in the quarantine program, as determined by the Authority.

Prior to being considered for participation in any specific quarantine event, approved processors shall be contacted by the Authority and asked to provide the name of the species they plan to harvest and the quantity they plan on harvesting. Quantities shall be described as approximate total number by species in addition to total number of baskets, containers, bags, etc. with specific weights (if applicable) for those baskets, containers, bags, etc.

Eligible processors should be aware that daily implementation of this program is contingent on marine Biotoxin laboratory availability as well as Authority staffing considerations given staff time necessary to fulfill the requirements of the program.

Regulatory considerations on behalf of the Authority and staffing considerations on behalf of the marine Biotoxin lab necessitate an Authority developed maximum number of samples that could be potentially tested on any given week.

The Authority may implement a lottery, random rotation or similar procedure to ensure a fair distribution of testing opportunities among the eligible processors. It is suggested that the Authority develop this procedure with industry involvement.

Once specific permission is received from the Authority, the processor:

(2) May receive properly tagged shellfish from eligible aquaculturists only as indicated in the Authority's authorization email;
(3) Must upon receipt of shellfish, separate and maintain the shellfish into specific lots [A Lot is defined as shellfish of one species from no more than one day's harvest from a specific zone within a shellfish growing area];
(4) Must place shellfish under proper controls and quarantine; Proper controls and quarantine are defined by bold, clear, warning signage signaling the properly tagged and segregated shellfish within the processor's cooler are under quarantine and must not be moved until Authority permission is obtained pending outcome of laboratory testing. The signage should be such that it is clear to anyone entering the cooler (including facility employees and/or regulatory inspectors) that the affected shellfish are under quarantine. Wrapping of the entire lot with a single bright red or yellow ribbon or equivalent attached to the bold warning sign will further reinforce the warning message.
(5) Must allow the Authority to take two (2) random samples [minimum of twenty (20) shellfish per each sample] from each lot and deliver to the approved laboratory for approved mouse bioassay;

	(6) Must hold all shellfish in quarantine at the approved processor's certified facility until receiving official written test result notice from the Authority via email or fax that the shellfish are cleared for sale; (7) Must either return shellfish to aquaculture lease(s) in the zone(s) from where harvested if any sample in a lot is 20 Mouse Units / 100 grams or greater or destroy the shellfish, both activities of which must be witnessed and documented by the Authority; (8) Must cease this activity if any Authority collected red tide cell counts in the specific zone exceeds 200,000 cells per liter of *Karenia brevis*; and (9) Must document all of the requirements listed above in the approved facility HACCP plan. C. If cell counts in all water samples fall to 5,000 cells/L or less Karenia brevis in the entire area, the Authority will collect shellfish meat samples for toxicity testing and the entire Shellfish Harvesting Area will be reopened if results of all samples are <20 MU/100g. I _____ (print name) have received a copy of this quarantine protocol and I agree to abide by all terms and conditions. I understand I am bound by the terms of this agreement during the period of time that I am processing shellfish from a shellfish growing area that is currently in the closed status due to Karenia brevis. _____ Signed Date
Public Health Significance	Closures of shellfish growing areas due to Neurotoxic Shellfish Poisoning (NSP) may occur at any time in the Gulf of Mexico and to a lesser degree, the Atlantic coast. Well established procedures for detecting and responding to *Karenia brevis* blooms have safeguarded public health. Clear early warning signs, a cell count action level with a high factor of safety and established sampling networks provide excellent public health protection. A very real impact of *Karenia brevis* blooms is the resulting long-term closures of shellfish growing areas and severe economic impact to commercial shellfish operations. Florida addressed this issue after studying years of water quality samples and mouse bioassay results from shellfish growing areas. Hydrodynamic studies linked to water samples obtained from fixed stations over an extended period of time established clear patterns in distribution of *Karenia brevis*. Working in conjunction with harmful algal bloom researchers, shellfish growing area managers, FDA and industry, Florida developed a NSP quarantine protocol that has resulted in the retention of a shellfish industry in one of the most severely impacted HAB regions of the Gulf while protecting public health as required by the Model Ordinance. An enormous amount of data has been generated and reviewed during the years this protocol has been used. Repeated mouse bioassay testing on shellfish exposed to different levels of *Karenia brevis* has provided Florida with sufficient data to refine the protocol into a powerful management tool. Florida's experience pre-quarantine protocol was unfortunate, as several fledgling businesses failed due to repeated NSP closures. It was this economic damage that spurred the aforementioned collaborative effort between leading edge HAB researchers, shellfish growing area managers, FDA and

	industry. If adopted, shellfish producing states impacted by *Karenia brevis* could reference this protocol in the Guidance Document and use it to effectively manage NSP closures.
Cost Information	The estimated cost for a full 96-well plate assay is ~$95.00. Including standards and samples with triplicate measurements (as well as three dilutions per sample to ensure the unknown samples fall within linear range of assay), the cost per sample for quantitative results would be ~$13.60. If running multiple plates or in screening mode, sample costs would be reduced. Further, the filter plates used in the RBA differ from ELISA plates in that all reagents are added to each well as needed rather than already being a component of the plate, making it more practical and cost-effective to analyze samples when there is less than a full plate.
Action by 2013 Task Force I	Recommended referral of Proposal 13-116 to an appropriate committee as determined by the Conference Chairman
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force I on Proposal 13-116.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-116.
Action by 2015 Biotoxin Committee	Recommended adoption of Proposal 13-116 with substitute language as follows: (4) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a state growing area while other parts of the same ~~the~~ growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. In state growing areas or designated portions of state growing waters that are closed, the authority may allow for harvesting if an end product testing program is developed and, ~~such as by batch release of~~ shellfish lots only after samples of each lot are tested and found to be below the action levels specified in Section C. The program must include at a minimum: i. Establishment of appropriate pre-harvest screening levels; ii. Establishment of appropriate screening and end product testing methods; iii. Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods; iv. Establishment of representative sampling plan for both i. and ii. above; and v. Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program. Should the above amended proposal be adopted by the conference, then the Biotoxin Committee should develop a Guidance Document that includes guidance for development of end-product testing programs to address biotoxins in closed state waters.
Action by 2015 Task Force I	Recommends adoption of Biotoxin Committee recommendation on Proposal 13-116.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-116.
Action by 2017 Task	Recommended the Biotoxin Committee should develop a Guidance Document that

Force I	includes guidance for development of end-product testing programs to address Biotoxins in closed State waters.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 13-116.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-116.
Action by 2019 Biotoxin Committee	
Action by 2019 Task Force I	Recommends no action on Proposal 13-116. Rationale: The Guidance Document was developed by the Biotoxin Committee and submitted in conjunction with other recommended Model Ordinance changes as part of Proposal 19-149.

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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 2015 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	Recommends the adoption of Laboratory Committee recommendation on Proposal 15-109.

<table>
<tr><td>Submitter</td><td>Executive Board</td></tr>
<tr><td>Affiliation</td><td>Interstate Shellfish Sanitation Conference (ISSC)</td></tr>
<tr><td>Address Line 1</td><td>209 Dawson Road</td></tr>
<tr><td>Address Line 2</td><td>Suite 1</td></tr>
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<tr><td>Email</td><td>issc@issc.org</td></tr>
<tr><td>Proposal Subject</td><td>Direct Plating Method for trh</td></tr>
<tr><td>Specific NSSP Guide Reference</td><td>Section IV. Guidance Documents
Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests</td></tr>
<tr><td>Text of Proposal/ Requested Action</td><td>This method was developed by Jessica Jones (FDA Gulf Coast Seafood Laboratory) and is being submitted by the ISSC Executive Board. The Executive Board granted interim approval to this method on March 13, 2015. The Executive Board is submitting this proposal to comply with Article V. Section 1. of the ISSC Constitution, Bylaws, and Procedures.

Submitted by method developer Jessica Jones (FDA Gulf Coast Seafood Laboratory)

5. Approved Methods for Vibrio Enumeration

<table>
<tr><th></th><th>Vibrio Indicator Type:</th><th>Application: PHP Sample Type: Shucked</th><th>Application: Reopening</th></tr>
<tr><td>EIA[1]</td><td>Vibrio vulnificus (V.v.)</td><td>X</td><td></td></tr>
<tr><td>MPN[2]</td><td>Vibrio vulnificus (V.v.)</td><td>X</td><td></td></tr>
<tr><td>SYBR Green 1 QPCR-MPN[5]</td><td>Vibrio vulnificus (V.v.)</td><td>X</td><td></td></tr>
<tr><td>MPN[3]</td><td>Vibrio parahaemolyticus (V.p.)</td><td>X</td><td></td></tr>
<tr><td>PCR[4]</td><td>Vibrio parahaemolyticus (V.p.)</td><td>X</td><td></td></tr>
<tr><td>Direct Plating[6]</td><td>trh+ Vibrio parahaemolyticus (V.p.)</td><td>X</td><td>X</td></tr>
</table>

Footnotes:

[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.
[2] 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 labeled gene probe (vvhA).
[3] MPN format with confirmation by biochemical analysis, gene probe methodology as listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can demonstrate is equivalent.
[4] PCR methods as they are listed in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, May 2004 revision, or a method that a State can
demonstrate is equivalent.
[5]Vibrio vulnificus, ISSC Summary of Actions 2009. Proposal 09-113, Page 123.</td></tr>
</table>

	[6]Direct plating method for *trh* as described in Nordstrom et al., 2006.
Public Health Significance	Scientific evidence suggests that the presence of the *trh* gene in *V. parahaemolyticus (V.p.)* is correlated with higher virulence. Additionally, at the 2013 conference, proposal 13-202 was adopted which requires testing for the presence of trh prior to reopening of growing areas closed as a result of *V.p.* illnesses [Chapter II @.01.F(5)]. Currently, there are no NSSP approved methods for enumeration of *trh*. This method is a needed option for testing following *V.p.* illness closures.
Cost Information	This method costs ~$5 per test for laboratory consumables, supplies, and reagents. Most equipment needed for testing is standard microbiology equipment, but purchase of a specialized water bath or environmental chamber may be necessary at a cost of ~$3,000-$5,000. Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair to further review the data submitted.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-112.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-112
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-112.
Action by 2017 Laboratory Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Lab Committee recommendation on Proposal 15-112.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 15-112.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-112.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 15-112 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 15-112.

Submitter	Executive Board
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Proposal Subject	Pre-Proposal for Male-Specific Coliphage Enumeration in Wastewater by Direct Double-Agar Overlay Method
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas .11 Approved NSSP Laboratory Tests
Text of Proposal/ Requested Action	The submitter of the pre-proposal requests approval to submit a full proposal to the ISSC for approval of the analytical method for use in the NSSP. Submitted by the developer Kevin Calci (FDA Gulf Coast Seafood Laboratory) Proposed Use of the Method: This method is applicable for the enumeration of MSC wastewater influent, effluent and sewage contaminated surface waters. The method will directly determine the quantity of MSC in wastewater to provide information of the viral reduction efficiencies of wastewater treatment plants. Method is also applicable for the analysis of surface source waters as part of a shoreline survey. Description of Method: This method employs E. coli HS (pFamp) RR as a male-specific coliphage host in a direct double agar overlay for the quantification of plaque forming units. All sample volumes are plated in triplicate. Briefly, 2.5ml of sample is mixed with 2.5ml of soft agar and 0.2ml of Famp host and then poured onto bottom agar petri plate. One ml of the sample is serially diluted down to 1:10 and 1:100. Those two dilutions are then plated by placing 2.5ml of sample is mixed with 2.5ml of soft agar and 0.2ml of Famp host and then poured onto bottom agar petri plate. The plates are incubated at 35-37°C for 16-20 h. Under indirect light the plaque forming units are counted. The working range of the 9 plate method would be 14pfu/1OOml to 1.0 x 106 pfu/1 OOml.
Public Health Significance	Scientific consensus at the MSC informational meeting supported the use of MSC to evaluated wastewater treatment plant viral reduction efficiency to better inform the SSCA's conditional management plans impacted by wastewater treatment plant operations. This method would identify a consistent and accurate measure of MSC load in wastewater influent, effluent and surface waters.
Cost Information	
Action by 2015 Laboratory Methods Review Committee	Recommended referral of Proposal 15-114 to an appropriate committee as determined by the Conference Chair to await SLV data.
Action by 2015 Task Force I	Recommended adoption of 2015 Laboratory Methods Review Committee recommendation on Proposal 15-114.
Action by 2015 General Assembly	Adopted recommendation of Task Force I on Proposal 15-114.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 15-114.
Action by 2017	Recommended referral of Proposal 15-114 to an appropriate committee as

Laboratory Committee	determined by the Conference Chair.
Action by 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 15-114.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 15-114.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 15-114.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 15-114 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 15-114.

Submitter	J. Michael Hickey
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Proposal Subject	Marina Definition
Specific NSSP Guide Reference	Section I Purposes and Definitions B. Definition of Terms (71) Marina
Text of Proposal/ Requested Action	**(71) Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is: (a) Used for docking or otherwise mooring vessels to a dock or pier; and (b) Constructed to provide temporary or permanent docking space for more than ten boats.
Public Health Significance	There has been ever increasing pressure to include mooring areas which are not defined in the Model Ordinance into the Marina Proper; Section II- Chapter IV **@ .05 Marinas**. When the criteria were developed to deal with the classification of Marinas as defined, and the determination of a buffer zone in adjacent waters; mooring areas were purposely not included. It was left to the discretion of the SSCA to determine, classification criteria that could be different from the marina calculations depending on local circumstances and local knowledge. FDA is now interpreting anchors, chains and mooring blocks as "structures "and as such is requiring that mooring areas be treated as Marinas. Structure in the Marina definition means "(docks, basin, floating docks, etc.)" not anchors and chains. There are many different kinds of marinas, some essentially parking lots with no overnight occupancy and others that are destination mooring areas. Some states have outstanding boat pump out programs and large areas, if not the entire state, that are federal No Discharge Areas, in addition to local well enforced no discharge and occupancy regulations or by-laws. SSCAs should be allowed to assess the pollution impact of mooring areas based on actual circumstances and data not just an assumed risk.
Cost Information	NONE, Possible savings to SSCAs.
Action By 2017 Task Force I	Recommended referral of Proposal 17-100 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-100.
Action by FDA February 7, 2018	Concurred with Conference action on proposal 17-100 with comments. (See February 7, 2018 FDA response to ISSC Summary of Actions)
Action by 2019 Marina Committee	Recommends adoption of Proposal 17-100 as amended. **Section I. Purpose & Definitions** **Definitions** (73) **Marina** means any water area with a structure (docks, basin, floating docks,

	etc.) which is :~~(a) Used~~ used for docking ~~or otherwise mooring vessels;~~ and ~~(b) Constructed~~ constructed to provide temporary or permanent docking space for more than ten boats. Add new definition. **Mooring Areas** mean any water area that is used to provide temporary or permanent anchorage for more than 10 boats. Mooring areas do not include any structures for docking boats. **Section II. Model Ordinance** **Chapter IV. Shellstock Growing Areas** @.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 with the marina proper does not require a pollution assessment by the Authority. ~~(1) Conditionally approved;~~ ~~(2) Conditionally restricted; or~~ ~~(3) Prohibited.~~ 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 fecal coliform per ninth power 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 predict 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 Public entity 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)The assignment of a prohibited classification with 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 x 10 fecal coliform per ninth power 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. (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.
Action by 2019 Task Force I	Recommends adoption of Proposal 17-100 as amended. **Section I. Purpose & Definitions** **Definitions** (73) **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 boats. Add new definition. **Mooring Areas** mean any water area that is used to provide temporary or permanent anchorage for more than twenty (20)~~10~~ boats. Mooring areas do not include any structures for docking boats. **Section II. Model Ordinance** **Chapter IV. Shellstock Growing Areas** @.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 with 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 fecal coliform per

ninth power 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 predict 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 Public entity 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 Management Area Plan, the area can be placed in the open status.

(~~2~~3)The assignment of a prohibited classification with 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 x 10 fecal coliform per ninth power 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. (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.

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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 in 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	Recommends adoption of Laboratory Committee recommendation on Proposal 17-103.

Submitter	Pacific Rim Shellfish Sanitation Association
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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	This 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 the 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 of Proposal 17-106 to an appropriate committee as determined by the Conference Chairperson.
Action by 2019 Task Force I	Recommends adoption of Laboratory Committee recommendation on Proposal 17-106.

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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	Recommends adoption of Laboratory Committee recommendation on Proposal 17-108.

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Proposal Subject	Alkaline Phosphatase Probe Method for *Vibrio vulnificus* and *Vibrio parahaemolyticus* Detection in Oysters - 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 Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the text of the attached checklist for the probe method for detecting *Vibrio vulnificus* (Vv) and *Vibrio parahaemolyticus* (Vp) in oysters 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	Currently, there is no checklist adopted by the ISSC for the probe method for detecting Vv and Vp in oysters. The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing this method in support of 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	NA
Action By 2017 Laboratory Committee	Recommended Proposal 17-110 be referred to an appropriate committee as determined by the Conference Chair.
Action By 2017 Task Force I	Recommended adoption of Laboratory Committee recommendation on Proposal 17-110.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-110.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-110.
Action by 2019 Laboratory Committee	Recommended referral of Proposal 17-110 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends adoption of the Laboratory Committee recommendation on Proposal 17-110.

Submitter	J. Michael Hickey Margaret Barette David Fyfe
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Proposal Subject	Reconditioning of Recalled Shellfish Implicated in a Norovirus Outbreak
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter II. Risk Assessment & Risk Management @.01 Outbreaks of Shellfish Related Illness.
Text of Proposal/ Requested Action	J. 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 PHPs or placing 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 State Shellfish Control Authority (SSCA). 2. Product associated with a Norovirus outbreak may be reconditioned by returning the product, within three (3) days of the recall, to the growing area from which it was harvested for an appropriate period of time. The period of time shall not be less than twenty-one (21) days. The Authority shall ensure appropriate controls and provide documentation of the activity.
Public Health Significance	A twenty-one (21) day submergence period is consistent with the amount of time required at Section II. Chapter IV. A. (5) (b) (ii) and C. (2) (c) (iii), Shellstock Growing Areas.
Cost Information	No substantial increased cost to SSCAs and to the shellfish industry. would constitute a cost saving
Action By 2017 Task Force I	Recommends referral of Proposal 17-115 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General	Adopted the recommendation of Task Force I on Proposal 17-114.

Assembly	
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-114.
Action by 2019 Shellfish Reconditioning Committee	Recommended the adoption of Proposal 17-115 as amended: **Section II. Model Ordinance** **Chapter II. Risk Assessment & Risk Management** @.01 Outbreaks of Shellfish Related Illness J. 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 PHPs or placing 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 State Shellfish Control Authority (SSCA). 2. Product associated with a Norovirus outbreak may be reconditioned by returning the product, within ~~three (3) days of the recall~~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 ~~twenty-one (21)~~thirtly-one (31) days. The Authority shall ensure appropriate controls and provide documentation of the activity.
Action by 2019 Task Force I	Recommends adoption of Proposal 17-115 as amended. **Section II. Model Ordinance** **Chapter II. Risk Assessment & Risk Management** @.01 Outbreaks of Shellfish Related Illness J. 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 PHPs or placing 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 State Shellfish Control Authority (SSCA). 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 ~~thirtly-one (31)~~sixty (60) days. The Authority shall ensure appropriate controls and provide documentation of the activity.

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Proposal Subject	Sanitary Control of Molluscan Shellfish Harvested From Federal Waters
Specific NSSP Guide Reference	Section I Purposes & Definitions Section II Model Ordinance Chapter IV Shellstock Growing Areas Section II Model Ordinance Chapter VI Shellfish Aquaculture
Text of Proposal/ Requested Action	TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT
Public Health Significance	Currently, the NSSP Guide does not explicitly cover requirements for the sanitary control of molluscan shellfish harvested from U.S. Federal waters. The lack of standards for this activity has impeded the harvest of shellfish, notably aquaculture, from Federal waters to date. FDA's policy on the classification of growing areas in offshore Federal waters as described in Verber 1977 was followed in drafting the Proposal. Adding specific language to the Model Ordinance on the appropriate requirements for this activity will facilitate safe and sanitary access to additional shellfish resources.
Cost Information	N/A
Action By 2017 Task Force I	Recommended adoption of Proposal 17-116 on an interim basis with a sunset date of November 1, 2021 and that during this period a committee be appointed to evaluate aquaculture activities in federal waters.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-116.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-116.
Actions by 2019 Federal Waters Committee	Recommended adoption of the following proposals: 19-202,19-203, 19-214, 19-223, 19-228, 19-229, 19-120 The Committee was provided a task list developed by the Federal Waters Subcommittee which includes a number of regulatory actions necessary to provide a framework for incorporating shellfish from Federal Waters into the NSSP.
Action by 2019 Task Force I	In 2017 the FDA requested a committee be appointed to evaluate aquaculture activities in Federal Waters. The committee is requested to identify the specific sanitary survey criteria requirements to be used by FDA. The text of Proposal 17-116 was adopted in 2017 and is not included in this report.

Proposal No. **17-121**

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Proposal Subject	Disposal of Human Sewage and Bodily Fluids
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting Requirements for Harvesters .02 Shellstock Harvesting and Handling. Section II. Model Ordinance Chapter IX. Transportation Requirements for Harvesters .01 Conveyances Used to Transport Shellstock to the Original Dealer and .02 Conveyances Used to Transport Shellstock from Dealer to Dealer
Text of Proposal/ Requested Action	Chapter VIII. .02 Shellstock Harvesting and Handling D. Disposal of Human Sewage and Bodily Fluids~~from Vessels~~. (1) Human sewage and bodily fluids shall not be discharged overboard from ~~a~~any vehicle or vessel used in the harvesting of shellstock, or from vehicles or vessels which buy shellstock while the vehicles or vessels are in growing areas. (2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vehicle or vessel to contain human sewage and bodily fluids. (3) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the vehicle or vessel~~boat~~; and (e) Not be cleaned in equipment used for washing or processing food. (4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are: (a) Constructed of impervious, cleanable materials and have tight fitting lids; (b) Indelibly labeled "Human Waste" in contrasting letters at least three (3) inches in height; and (c) Meet the requirements in Section D. (3). Chapter IX. .01 Conveyances Used to Transport Shellstock to the Original Dealer G. Disposal of Human Sewage and Bodily Fluids (1) Human sewage and bodily fluids shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock, or from vehicles or vessels which buy shellstock while the vehicles or vessels are in growing areas. (2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vehicle or vessel to contain human sewage and bodily fluids. Portable toilets shall meet the requirements of VIII. .02. D. (3).

	Chapter IX. 02 Conveyances Used to Transport Shellstock from Dealer to Dealer C. Disposal of Human Sewage and Bodily Fluids (1) Human sewage and bodily fluids shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock, or from vehicles or vessels which buy shellstock while the vehicles or vessels are in growing areas. (2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vehicle or vessel to contain human sewage and bodily fluids. Portable toilets shall meet the requirements of VIII. .02. D. (3).
Public Health Significance	During evaluations, harvesters and certified dealers buying trucks are observed within harvesting areas and aquaculture lease site areas. The vehicles are often there for hours while harvesting, husbandry, and purchasing activities are taking place. In many areas, there are no nearby toilet facilities to accommodate emergency (or non-emergency) needs for toilet facilities to accept human digestive waste or vomit, putting the area at risk of foodborne illness, e.g. norovirus, hepatitis A, etc. The requirement for marine sanitation devices should not only pertain to vessels in order to protect the public health.
Cost Information	~$5.00 for a five (5) gallon bucket with a lid.
Action By 2017 Task Force I	Recommended referral of Proposal 17-121 to an appropriate committee as determined by the Conference Chair.
Action by 2017 General Assembly	Adopted the recommendation of Task Force I on Proposal 17-121.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-121.
Action by 2019 Overboard Discharge Committee	Recommends the adoption of Proposal 17-121 as amended: **Section II. Model Ordinance** **Chapter VIII. Control of Shellfish Harvesting Requirements for Harvesters** .02 Shellstock Harvesting and Handling D. Disposal of Human Sewage and Bodily Fluids. (1) Human sewage and bodily fluids shall not be discharged overboard from any vehicle or vessel used in the harvesting of shellstock~~, or from vehicles or vessels which buy shellstock while the vehicles or vessels are in growing areas.~~ (2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the ~~vehicle or~~ vessel or available for the vehicle operator's use for the purpose of containing ~~to contain~~ human sewage and bodily fluids. (3) Portable toilets shall: (a) Be used only for the purpose intended; (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage; (c) Be emptied only into a sewage disposal system; (d) Be cleaned before being returned to the vehicle or vessel; and (e) Not be cleaned in equipment used for washing or processing food. (4) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:

	(a) Constructed of impervious, cleanable materials and have tight fitting lids; (b) Indelibly labeled "Human Waste" in contrasting letters at least three (3) inches in height; and (c) Meet the requirements in Section D. (3). **Chapter IX. Transportation Requirements for Harvesters** .01 Conveyances Used to Transport Shellstock to the Original Dealer G. Disposal of Human Sewage and Bodily Fluids (1) Human sewage and bodily fluids shall not be discharged overboard from any vehicle or vessel ~~used in the harvesting of shellstock, or from vehicles or vessels~~ which buys shellstock while the vehicles or vessels are in growing areas. (2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the ~~vehicle or~~ vessel or available for the vehicle operator's use for the purpose of containing ~~to contain~~ human sewage and bodily fluids. Portable toilets shall meet the requirements of VIII. .02. D. (3). .02 Conveyances Used to Transport Shellstock from Dealer to Dealer C. Disposal of Human Sewage and Bodily Fluids (1) Human sewage and bodily fluids shall not be discharged overboard from any ~~vehicle or~~ vessel used in the harvesting of shellstock, or from ~~vehicles or~~ vessels which buy shellstock while the ~~vehicles or~~ vessels are in growing areas. (2) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the ~~vehicle or~~ vessel to contain human sewage and bodily fluids. Portable toilets shall meet the requirements of VIII. .02. D. (3).
Action by 2019 Task Force I	Recommends adoption of Overboard Discharge Committee recommendation for Proposal 17-121.

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Proposal Subject	Determining Emergency Conditions
Specific NSSP Guide Reference	Section I. Purposes and Definitions Section II. Model Ordinance Chapter IV @.03 A.(1)
Text of Proposal/ Requested Action	Section I. Purposes and Definitions New Definition: B.(39) **Emergency Conditions** means potential or actual pollution conditions which were not specifically represented in the sanitary survey information used to establish the classification and support the status of a shellfish growing area. Emergency conditions include, but are not limited to, tropical storms, hurricanes, sewage spills, oil spills, poisonous or deleterious substance spills, excessive rainfall, and flooding events. Chapter IV @.03 A.(1): (1) Emergency Conditions. A growing area shall be placed in the closed status under Section @.03A. (5) when ~~pollution conditions exist which were not included in the database used to classify the area~~ emergency conditions exist. The Authority shall: (a) Develop a written emergency conditions protocol defining the thresholds and criteria used to determine if emergency conditions exist, including defining what conditions would trigger a growing area closure, and how to reopen a growing area once the emergency conditions no longer exist. The thresholds and criteria used to determine if emergency conditions exist, shall be based on the potential or actual pollution conditions which were not specifically represented in the sanitary survey information or database used to establish the classification and support the status of a shellfish growing area. These potential or actual pollution conditions may include, but are not limited to, tropical storms, hurricanes, sewage spills, oil spills, poisonous or deleterious substance spills, excessive rainfall, and flooding events; (b) Make a determination within 24 hours of a potential emergency condition event as to whether conditions exceed the established thresholds and criteria defined in the emergency conditions protocol and maintain a written record of the determination assessment; (c) Notify FDA and ISSC of the determination within 24 hours; (d) Once it is determined that an emergency condition exists, ~~If it is determined that an emergency condition or situation exists, then the growing area will be~~ immediately (within 24 hours) ~~placed in the closed status.~~ place the growing area in the closed status; (e) If a determination cannot be made within 24 hours, notify FDA and ISSC and immediately place the growing area in the closed status;

	(f) If the growing area is closed due to a precautionary closure and a determination is later made that the growing area did not experience emergency conditions based on the established protocol, the area may be immediately re-opened. The determination shall be documented in a written report and included in the sanitary survey for the area; and ~~(e)~~(g) If the growing area is closed due to emergency conditions, prior to re-opening, conduct an assessment of the growing area based on the established protocol and field observations and document the results in a written report to be included in the sanitary survey. Field observations include, but are not limited to, observations of actual or potential pollution sources made via shoreline survey, boat survey, sample collection, and/or analysis of sample results. The assessment shall include documentation of any new pollution sources and their effect on the growing area.
Public Health Significance	Current Model Ordinance language in Chapter IV states "If it is determined that an emergency condition or situation exists…", but does not specify the circumstances under which a determination must be made by the Authority. It will not be clear to a state Authority that pollution conditions exist which were not included in the data used to classify a growing area unless the Authority decides to check the data within the sanitary survey and perform an assessment in a situation which has the potential to meet emergency conditions. Not all Authorities do this in all situations that have the potential to meet "Emergency Conditions" under NSSP MO @.03 A.(1), such as excessive rainfall events with higher rainfall totals that what's recorded in the Authority's database. Additionally, the current language for "Emergency Conditions" does not clearly define "pollution conditions" or "the database used to classify the area". The "database" could be referring to the most recent 12 year sanitary survey or to all of the data ever collected for a growing area or to the most recent 30 water quality samples – it is not clear. In some instances, this has led to disagreements between FDA and state Authorities as to when a growing area needs to be closed due to emergency conditions, such as in the event of a tropical storm with rainfall levels or river stage levels which may or may not exceed the levels in the state's database. Since emergency conditions have the potential to significantly impact the water quality of a growing area and could lead to human fecal contamination, petroleum contamination, or poisonous or deleterious substance contamination in the area and possible shellfish-borne illnesses, it is important to clarify the definition of "Emergency Conditions".
Cost Information	Minimal Cost
Action by 2019 Task Force I	Recommends no action on Proposal 19-100. Issues are already addressed in the Model Ordinance.

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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	Recommends adoption of Proposal 19-101 as submitted.

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Proposal Subject	Laboratory approval for sample analysis with no Model Ordinance defined method or action level
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter III. Laboratory @.01 Quality Assurance (A)
Text of Proposal/ Requested Action	Chapter III. @.01 A. NSSP Conformance Required~~, for all laboratories supporting the NSSP~~. All laboratory analyses for compliance with classification requirements that require a specific method, actions level, and use defined in the Model Ordinance shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under the NSSP.
Public Health Significance	This proposed amendment to Chapter III, @.01 (A) updates the requirement related to the use of data analyzed by a laboratory that has not been certified by the FDA Shellfish LEO or FDA certified State Shellfish LEO and potentially used for regulatory purposes. The amendment allows state shellfish authorities to use non FDA approved laboratories when methods and action levels have not been defined in the Model Ordinance. Washington state has developed an extensive array of partnerships aimed at evaluating pollution conditions around shellfish growing areas primarily related to microbiological conditions and remediating any impacts identified. Local and state government agencies, tribes, and wastewater treatment plant operators collect data that may be used by the Shellfish Authority to manage the status of shellfish harvesting areas. Sampling activities from sewage spills, agricultural manure discharges, failing septic systems, and treatment loss at wastewater treatment plants have resulted in temporary closures of harvest areas. In turn, data collected from partner agencies has been used to identify when the pollution issue has been resolved and when the growing area can be opened. All sample analysis is completed by laboratories inspected by state regulatory agencies but have not evaluated for conformance by the FDA Shellfish LEO or FDA certified State Shellfish LEO. Washington state periodically uses laboratory analysis to determine if shellfish and shellfish harvesting areas are impacted by poisonous and deleterious substances. Shellfish closures or consumption advisories may be implemented based on this

	data. There are currently no laboratories approved by FDA Shellfish LEO for the analysis of poisonous and deleterious substances. The proposal assures that an FDA approved laboratory is required when laboratory methods and action levels are defined in the Model Ordinance and data may be used for regulatory action (marine water quality, marine biotoxins, Male Specific Coliphage). This proposal will give state shellfish authorities the flexibility to adapt to ongoing environmental conditions and make appropriate public health decisions based on laboratory data.
Cost Information	
Action by 2019 Task Force I	Recommends referral of Proposal 19-105 to an appropriate committee as determined by the Conference Chair

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Proposal Subject	Delete Notification Requirement to Pollution Control Agencies
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IV Shellstock Growing Areas @.01
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, hydrodynamic, 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 file shall include all data, results, and analyses from: (a) The sanitary survey; (b) The triennial reevaluation; and (c) The annual review. ~~(4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey.~~ ~~(5)~~(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.
Public Health Significance	This requirement does not have public health significance.
Cost Information	
Action by 2019 Task Force I	Recommends adoption of Proposal 19-106 as submitted.

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Proposal Subject	Determining shoreline survey area.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.01 Sanitary Survey D.(1) and (2)(a).
Text of Proposal/ Requested Action	(1) In the shoreline survey for each growing area, the Authority shall: (f) Conduct an in-field assessment of pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; and/or (iii) 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 ~~in-field~~ investigation ~~which identifies only the properties with the potential to impact the shellfish waters~~ that shall include, but not limited to, all properties with the potential to impact the shellstock growing area based on area topography, as well as field observations, and other sources of information;
Public Health Significance	The minimum requirements of the shoreline survey include an investigation and evaluation of pollution sources by trained, qualified, personnel. The investigation must be accomplished through an in-field assessment where the surveyor identifies actual and potential sources of pollution that might influence water quality. Given the technology available today, there are mutltiple options for identifing properties with the potential to impact growing areas. The Authority can define the shoreline survey area boundry by using various data resources such as geoprapohic information such as on-line maps. Using the term “only” as it is used in the existing language is confusing and, if taken literally, limiting. Example: One property two miles from the growing contains a large wastewater treatment plant that has the potential to impact shellfish waters. Another property one- and one-half miles from the growing area between that growing area and the property with the wastewater treatment plant on it has no identifiable pollution sources on it so that it does not have potential to impact shellfish waters. If the shoreline survey area is defined as a single area that includes the property with the wastewater treatment plant, it will also include the property with no identifiable pollution sources on it. Thus, it will not be an area that has “only” the properties with potential to impact the shellfish waters in it.
Cost Information	No cost.
Action by 2019 Task	Recommends adoption of Proposal 19-107 as amended.

Force I	(1) In the shoreline survey for each growing area, the Authority shall: (f) Conduct an ~~in-field~~ assessment of pollution sources which may include: (i) A drive-through survey; (ii) Observations made during sample collection; ~~and/or~~ ~~(ii)~~(iii) Other in-field assessments; and/or ~~(iii)~~(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 ~~in-field~~ investigation which identifies ~~only~~ the properties with the potential to impact the shellfish waters

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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. D. ~~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. C. 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	Recommends referral of Proposal 19-108 to an appropriate committee as determined by the Conference Chairperson.

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Proposal Subject	Offshore State Water classification requirements
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.02
Text of Proposal/ Requested Action	**@.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 assure 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 where a sanitary survey shows that there are no pollution sources that will impact the microbiological quality of the water. Offshore state waters are classified as approved.
Public Health	State waters extend 9 miles off shore of the State of Florida. If a sanitary survey

Significance	can show there are no pollution impacts (ie. Rivers, WWTPs discharges) to proposed areas for aquaculture the required 30 samples to classify should not be required.
Cost Information	This would reduce the cost and burden to state authorities having to sample waters that are far removed from any potential pollution sources.
Action by 2019 Task Force I	Recommends adoption of Proposal 19-109 as amended **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 assure 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 ~~are~~ may be classified as approved.

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Proposal Subject	Point source approved standard station locations.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.02 Microbiological Standards E.(3)(c).
Text of Proposal/ Requested Action	(c) Sample station locations shall be adjacent to actual or potential sources of pollution and adequate in terms of number and spatial distribution to support the conclusion that the growing area is characterized by water quality meeting the approved classification bacteriological requirements.
Public Health Significance	Stations in waters classified as approved are frequently not adjacent to pollution sources. Stations represent a miniscule portion of points within a growing area. The stations should be located so that it is reasonable to believe that, if a station were established at any point in the area where no station currently exists, that new station would yield bacteriological data meeting the relevant bacteriological standard consistent with the classification.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended referral of Proposal 19-110 to an appropriate committee as determined by the Conference Chairperson.

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Proposal Subject	Allowing the use of the SRS method in areas impacted by point sources
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.02E; Chapter IV. Shellstock Growing Areas @.02F; Chapter IV. Shellstock Growing Areas @.02F(2)(b); Chapter IV Shellstock Growing Areas @.02G; and Chapter IV. Shellstock Growing Areas @.02H
Text of Proposal/ Requested Action	Chapter IV, @.02 E. Standard for the Approved Classification of Growing Areas ~~Affected by Point Sources~~ when Evaluated for Adverse Pollution Conditions. Chapter IV, @.02 F. Standard for the Approved Classification of Growing Areas ~~Affected by Nonpoint Sources~~ 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~~:~~ ~~(a)~~ Impacted only by randomly occurring, intermittent events~~; and~~ ~~(b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.~~ Chapter IV, @.02 G. Standard for the Restricted Classification of Growing Areas ~~Affected by Point Sources~~ when Evaluated for Adverse Pollution Conditions and Used as a Shellstock Source for Shellstock Depuration. Chapter IV, @.02 H. Standard for the Restricted Classification of Growing Areas ~~Affected by Nonpoint Sources~~ when Evaluated for Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration
Public Health Significance	This proposed amendment to Chapter IV, @.02 updates the conditions under which the APC and SRS methods may be used. The proposal allows the use of the SRS method in areas impacted by discharges from sewage treatment facilities or combined sewage overflows where marine water stations have been placed to monitor nonpoint pollution.

	The intent of this proposal is to use the sampling methodology and statistical analysis most acceptable for the purpose of the marine water sampling station. If the station is placed to monitor nonpoint pollution, the SRS methodology should be used. If the station is placed to monitor adverse pollution conditions, the APC methodology should be used. In Washington state, marine water stations located in Conditionally Approved areas impacted by wastewater treatment plants are placed to monitor nonpoint pollution from the surrounding upland areas. The APC criterion is used to sample and evaluate data from these stations with the adverse condition defined as an upset at the treatment plant. Many wastewater treatment plants are high performing and upset conditions occur infrequently. The infrequency of the impact to the growing area does not allow for the intended use of the APC sampling strategy. Hydrographic studies and dilution analyses are more appropriate for the evaluation of the impact area around high performing wastewater treatment plants.
Cost Information	No impact
Action by 2019 Task Force I	Recommended adoption of Proposal 19-111 as submitted.

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Proposal Subject	Nonpoint source approved standard station locations.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.02 Microbiological Standards F.(6)(b)(i).
Text of Proposal/ Requested Action	(i) Sample station locations ~~are~~ shall be adequate ~~to produce the data to effectively evaluate all nonpoint sources of pollution~~in terms of number and spatial distribution to support the conclusion that the growing area is characterized by water quality meeting the approved classification bacteriological requirements;
Public Health Significance	The Model Ordinance Chapter IV.@.02B indicates "The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources." That includes all nonpoint sources of pollution so there is no need to state that requirement within IV.@.02F. Stations represent a miniscule portion of potential points within a growing area. The stations should be located so that it is reasonable to believe that, if a station were established at any point in the area where no station currently exists, that new station would yield bacteriological data meeting the relevant bacteriological standard consistent with the classification.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended referral of Proposal 19-112 to an appropriate committee as determined by the Conference Chairperson

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Proposal Subject	Authorizing unclassified areas and multiple classifications for single area.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.03 Growing Area Classification A.(2).
Text of Proposal/ Requested Action	(2) Classification of ~~All~~ Growing Areas. ~~All~~ Each growing ~~areas~~area which: (a) ~~Are~~ 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) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited classification established adjacent to the outfall in accordance with Section E. Prohibited Classification; and~~ (b~~e~~) ~~Are~~ 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 ~~only~~ one or more~~(1)~~ of the following: (i) Approved; (ii) Conditionally Approved; (iii) Restricted; (iv) Conditionally Restricted; and/or (v) Prohibited.
Public Health Significance	There is no reason to require that all growing areas be classified if the Authority is required to treat unclassified areas as prohibited areas. The current Section II. Chapter IV.@.03A.(2)(b) language is unnecessary. Requiring that each growing area be characterized by only one classification is not realistic and does not reflect common practice. There are many circumstances in which one growing area contains several classifications. Example: A 10 square mile growing area is generally classified as approved. However, there is a marina in it, so some waters associated with that marina are classified as prohibited and restricted. There is a business with a 5,000 gallon per day wastewater treatment system discharging along the shoreline so there is a prohibited zone adjacent to that point source. That circumstance literally represents violation of Chapter IV.@.03A.(2)(c) as that requirement now reads because there are multiple classifications within a single growing area.
Cost Information	No cost.
Action by 2019 Task Force I	Recommends adoption of Proposal 19-113 as amended.

	2) Classification of ~~All~~ 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) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited classification established adjacent to the outfall in accordance with Section E. Prohibited Classification; and~~ (b~~e~~) ~~Are~~ 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 or more of the following: (i) Approved; (ii) Conditionally Approved; (iii) Restricted; (iv) Conditionally Restricted; and/or (v) Prohibited.

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Proposal Subject	Emergency Conditions re-opening studies.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.03 Growing Area Classification A.(5)(c)(i).
Text of Proposal/ Requested Action	(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. When pathogens are of concern, ~~S~~studies establishing sufficient elapsed time shall document the interval necessary for reduction of ~~contaminant~~ coliform levels in the shellstock to pre-closure levels. ~~In addressing pathogen concerns, the~~ Such coliform studiesmay establish criteria for reopening based on coliform levels in the water. When poisonous or deleterious substances are the concern, studies 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
Public Health Significance	National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, Section IV Guidance Documents, Chapter II Growing Areas, .08 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood contains target levels for many poisonous or deleterious substances. Target levels for other substances can be established through risk evaluation. The 2010 Deepwater Horizon crisis provides an example of how emergency conditions involving poisonous or deleterious substances are addressed in practice. Levels of concern were established through risk evaluation then areas were re-opened based on determining that contaminant levels were below levels of concern rather than based on comparisons between pre and post closure levels.
Cost Information	Cost would potentially be reduced because studies to compare post closure levels of poisonous or deleterious substances to pre closure levels would no longer be required.
Action by 2019 Task Force I	Recommends adoption of Proposal 19-114 as amended. (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. When pathogens are of concern, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studiesmay establish criteria for reopening based on coliform levels in the water. When poisonous or deleterious substances are the concern, ~~studies~~ 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

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Proposal Subject	Emergency Conditions/closed status to reflect Chapter II use of harvest area
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification A. General (1) and (5)
Text of Proposal/ Requested Action	@.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 unpredicted pollution conditions exist ~~which were not included in the database 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. (a) If the growing area or harvest area is already closed due to resource conservation under existing fishery laws or regulation, the area is considered to be in the closed status. If the authority choses to uses this approach, an MOU detailing coordination and, communication between agencies and patrol shall be required. ~~(a)~~(b) If no harvest areas are impacted by Emergency Conditions, placement into the closed status is not required. (2)…….. (3)..... (4)…… (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 for a limited or temporary period

	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) 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:
Public Health Significance	Closed status following an emergency situation can include an entire growing area or a harvest area within the growing area; This change is consistent with Chapter II where, if appropriate, only a harvest area is closed due to an outbreak and not necessarily the entire growing area. In addition, the text stating conditions that were not included in the data base makes no sense related to emergency conditions and actually state the obvious. Deletion of that statement clarifies this part of the MO.
Cost Information	There should be no need to close an area that has no shellfish resource or is already closed by existing regulation. If this proposal is accepted by the Conference, it would save money for any state that is required to post closures in the newspaper (public notice); For Maryland the cost is ~$1500, so it would represent a significant savings.
Action by 2019 Task Force I	Recommended referral of Proposal 19-115 to an appropriate committee designated by the Conference Chair

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Proposal Subject	Adding a time frame to the limited or temporary period an area can be remain under a closed status prior to being reclassified.
Specific NSSP Guide Reference	Section II, Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification A. (5) (b).
Text of Proposal/ Requested Action	(b) Closed Status. Any classified growing area may be closed for a limited or temporary period, not to exceed more than one year prior to a reclassification because of: (i) An emergency…; (ii) The presence…; (iii) Conditions stipulated…; (iv) Failure of…; or (v) The requirements….
Public Health Significance	The M. O. Chapter IV @.03 A. (5) (b) states that any classified growing area may be closed for a limited or temporary period because of: (i) through (vi). The time frame "limited or temporary period "is not defined in the "Guide". The authority is required by @.03 A. (1) to place a growing area in the closed status ..." under Section @.03 A. (5) when pollution conditions exist which were not included in the database used to classify the area. If it is determined that an emergency condition or situation exists, then the growing area will be immediately (within 24 hours) placed in the closed status." Once the area is in the closed status, harvesting, attempting to harvest, possession, or sale of shellfish from the closed area is prohibited. A time limit of up to but not to exceed one year from the time the area was placed in the closed status allows the authority time with defined maximum to determine the source /cause(s) of a pollution or contamination problem before initiating a reclassification while still protecting public health by virtue of the area being in a closed status. The proposed change will not lessen public health protection.
Cost Information	Does not add any cost and may actually save administrative cost by averting multiple reclassifications in the process of sorting out the final correct classification.
Action by 2019 Task Force I	Recommends referral of Proposal 19-116 to an appropriate committee as determined by the Conference Chairperson.

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Proposal Subject	Shellfish cleansing studies
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification. C. Conditional Classifications. (2) (c) (iii)
Text of Proposal/ Requested Action	(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water. If the conditional management plan is based on effects of non-point sources of pollution such as rain events and /or storm water runoff, an area can be reopened 48 hours after the water quality has met acceptable classification criteria as long as shellstock are actively feeding.
Public Health Significance	There are a number of problems related to the current M. O. language." There is no guidance or criteria in the Guide concerning what constitutes an adequate study. There are a number of study related questions: 1) How many shellfish samples of each species of shellfish and sampling stations (locations) are needed in a growing area; 2) Are studies required in every conditional area? 3) can information obtained in one growing area be applied to shellstock in another growing area? 4) The first sentence at (iii) refers "*to reducing pathogens...to acceptable levels*", what are acceptable levels of pathogens. The second sentence at (iii) refers to *reduction of coliform levels in shellstock to pre-closure levels*. Pre-closure levels in shellstock can be variable both temporally and spatially. Thus the concept of reducing coliforms to pre-closure levels is at best ambiguous. In order to obtain the required data, there is a sampling and laboratory burden. This requires time consuming shellstock sampling during open periods and again after pollution events over the year as well as increased laboratory effort to establish a data base. Shellfish samples require two lab days thus reducing lab capacity to handle water samples. In the 1980's and early 1990's Massachusetts and other states sampled shellstock one or two days after water in Conditionally Approved areas reached the criteria for an Approved classification to ensure that the shellstock was well below the then existing NSSP 230 FC market standard. Usually 150 FC or less was considered adequate to reopen because there was no actual coliform harvest standard and it made sense to only allow harvest well below the market standard. This reduction was accomplished within two days or less of the water quality returning to acceptable levels. This approach compared coliform levels in shellfish after water quality reached acceptable levels to an existing standard. When this policy was established, it was endorsed by the FDA Shellfish Specialist. \Shellstock can accumulate bacteria up to 100 times the level in the water. In theory

	shellstock in water at geometric mean of 10 FC per 100 ml could accumulate FC bacteria to a level of 1000 FC per 100 g. Thus opening an area at a level below the former 230 FC market standard would seem appropriate. Two day purging time is well established. Literature supports elimination of greater than 95% of FC bacteria from shellstock in less than 24 hours including NSSP workshop studies. Temperature is the most important factor affecting elimination of bacteria because it governs shellfish feeding activity. Naturally contaminated shellfish can eliminate fecal coliform levels in 48 hours to levels below most market standards over a range of environmental conditions (Perkins, et al, 1979). Other studies show that soft –shelled clams at MPN 10,000 FC /100 g reduced to values below 50 in 48 hours (Arcisz, et al, 1955) and oysters at MPN 39,000FC/1000g can purge to values below 50 in 48 hours.
Cost Information	Could produce significant savings to state shellfish classification programs.
Action by 2019 Task Force I	Recommends adoption of Proposal 19-117 as amended. (iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water. If the conditional management plan is based on effects of non-point sources of pollution such as rain events and /or storm water runoff, an area can be reopened ~~48 hours after~~when the water quality ~~has met~~meets ~~acceptable~~ classification criteria without a cleansing study. ~~as long as shellstock are actively feeding~~

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Proposal Subject	Conditional areas not based on predicting microbiological indicator levels.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas Section @.03 Growing Area Classification C.(1).
Text of Proposal/ Requested Action	(1) Survey Required. The sanitary survey meets the following criteria: (a) ~~The area will be in the open status of the conditional classification for a reasonable period of time.~~ The factors determining the~~is~~ period the growing area is in open status are known and ~~, are~~ predictable~~, and are not so complex as to preclude a reasonable management approach~~; (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,~~M~~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~~is~~ data correlate~~s~~ with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.
Public Health Significance	Not all conditional management is based on predicted changes in microbiological water quality. Conditional management can be based, for example, on the operation of a wastewater treatment system that has never failed. In such a circumstance, demonstrating correlation with environmental conditions or other factors may play no role. The plan can be based completely on other means of predicting the impact of plant failure. Conditional management can also be based on changes in marina occupancy. Similarly, the Authority may use MSC data in some way to support conditional management without demonstrating correlation between MSC levels in shellfish tissues and environmental conditions or other factors.
Cost Information	No cost.
Action by 2019 Task Force I	Recommends adoption of Proposl 19-118 as amended. 1) Survey Required. The sanitary survey meets the following criteria: (a) The factors determining the~~is~~ 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~~s~~ with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.

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Proposal Subject	Reduced marine water sampling in conditionally approved areas impacted by point sources
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification C3. Reevaluation of Conditional Classification(b)(ii)
Text of Proposal/ Requested Action	Section II Model Ordinance Chapter IV Shellstock Growing Area @.03 Growing Area Classification C3. Reevaluation of Conditional Classification (b) Water Sample Collection (ii) When the conditional management plan is based on the operation and performance of a WWSD (s); combined sewer overflows(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 performance failure; and (b) Communication requirements are documented and the WWSD operator provides immediate notification to the Shellfish Authority during a performance failure.
Public Health Significance	This proposed amendment to Chapter IV, @.03C3(b)(ii) updates the requirements related to the monthly sampling requirement in Conditionally Approved areas classified based on the operation and performance of a WWSD, combined sewer overflow, or other point source. The proposal allows the Shellfish Authority to reduce the number of marine water samples in the area from monthly to five or six times per year, based on the sampling methodology used, if additional studies and appropriate communication channels have been developed. Based on the high performance of many treatment plants, upset conditions occur infrequently and are not evaluated through the placement of permanent marine water sampling stations. Dye and drogue studies coupled with computer modelling are commonly used to determine the potential impact from a point source of pollution on the growing area and are used to calculate the dilution available throughout the area. In Washington state, all NPDES permits issued to wastewater treatment plants contain requirements for operators to provide immediate notification to the Shellfish Authority during upset conditions. Failure of the operator to respond in a timely fashion could result in a significant penalty. Upset conditions impacting Conditionally Approved shellfish growing areas in Washington State are infrequent; however, during each event the Shellfish Authority has been immediately informed.

	The high performance of current treatment plants, effective use of hydrographic and dilution analysis, and immediate communication during upset conditions provide more effective and efficient protection of public health in Conditionally Approved areas impacted by point sources. Upset conditions are infrequent and random which can make monthly sampling inefficient and ineffective at evaluating impacts from the point source.
Cost Information	The reduced sampling option would be a cost savings for the Shellfish Authority.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-119 as submitted. Section II Model Ordinance Chapter IV Shellstock Growing Area @.03 Growing Area Classification C3. Reevaluation of Conditional Classification (b) Water Sample Collection (ii) When the conditional management plan is based on the operation and performance of a WWSD (s); combined sewer overflows(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~~ communication requirements are documented and the WWSD operator provides immediate notification to the Shellfish Authority during a performance failure; or ~~(a)~~(b) ~~.~~ Mooring assessment determines the mooring area is not a pollution source.

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Proposal Subject	Classification of Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Growing Area Classification F.
Text of Proposal/ Requested Action	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.
Public Health Significance	The FDA has taken the position that all Federal waters are approved unless closed. Currently shellfish harvesting is being allowed in areas with known marine biotoxin hazards. To address these hazards, harvesting restrictions are being required without the designation of appropriate harvesting classification. Currently the Model Ordinance does not include any restrictions for approved areas. Shellfish harvesting areas that have been closed are considered prohibited and harvesting for human consumption purposes is not allowed. If the FDA wants to continue to allow harvesting in Federal waters with restrictions, appropriate classification should be designated.
Cost Information	
Action by 2019 Task Force I	Recommends adoption of Proposal 19-120 as submitted.

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Proposal Subject	*Karenia brevis*
Specific NSSP Guide Reference	Section II Model Ordinance Chapter IV. Shellstock Growing Areas @.04
Text of Proposal/ Requested Action	Chapter IV. Shellstock Growing Areas @.04 C. Closed Status of Growing Areas. 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 - 5,000 cells/L *(Karenia brevis)* or 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)
Public Health Significance	The 5,000 cell count standard applies to *Karenia brevis* only
Cost Information	
Action by 2019 Task Force I	Recommended no action on Proposal 19-121. Rationale: This issue is addressed by Proposal 19-149.

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Proposal Subject	Use of "growing area" rather than "harvest area" in Patrol requirements language.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter VIII. Control of Shellfish Harvesting @.01 Control of Shellstock Growing Areas A.(2)(d), A.(3)(b), B.(2).
Text of Proposal/ Requested Action	A. General. (1) The Authority shall maintain an effective program to control shellstock growing areas and to assure that shellstock are harvested only: (a) From areas in an open status; and (b) With approval from areas classified as restricted, conditionally restricted, or prohibited, or in the closed status of the approved or conditionally approved classification. (2) This program shall include: (a) The patrol of growing areas; (b) The licensing of harvesters; (c) Enforceable legal penalties sufficient to encourage compliance; and (d) Appropriate identification of growing~~harvest~~ areas and/or portions of growing areas where shellstock harvest is not allowed. (3) At the time of issuance or renewal of a harvester's license or a dealer's certification, or an annual mail out to all licensed shellfish harvesters, the Authority shall provide each harvester or dealer with: (a) Information which explains the public health risk associated with illegal harvesting shellstock in areas classified as restricted, conditionally restricted, or prohibited or in the closed status; and (b) When requested, a current, comprehensive, itemized listing of all growing~~harvest~~ areas including their geographic boundaries and their classification. B. Patrol of Growing Areas. (1) The Authority shall assure that shellstock are harvested only as provided in this Chapter. (2) The Authority shall patrol growing~~harvest~~ areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting...
Public Health Significance	The NSSP Guide for the Control of Molluscan Shellfish contains definitions for "Harvest Area" and "Growing Area." "Growing Area" is the more appropriate term for the indicated locations.
Cost Information	No cost.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-122 as amended. A. General.

	(1) The Authority shall maintain an effective program to control shellstock growing areas and to assure that shellstock are harvested only: (a) From areas in an open status; and (b) With approval from areas classified as restricted, conditionally restricted, or prohibited, or in the closed status of the approved or conditionally approved classification. (2) This program shall include: (a) The patrol of growing areas; (b) The licensing of harvesters; (c) Enforceable legal penalties sufficient to encourage compliance; and (d) Appropriate identification of growing areas and/or portions of growing areas where shellstock harvest is not allowed. (3) At the time of issuance or renewal of a harvester's license or a dealer's certification, or an annual mail out to all licensed shellfish harvesters, the Authority shall provide each harvester or dealer with: (a) Information which explains the public health risk associated with illegal harvesting shellstock in areas classified as restricted, conditionally restricted, or prohibited or in the closed status; and (b) When requested, a current, comprehensive, itemized listing of all growing areas including their geographic boundaries and their classification. B. Patrol of Growing Areas. (1) The Authority shall assure that shellstock are harvested only as provided in this Chapter. (2) The Authority shall patrol growing areas or portions of growing areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting...

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Proposal Subject	Marine Biotoxin Control - Public Health Reasons
Specific NSSP Guide Reference	Section III. Public Health Reasons and Explanations, Model Ordinance Chapter IV. Shellstock Growing Areas, @.04
Text of Proposal/ Requested Action	**. @.04 Marine Biotoxin Control** **TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT**
Public Health Significance	Marine biotoxins can cause injury, illness, or death. More clearly presented information will assist NSSP participants in understanding the public health reasons for marine biotoxin contingency and management plans.
Cost Information	None
Action by 2019 Task Force I	Recommends referral of Proposal 19-123 to an appropriate committee as determined by the Conference Chair TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT.

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Proposal Subject	Marine Biotoxin Control – Guidance Document
Specific NSSP Guide Reference	Section IV Guidance Documents Chapter II. Growing Areas Chapter IV. Shellstock Growing Areas .02
Text of Proposal/ Requested Action	**.02 Guidance for Developing Marine Biotoxin Contingency and Management Plans.** TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT
Public Health Significance	Marine biotoxins can cause injury, illness, or death. More clearly presented guidance will assist control authorities in developing marine biotoxin contingency and management plans.
Cost Information	None
Action by 2019 Task Force I	Recommends referral of Proposal 19-124 to an appropriate committee as determined by the Conference Chairperson. TEXT OF PROPOSAL NOT INCLUDED IN THIS REPORT

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Proposal Subject	*Karenia brevis* Guidance
Specific NSSP Guide Reference	Section IV Guidance Documents – Chapter II. Growing Areas
Text of Proposal/ Requested Action	**.02 Guidance for Developing Marine Biotoxin Plans** Introduction Shellfish are filter… There are a… There are five… Both *Alexandrium* and… The minimum concentration… The NSSP Model… In shellfish growing… In Gulf coast… areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis*. The most common public health problem associated with *Karenia* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karenia brevis* blooms have been reported in Florida (Center for Disease Control, 1973 [a] and [b]). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. The NSSP Model Ordinance mandates that growing areas be placed in the closed status when any NSP toxin is found in shellfish meat at or above 20 MU per 100 grams of shellfish, or when the cell counts for ~~members of the genus~~ *Karenia brevis* in the water column equal or exceed 5,000 cells per liter of water.
Public Health Significance	The 5,000 cell count standard applies to *Karenia brevis* only
Cost Information	
Action by 2019 Task Force I	Recommends adoption of Proposal 19-125 as amended. **.02 Guidance for Developing Marine Biotoxin Plans** Introduction Shellfish are filter… There are a…

	There are five… Both *Alexandrium* and… The minimum concentration… The NSSP Model… In shellfish growing… In Gulf coast… areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karenia brevis*. The most common public health problem associated with *Karenia* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karenia brevis* blooms have been reported in Florida (Center for Disease Control, 1973 [a] and [b]). Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat. The NSSP Model Ordinance mandates that growing areas be placed in the closed status when any NSP toxin is found in shellfish meat at or above 20 MU per 100 grams of shellfish~~, or when the cell counts for *Karenia brevis* in the water column equal or exceed 5,000 cells per liter of water.~~

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Proposal Subject	MPN-Real-Time PCR for Enumeration of Vibrio vulnificus in Oysters
Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.
Text of Proposal/ Requested Action	**5. Approved Methods for Vibrio Enumeration**

	Vibrio Indicator Type:	**Application: PHP Sample Type: Shucked**	**Application: Reopening**
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**
MPN-Real Time PCR[7]	***Vibrio parahaemolyticus (V.p.)***	**X**	**X**
Direct Plating Method[8]	***Vibrio parahaemolyticus (V.p.)***		**X**
MPN-Real Time PCR[9]	***Vibrio vulnificus (V.v.)***	**X**	

Footnotes:

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

[2] 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.

[3] 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.

[4] 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 the vvh gene for total *V. vulnificus* as described in Kinsey et al., 2015.
Public Health Significance	This MPN-real-time PCR method provides results in as little as 24 h from receipt of sample. The current NSSP methods for enumeration of *Vv* have limitations: the traditional MPN requires a minimum of 3 days and the SYBR Green PCR is only validated on an instrument platform which is no longer supported by the manufacturer. This method provides an additional option for laboratories to maintain the same level of testing as has been maintained in the program.
Cost Information	This method costs ~$100 per sample for laboratory consumables, supplies, and reagents. Most equipment needed for testing is standard microbiology equipment, but purchase of a heat block (~$400) and/or centrifuge (~$2,500) may be necessary. Purchase of a real-time PCR instrument will be required ($30,000-$45,000). Additional costs for a laboratory would vary based on their operational overhead and labor.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-126 as submitted.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-126.

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Proposal Subject	Modification of the MARBIONC Brevetoxin ELISA Standard Operating Procedures
Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter II. Growing Areas. 14 Approved NSSP Laboratory Tests 4. Approved Limited Use Methods for Marine Biotoxin Testing
Text of Proposal/ Requested Action	In 2017, the ISSC approved the MARBIONC Brevetoxin ELISA as a Limited Use Method under the NSSP (Proposal 17-107). The Standard Operating Procedure (SOP) for the MARBIONC Brevetoxin ELISA submitted as a part of the supporting documents for Proposal 17-107 specifies that quantification of sample dilutions is restricted to those dilutions falling within the linear portion of the standard curve, which is specified as the range of concentrations that yield 20-70% inhibition in the assay. One of the QA/QC criterion in the SOP requires that the variation (%CV) of concentrations calculated from sample dilutions falling within this range must be <20%. This proposal is to modify the MARBIONC ELISA SOP to: a) narrow the range for quantifying sample dilutions to 30%-70%, b) update the QA/QC criteria to reflect this change, and c) make minor additions and corrections to the text of the SOP. The modified SOP with proposed changes is provided in Appendix A. Data and justification for the proposed changes are provided in Appendix B.
Public Health Significance	The approval of this ELISA as a Limited Use Method for testing to support the NSSP has enabled rapid testing for NSP, which has enhanced the protection of public health by enabling more frequent NSP testing. Revising the SOP and QA/QC criteria will help to minimize avoidable QA/QC failures while still controlling for errors and protecting public health.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-127 as submitted.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-127.

<table>
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<tr><td>Proposal Subject</td><td>Laboratory Method for Vibrio parahaemolyticus and Vibrio vulnificus Enumeration and Detection Through MPN and Real-Time PCR</td></tr>
<tr><td>Specific NSSP Guide Reference</td><td>Section IV Guidance Documents Chapter II Growing Areas .14 Approved NSSP Laboratory Tests</td></tr>
<tr><td>Text of Proposal/ Requested Action</td><td>5. Approved Methods fir Vibrio Enumeration
<table>
<tr><th></th><th>Vibrio Type:</th><th>Application: PHP Sample Type: Shucked</th><th>Application: Reopening</th></tr>
<tr><td>EIA[1]</td><td>Vibrio vulnificus (V.v.)</td><td>X</td><td></td></tr>
<tr><td>MPN[2]</td><td>Vibrio vulnificus (V.v.)</td><td>X</td><td></td></tr>
<tr><td>SYBR Green 1 QPCR-MPN[5]</td><td>Vibrio vulnificus (V.v.)</td><td>X</td><td></td></tr>
<tr><td>MPN[3]</td><td>Vibrio parahaemolyticus (V.p.)</td><td>X</td><td></td></tr>
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<tr><td>MPN-Real Time PCR[6]</td><td>tdh+ and trh+ Vibrio parahaemolyticus (V.p.)</td><td>X</td><td>X</td></tr>
<tr><td>MPN-Real Time PCR[7]</td><td>Vibrio parahaemolyticus (V.p.)</td><td>X</td><td>X</td></tr>
<tr><td>MPN-Real Time PCR[9]</td><td>Vibrio parahaemolyticus (V.p.) and Vibrio vulnificus (V.v.)</td><td>X</td><td>X</td></tr>
<tr><td>Direct Plating Method[8]</td><td>Vibrio parahaemolyticus (V.p.)</td><td>x</td><td>X</td></tr>
</table>
Footnotes:
[1] EIA procedure of Tamplin, et al, as described in Chapter 9 of the FDA Bacteriological Analytical Manual, 7th Edition, 1992.

[2] 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.</td></tr>
</table>

	[3] 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. [4] 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	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-128.

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Proposal Subject	Micropipettor Verification
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 Checklists, NSSP Laboratory Evaluation Checklists, 2. Shellfish Laboratory Evaluation Checklist for Mouse Bioassay (MBA) and Scotia Rapid Test for PSP.
Text of Proposal/ Requested Action	The requested action is to adopt the new text to be consistent across checklists for the NSSP MBS and Scotia Rapid Test (SRT) for PSP under Part III, Section 3.1, Screening by SRT item 3.1.7.
Public Health Significance	Quality Assurance and Standardization are integral to the validity of the NSSP laboratory. This includes verifying the measurement accuracy of pipetting instruments including micropipettors. There are no recognized references that state micropipettors must receive third party certifications. There is no indication as to what "Level" calibration should exist. The reference for this item is only **#2, Good Laboratory Practice**. Accuracy measurement assurance should be based on workload and use. Pipette calibration values on certificates obtained in a calibration laboratory (known as a controlled laboratory) do not accurately transfer to the NSSP laboratory and therefore do not provide assurance and defensibility. A pipette's measurement accuracy is influenced by its *physical uncertainty*, *environmental uncertainty* (i.e., temperature, vibration and humidity) and *operator use uncertainty*. These uncertainties will differ between laboratories. Pipette performance in the NSSP (non-controlled laboratories) is impacted by the temperature and viscosity of the fluid, the skill of the operator and choice of tip. Conducting in-house verifications for each operator, using a verified balance provides a better assessment of the actual measurement accuracy of what the pipet is delivering. When the uncertainty of measurement exceeds the stated laboratory established threshold, adjustments are made. As a component of a Laboratory's Quality Management System, the individual laboratory can institute legally defensible and measurement assurance practices appropriate for the laboratory's workload, testing and ambient conditions. Calibration Cost Information from one Pipet Manufacturer: 1. Calibration and Maintenance - Offers three "levels" of examination, with an assorted number of readings at 3 volumes, across different channel pipettors. Cost Range $30 - $225 per unit. 2. Calibration only (<u>center channel only</u>) - $30 - $180 if unit passed on the initial attempt. 3. Non-Operational pipette repair evaluation (no calibration and parts

	additional cost) starting at $28/unit.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-129. Rationale: The recommended new text would replace existing language that is needed.
Action by 2019 Task Force	Recommends adoption of Laboratory Committee recommendation on Proposal 19-129.

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Proposal Subject	Microbiology Laboratory Evaluation Checklist- Standards Thermometer
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 Checklists, 1. NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt modified standards thermometer language to correct checklist inconsistencies in Section 1.4 Laboratory Equipment item 1.4.21.
Public Health Significance	All standards thermometers allowed for in section 1.4.23, not just mercury-in-glass thermometers, should be calibrated and traceable to NIST at the points of use.
Cost Information	Cost of calibration.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-130 as submitted.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-130.

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Proposal Subject	NSSP Microbiology Laboratory Evaluation Checklist – Reagent Water Quality
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 Checklists, 1. NSSP Laboratory Evaluation Checklist for Microbiology.
Text of Proposal/ Requested Action	The requested action is to adopt the modified text and update the reference in Section 1.7 Media Preparation for checklist item 1.7.6.
Public Health Significance	The suggested change addresses the importance of accurate information used in laboratory Quality Assurance Programs (QAPs) for recommended limits for the quality of reagent water used for microbiology testing by correcting the maximum acceptable limits for conductivity and resistivity testing based on the most current ***Standard Methods*** Edition. For 26 years, the incorrect units of measure for conductivity and resistivity have been printed in laboratory reference materials: ***Standard Methods for the Examination of Water and Wastewater***, 1992, 18th Edition; ***Standard Methods***, 2012, 22nd Edition; and ***Standard Methods***, 2017, 23rd Edition. The QA information is finally corrected in the ERRATA, dated 5/29/18 for ***Standard Methods*** 23rd Edition. The material states "In Section 9020, Table 9020:II (p. 9-14), the recommended Maximum Acceptable Limit for Conductivity Test should be "<2 µmhos/cm (µSiemens/cm) at 25°C." The incorrect "resistance" statement from the 18th Edition is removed in the 22nd and 23rd Editions of ***Standard Methods***. The resistivity (also called specific resistance) is the reciprocal of the conductivity, not resistance. A resistivity recommendation can be found in the Reagent Grade Water section.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-131 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-131.

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Proposal Subject	Microbiology Laboratory Evaluation Checklist - Working Thermometers
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 Checklists, 1. NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt the modified text of the NSSP microbiology checklist, section 1.4 Laboratory Equipment, item 1.4.24:
Public Health Significance	The laboratory's goal is to ensure high-quality data using accepted scientific practices. The designated changes incorporate recommended best practices from a current recognized scientific publication. These types of acknowledged practices are used to develop a laboratory's Quality Assurance Program (QAP). The *verification* of working thermometers is now suitably referenced to support past and present practices in program laboratories and *recommends a rejection component (new)*. The newer/current reference material is cited to strengthen confidence in the acceptability of past practices for "checking" accuracy in working temperature monitoring devices. ***Standard Methods,*** 23rd Edition, states "Annually, or preferably semiannually, **verify** the accuracy of all working temperature-sensing devices (e.g., liquid-in-glass thermometers, thermocouples, and temperature-recording instruments) at the use temperature(s). To do this, compare each device's measurements to those of a certified NIST temperature-sensing device or one traceable to NIST and conforming to NIST specifications. Discard temperature-sensing devices that differ by >1ºC from the reference device."
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-132 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-132.

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Proposal Subject	Microbiology & PCR Laboratory Evaluation Checklists - Working Thermometers
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 Checklists, NSSP Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	The requested action is to adopt modified working thermometer language for these two NSSP laboratory evaluation checklists items. The modification is to remove the word "calibrated" and add thermometer accuracy requirements.
Public Health Significance	There are currently no NSSP accuracy criteria established for Liquid-in-Glass thermometers. This proposal establishes uncertainty requirements that should be considered prior to purchase since all thermometers and temperature recording devices are not created equally. Quality Assurance and Standardization are integral to the validity of the NSSP laboratory. For thermometers there are several factors that influence temperature readings; therefore, controlling thermometer accuracy will impact thermometer standardization across NSSP laboratories. A thermometer's accuracy is a product of its *manufacturing uncertainty*, *measurement uncertainty* and *environmental uncertainty* which all must be considered and evaluated by the purchaser. Only thermometers that are manufactured accurately and are found *fit for purpose* for the NSSP laboratory should be purchased. Some Liquid-in-Glass thermometers are manufactured with accuracies (> 0.2ºC) that are greater than the water bath temperature limit of ±0.2°C; these thermometers should not be purchased for the NSSP laboratory. As stated in Reference #4, NIST Monograph 150 "the accuracy attainable is principally limited by the characteristics of the thermometer itself." Therefore, a working thermometer's accuracy should be assessed prior to purchase. Calibration is performed post purchase. *Calibration quantifies <u>only</u> the temperature **measurement uncertainty** at the single temperature point assessed.* Calibration without also considering the ***manufacturing uncertainties*** of the thermometer is inaccurate: generating a false security for accuracy. Calibration values are only accurate at the environmental conditions found within the calibration laboratory; when total immersion thermometers are immersed to the test temperature being measured with the emergent stem at ambient temperature. In the NSSP laboratory, the emergent stem <u>is not</u> at ambient temperature. This creates ***environmental uncertainty*** which invalidates the calibration certificate and requires experience and knowledge in generating an accurate stem correction. An inaccurate stem correction compounds the degree of error in the final temperature

	reading. The current NSSP practice of calibrating an inappropriate thermometer against the undefined calibration standard (NIST, ASTM, Primary, Secondary, etc) and then using this thermometer incorrectly in the laboratory environment negates any assurance received by having a calibration certificate. This practice would not be legally defensible. NSSP Quality Assurance and Standardization would be better served to establish manufacturing accuracy requirements that only allow for the use of appropriate working thermometers. *These working thermometers will then be verified against a calibrated standards thermometer, that is traceable to NIST in section 1.4.24.* Savings: Calibration costs per thermometer: $125 for the first point and $60 for each additional point. Most lab are locked into local calibration facilities, within driving distance of their labs, if their thermometers are mercury. Postal hazard restrictions prohibit mercury thermometers being shipped in the mail.
Cost Information	none
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-133 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-133.

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Proposal Subject	Membrane Filtration Technique for Seawater using mEndo Agar LES 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 Checklists , NSSP Laboratory Evaluation Checklists, NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The Requested Action is to adopt the attached checklist for the Membrane Filtration Technique for Seawater using mEndo Agar LES and to append the NSSP Laboratory Evaluation Checklist for Microbiology found at the end of section .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists to include this checklist.
Public Health Significance	The NSSP does not have a checklist for Total Coliform analysis on UV Seawater using the NSSP approved method of Membrane Filtration with mEndo Agar LES. Checklists provide quality assurance and method support for laboratories and for Laboratory Evaluation Officers to standardize and evaluate laboratories which use approved methods in support of the NSSP. The attached checklist for this NSSP approved method provides such standardization, quality assurance and background documentation for method procedures. As a laboratory evaluation tool with critical and key codes identified it will be used for determination of laboratory conformance and compliance.
Cost Information	none
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-134. Rationale: This issue is addressed by Proposal 19-137.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-134.

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Proposal Subject	Microbiology Laboratory Evaluation Checklist - Sterilization
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 Checklists, 1. NSSP Laboratory Evaluation Checklist for Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt the modified text of the NSSP microbiology checklist, section 1.6 Sterilization and Decontamination, item 1.6.3:
Public Health Significance	The laboratory's goal is to ensure high-quality data using accepted scientific practices. The denoted information acknowledges recommended best practices used in recognized scientific publications to develop a laboratory's Quality Assurance Program (QAP) for sterilization practices at a wider range of temperature. The sterilization temperature range and the verification of working thermometers are now acceptably referenced to support past and present practices in program laboratories. The current reference material is cited to foster confidence in accepting the changes to an elevated sterilization temperature range and strengthen confidence in the acceptability of past practices for checking accuracy of working temperature monitoring devices. Most references for media sterilization simply state "121ºC for no less than 15 minutes." ***Difco***, a leading media manufacturer, states "A temperature range of 121-124ºC for 15 minutes is an accepted standard condition for sterilizing up to one liter of culture medium. The definition of "autoclave at 121ºC for 15 minutes" refers to the temperature of the contents of the container being held at 121ºC for 15 minutes, not to the temperature and time at which the autoclave has been set." ***Standard Methods,*** 23rd Edition, states "Annually, or preferably semiannually, **verify** the accuracy of all working temperature-sensing devices (e.g., liquid-in-glass thermometers, thermocouples, and temperature-recording instruments) at the use temperature(s). To do this, compare each device's measurements to those of a certified NIST temperature-sensing device or one traceable to NIST and conforming to NIST specifications. Discard temperature-sensing devices that differ by >1ºC from the reference device.….For general sterilization tasks, the recommended autoclave temperature range is 121 to 124ºC (at 200 kPa/29 PSI), although higher temperatures (≥121ºC) are acceptable for decontaminating laboratory material." *Each lab's QAP **must validate** temperature, time and pressure parameters for successful sterilization for media, reagents, supplies and spores using a verified working temperature monitoring device*.
Cost Information	No Cost. Minor adjustment during regularly scheduled sterilizer preventative maintenance service.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-135 as amended.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-135.

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Proposal Subject	NSSP DSP 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 Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the laboratory evaluation checklist for Diarrhetic Shellfish Poisoning LC-MS/MS.
Public Health Significance	The Diarrhetic Shellfish Poisoning (DSP) LC-MS/MS checklist will provide the means of assessing the competence of the laboratory to perform the test method.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-136 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-136

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Proposal Subject	Checklist for the Bacteriological Analysis of UV Treated Process Water Samples by Membrane Filtration (MF) using mEndo Agar LES
Specific NSSP Guide Reference	NSSP *Guide for the Control of Molluscan Shellfish*, 2017 Revision, "Guidance Documents", Chapter II. Growing Areas, .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists, 1. NSSP Laboratory Evaluation Checklists for Microbiology.
Text of Proposal/ Requested Action	Incorporate Sections 2.11 through 2.14 for the Bacteriological Analysis of UV Treated Process Water Samples by Membrane Filtration using mEndo Agar LES into the NSSP Laboratory Evaluation Checklist for Microbiology.
Public Health Significance	Incorporation of the mEndo Agar LES membrane filtration method into the Microbiology Checklist will provide the means of assessing the competence of the laboratory to perform the test method.
Cost Information	NA
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-137 as amended.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-137.

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Proposal Subject	NSSP Microbiology 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 Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the modified text of four (4) NSSP microbiology checklist items in the Laboratory Equipment and Sterilization and Decontamination sections; said NSSP checklist items are 1.4.5, 1.4.21, 1.6.10, and 1.6.11.
Public Health Significance	The proposed modifications are to improve consistency in current NSSP microbiology checklist language and account for technology improvements to laboratory equipment.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-138 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-138.

Submitter	NSSP Laboratory Evaluation Officers Team
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Proposal Subject	NSSP Microbiology 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 Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the modified text of NSSP microbiology checklist item 1.4.24 in the Laboratory Equipment section and 3.2.7 in the Preparation of Shellfish for Examination section and add an additional reference to item 3.2.7.
Public Health Significance	1.4.24: One of the most basic attributes of any thermometer is its accuracy, and because a thermometer is only as valuable as the temperature it measures, accuracy is of the utmost importance. Calibration defines the accuracy by quantifying and controlling uncertainties within the measurement process. The quality of data must be known and established beyond a reasonable doubt before it can be used logically in any application; thus, calibration is an integral part of the lab's Quality Assurance. When individuals record and maintain data, proof of calibration demonstrates that the measurements performed are consistent with the "true value." An intermediate check is an action that the user takes to verify that the measuring instrument continues to be suitable for its purpose. Currently, the NSSP requires laboratories to perform intermediate checks on incubator and water bath thermometers at the temperature at which they are used. This requirement does not include refrigerator or freezer thermometers; however, NSSP Microbiology checklist items 1.4.9 and 1.4.10 require laboratories to measure and record refrigerator temperature data. When properly performed, an ice point is recommended as a “fixed point” for calibration of liquid in glass thermometers as it provides a reliable reference temperature at 0 °C with an estimated measurement uncertainty of ± 0.002 °C for determining the thermometer’s accuracy at all calibration points. The reliability and high degree of accuracy achieved by performing a proper ice point is due to the ice-water mixture stabilizing at its own “triple point.” Due to the nature of an ice point, it is the most common calibration point used for intermediate checks. 3.2.7 and reference addition: This change corrects an oversight in the current checklist regarding the role of gloves when shucking.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-139 as submitted.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-139

Submitter	US Food & Drug Administration (FDA)
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Proposal Subject	NSSP Microbiology 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 Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the modified text of the attached checklist for Bacteriological Examination of Soft-shelled Clams and American Oysters for Male Specific Coliphage (MSC), starting at section 3.10.
Public Health Significance	The proposed modifications are to provide clarification to bench analysts and LEOs for consistent performance and evaluation of the method for the NSSP.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-140 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-140.

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Proposal Subject	NSSP Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP) 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 Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the laboratory evaluation checklist for the Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP).
Public Health Significance	The Receptor Binding Assay for Paralytic Shellfish Poisoning (PSP) checklist will provide the means of assessing the competence of the laboratory to perform the test method.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended referral of Proposal 19-141 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-141.

Submitter	Shelley Lankford
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Proposal Subject	Add the use of a mechanical shaker to the water microbiology methods checklist in the sample preparation requirements section and include a reference.
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 Checklists SHELLFISH LABORATORY EVALUATION CHECKLIST PART II - SEAWATER SAMPLES 2.2 Bacteriological Examination of Seawater by the APHA MPN 2.2.3 Sample and dilutions of sample are shaken vigorously (25 times in a 12" arc in 7 seconds) before inoculation. 2.5 Bacteriological Examination of Seawater by the MA-1 Method 2.5.5 Sample and dilutions of sample are shaken vigorously (25 times in a 12" arc in 7 seconds) before inoculation. 2.9 Sample Analyses - MF using mTEC Agar 2.9.3 The sample is shaken vigorously (25 times in a 12″ arc in 7 seconds) before filtration.
Text of Proposal/ Requested Action	Adopt the text of update the shellfish laboratory evaluation microbiology checklist (attached) to include the use of a mechanical shaker for sample preparation and include a reference for the use in the checklist's lists of references.
Public Health Significance	This proposal does not have direct public health significance but directly impacts the health of laboratorians performing water microbiological testing by allowing the use of a mechanical shaker to reduce or alleviate repetitive motion injuries caused by hand shaking the water samples. Work related injuries in the laboratory due to poor ergonomics are increasing every year and are costly to the laboratory due to work related injury claims. FDA LEO's currently allow the use of this equipment but there is no mention of the use of the equipment, no guidance for use of the equipment nor any reference from a reliable source in the current microbiology checklist for allowing the use of a mechanical shaker for sample preparation purposes.
Cost Information	This proposal updates text in the NSSP Manual wherever found in the microbiology checklist if approved by the conference. Minimal costs will be incurred by the ISSC administration when the laboratory evaluation checklist development and updating occurs at the ISSC office as part of the biannual NSSP Manual update process.
Action by 2019 Laboratory Committee	Recommended adoption of Proposal 19-142 as amended. .
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-142.

Submitter	Leanne Flewelling
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Proposal Subject	MARBIONC Brevetoxin (Neurotoxic Shellfish Poisoning; NSP) ELISA 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 Checklists
Text of Proposal/ Requested Action	The requested action is to adopt the text of the attached checklist for the MARBIONC Brevetoxin ELISA method 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 MARBIONC Brevetoxin ELISA method was approved for limited use at the 2017 ISSC meeting. Currently, there is no checklist adopted by the ISSC for this method. The attached checklist provides the quality assurance and method requirements that laboratory evaluation officers will use to evaluate laboratories implementing the MARBIONC Brevetoxin ELISA method 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	N/A
Action by 2019 Laboratory Committee	Recommends adoption of Proposal 19-143 as amended.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-143.

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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	Recommends referral of Proposal 19-144 to an appropriate committee as determined by the Conference Chairman.

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Proposal Subject	Guidance on cleansing studies
Specific NSSP Guide Reference	NSSP Section IV Chapter II .19 VI B.
Text of Proposal/ Requested Action	B. 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	This language will provide state shellfish Authorities with guidance regarding

Significance	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	Recommends 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 olace of cleansing studies.

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Proposal Subject	Micropipettor Verification
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 Checklists, NSSP Laboratory Evaluation Checklists, 6. Shellfish Laboratory Evaluation Checklist for PCR Microbiology
Text of Proposal/ Requested Action	The requested action is to adopt the new text for the NSSP PCR Microbiology checklist, section 1.4 Laboratory Equipment item 1.4.24.
Public Health Significance	Quality Assurance and Standardization are integral to the validity of the NSSP laboratory. One QA component includes verifying the measurement accuracy of pipetting instruments including micropipettors. There are no recognized references that state micropipettors must receive third party certifications. There is no indication as to what "Level" calibration should exist. The reference for this item is only **#2, Good Laboratory Practice**. Accuracy measurement assurance should be based on workload and use, not calendar year. Pipette calibration values on certificates obtained in a calibration laboratory (known as a controlled laboratory) do not accurately transfer to the NSSP laboratory and therefore do not provide assurance and defensibility. A pipette's measurement accuracy is influenced by its *physical uncertainty*, *environmental uncertainty* (i.e., temperature, vibration and humidity) and *operator use uncertainty*. These uncertainties will differ between laboratories. Pipette performance in the NSSP (non-controlled laboratories) is impacted by the temperature and viscosity of the fluid, the skill of the operator and choice of tip. Conducting in-house verifications for each operator, using a verified balance provides a better assessment of the actual measurement accuracy of what the pipet is delivering. When the uncertainty of measurement exceeds the stated laboratory established threshold, adjustments are made. As a component of a Laboratory's Quality Management System, the individual laboratory can institute legally defensible and measurement assurance practices appropriate for the laboratory's workload, testing and ambient conditions. Savings: Calibration Cost Information from one Pipet Manufacturer: 1. Calibration and Maintenance - Offers three "levels" of examination, with an assorted number of readings at 3 volumes, across different channel pipettors. Cost Range $30 - $225 per unit. 2. Calibration only (<u>center channel only</u>) - $30 - $180 if unit passed on the initial attempt. Non-Operational pipette repair evaluation (no calibration and parts additional cost)

	starting at $28/unit.
Cost Information	N/A
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-146. Rationale: The existing language is needed.
Action by 2019 Task Force I	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-146.

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Proposal Subject	Relay contaminant reduction studies.
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter V. Shellstock Relaying Section @.02 Contaminant Reduction B. (2)
Text of Proposal/ Requested Action	(2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA ~~tolerance~~action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluation; or
Public Health Significance	Action levels, tolerances and/or guidance levels have not been established for all poisonous or deleterious substances. When there is concern about contamination of shellstock by a poisonous or deleterious substance and no action level, tolerance, or guidance level for that substance, regulators must evaluate risk and establish a level of concern. Suggested change from "tolerance" to "action levels, tolerances, and/or guidance levels" is made to make the language consistent with the title of National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, Section IV Guidance Documents, Chapter II Growing Areas, .08 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood.
Cost Information	Possible increased cost of unknown magnitude related to time necessary to conduct risk evaluations.
Action by 2019 Task Force I	Recommends adoption of Proposl 19-147 as submitted.

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Proposal Subject	Correct language of MO to reflect current checklists
Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements B. Criteria for evaluation of shellfish sanitation program elements shall be as follows: 1. Laboratory
Text of Proposal/ Requested Action	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements 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. (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. (a) 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 technical.y evaluation and will be assigned the designation of conforms, provisionally conforms or non-confomance. 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

~~(b) Conforms. In order to achieve or maintain conforming status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:~~

~~(c) No critical nonconformities in the microbiological or marine biotoxin component under evaluation have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and~~

~~(d) (b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin components have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and~~

~~(c) Not more than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, twelve (12) critical, key and other nonconformities in total for the paralytic shellfish poisoning (PSP) and amnesic shellfish poisoning (ASP) components, or ten (10) critical, key and other nonconformities in total for the neurotoxic shellfish poisoning (NSP) component have been identifiedusing the appropriate NSSP Shellfish Laboratory Evaluation Checklist.~~

	~~This number must not exceed the numerical limits established for either the critical or key criteria; and~~ ~~(d) No repeat key nonconformities have been identified in the microbiological or marine biotoxin component under evaluation in consecutive evaluations using the appropriate NSSP Shellfish Laboratory Evaluation Checklist.~~ ~~iii. Technical Evaluation: Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:~~ ~~(a) Not more than three (3) critical nonconformities in the microbiological component, four (4) in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and~~ ~~(b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and~~ ~~(c) Not more than eighteen (18) critical, key and other nonconformities in total in the microbiological component, or twelve (12) critical, key and other nonconformities in total in the PSP and ASP components or ten (10) critical, key and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation umber must not exceed the numerical limits established for either the critical or key criteria; and~~ ~~(d) Not more than one (1) repeat key nonconformity has been identified in the microbiological or marine biotoxin component under evaluation in consecutive evaluations using the appropriate NSSP Shellfish Laboratory Checklist.~~ ~~iv. Technical Evaluation: Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:~~ (a) ~~More than three (3) critical nonconformities in the microbiological component or four (4)~~

	~~in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Checklist; or~~ ~~(b) More than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist;~~ ~~(c) More than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, or more than twelve (12) critical, key and other nonconformities in total in the PSP and ASP components, or more than ten (10) critical, key, and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; or~~ ~~(d) One (1) or more repeat critical or two (2) or more repeat key nonconformities have been identified in consecutive evaluations in either the microbiological or marine biotoxin components using the appropriate NSSP Shellfish Laboratory Evaluation Checklist.~~
Public Health Significance	The goal of a laboratory evaluation is to monitor implementation of NSSP Quality Systems and Approved methods. Laboratory data is standardized as a result of this process and reciprocity of shellfish in the commercial market is protected and preserved through defensible practices and transparent requirements. As the laboratory program in the NSSP continues to develop and grow it is prudent to keep requirements in accessible documents with few deviations. Checklists are a cornerstone document for laboratories, referring to these documents ensures laboratories have access to requirements at all times. As laboratorians are the target audience, this is the most sensible place for the actual numbers of nonconformities to reside, and the reference to the checklists in the Model Ordinance ensures the checklists are part of the overarching document adopted by reference or into legislation. Multiple locations of numbers of permissible nonconformities only ensures updates will be missed. As existing structure is in place through the Lab Committee to handle checklists and edits therein, this seems the most reasonable solution.
Cost Information	No cost incurred by change. Practice is already in place.
Action by 2019 Task Force I	Recommends adoption of Proposal 19-148 as submitted.

-2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	209 Dawson Road
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6. City, State, Zip	Columbia, SC 29223
7. Phone	(803) 788-7559
8. Fax	(803) 788-7576
9. Email	issc@issc.org
10. Proposal Subject	Biotoxin Guidance
11. Specific NSSP Guide Reference	Section II. Chapter IV Shellstock Growing Areas-
12. Text of Proposal/ Requested Action	In conjunction with the adoption of Proposal 13-116 at the 2017 ISSC Biennial Meeting, the voting delegates recommended the Biotoxin Committee develop a guidance document to include guidance for end product testing programs in closed state waters. In addition to proposing guidance, the committee will be making recommendations to modify the monitoring requirements of Chapter IV @.04 Marine Biotoxin Control. These proposed changes are under development. The purpose of this proposal is to advise the ISSC membership that the Biotoxin Committee will be making recommendations to modify Chapter IV @.04 as part of their committee charge from Proposal 13-116 -
13. Public Health Significance	The proposed changes should clarify and simplify biotoxin monitoring.
14. Cost Information	
Action by 2019 Biotoxin Committee	Recommended adoption of Proposal 19-149 as amended. **Section II. Model Ordinance** **Chapter IV. Shellstock Growing Areas** **@.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… (2) Classification of All… (3) Boundaries… (4) Revision of Classifications… (5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open, closed, controlled access in the case of biotoxins 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…

(b) Closed Status…
(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.
~~(c)~~(d) Reopened Status...
(e) Inactive Status…
(f) Remote Status...
(g) Seasonally Remote/Approved Status...

@.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 ~~and assay~~ 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.

~~**NOTE:** The plan may include other requirements, as deemed necessary by the Authority in the State of landing, to ensure adequate public health protection under the NSSP.~~

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .0~~6~~2

B. Marine Biotoxin Management Plan.
In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton ~~are known~~ have been documented to occur, ~~and~~ the toxins are prone to accumulate in shellfish, and ~~when appropriate at those~~during times when marine biotoxins ~~can be reasonably predicted~~are likely to occur, representative samples of ~~the~~ water ~~may be collected~~ and/or

shellfish shall be collected during harvest periods in accordance with one or a combination of the marine biotoxin management strategies listed below in 4. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. ~~The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples may be assayed for the presence of toxin-producing phytoplankton and shellfish meat samples shall be assayed for the presence of toxins.~~

~~**NOTE:** In situations in which the toxin of concern has an established cell count standard, such as *Karenia brevis*, water and shellfish samples would not be required. Management decisions could be made on either water or shellfish sampling results.~~

(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 ~~are known~~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 as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.~~Maintain a routine shellfish sampling and assay program including;~~

~~i. Establishment of appropriate shellfish screening levels;~~

~~ii. Establishment of appropriate shellfish screening and testing methods;~~

~~iii. Establishment of appropriate laboratories/analysts to conduct shellfish screening and testing methods;~~

~~iv. Establishment of a sampling plan for both (i) and (ii) above; and~~

~~v.~~i. ~~Other controls as necessary to ensure that shellstock are not harvested when levels of marine biotoxins meet or exceed the established criteria in Section C.~~

(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; ~~and~~
(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 ~~program~~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 ~~Section~~ 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:~~Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine biotoxins or so remote that adequate sampling cannot be achieved and thus the situation cannot be safely managed, the presence of marine biotoxins shall not affect the classification of the shellfish growing area under Section @.03. The Authority may use the conditionally approved classification for areas affected by marine biotoxins.~~
(a) Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species known or suspected to produce marine biotoxins. This is a complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish and must be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.
(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 II Growing Areas .02 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 II Growing Areas .02 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 II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

(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 II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans.

(5) The marine biotoxin management plan ~~may~~ shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in ~~designated parts of~~ a ~~State~~ growing area ~~while other parts of the same growing area are~~that is placed in the controlled access~~closed~~ status. Such ~~controlled~~ harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4). ~~In State growing areas or designated portions of State growing waters that are closed, the Authority may allow for harvesting if an end product testing program is developed and samples of~~

~~each lot are tested and found to be below the action levels specified in Section C.~~

~~The program must include at a minimum:~~

~~(a) Establishment of appropriate pre-harvest screening levels;~~

~~(b) Establishment of appropriate screening and end product testing methods;~~

~~(c) Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;~~

~~(d) Establishment of representative sampling plan for both (a) and (b) above;~~

~~(e) Disposal of shellfish should end product test results meet or exceed established criteria specified in Section C; and~~

~~(f) Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.~~

~~(6) Prior to allowing the landing of shellfish harvested from Federal waters where routine monitoring of toxin levels is not conducted, in addition to following State requirements in the Model Ordinance, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:~~

~~(a) Harvest permit requirements;~~

~~(b) Training for individuals conducting onboard toxicity screening using NSSP methods;~~

~~(c) Vessel monitoring;~~

~~(d) Identification of shellfish for each harvesting trip to include:~~

~~(i) Vessel name and owner;~~

~~(ii) Captain's name;~~

~~(iii) Person conducting onboard screening tests;~~

~~(iv) Port of departure name and date;~~

~~(v) Port of landing name and date;~~

~~(vi) Latitude and longitude coordinates of designated harvest area;~~

~~(vii) Onboard screening test results;~~

~~(viii) Volume and species of shellfish harvested;~~

~~(ix) Intended processing facility name, address and certification number; and~~

~~(x) Captain's signature and date;~~

~~(e) Pre-harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for toxins that are likely to be present harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels~~

~~in excess of half of the established criteria listed in Chapter IV@.04(1) (e.g., 44 µg/l00 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test for PSP toxins);~~

~~(f) Submittal of onboard screening homogenates and test results to the Authority in the State of landing;~~

~~(g) The collection of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory; the Authority may require more samples based on the size of the vessel and the volume of shellfish harvested;~~

~~(h) Holding and providing separation until dockside samples verify that toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins);~~

~~(i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins);~~

~~(j) Notification prior to unloading;~~

~~(k) Unloading schedule;~~

~~(l) Access for Dockside Sampling;~~

~~(m) Record Keeping; and~~

~~(n) Early Warning/Alert System.~~

~~NOTE: The plan may include other requirements, as deemed necessary by the Authority in the State of landing, to ensure adequate public health protection under the NSSP.~~

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 - ~~5,000 cells/L or~~ 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 ~~producing organism~~ 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 ~~from the marine biotoxin~~

~~management plan~~, 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.

~~(6)~~(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. 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.

Section IV. Guidance Documents
Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Plans

Section to be added:

Marine Biotoxin Management Strategies

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

with the strategies below.

A. Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species documented or suspected to produce marine biotoxins. This complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish must be used in combination with other management strategies.

The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of toxin-producing phytoplankton may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies for a time span of at least three years of phytoplankton counts, comparing with the onset of shellfish toxicity when toxic phytoplankton are present, should be developed before the biotoxin monitoring plan may be modified.

Phytoplankton monitoring can be applied to all growing areas where collecting, transporting and processing water samples is logistically feasible, taking into consideration effects of zooplankton grazing and durability of various cell types to temperature and transport. This management strategy may be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible wild harvest areas and aquaculture sites in state waters or aquaculture sites in federal waters.

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

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

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

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

Considerations should be made for how sampling is conducted such as phytoplankton net tows, filtered surface water, or whole water samples. The depth

	of water sampled should also be considered and evaluated for all species of phytoplankton being targeted. Some species of phytoplankton are known to display diurnal, vertical migration patterns within the water column, while other species are known to occur in dense patches. Laboratory and field methods may include, but are not limited to light microscopy, flowcytometry, DNA fingerprinting, rapid toxin detection tests, and PCR assays. Analysts should be trained in each method employed and consideration should be given to complimentary methods of analysis such as light microscopy with phytoplankton identification confirmed by a rapid test at least in the initial phases of the monitoring program. An appropriate sampling plan, station location, and sampling frequency should all factor in the location and type of the resource being monitored, the species of phytoplankton anticipated or observed, and the environmental conditions that might result in a rapid bloom or trigger the production of toxicity in an existing population. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxic phytoplankton are most likely to first appear, based either on experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are also significant. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom, or a hurricane may drive an offshore phytoplankton bloom onshore. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites. B. Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species-specific shellfish testing is conducted, the highest risk species (e.g. species that metabolizes toxin most quickly) occurring in the growing area shall be used. Many biotoxin monitoring programs have found mussels to be the best sentinal species. This strategy may be used alone or in combination with other management strategies. The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year. This management strategy can be applied to all growing areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to, easily accessible wild harvest areas and aquaculture sites in state waters or wild harvest areas and aquaculture sites in federal waters. The marine biotoxin management plan that incorporates this strategy must

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

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

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

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

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

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

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

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas .14.

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

This strategy requires representative samples for each lot of harvested shellstock. Lot testing shall be permitted in growing areas in the Controlled Access Status and

require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests are available. A dataset with at least 36 samples per harvest area over the span of at least three years shall be developed before the biotoxin monitoring plan may be modified.
This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.
The marine biotoxin management plan that incorporates this strategy must establish:

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

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14.
E. Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing or receipt at the initial certified dealer.
This strategy shall permit harvest in specific geographic locations from growing areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the growing area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.
This management strategy can be applied to all growing areas where harvest occurs. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible and remote wild harvest areas and aquaculture sites in state and federal waters.
The marine biotoxin management plan that incorporates this strategy must establish:

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

Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14.

Section IV. Guidance Documents
Chapter II. Growing Areas

~~**.06 Protocol for the Landing of Shellfish from Federal Waters**~~

~~Harvest of molluscan shellfish in Federal Waters not routinely monitored for toxins in shellfish (such as the Federal waters on Georges Bank closed due to PSP risks) may be authorized provided the Authority in the State of landing in cooperation with appropriate Federal agencies shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The following guidance provides descriptions of the specific information to be included in the protocol.~~

~~A. Harvest Permit Requirements~~

~~If harvesting from Federal waters closed due to toxins, the Authority in the landing State will only allow the landing of shellfish from vessels in possession of an appropriate Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) by vessels participating in the Federal Vessel Monitoring System (VMS). The NMFS shall receive concurrence from the Authority in the State of landing. Vessels operating in open Federal waters will also need applicable permits.~~

~~B. Training~~

~~The Authority shall ensure that all shipboard persons conducting onboard testing have been trained by a U.S. FDA LEO (LEO) or an FDA marine biotoxin expert to conduct onboard toxin screening using an NSSP recognized method(s). Shipboard persons conducting onboard toxin testing must receive refresher training every three (3) years. A designee of the FDA LEO or FDA marine biotoxin expert may be appointed in writing to provide the training and/or refresher training.~~

~~C. Vessel Monitoring~~

~~The Authority shall monitor the harvesting location(s) of each landing vessel.~~

~~D. Identification of Shellfish~~

~~Prior to landing each vessel Captain or Mate shall provide the Authority with a Harvest Record, which may be electronic provided that it is made available to the authorized individual at dockside, for each harvesting trip identifying each lot of shellfish as follows:~~

~~1. Vessel name and Federal Fishing Permit number;~~
~~2. Name and telephone number of the vessel Captain and vessel owner;~~

3. Date(s) of harvest;
4. Number of lots and volume of catch per lot or number of containers per lot;
5. Location(s) of harvest (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds);
6. Identification of each harvest lot, including cage tag numbers for surf clams and ocean quahogs, and container numbers or identification codes for other shellfish species;
7. Location (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds) of each toxin screening sample;
8. Results of each toxin screening test; and
9. Destination(s) and purchaser(s) of each lot and amount of each lot to each destination

The Captain or Mate shall sign the Harvest Record. The Harvest Record shall be checked by the individual authorized to sample the harvested shellfish. Failure to provide complete and accurate information will result in revocation or suspension of the NMFS EFP and rejection of the entire lot(s) of harvested shellfish. Four (4) copies of the Harvest Record shall be prepared. One (1) copy shall remain with the vessel, one (1) copy shall be provided to the Authority in the State of landing, one (1) copy shall accompany the catch to the processing firm(s), and one (1) copy shall be retained by the laboratory authorized to conduct lot sample analyses.

Container Labeling:

Each container of shellfish shall be clearly labeled (indelible and legible) with the following NSSP required information at the time of harvest:

1. Surf clams and ocean quahogs existing NMFS tagging requirements.
2. All other molluscan shellfish (including Stimpson clams also known as Arctic surf clams) using durable, waterproof, Authority sanctioned prior to use tags:
   a. Vessel name;
   b. Type and quantity of shellfish;
   c. Date of harvest; and
   d. Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds.

E. Pre-Harvest Sampling

Prior to harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected within each area of intended harvest (lot area) and tested for marine biotoxins that are likely to occur in accordance with an NSSP recognized method. Each screening sample shall be collected during a separate and distinct gear tow. Screening sample tows shall be conducted in a manner that evenly distributes the five (5) samples throughout the intended harvest area for each area of intended harvest (see Section H.). Only shipboard officials trained by an FDA LEO or FDA marine biotoxin expert (or their designee as expressly

~~indicated in writing) in the use of the designated NSSP method may conduct these tests. Each of the five (5) samples must test negative for toxins (i.e., below half of the established criteria in Section II. Model Ordinance Chapter IV @04.C. (1)). A positive result from any one (1) sample shall render the lot area unacceptable for harvest. The harvest vessel Captain shall immediately report all positive screening test results, by telephone or email, to the Authority within the intended State of landing, the FDA Shellfish Specialist, and the processor. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s). For each screening test, whether positive or negative, the remaining sample material (homogenate) shall be maintained under refrigeration for later use should the Authority in the State of landing request confirmatory testing using an NSSP recognized method.~~

~~Each screening sample shall be comprised of at least twelve (12) whole animals with the exception of mussels and "whole" or "roe-on" scallops. For mussels each sample shall be comprised of thirty (30) animals. For "whole" scallops each sample shall be comprised of twenty (20) scallop viscera and gonads. For "roe-on" scallops each sample shall be comprised of twenty (20) scallop gonads.~~

~~F. Submittal of Onboard Screening Homogenates and Test Results~~

~~All screening results shall be recorded on the Harvest Record as stipulated in Section D. of this Protocol. Upon landing of the harvest vessel, the Harvest Record and screening homogenates shall be provided to the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory in the State of landing authorized to sample the harvested shellfish as described in Section G. of this Protocol.~~

~~G. Dockside Sampling~~

~~After dockside samples are collected by the Authority or designee, molluscan shellfish may be processed while awaiting toxin results. Each lot must be identified and segregated during storage while awaiting dockside sample test results. Under no circumstances will product be released from the processor prior to receiving satisfactory toxin results that demonstrate that toxin levels are below the established criteria in Section II. Model Ordinance Chapter IV @04.C.(1).~~

~~The dockside sampling protocol for molluscan shellfish shall be as follows:~~

~~1. For each lot of molluscan shellfish, a minimum of seven (7) composite samples, each comprised of at least twelve (12) whole animals, shall be taken at random by the individual authorized by the Authority to sample, with the following exceptions:~~

a. For each lot of mussels, a minimum of seven (7) composite samples, each comprised of at least thirty (30) whole animals, shall be taken at random by the individual authorized to sample.

b. For each lot of "whole" scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop viscera and gonads, shall be taken at random by the individual authorized to sample.

c. For each lot of "roe-on" scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.

2. Shellfish samples collected in accordance with G.1 shall be tested for the presence of toxins using an NSSP recognized method(s).

3. Laboratory test results for each lot of shellfish shall be forwarded to the Authority in the State in which the shellfish is being held prior to the product being released by the Authority in the State of landing, or if processed in another State, the Authority in the State of processing.

H. Holding and Lot Separation

A harvest lot is defined as all molluscan shellfish harvested during a single period of uninterrupted harvest activity within a geographic area not to exceed three (3) square miles. Once harvesting has ceased and the harvest vessel moves to another location, regardless of the distance, a new harvest lot will be established. Any harvest vessel containing more than one (1)lot shall clearly mark and segregate each lot while at sea, during off loading, and during transportation to a processing facility. Prior to harvesting in Federal waters, each harvest vessel shall submit to the NMFS a written onboard lot segregation plan. The Authority in the intended State of landing and the FDA Shellfish Specialist must approve the proposed lot segregation plan.

I. Disposal of Shellfish

If test results of any one (1) of the seven (7) samples collected in accordance with G.1 equal or exceed the established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) (e.g., 80 µg /100 g for PSP toxins)(n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the Authority in accordance with State laws and regulations except when:

A lot of "whole" or "roe-on" scallops equals or exceeds the established criteria in Section II. Model Ordinance Chapter IV@.04C.(1), the adductor muscle may be shucked from the viscera and/or gonad and marketed. The remaining materials (viscera and/or gonad) must be discarded or destroyed under supervision of the Authority in accordance with State laws and

~~regulations.~~

~~Dockside toxin testing shall be according to NSSP recognized methods and shall be conducted by laboratories evaluated in accordance with NSSP guidelines. Private laboratories may be used if evaluated by an LEO in accordance with NSSP guidelines.~~

~~J. Notification Prior to Unloading~~

~~Prior to the issuance of an EFP, the harvester shall be responsible for notifying the Authority in the State of landing and in a manner approved by the Authority that molluscan shellfish is being harvested for delivery to the intended receiving processor.~~

~~Each vessel shall give at least twelve (12) hours' notice to the individual authorized to sample prior to unloading shellfish. Notice of less than twelve (12) hours may be approved by the authorized individual at his/her discretion. Authorities may appoint a designee in writing for sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the Authority under the NSSP. The procedures, as well as training and certification records, must be available for evaluation.~~

~~Shellfish from a Federal water harvest area(s) must be kept separate and not sold until so authorized by the Authority in the State of landing or, if processed in another State, the Authority in the State of processing.~~

~~Failure to comply with the provisions of this Protocol will result in the suspension or revocation of the vessel's permits through the NMFS.~~

~~K. Unloading Schedule~~

~~Unloading shall take place between 7:00 A.M. and 5:00 P.M. Monday through Friday, unless otherwise mutually agreed upon by the individual authorized to sample, the processing plant manager, the harvest vessel captain, and the Authority in the State of landing.~~

~~L. Access for Dockside Sampling~~

~~Individuals authorized to sample shall be provided access to the catch of shellfish.~~

~~M. Record Keeping~~

~~Record keeping requirements shall be as follows:~~

~~1. The vessel shall maintain Harvest Records for at least one (1) year.~~
~~2. The processor(s) shall maintain Harvest Records for at least one (1)~~

	~~year or two (2) years if the product is frozen.~~ ~~3. The Authority in the State of landing shall retain Harvest Records for at least two (2) years.~~ ~~N. Early Warning/Alert System~~ ~~Toxin data acquired as a result of onboard screening and dockside testing shall be transmitted to the FDA. These data, both screening and dockside, shall be transmitted to the FDA by the NSSP certified laboratory conducting toxin testing of the sampled lot(s) within one (1) week of the completion of the toxin analyses. The data provided shall include the following:~~ ~~1. Shellfish species;~~ ~~2. Harvest location name and coordinates (GPS or latitude/longitude);~~ ~~3. Harvest date;~~ ~~4. Onboard screening test method, date, and results; and~~ ~~5. Laboratory test date, test method, and test results for dockside samples.~~ ~~Results of all samples having acceptable levels of toxins (e.g.,<80 µg/100 g for PSP toxins) shall immediately be reported to the Authority in the State of landing. If the results of any one (1) sample equal or exceed the established criteria in Chapter IV @.04(c)(1) the testing laboratory shall immediately notify the FDA Shellfish Specialist, the Authority, and the processor by telephone. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s).~~ ~~NOTE: Due to the resources necessary to meet the requirements of this Protocol, Authorities (may find it necessary to require industry to fund associated costs. These costs may include sample collection, screening, transportation, analysis, inspection, enforcement, and other related expenses.~~
Action by 2019 Task Force I	Recommends adoption of Proposal 19-149 as amended. **Section II. Model Ordinance** **Chapter IV. Shellstock Growing Areas** **@.03 Growing Area Classification** B. 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… (2) Classification of All… (3) Boundaries… (4) Revision of Classifications… (5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open,

closed, controlled access in the case of biotoxins 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…
(b) Closed Status…
~~(d)~~(e) 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.
~~(e)~~(f) Reopened Status...
(h) Inactive Status…
(i) Remote Status...
(j) Seasonally Remote/Approved Status...

@.04 Marine Biotoxin Control

F. 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.

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

G. 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 or a combination of the marine

	biotoxin management strategies listed below in 4. and in accordance with Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. (1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP, and/or AZP; if toxin-producing phytoplankton have been documented to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur. (2) The plan shall define the administrative procedures and resources necessary to accomplish the following: (a) Maintain a toxin-producing phytoplankton and/or shellfish sampling as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in Section IV. Guidance Documents Chapter II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. (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 II Growing Areas .02 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 II Growing Areas .02 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 II Growing Areas .02 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 II Growing Areas .02 Guidance for Developing Marine Biotoxin Plans. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

(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 II Growing Areas .02 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).

H. 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. 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.

I. 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.

J. 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.

Section IV. Guidance Documents
Chapter II. Growing Areas

.02 Guidance for Developing Marine Biotoxin Plans

Section to be added:

Marine Biotoxin Management Strategies
It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. The Authority initiating biotoxin management plans should employ sampling in accordance with the strategies below until a baseline dataset of at least 36 samples per growing area or hydrographically linked waterbodies is developed. These samples should cover representative environmental conditions and a time span of at least three years. Once this dataset is developed, the Authority may consider modifying sample numbers and frequency in the marine biotoxin management plan in accordance with the strategies below.
A. Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species documented or suspected to produce marine biotoxins. This complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish must be used in combination with other management strategies.
The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of toxin-producing phytoplankton may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies for a time span of at least three years of phytoplankton counts, comparing with the onset of shellfish toxicity when toxic phytoplankton are present, should be developed before the biotoxin monitoring plan may be modified.
Phytoplankton monitoring can be applied to all growing areas where collecting,

transporting and processing water samples is logistically feasible, taking into consideration effects of zooplankton grazing and durability of various cell types to temperature and transport. This management strategy may be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to; easily accessible wild harvest areas and aquaculture sites in state waters or aquaculture sites in federal waters.

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

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

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

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

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

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

An appropriate sampling plan, station location, and sampling frequency should all factor in the location and type of the resource being monitored, the species of phytoplankton anticipated or observed, and the environmental conditions that might result in a rapid bloom or trigger the production of toxicity in an existing population. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxic phytoplankton are most likely to

	first appear, based either on experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Historical occurrences and fluctuations in coastal phytoplankton populations due to the influence of meteorological and hydrographic events are also significant. For example, a large rain storm may cause nutrient loading in coastal waters and trigger a toxic phytoplankton bloom, or a hurricane may drive an offshore phytoplankton bloom onshore. To facilitate knowledge transfer, it is advisable that the authority describe its rationale in selecting sampling sites. B. Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species-specific shellfish testing is conducted, the highest risk species (e.g. species that metabolizes toxin most quickly) occurring in the growing area shall be used. Many biotoxin monitoring programs have found mussels to be the best sentinal species. This strategy may be used alone or in combination with other management strategies. The level of monitoring required will vary based on the historical database available to inform the sampling strategy (i.e., growing areas with a long history of defined temporal and spatial patterns of shellfish toxicity may have a more targeted approach to sampling, requiring less monitoring than for growing areas where temporal and spatial patterns have not been determined). A dataset with at least 36 samples per growing area or hydrographically linked waterbodies across representative environmental conditions for a span of at least three years shall be developed before the biotoxin monitoring plan may be modified. Until the Authority is confident they understand the risk posed by marine biotoxins in the growing area, sampling should be as robust as possible, and managers should consider that harmful algal blooms can change dramatically from year to year. This management strategy can be applied to all growing areas where collecting, transporting and processing shellfish samples is feasible. This management strategy can be applied to aquaculture or wild harvest. Appropriate venues for this management strategy include but are not limited to, easily accessible wild harvest areas and aquaculture sites in state waters or wild harvest areas and aquaculture sites in federal waters. The marine biotoxin management plan that incorporates this strategy must establish: ▪ appropriate screening levels, ▪ appropriate methods, ▪ appropriate laboratory(s)/analyst(s), ▪ an appropriate sampling plan, ▪ appropriate sample locations (stations), ▪ appropriate sampling frequency; and ▪ a sufficient dataset to support management decisions. The routine shellfish toxicity monitoring strategy may be used independently or together with one or more of the other biotoxin management strategies. If used as the sole management strategy, predicting future toxicity levels in shellfish and the appropriate sampling frequency can be difficult. Long-term databases can provide valuable historic information on the timing of toxicity occurring in shellfish as well as toxicity elimination ~~depuration~~ from shellfish. Shellfish toxin levels that are below the regulatory levels may trigger emergency or expanded testing, or

	precautionary closures. Growing areas should be placed in the closed status at a level that provides an adequate margin of safety, since in many instances, toxicity levels will change rapidly and the time between sampling and results should be considered. Precautionary closures can be made in order to prevent the harvest of potentially toxic shellfish while sample results are being collected and processed. Consideration should be given to the different species of shellfish present in a growing area, the intensity and duration of harmful algal blooms and the uptake and elimination ~~depuration~~ rates of specific toxins from all species of shellfish harvested from the growing areastoxins (e.g., sea scallops). Methods shall be used in accordance with Section IV. Guidance Documents Chapter II Growing Areas.14. or Section II Chapter III @.02 C or The Authority should identify laboratories that can perform approved methods for marine biotoxins and identify laboratory capacity. An appropriate sampling plan, station location and sampling frequency should factor in the location and type of the resource being monitored, the species of shellfish harvested in the growing area and environmental conditions that might affect toxin uptake, such as water temperatures. Primary sampling stations (also referred to as indicator or sentinel stations) should be located at sites where toxin is most likely to first appear, based either on past experience or knowledge of site conditions. The geographic distribution for collection of samples should take into consideration the randomness of toxic algal blooms. Establishing the frequency and period for collection of samples to identify an event as early as possible is an important consideration. Sample collection, sample transportation, and sample analysis procedures should be developed, and predictable timeframes established between collection and results. The Authority should ensure that in an emergency, such as a suspected biotoxin illness, the normal timeframe can be compressed, and sample results known as quickly as possible. It is important to consider emergency coverage schedules for staff and lab availability outside of normal office hours during harmful algal bloom events. When an early warning system detects increased toxicity/cell counts or other information suggests that toxin levels are increasing, it is important that the Authority have procedures to promptly expand sampling to additional stations and/or increase the frequency of sampling for marine biotoxins. The procedures should include plans for obtaining the additional resources necessary to implement the expanded sampling and laboratory analysis program. C. Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvesting. This strategy, if used independent of any other strategy, shall permit harvest in specific geographic locations and for short durations. This strategy may also be used in combination with other management strategies and should be considered as a complementary strategy while developing datasets for alternative management strategies (e.g. pre-harvest shellfish toxicity testing in combination with phytoplankton monitoring which can evolve into a robust shellfish toxicity monitoring strategy). This strategy requires representative samples that cover the spatial distribution of the area to be harvested. The duration of permitted harvest following sampling will vary based on the species being tested and the historical database available to inform the sampling strategy. A dataset with at least 36 samples per harvest area shall be developed before the biotoxin monitoring plan may be modified. Without

at least 36 samples per harvest area over the span of at least three years, the short duration of permitted harvest shall not exceed three days from the time of shellfish collection for toxicity testing to harvest. The dataset could then be used to modify the duration of permitted harvest.

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

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

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

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

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

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

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

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

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

- appropriate screening levels,
- appropriate methods,
- appropriate laboratory(s)/analyst(s),

- an appropriate sampling plan,
- appropriate sampling frequency, and;
- representative number of samples per lot.

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

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

This strategy shall permit harvest ~~in specific geographic locations~~ from ~~growing~~ intended harvest areas in the Controlled Access Status and require Restricted Shellstock tags. The conditions for the area in Controlled Access Status shall be defined in the harvest permit and may include holding shellstock until lot tests results are available. A dataset with at least 36 samples taken monthly per harvest area spanning at least three years shall be developed before the biotoxin monitoring plan may be modified. In the absence of an adequate dataset, the initial number and frequency of pre-harvest and lot samples must be sufficient to conduct an evaluation of risk in the intended harvest area. The initial number of samples must be adequate to address the size of the intended harvest ~~growing~~ area and the amount of shellfish harvested. Single samples are not adequate for evaluation of risk. Should initial samples indicate minimal toxin levels or the absence of toxins, sampling can be reduced but must be conducted at least monthly or as often as necessary to monitor risk.

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

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

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

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

Section IV. Guidance Documents
Chapter II. Growing Areas

2. Submitter	Brooke Roman
3. Affiliation	Neogen Corporation
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5. Address Line 2	
6. City, State, Zip	Lansing, MI 48912
7. Phone	1-800-234-5333
8. Fax	1-517-372-2006
9. Email	broman@neogen.com
10. Proposal Subject	Neogen's 'Reveal 2.0 for PSP' for detection of PSP
11. Specific NSSP Guide Reference	Section IV. Guidance Documents, Chapter II. Growing Areas, .11 Approved NSSP Laboratory Tests
12. 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.
13. 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
14. Cost Information	Approximately $20 per test. Reader based assay – approximate cost of reader is $2,700.00 USD.
Action by 2019 Laboratory	Recommends referral of Proposal 19-150 to an appropriate committee as determined by the Conference Chair.
Action by 2019 Task Force	Recommends the adoption of Laboratory Committee recommendation on Proposal 19-150.

Submitter	Catalina Sea Ranch, LLC (CSR)
Affiliation	Catalina Sea Ranch, LLC (CSR)
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Proposal Subject	Update the Protocol for the Landing of Shellfish from Federal Waters
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter IV. Shellstock Growing Areas @.03 Section IV. Guidance Documents Chapter II Growing Areas .06
Text of Proposal/ Requested Action	**Section II. Model Ordinance** **Chapter VI. Shellfish Aquaculture** **@.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) biotoxin 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. **Section IV. Guidance Documents** **Chapter II. Growing Areas** **.06 Protocol for the Landing of Shellfish from Federal Waters** Harvest of molluscan shellfish in Federal Waters not routinely monitored for toxins in shellfish ~~(such as the Federal waters on Georges Bank closed due to PSP risks)~~ may be authorized provided the Authority in the State of landing in cooperation with appropriate Federal agencies shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The following guidance provides descriptions of the specific information to be included in the protocol. A. Harvest Permit Requirements ~~If harvesting from Federal waters closed due to toxins, t~~The Authority in the landing State will only allow the landing of shellfish from vessels in possession of an appropriate Aquaculture Permit issued by NOAA or an Exempted Fishing Permit (EFP) issued by the National Marine Fisheries Service (NMFS) by vessels participating in the Federal Vessel Monitoring System (VMS). ~~The NMFS shall receive concurrence from the Authority in the State of landing. Vessels operating in open Federal~~

~~waters will also need applicable permits.~~

~~Training~~

~~The Authority shall ensure that all shipboard persons conducting onboard testing have been trained by a U.S. FDA LEO (LEO) or an FDA marine biotoxin expert to conduct onboard toxin screening using an NSSP recognized method(s). Shipboard persons conducting onboard toxin testing must receive refresher training every three (3) years. A designee of the FDA LEO or FDA marine biotoxin expert may be appointed in writing to provide the training and/or refresher training.~~

B. Vessel Monitoring

The Authority shall monitor the harvesting location(s) of each landing vessel.

C. Identification of Shellfish

Prior to landing each vessel Captain or Mate shall provide the Authority with a Harvest Record, which may be electronic provided that it is made available to the authorized individual at dockside, for each harvesting trip identifying each lot of shellfish as follows:

1. Vessel name and Federal Fishing Permit number;
2. Name and telephone number of the vessel Captain and vessel owner;
3. Date(s) of harvest;
4. Number of lots and volume of catch per lot or number of containers per lot;
5. Location(s) of harvest (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds);
6. Identification of each harvest lot, including cage tag numbers for surf clams and ocean quahogs, and container numbers or identification codes for other shellfish species;
7. Location (GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds) of each toxin screening sample;
8. Results of each toxin screening test; and
9. Destination(s) and purchaser(s) of each lot and amount of each lot to each destination

The Captain or Mate shall sign the Harvest Record. ~~The Harvest Record shall be checked by the individual authorized to sample the harvested shellfish. Failure to provide complete and accurate information will result in revocation or suspension of the NMFS EFP and rejection of the entire lot(s) of harvested shellfish. Four (4) copies of the Harvest Record shall be prepared. One (1) copy shall remain with the vessel, one (1) copy shall be provided to the Authority in the State of landing, one (1) copy shall accompany the catch to the processing firm(s), and one (1) copy shall be retained by the laboratory authorized to conduct lot sample analyses.~~

Container Labeling:

Each container of shellfish shall be clearly labeled (indelible and legible) with the following NSSP required information at the time of harvest:

1. Surf clams and ocean quahogs existing NMFS tagging requirements.
2. All other molluscan shellfish (including Stimpson clams also known as Arctic surf clams) using durable, waterproof, Authority sanctioned prior to use tags:
   a. Vessel name;
   b. Type and quantity of shellfish;
   c. Date of harvest; and
   d. Harvest lot area defined by GPS coordinates or latitude/longitude coordinates in degrees:minutes:seconds.

D. ~~Pre-Harvest~~Shellfish Sampling

~~Prior to harvesting of molluscan shellfish, a minimum of five (5) screening samples shall be collected within each area of intended harvest (lot area) and tested for marine biotoxins that are likely to occur in accordance with an NSSP recognized method. Each screening sample shall be collected during a separate and distinct gear tow. Screening sample tows shall be conducted in a manner that evenly distributes the five (5) samples throughout the intended harvest area for each area of intended harvest (see Section H.). Only shipboard officials trained by an FDA LEO or FDA marine biotoxin expert (or their designee as expressly indicated in writing) in the use of the designated NSSP method may conduct these tests. Each of the five (5) samples must test negative for toxins (i.e., below half of the established criteria in Section II. Model Ordinance Chapter IV @04.C. (1)). A positive result from any one (1) sample shall render the lot area unacceptable for harvest. The harvest vessel Captain shall immediately report all positive screening test results, by telephone or email, to the Authority within the intended State of landing, the FDA Shellfish Specialist, and the processor. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease fishing in the affected area(s). For each screening test, whether positive or negative, the remaining sample material (homogenate) shall be maintained under refrigeration for later use should the Authority in the State of landing request confirmatory testing using an NSSP recognized method.~~

Each commercial shellfish grower is required to submit at least one shellfish sample per week, per lot, to an FDA conforming laboratory for testing of ASP and PSP during all harvest periods. Sample test results will be submitted to the Authority for review and data compilation.

Harvester representatives performing sample collection must receive initial training to ensure proper collection technique from the appropriate Authority. Sample collectors must receive refresher training every three (3)

years.

Location of sampling stations:
The sampling station should be centrally located in each harvest lot.

Sampling Frequency:
Samplers are required to achieve a sampling frequency of at least once sample per week during the months of May through October, and at least one sample per month during the months of November through April. When either PSP toxins or domoic acid are detected in shellfish, the frequency of sampling will double to allow better characterization of the event.

If test results of any sample collected equal or exceed 50% of the established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) (e.g., 40 µg /100 g for PSP toxins), sampling will double for all harvesters. If test results of any samples collected equal or exceed 75% of the established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) then sampling will commence for each harvest and the harvest will be held until final test results indicate toxin levels below that established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1).

If test results equal or exceed that established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) then the growing area will be placed in Closed Status pursuant to Section II. Model Ordinance Chapter IV@.04 C. (1).

Testing shall be according to NSSP recognized methods and shall be conducted by laboratories evaluated in accordance with NSSP guidelines. Private laboratories may be used if evaluated by an LEO in accordance with NSSP guidelines.

Sampling Methods:

Each screening sample shall be comprised of at least twelve (12) whole animals with the exception of mussels and “whole” or “roe-on” scallops. For mussels each sample shall be comprised of thirty (30) animals. For “whole” scallops each sample shall be comprised of twenty (20) scallop viscera and gonads. For “roe-on” scallops each sample shall be comprised of twenty (20) scallop gonads.

~~E. Submittal of Onboard Screening Homogenates and Test Results~~
~~F.~~

~~All screening results shall be recorded on the Harvest Record as stipulated in Section D. of this Protocol. Upon landing of the harvest vessel, the Harvest Record and screening homogenates shall be provided to the Authority or designee and the testing of those samples for toxins~~

~~using an NSSP method by an NSSP conforming laboratory in the State of landing authorized to sample the harvested shellfish as described in Section G. of this Protocol.~~

~~Dockside Sampling~~

~~After dockside samples are collected by the Authority or designee, molluscan shellfish may be processed while awaiting toxin results. Each lot must be identified and segregated during storage while awaiting dockside sample test results. Under no circumstances will product be released from the processor prior to receiving satisfactory toxin results that demonstrate that toxin levels are below the established criteria in Section II. Model Ordinance Chapter IV @04.C.(1).~~

~~The dockside sampling protocol for molluscan shellfish shall be as follows:~~

~~For each lot of molluscan shellfish, a minimum of seven (7) composite samples, each comprised of at least twelve (12) whole animals, shall be taken at random by the individual authorized by the Authority to sample, with the following exceptions:~~

~~For each lot of mussels, a minimum of seven (7) composite samples, each comprised of at least thirty (30) whole animals, shall be taken at random by the individual authorized to sample.~~

~~For each lot of "whole" scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop viscera and gonads, shall be taken at random by the individual authorized to sample.~~

~~For each lot of "roe-on" scallops, a minimum of seven (7) composite samples, each comprised of twenty (20) scallop gonads, shall be taken at random by the individual authorized to sample.~~

~~Shellfish samples collected in accordance with G.1 shall be tested for the presence of toxins using an NSSP recognized method(s).~~

~~Laboratory test results for each lot of shellfish shall be forwarded to the Authority in the State in which the shellfish is being held prior to the product being released by the Authority in the State of landing, or if processed in another State, the Authority in the State of processing.~~

~~G.~~E. Holding and Lot Separation

A harvest lot is defined as all molluscan shellfish harvested during a single period of uninterrupted harvest activity within a geographic area not to exceed three (3) square miles. Once harvesting has ceased and the harvest vessel moves to another location, regardless of the distance, a new harvest lot will be established. Any harvest vessel containing more than one (1)lot shall clearly mark and segregate each lot while at sea, during off loading, and during transportation to a processing facility. Prior to harvesting in Federal waters, each harvest vessel shall submit to the NMFS a written onboard lot segregation plan. The Authority in the intended State of landing and the FDA Shellfish Specialist must approve the proposed lot segregation plan.

~~H.~~F. Disposal of Shellfish

If test results of any harvest held based on D. Shellfish Sampling ~~one (1) of the seven (7) samples collected in accordance with G.1~~ equal or exceed the established criteria in Section II. Model Ordinance Chapter IV@.04 C. (1) (e.g., 80 µg /100 g for PSP toxins)(n=7, c=0), the entire lot must be discarded or destroyed at the cost of the harvester under the supervision of the Authority in accordance with State laws and regulations except when:

A lot of "whole" or "roe-on" scallops equals or exceeds the established criteria in Section II. Model Ordinance Chapter IV@.04C.(1), the adductor muscle may be shucked from the viscera and/or gonad and marketed. The remaining materials (viscera and/or gonad) must be discarded or destroyed under supervision of the Authority in accordance with State laws and regulations.

Dockside toxin testing shall be according to NSSP recognized methods and shall be conducted by laboratories evaluated in accordance with NSSP guidelines. Private laboratories may be used if evaluated by an LEO in accordance with NSSP guidelines.

~~I.~~G. Notification Prior to Unloading by Harvesters Under NMFS Permts

Prior to the issuance of an EFP, the harvester shall be responsible for notifying the Authority in the State of landing and in a manner approved by the Authority that molluscan shellfish is being harvested for delivery to the intended receiving processor.

Each vessel shall give at least twelve (12) hours' notice to the individual authorized to sample prior to unloading shellfish. Notice of less than twelve (12) hours may be approved by the authorized individual at his/her discretion. Authorities may appoint a designee in writing for sampling and sample transport to the NSSP certified testing laboratory in accordance with the practices and procedures used by the Authority under the NSSP. The procedures, as well as training and certification records, must be available for evaluation.

Shellfish from a Federal water harvest area(s) must be kept separate and not sold until so authorized by the Authority in the State of landing or, if processed in another State, the Authority in the State of processing.

Failure to comply with the provisions of this Protocol will result in the suspension or revocation of the vessel's permits through the NMFS.

	~~J.~~H. Unloading Schedule for Harvesters Under NMS Permits Unloading shall take place between 7:00 A.M. and 5:00 P.M. Monday through Friday, unless otherwise mutually agreed upon by the individual authorized to sample, the processing plant manager, the harvest vessel captain, and the Authority in the State of landing. ~~K. Access for Dockside Sampling~~ ~~L.~~ ~~Individuals authorized to sample shall be provided access to the catch of shellfish.~~ ~~M.~~I. Record Keeping Record keeping requirements shall be as follows: 1. The vessel shall maintain Harvest Records for at least one (1) year. 2. The processor(s) shall maintain Harvest Records for at least one (1) year or two (2) years if the product is frozen. 3. The Authority in the State of landing shall retain Harvest Records for at least two (2) years. ~~N.~~J. Early Warning/Alert System Toxin data acquired as a result of ~~onboard screening and dockside~~sample testing shall be transmitted to the FDA. These data~~, both screening and dockside,~~ shall be transmitted to the FDA by the NSSP certified laboratory conducting toxin testing of the sampled lot(s) within one (1) week of the completion of the toxin analyses. The data provided shall include the following: 1. Shellfish species; 2. Harvest location name and coordinates (GPS or latitude/longitude); 3. Harvest date; 4. Onboard screening test method, date, and results; and 5. Laboratory test date, test method, and test results for dockside samples. Results of all samples having unacceptable levels of toxins (e.g.,<80 µg/100 g for PSP toxins) shall immediately be reported to the Authority in the State of landing. If the results of any one (1) sample equal or exceed the established criteria in Chapter IV @.04(c)(1) the testing laboratory shall immediately notify the FDA Shellfish Specialist, the Authority, and the processor by telephone and email. The FDA shall notify the NMFS. The NMFS shall notify permitted harvesters to advise them to cease ~~fishing~~ harvesting in the affected area(s).
Public Health Significance	This proposal provides clarification to Chapter VI. @.03 by clarifying the type of testing requirements for aquaculture facilities. Additionally, the proposal modifies Section IV. Guidance Documents for the landing of shellfish in Federal Waters. These modifications would improve and simplify the protocols for landing shellfish in Federal Waters where a biotoxin concern exists.
Cost Information	
Action by 2019 Task Force I	Recommends no action on Proposal 19-151. Rationale: This issue is addressed by Proposal 19-149.

2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	209-1 Dawson Road
5. Address Line 2	
6. City, State, Zip	Columbia, SC 29223
7. Phone	803-788-7559
8. Fax	803-788-7576
9. Email	issc@issc.org
10. Proposal Subject	Alternative Pre-harvest Screening
11. Specific NSSP Guide Reference	Section II Model Ordinance – Chapter IV. Shellstock Growing Area @.04 Marine Biotoxin Control B. Marine Biotoxin Management Plan (6)e
12. Text of Proposal/ Requested Action	(6) Prior to allowing the landing of shellfish harvested from Federal waters where routine monitoring of toxin levels is not conducted, in addition to following State requirements in the Model Ordinance, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for: (a) Harvest permit requirements; (b) Training for individuals conducting onboard toxicity screening using NSSP methods; (c) Vessel monitoring; (d) Identification of shellfish for each harvesting trip to include: (i) Vessel name and owner; (ii) Captain's name; (iii) Person conducting onboard screening tests; (iv) Port of departure name and date; (v) Port of landing name and date; (vi) Latitude and longitude coordinates of designated harvest area; (vii) Onboard screening test results; (viii)Volume and species of shellfish harvested; (ix) Intended processing facility name, address and certification number; and (x) Captain's signature and date; (e) Pre-harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for toxins that are likely to be present. Harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels in excess of half of the established criteria listed in Chapter IV@.04(c)(1)As an alternative to pre-harvest (on-board) screening samples, end product (dockside) testing samples alone may be used. Should alternative be chosen, the minimum number of seven (7) dockside samples as stated in section (g) below must be expanded to ten (10). (e.g., 44 µg/l00 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test for PSP toxins); (f) Submittal of onboard screening homogenates and test results to the Authority in the State of landing;

	(g) The collection of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using a NSSP method by a NSSP conforming laboratory; the Authority may require more samples based on the size of the vessel and the volume of shellfish harvested; (h) Holding and providing separation until dockside samples verify that toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins); (i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins); (j) Notification prior to unloading; (k) Unloading schedule; (l) Access for Dockside Sampling; (m) Record Keeping; and (n) Early Warning/Alert System.
13. Public Health Significance	The ISSC Executive Board adopted the proposed language as an interim measure to address concerns with the Abraxis PSP Shipboard ELISA Kit. See attached report.
14. Cost Information	
Action by 2019 Task Force I	Recommends no action on 19-153.Rationale: This issue is addressed by 19-149.