Proposal No. **11-310**

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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Proposal Subject	Internal Authority Self-Assessment Using a National Program Standards Manual
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority
Text of Proposal/ Requested Action	@.01 Administration A. Scope… B. State Law and Regulations… C. Records… D. Shared Responsibilities… E. Administrative Procedures… F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness… G. Commingling… H. Program Evaluation. The Authority shall conduct a self-assessment using the National Program Standards Manual and report annually to the U.S. Food and Drug Administration the results of the assessment.
Public Health Significance	The purpose of this proposal is to begin discussions on how a self-assessment can be used by Authorities to conduct a comprehensive evaluation of their ability to promote the protection of public health. An assessment conducted by an Authority may encourage continuous improvement and innovation and can assure that individual program activities provide comparability among other domestic and international shellfish programs. The evaluation can be used to assist both the FDA and shellfish Authorities in fulfilling regulatory obligations and ensuring the implementation of the requirements set forth in the NSSP Model Ordinance
Cost Information	
Action by 2011 Task Force III	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairman.
Action by 2011 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 26, 2012	Concurred with Conference action on Proposal 11-310.
Action by 2013 NSSP Evaluation Criteria Committee	Recommended referral of Proposal 11-310 to the appropriate committee as determined by the Conference Chairperson with the following instructions. Establish a workgroup to evaluate the Manufactured Food Standards and determine the applicability of and/or use of these Manufactured Standards to the National Shellfish Sanitation Model Ordinance requirements and report their findings and recommendations to the NSSP Evaluation Criteria Committee at the next ISSC Meeting. The Committee further recommended that self-assessments should be voluntary and that the word “shall” should be replaced with the word “may”.
Action by 2013 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-310.

Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 11-310.
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 11-310.
Action by 2015 NSSP Evaluation Criteria Committee	Recommended that draft standards be developed for each program element. These draft standards will be developed using the stnadards from other programs and the FDA draft. It is further recommended that the ISSC identify volunteer states to ilot the standards once developed. The committee will review results from the pilot and submit a proposal for conference consideration.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendation on Proposal 11-210.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 11-310.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 11-310.
Action by 2017 NSSP Evaluation Committee	Recommended: 1. The full committee be allowed to review the Voluntary National Shellfish Regulatory Program Standards Plant Sanitation draft report. 2. This review should take place as soon as possible so that a decision can be made in January by the NSSP Evaluation Committee via a conference call. 3. If the full committee concurs, 2-4 state can move forward with a pilot study for the program standards as determined by the sub-committee chair.
Action by 2017 Task Force III	Recommended referral of Proposal 11-310 back to the NSSP Evaluation Criteria Committee with instructions to review the Plant Sanitation Standards developed by the Standards Subcommittee. The Committee is instructed to complete the review by January 31, 2018 and present recommendations to the ISSC Executive Board for interim approval and pilot testing.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 11-310.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 11-310.

Proposal No. **13-301**

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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

1. Written Sanitary Survey
   (A) Is there a written Sanitary Survey for each growing area that is classified other than prohibited?
   (B) Is the Sanitary Survey complete?

   A. Executive Summary
   B. Description of Growing Area
   C. Pollution Source Survey
   D. Hydrographic and Meteorological Characteristics
   E. Water Quality Studies
   F. Interpretation of Data in Determining Classification to Be Assigned to Growing Area: A discussion of how actual or potential pollution sources, wind, tide, rainfall, etc. affect or may affect water quality, that will address the following:
   G. Conclusions

   (C) Is the Sanitary Survey current?
   A. Annual
   B. Triennial
   C. 12 Year)

2. Shoreline Survey
   (A) Does Shoreline Survey include identification and evaluation of all actual and potential sources of pollution
   (B) Does Shoreline Survey include boundaries?
   (C) Does Shoreline Survey include unique designation?
   (D) Does Shoreline Survey include required maps?
   (E) Does Shoreline Survey include a summary of survey findings?

3. Adequate Sampling
   (A) Are the number and location of sampling stations adequate to effectively evaluate all pollution sources.
   (B) Were adequate samples collected for each area consistent with the classification and type of sampling approach used (i.e. Remote, Adverse Pollution, Systematic Random Sampling)?
   (C) Were samples collected under appropriate conditions consistent with the type of sampling approach?

4. Data to support Classification
   (A) The assigned classifications are based on data/information supporting the classification and performance standards?
   (B) Is appropriate data/information available to support the classification within each designated growing area?
5. Proper Classification
   (A) Are all growing areas properly classified?
   (B) Does SSCA have appropriate MOU(s) with appropriate parties for each area classified as conditional?

	2) The subcommittee will develop a scoring system which assigns appropriate significance to the criteria and establishes compliance standards which can be used to assign compliance designations as outlined in the other NSS elements. 3) Field testing of the complete evaluation criteria including compliance designation will be field tested in one state in each ISSC region. The results will be reviewed by the NSSP Evaluation Committee, modified as appropriate and presented to the ISSC as a proposal.
Action by 2015 Task Force III	Recommended adoption of the NSSP Evaluation Criteria Committee recommendations on Proposal 13-301.
Action by 2015 General Assembly	Adopted recommendation of Task Force III on Proposal 13-301.
Action by FDA January 11, 2016	Concurred with Conference action on Proposal 13-301.
Action by 2017 NSSP Evaluation Criteria Committee	Recommended: 1. The full committee is allowed to review the FDA proposed growing area evaluation criteria immediately. 2. Concurrence with FDA not to initiate a full pilot until the committee completes a review of the FDA proposed criteria.
Action by 2017 Task Force III	Recommended adoption of NSSP Evaluation Criteria Committee recommendation to refer Proposal 13-301 back to the NSSP Evaluation Criteria Committee with the following charge: Review the evaluation criteria provided to the NSSP Evaluation Criteria Committee and provide recommendation for interim approval by the ISSC Executive Board at the Spring Board meeting. The Executive Board is requested to coordinate the piloting of the criteria with FDA as soon as possible.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 13-301.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 13-301.

Proposal No. **17-302**

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	☐ Growing Area ☒ Harvesting/Handling/Distribution ☐ Administrative

Submitter	ISSC Executive Office
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Proposal Subject	NSSP Training Curriculum
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I Section IV. Guidance Documents Chapter I
Text of Proposal/ Requested Action	Presently the NSSP does not have a well defined training curriculum for State Shellfish Authority staff that are implementing the requirements of the NSSP. There are two (2) required courses for Authority staff and FDA provides other training on an as needed basis. In 2016, the Association of Food and Drug Officials received a cooperative program grant to support training for shellfish regulatory staff. A joint advisory group (JAG) was created to provide oversight. The lack of an established NSSP curriculum made it difficult to develop funding selection criteria. In response, the ISSC appointed a training committee which discussed available training and provided recommendations to the JAG. The purpose of this proposal is to charge the Training Committee with development of an NSSP training curriculum for inclusion into either Chapter I of the Model Ordinance or as a Guidance Document.
Public Health Significance	Adequate training of Authority staff is fundamental to successful implementation of the elements of the NSSP. A NSSP training curriculum would be a helpful tool to guide Authorities in selection of appropriate and helpful training for staff.
Cost Information	
Action by 2017 Task Force III	Recommended adoption of Proposal 17-302 as submitted.
Action by 2017 General Assembly	Adopted the recommendation of Task Force III on Proposal 17-302.
Action by FDA February 7, 2018	Concurred with Conference action on Proposal 17-302.

Proposal No. 17-305

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	☐ Growing Area ☐ Harvesting/Handling/Distribution ☒ Administrative

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Proposal Subject	Responsibilities of the FDA for Annual or Bi-Annual Evaluations
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures of the ISSC Procedure IV. Responsibilities of the FDA Section 3. and Model Ordinance Chapter I. @.03 (new) E.
Text of Proposal/ Requested Action	Procedures of the Interstate Shellfish Sanitation Conference Procedure IV. Responsibilities of the FDA Section 3. Subdivision a: FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation. FDA will include the specific NSSP Model Ordinance reference for each deficiency, non-compliance, or emerging concern. This can be accomplished during a close out session with state program officials or at any time during a field inspection or overall program evaluation and shall occur prior to finalizing the Program Element Evaluation Report (PEER) Subdivision b: FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose an imminent health hazard) identified prior to finalizing the PEER. If state program officials correct the identified deficiencies during the 30 day time frame, the final PEER will acknowledge the corrections and reflect compliance with any deficiencies identified or noted during the evaluation

	as in Subdivision a, above. If corrections cannot be accomplished within 30 days an agreed upon timeframe or action plan is required and should be included in the PEER. Subdivision c: All deficiencies, non-compliance, or emerging concerns cited in a PEER will include the specific Model Ordinance references of the requirements. Once a State has corrected any non-compliance FDA shall acknowledge the correction in writing. Model Ordinance Chapter I. @.03 (new) E. E. When notifying the Authority of deficiencies cited as part of a Program Evaluation, the FDA will adhere to the following: (1) FDA shall provide a description of all deficiencies/non-compliance or emerging concerns identified during the evaluation and include the specific NSSP Model Ordinance reference for each. (2) FDA shall allow state program officials a minimum of 30 days to correct any deficiencies/non-compliance or emerging concerns (that do not pose a public health hazard) identified prior to finalizing the Program Element Evaluation Report (PEER). If State program officials correct the identified deficiencies during the 30 day time frame, the PEER will acknowledge and reflect compliance. (3) Once a State has corrected or addressed any non-compliance, deficiencies, or emerging concerns, FDA shall acknowledge the correction in writing.
Public Health Significance	Provides a mechanism to assure consistency and encourages corrections during the evaluation process so that correctin of deficiencies occur in a timely manner. This is consistent with the existing FDA Compliance Program Guidance Manual. This language encourages the cooperative aspect of the NSSP by allowing FDA and State Authorities to work together to address problems sooner rather than later.
Cost Information	Would save time and resources for both FDA and State Regulators.
Action by 2017 Task Force III	Recommended referral of Proposal 17-305 to an appropriate committee as determined by the Conference Chairperson.
Action by 2017 General Assembly	Adopted the recommendation of Proposal 17-306 on Proposal 17-305.
Action by FDA February 7, 2018	Concurred with Conference action on proposal 17-305 with comments. (See February 7, 2018 FDA response to ISSC Summary of Actions)

Proposal No. 19-300

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative

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9. Email	issc@issc.org
10. Proposal Subject	Executive Committee Membership
11. Specific NSSP Guide Reference	ISSC Constitution By-laws & Procedures Article VIII. of the Constitution entitled *Duties of the Executive Director*
12. Text of Proposal/ Requested Action	Section 1. The Executive Director shall serve as chief administrator of the Conference and shall serve as a non-voting member of the Executive Board and the Executive Committee. The Executive Director shall conduct the affairs of the Conference and shall implement the decisions and policies of the Board and voting delegates.
13. Public Health Significance	It is critical that the Executive Director be included as a non-voting member of the Executive Committee for the same reason that the Executive Director is included as a non-voting member of the Executive Board. Given the duties and responsibilities of the Executive Director, it is imperative that the Executive Director participate in Executive Board and Executive Committee discussions for the purpose of providing information necessary to conduct conference discussions.
14. Cost Information	

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Laboratory Committee
3. Affiliation	Interstate Shellfish Sanitation Conference
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9. Email	issc@issc.org
10. Proposal Subject	Updating and Clarifying Laboratory Evaluation Checklist Submission Requirements
11. Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures, Procedure XV, Section 4 and Section 6
12. Text of Proposal/ Requested Action	Section 4., Subdivision a. All proposals shall include a completed ~~Single Laboratory Validation (SLV) Method Application and Checklist.~~ ISSC Method Application and Single Lab Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP. Submitters of AOAC and FDA methods will provide ~~a Single Laboratory Validation Method Application and Checklist~~ an ISSC Method Application and Single Lab Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP, along with the AOAC OMA or FDA Office of Foods Level 3 or 4 validations. Section 6., Subdivision a., Subdivision ii. Method documentation including: Subdivision (a) Method title, scope and references; Subdivision (b) Equipment and reagents required; Subdivision (c) Sample collection, preservation and storage requirements; Subdivision (d) Safety requirements; Subdivision (e) Step by step procedure; Subdivision (f) Specific quality control measures associated with the method; Subdivision (g) Laboratory Evaluation Checklist for use during evaluations of proper method implementation; Subdivision (~~g~~h) Cost of the method; Subdivision (~~h~~i) Sample turnaround time.
13. Public Health Significance	Whenever a new laboratory method is accepted for use within the National Shellfish Sanitation Program, an associated laboratory evaluation checklist to properly evaluate method implementation is necessary for laboratory evaluation officers (LEOs) to be able to fully and uniformly evaluate laboratories which have adopted the method. These checklists are often not prepared or submitted by the method developer/submitter in a timely manner, if at all, and the Laboratory Committee is often called upon instead to expend valuable time and resources

	preparing these checklists. Further, the method developer/submitter is the most appropriate individual for developing the technical aspects of the laboratory evaluation checklist, while the Laboratory Committee is better suited for ensuring consistency and uniformity with other NSSP laboratory evaluation checklists. There are a few reasons why these challenges with laboratory evaluation checklist submissions arise. First, there is often confusion among method developers between the laboratory evaluation checklist and the "ISSC Method Application and Single Lab Validation Checklist for Acceptance of a Method for Use in the NSSP," which is required to be completed when submitting a new method for adoption within the program. Developers often think that they have already fulfilled their checklist completion requirement by submitting this document. Additionally, laboratory evaluation checklists are not currently required to be prepared until after the method has been approved for use within the program, and there are no timeline standards associated with this expectation. This proposal attempts to eliminate the confusion between checklists by retitling the "ISSC Method Application and Single Lab Validation Checklist for Acceptance of a Method for Use in the NSSP" to "ISSC Method Application and Single Lab Validation Summary of Required Elements for Acceptance of a Method for Use in the NSSP," and to make laboratory evaluation checklist submission a required component of method submission for approval. The text of this proposal includes modifications to the ISSC Constitution, Bylaws, and Procedures, Procedure XV, as well as all other supporting documents that describe the process of method submission that would be available on the ISSC webpage.
14. Cost Information	No additional costs as laboratory evaluation checklist development is already a required part of the process, and this proposal simply changes where in the method approval process the checklist must be submitted for evaluation by the Laboratory Committee.

Single Laboratory Validation (SLV) Protocol

For Submission to the Interstate Shellfish Sanitation Conference (ISSC)

For Method Approval

Critical Information: Applicants shall attach all procedures, with materials, methods, calibrations and interpretations of data with the request for review and potential approval by the ISSC. The ISSC also recommends that submitters include peer-reviewed articles of the procedure (or similar procedures from which the submitting procedure has been derived) published in technical journals with their submittals. Methods submitted to the ISSC Laboratory Committee for acceptance will require, at a minimum, 6 months for review from the date of submission.

Note: The applicant should provide all information and data identified above as well as the following material, if applicable:

Justification for New Method

- Name of the New Method.
- Specify the Type of Method (e.g., Chemical, Molecular, or Culture).
- Name of Method Developer / Submitter.
- Developer / Submitter Contact Information [e.g., Address and Phone Number(s)].
- Date of Submission.
- Purpose and Intended Use of the Method.
- Need for the New Method in the NSSP, Noting Any Relationships to Existing Methods.
- Method Limitations and Potential Indications of Cases Where the Method May Not Be Applicable to Specific Matrix Types.
- Other Comments.

Method Documentation

- Method Title.
- Method Scope.
- References.
- Principle.
- Analytes/Measurands.
- Proprietary Aspects.
- Equipment.
- Reagents.
- Media.
- Matrix or Matrices of Interest.
- Sample Collection, Preservation, Preparation, Storage, Cleanup, etc.
- Safety Requirements.
- Other Information (Cost of the Method, Special Technical Skills Required to Perform the Method, Special Equipment Required and Associated Cost, Abbreviations and Acronyms Defined and Details of Turn Around Times [Time Involved to Complete the Method]).
- Test Procedures, (Be Specific and Provide Easy-to-Follow Step-by-Step Procedures and indicate critical steps.).
- Quality Control (Provide Specific Steps.).

- Validation Criteria (Include Accuracy / Trueness, Measurement Uncertainty, Precision [Repeatability and Reproducibility], Recovery, Specificity, Working and Linear Ranges, Limit of Detection, Limit of Quantitation / Sensitivity, Ruggedness, Matrix Effects and Comparability (if intended as a substitute for an established method accepted by the NSSP).
- Data and Statistical Analyses Performed for Each Validation Criterion Tested (Be Specific and Provide Clear Easy-to-Follow Step-by-Step Procedures.).
- Calculations and Formulas Used for Each Validation Criterion Tested.
- Results for Each Validation Criterion Tested.
- Discussion of Each Validation Criterion Tested.
- Summary of Results.
- Laboratory Evaluation Checklist for Use During Evaluations of Proper Method Implementation.

~~**Additional Requirement**~~

~~If a laboratory method is found acceptable for use in the National Shellfish Sanitation Program and adopted by the Interstate Shellfish Sanitation Conference, the method submitter will draft a laboratory checklist that can be used to evaluate laboratories performing their procedure. The checklist will be submitted to the ISSC and reviewed by the Laboratory Quality Assurance Committee for Conference approval.~~

(For guidance: refer to the checklists in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish 2017, Guidance Documents, Chapter II – Growing Areas, .15 Evaluation of Laboratories by State Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.)

ISSC Method Application and Single Lab Validation ~~Checklist~~ Summary of Required Elements for Acceptance of a Method for Use in the NSSP

The purpose of single laboratory validation in the National Shellfish Sanitation Program (NSSP) is to ensure that the analytical method under consideration for adoption by the NSSP is fit for its intended use in the Program. A ~~Checklist~~ summary of required elements has been developed which explores and articulates the need for the method in the NSSP; provides an itemized list of method documentation requirements; and, sets forth the performance characteristics to be tested as part of the overall process of single laboratory validation. For ease in application, the performance characteristics listed under validation criteria ~~on the Checklist~~ in this document have been defined and accompany the ~~Checklist~~ summary of required elements as part of the process of single laboratory validation. Further a generic protocol has been developed that provides the basic framework for integrating the requirements for the single laboratory validation of all analytical methods intended for adoption by the NSSP. Methods submitted to the Interstate Shellfish Sanitation Conference (ISSC) Laboratory ~~Methods Review (LMR)~~ Committee for acceptance will require, at a minimum, six (6) months for review from the date of submission.

Name of the New Method	
Name of the Method Developer/Submitter	
Developer Contact Information	

~~Checklist~~ Required Elements	~~Submitter Comments~~ Brief Description
A. Need for the New Method	
1. Clearly define the need for which the method has been developed.	
2. What is the intended purpose of the method?	
3. Is there an acknowledged need for this method in the NSSP?	
4. What type of method? i.e. chemical, molecular, culture, etc.	
B. Method Documentation	
1. Method documentation includes the following information:	
Method Title	
Method Scope	
References	
Principle	
Any Proprietary Aspects	
Equipment Required	
Reagents Required	
Sample Collection, Preservation and Storage Requirements	
Safety Requirements	
Clear and Easy to Follow Step-by-Step Procedure	
Quality Control Steps Specific for this Method	
Laboratory Evaluation Checklist for Use During Evaluations of Proper Method Implementation	
C. Validation Criteria	
1. Accuracy / Trueness	
2. Measurement Uncertainty	
3. Precision Characteristics (repeatability and reproducibility)	
4. Recovery	
5. Specificity	

6. Working and Linear Ranges	
7. Limit of Detection	
8. Limit of Quantitation / Sensitivity	
9. Ruggedness	
10. Matrix Effects	
11. Comparability (if intended as a substitute for an established method accepted by the NSSP)	
D. Other Information	
1. Cost of the Method	
2. Special Technical Skills Required to Perform the Method	
3. Special Equipment Required and Associated Cost	
4. Abbreviations and Acronyms Defined	
5. Details of Turn Around Times (time involved to complete the method)	
6. Provide Brief Overview of the Quality Systems Used in the Lab	
Submitters Signature	Date:
Submission of Validation Data and Draft Method to Committee	Date:
Reviewing Members	Date:
Accepted	Date:
Recommendations for Further Work	Date:
Comments:	

DEFINITIONS

1. Accuracy/Trueness - Closeness of agreement between a test result and the accepted reference value.
2. Analyte/measurand - The specific organism or chemical substance sought or determined in a sample.
3. Blank - Sample material containing no detectable level of the analyte or measurand of interest that is subjected to the analytical process and monitors contamination during analysis.
4. Comparability - The acceptability of a new or modified method as a substitute for an established method in the NSSP. Comparability must be demonstrated for each substrate or tissue type by season and geographic area if applicable.
5. Fit for purpose - The analytical method is appropriate to the purpose for which the results are likely to be used.
6. HORRAT value - HORRAT values give a measure of the acceptability of the precision characteristics of a method.[4]
7. Limit of Detection - The minimum concentration at which the analyte or measurand can be identified. Limit of detection is matrix and analyte/measurand dependent.[4]
8. Limit of Quantitation/Sensitivity - The minimum concentration of the analyte or measurand that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.
9. Linear Range - The range within the working range where the results are proportional to the concentration of the analyte or measurand present in the sample.
10. Measurement Uncertainty - A single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including: overall precision of the complete method, the method and laboratory bias and matrix effects.
11. Matrix - The component or substrate of a test sample.
12. Method Validation - The process of verifying that a method is fit for purpose.[1]
13. Precision - The closeness of agreement between independent test results obtained under stipulated conditions.[1, 2] There are two components of precision:
    a. Repeatability - The measure of agreement of replicate tests carried out on the same sample in the same laboratory by the same analyst within short intervals of time.
    b. Reproducibility - The measure of agreement between tests carried out in different laboratories. In single laboratory validation studies reproducibility is the closeness of agreement between results obtained with the same method on replicate analytical portions with different analysts or with the same analyst on different days.
14. Quality System - The laboratory's quality system is the process by which the laboratory conducts its activities so as to provide data of known and documented quality with which to demonstrate regulatory compliance and for other decision-making purposes. This system includes a process by which appropriate analytical methods are selected, their capability is evaluated, and their performance is documented. The quality system shall be documented in the laboratory's quality manual.
15. Recovery - The fraction or percentage of an analyte or measurand recovered following sample analysis.
16. Ruggedness - The ability of a particular method to withstand relatively minor changes in analytical technique, reagents, or environmental factors likely to arise in different test environments.[4]
17. Specificity - The ability of a method to measure only what it is intended to measure.[1]
18. Working Range - The range of analyte or measurand concentration over which the method is applied.

REFERENCES:

1. Eurachem Guide, 1998. The Fitness for Purpose of Analytical Methods. A Laboratory Guide to Method Validation and Related Topics. LGC Ltd. Teddington, Middlesex, United Kingdom.
2. IUPAC Technical Report, 2002. Harmonized Guidelines for Single-Laboratory Validation of Methods of Analysis, Pure Appl. Chem., Vol. 74, (5): 835-855.
3. Joint FAO/IAEA Expert Consultation, 1999. Guidelines for Single-Laboratory Validation of Anilytical Methods for Trace-Level Concentrations of Organic Chemicals.
4. MAF Food Assurance Authority, 2002. A Guide for the Validation and Approval of New Marine Biotoxin Test Methods. Wellington, New Zealand.
5. National Environmental Laboratory Accreditation. , 2003. Standards. June 5.
6. EPA. 2004. EPA Microbiological Alternate Procedure Test Procedure (ATP) Protocol for Drinking Water, Ambient Water, and Wastewater Monitoring Methods: Guidance. U.S. Environmental Protection Agency (EPA), Office of Water Engineering and Analysis Division, 1200 Pennsylvania Avenue, NW, (4303T), Washington, DC 20460. April.

Proposal No. 19-302

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Laboratory Committee
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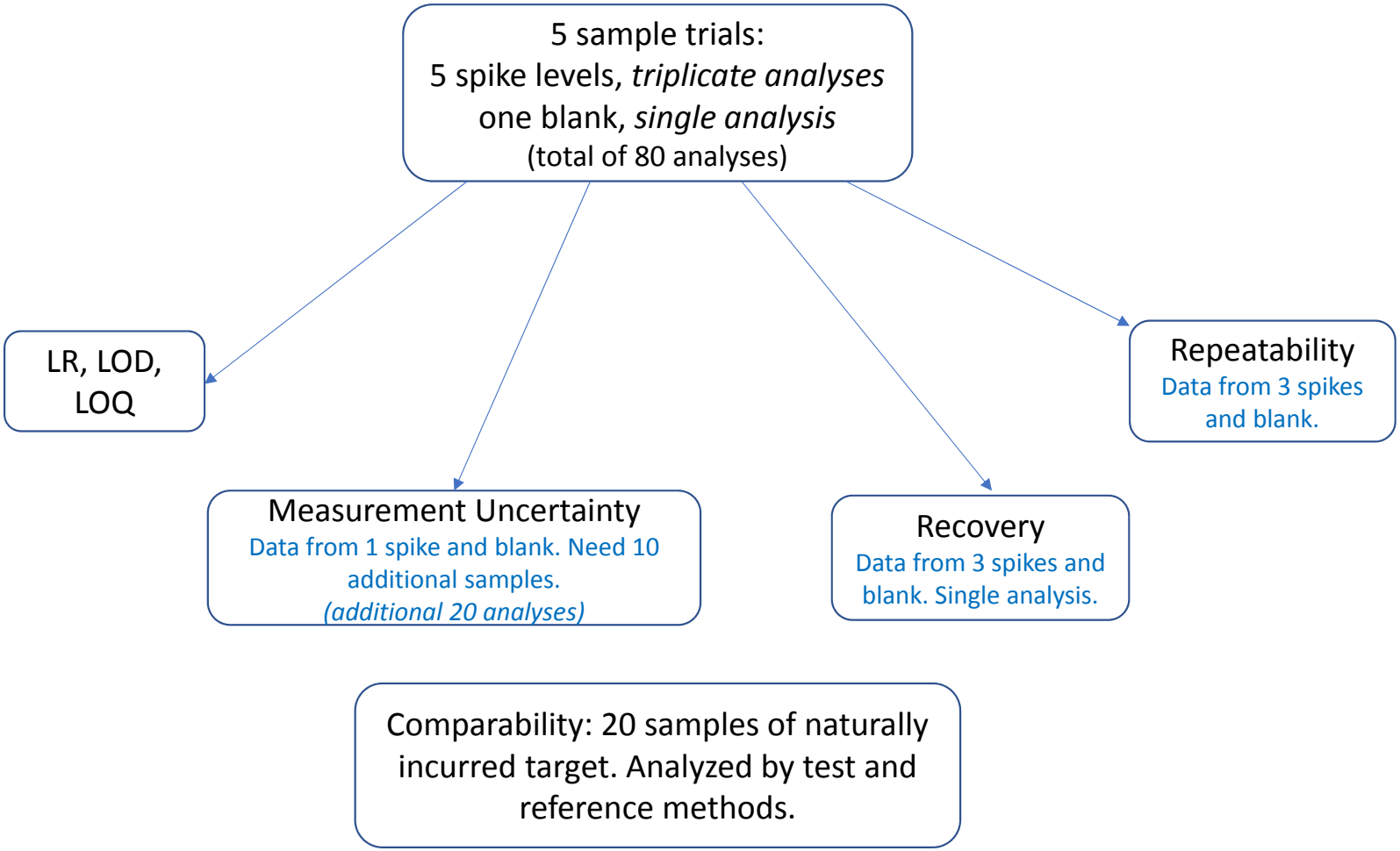
9. Email	issc@issc.org
10. Proposal Subject	Adding Matrix Extension Guidelines for Method Validation
11. Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures, Procedure XV, Add a new Section 10.
12. Text of Proposal/ Requested Action	Section 10. Matrix Extensions. For methods already adopted into the NSSP, consideration of expanding a method to a new molluscan shellfish species is accomplished using the "ISSC Method Application Format for Biotoxin Methods Matrix Extension" and the "ISSC Method Application Format for Microbiology Methods Matrix Extension." The simplified, reduced approach to method validation for expanding an NSSP method to new molluscan shellfish species is visually represented in the "Matrix Extension Guidelines" schematic.
13. Public Health Significance	Analytical methods employed in the National Shellfish Sanitation Program (NSSP) are validated for the intended purpose within the Program. Since individual molluscan shellfish matrices may impact the performance of certain methods in their ability to identify and quantify biotoxins or microbiological contaminants, each method must be validated for each molluscan shellfish. To date, a full single laboratory validation (SLV) for each molluscan shellfish matrix has been expected. However, the Interstate Shellfish Sanitation Conference Laboratory Committee has developed simplified method validation guidelines for extending an adopted NSSP method for the use of additional species. The reduced guidelines address the critical method performance criteria that may be impacted by a change in shellfish type.
14. Cost Information	No additional costs. The cost to laboratories performing the validation studies would be less since this represents a reduced version of the validation guidelines for extending an NSSP method to a new molluscan shellfish matrix.

Matrix Extension Guidelines



ISSC Method Application Format for Biotoxin Methods Matrix Extension

The purpose of laboratory validation in the National Shellfish Sanitation Program (NSSP) is to ensure that methods under consideration for adoption by the NSSP are fit for their intended use in the Program. This document provides a detailed outline of the types of information and data the Interstate Shellfish Sanitation Conference (ISSC) Laboratory Committee (LC) requests from submitters for extension of current NSSP methods to cover additional matrices (i.e., molluscan shellfish species). These recommendations are intended for methods which have already undergone a single laboratory validation (SLV) and are being considered for use with a new matrix. Included are the method performance criteria that should be examined for inclusion in the validation package, along with LC recommendations for each criterion. Data generated for the more robust performance criteria may be used to satisfy multiple criteria, if applicable.

Method Overview
Method Title:
Method Submitter(s) and Contact Information:
Intended or Target Use: (approved, approved limited use, or emergency use)
Rationale for this Method in the NSSP: (Does the method meet an immediate or continued need or improve analytical capability?)
Method Principle/Basis: (receptor binding assay, immunoassay, LC-MS, etc.)
Target Matrix/Matrices: (list shellfish species by common and scientific names)
Target Toxin(s):
Existing Certification(s) of the Method: (AOAC, etc.)
Equipment Required: (Provide a list of specialized equipment needed to perform the method.)
Reagents Required: (Provide a list of specialized chemicals, reagents, etc. needed to perform the method.)
Proprietary Aspects: (Provide any aspects of the method that are proprietary or trade secret.)
Safety Requirements: (Describe the safety measures, beyond those of routine laboratory practices, required to perform the method, including personal protective equipment, fume hoods, etc.)
Method Cost: (Provide an estimate of cost per analysis, including start-up costs for specialized equipment, personnel, etc.)
Sample Throughput: (Provide a description of how many samples can be analyzed by this method in a given time frame; please specify under what conditions this throughput can be achieved.)

Validation Data

1. Recovery: Recovery is the fraction or percentage of an analyte recovered following sample analysis. To determine method accuracy/trueness/recovery, the concentration of the target analyte as measured by the analytical method under study is compared to a true value or accepted reference concentration. Consider using certified reference materials (if available).

Suggested procedure: Use shellfish free of the target analyte(s); analyze intended blank matrix tissue for background interferents. For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. Take four aliquots of the sample homogenate appropriately sized for the work and spike one with the target analyte(s) at half the action level. Spike a second aliquot with the target analyte(s) at the action level. Spike the third aliquot with the target analyte(s) at twice the action level. Do not spike the fourth aliquot; this is the sample blank. Process each aliquot to determine the concentration for the target analyte(s). Repeat this process with a minimum of five samples for each shellfish type of interest collected from a variety of growing areas, the same growing area harvested on different days, or from different process lots. Additional samples may be required to examine the effects of seasonal and/or geographical differences in shellfish matrix components or analyte profiles on the method performance.

2. Repeatability: Repeatability is the measure of agreement of replicate tests carried out on the same sample in the same laboratory by the same analyst within short intervals of time.

Suggested procedure: Use shellfish free of the target analyte(s). For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. Take four aliquots of the sample homogenate appropriately sized for the work and spike one with the target analyte(s) at half the action level. Spike a second aliquot with the target analyte(s) at the action level. Spike the third aliquot with the target analyte(s) at twice the action level. Do not spike the fourth aliquot; this is the sample blank. For each aliquot, excluding the sample blank, prepare three sub-aliquots for analysis. Process each sub-aliquot, including the sample blank, to determine the method concentration of the target analyte(s). Repeat this process for each shellfish type of interest with a minimum of five samples collected from a variety of growing areas, the same growing area harvested on different days, or from different process lots.

When available, shellfish with naturally incurred target analyte(s) should be included. Use a minimum of 10-12 animals per sample and prepare as a homogenate. For each shellfish type of interest, use three samples at a range of concentrations bracketing the action level (below, at or near, and above). For each sample homogenate prepare a minimum of three aliquots for analysis. Process each aliquot to determine the method concentration of the target analyte(s).

3. Linear Range, Limit of Detection, and Limit of Quantitation: Linear range is the range within the working range where the results are proportional to the concentration of the analyte present in the sample. The limit of detection is the minimum concentration at which the analyte can be identified. Limit of detection is matrix and analyte dependent. The limit of quantitation is the minimum concentration of the analyte that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.

Suggested procedure: Use samples free of the target analyte(s); analyze intended blank matrix tissue for background interferents. For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. For each sample take a minimum of six aliquots of the homogenate appropriately sized for the work and spike five of the six aliquots with five different concentrations of the target analyte(s), spanning beyond the desired working range and including levels half, at, and twice the action level. Do not spike the sixth aliquot of each sample; this is the sample blank. Process each aliquot, including the sample blank to determine concentration for the target analyte(s). For each aliquot, excluding the sample blank, sub-aliquot for three replicate analyses. Repeat this process for each shellfish type of interest with a minimum of five samples collected from a variety of growing areas, the same growing area harvested on different days or from different process lots. Use the same spike levels for each of the samples analyzed.

4. Measurement Uncertainty: Measurement uncertainty is a single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including overall precision of the complete method, the method and laboratory bias, and matrix effects.

Suggested procedure: Use shellfish free of the target analyte(s). For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. Take two aliquots of the sample homogenate appropriately sized for the work and spike one with the target analyte(s) at the action level. Do not spike the second aliquot as this is the sample blank. Process each aliquot to determine the concentration for the target analyte(s). Repeat this process with a minimum of 15 samples for each shellfish type of interest collected from a variety of growing areas, the same growing area harvested on different days, or from different process lots.

5. Comparability: Comparability is the acceptability of a new or modified analytical method as an alternative or a substitute for an established method in the NSSP. To be acceptable the new or modified method must not produce a significant difference in results when compared to the officially recognized NSSP method. Comparability must be demonstrated for each substrate or type of interest by season and geographic area, if applicable.

Suggested procedure: For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. For each sample take two aliquots and analyze one by the officially recognized NSSP method and the other by the alternative test method. Naturally incurred samples having a variety of concentrations which span the range of the intended application of the method should be used in the comparison. Analyze a minimum of 20 paired samples, covering each season and a variety of growing areas. In cases where the occurrence of the target analyte(s) is intermittent, spiked samples can be used as described above for, but each spiked aliquot should be sub-aliquoted for analysis by both the officially recognized NSSP method and the alternative/test method.

Additional Information

References (Provide references that are pertinent and supplemental to the validation data submitted; these may include peer-reviewed publications in which the method was validated and/or applied, validation packages submitted to other entities, etc. Do not provide references in lieu of data in the "Validation Data" section.)

Standard Operating Procedure (SOP) (Provide a detailed procedure adequate for replication in additional laboratories.)

Laboratory Evaluation Checklist (Provide any additions and/or modifications to the current method checklist for laboratory evaluation based on inclusion of the new matrix/ces.)

Overview of Quality Systems (Provide an overview of the quality assurance/quality control systems utilized in the developer(s)/submitter(s) laboratory.)

ISSC Method Application Format for Microbiology Methods Matrix Extension

The purpose of laboratory validation in the National Shellfish Sanitation Program (NSSP) is to ensure that methods under consideration for adoption by the NSSP are fit for their intended use in the Program. This document provides a detailed outline of the types of information and data the Interstate Shellfish Sanitation Conference (ISSC) Laboratory Committee (LC) requests from submitters for extension of current NSSP methods to cover additional matrices (i.e., molluscan shellfish species). These recommendations are intended for methods which have already undergone a single laboratory validation (SLV) and are being considered for use with a new matrix. Included are the method performance criteria that should be examined for inclusion in the validation package, along with LC recommendations for each criterion. Data generated can be used to satisfy the requirements of multiple criteria, as applicable.

Method Overview
Method Title:
Method Submitter(s) and Contact Information:
Intended or Target Use: (approved, approved limited use, or emergency use)
Rationale for this Method in the NSSP: (Does the method meet an immediate or continued need or improve analytical capability?)
Method Principle/Basis: (MPN, plating, etc.)
Target Matrix/Matrices: (List shellfish species by common and scientific names.)
Target Organism(s):
Existing Certification(s) of the Method: (AOAC, etc.)
Equipment Required: (Provide a list of specialized equipment needed to perform the method.)
Reagents Required: (Provide a list of specialized chemicals, reagents, etc. needed to perform the method.)
Proprietary Aspects: (Provide any aspects of the method that are proprietary or trade secret.)
Safety Requirements: (Describe the safety measures, beyond those of routine laboratory practices, required to perform the method, including personal protective equipment, fume hoods, etc.)
Method Cost: (Provide an estimate of cost per analysis, including start-up costs for specialized equipment, etc.)
Sample Throughput and Personnel Labor Requirements: (Provide a description of how many samples can be analyzed by this method in a given time frame; please specify under what conditions this throughput can be achieved.)

Validation Data

1. Recovery: Recovery is the fraction or percentage of an organism recovered following sample analysis. To determine method accuracy/trueness/recovery, the concentration of the target organism as measured by the analytical method under study is compared to a true value or accepted reference concentration. Consider using certified reference materials (if available).

Suggested procedure: Use shellfish free of the target organism(s); analyze intended blank matrix tissue for background interferents. For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. Take four aliquots of the sample homogenate appropriately sized for the work and spike one with the target organism(s) at a low level of intended method use. Spike a second aliquot with the target organism(s) at a mid-level of intended method use. Spike the third aliquot with the target organism(s) at a high level of intended method use. Do not spike the fourth aliquot; this is the sample blank. Process each aliquot to determine the concentration for the target organism(s). Repeat this process with a minimum of five samples for each shellfish type of interest collected from a variety of growing areas, the same growing area harvested on different days, or from different process lots. Additional samples may be required to examine the effects of seasonal and/or geographical differences in shellfish matrix components or organism profiles on the method performance.

2. Repeatability: Repeatability is the measure of agreement of replicate tests carried out on the same sample in the same laboratory by the same analyst within short intervals of time.

Suggested procedure: Use shellfish free of the target organism(s). For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. Take four aliquots of the sample homogenate appropriately sized for the work and spike one with the target organism(s) at a low level of intended method use. Spike a second aliquot with the target organism(s) at a mid-level of intended method use. Spike the third aliquot with the target organism(s) at a high level of intended method use. Do not spike the fourth aliquot; this is the sample blank. For each aliquot, excluding the sample blank, prepare three sub-aliquots for analysis. Process each sub-aliquot, including the sample blank, to determine the method concentration of the target organism(s). Repeat this process for each shellfish type of interest with a minimum of five samples collected from a variety of growing areas, the same growing area harvested on different days, or from different process lots.

When available, shellfish with naturally incurred target organism(s) should be included. Use a minimum of 10-12 animals per sample and prepare as a homogenate. For each shellfish type of interest, use three samples at a range of concentrations bracketing the action level (below, at or near, and above). For each sample homogenate prepare a minimum of three aliquots for analysis. Process each aliquot to determine the method concentration of the target organism(s).

3. Linear Range, Limit of Detection, and Limit of Quantitation: Linear range is the range within the working range where the results are proportional to the concentration of the organism present in the sample. The limit of detection is the minimum concentration at which the organism can be identified. Limit of detection is matrix and organism dependent. The limit of quantitation is the minimum concentration of the organism that can be quantified with an acceptable level of precision and accuracy under the conditions of the test.

Suggested procedure: Use samples free of the target organism(s); analyze intended blank matrix tissue for background interferents. For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. For each sample take a minimum of six aliquots of the homogenate appropriately sized for the work and spike five of the six aliquots with five different concentrations of the target organism(s), spanning throughout the desired working range, including at the regulatory level (when such level exists). Do not spike the sixth aliquot of each sample; this is the sample blank. Process each aliquot, including the sample blank to determine concentration for the target organism(s). For each aliquot, excluding the sample blank, sub-aliquot for three replicate analyses. Repeat this process for each shellfish type of interest with a minimum of five samples collected from a variety of growing areas, the same growing area harvested on different days, or

from different process lots. Use the same spike levels for each of the samples analyzed.

4. Measurement Uncertainty: Measurement uncertainty is a single parameter (usually a standard deviation or confidence interval) expressing the possible range of values around the measured result within which the true value is expected to be with a stated degree of probability. It takes into account all recognized effects operating on the result including overall precision of the complete method, the method and laboratory bias, and matrix effects.

Suggested procedure: Use shellfish free of the target organism(s). For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. Take two aliquots of the sample homogenate appropriately sized for the work and spike one with the target organism(s) at the level of most interest. Do not spike the second aliquot as this is the sample blank. Process each aliquot to determine the concentration for the target organism(s). Repeat this process with a minimum of 15 samples for each shellfish type of interest collected from a variety of growing areas, the same growing area harvested on different days, or from different process lots.

5. Comparability: Comparability is the acceptability of a new or modified analytical method as an alternative or a substitute for an established method in the NSSP. To be acceptable the new or modified method must not produce a significant difference in results when compared to the officially recognized NSSP method. Comparability must be demonstrated for each substrate or type of interest by season and geographic area, if applicable.

Suggested procedure: For each shellfish type of interest use a minimum of 10-12 animals per sample and prepare as a homogenate. For each sample take two aliquots and analyze one by the officially recognized NSSP method and the other by the alternative test method. Naturally incurred samples having a variety of concentrations which span the range of the intended application of the method should be used in the comparison. Analyze a minimum of 20 paired samples, covering each season and a variety of growing areas. In cases where the occurrence of the target organism(s) is intermittent, spiked samples can be used as described above for, but each spiked aliquot should be sub-aliquoted for analysis by both the officially recognized NSSP method and the alternative/test method.

Additional Information

References (Provide references that are pertinent and supplemental to the validation data submitted; these may include peer-reviewed publications in which the method was validated and/or applied, validation packages submitted to other entities, etc. Do not provide references in lieu of data in the "Validation Data" section.)

Standard Operating Procedure (SOP) (Provide a detailed procedure adequate for replication in additional laboratories.)

Laboratory Evaluation Checklist (Provide any additions and/or modifications to the current method checklist for laboratory evaluation based on inclusion of the new matrix/ces.)

Overview of Quality Systems (Provide an overview of the quality assurance/quality control systems utilized in the developer(s)/submitter(s) laboratory.)

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative

2. Submitter	ISSC Training Committee
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	209 Dawson Road
5. Address Line 2	Suite 1
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	Definitions and Training Requirements
11. Specific NSSP Guide Reference	Section I. Purpose and Definitions Section II. Model Ordinance Chapter I, Shellfish Sanitation Program Requirements for the Authority Chapter IV. Shellstock Growing Areas Chapter VIII. Control of Shellfish Harvesting Section III. Public Health Reasons and Explanations Chapter I. Shellfish Sanitation Program
12. Text of Proposal/ Requested Action	Section I. Purpose and Definitions Definitions (120) ~~State~~ Shellfish Standardization Inspector means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). ~~that has successfully completed the FDA standardization training course (or one deemed acceptable by the FDA and the field evaluation phase of shellfish plant inspection with either an FDA standardization officer or a state standardization officer).~~ (121) ~~State~~ Shellfish Standardization Officer means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). ~~that has successfully completed the FDA standardization training course and the field evaluation phase of shellfish plant inspection with an FDA standardization officer.~~ Sanitary Survey Officer means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). Laboratory Evaluation Officer means a person from either a state, federal or foreign authority who has met the requirements established in Chapter 1 @.01 (H.). Section II. Model Ordinance Chapter I, Shellfish Sanitation Program Requirements for the Authority @.01

H. Personnel training requirements for implementing the NSSP
(1) Shellfish Dealer Inspections:
(a) Shellfish Standardization Officer (SSO) shall successfully complete:
(i) the FDA standardization training course,
(ii) seafood HACCP, and;
(iii) the field evaluation by a FDA standardization officer.
(b) Shellfish Standardized Inspector (SSI) shall successfully complete:
(i) the FDA standardization training course,
(ii) seafood HACCP, and;
(iii) the field evaluation by a FDA standardization officer or the SSO.
(2) Growing Area Classification:
(a) Sanitary Survey Officer shall successfully complete:
(i) the FDA growing area course, and;
(ii) have a minimum of one (1) year of on the job experience in a NSSP growing area classification program within the shellfish sanitation program
(3) Patrol Enforcement:
(a) Officers responsible for the patrol of shellfish growing areas shall obtain the following training:
(i) basic law enforcement before assuming patrol duties,
(ii) shellfish control regulations before assuming independent patrol duties, and;
(iii) updated shellfish control regulations at an interval deemed appropriate by the Authority.
(4) Laboratory:
(a) Laboratory Evaluation Officer (LEO) shall successfully complete:
(i) the FDA Laboratory Evaluation Officer training course,
(ii). field standardization by a FDA LEO, and;
(iii) have a minimum of two (2) years of shellfish laboratory experience or a laboratory background with a minimum of three (3) years of bench level experience with the method types that will be evaluated.

Chapter IV. Shellstock Growing Areas @.01
A. General.
(1) The sanitary survey…
(2) The sanitary survey…
(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 reviewed and signed by the Sanitary Survey Officer;
(b) The triennial reevaluation; and
(c) The annual review.

Chapter VIII. Control of Shellfish Harvesting @.01
B. Patrol of Growing Areas.
(1) The Authority shall…
(2) The Authority shall…
(3) Exceptions….

	(4) The Risk Category… (5) The Authority may… ~~(6) Officers responsible for the patrol of shellfish growing areas shall obtain the following training:~~ ~~(a) Basic law enforcement training, before assuming their patrol duties;~~ ~~(b) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties; and~~ ~~(c)~~(a) ~~In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change.~~ Section III. Public Health Reasons and Explanations Chapter I. Shellfish Sanitation Program @.01 H. Training Training is required for state, federal or foreign authorities implementing the NSSP. These training requirements ensure that persons in positions of responsibility understand the foundational elements of the program and demonstrate proficiency. Training is required for four elements of the program; Shellfish Dealer Inspection, Growing Area Classification, Patrol Enforcement and Laboratory. Each training requirement is linked to individuals designated as "Officers" who either sign off on reports or who enforce laws and regulations.
13. Public Health Significance	The modifications to the standardization definitions provide clarification regarding those required to have training. The proposal creates a training requirement for persons responsible for developing sanitary surveys and outlines the training requirements. The proposal creates a definition for Laboratory Evaluation Officer. The requirements are currently outlines in Chapter III. The proposal creates a new section in Chapter I @.01 H. that would include all required program training.
14. Cost Information	

Proposal No. 19-304

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Training Committee
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	209 Dawson Road
5. Address Line 2	Suite 1
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	Training Guidance
11. Specific NSSP Guide Reference	Section IV. Guidance Documents Chapter I. General
12. Text of Proposal/ Requested Action	Section IV Guidance Documents Chapter 1. General .03 Training requirements and recommendations
13. Public Health Significance	This guidance document will create a NSSP training curriculum. This curriculum will include required and recommended training for persons implementing the NSSP. This curriculum will be used in establishing priorities for scheduling and funding training. Currently, funding is made available to states through the FDA/AFDO Training Cooperative Agreement. The joint advisory group will use this curriculum in prioritizing funding requests.
14. Cost Information	

NSSP Training Curriculum

BASIC TRAINING	Integrated Food Safety System	Jurisdiction	Laws, Regulations, Policies and Proceedures	Communication Skills	Professionalism	Data and Information Systems	Public Health Principles	Biological Hazards	Environmental Hazards	Sampling	Tracability	Recalls	NSSP Program Overview

TRAINING BY ELEMENT (bold outline indicates required course)

LEADERSHIP AND MANAGEMENT	**GROWING AREA CLASSIFICATION**	**LABORATORY**	**PATROL ENFORCEMENT**	**SHELLFISH DEALER INSPECTION**
Risk Analysis	Shellfish Growing Area	Laboratories	Basic Law Enforcement	Seafood HACCP
Project Management	Sanitary Surveys of Shellfish Growing Areas; FD242	Shellfish Laboratory Methods and Evaluation; FD246	Shellfish Control Regulations	Shellfish Plant Standardization; FD245
Program Evaluation			Shellfish Control Regulations Update	Shellfish Plant Program
Policy Development			Inspections, Compliance and Enforcement	Inspections, Compliance and Enforcement
Leadership Skills			Shellfish Patrol Program	Labeling
Critical Thinking			Control of Harvest; FD243	Pest Control
Traceback Investigation; ER220				Plumbing
Imports				Basic Inspection; FD190
Investigation Principles				Sanitation Practices
Emergency Response; ER310				Transportation
Foodborne Illness Investigations; ER225				Shellfish State Standardization Officer; FD241
				Special Processes; FD152
				Shellfish Tanks at Retail; FD312

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Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	Kristin DeRosia-Banick David Carey Sue Ritchie
3. Affiliation	Connecticut Department of Agriculture NYS DEC – Division of Marine Resources
4. Address Line 1	190 Rogers Avenue
5. Address Line 2	
6. City, State, Zip	Milford, CT 06460
7. Phone	203-874-0696
8. Fax	
9. Email	Kristin.DeRosia-Banick@ct.gov
10. Proposal Subject	Evaluation of Shellfish Sanitation Program Elements
11. Specific NSSP Guide Reference	Section II Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements
12. Text of Proposal/ Requested Action	A. The goal of shellfish program evaluation shall be to monitor program implementation and work with States to determine where problems may exist and how to address them. 1. Shellfish program evaluation methodologies shall: a. Monitor State Program implementation; b. Assess State program effectiveness; and c. Evaluate the validity of the elements of the NSSP Guide for the Control of Molluscan Shellfish. 2. The minimum components of shellfish program evaluation shall include: a. A description of the program activity; b. A comparison of FDA observations with State observations; and c. A measurement of conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish. 3. The focus of data collection shall be on measuring conformity of shellfish program activities with elements of the NSSP Guide for the Control of Molluscan Shellfish. 4. The types of date collected shall include the following: a. Program records; b. Direct observation made by the evaluator; and c. Data and information from the Authority or other pertinent sources. 5. FDA shall not evaluate Shellfish Sanitation Program Elements while simultaneously training and/or standardizing newly hired FDA Shellfish Specialists or potential candidates being considered for a position as an FDA Shellfish Specialist. 6. FDA shall not evaluate Shellfish Sanitation Program Elements of any firm or a specific growing area that has been utilized to train and/or standardize newly hired FDA Shellfish Specialists or potential candidates being considered for a position as an FDA Shellfish Specialist for at least three (3) years from the date the candidate has been standardized as an FDA Shellfish Specialist with the following exceptions: a. When the State used for FDA training consists of less than the State's total inventory of certified shellfish dealers necessary to achieve a 95% probability of detecting a greater than or equal defect level of 20% for the State's Plant and Shipping Program Element; or b. When the State used for FDA training consists of less than the State's representative sampling plan designed to provide a 95% probability of detecting a 20% or greater defect level for the State's Growing Area

	Classification Program Element. Request that the NSSP Evaluation Committee consider changes to the Evaluation of Shellfish Sanitation Program Elements related to the use of a States' Shellfish Sanitation Program Element Evaluation for the purpose of training and standardizing newly hired FDA Shellfish Specialists. It is requested that the committee consider these or other additions to Section II. Chapter I. @.03 in order to more specifically define the purpose of an FDA PEER as intended to evaluate a States' compliance with the elements of the NSSP Guide for the Control of Molluscan Shellfish versus using a "PEER-modeled" evaluation of an SSCA to conduct training/standardization of a newly hired FDA Shellfish Specialist.
13. Public Health Significance	There are existing requirements in the NSSP for Standardizing FDA Shellfish Specialists and State Standardization Officers to conduct Shellfish Plant Inspections, whereby the inspections of certified dealers' facilities are used not to conduct regulatory inspections of the facilities, but are rather used as an opportunity to train and standardize the skills of the inspector. Similarly, the concept presented here is that a "PEER-modeled" Shellfish Plant and Growing Area Evaluation used for the training and standardization of a newly hired FDA specialist would be defined and separated from the formal PEER evaluation process. The goals of these two types of evaluations should be clearly identified as distinct from one another. The goals of the Evaluation of Shellfish Program Elements, as defined under Section II. Chapter I. @.03. A. is to "monitor program implementation and work with States to determine where problems may exist and how to address them." The purpose of conducting training/standardization of a newly hired FDA specialist is to ensure that newly hired FDA Specialists have the knowledge and ability to evaluate a State program effectively and objectively across the wide rang of State shellfish programs, while ensuring that Shellfish Specialists are standardized amongst themselves in the evaluation of State programs. By separating these two types of evaluations, valuable discussions can occur which may lead to immediate corrective actions of critical deficiencies and ensure that, above all, public health is protected. This would also remove some of the stigma that has resulted from what is perceived as an increase in the number of deficiencies that have been identified in recent years in many States' PEERs in which multiple Specialists with differing levels of experience were evaluating a program. During the period in which a new FDA Specialist is being trained in how to conduct a PEER evaluation of a shellfish program element for the State, information gathered during the training would not be used to determine a States' regulatory compliance with the requirements of the NSSP, but would rather provide an opportunity for an experienced Shellfish Specialist to impart his/her knowledge about how to evaluate a State's compliance, communicate his/her perception of the relative severity of compliance issues, and allows for open communication between a Specialist and the Authority. Issues discussed during the training process may or may not reflect significant compliance issues, however through open discussion, all parties would have the opportunity to communicate where disagreements of NSSP interpretation occur. While the critical importance of training new hires in the role of FDA Shellfish Specialist is recognized, it should also be recognized that there are inherent differences between these two types of evaluations, and the existing application of the PEER Evaluation to the training and Standardization of new FDA hires may be creating unnecessary conflict between State Shellfish Authorities and the FDA Shellfish Specialists tasked with the difficult job of evaluating State programs.

14. Cost Information	No cost will be incurred by the industry or State regulatory agencies.

Proposal 19-306 was moved to Task Force II as Proposal 19-242

Proposal No. 19-307

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	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	Add Audit, Research Management and Training to Standing Committees
11. Specific NSSP Guide Reference	Constitution of Bylaws and Procedures Article IV. Executive Board, Officers, Committees, Section 10.
12. Text of Proposal/ Requested Action	**Article IV. Executive Board, Officers, Committees** **Section 1.** The Conference shall… **Section 2.** The Board shall… **Section 3.** The immediate past… **Section 4.** The Treaty Tribes… **Section 5.** The Board Chairperson… **Section 6.** Each Board member… **Section 7.** Elected Board members… **Section 8.** The Board shall… **Section 9.** The Executive Committee… **Section 10**. The Board may appoint committees from industry, educational institutions, research fields, or any other areas as needed to report to the Board and will advise the Conference on proposals under consideration. Committee appointments will be made from the Conference membership by the Executive Board Chairperson. The following committees shall be designated as standing committees and shall convene as needed or as directed by the Executive Board or Chairperson of the Conference: • Audit Committee • Education Committee; • Foreign Relations Committee; • Laboratory Committee

	• Model Ordinance Effectiveness Review Committee; • Patrol Committee; • Proposal Review Committee; • Research Guidance Committee; • Research Management Committee, • Resolutions Committee; • Shellfish Restoration Committee • Study Design Guidance Committee • Training Committee • Vibrio Illness Review Committee; and • *Vibrio* Management Committee. The Vice-Chairperson of the Conference shall assist the Executive Director in encouraging development of committee work plans and completion of subcommittee assignments prior to convention of the Biennial Meeting.
13. Public Health Significance	The committees that are being proposed as standing committees provide ongoing support for conference activities.
14. Cost Information	

Proposal No. 19-308

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	ISSC Executive Office
3. Affiliation	Interstate Shellfish Sanitation Conference
4. Address Line 1	209 Dawson Road
5. Address Line 2	Suite 1
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	Standardization Definitions
11. Specific NSSP Guide Reference	Section I. Purpose and Definitions, Definitions
12. Text of Proposal/ Requested Action	**(120)** ~~**State**~~ **Shellfish Standardization Inspector** means a person that has successfully completed the FDA Shellfish Plant ~~s~~Standardization training course (or one deemed acceptable by the FDA and the field evaluation phase of shellfish plant inspection with either an FDA Shellfish Specialist standardization officer or a ~~State~~ standardization officer). **(121)** ~~**State**~~ **Shellfish Standardization Officer** means a person that has successfully completed the FDA Shellfish Plant ~~s~~Standardization training course and the field evaluation phase of shellfish plant inspection with an FDA ~~standardization~~ standardized Shellfish Specialist or the National Shellfish Standard.~~officer.~~
13. Public Health Significance	States should be deleted from the titles because MOU countries as well as states are required to be standardized. The other changes are included to reflect actual practice.
14. Cost Information	

Proposal 19-309 was moved to Task Force II as Proposal 19-243

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative

2. Submitter	Danielle Schools, Plant Program Manager, SSO
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7. Phone	(804) 864-7484
8. Fax	(804) 864-7481
9. Email	Danielle.Schools@vdh.virginia.gov
10. Proposal Subject	Plant Element Evaluation Criteria
11. Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority
12. Text of Proposal/ Requested Action	4. Plants Requirements for evaluation of the shellfish plant inspection program elements shall include at a minimum: a. Records audit of past shellfish processing facility inspections for a time frame not to exceed two certification periods. The number of files to be reviewed shall be based upon a representative sampling plan designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The ratio should be based upon the certification type of plants within that State's inventory (i.e. if 50% of plants are Shucker Packers, then 50% of the plants selected for evaluation should be Shucker Packers). b. ~~Direct observation of current shellfish processing facility conditions;~~ Evaluations of SSO(s), either via maintenance inspections or actual standardization depending on the expiration date of current SSO(s) during the plant element evaluation following the standardization protocol outlined in the NSSP MO Section IV Guidance Documents- Chapter III Harvesting, Handling, Processing and Distribution. No more than two SSOs will be evaluated per evaluation and no more than five maintenance inspections will be performed per SSO, not to exceed a total of ten inspections. For states having less than five plants during years when actual standardization is not required, the existing number of plants will be used for the SSO maintenance inspections. c. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program. d. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria evaluated during the file review: i. All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish. ii. ~~95~~ 90% of the certified dealers evaluated in the file review must have been inspected by the State at the frequency required by the current Guide for the Control of Molluscan Shellfish. iii. Where compliance schedules are required, no more than 10% of the certified dealers evaluated in the file review will be without such schedules.

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

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

e. Plant Evaluation Criteria

i. Legal Authority – Chapter I @ .01 B.

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

ii. Initial Certification – Chapter I @ .02 B.

The Plant Sanitation Element will be deemed in compliance with this requirement when all plants reviewed in the file review are certified in accordance with criteria listed below:

(a) HACCP requirements:

(i) A HACCP plan accepted by the Authority

(ii) No critical deficiencies;

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

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

(b) Sanitation and additional Model Ordinance Requirements:

(i) No critical deficiencies;

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

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

iii. Inspection frequency– Chapter I @ .02 F. and G.

The Plant Sanitation Element will be deemed in compliance with this requirement when during the file review , ~~one (1) or~~ 10% or less ~~of~~ plants ~~inspected~~ do~~esn't~~not meet the required inspection frequency ~~.~~

iv. Compliance schedules.

The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated during the file review are found to be without schedules.

v. Follow-Up.

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

vi. Deficiency Follow-up.

The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates via the file review and/or other supporting documentation that all critical deficiencies have been addressed

vii. ~~In-Field Plant Criteria.~~SSO(s) Standardization Maintenance

~~Certified plants will be evaluated to determine compliance with the criteria listed below:~~

~~(a) Shucker/packers and repackers HACCP requirements:~~

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

~~(ii) No critical deficiencies; and~~
~~(iii) Not more than four (4) key deficiencies.~~
~~(b) Shucker/packers and repackers sanitation and additional Model Ordinance requirements:~~
~~(i) No critical deficiencies; and~~
~~(ii) Not more than four (4) key deficiencies.~~
~~(c) Shellstock shippers and reshippers HACCP requirements:~~
~~(i) A HACCP plan accepted by the authority;~~
~~(ii) No critical deficiencies; and~~
~~(iii)Not more than three (3) key deficiencies.~~
~~(d) Shellstock shippers and reshippers sanitation and additional Model Ordinance requirements~~
~~(i) No critical deficiencies; and~~
~~(ii) Not more than three (3) key deficiencies.~~

The Plant Sanitation Element will be deemed in compliance with this requirement when a SSO(s) achieves standardization and/or successfully meets the requirements for the Performance Criteria described in the NSSP MO Section IV Guidance Documents .02 Shellfish Plant Inspection Standardization Procedures

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

i. Conformance: The program is in compliance with all of the criteria listed above and all plants evaluated are in compliance with Chapter I. @.03 B. 4. e. i-vii.

ii. Conformance with Deficiencies:
The program is in compliance with Chapter I. @ .03 B. 4. e. i ~~– vi. and has 25% or less of plants with deficiencies associated with Chapter I. @ .03 B. 4. e. vii.~~
but does not meet the criteria in one (1) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is given a "Needs Improvement" classification in the sections inspectional equipment and communication as described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures but is still standardized

iii.Nonconformance: The program is in compliance with Chapter I. @ .03 B. 4. e. i., but, does not meet the criteria in Chapter I. @.03 B. 4. e. ii. ~~or iii. or iv. or v. or vi. or has greater than 25% (but less than 51%) of plants with deficiencies associated with Chapter I. @.03 B. 4. e. vii~~ or does not meet the criteria in two (2) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is unable to meet the Performance Criteria described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures

iv.Major Nonconformance:
~~C. The program has multiple deficiencies. It is non-compliant with Chapter I. @.03 B. 4. e. i., or two (2) or more of Chapter I. @.03 B. 4. e. ii., or iii., or iv., or v., or vi., or 51% or greater of plants with deficiencies associated with Chapter I. @.03 B. 4. e. vii.~~ The program is non-compliant with both

	Chapter I. @ .03 B. 4. e. i and Chapter 1. @03 B. 4. e. ii, or does not meet the criteria in three (3) of Chapter I. @.03 B. 4. e. iii. or iv. or v. or vi. and the SSO is unable to meet the Performance Criteria described in the NSSP MO Section IV Guidance Documents.02 Shellfish Plant Inspection Standardization Procedures FDA will follow the current compliance program for communication with the State agencies. ~~D. All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Chapter I. @.03B.4.e.ii.~~
13. Public Health Significance	The Plant Element Evaluations conducted by FDA should be a comprehensive evaluation of the State Shellfish Control Authority's (SSCA) ability to promote the protection of public health as it relates to the handing of shellfish. State program audits should have a high level of uniformity and effectiveness in the actual audit criteria. The Plant Element Evaluation Criteria should focus on the actual SSCA's administration of the program with objective measurable items, which represent the SSCA work efforts along with a focus on the State Shellfish Standardization Officers (SSO). The SSCA SSO(s) are responsible for the standardization of the SSCA inspection staff and the NSSP MO already provides a methodology for the standardization and maintenance of the SSO staff which FDA can evaluate as part of the plant element evaluation criteria. The states participating in the ISSC do not all have the same amount or type of dealers. Geographic differences also exist in relation to producing states versus states consisting of mostly secondary processors. Because of this diversity in plant inventory amongst the States , the current in plant criteria element of the plant element evaluation in which FDA Specialist conduct actual inspections at a shellfish dealers facility cannot be uniform in implementation amongst States and does not uniformly assess a SSCA. The inclusion of actual plant inspections and the results of the individual dealer's compliance is not reflective of the SSCAs compliance with the NSSP as the in plant dealer evaluations are only assessments of the actual dealer, for which outside of a regulatory inspection or enforcement actions, the SSCA has no control. For example, a SSCA has no control over a refrigeration unit failing to maintain temperature on any particular day, a septic system failing due to age, a sewage back up, a roach infestation, and so on. Inspections of Shellfish dealer facilities are not true evaluations of the SSCA program's compliance with the NSSP. Focusing on the file review along with an evaluation of the State Shellfish Standardization Officer's (SSO) performance during actual standardization or standardization maintenance evaluations as a program element to be evaluated is key to assessing the uniform implementation of the NSSP MO.
14. Cost Information	none

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
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7. Phone	512-834-6757
8. Fax	512-834-6762
9. Email	kirk.wiles@dshs.texas.gov
10. Proposal Subject	NSSP Plant and Shipping Evaluation Criteria
11. Specific NSSP Guide Reference	Section II. Chapter I Shellfish Sanitation Program for the Authority @.02 Dealer Certification Section II. Chapter I Shellfish Sanitation Program for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements
12. Text of Proposal/ Requested Action	Request that the NSSP Evaluation Committee consider changes to the Evaluation of Shellfish Sanitation Program Elements related to plants. It is requested that the committee review the Cooperative Milk Program State Evaluation process and consider incorporating pertinent aspects into the Shellfish Plant Program element evaluation of state programs. The committee should specifically consider changes to include but are not limited to: • Developing a numerical score for plant inspections. • Using the numerical score to provide an average score for plants during the FDA In-Field Evaluation. This would be a better reflection of the true status of the plants that considers high performing plants as well as low performing plants. • Evaluating a state on model ordinance requirements of the authority to establish an authority performance rating. • Separating plant performance from authority and establish a plant performance rating based on a numerical average score of plants. The current plant element state evaluation is primarily dependent on In-Field Plant criteria. The current designations are in most cases dependent upon plant performance based upon a one-day evaluation by FDA. The criteria is based on plant failures with no credit toward plants that are high performing. The Authorities have model ordinance requirements in the plant element. State performance should be evaluated on those requirements. Authority performance and industry performance should be evaluated separately.
13. Public Health Significance	Changing the focus of the plant element evaluation away from plant performance would ensure that states are following model ordinance requirements that protect public health. Using the current In-Field evaluation process represents a one-day snap shot of industry performance. It is not reflective of whether the authority is meeting requirement of the model ordinance. Separating industry performance from the performance

	of the authority will encourage long term improvement in state implementation of model ordinance plant element requirements.
14. Cost Information	No cost increases.

Proposal No. 19-312

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☒ Administrative
2. Submitter	US Food & Drug Administration (FDA)
3. Affiliation	US Food & Drug Administration (FDA)
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10. Proposal Subject	Plant and Shipping Element Evaluation Criteria
11. Specific NSSP Guide Reference	Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 B. 4.
12. Text of Proposal/ Requested Action	We have been using the plant and shipping evaluation criteria for approximately 10 years and have identified some areas that need review. FDA requests that the NSSP Evaluation Criteria Committee be charged with reviewing the criteria, especially with respect to these areas of concern: (1) In-field Plant Criteria (2) Compliance Schedules (3) Follow-Up for Compliance Schedules (4) Conformance Designations
13. Public Health Significance	Many states have expressed concerns to FDA and the ISSC Executive Office surrounding the Plant and Shipping evaluation criteria. In addition, FDA has identified its own concerns with the implementation of the criteria.
14. Cost Information	No additional cost