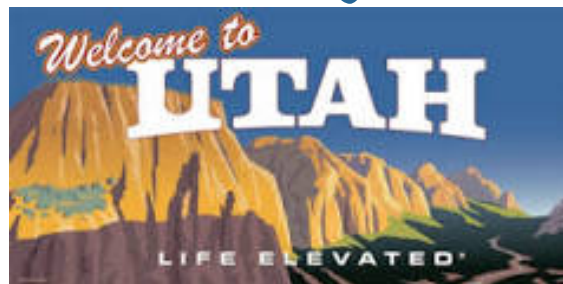


**Interstate Shellfish
Sanitation Conference**

**Task Force III
Proposals for Consideration**

**2015 Biennial Meeting
October 24 – 29, 2015
Sheraton Hotel**

Salt Lake City





ISSC Task Force III 2015 Proposal Inventory

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Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Submitter	Julie Henderson	
Affiliation	Virginia Department of Health Division of Shellfish Sanitation	
Address Line 1	109 Governor Street 6th Floor	
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City, State, Zip	Richmond, VA 23219	
Phone	804-864-7484	
Fax	804-864-7481	
Email	julie.henderson@vdh.virginia.gov	
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... <u>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.</u>	
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.



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Submitter	ISSC Executive Office	
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)	
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Phone	803-788-7559	
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Email	issc@issc.org	
Proposal Subject	Program Element Evaluation Criteria	
Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program	
Text of Proposal/ Requested Action	<p>The ISSC has adopted State Program Evaluation Criteria for several program elements including laboratory, patrol, and processing plants. These evaluation criteria are incorporated into the NSSP as follows:</p> <p>Laboratory: Model Ordinance Chapter II and Guidance Documents Chapter II Growing Areas .12 and Shellfish Laboratory Evaluation Checklists</p> <p>Patrol: Model Ordinance Chapter VIII; Guidance Documents Chapter I General .03; and Guidance Documents Chapter II Growing Areas .09</p> <p>Shellfish Plant Inspection Program: ISSC Constitution, Bylaws, and Procedures Procedure XV</p> <p>The purpose of this proposal is to move all NSSP evaluation criteria used by the USFDA to evaluate State program elements into a new Model Ordinance Chapter XVII. This proposed change will not involve modification of any criteria. The purpose is to locate all State evaluation criteria into one central location. Presently, the criteria are difficult to locate.</p>	
Public Health Significance	The proposed change does not have public health significance.	
Cost Information		
Action by 2013 Task Force III	Recommended referral of Proposal 13-300 to an appropriate committee as determined by the Conference Chairman.	
Action by 2013 General Assembly	Adopted recommendation of 2013 Task Force III on Proposal 13-300.	
Action by FDA May 5, 2014	Concurred with Conference action on Proposal 13-300.	



<p>Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting</p>	<p><input type="checkbox"/> Growing Area</p> <p><input type="checkbox"/> Harvesting/Handling/Distribution</p> <p><input checked="" type="checkbox"/> Administrative</p>
<p>Submitter</p>	<p>ISSC Executive Office</p>
<p>Affiliation</p>	<p>Interstate Shellfish Sanitation Conference (ISSC)</p>
<p>Address Line 1</p>	<p>209 Dawson Road</p>
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<p>Fax</p>	<p>803-788-7576</p>
<p>Email</p>	<p>issc@issc.org</p>
<p>Proposal Subject</p>	<p>Growing Area Classification Criteria</p>
<p>Specific NSSP Guide Reference</p>	<p>To Be Determined</p>
<p>Text of Proposal/ Requested Action</p>	<p>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.</p>
<p>Public Health Significance</p>	<p>Growing area classification criteria will enhance State classification efforts and ensure a high level of uniformity and effectiveness in FDA evaluations.</p>
<p>Cost Information</p>	<p></p>
<p>Action by 2013 Task Force III</p>	<p>The submitter of Proposal 13-301 requested that the following sentence be deleted from the proposal.</p> <p>Most illnesses associated with molluscan shellfish can be traced to problems associated with growing area classification.</p> <p>The Task Force recommended adoption of Proposal 13-301 with the amendment as requested by the submitter.</p>
<p>Action by 2013 General Assembly</p>	<p>Adopted recommendation of 2013 Task Force III on Proposal 13-301.</p>
<p>Action by FDA May 5, 2014</p>	<p>Concurred with Conference action on Proposal 13-301.</p>



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Submitter	Patti Fowler	
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Email	patti.fowler@ncdenr.gov	
Proposal Subject	Changes to Procedure for Evaluation of Shellfish Sanitation Program Elements.	
Specific NSSP Guide Reference	ISSC Constitution, Bylaws & Procedures Procedure XV. Procedure for Evaluation of Shellfish Sanitation Program Elements	
Text of Proposal/ Requested Action	<p>Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum:</p> <p>Subdivision a. Evaluation of growing area classification;</p> <p style="padding-left: 40px;">Subdivision i. Records audit of sanitary survey;</p> <p style="padding-left: 40px;">Subdivision ii. Bacteriological standards;</p> <p style="padding-left: 40px;">Subdivision iii. Growing area classification;</p> <p style="padding-left: 40px;">Subdivision iv. Marine Biotoxin control;</p> <p style="padding-left: 40px;">Subdivision v. Marinas.</p> <p>Subdivision b. Evaluation of shellfish plant inspection program;</p> <p style="padding-left: 40px;">Subdivision i. Records audit of past shellfish processing facility inspections;</p> <p style="padding-left: 40px;">Subdivision ii. Direct observation of current shellfish processing facility conditions;</p> <p style="padding-left: 40px;">Subdivision iii. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.</p> <p style="padding-left: 40px;">Subdivision iv. 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:</p> <p style="padding-left: 80px;">Subdivision (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.</p> <p style="padding-left: 80px;">Subdivision (b) 95% of the certified dealers evaluated must have been inspected by the state at the frequency required by the current Guide for the Control of Molluscan Shellfish.</p> <p style="padding-left: 80px;">Subdivision (c) Where compliance</p>	

	<p>schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.</p> <p>Subdivision (d) States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.</p> <p>Subdivision (e) All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.</p> <p>Subdivision v. Plant Evaluation Criteria</p> <p>Subdivision (a) Legal Authority – Chapter VIII. @ .01 A. (2) (c). 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]</p> <p>Subdivision (b) Initial Certification – Chapter I @ .02 B. The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below: HACCP requirements: (i) A HACCP plan accepted by the Authority (ii) No critical deficiencies; (iii) Not more than 2 key deficiencies; (iv) Not more than 2 other deficiencies. Sanitation and additional Model Ordinance Requirements: (i) No critical</p>
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	<p>deficiencies;</p> <p>(ii) Not more than 2 key deficiencies;</p> <p>(iii) Not more than 3 other deficiencies.</p> <p>Subdivision (c) Inspection frequency – Chapter I @ 02 F and G. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than one plant inspected doesn't meet the required inspection frequency.</p> <p>Subdivision (d) Compliance schedules. The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.</p> <p>Subdivision (e) 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 and if the compliance schedules were not met that administrative action was taken.</p> <p>Subdivision (f) Deficiency Follow-up. The Plant Sanitation Element will be deemed in compliance with this requirement when the state demonstrates that all critical deficiencies have been addressed.</p> <p>Subdivision (g) In-Field Plant Criteria. The in-field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:</p> <p>(i) Shucker/packers and repackers HACCP requirements:</p> <p>a. A HACCP plan</p>
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- accepted by the Authority;
- b. No critical deficiencies;
- c. Not more than 4 key deficiencies;
- d. Not more than 4 other deficiencies.

Sanitation and additional Model Ordinance Requirements

- a. No critical deficiencies except when the State demonstrates that all critical deficiencies have been addressed prior to the completion of the inspection of that facility;
- b. Not more than 4 key deficiencies;
- ~~e. Not more than 4 other deficiencies.~~

- (ii) Shellstock shippers and reshippers HACCP requirements:
 - a. A HACCP plan accepted by the authority;
 - b. No critical deficiencies;
 - c. Not more than 3 key deficiencies;
 - d. Not more than 3 other deficiencies.

Sanitation and additional Model Ordinance Requirements

- a. No critical deficiencies except when the

State demonstrates that all critical deficiencies have been addressed prior to the completion of the inspection of that facility;

- b. Not more than 3 key deficiencies;
- ~~e. Not more than 5 other deficiencies.~~

Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria

- Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations:
- (i) Conformance: The program is in compliance with all of the criteria listed above.
 - (ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with key ~~or other~~ compliance items in Procedure XV. Section 6. Subdivision (b) Sub-division (v) (g).
 - (iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision (v) (a), but, does not meet the criteria in Procedure XV.

	<p>Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with key-or other compliance items Procedure XV.</p> <p>Section 6. Subdivision (b) Subdivision (v) (g).</p> <p>(iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV.</p> <p>Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV.</p> <p>Section 6. Subdivision (b) Subdivision (v) (g).</p> <p>FDA will follow the current compliance program for communication with the State agencies.</p> <p>Subdivision c. Evaluation of shellfish laboratories;</p> <p>Subdivision i. Records audit of laboratory operations;</p> <p>Subdivision ii. Direct observation of current laboratory operating conditions;</p> <p>Subdivision iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.</p> <p>Subdivision d. Evaluation of shellfish growing area patrol;</p> <p>Subdivision i. Records audit of past patrol activities;</p> <p>Subdivision ii. Direct observation of current patrol activities;</p> <p>Subdivision iii. Information collection from the Authority and other pertinent sources.</p>
<p>Public Health Significance</p>	<p>Current Infield Plant Criteria automatically “fails” a plant even if the critical deficiency is address and corrected. This puts a plant in non-compliance but still operating which is inconsistent with the evaluation of deficiency follow-up in Subdivision v (f).</p> <p>States are deemed in compliance when evaluating deficiency follow-up when critical</p>

	<p>deficiencies have been addressed. During a plant inspection, the professional discretion of the inspector is used to determine the severity of the critical deficiency. In some cases a critical deficiency that is addressed and corrected at the time of inspection allows the plant to legally continue to process and sell product. Critical deficiencies that are addressed and corrected at the time of the infield Plant Sanitation Element should be consistent with this.</p> <p>Deficiencies with a criticality code of “Other” vary widely in public health significance and in many cases may be the result of normal wear or use during the operating season. This is especially true with items in Item 17; Plants and Grounds, and Item 21; Equipment Condition, Cleaning, Maintenance and Construction of Non-Food Contact Surfaces. Many of these “other” deficiencies are addressed prior to re-certification for the following season.</p>
<p>Cost Information</p>	<p>No cost to states or industry.</p>
<p>Action by 2013 Task Force III</p>	<p>Recommended referral of Proposal 13-308 to the NSSP Evaluation Criteria Committee</p>
<p>Action by 2013 General Assembly</p>	<p>Adopted recommendation of 2013 Task Force III on Proposal 13-308.</p>
<p>Action by FDA May 5, 2014</p>	<p>Concurred with Conference action on Proposal 13-308.</p>



<p>Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting</p>	<p><input type="checkbox"/> Growing Area</p> <p><input type="checkbox"/> Harvesting/Handling/Distribution</p> <p><input checked="" type="checkbox"/> Administrative</p>
<p>Submitter</p>	<p>ISSC Executive Office</p>
<p>Affiliation</p>	<p>Interstate Shellfish Sanitation Conference (ISSC)</p>
<p>Address Line 1</p>	<p>209 Dawson Road</p>
<p>Address Line 2</p>	<p>Suite 1</p>
<p>City, State, Zip</p>	<p>Columbia, SC 29223-1740</p>
<p>Phone</p>	<p>803-788-7559</p>
<p>Fax</p>	<p>803-788-7576</p>
<p>Email</p>	<p>issc@issc.org</p>
<p>Proposal Subject</p>	<p>Name of Organization</p>
<p>Specific NSSP Guide Reference</p>	<p>ISSC Constitution Bylaws and Procedure Article I. Organization</p>
<p>Text of Proposal/ Requested Action</p>	<p>ARTICLE I. ORGANIZATION</p> <p>Section 1. The name of the organization shall be the "Interstate Shellfish Sanitation Conference <u>Safety Congress</u>", hereinafter referred to as the Conference.</p> <p>Section 2. The Conference <u>Congress</u> shall be directed by and shall be under the control of the various states, federal agencies and shellfish industry that join together to form the Conference <u>Congress</u>.</p> <p>The word "Conference" shall be changed to "Congress" throughout the ISSC Constitution Bylaws and Procedures</p>
<p>Public Health Significance</p>	<p>The present name is misleading regarding the primary function of SSC which is to establish guidelines to foster and improve the sanitation of shellfish in the United States. The change would more clearly define the organization as a deliberative body and would encourage more participation by stakeholders.</p>
<p>Cost Information</p>	



<p>Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting</p>	<p><input type="checkbox"/> Growing Area</p> <p><input type="checkbox"/> Harvesting/Handling/Distribution</p> <p><input checked="" type="checkbox"/> Administrative</p>
<p>Submitter</p>	<p>ISSC Executive Office</p>
<p>Affiliation</p>	<p>Interstate Shellfish Sanitation Conference (ISSC)</p>
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<p>Fax</p>	<p>803-788-7576</p>
<p>Email</p>	<p>issc@issc.org</p>
<p>Proposal Subject</p>	<p><i>Vibrio Vulnificus</i> Illness Review Committee and Laboratory Committee</p>
<p>Specific NSSP Guide Reference</p>	<p>ISSC Constitution, Bylaws, & Procedures Article IV. Executive Board, Officers, Committees</p>
<p>Text of Proposal/ Requested Action</p>	<p>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 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:</p> <ul style="list-style-type: none"> • Education; • Foreign Relations; • Model Ordinance Effectiveness Review; • Patrol; • Proposal Review; • Research Guidance; • Resolutions; • Shellfish Restoration; and • <i>Vibrio Management</i>; • <u><i>Vibrio Vulnificus</i> Illness Review; and</u> • <u>Laboratory</u> <p>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 Annual Meeting.</p> <p><u>Section 16.</u></p> <p><u>The Executive Board Chairperson shall appoint a Laboratory Committee. The Committee will review and make recommendations that are presented to the ISSC for approval. Additionally, the Committee will be requested to provide recommendations regarding laboratory related matters.</u></p> <p>‘Laboratory Methods Review Committee’ shall be changed to ‘Laboratory Committee’ throughout the ISSC Constitution, Bylaws, and Procedures and the</p>



	NSSP Guide for the Control of Molluscan Shellfish.
Public Health Significance	
Cost Information	



<p>Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting</p>	<p><input type="checkbox"/> Growing Area</p> <p><input type="checkbox"/> Harvesting/Handling/Distribution</p> <p><input checked="" type="checkbox"/> Administrative</p>
<p>Submitter</p>	<p>Post-Harvest Processing Review Committee</p>
<p>Affiliation</p>	<p>Interstate Shellfish Sanitation Conference</p>
<p>Address Line 1</p>	<p>209 Dawson Road</p>
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<p>Fax</p>	<p>803-788-7576</p>
<p>Email</p>	<p>issc@issc.org</p>
<p>Proposal Subject</p>	<p>Study Design Guidance Committee</p>
<p>Specific NSSP Guide Reference</p>	<p>ISSC Constitution, Bylaws, & Procedures</p>
<p>Text of Proposal/ Requested Action</p>	<p>ARTICLE IV. EXECUTIVE BOARD, OFFICERS, COMMITTEES</p> <p>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 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:</p> <ul style="list-style-type: none"> • Education; • Foreign Relations; • Model Ordinance Effectiveness Review; • Patrol; • Proposal Review; • Research Guidance; • Resolutions; • Shellfish Restoration; and • <i>Vibrio</i> Management; and • <u>Study Design Guidance.</u> <p>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 Annual Meeting.</p> <p><u>Section 16.</u></p> <p><u>The Executive Board shall appoint a Study Design Guidance Committee. The Committee will develop guidance to assist States and the industry in establishing target levels and developing protocols for studies to determine the effectiveness of post-harvest processes.</u></p>
<p>Public Health Significance</p>	<p>Presently the NSSP requires that States conduct studies to (1) demonstrate the effectiveness of post-harvest processes and practices intended to reduce pathogen levels; or (2) to ensure that processes and practices do not result in unintended growth of pathogens. The NSSP offers no guidance for conducting these studies nor does the NSSP provide recommended pathogen target levels. This committee would serve as</p>



	technical expertise for developing guidance.
Cost Information	



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Submitter	ISSC Executive Office	
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)	
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City, State, Zip	Columbia, SC 29223-1740	
Phone	803-788-7559	
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Email	issc@issc.org	
Proposal Subject	Proposal Submission Procedure	
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XIII. Procedure for the Submission of Proposals	
Text of Proposal/ Requested Action	<p>Section 3. Proposals submitted by any Conference participants requiring Conference action are to be referred to the Executive Director for assignment to the appropriate Task Force. <u>Proposals that lack required information will be deemed incomplete and returned to the submitter.</u> The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid. <u>(Moved from Article XIII. Section 10.)</u></p> <p>Section 10. The Executive Director will consult with the Proposal Review Committee before declaring any problem or proposal invalid.</p>	
Public Health Significance	The purpose of this change is to encourage submitters to review and edit proposals for accuracy.	
Cost Information		



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Submitter	ISSC Executive Office	
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)	
Address Line 1	209 Dawson Road	
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Email	issc@issc.org	
Proposal Subject	Proposal Submission	
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Article XIII. Procedure for the Submission of Proposals	
Text of Proposal/ Requested Action	Add a new Section 8. To Article XIII. as follows: <u>Section 8. Proposals that are deemed technical in nature may be submitted to a committee for review. The committee will provide a recommendation to the appropriate Task Force(s).</u>	
Public Health Significance	Historically, technical, complex, and lengthy proposals have been referred to committee because of the difficulty of fully debating these types of proposals in Task Force. This change would allow a more thorough and meaningful review of the proposal.	
Cost Information		



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Submitter	Ken Moore Patti Fowler	
Affiliation	Interstate Shellfish Sanitation Conference(ISSC) North Carolina Division of Marine Fisheries	
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Phone	803-788-7559 252-808-8147	
Fax	803-788-7576	
Email	issc@issc.org patti.fowler@ncdenr.gov	
Proposal Subject	Unresolved Issue Procedure	
Specific NSSP Guide Reference	ISSC Constitution, Bylaws, and Procedures Procedure IX. Procedures for Handling Complaints and Challenges Regarding the Adequacy of Certification Controls	
Text of Proposal/ Requested Action	<p>Section 2. When an FDA field inspection or an overall program evaluation indicates a state program is not meeting the minimum requirements of the NSSP Model Ordinance, the following actions shall be taken:</p> <p>Subdivision a. FDA shall provide written notification to the state shellfish control authority of the item(s) requiring action with supporting documentation and recommendations as appropriate.</p> <p>Subdivision b. The state shall investigate the item(s) and provide a written response within thirty (30) days that it has been corrected, that a corrective action plan has been developed and will be implemented within a specific time frame, or that it disagrees with FDA's finding. The state shall provide supporting documentation regarding any disagreements. FDA shall review the materials submitted by the state and respond to the state within thirty (30) days.</p> <p>Subdivision c. When a state does not disagree with FDA findings, but does disagree with an FDA report, the state shall provide written notification to FDA of the areas of disagreement with supporting documentation and recommendations as appropriate. FDA shall review the information submitted and provide a written response within thirty (30) days that it agrees and the report has been corrected, that it agrees but the report cannot be corrected, or that it disagrees with the state. FDA shall provide supporting documentation regarding any inability to correct a report or any disagreement. The state shall review the materials submitted by FDA and respond to FDA within thirty (30) days.</p>	



	<p>Subdivision d. If corrective action is taken by the state or by the FDA or a mutually agreed upon action plan is developed and implemented, no action by the Conference will be necessary.</p> <p>Subdivision e. If FDA considers the action (or lack of action) taken by the state to be inadequate to resolve the item(s), <u>FDA shall notify the ISSC Executive Director of</u> or if the state disagrees with FDA's findings or response, it shall be considered an unresolved issue. <u>If the State disagrees with FDA's findings or response, the State may pursue one of the following actions:</u></p> <p style="padding-left: 40px;"><u>Subdivision i. The State may request consultation from the Consultation Subcommittee of the ISSC Unresolved Issues Committee. The purpose of this consultation will allow the State the opportunity to seek guidance from the Consultation Subcommittee regarding program requirements and FDA findings; or</u></p> <p style="padding-left: 40px;"><u>Subdivision ii. The State shall notify the ISSC Executive Director of an unresolved issue.</u></p> <p><u>Subdivision f. Upon notification of an unresolved issue,</u> FDA or the state shall notify the ISSC Executive Director who shall consult with both the state and FDA and prepare recommendations, which will be submitted to the Board with the unresolved issue. The referred unresolved issue shall be handled according to Procedure IX., Section 3. FDA may also take any actions it considers appropriate to deal with any adulterated product.</p>
Public Health Significance	
Cost Information	



Proposal for Task Force Consideration at the ISSC 2015 Biennial Meeting		<input type="checkbox"/> Growing Area <input type="checkbox"/> Harvesting/Handling/Distribution <input checked="" type="checkbox"/> Administrative
Submitter	Executive Office	
Affiliation	Interstate Shellfish Sanitation Conference (ISSC)	
Address Line 1	209 Dawson Road	
Address Line 2	Suite 1	
City, State, Zip	Columbia, SC 29223-1740	
Phone	803-788-7559	
Fax	803-788-7576	
Email	issc@issc.org	
Proposal Subject	Critical Deficiencies	
Specific NSSP Guide Reference	ISSC Constitution Bylaws & Procedures Procedure XV. Section 6. Subdivision vi.	
Text of Proposal/ Requested Action	<p>Subdivision vi. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria</p> <p>Subdivision (a) The overall Plant Sanitation Program element will be assigned one of the following designations:</p> <ul style="list-style-type: none"> (i) Conformance: The program is in compliance with all of the criteria listed above. (ii) Conformance with Deficiencies: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Subdivision v. (a), (b), (c), (d), (e), and (f) and has 25% or less of plants with deficiencies associated with <u>critical</u>, key or other compliance items in {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. (iii) Non-Conformance: The program is in compliance with Procedure XV. Section 6. Subdivision (b) Sub-division (v) (a), but, does not meet the criteria in Procedure XV. Section 6. Subdivision (b) Subdivision (v) Sub-division (b) or (c) or (d) or (e) or (f) has greater than 25% (but less than 51%) of plants with deficiencies associated with <u>critical</u>, key or other compliance items {Procedure XV. Section 6. Subdivision (b) Subdivision (v) (g)}. (iv) Major Non-Conformance: The program has multiple deficiencies. It is non-compliant with Procedure XV. Section 6. Subdivision (b) Subdivision (v) Subdivision (b) or (c) or (d) or (e) or (f) or 51% or greater of plants with deficiencies associated with Procedure XV <u>critical, key or other compliance items {Procedure XV. Section 6. Subdivision (b)</u> 	



	Subdivision (v) (g) <u>1</u> . FDA will follow the current compliance program for communication with the State agencies.
Public Health Significance	Presently Procedure XV. is unclear regarding how observed criticals identified during the in-plant evaluation will be used in assigning overall plant sanitation program designations. The in-field plant criteria in Section 6. Subdivision g. includes critical deficiencies; however, Subdivision vi. does not include any reference to critical deficiencies.
Cost Information	