Proposal No. 2 7 - 1 0 6

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Model Ordinance Effectiveness Review Committee
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9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter I. Shellfish Sanitation Program Requirements for the Authority
11. Text of Proposal/ Requested Action	**@.01 Administration** A. **Scope.** (1) **The Authority shall establish a statewide shellfish safety and sanitation program to regulate:** (a) **The classification of shellfish growing areas;** (b) **The harvesting of shellfish;** (c) **Shellfish processing procedures and facilities;** (d) **Product labeling;** (e) **Storage, handling and packing;** (f) **Shellfish shipment in interstate commerce;** (g) **Shellfish dealers; and** (h) **Bivalve aquaculture.** (2) **All foreign countries shipping shellfish into the United States will have a memorandum of understanding or an equivalency agreement with the United States.** (3) **The regulatory responsibility for growing area and harvest control in federal waters will be the responsibility of the FDA and NOAA.** B. **State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A. Federal Agencies shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of growing areas and harvest control.** C. **Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be made available~~maintained in a central file and made available physically and/or electronically~~ to any interested person upon request, consistent with appropriate State and Federal law.** D. **Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation**

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

E. **Administrative Procedures.**

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

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

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

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

(d) **Assure compliance with Shellfish Plant Inspection Standardization.**

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

F. **Epidemiologically Implicated Outbreaks of Shellfish-Related Illness.**

The Authority shall:

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

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

G. **Commingling.**

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

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

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

(b) **Define a primary dealer;**

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

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

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

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

(1) **Shellfish Dealer Inspections**

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

(i) the FDA standardization training course;

(ii) seafood HACCP; and

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

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

(i) the FDA standardization training course;

(ii) seafood HACCP; and

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

(2) **Growing Area Classification**

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

(i) the FDA growing area course; and

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

(3) **Patrol Enforcement**

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

(i) basic law enforcement before assuming patrol duties;

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

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

(4) **Laboratory**

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

(i) the FDA Laboratory Evaluation Officer training course;

(ii) field standardization by a FDA LEO; and

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

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

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

@.02 Dealer Certification

A. **General**

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

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

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

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

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

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

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

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

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

(a) **Inspection reports of dealers;**
(b) **Notification letters and enforcement actions;**
(c) **Shellfish sample results and follow-up actions taken;**
(d) **Records of complaints or inquiries and follow-up actions taken; and**
(e) **Administrative hearing transcripts and records.**

B. **Initial Certification.**

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

(a) **HACCP requirements:**
(i) **A HACCP plan accepted by the Authority;**
(ii) **No critical deficiencies;**
(iii) **Not more than two (2) key deficiencies; and**
(iv) **Not more than two (2) other deficiencies.**

(b) **Sanitation and additional Model Ordinance Requirements**
(i) **No critical deficiencies;**
(ii) **Not more than two (2) key deficiencies; and**
(iii) **Not more than three (3) other deficiencies.**

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

dealer during the inspection.

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

C. **Renewal of Certification.**

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

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

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

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

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

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

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

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

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

Designations:

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

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

~~(a) Suspended; or~~

~~F. Revoked.~~

~~G.~~F. Inspections.

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

seizures to accomplish the implementation of this Ordinance.

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

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

(ii) Document why an option was selected.

(2) Actions Triggered by Inspections.

(a) When any inspection detects a critical deficiency:

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

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

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

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

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

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

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

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

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

(i) Revise the existing compliance schedule;

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

(iii) Seek other administrative remedies.

@.03 Evaluation of Shellfish Sanitation Program Elements

A. The goal of shellfish program evaluation shall be to monitor program implementation and work with States to determine where problems may exist and how to address them.

1. Shellfish program evaluation methodologies shall:

a. Monitor State program implementation;

b. Assess State program effectiveness; and

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

the NSSP Guide for the Control of Molluscan Shellfish.

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

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

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

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

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

	in question. e. **Nonconformance.** i. **Upon a determination of nonconforming status in any of the technical method components, the laboratory has up to thirty (30) days to demonstrate successful correction of all nonconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming for the laboratory component(s) in question. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory components will continue to be unacceptable for use in support of the NSSP.** ii. **Upon a determination of nonconformance for the Quality Systems component, the laboratory will have to successfully implement a quality system prior to the onsite technical evaluation. Once all nonconformities are reconciled successfully, a technical evaluation for NSSP methods using the appropriate method specific NSSP Shellfish Laboratory Evaluation Checklist will be scheduled with the laboratory.** iii. **When a laboratory is found to be nonconforming in either the technical or quality component or in both components for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority will ensure that an action plan is developed to correct the situation in an acceptable and expeditious manner or discontinue use of the laboratory to support the NSSP.** iv. **For each laboratory component evaluated, the laboratory will be reevaluated either on-site or through a thorough desk audit as determined by the FDA Shellfish LEO and the FDA certified State Shellfish LEO if one is utilized by the State. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP for the laboratory components in question.** 2. **Growing Areas** **Requirements for evaluation of the shellfish growing area program element shall include at a minimum:** a. **Records audit of sanitary survey;**

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

3. **Patrol**

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

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

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

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

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

penalties, which are directly related to effective control of illegal harvest activities;

(c) **The organizational structure of the unit responsible for patrol activities, including:**

(1) **Patrol unit(s) name, address, and phone number;**

(2) **The roster and chain of command;**

(3) **Area assignments that support the frequencies of patrol delineated in B. (2); and**

(4) **A listing of specific vessels, vehicles, and equipment that support the frequencies of patrol delineated in @.01 B. (2);**

(d) **Summaries of training in shellfish patrol techniques;**

(e) **The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;**

(f) **A listing of growing areas where patrol is required;**

(g) **An identification of any patrol problems;**

(h) **The type and frequency of reporting by patrol personnel;**

(i) **Copy of agreements with other agencies responsible for shellfish control activities; and**

(j) **Citations/summons for the past year. If available, this information may include:**

(1) **The number of convictions or dismissals;**

(2) **Fines in dollar amount;**

(3) **Equipment or property confiscations and forfeitures;**

(4) **License suspensions or revocations; and**

(5) **Jail sentences; and**

(6) **Written warnings.**

iii. **Is the patrol policy document updated annually?**
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Authority can demonstrate that the patrol policy document is updated every calendar year. [Key]

f. **Officer Training – Chapter I. @.01 H. (3) (a) (i-iii)**
Has the Patrol Agency met the NSSP patrol training requirements?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Agency can demonstrate that all officers have met or are scheduled for the training requirements of Chapter VIII. @.01 B. (6) before assuming their patrol duties [Key].

g. **Patrol Frequency – Chapter VIII. @.01 B. (2).**

i. **Has the agency determined risk categories for all**

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

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

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

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

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

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

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

i. **The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above patrol evaluation criteria.**

i. **The overall Patrol Program element will be assigned one (1) of the following designations:**

(a) **Conformance: The program is in compliance with all of the criteria listed above.**
(b) **Conformance with Deficiencies: The program only has minor deficiencies associated with a key compliance item.**
(c) **Nonconformance: The program has:**
i. **at least one (1) critical deficiency;**
ii. **two (2) or more key deficiencies; or**
iii. **a repeat [Key] deficiency from the previous evaluation.**
(d) **Major Nonconformance: The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.**

ii. **During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the State patrol agency;**
iii. **Within thirty (30) days of the closeout meeting, the Shellfish Specialist shall provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;**
iv. **Within thirty (30) days of receiving the PEER, the State patrol agency shall provide a written response that indicates:**
(a) **The item(s) was corrected;**
(b) **A correction plan has been developed with a completion date; or,**
(c) **The reasons why the State disagrees with FDA's finding(s).**
v. **Within fifteen (15) days of receipt FDA shall review the State response, and respond to the State;**
vi. **Any CRITICAL item deficiency shall be corrected within thirty (30) days of acceptance by FDA of the correction plan;**
vii. **Any KEY item deficiency shall be corrected within one (1) year of acceptance by FDA of the correction plan.**
viii. **FDA shellfish specialists shall be responsible for monitoring the progress of State action plans.**
ix. **Patrol Program recommendations addressing improvements not associated with the criteria included in Section I or recommendations addressing improvements beyond the requirements of the Model Ordinance should be submitted to the Authority in correspondence.**

4. Plants

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

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

inspections;

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

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

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

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

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

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

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

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

e. **Plant Evaluation Criteria**

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

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

(a) **HACCP requirements:**

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

(ii) **No critical deficiencies;**

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

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

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

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

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

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

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

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

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

sanitation and additional Model Ordinance requirements

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

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

viii.

f. **Conformance Designations**

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

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

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

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

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

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

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

specific compliance schedules in plants audited by FDA.

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

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

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

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

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

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

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

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

acknowledged in FDA correspondence to the Authority.

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

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

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

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