Committee Report

Committee Name : NSSP Evaluation Criteria Committee
Chairperson: Mike Hickey
Date of Meeting: **Approved By:**_____
Recorder: Cathy Mantooth **Printed Name:**

Committee Members Present:

Mike Hickey (Chairperson)
Kathy Brohawn
Erin Butler
David Carey
Jerrod Davis
Johnathan Gerhardt
Terri Gerhardt
Julie Henderson
Shannon Jenkins
Kirk Wiles
Angela Ruple
Joel Hansel (NOAA Delegate)
Jessie Deloach (EPA Delegate)
(FDA Delegate)

Charges

Charge 1: Proposal 11-310 Internal Authority Self-Assessment Using a National Program Standards Manual.

NSSP National Standards Subcommittee Recommendations:

The Subcommittee recommends the NSSP Evaluation Criteria Committee recommend to Task Force III that draft standards be developed for each program element. These draft standards will be developed using the standards from other programs and the FDA draft (see Attachment 1).

It is further recommended that the ISSC identify volunteer states to pilot the standards once the standards are developed. The committee will review results from the pilot and submit a proposal for conference consideration.

NSSP Evaluation Criteria Committee Findings & Conclusions:

The Committee finds merit in the recommendations from the Subcommittee.

The Committee adopted the recommendations of the Subcommittee to continue development of standards for each program element and to further identify volunteer states to pilot said standards.

Recommendations:

Recommend that Task Force III adopt the recommendations of the Committee.

Charge 2: Proposal 13-300 State Program Evaluation Criteria.

Committee Findings & Conclusions:

The committee recognizes that locating the evaluation criteria for the Program into a central location would be a logical step.

Committee Recommendation:

The Committee recommends the creating a new Chapter I @ .03 Procedure For Evaluation of Shellfish Sanitation Program Elements. Existing Evaluation Criteria language from Chapter III, Chapter VIII, Guidance Chapter I .03 and the ISSC Constitution, Bylaws and Procedures will be moved in the new @ .03 section of Chapter I. This change will not result in any modification to existing criteria. This change will be made for the sole purpose of moving all evaluation criteria in one location. (see Attachment 2)

Charge 3: Proposal 13-301 Growing Area Classification Criteria.

NSSP Growing Area Classification Subcommittee Recommendations:

The Growing Area Classification Evaluation Criteria Subcommittee recommends

1) The following criteria be used in evaluating the State Growing Area classification element(see Attachment 3)
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 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.

Committee Findings & Conclusions:

Committee finds merit in the recommendations of the Subcommittee.

Committee adopted the recommendations of the Subcommittee.

Recommendation:

Recommend Task Force III adopt the recommendations of the Committee.

Charge 4: Proposal 13-308 Procedure for Evaluation of Shellfish Sanitation Program Elements.

Committee Findings & Conclusions:

Several changes to Procedure XV of the ISSC Constitution, Bylaws and Procedures are needed to address this proposal.

Committee amended the Proposal to reflect how critical elements would be treated in evaluation (see Attachment 4).

Committee Recommendation:

Recommend adoption of Proposal 12-308 as amended by the Committee by Task Force III

2015 Interstate Shellfish Sanitation Conference - National Voluntary Shellfish Regulatory Program Standards (NVSRP)

Introduction

The National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs. Proposal 11-310 discusses assessing the use of a voluntary continuous program improvement model called Program Standards. If this voluntary model were designed within the ISSC, below is what the framework may entail for just one element of the program (plant and shipping inspection), as well as the benefits of using standards.

What are the Standards? Standards establish a uniform foundation for the design and management of State programs in a specific area such as the regulation of food plants. The elements of the program standards describe best practices of a high-quality regulatory program. Standards are developed in collaboration among states.

Benefits of National Standards

- Promote uniformity and consistency among food safety regulatory programs
- Provides a platform for mutual reliance within the Integrated Food Safety System (IFSS)
- Provides programs with a mechanism for self-assessment and continual improvement against a national standard, a proven quality assurance system
- Improves staff training
- Helps identify resources needs especially for possible legislative consideration
- Improves documentation of accomplishments

How are Standards Different from the NSSP and the current FDA Evaluation?

The NSSP is a model ordinance with guidelines that states adopt and implement for the public health elements of a shellfish program. FDA evaluates state programs on these NSSP elements, specifically Growing Area Classification; *Vibrio* Management; Plant and Shipping; and Control of Harvest. Standards are a voluntary quality assurance system that states program managers use to conduct a self-assessment and evaluate their own program.

Next Steps

- The appropriate ISSC workgroup should conduct a comprehensive gap analysis of how the NSSP is comparable to the MFRPS
- The appropriate ISSC workgroup should develop draft national voluntary shellfish regulatory program standards with standards and appendices
- Standards include Program Elements, Outcomes, and Required Documentation and Appendices include Worksheets and examples
- ISSC Committee members are provided an opportunity to review and provide comments on all standards and appendices
- ISSC adopts final voluntary standards; FDA reviews to concur; Office of Management and Budget (OMB) must publish draft standards for public review and comment under the Paperwork Reduction Act. FDA then releases standards with approved OMB number
- Pilot states begin utilizing standards and reporting back to ISSC Committee on any issues with standards/appendices, not assessment results

2015 Interstate Shellfish Sanitation Conference - National Voluntary Shellfish Regulatory Program Standards (NVSRP)

Manufactured Food Regulatory Program Standards (MFRPS)	Description of Food Program Standard Criteria	Examples of Voluntary Shellfish Standards Components for Shellfish Plant Inspection Program (Bolded items are in NSSP)
1.Regulatory Foundation	State program evaluates the scope of its legal authority and regulatory provisions to ensure the protection of manufactured food. The evaluation includes a determination of how the State's regulatory foundation corresponds to FDA's.	**A. Laws equivalent or identify differences including year of most recent adoption of NSSP** B. Procedures for timely review
2. Training Program	State program has a written training plan that promotes development and demonstrates that all inspectors conducting inspections complete course curriculums, field training, and continuing education.	A. Written training plan that includes minimum classroom and field training (basic and advanced) B. Maintain history of and documentation of inspector training C. Any Standardized State Shellfish Plant Inspector (SSI) Training Coursework D. Basic inspection training requiring #? of joint/audit inspections (w/SSO) E. Passing audits in first #? months and prior to independent inspections **F. Advanced Standardization Shellfish Officer (SSO) Inspection Training (FD425)** **G. Advanced SSO Inspection Field training including #? joint inspections with #? passing audits prior to independent inspections SSO Procedures** H. Any Continuing Education requirements including #? joint/audit inspections w/#? passing audits
3. Inspection Program	State program has an inspection system that provides the foundation for inspecting food plants to determine compliance with Federal, State, and/or local laws	**A. A Risk based inspection program - NSSP** B. Written inspection procedures C. Written inspection report procedure D. Written system to respond to consumer complaints E. Written recall system F. Written system to resolve industry complaints about inspections G. Written sampling procedure
4. Inspection Audit Program	State program has a quality assurance program (QAP) that conducts audits to assess the effectiveness and accuracy of its inspections and sample collections	A. A field inspection audit component (on-site performance evaluation of inspection) B. A desk audit component (performance review of the written reports of inspections and sample collections) C. A Corrective Action plan when rating falls below #?%
5. Illness and Outbreak Response	State program has a written food emergency response program	Written shellfish emergency response program should: **A. Use epidemiological info from state, local or federal agencies to detect incidents or outbreaks of illness** **B. Investigate reports of illness, injury and suspected outbreaks** C. Correlate and analyze data D. Rapidly notify customers and consumers E. Share outbreak reports and surveillance summaries with other agencies F. Disseminate current guidance to industry on food defense G. Provide guidance for immediate notification of law enforcement agencies when intentional contamination or terrorism is suspected or threatened H. Collaborate as necessary with FDA and other federal authorities I. Develop and coordinate the operation of written support service agreements such as MOU/MOA, between the program and the epidemiology support program(s), agreement identifies and describes the roles and responsibilities of each program for: 1. receiving reports of food borne illness or injury 2. performing investigational activities to identify the source of the problem

Manufactured Food Regulatory Program Standards (MFRPS)	Description of Food Program Standard Criteria	Examples of Voluntary Shellfish Standards Components for Shellfish Plant Inspection Program (Bolded items are in NSSP)
		3. reporting and recording the results of the investigations 4. containing or mitigating the incident 5. preventing reoccurrence
6. Compliance and Enforcement Program	State program has a written compliance and enforcement program, which describes its compliance strategy and procedures. The State calculates an overall rating which is used to determine if procedures were followed. Results are used to identify improvements and modify procedures.	A. Written compliance program that describes compliance and enforcement strategies and procedures B. Tracks critical and chronic violations C. Tracks critical and chronic violators D. Uses a risk based system for directed investigation, follow-up or re-inspection as needed E. Establishes timeline for corrective actions F. Has a system to communicate verbal and written policy and guidance to staff G. Annual review of enforcement actions H. Calculates overall rating for performance review
7. Industry and Community Relations	State program participates in activities that support communication and information exchange among stakeholders. It also coordinates or participates in outreach activities that provide information about shellfish sanitation.	A. Document outreach activities B. Perform evaluation and critique of outreach activity
8. Program Resources	State program conducts an assessment of resource needs for staffing, equipment, and funding for the food program.	A. Calculate FTEs needed based on inventory and risk classifications
9. Program Assessment	Managers conduct periodic self-assessments of the food program against the criteria established in each program standard. Self-assessments are designed to identify the strengths and weaknesses of the program and determine areas or functions that need improvement. Subsequent self-assessments are used to track progress toward meeting and maintaining conformance with the program standards.	A. Program conducts self-assessment B. Program elements not met are documented on a strategic plan that identifies improvements needed with a projected completion date
10. Laboratory Support	State program has access to laboratory services needed to support program functions and documents its laboratory capabilities including agreements with external laboratories.	A. Program has a contract or written agreement with its primary services lab **B. Program maintains a list of services for routine and non-routine analyses such as biological hazard determinations (biotoxins, viruses, microbiological)** C. Program utilizes labs that have a current accreditation

Chapter I. Shellfish Sanitation Program New Section

@.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 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;
- (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) 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 the Guidance Documents Chapter II. Growing Areas .12 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
  - (i) Conforms. In order to achieve or maintain conforms status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:
  - (ii) No critical nonconformities in the microbiological or marine Biotoxin (PSP or NSP) component under evaluation have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and
  - (iii) Not more than twelve (12) key nonconformities in the microbiological component or five (5) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and
  - (iv) Not more than seventeen (17) critical, key, and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total for the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and
  - (v) No repeat key nonconformities have been identified in the microbiological

or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

(b) Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:

(i) Not more than three (3) critical nonconformities in the microbiological component or two (2) in the marine Biotoxin (PSP or NSP) component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and

(ii) Not more than twelve (12) key nonconformities in the microbiological component or five (5) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and

(iii) Not more than seventeen (17) critical, key and other nonconformities in total in the microbiological component or nine (9) critical, key and other nonconformities in total in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and

(iv) Not more than one (1) repeat key nonconformity has been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Checklist.

(c) Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:

(i) More than three (3) critical nonconformities in the microbiological component or two (2) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Checklist; or

(ii) More than twelve (12) key nonconformities in the microbiological component or five (5) in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist;

(iii) More than seventeen (17) critical, key, and other nonconformities in total in the microbiological component or more than nine (9) critical, key and other nonconformities in total in the marine Biotoxin (PSP or NSP) components have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; or

(iv) One (1) or more repeat critical or two (2) or more repeat key nonconformities have been identified in consecutive evaluations in either the microbiological or marine Biotoxin components using the appropriate FDA Shellfish Laboratory Evaluation Checklist.

(d) Time Limit on Laboratory Status.

(i) Conforming Status. A laboratory found to be in conforming status for either the microbiological or marine Biotoxin component or for both components 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.

(e) Provisionally Conforms Status. A laboratory found to be in provisionally conforming status for either the microbiological or marine Biotoxin component or for both components 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. 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.

(f) Nonconformance.

(i) Upon a determination of nonconforming status in either the microbiological or marine Biotoxin component or in both 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) When a laboratory is found to be nonconforming in either the microbiological or marine Biotoxin 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.

(iii) 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 Laboratory Evaluation Officer and the FDA certified State Shellfish Laboratory Evaluation Officer 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.

NOTE: This section is being moved from Model Ordinance Chapter III. Laboratory @.01 Quality Assurance Sections D. and E.

Delete Model Ordinance Chapter III. Laboratory @.01 Quality Assurance Sections D. and E.

(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;
(e) Marinas.

(3) Patrol

(a) 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]**

(b) 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 E. (2)
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the appropriate State Authority demonstrates that the industry has been notified of the boundaries. **[Critical]**

(c) Comprehensive Listing of Harvest Restricted Areas – Chapter VIII. @ .01
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 State Authority has a comprehensive listing of all Harvest Restricted areas. **[Critical]**

(d) Patrol Policy Document – Chapter VIII. @.01 B. (7).

(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 State 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;

(iii) The organizational structure of the unit responsible for patrol activities, including;

a. Patrol unit(s) name, address, and phone number;
b. The roster and chain of command;
c. Area assignments that support the frequencies of patrol delineated in B. (2); and
d. A listing of specific vessels, vehicles, and equipment that support

the frequencies of patrol delineated in B. (2);

(iv) Summaries of training in shellfish patrol techniques;

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

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

(vii) An identification of any patrol problems;

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

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

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

a. The number of convictions or dismissals;

b. Fines in dollar amount;

c. Equipment or property confiscations and forfeitures;

d. License suspensions or revocations; and

e. Jail sentences; and

f. Written warnings.

(xi) Is the patrol policy document updated annually?

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

(e) Officer Training – Chapter VIII. @.01 B. (6)

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]**

(i) Basic law enforcement training, before assuming their patrol duties;

(ii) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties;

(iii) In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change.

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

b. When the State Authority achieved 80 – 94 percent of required patrols in all harvest restricted areas the program is considered to be in non- conformance with NSSP patrol frequency requirements. **[Key]**

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

(g) 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]**

(h) 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 of the following designations: (a) **Conformance:** The program is in compliance with all of the criteria listed above.

a. **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item.

b. **Non-Conformance:** 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.

c. **Major Non-Conformance:** 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:

(i) The item(s) was corrected;

(ii) A correction plan has been developed with a completion date; or,

(iii) 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 State Authority in correspondence

NOTE: This section is being moved from Guidance Documents Chapter I. General Section .03 Patrol Evaluation Guidance.

Delete Guidance Document Chapter I. General Section .03 Patrol Evaluation Guidance.

(4) Plants

Requirements for evaluation of the shellfish plant inspection program element 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 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]**

(ii) 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:

a. 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.

b. Sanitation and additional Model Ordinance Requirements:
   i. No critical deficiencies;
   ii. Not more than 2 key deficiencies;
   iii. Not more than 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 no more than one plant 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 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 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.

The In-Field Plant Sanitation Element will be deemed in compliance with this requirement when the plant meets the following criteria:

a. Shucker/packers and repackers HACCP requirements:
   i. A HACCP plan accepted by the Authority;
   ii. No critical deficiencies;
   iii. Not more than 4 key deficiencies;
   iv. Not more than 4 other deficiencies.

b. Shucker/packers and repackers sanitation and additional Model Ordinance requirements:
   i. No critical deficiencies;
   ii. Not more than 4 key deficiencies;
   iii. Not more than 6 other deficiencies.

c. Shellstock shippers and reshippers HACCP requirements:
   i. A HACCP plan accepted by the authority;
   ii. No critical deficiencies;
   iii. Not more than 3 key deficiencies;
   iv. Not more than 3 other deficiencies.

d. Shellstock shippers and reshippers sanitation and additional Model Ordinance requirements
   i. No critical deficiencies;
   ii. Not more than 3 key deficiencies;
   iii. Not more than 5 other deficiencies.

(f) The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above plant evaluation criteria:

(i) The overall Plant Sanitation Program element will be assigned one of the following designations:

a. Conformance: The program is in compliance with all of the criteria listed above.

b. Conformance with Deficiencies:
The program is in compliance with Procedure XV. Section F. (2) (e) (i), (ii), (iii), (iv), (v), and (vii) and has 25% or less of plants with deficiencies associated with key or other compliance items in Procedure XV. Section F. (2) (e) (vii).

c. Non-Conformance:
The program is in compliance with Procedure XV. Section F. (2) (e) (i), but, does not meet the criteria in Procedure XV. Section F. (2) (e) (ii) or (iii) or (iv) or (v) or (vi) has greater than 25% (but less than 51%) of plants with deficiencies associated with key or other compliance items Procedure XV. Section F. (2) (e) (vii).

d. Major Non-Conformance:
The program has multiple deficiencies. It is non-compliant with Procedure XV. Section F. (2) (e) (ii) or (iii) or (iv) or (v) or (vi) or 51% or greater of plants with deficiencies associated with Procedure XV. Section F. (2) (e) (vii).

(3) Evaluation of shellfish laboratories:
(a) Records audit of laboratory operations;
(b) Direct observation of current laboratory operating conditions;
(c) Information collection from the Authority and other pertinent sources concerning laboratory operations.

(4) Evaluation of shellfish growing area patrol:
(a) Records audit of past patrol activities;
(b) Direct observation of current patrol activities;
(c) Information collection from the Authority and other pertinent sources.

C. FDA will follow the current compliance program for communication with the State agencies.

State Growing Area Evaluation Elements

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?

PROCEDURE XV. PROCEDURE FOR EVALUATION OF SHELLFISH SANITATION PROGRAM ELEMENTS.

Section 6. Requirements for evaluation of shellfish sanitation program elements shall include, at a minimum:

Subdivision a. Evaluation of growing area classification;

- Subdivision i. Records audit of sanitary survey;
- Subdivision ii. Bacteriological standards;
- Subdivision iii. Growing area classification;
- Subdivision iv. Marine Biotoxin control;
- Subdivision v. Marinas.

Subdivision b. Evaluation of shellfish plant inspection program;

- Subdivision i. Records audit of past shellfish processing facility inspections;
- Subdivision ii. Direct observation of current shellfish processing facility conditions;
- Subdivision iii. Information collection from the Authority and other pertinent sources concerning shellfish processing facility inspection program.
- 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:
  - Subdivision (a) All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.
  - 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.
  - Subdivision (c) Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.
  - 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.

Subdivision (e) All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.

Subdivision v. Plant Evaluation Criteria

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]

Subdivision (b) Initial Certification – Chapter I @ 02B. 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 deficiencies;
(ii) Not more than 2 key deficiencies;
(iii) Not more than 3 other deficiencies.

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.

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.

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.

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.

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

(i) Shucker/packers and repackers HACCP requirements:

a. A HACCP plan accepted by the Authority;

b. No critical deficiencies;
c. Not more than 4 key deficiencies;
d. ~~Not more than 4 other deficiencies.~~

Sanitation and dditional Model Ordinance Requirements

a. No critical deficiencies;
b. Not more than 4 key deficiencies;
c. ~~Not more than 6 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;
b. Not more than 3 key deficiencies;
c. ~~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 conformance designations~~:~~ based on compliance with the criteria listed in Subdivision v.

(i) Conformance: The

program is in compliance with all of the criteria listed above and all plants evaluated are in compliance with Procedure XV Section 6 Subdivision (b) Subdivision (v) (g)

(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) 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 ~~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. Section 6. Subdivision (b) Subdivision (v) (g).

Subdivision (vii) FDA will follow the current compliance program for communication with the State agencies.

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NOTE: 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 Section 6 Subdivision (b) Subdivision (v) (g).

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