

## **VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS PLANT SANITATION**

### **INTRODUCTION**

The **Voluntary National Shellfish Regulatory Program Standards** (VNSRPS or shellfish program standards) establishes a uniform foundation for the design and management of a molluscan shellfish regulatory program. The shellfish program standards can be applied by State and Tribal programs responsible for the safety and regulation of molluscan shellfish. The elements of the shellfish program standards describe best practices for a high-quality regulatory shellfish program. Achieving conformance with the shellfish program standards will include comprehensive self-assessment and system improvements by the participating shellfish Authority. The use of the systems included in the standards will encourage continuous improvement and innovation in the safety and regulation of molluscan shellfish.

The shellfish program standards are comprised of ten standards that establish requirements for the critical elements of a regulatory program designed to protect the public from shellfish-borne illness and injury. These standards include Regulatory Foundation and Authority; Training; Plant Sanitation Inspection; Inspection Audit; Shellfish Related Illness, Outbreak and Hazards Response Program; Compliance and Enforcement Program; Industry and Community Relations; Program Resources; Program Assessment; and Laboratory Support. The shellfish program standards are not intended to address the performance appraisal processes that authorities may use to evaluate individual employee performance. Shellfish authorities can use the shellfish program standards as a tool to manage and improve the quality of their regulatory program.

The goal is to improve the quality and effectiveness of shellfish regulatory programs in the United States. The development and implementation of these program standards will help Federal, State, and Tribal shellfish programs apply resources and direct regulatory activities with a focus on implementing a quality regulatory program designed to protect public health. This does not replace the requirements of the National Shellfish Sanitary Program (NSSP) Model Ordinance but is intended to complement them and assist and provide a mechanism for self-evaluation for state shellfish control authorities to better comply with the Model Ordinance.

These standards do not replace any requirements of the NSSP but are intended to complement the NSSP, and assist with a mechanism for self-evaluation for shellfish control authorities to better improve their regulatory programs.

Each standard is laid out in the following format to ensure uniformity with other national regulatory program standards: purpose statement (x.1), Reserved for possible removal (x.2), description of program elements (x.3), Reserved for possible removal (x.4), and a list of required documentation (x.5). Sections x.2 and x.4 have been reserved for future removal to simplify the standards. The program elements describe the best practices of a quality regulatory program. Required elements for implementation are found in the program elements (x.3) and documentation (x.5) sections for each standard. Terms in all capital letters correspond to a defined term in the Definition section of the document.

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### **PURPOSE**

The shellfish program standards serve as a guide to regulatory shellfish program managers in the design and management of a quality shellfish regulatory program that uses best practices and provide a means of recognition for programs that apply the standards. Program managers and administrators may establish additional requirements to meet individual program needs. The shellfish program standards are designed to help shellfish regulatory programs enhance the services they support and provide to the public by applying quality system requirements into their daily operating procedures. When applied, the shellfish program standards should:

1. Identify program areas where an agency can have the greatest impact on shellfish safety and sanitation;
2. Assist in identifying program areas most in need of additional resources or attention (such as enforcement or outreach);
3. Provide information needed to justify maintenance or increase in program budgets by assessing the resource needs of the regulatory program and applying available resources to higher risk facilities by maintaining current inventory systems based on risk assessments;
4. Lead to innovations in program implementation and administration by the creation and use of task specific standard operating procedures or expectations of inspector competencies; and
5. Create a system of mutual reliance and systems recognition between stakeholders by the application of quality management practices in a regulatory program.

Each Standard has a self-assessment worksheet. Program participants are not obligated to use the forms provided in this standard. Other manual or automated forms, worksheets and templates may be used if the pertinent data elements are present.

### **BACKGROUND**

The Voluntary National Shellfish Regulatory Program Standards are a result of Proposal 11-310 that was submitted by the state of Virginia to the 2011 Interstate Shellfish Sanitation Conference (ISSC). This proposal recommended adding a new Item H to Model Ordinance Chapter I. @.01 which establishes Administrative requirements for the Authority @.01 Administration Program Evaluation which required "*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.*"

The purpose of this proposal was to require a self-assessment that can be used by Authorities to conduct a comprehensive evaluation of their systems and abilities to promote shellfish safety and public health. An assessment conducted by an Authority would encourage continuous improvement and innovation and assure that individual program activities provide comparability among other domestic and international shellfish programs.

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The 2011 ISSC Task Force III assigned this proposal to the NSSP Evaluation Criteria Committee for the 2013 ISSC. Action by 2013 NSSP Evaluation Criteria Committee (with concurrence by Task Force III, General Assembly, and FDA) recommended referral of Proposal 11-310 to the appropriate committee 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 Program (NSSP) 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” be replaced with the word “may”. The 2013 General Assembly adopted the recommendation and FDA concurred. The 2015 NSSP Evaluation Criteria Committee recommended that draft standards be developed for each program element (plant sanitation, growing area, control of harvest, laboratory). These draft standards are to be developed using the standards from other programs and the FDA draft presented. It was further recommended that the ISSC identify volunteer states to pilot the standards once developed. The committee will review results from the pilot and submit a proposal for conference consideration.”*

The Standards Subcommittee was formed and initially met in Salt Lake City in 2015. The group agreed with the continuation of creating “regulatory program standards” for states to utilize. The subcommittee prepared this draft set of Voluntary National Shellfish Regulatory Program Standards for the plant sanitation element for submission to the NSSP Evaluation Criteria Committee at the 2017 ISSC Meeting. The sub-committee plans to continue working on program standards for the other NSSP elements, unless otherwise directed by the full Committee.

Program managers and other health professionals participating in this voluntary program who have demonstrated means or methods other than those described here may submit those to ISSC for consideration and inclusion in the Voluntary National Shellfish Regulatory Program Standards. Improvements to future versions of the Standards will be made through the ISSC to allow for constant program enhancement and promotion of national uniformity.

### **COMMENTS AND INQUIRIES**

To promote uniform and reasonable application of these Standards, interested persons are invited to submit comments and inquiries to the Interstate Shellfish Sanitation Conference.

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**DEFINITIONS**

1. CONFORMANCE OR CONFORMITY: means the fulfillment of a requirement, specifically a program is using and can demonstrate the use of a particular element, system, or program listed in the Voluntary National Shellfish Regulatory Program Standards (VNSRPS or shellfish program standards).
2. CONSUMER COMPLAINTS: are complaints made by the public regarding shellfish products, facilities, practices, labeling, and any other related activities.
3. CONTACT HOUR: an inspector qualifies for one contact hour of continuing education for each clock hour of participation. Contact hours for a specified presentation, course, or training activity will be recognized.
4. CRITICAL DEFICIENCIES: means a condition or practice which:
  - a) Results in the production of a product that is unwholesome; or
  - b) Presents a threat to the health or safety of the consumer.
5. CURRENT AND FIT-FOR-USE: “current” indicates that documentation is signed and dated in accordance with program policies and procedures that meet criteria in the most current standard. “Fit-for-use” is a quality term used to indicate that a product or service fits the defined purpose for that product or service. For standards, this means the policies and procedures meet the defined purpose.
6. CURRENT EXPERIENCED STAFF: defined by the State program in their training plan.
7. DOCUMENT CONTROL: document control ensures that documents are reviewed for adequacy, approved for release by authorized personnel and distributed to and used at the location where the prescribed activity is performed.
8. ENVIRONMENTAL ASSESSMENT (Also called “Environmental Health Assessment”): means an on-site shellfish product investigation, conducted in conjunction with investigations (e.g., traceback) as needed to assess and rule out the potential that the contaminant of concern was introduced at a particular point in the distribution or production system. This is achieved by identifying contributing factors and environmental antecedents.
9. EQUIVALENT: means that the State law directly references the relevant provision or regulation of the National Shellfish Sanitation Program (NSSP) Model Ordinance. The State program specifies the Model Ordinance that is incorporated into the State law, including the revision date of the State statutory provision or regulation, the date the Model Ordinance provision or regulation was incorporated into the State law, and whether that statutory or regulatory provision is included in whole, in part, or modified from the original.

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10. **EQUIVALENT IN EFFECT:** means that the State law has the same regulatory effect as the relevant National Shellfish Sanitation Program Model Ordinance. A State law may have the same regulatory effect as the Model Ordinance if either a single State law or rule has the same regulatory effect as the Model Ordinance, or when multiple laws of that State are combined and deemed equivalent to a single Model Ordinance provision. In conducting such self-assessment, the State program may need to consult with its legal counsel when a provision is determined to be EQUIVALENT IN EFFECT.

11. **EVALUATION:** means an inspection in which the ability of an inspector is assessed to determine if they are competent to complete independent inspections. The evaluation should assess an inspector's ability to:

- a) Prepare for an inspection
- b) Conduct an inspection
- c) Follow procedures identified by the State for the specific type of inspection
- d) Communicate during the inspection and on the inspection report; and
- e) Assess specialized processes (as applicable).

12. **FIELD INSPECTION AUDIT:** means an inspection in which a state inspector is accompanied by a **QUALIFIED FIELD INSPECTION AUDITOR** (either FDA or State) for the purpose of assessing the quality and performance of inspections. These inspections may be counted under 2.3.3.1 and 2.3.3.2 Field Training as evaluations and under 4.3.2 Field Inspection Audit if Appendix 4.2 is used.

13. **HAZARD:** means any biological, chemical, or physical agent in shellfish that is reasonably likely to cause illness or injury in the absence of its control.

14. **INDUSTRY COMPLAINTS:** are complaints made by Industry about inspections or inspectors.

15. **JOINT FIELD TRAINING INSPECTION:** means an inspection conducted jointly by the FDA and/or state personnel for the purposes of training or enforcement. A joint inspection may be used to provide training to a state inspector during an inspection of a firm and may either be trainer led or trainee led.

16. **NOTEQUIVALENT:** means there is no State law equivalent to the relevant Federal law or regulation, there is such a State law but it does not apply to the State's shellfish plant sanitation program, or the Federal and State laws address the same matter but are inconsistent and do not have the same regulatory effect.

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17. OUTREACH ACTIVITY EVENT: means an outreach activity which the State program hosts, co-hosts or is an invited presenter such as seminars, workshops, conferences, trainings, or meetings that relate to shellfish protection topics and that support communication and information exchange among regulators, industry, academia, and consumer representatives.

18. PRIMARY SERVICING LABORATORY: means any laboratory used by the State program for ongoing or routine testing.

19. QUALIFIED FIELD INSPECTION AUDITOR: means an individual who is recognized by the regulatory jurisdiction's shellfish safety program manager as having field experience and communication skills necessary to audit other inspectors/investigators and who has:

- a) Demonstrated the competency for shellfish inspection auditing to the shellfish program manager;
- b) Successfully completed shellfish inspection training coursework and field training as defined by the Authority;
- c) Been assigned this auditing responsibility; and
- d) Completed the required audit training per the State program requirements.

20. QUALIFIED DATE: qualified date begins when an inspector has completed all course and field elements and has been signed off to do independent inspections.

21. QUALIFIED FIELD INSPECTION TRAINER: means an individual who is recognized by the regulatory jurisdiction's shellfish program manager as having field experience and communication skills necessary to train or supervise other inspectors/investigators and who has:

- a) Demonstrated the competency for shellfish inspection training to the shellfish program manager;
- b) Successfully completed shellfish inspection training coursework and field training in areas per the State program requirements; and
- c) Been assigned this training responsibility.
- d) State program includes a definition of "qualified trainer" within their training plan.

22. RECALL AUDIT CHECKS: are conducted by the State Agency to verify that the firm's recall was successful as defined by the State's recall procedures.

23. REGULATORY FOUNDATION: means laws, regulations, rules, ordinances, or other regulatory requirements that govern the shellfish sanitation program.

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24. SAMPLE COLLECTION: means a program in which the state collects samples as part of their shellfish program in one or more of the sampling types as defined in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish. The program can be based on state defined sampling frequency and does not have to be continuous or routine.
25. SHELLFISH-RELATED INCIDENT: means an unintentional or deliberate contamination, threatened or actual, of shellfish that may occur at any point in the production system (e.g., pre-harvest production, processing, and distribution) and may cause shellfish-related illness, injury, outbreaks and HAZARDS. Examples of SHELLFISH RELATED INCIDENTS include but are not limited to shellfish-borne illness outbreaks and shellfish tampering
26. START DATE: date of newly hired or newly reassigned staff into the shellfish program as the start time for training timelines for employees.
27. STRATEGIC IMPROVEMENT PLAN: means a type of improvement plan that includes the following information: (a) the individual element or documentation requirement of the standard that was not met, (b) improvements needed to meet the program element or documentation requirement of the standard, (c) projected completion dates for each task, (d) personnel responsible, and (e) date completed.
28. TRACEBACK: means (a) The method used to determine the source and scope of the product/processes associated with an outbreak and document the distribution and production chain of the product that has been implicated in a shellfish-borne illness or outbreak. (b) The process by which the origin or source of a cluster of contaminated shellfish is identified.
29. TRACEFORWARD: mean (a) Once the source of an implicated shellfish item is established, investigators may do a "traceforward" to document the distribution of all implicated lots of shellfish from the source. This can help epidemiologists with case finding and can be used to test hypotheses about the outbreak. A product recall also involves a traceforward to determine the suppliers that received the product. (b) Tracking a recalled product from the origin or source through the distribution system.

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**STANDARD No. 1  
Plant Sanitation  
Regulatory Foundation and Authority**

**1.1 Purpose**

This standard describes the elements of the regulatory foundation and authority used by an Authority to implement a Shellfish Plant Sanitation Program under the National Shellfish Sanitation Program (NSSP).

**1.2 Reserved**

**1.3 Program Elements**

**1.3.1 Evaluation of Legal Authority and Regulatory Provisions**

- 1.3.1.1 Assess legal authority and regulatory provisions as applicable to certify, license, inspect, and investigate shellfish harvesters, growers, aquaculturists, and dealers including their facilities; collect and analyze samples; and take enforcement actions.
- 1.3.1.2 Describe the regulatory foundation assessment process (see 1.3.2).
- 1.3.1.3 Identify timeframes for regulatory foundation assessment.
- 1.3.1.4 Describe process for consulting with legal review to determine equivalency-in-effect if necessary.
- 1.3.1.5 Identify statutes, regulations, rules, ordinances and other prevailing regulatory requirements including inter-agency agreements for the Shellfish Plant Sanitation Program that:
  - 1.3.1.5.1 Apply to the regulation;
  - 1.3.1.5.2 Delegate authority;
  - 1.3.1.5.3 Describe the regulatory program's administrative procedures for rulemaking for implementation and enforcement; and
  - 1.3.1.5.4 Describe inter-agency authority and sharing of authority and information in multi-jurisdictional events.

**1.3.2 Regulatory Foundation Assessment**

- 1.3.2.1 Conduct baseline regulatory foundation self-assessment using Appendix 1 Regulatory Foundation Worksheet or equivalent form associated with shellfish laws and regulations to determine equivalency or equivalency-in-effect with current federal laws and regulations.

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- 1.3.2.2 Identify date of applicable federal laws and regulations adopted in Appendix 1, if the Authority does not immediately adopt the most current version by reference.
- 1.3.2.3 Identify other agencies that have authority for any part of the regulatory foundation that the Authority relies upon or coordinates to protect public health on Appendix 1.
- 1.3.2.4 Identify any additional laws and regulations promulgated under the Authority's regulatory authority that are necessary for implementation and enforcement.

**1.4 Reserved**

**1.5 Documents**

- 1.5.1 The program maintains the records listed here:
  - 1.5.1.1 Written procedure for periodic evaluation of legal authority and regulatory provisions as required in 1.3.1.2, 1.3.1.3, and 1.3.1.4.
  - 1.5.1.2 The statutes, regulations, rules, ordinances and other prevailing regulatory requirements 1.3.1.5.
  - 1.5.1.3 Appendix 1 Regulatory Foundation Worksheet or equivalent form.
  - 1.5.1.4 Legal Review, if applicable.

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**STANDARD No. 2  
Plant Sanitation  
Training**

**2.1 Purpose**

This standard describes the essential elements of a training program for inspectors in a state program to ensure they have the knowledge, skills and abilities to competently perform their work in shellfish plant sanitation.

**2.2 Reserved**

**2.3 Program Elements**

**2.3.1 Written Training Plan and Training Records**

- 2.3.1.1 The Authority uses a written training plan that ensures all inspectors receive training required to adequately perform their work assignments.
- 2.3.1.2 The written training plan includes course curriculums which provides for inspection training, continuing education as well as exemptions for recognition of experienced inspectors.
- 2.3.1.3 The training plan requires that each inspector who will conduct shellfish plant inspections complete training curriculum that consists of coursework and field training prior to performing independent shellfish plant inspections.
- 2.3.1.4 The training plan requires that each inspector who will conduct standardizations meet the requirements of the NSSP Model Ordinance.
- 2.3.1.5 Appendix 2.2 or equivalent forms is used and maintained to document and summarize training records provided to inspectors.
- 2.3.1.6 Appendix 2.3 or equivalent forms is used and maintained to document that individual plant sanitation inspector training has been provided.
- 2.3.1.7 The training history for all active and inactive inspectors are kept per the Authority's written record retention policy.
- 2.3.1.8 The Authority's training record summary and individual training records must include the inspector's START DATE or QUALIFIED DATE for inspections.

**2.3.2 Shellfish Plant Inspection Coursework Training**

- 2.3.2.1 Timeframe: The Authority requires each inspector who will conduct shellfish plant inspections complete a training curriculum that consist of coursework prior to performing independent shellfish plant inspections
- 2.3.2.2 Coursework: The minimum shellfish plant inspection coursework training shall consist of subject areas listed below:

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- 2.3.2.3.1 Prevailing statutes, regulations, and ordinances.
- 2.3.2.3.2 (Reserved)
- 2.3.2.3.3 (Reserved)
- 2.3.2.3.4 (Reserved)

**2.3.3 Inspection Field Training**

The Authority requires each inspector staff who will conduct shellfish program inspections to complete field training prior to performing independent shellfish inspections.

- 2.3.3.1 Identify the number of joint field training inspections each inspector who will perform inspections in the shellfish plant sanitation regulatory program must complete with a QUALIFIED FIELD INSPECTION TRAINER prior to conducting independent inspections.
- 2.3.3.2 Identify the number of acceptable field EVALUATIONS conducted with a QUALIFIED FIELD INSPECTION TRAINER.
- 2.3.3.3 The JOINT FIELD TRAINING INSPECTION is conducted in dealer firms that are representative of the dealer firms to be inspected independently by the inspector.
- 2.3.3.4 Each inspector completes the minimum field training requirements prior to conducting independent inspections.

**2.3.4 Reserved**

**2.3.5 Reserved**

- 2.3.6 Training Exemptions for current and newly hired experienced inspection staff.** For experienced staff or where such documentation is not available, the Authority conducts an evaluation of the inspector's previous performance and experience to determine if the inspector has completed the required training or whether additional training is needed.

- 2.3.6.1 Identify the criterion used to grant current and newly hired experienced inspectors staff training exemptions for inspections including if the exemption is from course and/or field work.
  - 2.3.6.2 Explain how the supervisor /training officer will conduct and document evaluations and granted exemptions for current experienced inspectors (as defined by the program) and newly hired experienced staff.
- 2.3.7 Continuing Education (CE) (if applicable or as required by the state environmental health specialists or equivalent board).**

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The Authority requires each inspector who will conduct shellfish plant inspections complete a training curriculum that consists of Continuing Education (CE).

- 2.3.7.1 Identify the number of CONTACT HOURS of continuing education each inspector completed in a specified timeline.
- 2.3.7.2 Identify the timeline for when the continuing education interval starts at the QUALIFIED DATE. This may be when the training cycle is completed.
- 2.3.7.3 Identify the established timeframe used to track continuing education and include the minimum number of contact hours every number of months.
- 2.3.7.4 Identify continuing education programs and activities that fulfill the Authority's requirements for CONTACT HOURS, such as:
  - 2.3.7.4.1 Attendance at national or regional seminars / technical conferences;
  - 2.3.7.4.2 Professional symposiums / college courses;
  - 2.3.7.4.3 Shellfish Program-related training provided by government agencies (e.g., FDA, USDA, NOAA, EPA, CDC, State, local);
  - 2.3.7.4.4 Shellfish Program related conferences and workshops (e.g., ISSC, Regional Shellfish Seminars/Meetings);
  - 2.3.7.4.5 Distance learning opportunities that pertain shellfish sanitation; or
  - 2.3.7.4.6 Training approved by a QUALIFIED FIELD INSPECTION TRAINER.
  - 2.3.7.4.7 Reserved
- 2.3.7.5 The Authority identifies what documentation accompanies each activity submitted for continuing education credit, such as:
  - 2.3.7.5.1 Certificates of completion indicating the course date(s) and number of hours attended or CE credits granted;
  - 2.3.7.5.2 Transcripts from a college or university;
  - 2.3.7.5.3 An agenda and attendance roster; or
  - 2.3.7.5.4 Documentation approved by the QUALIFIED FIELD INSPECTION TRAINER.

### 2.3.8 Coursework Sources

The Authority defines their sources of coursework: (examples below)

- 2.3.8.1 Training provided by a government agency (including in house training).
- 2.3.8.2 Distance learning, for example, satellite downlinks or web-based training.
- 2.3.8.3 Colleges, schools, research centers, and institutes.
- 2.3.8.4 Recognized Safety Alliances.
- 2.3.8.5 Other sources.

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**2.3.9 Corrective and Preventive Actions**

- 2.3.9.1 The Authority identifies procedure used to document corrective and preventative actions to prevent reoccurrences of training plan gaps or areas of improvement.

**2.3.10 Reserved**

**2.4 Reserved**

**2.5 Documents**

The Authority maintains the records listed here (examples below):

- 2.5.1 Appendix 2.1 Self-Assessment Worksheet
- 2.5.2 The Authority's Training Plan
- 2.5.3 Appendix 2.2 Inspector Training Record Summary.
- 2.5.4 Appendix 2.3 Individual Training Record Summary.
- 2.5.5 Documents verifying successful completion of required courses.
- 2.5.6 Course description and/or agendas.
- 2.5.7 Supervisor or supervisor designee signed affidavits/statements and acceptable evaluations for exempting experienced or newly hired inspector training.
- 2.5.8 ACCEPTABLE EVALUATIONS.
- 2.5.9 Documentation for Continuing Education Credits.
- 2.5.10 Documentation for Corrective and Preventative Actions.
- 2.5.11 Reserved

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**STANDARD No. 3  
Plant Sanitation Inspection**

**3.1 Purpose**

This standard describes the elements of a risk-based inspection program that reduces the occurrence of injury and illness due to shellfish as defined by the NSSP.

**3.2 Reserved**

**3.3 Program Elements**

**3.3.1 Dealer Certification**

The Authority defines and maintains an inventory of shellfish dealers for which it has regulatory oversight. The inventory shall be categorized by the dealer certification identified in the NSSP.

- 3.3.1.1 The Authority has a written procedure to ensure their dealer certification criteria and inspection frequencies are consistent with the dealer certification requirements in the current NSSP Model Ordinance Chapter I.02. Dealer Certification.
- 3.3.1.2 The written procedure describes how the dealer inventory is identified and maintained as described in 3.3.1.1.
  - 3.3.1.2.1 The dealer inventory shall identify the certification designation; and
  - 3.3.1.2.2 Dealer certifications includes the minimum inspection frequencies as identified in the NSSP for dealer designation types.

**3.3.2 Inspection Procedure**

The Authority has written procedures for inspecting shellfish dealers, that require the inspectors to:

- 3.3.2.1 Review the previous inspection report and CONSUMER COMPLAINTS.
- 3.3.2.2 Have appropriate equipment and forms to conduct inspections. Note: See Appendix 8.3.
- 3.3.2.3 Make appropriate introductions and explain the purpose and scope of the inspection.
- 3.3.2.4 Establish jurisdiction if appropriate.
- 3.3.2.5 Assess dealer's practices critical to the safe and sanitary production and storage of shellfish.

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- 3.3.2.6 Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded.
  - 3.3.2.7 Recognize significant violative conditions or practices, if present, and record findings consistent with Authority inspection writing procedures.
  - 3.3.2.8 Distinguish between NSSP's critical, key, other and swing observations; and isolated incidents versus trends.
  - 3.3.2.9 Review and evaluate the appropriate records and procedures for the establishment's operation and effectively apply the information obtained from this review during the inspection.
  - 3.3.2.10 Collect adequate evidence and documentation to support inspection observations in accordance with the Authority's inspection procedures.
  - 3.3.2.11 Assess status of current corrective action plan and document any corrections made.
  - 3.3.2.12 Behave professionally and demonstrate proper sanitary practices during the inspection.
  - 3.3.2.13 Use current versions of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish to identify and evaluate the HAZARDS associated with products and processes when conducting inspections.
  - 3.3.2.14 Assess the dealer's implementation of sanitation monitoring for the applicable eight key areas of sanitation.
  - 3.3.2.15 Review the dealer's HACCP plan or necessary process controls and applicable monitoring, verification and deviation or corrective action records, including those related to sanitation.
  - 3.3.2.16 Recognize deficiencies in the dealer's monitoring controls and sanitation procedures through facility observations.
  - 3.3.2.17 Use suitable interviewing techniques.
  - 3.3.2.18 Explain findings clearly and adequately throughout the inspection.
  - 3.3.2.19 Alert the dealer's person in charge when any inspection detects a critical deficiency.
  - 3.3.2.20 Answer questions and provide information in an appropriate manner. Write findings accurately, clearly, and concisely on the NSSP plant inspection form or equivalent and provide a copy to the dealer's person in charge.
  - 3.3.2.21 Additional procedures as required by the Authority.
- 3.3.3 Inspection Reports
- The Authority has written inspection report procedures with the following inspection report elements that require inspectors to:
- 3.3.3.1 Submit the inspection report within designated timeframes;

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- 3.3.3.2 Complete the inspection report form completely and accurately;
- 3.3.3.3 Document violations and observations clearly, legibly, and concisely; and
- 3.3.3.4 Follow up with corrective action, compliance and enforcement if applicable, as required in the NSSP Model Ordinance Chapter I. @.02.H.
- 3.3.3.5 Or other procedures required by the Authority

**3.3.4 Recalls**

The Authority has a written recall system with written recall procedures as defined in the NSSP Section IV. Guidance Documents Chapter V. Illness Outbreaks and Recall Guidance. The recall system includes:

- 3.3.4.1 Sharing information about recalls with relevant agencies and/or stakeholders;
- 3.3.4.2 Promptly removing recalled products from commerce;
- 3.3.4.3 Maintaining essential recall information; and
- 3.3.4.4 Performing RECALL AUDIT CHECKS.
- 3.3.4.5 Or other procedures as required by the Authority

**3.3.5 Consumer Complaints**

The Authority has a system for handling CONSUMER COMPLAINTS. The system contains written procedures for:

- 3.3.5.1 Receiving;
- 3.3.5.2 Tracking;
- 3.3.5.3 Evaluating;
- 3.3.5.4 Responding;
- 3.3.5.5 Closing; and
- 3.3.5.6 Maintaining records of consumer complaints.
- 3.3.5.7 Or other procedures as required by the Authority

**3.3.6 Industry Complaints**

The Authority has a system for handling INDUSTRY COMPLAINTS about inspections. The system contains written procedures for:

- 3.3.6.1 Receiving;
- 3.3.6.2 Evaluating;
- 3.3.6.3 Responding; and
- 3.3.6.4 Maintaining records of industry complaints.
- 3.3.6.5 Other procedures as required by the Authority

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**3.3.7 SAMPLE COLLECTION Reports**

The Authority has written SAMPLE COLLECTION report procedures with the minimum SAMPLE COLLECTION report elements that require inspectors to:

- 3.3.7.1 Submit the SAMPLE COLLECTION report within designated timeframes;
- 3.3.7.2 Complete the SAMPLE COLLECTION report form completely and accurately;
- 3.3.7.3 Follow up with corrective action, compliance and enforcement if applicable;
- 3.3.7.4 Other procedures required by the Authority

**3.4 Reserved**

**3.5 Documents**

The Authority maintains the records listed here:

- 3.5.1 Appendix 3.1 Self-Assessment Worksheet
- 3.5.2 Inventory of facilities for which the Authority has regulatory oversight
- 3.5.3 Written procedure documenting the certification criteria and associated inspection frequencies of certified dealers
- 3.5.4 Written procedures for inspecting specific dealer activities, i.e., shucking/packing/repacking
- 3.5.5 Written inspection report procedure which includes requirement for follow up activities for corrective actions, compliance or enforcement activities
- 3.5.6 Written procedures for product recall system
- 3.5.7 Written procedures for maintaining essential recall information
- 3.5.8 Written procedures for handling CONSUMER COMPLAINTS
- 3.5.9 Written procedures for handling INDUSTRY COMPLAINTS about inspections
- 3.5.10 Written SAMPLE COLLECTION report procedures

**VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS  
PLANT SANITATION**

**STANDARD No. 4  
Plant Sanitation  
Inspection Audit**

**4.1 Purpose**

This standard describes the Quality Assurance Program (QAP) and auditing procedures necessary for an Authority to evaluate the effectiveness and accuracy of its inspection program, inspection records, and sampling records; and identify best practices used to achieve quality inspections and sample collections.

**4.2 Reserved**

**4.3 Program Elements**

**4.3.1 Quality Assurance Program**

The Authority has a written Quality Assurance Program (QAP) that contains written procedures for:

- 4.3.1.1 Conducting FIELD INSPECTION AUDITS as described in section 4.3.2; and
- 4.3.1.2 Conducting inspection report audits as described in section 4.3.3; and
- 4.3.1.3 Conducting SAMPLE COLLECTION report audits as described in section 4.3.4; and
- 4.3.1.4 A corrective action plan as described in section 4.3.5.

**4.3.2 FIELD INSPECTION AUDITS**

- 4.3.2.1 A State Standardization Officer (SSO) or FDA Shellfish Specialist conducts FIELD INSPECTION AUDITS as a QUALIFIED FIELD INSPECTION AUDITOR.
- 4.3.2.2 SSOs have successfully completed shellfish inspection coursework (FD 245) and field training as required by the NSSP prior to conducting FIELD INSPECTION AUDITS.
- 4.3.2.3 Frequency: Two (2) FIELD INSPECTION AUDITS of each inspector are conducted every 36 months.
- 4.3.2.4 Performance Factors: At a minimum, performance factors described in the inspection procedures in Section 3.3.2 within Standard 3: Inspection Program, and as listed in Appendix 4.2 or equivalent form, are evaluated.

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- 4.3.2.5 Documentation: Appendix 4.2 or equivalent form is used to record the rating of each performance factor, and record the calculated performance scores and cumulative score for the Authority's program.

**4.3.3 Inspection Report Audits**

- 4.3.3.1 The Authority audits at least ten percent (10%) of the inspection reports of each dealer type certified by the Authority completed in the last twelve (12) months.
- 4.3.3.2 At least ten percent (10%) of inspection reports of each dealer type certified by the Authority that are reviewed for desk audits are taken from inspections that were field audited as required in 4.3.2.
- 4.3.3.3 Performance Factors: At a minimum, performance factors described in the inspection reports in Section 3.3.3 within Standard 3: Inspection Program, and as listed in Appendix 4.3 or equivalent form, are evaluated.
- 4.3.3.4 Documentation: Appendix 4.3 or equivalent form is used to record the rating of each performance factor and record the calculated performance factor scores and cumulative score for the Authority's program.

**4.3.4. SAMPLE COLLECTION Report Audit**

- 4.3.4.1 The Authority conducts SAMPLE COLLECTION report audits of samples collected by the Authority for a shellfish operation or an illness investigation.
- 4.3.4.2 The Authority audits at least ten percent (10 %) of the SAMPLE COLLECTION reports of each sample type collected by the Authority in the last twelve (12) months.
- 4.3.4.3 Performance Factors: At a minimum, performance factors described in the SAMPLE COLLECTION reports in Section 3.3.7 within Standard 3: Inspection Program, and as listed in Appendix 4.4 or equivalent form are evaluated.
- 4.3.4.4 Documentation: Appendix 4.4 or equivalent form is used to record the rating of each performance factor and record the calculated performance factor scores and cumulative score for the Authority's program.

**4.3.5 Corrective Action Preventative Action Plan**

The Authority has a written corrective action plan for the field inspection, report audit and SAMPLE COLLECTION report audits (4.3.2 through 4.3.4) that identify the action to be taken if any of the following occur for any type of audit.

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- 4.3.5.1 An inspector receives an overall rating below 70 percent, “needs improvement.”
- 4.3.5.2 A single performance factor for the Authority falls below 70 percent acceptable ratings as a result of all audits over a twelve (12) month period.
- 4.3.5.3 An overall rating when an Authority falls below 70 percent acceptable ratings as a result of all audits over a twelve (12) month period.

**4.4 Reserved**

**4.5 Documents**

The Authority maintains the records listed here:

- 4.5.1 Appendix 4.1 Self-Assessment Worksheet or equivalent form
- 4.5.2 Appendix 4.2 Performance Rating for the FIELD INSPECTION AUDITS or equivalent form
- 4.5.3 Appendix 4.3 Performance Rating for Inspection Report Audits or equivalent form
- 4.5.4 Appendix 4.4 Performance Rating for SAMPLE COLLECTION Reports Audits or equivalent form

**VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS  
PLANT SANITATION**

**STANDARD No. 5  
Plant Sanitation  
Shellfish Related Illness, Outbreak and Hazards Response Program**

**5.1 Purpose**

This standard describes the shellfish emergency response functions and related activities necessary to investigate SHELLFISH-RELATED INCIDENTS to stop, control and prevent HAZARDS that are likely to result in a shellfish related foodborne illness, injury or outbreak.

**5.2 Reserved**

**5.3 Program Elements**

**5.3.1 Coordination of Shellfish Related Illness, Outbreak and Hazards Response Activities with other Authorities.**

5.3.1.1 Memorandum of Understanding (MOU) or other documentation with other state agencies: If the responsibility for shellfish related illness and outbreak investigations is assigned to another state agency or Authority, a memorandum of understanding or other documentation with that agency is required to fulfill the requirements of this standard.

5.3.1.2 The Authority has written procedures that:

- 5.3.1.2.1 Identifies and describes the roles, duties, and responsibilities of each program for the requirements in 5.3.2 through 5.3.5;
- 5.3.1.2.2 Describes agency collaboration as necessary with FDA and other appropriate local, state and federal authorities in multi-jurisdictional SHELLFISH-RELATED INCIDENTS;
- 5.3.1.2.3 Designates response coordinator(s) to guide program investigation efforts in collaboration with all agencies involved;
- 5.3.1.2.4 Describes how all relevant agencies are notified in case of SHELLFISH-RELATED INCIDENTS;
- 5.3.1.2.5 Provides guidance for notification of appropriate law enforcement agencies when intentional shellfish contamination is suspected or threatened; and
- 5.3.1.2.6 Describes the maintenance of a list(s) of relevant agencies and emergency contacts and frequency of updates.

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**5.3.2 Surveillance**

The Authority has written procedures that:

- 5.3.2.1 Uses epidemiological information from local, state, or federal agencies to detect incidents or outbreaks of shellfish related illness or injury.
- 5.3.2.2 Maintains notifications of SHELLFISH-RELATED INCIDENTS that are reported to the program, in a log(s) or database(s).

**5.3.3 Investigation/Environmental Assessment**

The Authority has written procedures for:

- 5.3.3.1 Investigating reports of SHELLFISH-RELATED INCIDENTS using the established procedures in NSSP Model Ordinance Chapter I and Chapter II.
- 5.3.3.2 Collecting environmental data (if applicable) using established procedures found in the most current versions of *NSSP Guide for the Control of Molluscan Shellfish, Section IV. Guidance Documents – Chapter V. Illness Outbreaks and Recall Guidance*. Additional resources for developing procedures may include “*International Association for Food Protection Procedures to Investigate Foodborne Illnesses*” and “*Guidelines for Foodborne Disease Outbreak Response*” by Council to Improve Foodborne Outbreak Response.
- 5.3.3.3 Coordinating the TRACEBACK and TRACEFORWARD of shellfish implicated in an illness, injury, outbreak or found to contain a HAZARD in accordance with written procedures.
- 5.3.3.4 Accessing laboratory support for investigation of reports of SHELLFISH-RELATED INCIDENTS.
- 5.3.3.5 Correlating and analyzing ENVIRONMENTAL ASSESSMENT data to identify contributing factors and antecedents that led to shellfish contamination or adulteration causing illness, injury or outbreak.

**5.3.4 Control Measures**

The Authority has written procedures for:

- 5.3.4.1 Mitigating and containing shellfish related illness, injury and HAZARDS through strategies that include industry education, enforcement and public awareness activities.

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- 5.3.4.2 Releasing prevention guidance and information to the public (includes identifying a media person and developing guidelines for coordinating media information with other jurisdictions).

**5.3.5 Post Response**

The Authority has written procedures for:

- 5.3.5.1 Maintaining program investigation and ENVIRONMENTAL ASSESSMENT findings and reports.
- 5.3.5.2 Distributing final program investigation report(s), including an ENVIRONMENTAL ASSESSMENT if completed to relevant agencies responsible for reporting contributing factors and antecedents to CDC.
- 5.3.5.3 Distributing recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach.
- 5.3.5.4 Optional: A process or procedure for conducting a post response assessment to identify areas to improve response activities by using corrective actions.
  - 5.3.5.4.1 Documenting the post response assessment which includes a written corrective action plan (if applicable) for shellfish-borne illness, outbreak and hazards response program investigations if the post response assessment identifies possible corrective actions to improve response activities.

**5.4 Reserved**

**5.5 Documentation**

The Authority maintains the records listed here:

- 5.5.1 Appendix 5.1 Self-Assessment worksheet.
- 5.5.2 A Memorandum of Understanding or other documentation.
- 5.5.3 Written procedures for coordination, surveillance, ENVIRONMENTAL ASSESSMENT, control measures, and post response.
- 5.5.4 Records associated with coordination, surveillance, ENVIRONMENTAL ASSESSMENT, control measures, post response assessments, corrective actions and mutual reliance plans.
- 5.5.5 A log(s) or database(s) that tracks notification and provides records maintenance of shellfish related illnesses, outbreaks, and HAZARDS, whether intentional or unintentional.
- 5.5.6 ENVIRONMENTAL ASSESSMENT, reports and summaries.
- 5.5.7 Optional: Post Response Assessments.
- 5.5.8 Optional: Corrective Actions Plans if applicable.

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**STANDARD No. 6  
Plant Sanitation  
Compliance and Enforcement Program**

**6.1 Purpose (Example of Purpose Statement Below)**

This standard describes the strategies, procedures, and actions used by the Authority to enforce the laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program.

**6.2 Reserved**

**6.3 Program Elements**

**6.3.1 Compliance and Enforcement Program**

The Authority has a written compliance and enforcement program that:

- 6.3.1.1 Contains written compliance and enforcement strategies;
- 6.3.1.2 Describes the procedure to monitor
  - 6.3.1.2.1 CRITICAL and Key deficiencies;
  - 6.3.1.2.2 Repeat deficiencies; and
  - 6.3.1.2.3 Other deficiencies.
- 6.3.1.3 Uses the process as required in the NSSP to determine when an investigation, follow-up, or re-inspection is needed;
- 6.3.1.4 Establishes a framework for compliance and enforcement actions; and
- 6.3.1.5 Has a system to communicate policy and guidance to managerial and non-managerial staff.

**6.3.2 Compliance and Enforcement Performance Review**

The Authority reviews compliance and enforcement actions as defined by the Authority:

- 6.3.2.1 At least annually;
- 6.3.2.2 Document on Appendix 6.2 or equivalent form to evaluate if internal compliance and enforcement actions are followed;
- 6.3.2.3 Use results of the review to identify improvements and modify procedures; and
- 6.3.2.4 Require a corrective action if performance ratings fall below 70 percent.

**6.4 Reserved**

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**6.5 Documentation**

The Authority maintains the records listed here.

- 6.5.1 Appendix 6.1 Self-Assessment Worksheet
- 6.5.2 Written Compliance and Enforcement Program (includes written compliance and enforcement strategies)
- 6.5.3 Appendix 6.2 Performance Review of Enforcement Actions or equivalent form

**VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS  
PLANT SANITATION**

**STANDARD No. 7  
Plant Sanitation  
Industry and Community  
Relations**

**7.1 Purpose**

This standard describes the elements of OUTREACH ACTIVITY EVENTS developed and accomplished by the Authority.

**7.2 Reserved**

**7.3 Program Elements**

The Authority has a written procedure of the methods that will be used for communication and OUTREACH ACTIVITY EVENTS with shellfish stakeholders. The written procedure includes how the Authority will:

- 7.3.1 Identify shellfish stakeholders and methods for communication.
- 7.3.2 Interact with the shellfish stakeholders by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees.
- 7.3.3 Tailor outreach efforts to include dissemination of information using electronic sources and traditional methods such as mailings. Topics of outreach efforts may include shellfish sanitation, investigation strategies, regulatory requirements, violation trends, and emerging issues regarding shellfish.
- 7.3.4 Document and evaluate OUTREACH ACTIVITY EVENTS using Appendix 7.2 or an equivalent form. Include documents such as agendas and meeting summaries and program evaluations.

**7.4 Reserved**

**7.5 Documentation**

The Authority maintains the records listed here.

- 7.5.1 Appendix 7.1 Self-Assessment Worksheet.
- 7.5.2 Appendix 7.2 OUTREACH ACTIVITY EVENTS and Self-Evaluation Worksheet or equivalent documentation.
- 7.5.3 Meeting summaries, agendas, or other records documenting interaction with shellfish stakeholders.
- 7.5.4 Written procedure for methods used to communicate with shellfish stakeholders.

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**STANDARD No. 8  
Plant Sanitation  
Program Resources**

**8.1 Purpose**

This standard describes the elements for assessing the resources (staff, equipment, and funding) needed to support a shellfish regulatory program.

**8.2 Reserved**

**8.3 Program Elements**

**8.3.1 Program Assessment**

The Authority completes the self-assessment to assess staffing, funding, and equipment using Appendix 8.1 or equivalent form. The administrative functions needed to support shellfish dealer inspections must be considered when determining program resources.

**8.3.2 Staffing**

The Authority conducts a calculation for determining a required number of shellfish inspectors and documents the formula used to calculate number of staff needed to conduct inspections and sample collections with supporting data. The Authority has staff to inspect shellfish plants in its establishment inventory at a frequency required in the NSSP and the necessary inspection and travel time.

**Note: Appendix 8.2 provides example formulas that can be used as a baseline for the Authority.**

**8.3.3 Equipment**

The Authority establishes a list of the equipment required and maintained for shellfish plant inspections and sample collections using Appendix 8.3 or equivalent form.

**8.4 Reserved**

**8.5 Documentation**

The Authority maintains the records listed here:

**8.5.1 Appendix 8.1 Self-Assessment Worksheet**

8.5.2 Formula used to calculate number of staff needed to conduct inspections and sample collections with supporting data. Examples on Appendix 8.2.

8.5.3 Appendix 8.3 Inspection Equipment List or equivalent form.

**VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS  
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**STANDARD No. 9  
Plant Sanitation  
Program Assessment**

**9.1 Purpose**

This standard describes the process an Authority uses to assess and demonstrate its implementation and CONFORMANCE with each of the program standards.

**9.2 Reserved**

**9.3 Program Elements**

**9.3.1 Baseline Self-Assessment**

The Authority conducts a baseline self-assessment within the first year to determine if the program meets the elements of each standard. The Authority uses the Appendices and Worksheets contained herein or equivalent forms. The Authority uses the results of its self-assessments to complete the Self-Assessment Summary Report (also known as Appendix 9.1).

**9.3.2 The Authority has a written DOCUMENT CONTROL procedure that may include a master document list. The DOCUMENT CONTROL procedure ensures information contained in the appendices and supporting documents for program elements are CURRENT AND FIT-FOR-USE.**

**9.3.3 Document Control Procedures describes that documents are:**

**9.3.3.1 Reviewed for adequacy;**

**9.3.3.2 Approved for release by authorized personnel;**

**9.3.3.3 Distributed to and used at the location where the prescribed activity is performed; and**

**9.3.3.4 Signed and dated in accordance with document control procedures (electronic or hardcopy).**

**9.3.4 The Authority retain records or procedures required under Section x.5 of each standard for the three previous years, or per the Authority's record retention policy, whichever is longer. Records or procedures can be maintained either electronically or in hardcopy.**

**9.3.5 If the Authority fails to meet any of the program elements and documentation requirements of a standard, the Authority develops a written STRATEGIC IMPROVEMENT PLAN that includes the following information:**

**9.3.5.1 The individual element or documentation requirement of the standard that was not met;**

**VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS  
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- 9.3.5.2 Improvements or corrective actions needed to meet the program element or documentation requirement of the standard;
  - 9.3.5.3 Projected completion dates for each task;
  - 9.3.5.4 Personnel responsible; and
  - 9.3.5.5 Date completed for each task.
- 9.3.6 The Authority reviews self-assessment worksheets/appendices and its STRATEGIC IMPROVEMENT PLAN at least annually or as determined by the individual standard and update as needed.

**9.4 Reserved**

**9.5 Reserved**

**9.6 Documentation**

The Authority maintains records listed here.

- 9.5.1 Appendix 9.1 Self-Assessment Summary Report
- 9.5.2 STRATEGIC IMPROVEMENT PLAN
- 9.5.3 DOCUMENT CONTROL procedure
- 9.5.4 Record retention rules, policies or procedures

**VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS  
PLANT SANITATION**

**STANDARD No. 10  
Plant Sanitation  
Laboratory Support**

**10.1 Purpose**

This standard describes the elements of laboratory support for shellfish plant sanitation regulatory program as defined by the NSSP.

**10.2 Reserved**

**10.3 Program Elements**

**10.3.1 Laboratory Support**

- 10.3.1.1 The Authority has access to a laboratory that is capable of analyzing shellfish samples.
- 10.3.1.2 The Authority maintains a list of services for routine and non-routine analyses such as biological HAZARD determinations.
- 10.3.1.3 The Authority has a contract or documented written agreement with each PRIMARY SERVICING LABORATORY unless under the same administrative agency. The contract or agreement contains the components below:
  - 10.3.1.3.1 Defines the responsibilities of each party;
  - 10.3.1.3.2 Describes the types of testing services to be performed; and
  - 10.3.1.3.3 Describes how exceptions to planned work will be communicated.
- 10.3.1.4 When an Authority uses a laboratory service from a non-primary servicing laboratory, the Authority has documentation of the service provided; the documentation can be in a simplified format, such as a letter, email, etc.

**10.3.2 Reserved**

**10.3.3 Reserved**

- 10.3.4 The Authority ensures all laboratory analysis supporting the NSSP is performed by a laboratory found to conform or provisionally conform by the FDA Shellfish Laboratory Evaluation Officer (LEO) or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the current NSSP Model Ordinance Chapter III. Laboratory @.01 Quality Assurance.

**10.4 Reserved**

**10.5 Documentation**

**VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS  
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The Authority maintains records listed here.

- 10.5.1 Appendix 10 Self-assessment worksheet
- 10.5.2 Contracts or written agreements with PRIMARY SERVICING LABORATORIES
- 10.5.3 A list of laboratories used by the Authority that are non-primary servicing laboratories.
- 10.5.4 Documentation of services provided by PRIMARY SERVICING LABORATORIES and non-primary servicing laboratories.
- 10.5.5 FDA Shellfish Laboratory Evaluation
- 10.5.6 Reserved
- 10.5.7 Reserved

## VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS PLANT SANITATION

### Appendix 1: Regulatory Foundation Worksheet

**Instructions:** Determine if the Authority's laws and regulations are "EQUIVALENT," "EQUIVALENT IN EFFECT," or "NOT EQUIVALENT" to Federal statutes and NSSP regulations. If there is no Authority law or regulation that is EQUIVALENT or EQUIVALENT IN EFFECT, mark the NOT EQUIVALENT box; otherwise list the Authority law or regulation citation and complete the columns for either EQUIVALENT or EQUIVALENT IN EFFECT as appropriate. The Notes section shall be used in part to detail differences between Authority and Federal laws and regulations. If regulatory responsibility for a portion of the NSSP regulation falls under the jurisdiction of another agency, that NSSP row should be left blank. The notes section shall be used to identify which agency has the jurisdiction. Please note that to the extent that any federal statutes or regulations guided below reference FDA regulated products other than shellfish (i.e. tobacco), such references are not intended to be within the scope of this self-assessment which relates only to molluscan shellfish.

Authority Citation	EQUIVALENT		EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
	Revision Date of NSSP Law/Regulation	Date Incorporated into Authority Law	Review Date		
<b>National Shellfish Sanitation Program (NSSP)</b>					
<b>Section I</b> Purposes & Definitions					
<b>Section II</b> <b>Chapter I</b> <b>Requirements for the Authority</b> @.01 Administration					[NSSP Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]
@.02 Dealer Certification					
@.03 Evaluation of Shellfish Sanitation					

## VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS PLANT SANITATION

Authority Citation	EQUIVALENT		EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
	Revision Date of NSSP Law/Regulation	Date Incorporated into Authority Law			
Program Elements					
<b>Chapter II Risk Assessment and Risk Management Requirements for the Authority</b> @.01 Outbreaks of Shellfish Related Illness					
@.02 Shellfish Related Illnesses Associated with V.p.					
@.03 Annual Assessment of V.v. and V.p. Illness and Shellfish Production					
@.04 Presence of Human Pathogens in Shellfish Meats					
@.05 Presence of Toxic Substances in Shellfish Meats					

## VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS PLANT SANITATION

Authority Citation	EQUIVALENT		EQUIVALENT IN EFFECT	NOT EQUIVALENT	Notes
	Revision Date of NSSP Law/Regulation	Date Incorporated into Authority Law			
@.06 V.v. Control Plan					
@.07 V.p. Control Plan					
<b>Chapter III. Laboratory</b> @.01 Quality Assurance					
@/02 Methods					
<b>Chapter VII. Wet Storage in Approved and Conditional Approved Growing Areas</b> @.01 General					
<b>Chapter XI. Shucking and Packing</b> @.01 Heat Shock					

## **VOLUNTARY NATIONAL SHELLFISH REGULATORY PROGRAM STANDARDS PLANT SANITATION**

### **Authority law and regulations:**

Authority laws and regulations used by the Authority to address regulatory responsibilities outside of the NSSP are listed below.

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### **Assessment completed by:**

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(NAME)

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(DATE)

## **Appendix 2.1: Self-Assessment Worksheet**

**Authority:** \_\_\_\_\_

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
<b>2.3.1. Training Plan and Training Records</b>		
Does the Authority:		
1. Has a written training plan that ensures all inspectors receive training required to adequately perform their work assignments?		
2. Maintain a training history for active inspectors?		
3. Maintain a history for all inactive inspectors for three years or per the Authority's record retention policy?		
4. Use Appendix 2.2 or equivalent form to document and summarize all training provided to inspectors?		
5. Use Appendix 2.3 or equivalent form to document training for each inspector?		
6. Training record summary and individual training records include the inspector's Program START DATE?		
<b>2.3.2. Shellfish Inspection Training</b>		
Does the Authority require that each inspector:		
1. Complete all NSSP Inspection Training coursework within 24 months of Program START DATE with shellfish Authority?		
2. Complete the course curriculum in the subject areas listed in 2.3.2.2?		
3. Complete (identify the number acceptable) JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS or EVALUATIONS with a QUALIFIED FIELD INSPECTION TRAINER?		
4. Complete (identify the number acceptable) FIELD INSPECTION AUDITS or EVALUATIONS by a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR (Authority or FDA)?		
5. Complete the minimum field training requirements prior to conducting independent inspections?		
<b>2.3.3. Inspection Field Training</b>		

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
Does the Authority require each inspector:		
1. Who performs shellfish inspections to complete the coursework specific to the type of shellfish inspection they will be performing?		
2. Who performs shellfish inspections to participate in [ <i>identify number</i> ] JOINT FIELD TRAINING INSPECTIONS?		
3. After successful completion of the course; participate in [ <i>identify number</i> ] EVALUATION or FIELD INSPECTION AUDIT with a QUALIFIED FIELD INSPECTION TRAINER or QUALIFIED FIELD INSPECTION AUDITOR prior to conducting independent inspections?		
<b>2.3.6 Experienced Inspectors</b>		
For CURRENT EXPERIENCED STAFF or newly hired experienced STAFF an Authority's training plan shall include the following unless the Authority determines in their training plan that all staff will be required to complete the Authority elements in 2.3.2 and 2.3.3:		
1. Missing course work, does the Authority have a statement or affidavit that explains the background or experience that justifies the waiver?		
2. Missing JOINT FIELD TRAINING INSPECTIONS, does the Authority have a statement or affidavit explaining the background or experience that justifies a waiver of the JOINT FIELD TRAINING INSPECTIONS?		
3. For newly hired who had JOINT FIELD TRAINING INSPECTIONS waived, were two successful EVALUATIONS or FIELD INSPECTION AUDITS completed within 6 months of the inspector's QUALIFIED DATE?		
<b>2.3.7 Continuing Education and Training</b>		
1. Does each inspector conducting shellfish inspections accumulate [ <i>identify number</i> ] CONTACT HOURS of continuing education every [ <i>identify number</i> ] months from the start of the QUALIFIED DATE?		
2. Does the Authority maintain documentation for continuing education credit as outlined in 2.3.7.5?		
<b>2.3.8 Coursework Sources</b>		
Is all coursework, and continuing education coursework obtained from sources listed in 2.3.8.1 – 2.3.8.5?		

Authority Elements	Yes/No	If no, please explain why element is not met
<b>2.3.9 Corrective and Preventative Actions</b>		
1. Does the Authority have a procedure used to document corrective and preventative actions to prevent reoccurrences of training plan gaps or areas of improvement?		

Assessment completed by: \_\_\_\_\_  
 \_\_\_\_\_ (NAME) \_\_\_\_\_ (DATE)

## **Appendix 2.2: Inspector Training Record Summary**

*Instructions: This Appendix is used to document and track inspectors' training status. Enter the name of all active inspectors. Include the Program STARTDATE of employment and record the date the inspector completed the coursework and field training for the curriculums. For continuing education, indicate the QUALIFIED DATE and number of CONTACT HOURS completed.*

Employee name	PROGRAM START DATE	Shellfish Dealer Inspection Curriculum		Continuing Education	
		Course work	Field work	QUALIFIED DATE	CONTACT HOURS
<b>Ex. Susan Brown</b>	<b>1/1/2016</b>	<b>06/1/16</b>	<b>12/1/16</b>	<b>12/1/2016</b>	

Assessment completed by: \_\_\_\_\_  
(NAME) \_\_\_\_\_ (DATE) \_\_\_\_\_

## **Appendix 2.3: Inspector Training Record**

**Authority:** \_\_\_\_\_

**Name of Inspector** \_\_\_\_\_ **PROGRAM START DATE** \_\_\_\_\_

### **Appendix 2.3: Inspector Training Record (continued)**

**Inspector Name** \_\_\_\_\_

<b>Shellfish Inspection Curriculum Fieldwork</b>				
<b>JOINT FIELD TRAINING INSPECTION or FIELD INSPECTION AUDITS</b>	<b>Date Completed</b>	<b>EVALUATION/AUDIT Acceptable (Y/N)</b>	<b>Documentation Available for Review (Y/N)</b>	
<i>Please provide the name of the shellfish dealer and certification number.</i>				
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

### **Appendix 2.3: Inspector Training Record (continued)**

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**Name of Inspector** \_\_\_\_\_ **QUALIFIED DATE** \_\_\_\_\_

<b>CONTINUING EDUCATION COURSEWORK</b>			
<i>A total of (identify number) CONTACT HOURS required every (identify number) months</i>			
<b>Activities in Authority Element 2.3.7</b>			
Type of Activity <i>(Provide Title and Brief Description</i>	Date Completed	Documentation Available for Review (Y/N)	CONTACT HOURS Earned
<i>Subtotal</i>			
<b>Total CONTACT HOURS Earned</b>			

## **Appendix 3.1: Self-Assessment Worksheet**

**Authority:** \_\_\_\_\_

Authority Elements	Yes/No	If no, please explain why element is not met
<b>3.3.1 Dealer Certification Inspection Program and Inventory</b>		
1. Does the Authority have a written procedure documenting the certification criteria and inspection frequencies?		
2. Does the Authority maintain an inventory of shellfish dealers for which the Authority has regulatory oversight?		
<b>3.3.2 Inspection Procedure</b>		
Does the Authority's inspection procedure require inspectors to:		
1. Review the previous inspection report and CONSUMER COMPLAINTS?		
2. Have appropriate forms (if necessary) and equipment <sup>1</sup> that has been verified and maintained as defined by the Authority's standard operating procedures or manufacturer's recommendations?		
3. Make appropriate introductions, and explain the purpose and scope of the inspection?		
4. Establish jurisdiction?		
5. Assess dealer practices critical to the safe and sanitary production and storage of shellfish?		
6. Properly evaluate the likelihood that conditions, practices, components, and/or labeling could cause the product to be adulterated or misbranded?		
7. Recognize significant violative conditions or practices, and record findings consistent with Authority procedures?		
8. Distinguish between critical, key, other and swing observations, and isolated incidents versus trends?		

<sup>1</sup> Voluntary National Shellfish Regulatory Programs Standard 8: Program Resources and appendix 8.3 Inspection Equipment

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
9. Review and evaluate the appropriate operational records and procedures and apply the information obtained from this review?		
10. Collect adequate evidence and documentation in accordance with Authority procedures to support the inspectional observations?		
11. Assess status of current corrective action plan and document any corrections made.		
12. Behave professionally and demonstrate proper sanitary practices during the inspection?		
13. Use current versions of applicable hazard guides or other guidance, to identify and evaluate the HAZARDS associated with product(s) and process(es) when conducting inspections of specialized shellfish and processes?		
14. Assess the dealer's implementation of sanitation monitoring for the applicable eight key areas of sanitation when required by regulation?		
15. When appropriate review the dealer's: scheduled process; HACCP plan or necessary process controls in the absence of a HACCP plan; shellfish safety control plan and applicable monitoring, verification and deviation or corrective action records, including those related to sanitation.		
16. Recognize deficiencies in the dealer's monitoring controls and sanitation procedures through in-facility observations?		
17. Use suitable interviewing techniques?		
18. Explain findings clearly and adequately throughout the inspection?		
19. Alert the dealer's person in charge when any inspection detects a critical deficiency?		
20. Answer questions and provide information in an appropriate manner?		
21. Write findings accurately, clearly, and concisely on the Authority document and provide a copy to dealer's person in charge?		
<b>3.3.3 Inspection Reports</b>		
Does the Authority have written inspection report		

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
procedures that require inspectors to:		
1. Submit inspection report to the Authority in a timely manner?		
2. Complete the inspection report form completely and accurately?		
3. Document violations and observations clearly, legibly, and concisely?		
4. Follow up with corrective action, compliance and enforcement or other procedures required by the Authority?		
<b>3.3.4 Shellfish Recalls</b>		
Does the Authority have a shellfish recall system that has written procedures as written in the NSSP Section IV. Guidance Documents Chapter V Illness Outbreaks and Recall Guidance for:		
1. Sharing information about recalls with relevant agencies?		
2. Ensuring recalled products are removed promptly from the market?		
3. Performing RECALL AUDIT CHECKS or other procedures as required by the Authority?		
<b>3.3.5 CONSUMER COMPLAINTS</b>		
Does the Authority have procedures for receiving, tracking, evaluating, responding to, and closing CONSUMER COMPLAINTS?		
<b>3.3.6 Industry Complaints</b>		
Does the Authority have procedures for receiving, evaluating, and responding to shellfish INDUSTRY COMPLAINTS about inspections?		
<b>3.3.8 Records Retention</b>		
Does the Authority maintain records as required under 9.3.2 for the following:		
1. Inspection reports which include follow up activities?		
2. Essential recall information?		

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
3. CONSUMER COMPLAINTS?		
4. INDUSTRY COMPLAINTS about inspections? <sup>2</sup>		
5. Documentation associated with SAMPLE COLLECTION?		

**Assessment completed by:** \_\_\_\_\_  
 \_\_\_\_\_  
**(NAME)** \_\_\_\_\_  
**(DATE)**

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<sup>2</sup> Records dealing with personnel actions are not subject to review during an ASSESSMENT.

## **Appendix 4.1: Self-Assessment Worksheet**

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**Authority:** \_\_\_\_\_

Authority Elements	Yes/No	If no, please explain why element is not met
<b>4.3.1 Quality Assurance</b>		
The Authority has a written Quality Assurance Program (QAP) that contains written procedures:		
1. Conducting FIELD INSPECTION AUDITS as described in section 4.3.2?		
2. Conducting inspection report audits as described in section 4.3.3?		
3. Conducting sample report audits as described in section 4.3.4?		
4. A corrective action plan as described in section 4.3.5?		
<b>4.3.2 FIELD INSPECTION AUDITS</b>		
Does the Authority:		
1. Use a STATE STANDARDIZATION OFFICER (SSO) OR FDA SHELLFISH SPECIALIST to conduct FIELD INSPECTION AUDITS to verify that inspections are consistently performed per the Authority's written inspection procedures described in Standard 3?		
2. Conduct a minimum of two FIELD INSPECTION AUDITS per inspector conducted every 36 months?		
3. Select inspections for FIELD INSPECTION AUDITS that include the dealers that the inspector is trained for including shucker packers, depuration, and wet storage?		
4. Complete NSSP Inspection form to document FIELD INSPECTION AUDITS?		
5. Complete Appendix 4.2 or equivalent form document overall rating calculations of FIELD INSPECTION AUDITS?		
<b>4.3.3 Inspection Report Audits</b>		
Does the Authority:		
1. Conduct a periodic review of inspection reports to verify that inspectional findings are obtained and reported per established written procedure?		

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
2. Use a random selection of inspection reports based on the number of inspections completed in the last 12 months?		
3. Take ten percent (10%) of inspection reports reviewed from inspections that were FIELD INSPECTION AUDITS?		
4. Complete Appendix 4.3 or equivalent form to document inspection report audits?		
5. Complete Appendix 4.3 or equivalent form to document overall rating calculations of inspection report audits?		

#### **4.3.4 Sample Report Audits**

Does the Authority:		
1. Conduct a periodic review of sample reports to verify that samples were collected, identified, recorded, and submitted per established written procedure?		
2. Use a random selection of sample reports based on the number of samples collected in the last 12 months?		
3. Complete Appendix 4.4 or equivalent form to document sample report audits?		
4. Complete Appendix 4.4 or equivalent form to document overall rating calculations of sample report audits?		

#### **4.3.5 Corrective Action Plan**

Does the Authority have a written corrective action plan that addresses actions when one or more of the conditions below are met:		
1. An inspector receives a rating of “needs improvement”?		
2. A single performance factor for the Authority falls below 70% acceptable ratings?		
3. An overall rating for the Authority falls below 70%?		

**Assessment completed by:** \_\_\_\_\_

(NAME)

(DATE)

## Appendix 4.2: Performance Rating for the Field Inspection Audits

Authority: _____	Performance period: _____	
Performance rating (4): _____		
Reviewed by: _____	Office: _____	Date: _____

Minimum Requirements Standard 3	Dealer identification number and date of inspection (1)																		T O T A L (3)	At (3)	Nl (3)
3.3.2.1																					
3.3.2.2																					
3.3.2.3																					
3.3.2.4																					
3.3.2.5																					
3.3.2.6																					
3.3.2.7																					
3.3.2.8																					
3.3.2.9																					
3.3.2.10																					
3.3.2.11																					
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																				
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																				

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.

## Appendix 4.2: Performance Rating for the Field Inspection Audits (continued)

Authority: _____	Performance period: _____
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Minimum Requirements	Dealer identification number and date of inspection (1)																		TOTAL (3)	At (3)	Not Applicable (3)
Standard 3	Performance ratings (2)																				
3.3.2.12																					
3.3.2.13																					
3.3.2.14																					
3.3.2.15																					
3.3.2.16																					
3.3.2.17																					
3.3.2.18																					
3.3.2.19																					
3.3.2.20																					
3.3.2.21																					
3.3.2.22																					
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																				
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																				

**(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.**

## **Appendix 4.2a: Instructions for Completing the Performance Rating for the Field Inspection Audit Appendix**

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The summary of the performance factor ratings for all FIELD INSPECTION AUDITS allows the Authority to recognize trends in inspectional coverage and identify specific areas in the inspection Authority that may need improvement.

Appendix 4.2 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in Standard 3. A rating below 70 percent indicates a need for improvement and requires corrective action.

**INSTRUCTIONS:** (1) For each field inspection audited, record the auditor’s initials and date of audit in the box.

(2) For each field inspection audited, record the rating for each performance factor listed in Standard 3 (3.3.2.1 through 3.3.2.22). Remove 3.3.2.22 from Appendix 4.2 if the Authority does not require any additional procedures.

A = acceptable; NI = needs improvement.

(3) Record the  $A_t$  and  $NI_t$  for each performance factor.

$A_t$  = horizontal total of acceptable ratings.

$NI_t$  = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the FIELD INSPECTION AUDITS.

Record the rating in the space provided in the box located at the top of Appendix 4.2.

**FORMULA:**

FIELD INSPECTION AUDIT performance rating =  
[  $\sum A_t / (\sum A_t + \sum NI_t)$  ] x 100

**NOTE:**  $\Sigma$  is the statistical symbol for the sum of all numbers.

$\sum A_t$  = vertical sum of acceptable ratings.

$\sum NI_t$  = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of Appendix 4.2 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

### Appendix 4.3: Performance Rating for Inspection Report Audits

Authority: _____	Performance period: _____	
Performance rating (4): _____		
Reviewed by: _____	Office: _____	Date: _____

Minimum Requirements Standard 3	Dealer identification number and date of inspection (1)																		At (3)	NI <sub>t</sub> (3)
	Performance ratings (2)																			
3.3.3.1																				
3.3.3.2																				
3.3.3.3																				
3.3.3.4																				
3.3.3.5																				
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																			
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																			

**(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.**

## Appendix 4.3: Performance Rating for Inspection Report Audits (continued)

Authority: _____	Performance period: _____
------------------	---------------------------

	Dealer identification number and date of inspection (1)																		At (3)	NI <sub>t</sub> (3)
	Performance ratings (2)																			
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																			
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																			

**(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.**

## **Appendix 4.3a: Instructions for Completing Performance Rating for the Inspection Report Audits Appendix**

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The summary of the performance factor ratings for all inspection report audits allows the Authority to recognize trends in inspectional coverage and identify specific areas in the inspection Authority that may need improvement.

Appendix 4.3 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in Standard 3. A rating below 70 percent indicates a need for improvement and requires corrective action.

**INSTRUCTIONS:** (1) For each inspection report audited, record the dealer identification number and date of the inspection in the box.

(2) For each inspection report audited, record the rating for each performance factor listed in Standard 3 (3.3.3.1 through 3.3.3.5). Remove 3.3.3.5 from Appendix 4.3 if the Authority does not require any additional procedures.

A = acceptable; NI = needs improvement.

(3) Record the  $A_t$  and  $NI_t$  for each performance factor.

$A_t$  = horizontal total of acceptable ratings.

$NI_t$  = horizontal total of needs improvement ratings.

(4) Calculate the overall rating for the inspection report audits.

Record the rating in the space provided in the box located at the top of Appendix 4.3.

**FORMULA:**

Inspection report audit performance rating =  
 $[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

***NOTE:  $\sum$  is the statistical symbol for the sum of all numbers.***

$\sum A_t$  = vertical sum of acceptable ratings.

$\sum NI_t$  = vertical sum of needs improvement ratings.

(5) Evaluate audit ratings for a single performance factor. Use the blank page of Appendix 4.3 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

## Appendix 4.4: Performance Rating for the Sample Collection Report Audits

Authority: _____	Performance period: _____
Performance rating (4): _____	
Reviewed by: _____	Office: _____ Date: _____

Performance factors (5)	Sample report identification number and date of SAMPLE COLLECTION (1)																		At (3)	NI <sub>t</sub> (3)
	Performance ratings (2)																			
3.3.7.1																				
3.3.7.2																				
3.3.7.3																				
3.3.7.4																				
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>																			
Total	<i>Enter the final sums (subtotal + sums of (3) on this form).</i>																			

**(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.**

#### Appendix 4.4: Performance Rating for the Sample Report Audits (continued)

Authority: _____															Performance period: _____		
Performance factors (5)	Sample report identification number and date of SAMPLE COLLECTION (1)															At (3)	NI <sub>t</sub> (3)
	Performance ratings (2)																
Total	<i>Enter the sums of (3).</i>																

(5) USE THIS SPACE TO IDENTIFY AND MAKE NOTES ABOUT SINGLE PERFORMANCE FACTORS RATED AS “NEEDS IMPROVEMENT” IN MULTIPLE AUDITS.

## **Appendix 4.4a: Instructions for Completing the Performance Rating for the Sample Report Audits Appendix**

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The summary of the performance factor ratings for all sample report audits allows the Authority to recognize trends in inspectional coverage and identify specific areas in the inspection Authority that may need improvement.

Appendix 4.4 is used to calculate an overall rating for the performance period and identify single performance factors rated as “needs improvement” in multiple audits. The performance factors are described in Standard 3.3.7. A rating below 70 percent indicates a need for improvement and requires corrective action.

- INSTRUCTIONS:**
- (1) For each sample report audited, record the sample report identification number and date of SAMPLE COLLECTION in the box.
  - (2) For each sample report audited, record the rating for each performance factor listed in Standard 3.3.7. Remove 3.3.7.4 from Appendix 4.4 if the Authority does not require any additional procedures.
- A = acceptable; NI = needs improvement.
- (3) Record the  $A_t$  and  $NI_t$  for each performance factor.  
 $A_t$  = horizontal total of acceptable ratings.  
 $NI_t$  = horizontal total of needs improvement ratings.
  - (4) Calculate the overall rating for the sample report audits.  
Record the rating in the space provided in the box located at the top of Appendix 4.4.

**FORMULA:**

Sample report audit performance rating =  
 $[\sum A_t / (\sum A_t + \sum NI_t)] \times 100$

***NOTE:  $\sum$  is the statistical symbol for the sum of all numbers.***

**$\sum A_t$  = vertical sum of acceptable ratings.**

**$\sum NI_t$  = vertical sum of needs improvement ratings.**

- (5) Evaluate audit ratings for a single performance factor. Use the space at the bottom of Appendix 4.4 to identify and make notes about single performance factors rated as “needs improvement” in multiple audits.

## **Appendix 5.1: Self-Assessment Worksheet**

---

**Authority:** \_\_\_\_\_

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
<b>5.3.1 Coordination with Other Authorities</b>		
Does the Authority:		
1. If required, have an MOU for shellfish-borne illness outbreak investigations, if required?		
2. Have a written procedure that identifies and describes the roles, responsibilities and duties of each Authority responsible for supporting shellfish borne illness outbreak response in requirements 5.3.2-5.3.4?		
3. Have a written procedure that describes collaboration with FDA and other agencies in multi-jurisdictional SHELLFISH-RELATED INCIDENTS?		
4. Have a written procedure that designates a response coordinator(s) to guide the Authority's investigation efforts in collaboration with all agencies involved?		
5. Have a written procedure that notifies all relevant agencies of SHELLFISH-RELATED INCIDENTS?		
6. Have written procedure that provides guidance for notification of appropriate law enforcement agencies when intentional shellfish contamination is suspected or threatened?		
7. Have a written procedure that describes the maintenance of a list(s) of relevant agencies and emergency contacts that is updated at least yearly?		
<b>5.3.2 Surveillance</b>		
Does the Authority:		
1. Use epidemiological information from local, Authority, or federal agencies to detect incidents or outbreaks of shellfish borne illness or injury?		
2. Maintain notifications of SHELLFISH-RELATED INCIDENTS that are reported to the Authority, in a		

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
log or database?		
<b>5.3.3 Investigation/Environmental Assessment</b>		
Does the Authority:		
1. Use established procedures with recommended timeframes to investigate reports of SHELLFISH-RELATED INCIDENTS?		
2. Collect ENVIRONMENTAL ASSESSMENT data (if applicable) using established procedures similar to those found in NSSP?		
3. Coordinate the TRACEBACK and TRACEFORWARD of shellfish implicated in an illness, injury, outbreak or found to contain a HAZARD?		
4. Have access to laboratory support for investigation of reports of SHELLFISH-RELATED INCIDENTS?		
5. Correlate and analyze ENVIRONMENTAL ASSESSMENT data to identify contributing factors and antecedents?		
<b>5.3.4 Control Measures</b>		
Does the Authority:		
1. Mitigate and contain shellfish-related illness, injury and HAZARDS through strategies that include industry education, enforcement and public awareness activities?		
2. Maintain a written media procedure with criteria for releasing prevention guidance and information to the public?		
<b>5.3.5 Post Response</b>		
Does the Authority:		
1. Maintain written Authority investigation and ENVIRONMENTAL ASSESSMENT findings and reports?		
2. Distribute final Authority investigation report, including an ENVIRONMENTAL ASSESSMENT, if completed, to relevant agencies responsible for reporting contributing factors and antecedents to CDC?		

<b>Authority Elements</b>	Yes/No	<b>If no, please explain why element is not met</b>
3. Distributes recommendations, when available, from investigation and ENVIRONMENTAL ASSESSMENT findings and reports to relevant agencies and stakeholders responsible for prevention, education and outreach.		

**Assessment completed by:** \_\_\_\_\_  
 \_\_\_\_\_ (NAME) \_\_\_\_\_ (DATE)

## **Appendix 6.1: Self-Assessment Worksheet**

---

**Authority:** \_\_\_\_\_

<b>Program Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
<b>6.3.1 Compliance and Enforcement Authority</b>		
Does the Authority have a written compliance and enforcement program that:		
1. Contains written compliance and enforcement strategies?		
2. Describes the procedure to monitor: Critical, Key, Repeat and Other Deficiencies?		
3. Uses the NSSP process to determine when an investigation, follow-up, or re-inspection is needed?		
4. Establishes a framework for compliance and progressive enforcement actions?		
5. Has a system to communicate policy and guidance to managerial and non-managerial staff?		
<b>6.3.2 Compliance and Enforcement Performance Review</b>		
Does the Authority conduct a review:		
1. Annually?		
2. Document on Appendix 6.2, or equivalent form to evaluate if internal compliance and enforcement actions are followed?		
3. Use results of the review to identify improvements and modify procedures?		
4. Require a corrective action if performance ratings fall below 70 percent?		

**Assessment completed by:** \_\_\_\_\_  
(NAME) \_\_\_\_\_ (DATE) \_\_\_\_\_

## Appendix 6.2: Calculation of the Level of Conformance to Compliance Procedures

Authority: \_\_\_\_\_

**Rating for conformance to compliance procedures (4):**

Shellfish dealer Certification number (1)	Enforcement action recommended (1)	Compliance procedures followed? (2)	USE THIS SPACE TO EXPLAIN IMPROVEMENTS NEEDED TO FOLLOW COMPLIANCE PROCEDURES	
Subtotal	<i>Enter the sum of the totals from all continuation sheets.</i>	A <sub>t</sub> =	NI <sub>t</sub> =	
Total	<i>Enter the final sums -- subtotal + sums of (2) -- on this form.</i>	A <sub>t</sub> =	NI <sub>t</sub> =	

Assessment completed by: \_\_\_\_\_  
(NAME) \_\_\_\_\_ (DATE) \_\_\_\_\_

## **Appendix 6.2: Calculation of the Level of Conformance to Compliance Procedures (continued)**

## **Appendix 6.2a: Instructions for Calculating Performance Review of Enforcement Actions**

Appendix 6.2 is used to record the enforcement actions recommended in the past 12 months and to calculate the Authority's rating for conformance to compliance procedures. Supporting documents should be referenced and maintained by the Authority. Please indicate if an action was taken because voluntary compliance was not achieved.

It is recommended that all cases be reviewed; otherwise, a statistical approach should be used to determine a representative number of cases. Use continuation sheets as necessary.

**INSTRUCTIONS:** (1) Record the shellfish dealer certification number and the recommended enforcement action.

(2) For each type of enforcement action, record the level of conformance to compliance procedures.  
A = acceptable; NI = needs improvement

(3) Record the A and NI .

A = vertical sum of acceptable ratings.

NI = vertical sum of needs improvement ratings.

(4) Calculate the overall rating for the Authority's conformance to compliance procedures. Record the rating in the box located at the top of Appendix 6.2.

**FORMULA:**

Performance factor rating =  $[A / (A + NI)] \times 100$

## **Appendix 7.1: Self-Assessment Worksheet**

**Authority:** \_\_\_\_\_

Authority Elements	Yes/No	If no, please explain why element is not met
<b>7.3 Outreach Methods</b>		
Does the Authority have a written procedure that includes how the program will:		
1. Identify the methods that will be used for communication with the shellfish stakeholders?		
2. Interact with shellfish stakeholders by sponsoring or actively participating in meetings such as task forces, advisory boards, or advisory committees?		
3. Tailor outreach efforts to include dissemination of information using electronic sources and traditional methods such as mailings?		
4. Document and OUTREACH ACTIVITY EVENT using Appendix 7.2 or equivalent form? Include documents such as agendas and meeting summaries and program evaluations.		

## **Appendix 7.2: Outreach Activity Event and Self-Evaluation Worksheet**

**Authority:** \_\_\_\_\_

This worksheet is completed by the Authority to document OUTREACH ACTIVITY EVENTS. Attach verifying documents such as agendas and meeting summaries and Authority evaluations to this form.

### **Section I. Overview of Outreach Activity**

a. Type of OUTREACH ACTIVITY EVENT (check one):

- Seminar       Workshop       Training course  
 Other: \_\_\_\_\_

b. Subject or name of OUTREACH ACTIVITY EVENT: \_\_\_\_\_

c. Date of OUTREACH ACTIVITY EVENT: \_\_\_\_\_

d. Host organization: \_\_\_\_\_

### **Section II. Self-Evaluation of OUTREACH ACTIVITY EVENTS**

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain.</b>
a. The purpose and objectives were clearly defined		
b. The content of the OUTREACH ACTIVITY EVENT was consistent with the objectives		
c. The activity was tailored to a target population Identify target population:		
d. An evaluation was completed by attendees		
e. Authority addressed comments from attendees in Section III of this form.		

### **Section III. Critique of OUTREACH ACTIVITY EVENT**

Discuss what went well, what could be done better, and what more could be done to improve the OUTREACH ACTIVITY EVENT. Address comments from attendees, if available.

Assessment completed by: \_\_\_\_\_  
(NAME) \_\_\_\_\_ (DATE) \_\_\_\_\_

## **Appendix 8.1: Self-Assessment Worksheet**

---

**Authority:** \_\_\_\_\_

**Assessment completed by:** \_\_\_\_\_  
**(NAME)** \_\_\_\_\_ **(DATE)** \_\_\_\_\_

*Does the Authority have sufficient funds, staff, equipment, and resources necessary to meet the program standards? Answer yes or no in each block. If no, please explain. Use additional pages as needed*

<b>Standard</b>		<b>Funding</b>	<b>Staffing</b>	<b>Equipment</b>	<b>Other resources needed</b>
1	Regulatory Foundation				
2	Training Program				
3	Inspection Program				
4	Inspection Audit Program				
5	Shellfish-related Illness, Outbreak and Hazards Response				
6	Compliance and Enforcement				
7	Industry and Community Relations				
8	Program Resources				
9	Program Assessment				
10	Laboratory Support				

## **Appendix 8.1a: Self-Assessment Worksheet Instructions**

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The Appendix 8.1 Self-Assessment Worksheet summarizes the Authority's assessment of their resources for all ten Standards.

### **Instructions:**

For each Standard, the Authority conducts an assessment of resource needs for staffing, equipment, and funding for the shellfish regulatory Authority. Answer yes or no in each block. If the response is no, please explain the additional resources needed. Use additional pages as needed.

When completing Appendix 8.1 the Authority should consider the following items:

- Regulatory Foundation (Standard 1). The Authority has resources to evaluate the scope of its legal Authority and regulatory provisions to ensure the protection of shellfish within its jurisdiction.
- Training Program (Standard 2). The Authority has resources to implement a training plan that ensures all inspectors conducting shellfish inspections complete course curriculums, field training, and continuing education to adequately perform their work.
- Inspection Program (Standard 3). The Authority has resources to implement a risk-based inspection program that reduces the occurrence of shellfish-borne illness, injury, or allergic reactions.
- Inspection Audit Program (Standard 4). The Authority has resources to administer and monitor the quality of its inspections and sample collections.
- Shellfish-related Illness and Outbreaks and Shellfish Defense Preparedness and Response (Standard 5). The Authority has the resources necessary to detect, investigate, mitigate, document and analyze the SHELLFISH-RELATED INCIDENTS to stop, control and prevent HAZARDS that are likely to result in a shellfish-borne illness, injury or outbreak.
- Compliance and Enforcement Program (Standard 6). The Authority has resources to administer and monitor a compliance and enforcement program.
- Industry and Community Relations (Standard 7). The Authority has resources that allow participation and assessment of outreach activities and OUTREACH ACTIVITY EVENTS.
- Program Resources (Standard 8). The Authority has resources to conduct an assessment of resource needs for staffing, equipment, and funding to support a shellfish regulatory program.
- Program Assessment (Standard 9). The Authority has the resources to conduct self-assessments and develop and manage a STRATEGIC IMPROVEMENT PLAN resulting in conformance with the National Shellfish Sanitation Program and a process for continuous improvement.
- Laboratory Support (Standard 10). The Authority has resources to assess laboratory services needed to support Authority functions.

## **Appendix 8.2: Calculation for determining a required number of inspectors**

*This appendix is an example of how to calculate the number of field staff required to conduct inspections<sup>3</sup> of shellfish dealers. The data in the following table will vary significantly based on local or regional conditions. The Authority may use the certification and inspection frequencies found in the NSSP Model Ordinance Chapter I as a basis for determining the required number of inspectors.*

Dealer Certification	Number in inventory	Inspection frequency	Average inspection time (includes travel) <sup>4</sup>	Reinspection frequency
Shucker Packer	#dealers	3 months	# hours	10%
Repacker	#dealers	3 months	# hours	10%
Shellstock Shipper	#dealers	6 months	# hours	10%
Reshipper	#dealers	6 months	# hours	10%
Depurator	#dealers	monthly	# hours	10%

1. Calculate available annual inspection time per full time equivalent (FTE).

For example, the Authority determines that after allowances for annual leave, sick leave, holidays, training, administrative time, and other activities each Authority FTE has 1200 hours available for conducting inspections.

2. Calculate the number of hours required to inspect establishments in each dealer certification. Consideration can be given for sample collections, compliance activities, administrative, or other programmatic activities.

### **Example**

Formula for Shucker Packer/Repacker (SP/RP) Dealer inspection time:

$$100 \text{ dealers} \times 4 \text{ (times a year)} = 400 \text{ inspections} + 10\% \text{ reinspection} = 400 \text{ total inspections per year} \times 7.2 \text{ hours} = 3168 \text{ hours}$$

Formula for Shellstock Shipper/Reshipper (SS/RS) Dealer inspection time:

$$100 \text{ dealers} \times 2 \text{ (times per year)} = 200 \text{ inspections} + 10\% \text{ reinspection} = 220 \text{ total inspections per year} \times 5.7 \text{ hours} = 1254 \text{ hours}$$

Formula for Depuration (DP) Dealer inspection time:

$$1 \text{ dealers} \times 12 \text{ (times a year)} = 12 \text{ inspections} + 10\% \text{ reinspection} = 13 \text{ inspection total inspections} \times 7.2 \text{ hours} = 94 \text{ hours}$$

3. Calculate the number of FTE's required.

Formula:

$$3168 \text{ hours for SP/RP Dealers} + 1254 \text{ hours for SS/RS Dealers} + 94 \text{ hours for DP Dealers} = 4516 \text{ inspection hours required} / 1200 \text{ inspection hours available per FTE} = \underline{\text{3.8 FTEs}}$$

<sup>3</sup> Includes routine surveillance, reinspections, complaint or outbreak investigations, compliance follow-up investigations, risk assessment reviews, process reviews, and other direct establishment contact time such as on-site training.

<sup>4</sup> Inspection times based on calculations presented in "DHHS Office of Inspector General's FDA Oversight of State Shellfish Dealer Inspections" dated June 2000.

## **Appendix 8.3: Inspection Equipment**

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**Authority:** \_\_\_\_\_

**Assessment completed by:** \_\_\_\_\_

(NAME)

(DATE)

*Standard 8 requires the Authority to develop a list of equipment needed to conduct inspections and sample collections. The list provided below is an example equipment list for inspections and sample collections. The Authority may add and remove equipment from the table in developing the list of equipment. After the Authority finalizes its list, they can use the chart below to record whether the equipment is assigned, available to inspectors, or not available. The Authority indicates in the verified column if the equipment item is to be verified and maintained. Items checked as “verified” will need to have a written verification and maintenance procedure as required in Standard 3, 3.3.2.2.*

EQUIPMENT	ASSIGNED	AVAILABLE	WISH LIST	VERIFIED
Computer and printer				
Camera				
Credentials				
Important phone numbers (supervisor and servicing laboratory)				
Regulation and policies				
Paper, pen, masking tape, and permanent marker				
Clipboard				
Required forms (attached)				
Alcohol swabs and wipes				
Flashlight and holder				
Blacklight				
Light meter				
Thermometer				
Infrared thermometer				
Exacto knife and scissors				
Putty knife and scraper				
Sampling devices (sieves, triers, and swabs)				
Sampling equipment (sterile containers and scoops)				
Coolant (ice and freezer packs)				
Shipping containers				
Appropriate sanitizer test strips				
Official seals				
Protective clothing (lab coat, gloves, and boots)				
Eye protection				
Hair restraint				
Hearing protection				
Hard hat				

Safety shoes				
Respirator				
(Other)				

## Appendix 9.1: Self-Assessment Summary Report

**Authority:** \_\_\_\_\_

**Report completed by:** \_\_\_\_\_  
**(NAME)** \_\_\_\_\_ **(DATE)** \_\_\_\_\_

Standard	Self-Assessment/Worksheet	Implementation	Explain improvements needed to fully IMPLEMENT standards <i>(required for incomplete self-assessment and partial implementation)</i>
1. Regulatory Foundation	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used <u>      </u> (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
2. Training Program	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used <u>      </u> (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
3. Inspection Program	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used <u>      </u> (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
4. Inspection Audit Program	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used <u>      </u> (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
5. Shellfish-related Illness, Outbreak, and Hazards Response	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used <u>      </u> (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
6. Compliance and Enforcement	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used <u>      </u> (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
7. Industry and Community Relations	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used <u>      </u> (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	

## **Appendix 9.1: Self-Assessment Summary Report (continued)**

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**Authority:** \_\_\_\_\_

**Report completed by:** \_\_\_\_\_  
(NAME) \_\_\_\_\_ (DATE) \_\_\_\_\_

<b>Standard</b>	<b>Self-Assessment</b>	<b>Implementation</b>	<b>Explain improvements needed to fully IMPLEMENT standards (required for incomplete self-assessment and partial implementation)</b>
<b>8. Authority Resources</b>	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used _____ (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
<b>9. Authority Assessment</b>	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used _____ (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	
<b>10. Laboratory Support</b>	Complete <input type="checkbox"/> Incomplete <input type="checkbox"/>  Hours used _____ (Optional)	Full <input type="checkbox"/>  Partial <input type="checkbox"/>	

## **Appendix 10.1: Self-Assessment Worksheet**

**Authority:** \_\_\_\_\_

<b>Authority Elements</b>	<b>Yes/No</b>	<b>If no, please explain why element is not met</b>
<b>10.3.1 Laboratory Support</b>		
Does the Authority:		
1. Have access to a laboratory that is capable of analyzing a variety of samples including shellfish, environmental, and clinical samples?		
2. Maintains a list of services for routine and non-routine analyses such as biological HAZARD determinations?		
3. Have a contract or agreement with each PRIMARY SERVICING LABORATORY unless under the same administrative agency? The contract or agreement can be a memorandum of understanding, e-mail, or any written format but must contain the components below: 1) Define the responsibilities of each party; 2) Describe the types of testing services to be performed; and 3) Describe how exceptions to planned work will be communicated.		
4. Have documentation of the services provided, if services are provided from a non- PRIMARY SERVICING LABORATORY?		
<b>10.3.4</b>		
Does the Authority ensure all laboratory analysis supporting the NSSP is performed by a laboratory found to conform or provisionally conform to the FDA Shellfish Laboratory Evaluation Officer or FDA certified State Shellfish Laboratory Evaluation Officer in accordance with the requirements established under the current NSSP Model Ordinance Chapter III. Laboratory @.01 Quality Assurance?		

**Assessment completed by:** \_\_\_\_\_  
(NAME) \_\_\_\_\_ (DATE) \_\_\_\_\_