

Chapter I. Shellfish Sanitation Program Requirements for the Authority.

Additional Guidance: [Section IV. Guidance Documents - Chapter I. General .02 Procedures for Initiating a New State Program](#)

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 Administration.

- A. Scope. The Authority shall establish a statewide shellfish safety and sanitation program to regulate:
 - (1) The classification of shellfish growing areas;
 - (2) The harvesting of shellfish;
 - (3) Shellfish processing procedures and facilities;
 - (4) Product labeling;
 - (5) Storage, handling and packing;
 - (6) Shellfish shipment in interstate commerce;
 - (7) Shellfish dealers; and
 - (8) Bivalve aquaculture.
- B. State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A.
- C. Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be maintained in a central file and made available physically and/or electronically to any interested person upon request, consistent with appropriate state and federal law.
- D. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.
- E. Administrative Procedures. The Authority shall have administrative procedures sufficient to:
 - (1) Regulate shellfish harvesting, sale, or shipment; and
 - (2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the state from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its state to purchase the shellstock.
 - (3) Detain, condemn, seize, and embargo shellfish.
 - (4) Assure compliance with Shellfish Plant Inspection Standardization.
- F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The Authority shall have procedures for investigating incidents of shellfish borne disease.
- G. Commingling.
 - (1) Except for any shellfish included in the Authority's commingling plan, the Authority shall not permit the commingling of shellfish.
 - (2) If the Authority permits shellfish product commingling, the Authority shall develop a commingling management plan. The plan shall:
 - (a) Minimize the commingling dates of harvest and growing areas;
 - (b) Define a primary dealer;
 - (c) Limit the practice of commingling to primary dealers;

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22. (d) Limit commingling to shellfish harvested from specific growing areas within the State
as identified by the Authority and purchased directly from harvesters; and
23. (e) Define how the commingled shellfish will be identified.

Additional Guidance: [Section IV Guidance Documents - Chapter III. Harvesting, Handling, Processing, and Distribution .02 Shellfish Plant Inspection Standardization Procedures NSSP Standardized Shellfish Processing Plant Inspection Form](#)

@.02 Dealer Certification.

A. General

24. (1) A person requesting certification shall be subject to a comprehensive, onsite inspection and
meet the criteria in Section B. or Section C., as appropriate. The plant inspection shall be
conducted by the state shellfish standardization inspector, using the appropriate inspection
form, within the 120-day period immediately prior to the issuance or renewal of the
certification.
25. (2) Certification shall be given only to persons who meet the established requirements
established for certification.
26. (3) All certifications shall expire annually. The month selected for certification expiration shall
be at the discretion of the Authority.
27. (4) The Authority shall issue only one certification number to a dealer for a location. A person
or dealer may obtain more than one certification if each business is:
28. (a) Maintained as a separate entity; and
29. (b) Is not found at the same location.
30. (5) The Authority may permit separate certified dealers to share a facility.
31. (6) The certification number issued to each dealer by the Authority shall be unique.
32. (7) Adequate records documenting each dealer's compliance with certification requirements
shall be maintained for at least three years. These records shall include:
33. (a) Inspection reports of dealers;
34. (b) Notification letters and enforcement actions;
35. (c) Shellfish sample results and follow-up actions taken;
36. (d) Records of complaints or inquiries and follow-up actions taken; and
37. (e) Administrative hearing transcripts and records.

B. Initial Certification.

38. (1) Initial certification shall be given only to persons who meet the following requirements:
39. (a) HACCP requirements:
40. (i) A HACCP plan accepted by the Authority;
41. (ii) No critical deficiencies;
42. (iii) Not more than two (2) key deficiencies;
43. (iv) Not more than two (2) other deficiencies.
44. (b) Sanitation and additional Model Ordinance Requirements
45. (i) No critical deficiencies;
46. (ii) Not more than two (2) key deficiencies;
47. (iii) Not more than three (3) other deficiencies.
48. (2) The initial certification shall include a compliance schedule to correct any deficiencies not
corrected by the dealer during the inspection.

C. Renewal of Certification.

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

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

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

D. Revocation or Suspension of Certification.

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

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

E. Interstate Certified Shellfish Shippers List (ICSSL).

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

Designations:

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

(2) The Authority shall notify the FDA for the purpose of having the dealer removed from the ICSSL whenever a dealer's certificate or permit is:

(a) Suspended; or

(b) Revoked.

F. Inspections.

(1) After any person is certified, the Authority shall make unannounced inspections of the dealer's facilities:

(a) During periods of activity; and

(b) At the following minimum frequencies:

(i) Within thirty (30) days of beginning activities if the dealer was certified on the basis of a pre-operational inspection;

(ii) At least monthly for dealer facilities certified as depuration processors;

(iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and

(iv) At least semiannually for other dealer activities.

(2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection. The inspection form shall contain a listing of deficiencies by area in the operation and inspection item with corresponding citations to this Model Ordinance.

G. Performance Based Inspection Program (PIP).

(1) A performance based inspection program may be instituted by the Authority for any dealer who meets the requirements of this section.

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(2) The minimum frequency of inspection under a PIP shall be no less than one inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.

(3) To be eligible for a PIP, the dealer shall have demonstrated a history of satisfactory compliance for the previous three-year period. The three-year demonstration shall include:

(a) Full compliance with the minimum inspection frequency shown under Section F.;

(b) Recertification of the dealer by the Authority;

(c) Verification that no critical deficiencies, no more than one key deficiency and no more than two other deficiencies have occurred in any one inspection;

(d) Correction of all identified deficiencies in accordance with the compliance schedule approved by the Authority; and

(e) No repetition of the identified deficiencies.

H. Enforcement.

(1) General.

(a) The Authority shall use any combination of administrative hearings, fines, certification cancellations, temporary suspension of operating licenses, embargoes, product condemnations or product seizures to accomplish the implementation of this Ordinance.

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

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

(ii) Document why an option was selected.

(2) Actions Triggered by Inspections.

(a) When any inspection detects a critical deficiency:

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

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

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

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

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

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

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

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

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

(i) Revise the existing compliance schedule;

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

(iii) Seek other administrative remedies.

Rationale for Removal

Model Ordinance Review Section 1

General

| Reference # | Recommendation | Rationale | Agree | Disagree |
|-------------|--------------------|--|-------|----------|
| ALL MO | Need Clarification | Possible clarification: at each mention of records throughout the MO - consider cross-reference to Chapter 1, @ .01C (See Chapter I reference #32 for example) | 5 | 6 |

Chapter I

| Reference # | Recommendation | Rationale | Agree | Disagree |
|-------------|--------------------|--|-------|----------|
| 13 | Need Clarification | Should there be minimum requirements for such a memorandum between SSCAs? | 6 | 6 |
| 13 | Need Clarification | confusing language | 5 | 7 |
| 14 | Need Clarification | Add the word " <u>recall</u> " to the administrative procedures to be more inclusive. | 7 | 5 |
| 20 and 22 | Need Clarification | "and purchased directly from harvesters" seems to define primary dealer, 20 requires primary dealer to be defined, can it be both? If not, then remove 20 (@01 G(b)) | 9 | 3 |
| 25 | Need Clarification | Reword as follows for better clarification regarding certification, "Certification shall be given only to persons <u>dealers</u> who meet established <u>NSSP</u> requirements established for certification." | 10 | 2 |
| 27 | Need Clarification | Should this say per location? | 9 | 2 |
| 27 | Need Clarification | Provide language to indicate that the official certification number shall include three parts, 1) state abbreviation, 2) a unique number assigned by the state, and 3) the dealer type (SP, RP, SS, RS, DP). A permit designation (PHP, AQ, WS) shall not be a part of the official certification number | 8 | 4 |
| 28 | Need Clarification | should this and be an or? | 7 | 5 |
| 30 | Recommend Removal | facility deficiencies are the responsibility of which certified dealer | 2 | 8 |
| 31 | Recommend Removal | if each location and dealer has a number, it logically has to be unique, why state the obvious? | 3 | 8 |
| 32 | Need Clarification | The Authority shall maintain adequate records documenting each dealer's compliance with certification requirements for at least three years. | 7 | 5 |
| 38 | Need Clarification | this and other parts of this section use person and dealer, do they mean the same thing? Why not use one term, dealer? | 10 | 2 |

| | | | | |
|----|--------------------|--|---|---|
| 48 | Need Clarification | add language that initial certification not issued until deficiencies are corrected | 5 | 7 |
| 52 | Need Clarification | Add "in interstate commerce" at end of sentence | 7 | 5 |
| 54 | Need Clarification | person or dealer? | 7 | 4 |
| 54 | Need Clarification | Reword as follows to clarify that a permit designation is only provided for inclusion in the ICSSL and not for use as part of the certification number, "The authority shall include <u>provide</u> any permit designation to be included in the ICSSL, <i><u>but that designation shall not be included as part of the official certification number applied to packages of shellfish.</u></i> " | 6 | 6 |
| 57 | Need Clarification | Do we want to add in (c) Not renewed? | 6 | 6 |
| 65 | Need Clarification | There may be times when leaving an inspection report at the time of the inspection is not possible. Reword as follows... (2) The Authority shall provide a copy of the completed inspection form to the person in-charge at the dealer's operation at the time of inspection as soon as is appropriate. | 9 | 3 |
| 66 | Recommend Removal | Many states conduct recertification at end of year which means many dealers are inspected after warm weather months when risk is greatest. With new time/temp requirements and most states implementing vibrio control plans there is greater opportunity for non-compliance. | 4 | 7 |
| 66 | Recommend Removal | PIP seems to create a loophole for inspection frequency and contradicts previous section | 5 | 6 |
| 67 | Recommend Removal | already established that minimum one inspection per year and certification is only good for a year, not needed. | 5 | 6 |
| 68 | Recommend Removal | In seven years , I have only had one dealer who came close to PIP. Maybe change the criteria to less than three years? However, I do have language for PIP in our rules | 3 | 7 |
| 84 | Need Clarification | Reword as follows to clarify actions to be taken when a critical deficiency is identified, "Product affected by a critical deficiency shall be controlled <u>assessed</u> to prevent contaminated or adulterated product from reaching consumers. When necessary <u>the assessment deems the affected product to be unsafe</u> the authority shall:" | 8 | 3 |
| 89 | Need Clarification | what is the rationale for four key deficiencies? | 7 | 5 |