

Section II

Model Ordinance

Chapter VIII

Control of Shellfish Harvesting

@.02 Shellstock Time to Temperature Controls

A. Each shellfish producing State shall establish time to temperature requirements for the harvesting of all shellstock to ensure that harvesters shall comply with one of the following:

(1) The State *Vibrio vulnificus* Control Plan as outlined in Chapter II. @.04; or

(2) The State *Vibrio parahaemolyticus* Plan as outlined in Chapter II. @.05; or

(3) All other shellstock shall comply with the matrix below:

<u>Action Level</u>	<u>Average Monthly Maximum Air Temperature</u>	<u>Maximum Hours from Exposure to Receipt at a Dealer's Facility</u>
<u>Level 1</u>	<u><50°F (10°C)</u>	<u>36 hours</u>
<u>Level 2</u>	<u>50°F - 60 °F (10°C - 15 °C)</u>	<u>24 hours</u>
<u>Level 3</u>	<u>>60 °F - 80 °F (15 °C - 27 °C)</u>	<u>18 hours</u>
<u>Level 4</u>	<u>>80 °F (≥27 °C)</u>	<u>12 hours</u>

B. For the purposes of this section, temperature control is defined as the management of the temperature of shellstock by means of ice, mechanical refrigeration or other approved means necessary to lower and maintain the temperature of the shellstock to comply with Chapter XI, XIII., or XIV.

C. The Authority shall establish the water or air temperature to be applied to the requirements above for each growing area by averaging the previous five (5) years maximum monthly water or air temperatures.

D. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.

E. The Authority shall ensure that harvesters document and provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements.

F. Shellstock intended for Wet Storage, Depuration, Post Harvest Processing (PHP) or “For Shucking Only by a Certified Dealer” must either be shucked, introduced into PHP, Wet Storage, or Depurated within the times outlined in the matrix in Chapter VIII. @ .02 A (3) or meet the applicable time to temperature controls of Chapter VIII. @ .02 A. (3). Shellstock harvested under a State *Vibrio* Plan intended for Wet Storage or Depuration, must be placed in Wet Storage, Depuration or refrigeration to comply with time to temperature controls outlined in the State Authority Vv or Vp Control Plan.

G. Ocean Quahogs (*Arctica islandia*) and surf clams (*Spisula solidissima*) are exempt from this temperature control plan when these products are intended for thermal processing.

H. Authorities shall consider the need for shading in developing Vv and Vp Control Plans. Shading shall be required when deemed appropriate by the Authority when implementing @.02 A. (1) (2) and (3).

Requirements for Harvesters

.01 General.

- A. Each harvester shall have a valid license, and a special license if necessary, in his possession while engaged in shellstock harvesting activities.
- B. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license.
- C. In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the riparian owner or lessee shall be licensed as a harvester prior to harvesting his shellstock. A licensed riparian owner or lessee may employ unlicensed harvesters to work his property or lease.

.02 Shellstock Harvesting and Handling.

- A. Harvesters. Any harvester who engages in shellfish packing as defined in this Ordinance shall:
 - (1) Be a dealer; or
 - (2) Pack shellstock for a dealer.
- B. Non-Vessel Harvesting
Harvesters shall assure shellstock are harvested, handled, and transported to prevent contamination, deterioration, and decomposition.
- C. Vessels.
 - (1) The operator shall assure that all vessels used to harvest and transport shellstock are properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.
 - (a) Decks and storage bins shall be constructed and located to prevent bilge water or polluted overboard water from coming into contact with the shellstock.
 - (b) Bilge pump discharges shall be located so that the discharge shall not contaminate shellstock.
 - (c) Containers used for storing shellstock shall be clean and fabricated from safe materials.
 - (d) Boat decks and storage bins used in the harvest or transport of shellstock for direct marketing shall be:
 - (i) Kept clean with potable water or water from a growing area in the approved classification or in the open status of the conditionally approved classification; and
 - (ii) Provided with effective drainage.
 - (e) Vessels and all other equipment coming in contact with shellstock during handling or transport for relaying or depuration shall be thoroughly cleaned before the vessels or equipment are used to transport or handle shellfish for direct marketing.
 - (f) When necessary, effective coverings shall be provided on harvest boats to protect shellstock from exposure to:
 - (i) Hot sun;
 - (ii) Birds; and
 - (iii) Other adverse conditions.
 - (2) Cats, dogs, and other animals shall not be allowed on vessels.
- D. Disposal of Human Sewage from Vessels.
 - (1) Human sewage shall not be discharged overboard from a vessel used in the harvesting of shellstock, or from vessels which buy shellstock while the vessels are in growing areas.

- (2) The Authority shall educate all licensed harvesters and shellstock dealers concerning the public health significance of discharging human sewage overboard.
 - (3) As required by the Authority, in consultation with FDA, an approved marine sanitation device (MSD), portable toilet or other sewage disposal receptacle shall be provided on the vessel to contain human sewage.
 - (4) Portable toilets shall:
 - (a) Be used only for the purpose intended;
 - (b) Be secured while on board and located to prevent contamination of shellstock by spillage or leakage;
 - (c) Be emptied only into a sewage disposal system;
 - (d) Be cleaned before being returned to the boat; and
 - (e) Not be cleaned in equipment used for washing or processing food.
 - (5) Use of other receptacles for sewage disposal may be approved by the Authority if the receptacles are:
 - (a) Constructed of impervious, cleanable materials and have tight fitting lids; and
 - (b) Meet the requirements in §D.(3).
- E. Shellstock Washing.
- (1) Shellstock shall be washed reasonably free of bottom sediments as soon after harvesting as practicable.
 - (2) The harvester shall be primarily responsible for washing shellstock.
 - (3) If shellstock washing is not feasible at the time of harvest, the dealer shall assume this responsibility.
 - (4) Water used for shellstock washing shall be obtained from:
 - (a) A potable water source; or
 - (b) A growing area in the:
 - (i) Approved classification; or
 - (ii) In the open status of the conditionally approved classification.
 - (5) If the harvester or dealer elects to use tanks or a recirculating water system to wash shellstock, the shellstock washing activity shall be constructed, operated, and maintained in accordance with Chapter XI.02.A.(3) and Chapter XIII.02.A.(3).
- F. Shellstock Identification.
- (1) Each harvester shall affix a tag to each container of shellstock which shall be in place while the shellstock is being transported to a dealer.
 - (2) If the shellstock was harvested at more than one location, each container shall be tagged at its growing area.
 - (3) When the harvester is also the dealer, the harvester has the option to tag the shellfish with a harvester's tag or a dealer's tag meeting the requirements outlined in Chapter X. 05.
 - (4) The harvester's tags shall:
 - (a) Be durable, waterproof and sanctioned by the Authority prior to use; and
 - (b) Be at least 13.8 square inches (89.03 cm²) in size.
 - (5) The harvester's tag shall contain the following indelible, legible information in the order specified below:
 - (a) The harvester's identification number as assigned by the Authority;
 - (b) The date of harvest;
 - (c) The most precise identification of the harvest location or aquaculture site as is practicable, including the initials of the State of harvest, and the Authority's designation of the growing area by indexing, administrative, or geographic designation. If growing areas have not been indexed by the Authority, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number).

- (d) The type and quantity of shellstock; and
- (e) The following statement in bold capitalized type on each tag
**"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS
EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90
DAYS."**
- (6) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in Chapter VIII. .02 F.
- (7) Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities may be used as follows:
 - (a) When shellstock are harvested from one harvest area on a single day, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, or other container and the unit tagged with a single tag in accordance with the requirements of Chapter VIII. .02 F.
 - (b) In addition to the information required in Chapter VIII. .02 F. the unit tag shall also include:
 - (i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest"; and
 - (ii) Number of individual containers in the unit.
- (8) Bulk Sale of Shellstock. If shellstock are sold in bulk, the harvester or dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in Chapter VIII .02 F. with the addition of the name of the consignee.

G. Shellstock Temperature Control

- (1) All harvesters shall comply with the applicable time to temperature requirements of
 - (a) State Vv and Vp Control Plans outlined in Chapter II. @.04 and @.05; or
 - (b) Chapter VIII. @.02 Shellstock Time to Temperature Controls A. (3).
- (2) All harvesters shall provide trip records to the initial dealer demonstrating compliance with the time to temperature requirements.

NOTE: State Vv and Vp Control Plans can be accessed on the ISSC web site using the following link: www.issc.org.

~~.03 Shellstock Temperature Control.~~

~~Note: The Authority shall select one of the following options for implementation in its State. The time-temperature matrix for each of the options applies only to the original harvester or harvester/dealer of shellstock for the purposes of handling and transporting shellstock to the first point of processing or packing.~~

~~OPTION 1~~

~~**(Mandatory for confirmed *Vibrio vulnificus* problem)** If the waters of a State have been confirmed as an original source of product associated with two (2) or more *Vibrio vulnificus* illnesses, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below only for shellfish intended to be consumed raw.~~

~~**A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other**~~

~~approved means which is capable of lowering the temperature of the shellstock and will maintain it at 50 degrees Fahrenheit (10 degrees Centigrade) or less.~~

Time-Temperature Matrix for <i>Vibrio vulnificus</i>:		
Action Level	Water Temperature	Maximum Hours from Exposure to Temperature Control
Level 1	<65 °F	36 hours
Level 2	65 °F - 74 °F (18 °C - 23 °C)	14 hours
Level 3	>74 °F - 84 °F (>23 °C - 28 °C)	12 hours
Level 4	>84 °F (>28 °C)	10 hours

~~B. The Authority shall establish the water temperature to be applied in the matrix above for each growing area by averaging the previous 5 years maximum monthly water temperatures.~~

~~C. The time to refrigeration in the above matrix shall be based upon the first shellstock harvested.~~

~~D. During Action Levels 2, 3, and 4, the product shall be shaded.~~

~~E. The Authority may approve other measures proposed by the industry to provide controls equivalent to the time-temperature requirements in the above matrix.~~

~~F. The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest processed with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.~~

~~G. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.~~

OPTION 2

~~If a growing area in the State has been confirmed as an original source of product associated with two (2) or more *Vibrio parahaemolyticus* illnesses within the past three years, the Authority shall adopt the following exposure time to temperature controls in the time-temperature matrix below or use Option 1. This *Vibrio parahaemolyticus* control measure applies only to shellfish from the affected growing area(s) which are intended to be consumed raw.~~

~~For the purposes of this control measure, identify and define growing areas in the State affected by *Vibrio parahaemolyticus* based on hydrographic and geographic parameters and other considerations relevant to control of a naturally occurring pathogen.~~

~~A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at 50 °Fahrenheit (10 °Centigrade) or less.~~

~~B. Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five years as reported by the National Weather Service and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandica*) are exempted from this temperature control plan.~~

~~C. The Authority may set up a plan that allows for exemption of this option for shellstock that is to be post-harvest treated with an approved post-harvest process in accordance with NSSP Model Ordinance Chapter XVI. The Authority must develop a plan to ensure the security of shellstock harvesting.~~

~~D. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix.~~

Time Temperature Matrix for <i>Vibrio parahaemolyticus</i> :		
Action Level	Average Monthly Maximum Air Temperature	Maximum Hours from Exposure to Temperature Control
Level 1	<66 °F (18 °C)	36 hours
Level 2	66 °F – 80 °F (19 °C – 27 °C)	12 hours
Level 3	≥81 °F (≥27 °C)	10 hours

OPTION 3

~~For those states that do not have to follow Option 1 or Option 2, the following time/temperature matrix will apply.~~

~~A. For the purposes of this section, temperature control is defined as the management of the environmental temperature of shellstock by means of ice, mechanical refrigeration or other approved means which is capable of lowering temperature of the shellstock to, and will maintain it at, 50 °Fahrenheit (10 °Centigrade) or less.~~

~~B. Ocean Quahogs (*Arctica islandica*) and surf clams (*Spisula solidissima*) are exempted from this temperature control plan when these products are intended for thermal processing.~~

~~C. Temperature determinations for application in the time-temperature matrix below shall be based on average monthly maximum air temperatures for defined regions within the state. The average monthly maximum air temperature for each region shall be established by determining the mean daily high temperature for the month in each of the previous five~~

~~years as reported by the National Weather Service, and then averaging the five resulting temperatures. Ocean Quahogs (*Arctica islandia*) are exempted from this temperature control plan.~~

~~D. The Authority shall ensure the dealer has adequate methods in place to demonstrate compliance with the time/temperature matrix:~~

Action Level	Average Monthly Maximum Air Temperature	Maximum Hours from Exposure to Temperature Control
Level 1	<66 °F (18 °C)	36 hours
Level 2	66 °F – 80 °F (19 °C – 27 °C)	24 hours
Level 3	≥81 °F (≥27 °C)	20 hours

Section II

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Chapter IX

Transportation

Requirements for the Authority

~~@.01 General.~~

- ~~A. The Authority shall apply these requirements to all shellfish shipped in interstate commerce.~~
- ~~B. The Authority shall assure that:
 - ~~(1) Shellfish are transported and maintained in accordance with the requirements of this Chapter; and~~
 - ~~(2) Shellfish shipments originate from a dealer.~~~~
- ~~C. The Authority shall use the temperatures included in the sections below entitled @.02 Shipment Acceptability, @.03 Shipment Rejection, and @.04 Bacteriological Examination of Shellfish Shipments as the initial basis for taking regulatory action against any shellfish shipment in interstate commerce.~~
- ~~D. If an interstate shipment of shellfish is monitored, the monitoring shall take place within 24 hours of the shellfish entering the State.~~

~~@.02 Shipment Acceptability.~~

~~Shellfish shipments shall be considered acceptable when:~~

- ~~A. Shipments are properly identified with tags and/or labels and shipping documents;~~
- ~~B. Shellstock is alive and cooled to an internal shellstock body temperature of 50° Fahrenheit (10° Centigrade) or less;~~
- ~~C. Shucked shellfish and in-shell product are cooled to a temperature of 45° Fahrenheit (7.2° Centigrade) or less; and~~
- ~~D. The time-temperature indicating device shows that the ambient air temperature has exceeded 45° Fahrenheit (7.2° Centigrade) but the shellstock internal body temperature is 50° Fahrenheit (10° Centigrade) or less; and~~
- ~~E. All other conditions of shipment in this Chapter are met.~~

~~Additional Guidance—Section IV Guidance Documents~~

~~Chapter II.12 Bacteriological Examination of Shellfish Shipments Decision Tree~~

~~@.03 Shipment Rejection.~~

- ~~A. Shellfish shall be rejected when:
 - ~~(1) Shellfish are not properly identified with tags or shipping documents;~~
 - ~~(2) The internal shellstock body temperature exceeds 60° Fahrenheit (15.6° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII §@.03;~~
 - ~~(3) Shucked shellfish temperature or the internal body temperature of in-shell product exceeds 50° Fahrenheit (10° Centigrade); or~~
 - ~~(4) The Authority determines that the product is unwholesome or unsafe for human consumption. The Authority shall notify the shipping dealer, the receiving dealer, and the Authority in the State where the shipment originated of the shipment's rejection.~~~~

~~@.04 Bacteriological Examination of Shellfish Shipments.~~

~~If the State chooses to sample, the following protocol shall be used.~~

- ~~A. Bacteriological samples of any shellfish taken for the purpose of rejection of shipments from out-of-state dealers shall be collected within twenty-four hours of the shellfish entering a State.~~
- ~~B. Bacteriological examination shall be made of the shellfish shipment if:~~
- ~~(1) The internal body temperature of the shellstock exceeds 50° Fahrenheit (10° Centigrade) and is less than or equal to 60° Fahrenheit (15.6° Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements in Chapter VIII @ .03;~~
 - ~~(2) The shucked shellfish temperature or the internal body temperature of in-shell product exceeds 45° Fahrenheit (7.2° Centigrade) and is less than or equal to 50° Fahrenheit (10° Centigrade);~~
 - ~~(3) The shipping time exceeds four hours and there is no temperature recording device or the recording device is inoperative; or~~
 - ~~(4) The Authority determines it is necessary.~~

Requirements for the Harvester/Dealer

~~.01 Trucks or Other Vehicles~~ Conveyances Used to Transport Shellstock to the Original Dealer.

- ~~A. The harvester or dealer who transports shellstock from the harvester to the original dealer, shall assure that all trucks~~ Any conveyance ~~used to transport shellstock are to the original dealer shall be~~ properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.
- ~~B. Storage bins on conveyances trucks or other vehicles used in the transport of shellstock for direct marketing shall be:~~
- ~~(1) Kept clean with potable water or water from an approved area or conditionally approved area in the open status; and~~
 - ~~(2) Provided with effective drainage.~~
- ~~C. Shellstock shall be transported in adequately refrigerated trucks when the shellstock have been previously refrigerated or when ambient air temperature and time of travel are such that unacceptable bacterial growth or deterioration may occur. When transporting shellstock to the original dealer within the applicable time to temperature controls in Chapter VIII @ .02 A (1), (2) and (3) the temperature inside the conveyance or truck shall not exceed the ambient air temperature when the ambient air temperature is above 50° Fahrenheit (10° Centigrade).~~
- ~~D. Prechilling trucks or other vehicles shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.~~
- ~~DE.~~ When mechanical refrigeration units are used, the units shall be:
- ~~(1) Equipped with automatic controls; and~~
 - ~~(2) Capable of maintaining the at an ambient air temperature necessary to comply with .01 C. above, in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.~~
- ~~EF.~~ Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI. .02 A. (2).
- ~~FG.~~ Cats, dogs, and other animals shall not be allowed in any part of the ~~truck or other vehicle conveyance~~ where shellstock is stored.

~~.02 Receiving Shellfish~~

- ~~A. The dealer shall reject or discard any shellfish shipments which:~~
- ~~(1) Do not originate from a licensed harvester or dealer; and/or~~
 - ~~(2) Are unwholesome, inadequately protected, or whose source cannot be identified.~~
- ~~B. Transportation agents or common carriers used by a dealer are not required to be certified.~~
- ~~C. The dealer shall:~~

- ~~(1) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this Chapter;~~
 - ~~(2) Place shellstock under temperature control within 2 hours after receipt from the harvester, or when the dealer is also the harvester, when shellstock reaches the dealer's facility;~~
 - ~~(3) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than 2 hours at points of transfer such as loading docks;~~
 - ~~(4) Ensure that shucked shellfish and in-shell product are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and~~
 - ~~(5) Ensure that frozen shellfish remain frozen.~~
- ~~D. For the purpose of this section, temperature control is defined as the management of the environmental temperature of the shellstock by means of ice, mechanical refrigeration or other means approved by the Authority.~~

.032 Transportation Containers. Conveyances Used to Transport Shellstock from Dealer to Dealer

- A. All containers used to transport shellstock shall be:
 - (1) Constructed to allow for easy cleaning; and
 - (2) Operated and maintained to prevent product contamination.
- B. All containers shall be cleaned with:
 - (1) Potable water; and
 - (2) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

.043 Cargo Protection From Cross Contamination.

- A. All containers used for storing shellfish shall be clean and fabricated from safe materials.
- B. Shellfish Cargo Only:
 - (1) The entire cargo shall consist of shellfish products only.
 - (2) Except for bulk shipments, shellstock shipments shall be shipped on pallets.
 - (3) In-shell product shipments shall be shipped on pallets.
 - (4) If the conveyance does not have a channeled floor, pallets shall be used for all shellfish.
- C. Mixed Cargoes. Shellfish shall be shipped as part of a mixed cargo of seafood or other food product only when:
 - (1) Shellfish products are protected from contamination by the other cargo;
 - (2) All cargo is placed on pallets; and
 - (3) No other cargo is placed on or above the shellfish unless all cargo is packed in sealed, crush resistant, waterproof containers.
- D. Ice. Any ice used to cool shellfish shall meet the requirements of Chapter XI. 02 A. (2).

.054. Shipping ~~Temperatures~~ Times.

Shellfish dealers shall ship shellstock adequately iced; or in a conveyance pre-chilled at or below 45°F (7.2°C) ambient air temperature.

.05 Transportation Records

All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of Chapter IX.04. This

documentation must include a notice of all shellstock harvested under the requirements of Chapter VIII. @.02 A. (3) that has not been cooled to an internal temperature of 50° F (10° C) and indicate the presence of a time/temperature recording device.

~~A.Shipping Time is No More Than Four Hours.~~

- ~~(1)When the shipping time is four hours or less, the dealer shall ship all shellfish:
 - ~~(a)Well iced; or~~
 - ~~(b)Using other acceptable means of refrigeration.~~~~
- ~~(2)When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.~~
- ~~(3)The dealer shall not be required to provide thermal recorders during shipment.~~
- ~~(4)Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.~~

~~B.Shipping Time is Greater Than Four Hours.~~

- ~~(1)When the shipping time is greater than four hours, the dealer shall ship all shellfish in:
 - ~~(a)Mechanically refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less; or~~
 - ~~(b)Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.~~~~
- ~~(2)Unless the dealer has an approved HACCP plan with an alternate means of monitoring time temperature, the initial dealer shall assure that a suitable time temperature recording device accompanies each shipment of shellfish.~~
- ~~(3)The initial dealer shall note the date and time on the temperature indicating device, if appropriate.~~
- ~~(4)Each receiving dealer shall write the date and time on the temperature indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.~~
- ~~(5)The final receiving dealer shall keep the time temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.~~
- ~~(6)An inoperative temperature indicating device shall be considered as no recording device.~~

~~C.Shellfish dealers shall ship shellstock:~~

- ~~(1)Harvested under the requirements of a State Vv or Vp Control Plan:
 - ~~(a)Adequately iced; or~~
 - ~~(b)In a conveyance at or below 45° Fahrenheit (7.2° Centigrade) ambient air temperature; and~~
 - ~~(c)At an internal temperature as required of the initial dealer.~~~~
- ~~(2)Harvested under the requirements of Option 3 in a conveyance that has been pre-chilled to 45° Fahrenheit (7.2° Centigrade).~~

~~NOTE: Include record requirements for above. Shellfish dealers shall provide and maintain records demonstrating compliance with shipping temperature requirements~~

~~D.Shipping Time is No More Than Four Hours.~~

- ~~(1)When the shipping time is four hours or less, the dealer shall ship all shellfish:
 - ~~(a)Well iced; or~~
 - ~~(b)Using other acceptable means of refrigeration.~~~~
- ~~(2)When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less.~~
- ~~(3)The dealer shall not be required to provide thermal recorders during shipment.~~

~~(4) Lack of ice or other acceptable types of refrigeration shall be considered an unsatisfactory shipping condition.~~

~~E. Shipping Time is Greater Than Four Hours.~~

~~(1) When the shipping time is greater than four hours, the dealer shall ship all shellfish in:~~

~~(a) Mechanically refrigerated conveyances which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of 45° Fahrenheit (7.2° Centigrade) or less; or~~

~~(b) Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2° Centigrade) or less.~~

~~(2) Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.~~

~~(3) The initial dealer shall note the date and time on the temperature indicating device, if appropriate.~~

~~(4) Each receiving dealer shall write the date and time on the temperature indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.~~

~~(5) The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Authority upon request.~~

~~(6) An inoperative temperature indicating device shall be considered as no recording device.~~

Section II

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Chapter XI

Shucking and Packing

Requirements for the Authority.

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

@.01 Heat Shock.

- A. The Authority shall approve the scheduled process for heat shock. The process may be developed by the Authority or qualified persons with adequate facilities for conducting the appropriate studies;
- B. The Authority shall assure that the critical factors, which may affect the heat shock process, have been adequately studied and provided for in establishing the process. The critical factors shall include:
 - (1) Type and size of shellfish;
 - (2) Time and temperature of exposure;
 - (3) Type of process;
 - (4) Size of tank, tunnel or retort;
 - (5) Water to shellfish ratios in tanks; and
 - (6) Temperature and pressure monitoring devices;
- C. The Authority shall assure that heat shock process does not:
 - (1) Change the physical and organoleptic properties of the species;
 - (2) Kill the shellfish prior to shucking; and
 - (3) Increase microbial deterioration of the shucked shellfish.
- D. The Authority shall retain records covering all aspects of the establishment of the heat shock process.

Additional Guidance - Section IV Guidance Documents Chapter II
2H15. Decision Tree for Shellfish from Non-MOU Countries

Requirements for Dealers.

.01 Critical Control Points.

- A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall shuck and pack only:~~
 - (1) ~~The dealer shall shuck and pack only~~ shellstock obtained from a licensed harvester who has:
 - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and [C]
 - (b) Identified the shellstock with a tag on each container or a transaction record on each bulk shipment; and [C]
 - (c) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @ .02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII .02 G. (2) [C].
 - (2) ~~The dealer shall shuck and pack only~~ shellstock obtained and transported from a dealer ~~other than the original harvester who has~~ who has:
 - (a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); and [C]
 - (b) Provided documentation as required in Chapter IX. .04 and .05; and [C]

- ~~(a)(c) Shipped the shellstock a~~Adequately iced the shellstock; ~~or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less~~ [C]
- ~~(d) Placed~~ Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or [C]
- ~~(e) Cooled the shellstock to an 50°F (10°C) internal temperature of 50°F (10°C) or less. ; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less; [C]~~
- ~~(3) Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A. (3) the dealer shall shuck and pack only shellstock accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. [C]~~
- A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (b) and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). [C]
- ~~(34) The dealer shall shuck and pack only~~ in-shell product obtained from a dealer who has:
- (a) Shipped the in-shell product:
 - (i) Adequately iced; or
 - (ii) In a conveyance at or below 45°F (7.2°C) ambient air temperature; or
 - (iii) At an internal temperature of 45°F (7.2°C) or less; and [C]
 - (b) Identified the in-shell product with a tag on each container [C]
- B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:
- (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and [C]
 - (2) Once placed under temperature control and until ~~shucked the sale to the processor or final consumer,~~ shellstock shall ~~be~~:
 - (a) ~~Be~~ Iced; or [C]
 - (b) ~~Be P~~laced and stored in a storage area or conveyance maintained at 45° F (7.2° C) or less; and [C]
 - (c) Not ~~be~~ permitted to remain without ice, mechanical refrigeration or other approved methods of storage, as required in .01 B. (1) or .01 B. (2) (a) or (b) for more than two (2) hours at points of processing or transfer such as loading docks. [C]
- ~~(3) All shellstock intended for shucking must be shucked or cooled to an internal temperature of 50°F (10°C) within ten (10) hours of receipt. [C]~~
- C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:
- (1) Iced; or [C]
 - (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. [C]
- D. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:
- (1) For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within three (3) hours of shucking. [C]

- (2) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45° F (7.2° C) or less within four (4) hours of removal from refrigeration. [C]
- (3) If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to 45° F (7.2° C) or less within two (2) hours after the heat shock process. [C]
- (4) When heat shock shellstock are cooled and held under refrigeration for later shucking, the heat shocked shellstock shall be cooled to an internal temperature of 45° F (7.2° C) within two (2) hours from time of heat shock. [C]
- (5) For in-shell product the internal temperature of meats does not exceed 45°F (7.2°C) for more than two (2) hours during processing. [C]
- E. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45° F (7.2° C) or less or covered with ice. [C]
- F. Shellstock Shipping Critical Control Point.
The dealer shall ensure that shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. [C]

.02 Sanitation.

A. Safety of Water for Processing and Ice Production.

Additional Guidance - Section IV Guidance Documents

1HChapter III Harvesting, Handling, Processing, and Distribution .01 Shellfish Industry Equipment Guide

- (1) Water Supply.
 - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]
 - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
 - (i) Prior to use of the water supply; [C]
 - (ii) Every six months while the water supply is in use; and [K]
 - (iii) After the water supply has been repaired and disinfected. [S^{C/K}]
- (2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall be made on-site from potable water in a commercial ice machine;[C]
- (3) Shellstock Washing.
 - (a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. [C]
 - (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
 - (i) Obtain approval for the construction or remodeling of the system from the Authority. [K]
 - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and [C]
 - (iii) Test bacteriological water quality daily; [S^{C/K}]
 - (c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20

nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. [K]

(4) Plumbing and Related Facilities.

- (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
 - (i) Prevent contamination of water supplies; [C]
 - (ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

- (a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guidelines*. [K]
- (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
 - (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]
 - (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and [K]
 - (iii) Fabricated from food grade materials. [K]
- (c) The dealer shall assure that all joints on food contact surfaces
 - (i) Have smooth easily cleanable surfaces and [K]
 - (ii) Are welded. [K]
- (d) Shucking blocks shall be provided which are:
 - (i) Easily cleanable; [K]
 - (ii) Fabricated from safe material; [K]
 - (iii) Solid, one piece construction; and [K]
 - (iv) Easily removed from the shucking bench, unless the block is an integral part of the bench. [K]
- (e) The dealer shall provide a temperature measuring device accurate to +/- 2° Fahrenheit for use in monitoring product temperatures. [K]
- (f) All equipment used in heat shock processing shall meet the requirements of Chapter XI.02B.(1)(a), (b), and (c). [K]
- (g) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B.(1)(a), (b), and (c). [K]
- (h) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
 - (i) Is easily accessible for cleaning and inspection; [K]
 - (ii) Is self draining; and [K]
 - (iii) Meets the requirements for food contact surfaces. [K]

(2) Cleaning and sanitizing of food contact surfaces.

- (a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
 - (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; [K]

- (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]
 - (iii) Wash and rinse equipment and utensils at the end of each day. [K]
 - (b) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling. [K]
 - (c) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. [K]
 - (d) Shucked shellfish shall be packed in clean covered containers and stored in a manner which assures their protection from contamination:
 - (i) Fabricated from food grade materials; and [K]
 - (ii) Stored in a manner which assures their protection from contamination. [K]
 - (e) If used, the finger cots or gloves shall be:
 - (i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; [O]
 - (ii) Sanitized at least twice daily; [K]
 - (iii) Cleaned more often, if necessary [K];
 - (iv) Properly stored until used; and [K]
 - (v) Maintained in a clean, intact, and sanitary condition. [K]
- C. Prevention of Cross Contamination.
 - (1) Protection of Cross Contamination.
 - (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S^{C/K}]
 - (b) Shellfish shall be protected from contamination. [S^{C/K}]
 - (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. [K]
 - (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [S^{K/O}]
 - (2) Separation of operations.
 - (a) Facilities for shucking and packing activities shall be separated by use of:
 - (i) Separate rooms; [K]
 - (ii) Partitions; or [K]
 - (iii) Sufficient spacing. [K]
 - (b) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers. [K]
 - (3) Employee practices.
 - (a) Where the same employee works in both the shucking and packing activities, the employee shall wash his hands thoroughly after entering. [K]
 - (b) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
 - (i) Before starting work; [K]
 - (ii) After each absence from the work station; [K]
 - (iii) After each work interruption; and [K]
 - (iv) Any time when their hands may have become soiled or contaminated. [K]
 - (c) Any employee handling shucked shellfish shall be required to:
 - (i) Wear effective hair restraints; [O]
 - (ii) Remove any hand jewelry that cannot be sanitized or secured; [O]
 - (iii) Wear finger cots or gloves if jewelry cannot be removed; and [O]
 - (iv) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean. [O]

- (v) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
 - a. Store clothing or other personal belongings; [O]
 - b. Eat or drink; [K]
 - c. Spit; and [K]
 - d. Use tobacco in any form. [K]
- D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
 - (1) Hand washing facilities with warm water at a minimum temperature of 100° F (37.8°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [S^{K/O}]
 - (2) Hand washing facilities shall be provided which are:
 - (a) Convenient to work areas; [O]
 - (b) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
 - (c) Directly plumbed to an approved sewage disposal system, and [S^{O/K}]
 - (d) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
 - (3) The dealer shall provide at least one hand sink in the packing room. [O]
 - (4) The dealer shall provide at each hand washing facility:
 - (a) Supply of hand cleansing soap or detergent; [K]
 - (b) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
 - (c) Easily cleanable waste receptacle; and [O]
 - (d) Hand washing signs in a language understood by the employees; [O]
 - (5) Sewage [C] and liquid disposable wastes shall be properly removed from the facility [K]
 - (6) The dealer shall provide:
 - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; [K]
 - (b) An adequate number of conveniently located, toilets [K]
 - (c) Each toilet facility with an adequate supply of toilet paper [K] in a suitable holder. [S^{K/O}]
- E. Protection from Adulterants.
 - (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. [K]
 - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]
 - (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. [K]
 - (4) Protection of ice used in shellfish processing.
 - (a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S^{C/K}]
 - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S^{C/K}]
 - (c) Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]
 - (5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. [S^{K/C}]

- (6) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. [K]
- (7) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. [O]
- F. Proper Labeling, Storage and Use of Toxic Compounds.

Additional Guidance - Section IV Guidance Documents Chapter III. 0H07 Guidance for Reinstating a Previously Infected Employee
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- (1) Storage of toxic compounds.
 - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]
 - (b) Each of the following categories of toxic substances shall be stored separately:
 - (i) Insecticides and rodenticides; [K]
 - (ii) Detergents, sanitizers, and related cleaning agents; and [K]
 - (iii) Caustic acids, polishes, and other chemicals. [K]
 - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]
- (2) Use and labeling of toxic compounds.
 - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]
 - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. [K]
 - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. [K]
 - (d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]
- B. Control of Employees with Adverse Health Conditions
 - (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]
 - (a) Norovirus
 - (b) Hepatitis A virus,
 - (c) *Shigella* spp.,
 - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
 - (e) *Salmonella typhi*;
 - (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
 - (a) Has any of the following symptoms:
 - (i) Vomiting

- (ii) Diarrhea,
 - (iii) Jaundice,
 - (iv) Sore throat with fever, or
 - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
 - (b) Has an illness diagnosed by a health practitioner due to:
 - (i) Norovirus
 - (ii) Hepatitis A virus,
 - (iii) *Shigella* spp.,
 - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
 - (v) *Salmonella typhi*;
 - (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
 - (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
 - (i) Norovirus within the past 24 hours of the last exposure:
 - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. Within the past 3 days of the last exposure;
 - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
 - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
 - (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
 - (i) Norovirus within the past 24 hours of the last exposure;
 - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. Within the past 3 days of the last exposure;
 - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or
 - (iv) Hepatitis A virus within the past 30 days of the last exposure.
 - (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. [K]
 - (4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]
- C. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]

.03 Other Model Ordinance Requirements

A. Plants and Grounds.

- (1) General.
 - (a) The physical facilities shall be maintained in good repair. [O]
- (2) Flooding.
 - (a) Facilities in which shellfish are stored, shucked, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]
 - (b) If facilities are flooded:
 - (i) Shellfish processing, shucking or repacking activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]
 - (ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use. [C]
- (3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [S^{C/K}]
- (4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.
 - (a) Tight fitting, self closing doors: [K]
 - (b) Screening of not less than 15 mesh per inch; [K] and
 - (c) Controlled air current. [K].
- (5) Plant Interior.
 - (a) Sanitary conditions shall be maintained throughout the facility. [O]
 - (b) All dry area floors shall be hard, smooth, easily cleanable; and [O]
 - (c) All wet area floors used in areas to store shellfish, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
 - (i) Are graded to provide adequate drainage; [O]
 - (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; [O]
 - (iii) Have sealed junctions between floors and walls to render them impervious to water; and [O]
 - (d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials [O].
- (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:
 - (a) Rodent attraction and harborage; and [O]
 - (b) Inadequate drainage. [O]

B. Plumbing and Related Facilities.

- (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks; [K]
- (2) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - (a) Used in shellfish storage; [K]
 - (b) Used for food holding units [K] (e.g. refrigeration units);
 - (c) Cleaned by hosing, flooding, or similar methods [K]; and
 - (d) Subject to the discharge of water or other liquid waste including three-compartment sinks on the floor during normal activities. [K]

- (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S^{C/K}]
 - (4) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]
- C. Utilities.
 - (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S^{C/K}]
 - (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S^{C/K}]
- D. Disposal of Other Wastes.
 - (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
 - (2) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table. [O]
 - (3) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and [O]
- E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.
 - (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced. [O]
 - (2) The dealer shall use easily cleanable, corrosion-resistant impervious materials, free from cracks to construct:
 - (a) Shucking benches and contiguous walls; and [O]
 - (b) Stands or stalls and stools for shucker. [O]
 - (c) Any non-food contact surfaces in shellfish storage or handling areas. [O]
 - (3) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches. [O]
 - (4) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. [K]
 - (5) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
- F. Shellfish Storage and Handling.

The dealer shall:

 - (1) Assure that shellstock is:
 - (a) Reasonably free of sediment [O]; and
 - (b) Culled; [K]
 - (2) Assure shucking buckets are completely empty at the packing room so that no overage is returned to the shucker; [K]
 - (3) Inspect incoming shipments and shall reject dead or inadequately protected shellstock; [K]
 - (4) Not allow the use of dip buckets for hand or knife rinsing; [K]
 - (5) Not have on the premises any usable containers or container covers bearing a certification number different from the one issued for those premises unless documentation exists to verify the legitimate source of the containers and the containers contain shellfish from that source; [K]
 - (6) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161§130. [K]
 - (7) Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room; [K]
 - (8) Conduct packing activities so as to conform to applicable food additive regulations; [K]

- (9) During storage frozen shellfish shall be maintained frozen. [S^{K/0}]
 - (10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan. [K]
 - (11) All shellstock obtained from a licensed harvester shall be
 - (a) Adequately iced;-
 - (b) Placed in a storage area maintained at 45°F (7.2°C); or
 - (c) Shucked within two (2) hours of receipt. [S^{C/K}]
- G. Heat Shock. A dealer may elect to use heat shock to prepare shellstock for shucking.
- (1) The dealer shall:
 - (a) Post the schedule for the heat shock process in a conspicuous location; and [K]
 - (b) Make sure all responsible persons are familiar with requirements. [K]
 - (c) Cool all hot dipped shellstock immediately after the heat shock process. [K] This cooling shall be accomplished by:
 - (i) Dipping in a ice bath; or [K]
 - (ii) Use of flowing potable water. [K]
 - (2) If a heat shock tank is used, and the water is maintained at or above 140°F degrees the dealer shall completely drain and flush the tank at the end of each day's operation so that all the mud and debris which have accumulated in the dip tank are eliminated. If the temperatures are maintained below 140°F degrees, the dealer shall completely drain and flush the tank at three hour intervals. [K]
- H. Supervision.
- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]
 - (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. [K]
 - (3) All supervisors shall be:
 - (a) Trained in proper food handling techniques and food protection principles; and [K]
 - (b) Knowledgeable of personal hygiene and sanitary practices [K]
 - (4) The dealer shall require:
 - (a) Supervisors to monitor employee hygiene practices, including hand washing, eating, and smoking at work stations, and storing personal items or clothing. [K]
 - (b) Supervisors to assure that proper sanitary practices are implemented, including:
 - (i) Plant and equipment clean-up; [K]
 - (ii) Rapid product handling; and [K]
 - (iii) Shellfish protection from contamination. [K]
 - (c) Supervisors shall not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
 - (d) Employees shall:
 - (i) Be trained in proper food handling and personal hygiene practices, and [K]
 - (ii) Report any symptoms of illness to their supervisor. [K]

Section II

Model Ordinance

Chapter XIII

Shellstock Shipping

Exceptions. Shellstock Shippers are not required to pack shellstock in a building that complies with Sections .02 and .03 of this chapter when the Authority has determined that a shellstock shipper's practices and conditions do not warrant requiring shellstock to be packed in a building.

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits. ~~The dealer shall ship or repack only:~~

- (1) ~~The dealer shall ship or repack only~~ shellstock obtained from a licensed harvester who has:
 - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as identified by the tag; and [C]
 - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; and [C]
 - (c) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII. @ .02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII .02 G (2) [C].
- (2) ~~The dealer shall ship or repack only~~ shellstock obtained and transported from a dealer who has ~~other than the original harvester who has:~~
 - (a) Identified the shellstock with a tag on each container as outlined in Chapter X. .05; and [C]
 - (b) Provided documentation as required in Chapter IX .04 and .05; and [C]
 - (c) ~~Shipped the shellstock a~~adequately iced the shellstock, ~~or in a conveyance at or below 45°F (7.2°C) ambient air temperature or 50°F (10°) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°) or less [C]; and~~
 - (d) ~~Placed~~ Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or [C]
 - (e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less. [C]
- (3) ~~Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A (3) does not meet the requirements of A. 2. () above, the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device. [C]~~
A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (b) and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). [C]
- (4) ~~The dealer shall ship or repack only~~ in-shell product obtained from a dealer who has;
 - (a) Shipped the in-shell product:
 - (i) Adequately iced; or
 - (ii) In a conveyance at or below 45°F (7.2°C) ambient air temperature; or
 - (iii) At an internal temperature of 45°F (7.2°C) or less; and [C]
 - (b) Identified the in-shell product with a tag on each container. [C]

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that:

- (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; and [C]

- (2) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall ~~be~~:
 - (a) ~~Be~~ Iced; or [C]
 - (b) ~~Be~~ Placed in a storage area or conveyance maintained at 45° F (7.2° C) or less; and [C]
 - (c) Not ~~be~~ permitted to remain without ice, mechanical refrigeration, or other approved methods of storage+, as required in .01 B. (1) or .01 B. (2) (a) or (b) for more than two (2) hours at points of processing or transfer such as loading docks. [C]
- (3) All oysters harvested under State *Vibrio* Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:
 - (a) Cooled to an internal temperature of 55°F (12.7°C) within the time periods outlined in the State *Vv* Control Plans. [C]
 - (b) Cooled to an internal temperature of 50°F (10°C) within the time periods outlined in the State *Vp* Control Plans. Shellstock cooled to an internal temperature of 55°F (12.7°C) to comply with a *Vv* Control Plan is considered in compliance with this requirement. [C]
- (4) All other shellstock obtained from a licensed harvester shall be placed in a conveyance pre-chilled or a storage area maintained to 45°F (7.2°C) or less and cooled to an internal temperature of 50°F (10°C) prior to shipment. [C]
- (5) Product intended for relay, wet storage, depuration, or *Mercenaria sp* which is being cooled utilizing an Authority approved tempering plan are exempt from the requirement listed above in .01 B. (4) above.[C]
- C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:
 - (1) Iced; or [C]
 - (2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. [C]
- D. Shellstock Shipping Critical Control Point – The dealer shall ensure that
 - (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. [C]
 - (2) ~~All shellstock is cooled to meet the requirements outlined in .01 B. 3. and 4. above prior to shipment. Should the original dealer ship shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C), the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. [C]~~
All shellstock is cooled to meet the requirements outlined in .01 B. 3. and 4. above prior to shipment. The original dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C). Should the original dealer choose this option the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. [C]

.02 Sanitation.

- A. Safety of Water for Processing and Ice Production.
 - (1) Water Supply.
 - (a) The dealer shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]

- (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
 - (i) Prior to use of the water supply; [C]
 - (ii) Every six months while the water supply is in use; and [K]
 - (iii) After the water supply has been repaired and disinfected. [S^{C/K}]
- (2) Ice Production. Any ice used in the processing, storage, or transport of shellfish shall be made on-site from potable water in a commercial ice machine; or [C]
- (3) Shellstock Washing.
 - (a) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock. [C]
 - (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
 - (i) Obtain approval for the construction or remodeling of the system from the Authority. [K]
 - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing which, after disinfection, meets the coliform standards for drinking water, and does not leave any unacceptable residues in the shellstock; and [C]
 - (iii) Test bacteriological water quality daily; [S^{C/K}]
 - (c) The dealer may use ultra-violet (UV) disinfection in the recirculating wash water system, provided that the turbidity of the water to be disinfected shall not exceed 20 nephelometric turbidity units (NTUs) measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. [K]
- (4) Plumbing and Related Facilities. The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
 - (a) Prevent contamination of water supplies; [C]
 - (b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source [C]
 - (c) The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]

Additional Guidance - Section IV Guidance Documents Chapter III 0H Harvesting, Handling, Processing, and Distribution .01 Shellfish Industry Equipment Guide

B. Condition, and Cleanliness, of Food Contact Surfaces.

- (1) Equipment and utensil construction for food contact surfaces.
 - (a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to *Shellfish Industry Equipment Construction Guides*. [K]
 - (b) The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
 - (i) Constructed in a manner and with materials that can be cleaned, and sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]
 - (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and [K]
 - (iii) Fabricated from food grade materials. [K]
 - (c) The dealer shall assure that all joints on food contact surfaces
 - (i) Have smooth easily cleanable surfaces and [K]
 - (ii) Are welded [K]

- (d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in Chapter XI.02.B. (1) (a), (b), and (c). [K]
- (e) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
 - (i) Is easily accessible for cleaning and inspection; [K]
 - (ii) Is self-draining; and [K]
 - (iii) Meets the requirements for food contact surfaces [K]
- (2) Cleaning and sanitizing of food contact surfaces.
 - (a) Food contact surfaces of equipment, utensils and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
 - (i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant; [K]
 - (ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]
 - (iii) Wash and rinse equipment and utensils at the end of each day. [K]
 - (b) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded. [K]
- (3) If used, the finger cots or gloves shall be:
 - (a) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done; [O]
 - (b) Cleaned more often, if necessary [K];
 - (c) Properly stored until used; and [K]
 - (d) Maintained in a clean, intact, and sanitary condition. [K]
- C. Prevention of Cross Contamination.
 - (1) Protection of shellfish.
 - (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S^{C/K}]
 - (b) Shellfish shall be protected from contamination. [S^{C/K}]
 - (c) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment. [K]
 - (d) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. [S^{K/0}]
 - (2) Employee practices.
 - (a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
 - (i) Before starting work; [K]
 - (ii) After each absence from the work station; [K]
 - (iii) After each work interruption; and [K]
 - (iv) Any time when their hands may have become soiled or contaminated. [K]
 - (b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
 - (i) Store clothing or other personal belongings: [O]
 - (ii) Eat or drink; [K]
 - (iii) Spit; and [K]
 - (iv) Use tobacco in any form. [K]
- D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities.
 - (1) Hand washing facilities with warm water at a minimum temperature of 100° F (37.8°C), dispensed from a hot and cold mixing or combination faucet, shall be provided. [S^{K/0}]

- (a) Hand washing facilities shall be provided which are:
 - (i) Convenient to work areas; [O]
 - (ii) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
 - (iii) Directly plumbed to an approved sewage disposal system, and [S^{O/K}]
 - (iv) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
 - (b) The dealer shall provide at each hand washing facility:
 - (i) Supply of hand cleansing soap or detergent; [K]
 - (ii) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
 - (iii) Easily cleanable waste receptacle; and [O]
 - (iv) Hand washing signs in a language understood by the employees; [O]
- (2) Sewage [K] and liquid disposable wastes [K] shall be properly removed from the facility.
- (3) The dealer shall provide
 - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area. [K]
 - (b) An adequate number of conveniently located, toilets. [K]
 - (c) Each toilet facility with an adequate supply of toilet paper [K] in a suitable holder. [S^{K/O}].
- E. Protection from Adulterants.
 - (1) Shellfish shall be protected from contamination while being transferred from one point to another during handling and processing. [K]
 - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellfish are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]
 - (3) Food contact surfaces shall be protected from contamination by adulterants by using cleaning compounds and sanitizing agents only in accordance with applicable federal and state laws and regulations. [K]
 - (4) Shellstock shall be packed in clean containers. [K]
 - (5) Protection of ice used in shellfish processing.
 - (a) Any ice which is not made on site in the shellfish processing facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S^{C/K}]
 - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S^{C/K}]
 - (c) Any ice used in the processing, storage, or transport of shellfish shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]
 - (6) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. [S^{K/C}]
 - (7) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations. [K]
- F. Proper Labeling, Storage and Use of Toxic Compounds.
 - (1) Storage of toxic compounds.
 - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]
 - (b) Each of the following categories of toxic substances shall be stored separately:
 - (i) Insecticides and rodenticides; [K]
 - (ii) Detergents, sanitizers, and related cleaning agents; and [K]
 - (iii) Caustic acids, polishes, and other chemicals. [K]

- (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]
- (2) Use and labeling of toxic compounds.
 - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]
 - (b) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations. [K]
 - (c) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions. [K]
 - (d) Provide a test kit or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use [K]

Additional Guidance - Section IV Guidance Documents 1HChapter III.07 Guidance for Reinstating a Previously Infected Employee

G. Control of Employees with Adverse Health Conditions.

- (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]
 - (a) Norovirus
 - (b) Hepatitis A virus,
 - (c) *Shigella* spp.,
 - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
 - (e) *Salmonella typhi*;
- (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
 - (a) Has any of the following symptoms:
 - (i) Vomiting
 - (ii) Diarrhea,
 - (iii) Jaundice,
 - (iv) Sore throat with fever, or
 - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
 - (b) Has an illness diagnosed by a health practitioner due to:
 - (i) Norovirus
 - (ii) Hepatitis A virus,
 - (iii) *Shigella* spp.,
 - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
 - (v) *Salmonella typhi*;
 - (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;

(d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:

(i) Norovirus within the past 24 hours of the last exposure;

(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. Within the past 3 days of the last exposure;

(iii) *Salmonella typhi* within the past 14 days of the last exposure;

(iv) Hepatitis A virus within the past 30 days of the last exposure; or

(e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:

(i) Norovirus within the past 24 hours of the last exposure;

(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. Within the past 3 days of the last exposure;

(iii) *Salmonella typhi* within the past 14 days of the last exposure; or

(iv) Hepatitis A virus within the past 30 days of the last exposure.

(3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. [K]

(4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]

H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]

I.

.03 Other Model Ordinance Requirements

A. Plants and Grounds.

(1) General.

(a) The physical facilities shall be maintained in good repair. [O]

(2) Flooding.

(a) Facilities in which shellfish are stored, packed, repacked or reshipped shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]

(b) If facilities are flooded:

(i) Shellfish processing, repacking or shipping activities shall be discontinued until the flood waters have receded from the building; and the building is cleaned and sanitized. [C]

(ii) Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use.[C]

(3) The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities. [S^{C/K}]

(4) The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in the facility.

- (a) Tight fitting, self closing doors: [K]
 - (b) Screening of not less than 15 mesh per inch; [K] and
 - (c) Controlled air current. [K].
- (5) Plant Interior.
 - (a) Sanitary conditions shall be maintained throughout the facility. [O]
 - (b) All dry area floors shall be hard, smooth, easily cleanable; and [O]
 - (c) All wet area floors used in areas to store shellfish, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
 - (i) Are graded to provide adequate drainage; [O]
 - (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; [O]
 - (iii) Have sealed junctions between floors and walls to render them impervious to water; and [O]
 - (d) Walls and Ceilings. Interior surfaces of rooms where shellfish are stored, handled, processed, or packaged shall be constructed of easily cleanable, corrosion resistant, impervious materials [O].
- (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:
 - (a) Rodent attraction and harborage; and [O]
 - (b) Inadequate drainage. [O]
- B. Plumbing and Related Facilities.
 - (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks; [K]
 - (2) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - (a) Used in shellfish storage; [K]
 - (b) Used for food holding units [K] (e.g. refrigeration units);
 - (c) Cleaned by hosing, flooding, or similar methods [K]; and
 - (d) Subject to the discharge of water or other liquid waste including three compartment sinks on the floor during normal activities. [K]
 - (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S^{C/K}]
 - (4) Installation of drainage or waste pipes over food processing or food storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]
- C. Utilities.
 - (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S^{C/K}]
 - (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S^{C/K}]
- D. Disposal of Other Wastes.
 - (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
 - (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and [O]
- E. Equipment Condition, Cleaning, Maintenance, and Construction of Non-Food Contact Surfaces.
 - (1) The dealer shall use only equipment, including approved plastic ware, which is constructed in a manner and with materials that can be cleaned, sanitized, maintained, or replaced; and [O]

- (2) The dealer shall use easily cleanable, corrosion-resistant, impervious materials, free from cracks to construct any non-food contact surfaces in shellfish storage or handling areas. [O]
- (3) Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces. [K]
- (4) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]

F. Shellfish Storage and Handling.

- (1) The dealer shall:
 - (a) Assure that shellstock is:
 - (i) Alive; [K]
 - (ii) Reasonably free of sediment [O]; and
 - (iii) Culled; [K]
- (2) The dealer shall inspect incoming shipments and shall reject dead or inadequately protected shellstock; [K]
- (3) A dealer whose activity consists of trucks or docking facilities only shall:
 - (a) Have a permanent business address at which records are maintained and inspections can be performed; and [K]
 - (b) Not repack shellstock. [K]
- (4) A dealer who stores or repacks shellstock shall have:
 - (a) His own facility for proper storage or repacking of shellstock; or [K]
 - (b) Arrangements with a facility approved by the Authority of the storage or repacking of shellstock. [K]
- (5) During storage frozen shellfish shall be maintained frozen. [S^{K/O}]
- (6) All shellstock obtained from a licensed harvester shall be:
 - (a) Adequately iced;
 - (b) Placed in a storage area maintained at 45°F (7.2°C); or
 - (c) Processed within two (2) hours of receipt. [S^{C/K}]

G. Heat Shock. - N/A

H. Supervision.

- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]
- (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces. [K]
- (3) All supervisors shall be:
 - (a) Trained in proper food handling techniques and food protection principles; and [K]
 - (b) Knowledgeable of personal hygiene and sanitary practices. [K]
- (4) The dealer shall require:
 - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing. [K]
 - (b) Supervisors to assure that proper sanitary practices are implemented, including:
 - (i) Plant and equipment clean-up; [K]
 - (ii) Rapid product handling; and [K]
 - (iii) Shellfish protection from contamination. [K]
 - (c) Supervisors shall not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
 - (d) Employees shall:
 - (i) Be trained in proper food handling and personal hygiene practices, and [K]
 - (ii) Report any symptoms of illness to their supervisor. [K]

Section II

Model Ordinance

Chapter XIV

Reshipping

Exceptions. Reshippers are not required to comply with the building requirements in Sections .02 and .03 of this chapter when the Authority has determined that a reshipper's practices and conditions do not warrant requiring a building.

.01 Critical Control Points.

A. Receiving Critical Control Point - Critical Limits.

~~(1) The dealer shall reship only shellfish obtained and which originated and was transported from a dealer who has:~~

~~(2) Originated from a dealer other than the original harvester who has:~~

~~(1)(a) Identified the shellstock with a tag as outlined in Chapter X. .05, identified the in shell product with a tag as outlined in Chapter X. .07, and/or identified the shucked shellfish with a label as outlined in Chapter X. .06; and [C]~~

~~(b) Provided documentation as required in Chapter IX .04 and .05; and [C]~~

~~(a)(c) Shipped the shellstock aadequately iced the shellstock or ; [C]or in a conveyance at or below 45°F (7.2°C) ambient air temperature; or 50°F (10°C) internal temperature or less; or in a conveyance capable of lowering the temperature of the shellstock and will maintain it at 50°F (10°C) or less; [C]; and/or~~

~~(d) Placed Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or [C]~~

~~(3)(e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less. [C]Shipped the shucked shellfish and/or in shell product iced or in a conveyance at or below 45°F (7.2°C) ambient air temperature; [C] and~~

~~(2) Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A (3) the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. [C]~~

~~A dealer may receive shellstock from a dealer who has elected to ship shellstock in accordance with Chapter XIII. .01 D. (2) without the shellstock meeting the receiving requirements of Chapter XIII. .01 A. (2) (c) (d) or (e). The product must be accompanied with documentation as outlined in Chapter XIII. A. (2) (b) and must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device or comply with Chapter XIII. .01 A. (2) (c) (d) or (e). Shipments of four (4) hours or less must have documentation as required in Chapter XIII. .01 A. (2) (b). [C]~~

B. Shellstock Storage Critical Control Point - Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall ~~be~~:

(1) ~~Be I~~iced; or [C]

(2) ~~Be P~~placed in a storage area or conveyance maintained at 45 °F (7.2 ° C) or less; and [C]

(3) Not ~~be~~ permitted to remain without ice, mechanical refrigeration, or other approved means of storage for more than two (2) hours at points of processing or transfer such as loading docks. [C]

C. In-shell Product Storage Critical Control Point - Critical Limits. The dealer shall ensure that in-shell product shall be:

(1) Iced; or [C]

(2) Placed and stored in a storage area or conveyance maintained at 45°F (7.2°C) or less. [C]

D. Shucked Meat Storage Critical Control Point - Critical Limit. The dealer shall store shucked shellfish at an ambient temperature of 45 ° F (7.2 ° C) or less.[C]

E. Shellstock Shipping Critical Control Point. The dealer shall ensure that:

- (1) Shellstock that is received bearing a restricted use tag shall only be shipped to a certified dealer and shall include specific language detailing the intended use of the shellstock. [C]
- (2) All shellstock received from a dealer which elected to ship restricted use shellstock or shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C) must be cooled to an internal temperature of 50°F (10°C) prior to shipment. The dealer may elect to ship restricted use shellstock and shellstock which has been harvested in accordance with Chapter VIII. @.02 A. 3. prior to achieving the internal temperature of 50°F (10°C). Should the dealer choose this option the shipment shall be accompanied with a time/temperature recording device indicating continuing cooling. Shipments of four (4) hours or less will not be required to have a time/temperature recording device. [C]

Section II

Model Ordinance

Chapter XV

Depuration

Note: In those States where depuration is not practiced, this Chapter may be deleted from the Ordinance, as well as references to depuration throughout the Ordinance.

Requirements for the Authority

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

- A. Prior to authorizing depuration, the Authority shall develop and maintain an effective program to:
 - (1) Control shellstock harvesting by special license in accordance with Chapter VIII. @.01 C.;
 - (2) Control shellstock transportation between the harvest area and the depuration facility to prevent shellstock from being illegally diverted to direct marketing;
 - (3) Approve the design and construction of the depuration facility or activity including subsequent changes;
- B. If shellstock is transported interstate to be depurated, the Authorities in both States shall execute a memorandum of agreement to provide adequate control measures to prevent diversion prior to depuration.
- C. The Authority shall review and approve the Depuration Plant Operating Manual prior to granting depuration certification.
- D. The Authority shall review the depuration plant performance index and other records as part of the monthly inspections to verify that the process and CCP are effective and the process verification analysis is being performed properly.
- E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years:
 - (1) Inspection reports and reviews of the plant performance in accordance to §D. (above);
 - (2) Current Depuration Plant Operations Manual for each dealer (§.03).
- F. The Authority shall assure that each dealer has procedures to assure that no shellstock which has not been depurated is removed from the depuration facility without the direct supervision of the Authority.

Requirements for the Dealer

.01 Critical Control Points.

- A. Receiving Critical Control Point - Critical Limits.
 - ~~B.(1)~~ The dealer shall receive and depurate only shellstock which is:
 - ~~(+) Obtained from a licensed harvester who has:~~
 - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; [C] and
 - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; [C] and
 - ~~(c) Harvested the shellstock in compliance with the time temperature requirements of Chapter VIII.@ .02 A. (1), (2), or (3) as determined from records supplied by the harvester described in Chapter VIII .02 G (2) [C].~~
 - (2) The dealer shall receive and depurate only shellstock obtained and transported from a dealer who has:

- ~~(a)~~ Identified the shellstock with a tag on each container as outlined in Chapter X. .05 or transaction record with each bulk shipment as outlined in Chapter VIII. .02 F. (8); [C] and
 - (b) Provided documentation as required in Chapter IX .04 and .05; and [C]
 - (c) Adequately iced the shellstock, or [C]
 - (d) Shipped the shellstock in a conveyance maintained at or below 45°F (7.2°C) ambient air temperature; or [C]
 - (e) Cooled the shellstock to an internal temperature of 50°F (10°C) or less. [C]
 - (3) Should a dealer receive shellstock from a dealer who is shipping shellstock harvested in accordance with Chapter VIII. @.02 A (3) or restricted use shellstock that has not been cooled to an internal temperature of 50°F (10°C), the shellstock must be accompanied with a time/temperature recording device indicating that continuing cooling has occurred. This product can be received without meeting the receiving requirements of Chapter XIII. .01 A. (2) (c), (d) or (e). Shipments of four (4) hours or less will not be required to have a time/temperature device. [C]
 - ~~(3)~~(4) The dealer shall receive and depurate only shellstock Obtained from a special licensed harvester who has:
 - (a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; [C] and
 - (b) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. [C]
- B. Processing Critical Control Points - Critical Limits. The dealer shall assure that:
 - (1) All depuration lots are treated for a minimum of 44 hours; [C] and
 - (2) The water treatment system is operating to design specifications; [C] and
 - (3) All critical limits established during verification of the specific depuration process are being met. [C]
- C. Finished Shellstock Storage Critical Control Point - Critical Limits. The dealer shall assure that:
 - (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; [C] and
 - (2) Once placed under temperature control while in the possession of the dealer, shellstock shall be:
 - (a) Iced; [C] or
 - (b) Placed in a storage area or conveyance maintained at 45 °Fahrenheit (7.2 °Centigrade) or less; [C] and
 - (c) Not permitted to remain outside temperature control for more than 2 hours at points of processing or transfer such as loading docks. [C]

.02 Sanitation

- A. Safety of Water for Processing and Ice Production
 - (1) Water Supply.
 - (a) Dealers shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]
 - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
 - (i) Prior to use of the water supply; [C]
 - (ii) Every six months while the water supply is in use; [K] and
 - (iii) After any water supply has been repaired and disinfected. [S^{C/K}]
 - (2) Ice production. Any ice used in the processing or storage of shellfish shall

- be made on-site from potable water in a commercial ice machine. [C]
- (3) Shellstock washing
- (a) Water from either a potable water supply, a growing area in the approved classification, a saltwater well approved by the authority, or the restricted area at the time and place of harvest, shall be used to wash shellstock. [C]
 - (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
 - (i) Obtain approval for the construction or remodeling of the system from the Authority; [K]
 - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing, which, after disinfection, meets the coliform standards for drinking water; and does not leave any unacceptable residues in the shellstock; [C]
 - (iii) Test wash water daily for bacteriological water quality; [S^{C/K}]
 - (iv) Clean, service, and test disinfection units at the frequency necessary to ensure effective disinfection. [K]
 - (c) The dealer may use ultra-violet (UV) disinfection in his recirculating wash water system, provided that the turbidity of the water to be disinfected:
 - (i) shall not exceed 20 nephelometric turbidity units (NTUs); [K] and
 - (ii) Is measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. [K]
 - (d) Food contact plumbing which is designed and installed to permit effective cleaning and sanitization shall be used. [C]
- (4) Depuration Process Water. The dealer shall:
- (a) Continuously treat process water with a disinfection system approved by the Authority that does not leave any unacceptable residue in the shellstock; [C] and
 - (b) Verify that the disinfection system produces process seawater with no detectable coliform organisms as measured using an NSSP approved method in the tank influent according to the following sampling protocols.
 - (i) If the source water is an approved growing area, approved well, or other approved source, then the tank influent produced by each disinfection unit is evaluated once per process batch; [C]
 - (ii) If the source water is a restricted growing area, then:
 - a. A study meeting the requirements of Chapter VII. 04. C. is required; [C]
 - b. The tank influent produced by each disinfection unit is evaluated daily; [C] and
 - c. Source water prior to final disinfection must meet the water quality criteria for restricted for depuration in accordance with Chapter IV.02. G-H. [C]
 - (iii) If the source water is a recirculating water system, then:
 - a. A study meeting the requirements of Chapter VII. 04. C. [C] is required; and
 - b. The tank influent produced by each disinfection unit is verified daily. [C]
 - c. A prohibited growing area may not be used for source water. [C]
- (5) Plumbing and Related Facilities.
- (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
 - (i) Prevent contamination of water supplies; [C] and
 - (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]
 - (b) Depuration Plant Design and Construction. The dealer shall ensure that:

- (i) Depuration tanks, processing containers, and piping are fabricated from non-toxic corrosion-resistant materials and are easily cleanable; [K]
 - (ii) Depuration tank design, hydraulics, and typical container configuration are such that process water is evenly circulated throughout all the shellfish containers within a given tank; [K]
 - (iii) Shellfish containers allow process water to flow freely and uniformly to all shellfish within each container. [K]
- (6) Depuration unit
 - (a) Depuration unit including depuration tanks, all reservoir tanks, and related piping shall be fabricated from safe materials, and depuration unit construction is such that it:
 - (i) Is easily accessible for cleaning and inspection; [K]
 - (ii) Is self-draining; [K] and
 - (iii) Meets the requirements for food contact surfaces. [K]

Additional Guidance - Section IV Guidance Documents
Chapter III. Harvesting, Handling, Processing & Distribution .01 Shellfish Industry Equipment Guide

B. Condition and Cleanliness of Food Contact Surfaces.

- (1) Equipment and utensil construction for food contact surfaces.
 - (a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to Shellfish Industry Equipment Construction Guides (August 1993), U.S. Department of Health and Human Services. [K]
 - (b) The dealer shall use only equipment and utensils, including approved plastic ware which is:
 - (i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products; [K]
 - (ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces [K] and
 - (iii) Fabricated from food grade materials.[K]
 - (c) The dealer shall assure that all joints on food contact surfaces:
 - (i) Have smooth easily cleanable surfaces; [K] and
 - (ii) Are welded. [K]
 - (d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in §.02 B (1) (a), (b), and (c). [K]
 - (e) Shellstock washing tanks and related plumbing shall be fabricated from safe materials.
 - (i) Is easily accessible for cleaning and inspection: [K]
 - (ii) Meets requirements for food contact surfaces [K]
- (2) Cleaning and sanitizing of food contact surfaces.
 - (a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces. The dealer shall:
 - (i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses. [K]
 - (ii) Wash, rinse and sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]

- (b) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]
- (c) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. [K]
- C. Prevention of Cross Contamination.
 - (1) Protection of shellfish.
 - (a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S^{C/K}]
 - (b) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment; [K]
 - (2) Separation of Operations: Manufacturing activities which could result in the contamination of the shellstock shall be separated by adequate barriers. [K]
 - (3) Employee practices.
 - (a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
 - (i) Before starting work; [K]
 - (ii) After each absence from the work station; [K]
 - (iii) After each work interruption; [K] and
 - (iv) Any time when their hands may have become soiled or contaminated. [K]
 - (b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
 - (i) Store clothing or other personal belongings [O]
 - (ii) Eat or drink; [K]
 - (iii) Spit; and [K]
 - (iv) Use tobacco in any form. [K]
- D. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities
 - (1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C), dispensed from a hot and cold mixing or combination faucet, shall be provided; [S^{K/O}]
 - (2) Hand washing facilities shall be provided which are:
 - (a) Convenient to work areas; [O]
 - (b) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
 - (c) Directly plumbed to an approved sewage disposal system, and [S^{K/O}]
 - (d) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
 - (3) The dealer shall provide at each hand washing facility;
 - (a) Supply of hand cleansing soap or detergent; [K]
 - (b) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
 - (c) Easily cleanable waste receptacle; and [O]
 - (d) Hand washing signs in a language understood by the employees; [O]
 - (4) Sewage [C] and liquid disposable wastes [K] shall be properly removed from the facility.
 - (5) The dealer shall provide:
 - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; [K]
 - (b) An adequate number of conveniently located toilets. [K]
 - (c) Each toilet facility with an adequate supply of toilet paper [K] in a suitable holder. [S^{K/O}]
- E. Protection from Adulterants.
 - (1) Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing; [K]

- (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]
 - (3) Conveyances or devices used to transport shellstock shall be constructed, maintained and operated to prevent contamination of the shellstock. If overhead monorails or conveyors are used, the dealer shall take precautions to assure that hydraulic fluids or lubricants do not leak or drip onto the shellstock or conveyance surfaces. [K]
 - (4) Adequate ventilation shall be provided to minimize condensation in areas where shellfish are stored, processed or packed. [S^{K/C}]
 - (5) Shellstock packing activities shall be conducted to provide adequate protection from contamination and adulteration. [K]
 - (6) Protection of ice used in shellstock shipping.
 - (a) Any ice which is not made on-site in the depuration facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S^{C/K}]
 - (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S^{C/K}]
 - (c) Any ice used in the processing, storage, or transport of shellstock shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]
 - (7) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations; [K]
 - (8) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. [O]
- F. Proper Labeling, Storage and Use of Toxic Compounds.
- (1) Storage of toxic compounds.
 - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]
 - (b) Each of the following categories of toxic substances shall be stored separately:
 - (i) Insecticides and rodenticides; [K]
 - (ii) Detergents, sanitizers, and related cleaning agents; [K] and
 - (iii) Caustic acids, polishes, and other chemicals. [K]
 - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]
 - (2) Use and labeling of toxic compounds.
 - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]
 - (b) Cleaning compounds/supplies, detergents and sanitizing agents shall be used only in strict accordance with the manufacturer's label instructions and all applicable federal and state laws and regulations. [K]
 - (c) Toxic substances shall be used only in strict accordance with the manufacturer's label instructions. [K]
 - (d) Provide a test kit, strips or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]

Additional Guidance - Section IV Guidance Documents Chapter III. .06 Guidance for Reinstating a Previously Infected Employee

- G. Control of Employees with Adverse Health Conditions.

(1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]

- (a) Norovirus;
- (b) Hepatitis A virus;
- (c) *Shigella* spp.;
- (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*; or
- (e) *Salmonella typhi*.

(2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]

- (a) Has any of the following symptoms:
 - (i) Vomiting;
 - (ii) Diarrhea;
 - (iii) Jaundice;
 - (iv) Sore throat with fever; or
 - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body., or
- (b) Has an illness diagnosed by a health practitioner due to:
 - (i) Norovirus;
 - (ii) Hepatitis A virus;
 - (iii) *Shigella* spp.;
 - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*; or
 - (v) *Salmonella typhi*.
- (c) Had a previous illness, diagnosed by a health practitioner, within the past three (3) months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
- (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
 - (i) Norovirus within the past 24 hours of the last exposure;
 - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. within the past 3 days of the last exposure;
 - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
 - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
- (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
 - (i) Norovirus within the past 24 hours of the last exposure;
 - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. within the past 3 days of the last exposure;
 - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or

- (iv) Hepatitis A virus within the past 30 days of the last exposure.
- (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. **[K]**
- (4) The dealer shall notify the State Shellfish Control Authority and Health Department when *notified* by an employee *of a diagnosis or exhibits symptoms of hepatitis*, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. **[K]**
- H. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from his facility and his activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or where food handling equipment, utensils, and packaging materials are cleaned and stored. **[K]**

.03 Other Model Ordinance Requirements

A. Plants and Grounds.

(1) General

The physical facilities shall be maintained in good repair. **[O]**

(2) Flooding.

(a) Facilities in which shellstock are stored, packed, or repacked shall be located so that these facilities are not subject to flooding during ordinary high tides. **[C]**

(b) If facilities are flooded:

(i) Shellstock processing or repacking activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized. **[C]**

(ii) Any shellstock coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. **[C]**

(3) The dealer shall operate his/her facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from the facility and activities. **[S^{C/K}]**

(4) The dealer shall employ necessary internal and external insect and vermin control measures to insure insects and vermin are not present in the facility.

(a) Tight fitting, self closing doors; **[K]**

(b) Screening of not less than 15 mesh per inch; **[K]** and

(c) Controlled air current. **[K]**

(5) Plant Interior.

(a) Sanitary conditions shall be maintained throughout the facility. **[O]**

(b) Interior surfaces are kept in good repair. **[O]**

(c) All dry area floors are hard, smooth, easily cleanable and in good repair; **[O]** and

(d) All wet area floors used in areas to store shellstock, food processing, and cleaning equipment are constructed of easily cleanable, impervious, and corrosion resistant materials which:

(i) Are graded to provide adequate drainage; **[O]**

(ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; **[O]** and

(iii) Have sealed junctions between floors and walls to render them impervious to water. **[O]**

(e) Walls and ceilings. Interior surfaces of rooms where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials shall be

constructed of easily cleanable, corrosion resistant, impervious and light colored materials. [O]

(6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

- (a) Rodent attraction and harborage; [O]
- (b) Inadequate drainage. [O]

B. Plumbing and Related Facilities.

(1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks. [K]

(2) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:

- (a) Used in shellstock storage; [K]
- (b) Used for food holding units (e.g. refrigeration units); [K]
- (c) Cleaned by hosing, flooding, or similar methods; [K] and
- (d) Subject to the discharge of water or other liquid waste, including, if applicable, three compartment sinks, on the floor during normal activities; [K]

(3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S^{C/K}]

(4) Installation of drainage or waste pipes over processing or storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]

(5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials such that it:

- (a) Is easily accessible for inspection. [K]
- (b) Is self draining. [K]

C. Utilities.

(1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S^{C/K}]

(2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S^{C/K}]

D. Disposal of Wastes.

(1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]

(2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin. [O]

E. Equipment Condition, Cleaning, Maintenance and Construction of Non-food Contact Surfaces.

(1) The dealer shall use only equipment which is constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellstock. [O]

(2) The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks, to construct any non-food contact surfaces in shellfish storage or handling areas. [O]

(3) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. [K]

(4) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]

F. Shellstock Storage and Handling.

(1) The dealer shall assure that shellstock is:

- (a) Reasonably free of sediment; [O] and

- (b) Culled. [K]
- (2) Shellstock shall be stored in a protected location which assures complete and rapid drainage of water away from the shellstock by:
 - (a) Placing shellstock at an adequate height off the floor; [K] or
 - (b) Grading the floor. [O]
- (3) Any mechanical refrigeration equipment used for shellstock storage shall be adequate in size and are equipped with:
 - (a) An automatic temperature regulating control; [K] and
 - (b) Installed thermometers to accurately measure temperature within the storage compartments. [K]
- (4) Inspect incoming shipments and shall reject dead or inadequately protected shellstock. [K]
- (5) Ensure that separate dry storage facilities are provided for depurated and undepurated shellfish. [K]
- (6) Cull and wash the shellstock prior to loading into the depuration tanks. This process may occur before the shellstock is received at the facility by;
 - (a) Licensed harvester(s) at the harvest site; [K] or
 - (b) Certified dealer(s) at their certified facility. [K]
- (7) Assure that culled shellfish are destroyed or disposed of in such a manner as to prevent their use for human food. [K]
- (8) Transport, store, and handle shellstock so that:
 - (a) Shellstock potential for normal physiological activity during depuration is not compromised; [K] and
 - (b) Shellstock quality is not degraded. [K]
- (9) Assure that different harvest lots of shellfish are not commingled during washing, culling, processing, or packing. If more than one harvest lot of shellfish is being processed at the same time, the identity of each harvest lot is maintained throughout the stages of depuration. [K]
- (10) Wash and cull shellstock after depuration and pack the shellstock in clean shipping containers fabricated from safe materials. [K]
- (11) Depurated packaged shellstock shall be protected from contamination at all times and be held at an ambient temperature not to exceed 45 °Fahrenheit (7.2 °Centigrade). [K]
- (12) All shellstock received from a licensed harvester intended for depuration must be introduced into depuration, adequately iced, or placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt.

G. Heat Shock. N/A

H. Supervision.

- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]
- (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellstock or food contact surfaces. [K]
- (3) All supervisors shall be:
 - (a) Trained in proper food handling techniques and food protection principles; [K] and
 - (b) Knowledgeable of personal hygiene and sanitary practices. [K]
- (4) The dealer shall require:
 - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, smoking and/or storing personal items and clothing at work stations. [K]
 - (b) Supervisors to assure that proper sanitary practices are implemented, including:
 - (i) Plant equipment clean up; [K]
 - (ii) Rapid product handling; [K] and
 - (iii) Shellstock protection from contamination. [K]

- (c) Supervisors shall not allow unauthorized persons in those portions of the facility where shellfish are processed, handled, stored or packaged or where food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
- (d) Employees
 - (i) Shall be trained in proper food handling and personal hygiene practices, [K] and
 - (ii) Shall report any symptoms of illness to their supervisor. [K]
- I. Plant Operations Manual. The dealer shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a Depuration Plant Operations Manual (below); and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a Depuration Plant Operations Manual shall address:
 - (1) Introduction including:
 - (a) Status of document (to create, revise, or update DPOM);
 - (b) Ownership and principal(s) involved with operation of facility;
 - (c) Address and phone number of owners and principles; and
 - (d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.
 - (2) Description of the facility including:
 - (a) Site plan drawings;
 - (b) Facility layout including detailed schematic of the entire depuration system;
 - (c) Schematic drawing of process;
 - (d) Product flow diagram showing product movement through facility (may be combined with §01.B.(3);
 - (e) Statement that construction materials and fabrication will meet the requirements of §.03.E. (1) and (2); and
 - (f) Schematic of seawater delivery and distribution system.
 - (3) Design specifications of depuration unit including:
 - (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
 - (b) Process water system describing type of system (flow-through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
 - (c) Shellfish containers construction and material meets §.04 and §.08 of this Chapter; and
 - (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitation equipment.
 - (4) Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);
 - (5) Depuration process monitoring including:
 - (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock, depurated shellstock, and growing waters;
 - (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;
 - (c) Process water monitoring protocol for physical and chemical parameters; and
 - (d) Data analysis and evaluation.
 - (6) Standard Operating Procedure for:
 - (a) Receiving and holding;
 - (b) Washing, culling, and placement of undepurated product in process tanks;
 - (c) Depuration unit operation;

- (d) Monitoring of depuration unit operation;
 - (e) Removal of depurated product from process tanks;
 - (f) Storage parameters and procedures;
 - (g) Labeling/tagging procedures;
 - (h) Plant cleaning and sanitation; and
 - (i) Data analysis.
 - (j) Recall procedures.
- (7) Record Keeping. List categories of information that will be recorded. Include copies of proposed forms to be used in each category. A single form may be used for several categories if properly designed.
- (a) Shipping and receiving records;
 - (b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;
 - (c) Maintenance and Sanitation Log(s);
 - (d) Laboratory records;
- J. Process Verification.
- The Dealer shall continually:
- (1) Routine Verification. Perform process verification on a continuous basis according to the following protocol:
- (a) Following completion of a minimum of 44 hours of depuration, collect and assay at least one end-product sample;
 - (i) From each lot of restricted shellstock to be depurated in the depuration unit.
 - (ii) Weekly from each lot of approved shellfish to be depurated in the depuration unit.
 - (b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.
 - (c) Compare daily, or as a results become available, the depuration performance indices with the following Critical Limits for the Indices of Depuration Plant Performance.

Limits for Verification of Depuration Plant Performance
Fecal Coliform per 100 grams

Species	Geometric Mean	90 th Percentile
Soft Clams (<i>Mya arenaria</i>)	50	130
Hard Clams (<i>Mercenaria mercenaria</i>)	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

- (d) If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.
- (e) For the purpose of making calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. Thus, <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are considered to have >100

colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.

(2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols:

(a) The depuration processor shall collect and assay at least one zero hour and three end-product samples from each harvest lot;

(b) Environmental parameters including process water temperature, salinity, dissolved oxygen, and turbidity and/or other operational conditions may inhibit the physiological process and must be identified. The condition(s), once identified and quantified, become critical control points (CCP) for specific species in the specific plant and the hazard analysis and HACCP plan shall be revised accordingly;

(c) Shellstock which are processed during this conditional protocol must meet the following release criteria before they may be released to market:

(i) Geometric mean (from three samples) of soft clams not to exceed 110 and no single sample to exceed 170; or

(ii) Geometric mean (from three samples) of other clam species, mussels, or oysters not to exceed 45 and no single sample to exceed 100.

(d) If the harvest lot fails to meet the release criteria, the depuration processor may choose to subject the product to additional depuration processing whereupon the shellfish can be resampled for release criteria or the disposition of the shellfish shall be as follows:

(i) The Authority, in consultation with the depuration processor, may order the destruction of the shellfish; or

(ii) The Authority, in consultation with the depuration processor, may allow non-food use of the shellfish; or

(iii) The Authority, in consultation with the depuration processor, may allow the shellfish to be relayed in accordance with Chapter V.

(e) When in Conditional Protocol Verification due to a failure of an established harvest area to meet the above Indices for Depuration Plant Performance, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive end product samples for each species depurated and for each harvest area used

(i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.

(ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in XV§.03 J. (1).

(iii) If either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until the above Indices of Depuration Plant Performance are attained.

(f) When in Conditional Protocol Verification due to the use of a new harvest area as the source of shellfish or if a new depuration process has generated less than 10 process batches of data, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform

- (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.
- (i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.
 - (ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in §XV.03 J. (1).
 - (iii) If less than 10 process batches of data have been collected or either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, from this particular harvest area, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until 10 batches of data have been collected and the above Indices of Depuration Plant Performance are attained.
- (3) When depuration units with multiple tanks are used, it is necessary to determine whether the individual tanks are similar.
- (a) Tanks are considered similar if the difference between physical tank dimensions and process water flow rate is less than 10%.
 - (b) If they are not similar, then the process verification protocols contained in Section .03 J. (1) - (2) must be employed for each tank.
- (4) The dealer shall ensure that all microbiological assays of end-point samples of shellstock:
- (a) Are analyzed by a laboratory which has been evaluated and approved pursuant to the requirements in Chapter III, using an NSSP-approved method;
 - (b) Sample size consists of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish); and
 - (c) Samples are collected at locations within the depuration unit that are considered to be most compromised as regards shellfish activity, based on the sampling plan contained in the Depuration Plant Operations Manual.

Section II

Model Ordinance

Chapter XVI

Post Harvest Processing

- A. If a dealer elects to use a process to reduce the level(s) of one target pathogen or some target pathogens, or all pathogens of public health concern in shellfish, and wishes to make labeling claims regarding the reduction of pathogens, the dealer shall:

(1) Have a HACCP plan approved by the Authority for the process that ensures that the target pathogen(s) are at safe levels for the at risk population in product that has been subjected to the process. The HACCP Plan shall include:

- (a) Process controls to ensure that the end point criteria are met for every lot; and
- (b) A sampling program to periodically verify that the end point criteria are met.
- (c) Analytical results used for validation and verification of a PHP shall come from an analytical laboratory that is evaluated by the State and/or FDA and found to be in compliance with applicable NSSP laboratory requirements.

Additional Guidance - Section IV Guidance Documents
Chapter II Growing Areas 10 Approved NSSP Laboratory Tests

(2) Validate the process by demonstrating that the process will reliably achieve the appropriate reduction in the target pathogen(s). The process shall be validated by a study as outlined in Guidance Documents Chapter IV, Naturally Occurring Pathogens, Section .04 and be approved by the Authority, with concurrent of FDA.

(a) The dealer must demonstrate that the process reduces the level of *Vibrio vulnificus* and/or *Vibrio parahaemolyticus* in the process to non-detectable (<30MPN/gram) and the process achieves a minimum 3.52 log reduction. Determination of *V. vulnificus* and/or *V. parahaemolyticus* levels must be done using the MPN protocols described in Guidance Documents, Chapter IV, Naturally Occurring Pathogens, Section .04 followed by confirmation using methods approved for use in the NSSP.

(b) For processes that target other pathogens the dealer must demonstrate that the level of those pathogens in processed product has been reduced to levels below the appropriate FDA action level, or, in the absence of such a level, below the appropriate level as determined by the ISSC.

(3) Conduct verification sampling to verify that the validated process is working properly. Verification sampling shall be at least equivalent to the verification protocol found in Guidance Documents, Chapter IV, Naturally Occurring Pathogens, Section .04 as determined by the Authority and shall be reviewed annually by the Authority.

(4) Package and label all shellfish in accordance with all requirements of this Ordinance. This includes labeling all shellfish which have been subject to the process but which are not frozen in accordance with applicable shellfish tagging and labeling requirements in Chapter X.05 and X.06.

(5) Keep records in accordance with Chapter X.07.

- B. A dealer who meets the requirements of this section may label product that has been subjected to the reduction process as:

(1) "Processed for added safety", if the process reduces the levels of all pathogens of public health concern to safe levels for the at risk population;

- (2) "Processed to reduce [name of target pathogen(s)] to non-detectable levels," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or
 - (3) "Processed to reduce [name of target pathogen(s)] to non-detectable levels for added safety," if the process reduces one or more, but not all, pathogens of public health concern to safe levels for the at risk population, and if that level is non-detectable; or
 - (4) A term that describes the type of process applied (e.g. "pasteurized," "individually quick frozen," "pressure treated") may be substituted for the word "processed" in the options contained in B. (1) - (3).
- C. For the purposes of ~~refrigeration~~ product temperature the receiving and storage critical control points of Chapter XI, ~~shall apply to shellstock prior to PHP processing.~~ Following PHP processing, if the product is dead, the product shall be treated as in-shell or shucked product. If the product is live, the product shall be treated as shellstock.