National Shellfish Sanitation Program (NSSP)

Guide for the Control of Molluscan Shellfish 2017 Revision

From the U.S. Food and Drug Administration website
http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2006754.htm

This document is intended to provide guidance and shall supersede the 2015 NSSP Model Ordinance. It represents the Agency's current thinking on the safe and sanitary control of the growing, processing, and shipping of molluscan shellfish for human consumption. It does not create any rights for or on any persons and does not operate to bind FDA or the public under Federal law. However, through their participation in the National Shellfish Sanitation Program and membership in the Interstate Shellfish Sanitation Conference, States have agreed to enforce the Model Ordinance as the requirements which are minimally necessary for the sanitary control of molluscan shellfish.

U. S. Department of Health and Human Services
Public Health Service
Food and Drug Administration

Interstate Shellfish Sanitation Conference

2017 Revision

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Section I. Purpose & Definitions

Purpose

The National Shellfish Sanitation Program (NSSP) is the Federal/State cooperative program recognized by the U. S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and whole or roe-on scallops) moving in interstate commerce through Federal/State cooperation and uniformity of State shellfish programs.

Participants in the NSSP include agencies from shellfish producing and non-producing States, FDA, EPA, NOAA, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP. Other components of the NSSP include program guidelines, State growing area classification and dealer certification programs, and FDA evaluation of State program elements.

In 1984, the FDA entered into a Memorandum of Understanding (MOU) with the Interstate Shellfish Sanitation Conference recognizing the ISSC as the primary voluntary national organization of State shellfish regulatory officials that provide guidance and counsel on matters for the sanitary control of shellfish. The purpose of the ISSC is to provide a formal structure for State regulatory authorities to participate in establishing updated regulatory guidelines and procedures for uniform State application of the Program. The ISSC has adopted formal procedures for State representatives to review shellfish sanitation issues and develop regulatory guidelines. Following FDA concurrence, these guidelines are published in revisions of the NSSP Model Ordinance.

The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the Program. The Model Ordinance includes guidelines to ensure that the shellfish produced in States in compliance with the guidelines are safe and sanitary. The Model Ordinance provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish.

Definitions

Purpose

This Ordinance establishes the minimum requirements necessary to regulate the interstate commerce of molluscan shellfish and to establish a program to protect the public health of consumers by assuring the sale or distribution of shellfish from safe sources and assuring shellfish have not been adulterated during cultivating, harvesting, processing, shipping, or handling.

Definitions

A. General. The definitions provided below are consistent in intent with the NSSP.

B. Definition of Terms.

(1) **Adequately Iced** means that the amount and application of the ice is sufficient to ensure that immediate cooling begins and continues for all shellfish. If ice slurry is used and the shellfish are submerged the presence of ice in the slurry indicates adequate icing.

(2) **Adverse Pollution Condition** means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that has historically resulted in elevated fecal coliform levels in a particular growing area. [In States using total coliform standard, insert "total coliform" for "fecal coliform".]

(3) **Air Gap** means the unobstructed vertical distance through the free atmosphere between the lowest opening from any pipe or faucet supplying water to a tank, plumbing fixture or other device and the flood level rim of that receptacle.

(4) **AOAC** means the Association of Official Analytical Chemists.

(5) **APHA** means the American Public Health Association.

(6) **Approved** means a classification used to identify a growing area where harvest for direct marketing is allowed.

(7) **Approved Limited Use Methods** are permanent methods accepted for use in the NSSP and listed in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests. These methods include new methods, alternative methods or screening methods within the NSSP that meet an immediate need of the NSSP, improve turnaround time, cost effectiveness, and/or increase analytical capacity. These methods have been evaluated and the performance characteristics for specific applications in the NSSP have been determined through the Single Laboratory Validation Method Protocol (SLV) to be fit for purpose within the NSSP. These methods are referred to as being of limited use within the NSSP either because of their status as newly adopted methods with little corroborating data beyond the SLV or because the application for which the method can be or is used within the NSSP is limited in scope with little laboratory participation within the NSSP and little to no subsequent corroborating data or because of the nature of the test method itself and/or restrictions that have been placed on its use that limit its usefulness within the NSSP.

(8) **Approved NSSP Methods** are the primary/core methods used in the NSSP and cited in the NSSP Guide for the Control of Molluscan Shellfish, Guidance Documents Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests. These methods have been described

in scientific or other peer-reviewed professional publications; have been used historically or are used throughout the NSSP and elsewhere to effectively detect or quantify and have been extensively evaluated and the performance characteristics for specific applications in the NSSP determined as fit for purpose through long use in the NSSP and/or Single Laboratory Validation (SLV) testing and/or collaborative study.

(9) **Aquaculture** means cultivating shellfish in controlled conditions for human consumption. Cultivation includes propagation and growing of shellfish. These activities may occur in natural or man-made water bodies. These activities include seed collection, production, and cultivation in natural water bodies when shellfish are held off the bottom such as the use of racks, bags, or cages, and when shellfish are held in man-made water bodies such as the use of tanks, ponds, or raceways. These activities do not include depuration or wet storage.

(10) **Authority** means the State or local shellfish control authority or authorities or its designated agents, which are responsible for the enforcement of this Code.

(11) **Assure** means to make best efforts within the reasonable limits of manpower and resources to fulfill the objectives of this Ordinance.

(12) **Backflow** means the flow of water or other liquids, mixtures or substances into the distribution pipes of a potable water supply from any source or sources other than the intended source.

(13) **Back Siphonage** means the flowing back of used, contaminated or polluted water from a plumbing fixture, vessel or other source into potable water supply pipes because of negative pressure in the water supply pipes.

(14) **Blower** means a receptacle for washing shucked shellfish which uses forced air as a means of agitation.

(15) **Broker** means any person who is not a dealer but who arranges the packaging, shipping, sale, or distribution of molluscan shellfish without taking ownership or physical custody of the shellfish.

(16) **Certification or Certify** means the issuance of a numbered certificate to a person for a particular activity or group of activities that indicates:
(a) Permission from the Authority to conduct the activity; and
(b) Compliance with the requirements of this Code.

(17) **Certification Number** means the unique identification number issued by the Authority to each dealer for each location. Each certification number shall consist of a one (1) to five (5) digit Arabic number preceded by the two letter State abbreviation and followed by a two (2) letter abbreviation for the type of activity or activities the dealer is qualified to perform in accordance with this Ordinance using the following terms:
(a) Shellstock shipper (SS);
(b) Shucker-packer (SP);
(c) Repacker (RP);
(d) Reshipper (RS); and
(e) Depuration processor (DP).

(18) **Coliform Group** means all of the aerobic and facultative anaerobic, gram negative, non-spore forming, rod shaped bacilli which ferment lactose broth with gas formation within 48 hours at 95 °Fahrenheit (35 ± 0.5 °Centigrade).

(19) **Commingle or Commingling** means the act of combining different lots of shellfish.

(20) **Compliance Schedule** means a written schedule that provides a correction time period to eliminate Key and Other deficiencies.

(21) **Conditionally Approved** means a classification used to identify a growing area which meets the criteria for the approved classification except under certain conditions described in a

management plan.

(22) **Conditionally Restricted** means a classification used to identify a growing area that meets the criteria for the restricted classification except under certain conditions described in a management plan.

(23) **Container** means any bag, sack, tote, conveyance or other receptacle used for containing shellfish for holding or transporting.

(24) **Corrosion Resistant Materials** means materials that maintain their original surface characteristics under normal exposure to the foods being contacted, normal use of cleaning compounds and bactericidal solutions, and other conditions of use.

(25) **Conveyance** means any type of container used to transport shellfish. The controls of the NSSP are intended to address the container in which the shellfish are being held during transport from landing to final consumer. For the purposes of meeting the NSSP time temperature requirements for conveyances, the containers in which the shellfish are being held must meet the required temperatures. Should shellfish be shipped in a small container within a cargo space, the temperature requirement would apply only to the temperature within the container.

(26) **Critical Control Point (CCP)** means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.

(27) **Critical Deficiency** means a condition or practice which:
(a) Results in the production of a product that is unwholesome; or
(b) Presents a threat to the health or safety of the consumer.

(28) **Critical Limit** means the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate or reduce to an acceptable level the occurrence of the identified food safety hazard.

(29) **Critical Nonconformity** means a deviation of a laboratory requirement which has the highest likelihood of adversely affecting the quality of the analytical results if out of conformance.

(30) **Cross Connection** means an unprotected actual or potential connection between a potable water system and any source or system containing unapproved water or a substance that is not or cannot be approved as safe and potable. Examples are bypass arrangements, jumper connection, removable sections, swivel or change over devices, or other devices through which backflow could occur.

(31) **Cull** means to remove dead or unsafe shellstock from a lot of shellstock.

(32) **Dealer** means a person to whom certification is issued for the activities of shellstock shipper, shucker-packer, repacker, reshipper, or depuration processor.

(33) **Depletion** means the removal, under the direct control of the Authority, of shellstock from a growing area classified as prohibited.

(34) **Depuration** or **Depurate** means the process of reducing the pathogenic organisms that may be present in shellstock by using a controlled aquatic environment as the treatment process.

(35) **Depuration Processor (DP)** means a person who harvests or receives shellstock from growing areas in the approved or conditionally approved, restricted, or conditionally restricted classification and submits such shellstock to an approved depuration process.

(36) **Direct Marketing** means the sale for human consumption of shellfish which:
(a) Does not require depuration or relaying prior to sale; or
(b) Has been subjected to depuration or relaying activities.

(37) **Dry Storage** means the storage of shellstock out of water.

(38) **Easily Cleanable** means a surface which is:
(a) Readily accessible; and
(b) Is made of such materials, has a finish, and is so fabricated that residues may be effectively removed by normal cleaning methods.

(39) **Emergency Use Methods** are methods used to meet an immediate or ongoing critical need for

a method of analysis and no NSSP approved method exists. Emergency Use Methods may be given interim approval by the ISSC Executive Board provided the criteria in Procedure XV. of the ISSC Constitution, Bylaws, and Procedures are provided.

(40) **EPA** means the United States Environmental Protection Agency.

(41) **Facility** means a structure. For other connotations, use person or activity.

(42) **Fecal Coliform** means that portion of the coliform group which will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within 24 (± 2) hours in a water bath maintained at 112 °Fahrenheit (44.5 ± 0.2 °Centigrade).

(43) **Federal Waters** means the waters that fall outside of State and local jurisdiction but within U.S. sovereignty (typically 3-200 nautical miles offshore). Federal waters include the territorial sea and exclusive economic zone.

(44) **FDA** means the United States Food and Drug Administration.

(45) **Float Aquaculture** means open water aquaculture where the shellfish product is suspended at the water surface using floats.

(46) **Food Contact Surface** means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.

(47) **Food Safety Hazard** means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.

(48) **Geometric Mean** means the antilog (base 10) of the arithmetic mean of the sample result logarithm (base 10).

(49) **Growing Area** means any site which supports or could support the propagation of shellstock by natural or artificial means.

(50) **HACCP** is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science-based approach used in food production as a means to assure food safety. The concept is built upon the seven principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992).

(51) **HACCP Plan** means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 Code of Federal Regulations (CFR) 123.6 as adopted by the Interstate Shellfish Sanitation Conference.

(52) **Harvest** means the act of removing shellstock from growing areas and its placement on or in a manmade conveyance or other means of transport.

(53) **Harvest Area** means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.

(54) **Harvester** means a person who takes shellstock by any means from a growing area.

(55) **Heat Shock** means the process of subjecting shellstock to any form of heat treatment prior to shucking, including steam, hot water or dry heat, to facilitate removal of the meat from the shell without substantially altering the physical or organoleptic characteristics of the shellfish.

(56) **Importer** means any dealer who introduces molluscan shellfish into domestic commerce. An importer has ownership of the shellfish, but need not take physical custody of the shellfish.

(57) **Includes or Including** means includes or including by way of illustration and not by way of limitation.

(58) **In-Shell Product** means non-living, processed shellfish with one or both shells present.

(59) **In-Shell Product Packing** means the process of placing in-shell product into containers for introduction into commerce.

(60) **Inspection Item** means one of the standard criteria listed in the NSSP Plant Inspection Form under which single or multiple observations of specific critical, key or other deficiencies can be debited. [Note: term "item" appears several places in the Ordinance with a larger connotation than this definition. In the section addressing the use of the inspection form, however, the Ordinance uses the term "inspection item" hence that is provided here as

the defined term.]

(61) **Interstate Certified Shellfish Shippers List (ICSSL)** means an FDA publication of shellfish dealers, domestic and foreign, who have been certified by a State or foreign Authority as meeting the public health control measures specified in this Ordinance.

(62) **Interstate Shellfish Sanitation Conference (ISSC)** means the organization which consists of agencies from shellfish producing and receiving States, FDA, the shellfish industry, NOAA, and the EPA. The ISSC provides the formal structure wherein State regulatory authorities, with FDA concurrence, can establish updated guidelines and procedures for sanitary control of the shellfish industry.

(63) **Key Deficiency** means a condition or practice which may result in adulterated, decomposed, misbranded or unwholesome product.

(64) **Key Nonconformity** means a deviation of a laboratory requirement that has a significant potential to adversely affect the quality of the analytical results if out of conformance.

(65) **Label** means any written, printed or graphic matter affixed to or appearing upon any package containing shellfish.

(66) **Landing** means the point at which shellstock is put on land or a dock.

(67) **License** means the document issued by the Authority to a person to harvest or transport shellstock for commercial sale. [In those States issuing permits as opposed to licenses, the term license would be replaced with the term "permit" which would be defined the same as "license".]

(68) **Lot of In-Shell Product** means a single type of container of in-shell product of no more than one day's harvest from a single defined growing area.

(69) **Lot of Shellstock** means a single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area gathered by one (1) or more harvesters. A lot may also be used to segregate the harvest times and intended uses of shellstock for the purposes of complying with time to temperature requirements.

(70) **Lot of Shellstock for Depuration** means shellstock harvested from a particular area during a single day's harvest and delivered to one depuration plant.

(71) **Lot of Shucked Shellfish** means a collection of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible and designated by a common container code or marking.

(72) **Male-specific Coliphage (MSC)** are a group of bacterial viruses that infect and lyse *E. coli Famp* and produce plaques within 18 ± 2 hours at 35-37 ± 0.5 °Centigrade.

(73) **Marina** means any water area with a structure (docks, basin, floating docks, etc.) which is:

(a) Used for docking or otherwise mooring vessels; and

(b)Constructed to provide temporary or permanent docking space for more than ten (10) boats.

(74) **Marine Biotoxin** means any poisonous compound produced by marine microorganisms and accumulated by shellstock. Examples include toxins produced by *Alexandrium spp.* [*Protogonyaulax* species] and *Karenia brevis*.

(75) **May** means discretionary and is not mandatory or required.

(76) **Milliliter (ml)** means a unit of measurement equal to the 0.001 portion of a liter.

(77) **Monoculture** means the culture of a single bivalve species.

(78) **Most Probable Number (MPN)** means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.

(79) **National Shellfish Sanitation Program (NSSP)** means the cooperative State-FDA-Industry program for the sanitary control of shellfish that is adequate to ensure that the shellfish produced in accordance with these guidelines will be safe and sanitary.

(80) **Open Water Aquaculture** means the cultivation of bivalve shellfish in natural shellfish growing areas.

(81) **Other Deficiency** means a condition or practice that is not defined as critical or key and is

not in accordance with the requirements of this Model Ordinance.

(82) **Other Nonconformity** means a deviation of a laboratory requirement which does not normally compromise the quality of the analytical results, but generally serves to enhance the overall operation of the laboratory.

(83) **Person** means any individual, receiver, trustee, guardian, personal representative, fiduciary, or representative of any kind, and any partnership, association, corporation or other entity. Person includes the Federal government, the State, and any other public or private entity.

(84) **Point Source** means any discernible, confined and discrete conveyance including any pipe, ditch, channel, tunnel or conduit that carries pollution.

(85) **Poisonous or Deleterious Substance** means a toxic substance occurring naturally or added to the environment for which a regulatory tolerance limit or action level has been established in shellfish to protect public health.

(86) **Polyculture** means the cultivation of:
(a) Two (2) or more species of shellfish; or
(b) Shellfish with other species in a common environment.

(87) **Post-Harvest Processing** means any process which has been validated using NSSP validation procedures which reduces the levels of pathogenic hazards to below the appropriate FDA action level or in the absence of such a level, below the appropriate level as determined by the ISSC.

(88) **Post-Harvest Processor** means a designation given to a shellfish dealer that has incorporated a post-harvest process.

(89) **Potable Water** means a water supply, which meets the requirements of the Safe Drinking Water Act, as, administered by the EPA, and any applicable state or local requirements.

(90) **Principal Display Panel** means that part of a label that is most likely to be displayed, presented, shown or examined under customary conditions of retail sale.

(91) **Processing** means any activity associated with the handling, shucking, freezing, packing, labeling or storing of shellfish in preparation for distribution. This would include the activities of a shellstock shipper, shucker packer, repacker, reshipper, or depuration processor.

(92) **Process Batch** means a quantity of shellstock used to fill each separate tank or a series of tanks supplied by a single process water system for a specified depuration cycle in a depuration activity.

(93) **Process Water** means the water used in the scheduled depuration process.

(94) **Prohibited** means a classification used to identify a growing area where the harvest of shellstock for any purpose, except depletion, gathering of seed or nursery culture for aquaculture, is not permitted.

(95) **Raw** means shellfish that have not been thermally processed:
(a) to an internal temperature of 145 °Fahrenheit or greater for 15 seconds (or equivalent); or
(b) altering the organoleptic characteristics.

(96) **Receipt of Shellfish** means the Critical Control Point where a shellfish dealer takes possession of shellfish at a location where it will be processed and/or will be shipped to another dealer or retail establishment. At this (location) point the dealer will monitor at receiving Critical Control Points to ensure compliance with Critical Limits. This is also the (location) point at which the dealer will monitor storage and shipping Critical Control Points.

(97) **Relay** means to transfer shellstock from a growing area classified as restricted or conditionally restricted to a growing area classified as approved or conditionally approved for the purpose of reducing pathogens as measured by the coliform indicator group or poisonous or deleterious substances that may be present in the shellstock by using the ambient environment as the treatment process.

(98) **Remote status** means a designation applied to a shellfish growing area that has no human habitation and is not impacted by any actual or potential pollution sources.

(99) **Repacker (RP)** means any person, other than the original certified shucker-packer, who repackages shucked shellfish into other containers.

(100) **Repacking In-Shell Product** means the practice of removing in-shell product from containers and placing it into other containers.

(101) **Repacking Shellstock** means the practice of removing shellstock from containers and placing it into other containers.

(102) **Replicate** is defined as two (2), or more, laboratory analyses conducted from the same sample at the same dilution using the same method.

(103) **Reshipper (RS)** means a person who purchases shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers, or retailers.

(104) **Restricted** means a classification used to identify a growing area where harvesting shall be by special license and the shellstock, following harvest, is subjected to a suitable and effective treatment process through relaying or depuration.

(105) **Restricted Use Shellstock** means shellstock that is harvested from growing areas classified as approved or conditionally approved in the open status and under conditions that do not allow the sale of the shellstock for direct marketing for raw consumption. Restricted use shellstock is identified with a tag indicating that the shellstock is intended for further processing prior to distribution to retail or food service.

(106) **Safe Materials** means articles manufactured from or composed of materials that may not reasonably be expected to, directly or indirectly, become a component of or otherwise adversely affect the characteristics of any food.

(107) **Sanitation Control Record** means records that document the monitoring of sanitation practices and conditions during processing.

(108) **Sanitary Survey** means the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on the water quality in a shellfish growing area.

(109) **Sanitize** means to adequately treat food contact surfaces by a process that is effective in:
(a) Destroying vegetative cells of microorganisms of public health significance;
(b) Substantially reducing the numbers of other undesirable microorganisms; and
(c) Not adversely affecting the product or its safety for the consumer.

(110) **Seed** means shellstock which is less than market size.

(111) **Shall** means mandatory and required.

(112) **Shellfish** means all species of:
(a) Oysters, clams or mussels, whether:
(i) Shucked or in the shell;
(ii) Raw, including post-harvest processed;
(iii) Frozen or unfrozen;
(iv) Whole or in part; and
(b) Scallops in any form, except when the final product form is the adductor muscle only.

(113) **Shellfish Gardening** is non-commercial shellfish culture for the purposes of enhancing water quality, or enhancing natural stocks and not for sale for consumption.

(114) **Shellstock** means live molluscan shellfish in the shell.

(115) **Shellstock Packing** means the process of placing shellstock into containers for introduction into commerce.

(116) **Shellstock Shipper (SS)** means a dealer who grows, harvests, buys, or repacks and sells shellstock. They are not authorized to shuck shellfish nor to repack shucked shellfish. A shellstock shipper may also buy, repack, and sell in-shell product as well as ship shucked shellfish.

(117) **Should** means recommended but is not required.

(118) **Shucker-Packer (SP)** means a person who shucks and packs shellfish. A shucker-packer may

act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.

(119) **Standardization** means a process in which applicable staffs from the FDA and the Authority conduct evaluations using standard criteria in a uniform manner.

(120) **State Shellfish Standardization Inspector** means a person that has successfully completed the FDA standardization training course (or one deemed acceptable by the FDA and the field evaluation phase of shellfish plant inspection with either an FDA standardization officer or a State standardization officer).

(121) **State Shellfish Standardization Officer** means a person that has successfully completed the FDA standardization training course and the field evaluation phase of shellfish plant inspection with an FDA standardization officer.

(122) **Swing Deficiency** means a deficiency noted on the NSSP Standardized Shellfish Processing Plant Inspection Form which, depending upon the severity and circumstances, can be either a "Critical" or a "Key" deficiency.

(123) **Transaction Record** means the form or forms used to document each purchase or sale of shellfish at the wholesale level and includes shellfish harvest and sales records, ledgers, purchase records, invoices and bills of lading.

(124) **Trip Records** means a form of written documentation that includes the date and time of each lot of shellfish harvested.

(125) **Wastewater Collection System** means a collection system which may comprise of sanitary sewer pipes, or a combination of sanitary sewer pipes and storm water pipes, and pump stations to ensure that disposed wastewater is delivered to the wastewater treatment plant to be treated.

(126) **Wastewater Treatment Plant (WWTP)** means a facility that treats or removes contaminants from sanitary and industrial sewage through a combination of processes to a point where it can be discharged to the environment or reclaimed for other purposes.

(127) **Wastewater Treatment Plant Design Flow** means the flow that the WWTP is designed to discharge over a specified time period (such as hourly, daily, monthly, or annually) and typically expressed as a daily or hourly average with the expectation of meeting permit requirements.

(128) **Wet Storage** means the storage, by a dealer, of shellstock from growing areas in the approved classification or in the open status of the conditionally approved classification in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater at any permitted land-based activity or facility.

Section II. Model Ordinance

Chapter I. Shellfish Sanitation Program Requirements for the Authority

Additional Guidance: Section IV. Guidance Documents - Chapter I. Section .02

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

@.01 Administration

A. Scope. The Authority shall establish a statewide shellfish safety and sanitation program to regulate:
   (1) The classification of shellfish growing areas;
   (2) The harvesting of shellfish;
   (3) Shellfish processing procedures and facilities;
   (4) Product labeling;
   (5) Storage, handling and packing;
   (6) Shellfish shipment in interstate commerce;
   (7) Shellfish dealers; and
   (8) Bivalve aquaculture.

B. State Laws and Regulations. The Authority shall have laws and regulations which provide an adequate legal basis for the safety and sanitary control of all program elements including but not limited to the elements outlined in @.01 A.

C. Records. The Authority shall maintain records to demonstrate the effective administration of a statewide shellfish safety and sanitation program. These records shall be maintained in a central file and made available physically and/or electronically to any interested person upon request, consistent with appropriate State and Federal law.

D. Shared Responsibilities. If more than one agency is involved in the administration of the statewide shellfish safety and sanitation program, memoranda of agreement shall be developed between the agencies to define each agency's responsibilities.

E. Administrative Procedures. The Authority shall have administrative procedures sufficient to:
   (1) Regulate shellfish harvesting, sale, and shipment;
   (2) Ensure that all shellfish shipped in interstate commerce originate from a dealer located within the State from which the shellstock are harvested or landed, unless the Authority has a memorandum of understanding with the Authority in another State to allow dealers from its State to purchase the shellstock;
   (3) Detain, condemn, seize, and embargo shellfish; and
   (4) Assure compliance with Shellfish Plant Inspection Standardization.

F. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness.
   The Authority shall:
   (1) Have a written protocol with the appropriate State agencies responsible for collecting epidemiological information related to reported foodborne illnesses. The protocol shall outline the procedure to ensure that all shellfish related illnesses are reported to the shellfish Authority(s); and
   (2) Have procedures for investigating incidents of shellfish borne disease.

G. Commingling.

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

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

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

(b) Define a primary dealer;

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

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

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

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

@.02 Dealer Certification

A. General

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

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

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

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

(a) Maintained as a separate entity; and

(b) Is not found at the same location.

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

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

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

(a) Inspection reports of dealers;

(b) Notification letters and enforcement actions;

(c) Shellfish sample results and follow-up actions taken;

(d) Records of complaints or inquiries and follow-up actions taken; and

(e) Administrative hearing transcripts and records.

B. Initial Certification.

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

(a) HACCP requirements:

(i) A HACCP plan accepted by the Authority;

(ii) No critical deficiencies;

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

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

(b) Sanitation and additional Model Ordinance Requirements

(i) No critical deficiencies;

(ii) Not more than two (2) key deficiencies; and
(iii) Not more than three (3) other deficiencies.

(2) The initial certification shall include a compliance schedule to correct any deficiencies not corrected by the dealer during the inspection.

C. Renewal of Certification.

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

(a) Meets the requirements of Section B. 1. (a) and Section B. 1. (b). The number of deficiencies allowed under Section B. 1. (a) and Section B. 1. (b) shall include carry over deficiencies from an existing compliance schedule approved by the Authority and new deficiencies identified during the certification renewal inspection; and
(b) Agrees to a compliance schedule to address any new deficiencies not corrected by the dealer during the inspection.

D. Revocation or Suspension of Certification.

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

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

E. Interstate Certified Shellfish Shippers List (ICSSL).

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

Designations:

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

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

(a) Suspended; or
(b) Revoked.

F. Inspections.

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

(a) During periods of activity; and
(b) At the following minimum frequencies:
(i) Within thirty (30) days of beginning activities if the dealer was certified on the basis of a pre-operational inspection;
(ii) At least monthly for dealer facilities certified as depuration processors;
(iii) At least quarterly for dealer's activities certified as shucker-packer or repacker; and
(iv) At least semiannually for other dealer activities.

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

Ordinance.

G. Performance Based Inspection Program (PIP).

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

(2) The minimum frequency of inspection under a PIP shall be no less than one (1) inspection per certification period. The recertification inspection may qualify as the required minimum inspection frequency.

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

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

(b) Recertification of the dealer by the Authority;

(c) Verification that no critical deficiencies, no more than one (1) key deficiency and no more than two (2) other deficiencies have occurred in any one inspection;

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

(e) No repetition of the identified deficiencies.

H. Enforcement.

(1) General.

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

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

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

(ii) Document why an option was selected.

(2) Actions Triggered by Inspections.

(a) When any inspection detects a critical deficiency:

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

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

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

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

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

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

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

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

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

(i) Revise the existing compliance schedule;

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

(iii) Seek other administrative remedies.

@.03 Evaluation of Shellfish Sanitation Program Elements

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

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

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

1. Laboratory
   a. Requirements for evaluation of shellfish laboratories shall include at a minimum:
      i. Records audit of laboratory operations both Quality Systems and Technical methods;
      ii. Direct observation of current laboratory operating conditions; and
      iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.
   b. Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists found in Section IV Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
      i. Quality System Evaluation.
         (a) This checklist includes a conforming and nonconforming status only. All nonconformities must be reconciled prior to scheduling an onsite evaluation of technical methods in NSSP laboratories. As this part of the evaluation specifically refers to the Quality manual and SOPs and other documentation considered the basis for data defensibility, this documentation must be in order prior to further Laboratory Evaluation Officer (LEO) scheduling. The Quality Systems evaluation is performed as a desk audit and is in accordance with the checklist found in Section IV Chapter II.
      ii. Technical Evaluation: Conforms. In order to achieve or maintain conforming status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:
         (a) No critical nonconformities in the microbiological or marine biotoxin component under evaluation have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and
         (b) Not more than thirteen (13) key nonconformities in the microbiological

component or six (6) in the marine biotoxin components have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and

(c) Not more than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, twelve (12) critical, key and other nonconformities in total for the paralytic shellfish poisoning (PSP) and amnesic shellfish poisoning (ASP) components, or ten (10) critical, key and other nonconformities in total for the neurotoxic shellfish poisoning (NSP) component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and

(d) No repeat key nonconformities have been identified in the microbiological or marine biotoxin component under evaluation in consecutive evaluations using the appropriate NSSP Shellfish Laboratory Evaluation Checklist.

iii. Technical Evaluation: Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:

(a) Not more than three (3) critical nonconformities in the microbiological component, four (4) in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and

(b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and

(c) Not more than eighteen (18) critical, key and other nonconformities in total in the microbiological component, or twelve (12) critical, key and other nonconformities in total in the PSP and ASP components or ten (10) critical, key and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and

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

iv. Technical Evaluation: Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:

(a) More than three (3) critical nonconformities in the microbiological component or four (4) in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Checklist; or

(b) More than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist;

(c) More than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, or more than twelve (12) critical, key and other nonconformities in total in the PSP and ASP components, or more than ten (10) critical, key, and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; or

(d) One (1) or more repeat critical or two (2) or more repeat key nonconformities

have been identified in consecutive evaluations in either the microbiological or marine biotoxin components using the appropriate NSSP Shellfish Laboratory Evaluation Checklist.

c. Corrective Actions for Conforming Status. A laboratory found to be in conforming status for technical checklists, other than the Quality Systems checklist, has up to ninety (90) days to successfully correct all nonconformities noted in each component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory's status will be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component in question.

d. Corrective Actions for Provisionally Conforming Status. A laboratory found to be in provisionally conforming status for technical methods checklists has up to sixty (60) days to successfully correct all nonconformities found in each provisionally conforming component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory will be assigned the following status for the laboratory component(s) in question:

   i. Conforms if all the critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated; or

   ii. Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluated or if the lab is not able to be evaluated because of a nonconforming Quality System. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component in question.

e. Nonconformance.

   i. Upon a determination of nonconforming status in any of the technical method components, the laboratory has up to thirty (30) days to demonstrate successful correction of all nonconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming for the laboratory component(s) in question. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory components will continue to be unacceptable for use in support of the NSSP.

   ii. Upon a determination of nonconformance for the Quality Systems component, the laboratory will have to successfully implement a quality system prior to the onsite technical evaluation. Once all nonconformities are reconciled successfully, a technical evaluation for NSSP methods using the appropriate method specific NSSP Shellfish Laboratory Evaluation Checklist will be scheduled with the laboratory.

   iii. When a laboratory is found to be nonconforming in either the technical or quality component or in both components for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority will ensure that an action plan is developed to correct the situation in an acceptable and expeditious manner or discontinue use of the laboratory to support the NSSP.

   iv. For each laboratory component evaluated, the laboratory will be reevaluated either on-site or through a thorough desk audit as determined by the FDA Shellfish LEO and the FDA certified State Shellfish LEO if one is utilized by the State. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable

to the NSSP will restore its acceptability for use in the NSSP for the laboratory components in question.

2. Growing Areas

Requirements for evaluation of the shellfish growing area program element shall include at a minimum:

a. Records audit of sanitary survey;
b. Bacteriological standards;
c. Growing area classification;
d. Marine biotoxin control; and
e. Marinas.

3. Patrol

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

b. Legal Penalties – Chapter VIII. @.01 A. (2) (c) Are there penalties in place to address illegal harvest?

   Compliance Criteria: The patrol element will be deemed in compliance if laws and regulations exist that provide penalties for controlling harvest from harvest restricted areas. **[Critical]**

c. Notification of Harvest Restricted Areas – Chapter VIII. @.01 A. (2) (d)
   Is the industry notified of the boundaries of Harvest Restricted Areas? – Chapter VIII. @.01 A. (3) (b)

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

d. Comprehensive Listing of Harvest Restricted Areas –
   Does the Patrol Agency have a comprehensive listing of Harvest Restricted areas?

   Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the Authority has a comprehensive listing of all Harvest Restricted areas. **[Critical]**

e. Patrol Policy Document – Chapter VIII. @.01 B. (7).
   i. Does the Patrol Agency have a patrol policy document?

      Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Authority provides a patrol policy document. **[Key]**

   ii. Is the patrol policy document complete?

      Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the patrol policy document includes all items in Chapter VIII. @.01 B. (7) listed below. **[Key]**

      (a) Citation of the law providing the legal basis for enforcement authority
      (b) Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;
      (c) The organizational structure of the unit responsible for patrol activities, including:
         (1) Patrol unit(s) name, address, and phone number;
         (2) The roster and chain of command;
         (3) Area assignments that support the frequencies of patrol delineated in B. (2); and
         (4) A listing of specific vessels, vehicles, and equipment that support the

frequencies of patrol delineated in @.01 B. (2);
(d) Summaries of training in shellfish patrol techniques;
(e) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;
(f) A listing of growing areas where patrol is required;
(g) An identification of any patrol problems;
(h) The type and frequency of reporting by patrol personnel;
(i) Copy of agreements with other agencies responsible for shellfish control activities; and
(j) Citations/summons for the past year. If available, this information may include:
(1) The number of convictions or dismissals;
(2) Fines in dollar amount;
(3) Equipment or property confiscations and forfeitures;
(4) License suspensions or revocations; and
(5) Jail sentences; and
(6) Written warnings.

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

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

g. Patrol Frequency – Chapter VIII. @.01 B. (2).
i. Has the agency determined risk categories for all harvest restricted areas? – Chapter VIII. @.01 B. (4)?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Authority assigns risk categories for each harvest restricted area and provides a listing of those categories. **[Critical]**

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

iii. Has the patrol frequency requirement been met in all areas? – Chapter VIII. @.01 B. (3) (b), (c), and (d)
Compliance Criteria: The patrol element will be deemed in compliance as follows:
(a) When the Authority achieved 95-100 percent of required patrols in all harvest restricted areas the program is considered to be in conformance with NSSP patrol frequency requirements.
(b) When the Authority achieved 80 – 94 percent of required patrols in all harvest restricted areas the program is considered to be in nonconformance with NSSP patrol frequency requirements. **[Key]**
(c) When the Authority achieved <80 percent of required patrols in all harvest restricted areas the program is considered to be in major non- conformance with

NSSP patrol frequency requirements. **[Critical]**

h. Memorandum of Understanding/Agreements - Chapter VIII. @.01 B. (5). If enforcement of shellfish regulations is shared with another agency(s), is there a formalized MOU/MOA with the other agency(s)?

Compliance Criteria: The patrol element will be deemed in compliance when the authority has developed a Memorandum of Understanding/Agreement with all Authorities which have delegated patrol responsibilities. **[Key]**

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

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

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

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

(c) **Nonconformance:** The program has:

i. at least one (1) critical deficiency;

ii. two (2) or more key deficiencies; or

iii. a repeat **[Key]** deficiency from the previous evaluation.

(d) **Major Nonconformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest in harvest restricted waters.

ii. During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the State patrol agency;

iii. Within thirty (30) days of the closeout meeting, the Shellfish Specialist shall provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;

iv. Within thirty (30) days of receiving the PEER, the State patrol agency shall provide a written response that indicates:

(a) The item(s) was corrected;

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

(c) The reasons why the State disagrees with FDA's finding(s).

v. Within fifteen (15) days of receipt FDA shall review the State response, and respond to the State;

vi. Any CRITICAL item deficiency shall be corrected within thirty (30) days of acceptance by FDA of the correction plan;

vii. Any KEY item deficiency shall be corrected within one (1) year of acceptance by FDA of the correction plan.

viii. FDA shellfish specialists shall be responsible for monitoring the progress of State action plans.

ix. Patrol Program recommendations addressing improvements not associated with the criteria included in Section I or recommendations addressing improvements beyond the requirements of the Model Ordinance should be submitted to the Authority in correspondence.

4. Plants

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

a. Records audit of past shellfish processing facility inspections;

b. Direct observation of current shellfish processing facility conditions;

c. Information collection from the Authority and other pertinent sources concerning

shellfish processing facility inspection program.

d. Shellfish sanitation program element criteria shall be used to evaluate consecutive full evaluations (not including follow up). If a violation of the same criteria is repeated, the program element is considered out of compliance. This program element compliance will be based on the following criteria:
   i. All dealers are required to be certified in accordance with the Guide for the Control of Molluscan Shellfish.
   ii. 95% of the certified dealers evaluated must have been inspected by the State at the frequency required by the current Guide for the Control of Molluscan Shellfish.
   iii. Where compliance schedules are required no more than 10% of the certified dealers evaluated will be without such schedules.
   iv. States must demonstrate that they have performed proper follow up for compliance schedules for 90% of dealers evaluated, and if the compliance schedules were not met, that proper administrative action was taken by the State.
   v. All critical deficiencies have been addressed by the State inspector in accordance with the Guide for the Control of Molluscan Shellfish.

e. Plant Evaluation Criteria
   i. Legal Authority – Chapter I @ .01 B.
   The plant sanitation element will be deemed in compliance if administrative laws and regulations exist that provide the administrative authority to implement the Dealer Certification requirements listed in Chapter I @ .01 and @ 02. **[Critical]**
   ii. Initial Certification – Chapter I @ .02 B.
   The Plant Sanitation Element will be deemed in compliance with this requirement when all plants are certified in accordance with criteria listed below:
      (a) HACCP requirements:
         (i) A HACCP plan accepted by the Authority
         (ii) No critical deficiencies;
         (iii) Not more than two (2) key deficiencies;
         (iv) Not more than two (2) other deficiencies.
      (b) Sanitation and additional Model Ordinance Requirements:
         (i) No critical deficiencies;
         (ii) Not more than two (2) key deficiencies;
         (iii) Not more than three (3) other deficiencies.
   iii. Inspection frequency – Chapter I @ .02 F. and G.
   The Plant Sanitation Element will be deemed in compliance with this requirement when one (1) or less plants inspected doesn't meet the required inspection frequency.
   iv. Compliance schedules.
   The Plant Sanitation Element will be deemed in compliance with this requirement when no more than 10% of the certified dealers evaluated are found to be without schedules.
   v. Follow-Up.
   The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates that they have performed proper follow-up for compliance schedules for 90% of dealers evaluated and if the compliance schedules were not met that administrative action was taken.
   vi. Deficiency Follow-up.
   The Plant Sanitation Element will be deemed in compliance with this requirement when the State demonstrates that all critical deficiencies have been addressed.
   vii. In-Field Plant Criteria.
   Certified plants will be evaluated to determine compliance with the criteria listed

below:

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

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

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

(d) Shellstock shippers and reshippers sanitation and additional Model Ordinance requirements
  (i) No critical deficiencies; and
  (ii) Not more than three (3) key deficiencies.

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

i. Conformance: The program is in compliance with all of the criteria listed above and all plants evaluated are in compliance with Chapter I. @.03 B. 4. e. vii.

ii. Conformance with Deficiencies:
The program is in compliance with Chapter I. @ .03 B. 4. e. i - vi. and has 25% or less of plants with deficiencies associated with Chapter I. @ .03 B. 4. e. vii.

iii. Nonconformance:
The program is in compliance with Chapter I. @ .03 B. 4. e. i., but, does not meet the criteria in Chapter I. @.03 B. 4. e. ii. or iii. or iv. or v. or vi. or has greater than 25% (but less than 51%) of plants with deficiencies associated with Chapter I. @.03 B. 4. e. vii.

iv. Major Nonconformance:

C. The program has multiple deficiencies. It is non-compliant with Chapter I. @.03 B. 4. e. i., or two (2) or more of Chapter I. @.03 B. 4. e. ii., or iii., or iv., or v., or vi., or 51% or greater of plants with deficiencies associated with Chapter I. @.03 B. 4. e. vii. FDA will follow the current compliance program for communication with the State agencies.

D. All deficiencies observed by FDA while conducting the in-plant inspection portion of the evaluation will be documented and included in the compliance determination outlined in Chapter I. @.03B.4.e.ii.

Chapter II. Risk Assessment and Risk Management

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.]

Additional Guidance: Section IV. Guidance Documents - Chapter V. Illness Outbreaks and Recall Guidance

@.01 Outbreaks of Shellfish-Related Illness

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one (1) or more persons in the case of shellfish toxicity poisoning associated with marine biotoxins), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:
   (1) Each consumer's food history;
   (2) Shellfish handling practices by the consumer and/or retailer;
   (3) Whether the disease has the potential or is known to be transmitted by shellfish; and
   (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall:
   (1) Notify the FDA Shellfish Specialist that a shellfish related outbreak has occurred.
   (2) Conduct an investigation of the illness outbreak within twenty-four (24) hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.
   (3) Determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21Code of Federal Regulations (CFR) Part 7. The recall shall include all implicated products.

C. When the investigation outlined in Model Ordinance Chapter II. @.04 B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:
   (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;
   (2) Notify the ISSC and the FDA Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
   (3) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.
   (4) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.
   (5) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include

dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

D. When the investigation outlined in Model Ordinance Chapter II. @.04 B. demonstrates that the illnesses are related to post- harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:
   (1) Notify the ISSC and the FDA Shellfish Specialist of the problem; and
   (2) Initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.
   (3) Transmit to the ISSC and FDA information identifying the dealers shipping the implicated shellfish.
   (4) The ISSC will notify States and FDA Shellfish Specialists of growing area closures and recalls. In the case of recalls, ISSC will notify States with information identifying dealers shipping the implicated shellfish. Closure and recall notices (not to include dealers) will be posted on the ISSC website. ISSC will maintain an inventory of closure and recall information.

E. When the investigation outlined in Model Ordinance Chapter II. @.04 B. cannot be completed within 24 hours, the Authority shall:
   (1) Follow the closure procedure outlined in Chapter II @.01 C.; and if the investigation does not indicate a growing area problem, the area may be immediately reopened and product recall terminated.

F. Upon closing an implicated area for problems other than naturally occurring pathogens and/or biotoxins, the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:
   (1) A review of the growing area classification file records;
   (2) A field review of existing pollution sources;
   (3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and
   (4) Examination of water quality subsequent to the illness outbreak.

G. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or biotoxins, the Authority:
   (1) Shall follow an existing marine biotoxin contingency plan, if appropriate.
   (2) Shall collect and analyze samples relevant to the investigation, if appropriate.
   (3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or biotoxins are not a public health concern.
   (4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

H. When the growing area is determined the problem, the Authority shall:
   (1) Place the growing area in the closed status until:
      (a) The Authority verifies that the area is properly classified, using current data, in compliance with the NSSP Model Ordinance; or
      (b) Shellfish from the growing area are confirmed as the cause of illness but it has been determined that the event which caused the contamination no longer exists;
   (2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and
   (3) Develop a written report summarizing the findings of the investigation and actions taken.

I. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA, ISSC and the Authorities in other States involved in the recall. The

Authority shall submit periodic recall status reports to the FDA Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 CFR Part 7, Subpart C, Section 7.53 (b) (1- 6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the State of product origin regarding recall efforts within their State until such time that the Authority in the State of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any State involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

J. Molluscan shellfish product that is recalled as a result of an illness outbreak associated with *V.v.* or *V.p.* may be reconditioned. Validated reconditioning processes include subjecting product to validated post-harvest processing (PHP) or placing product into approved, conditionally approved, conditionally restricted, or restricted growing areas for an appropriate period of time, not less than fourteen (14) days, with appropriate controls and documentation to be determined by the Authority.

Additional Guidance: Section IV. Guidance Documents Chapter IV. Section .01

@.02 Shellfish Related Illnesses Associated with *Vibrio parahaemolyticus (V.p.)*

A. When the investigation outlined in Section @.01 A. indicates the illness(es) are associated with the naturally occurring pathogen *Vibrio parahaemolyticus (V.p.)*, the Authority shall determine the number of laboratory confirmed cases epidemiologically associated with the implicated area and actions taken by the Authority will be based on the number of cases and the span of time as follows.

(1) When sporadic cases do not exceed a risk of one (1) illness per 100,000 servings or involves at least two (2) but not more than four (4) cases occurring within a thirty (30) day period from an implicated area in which no two (2) cases occurred from a single harvest day, the Authority shall determine the extent of the implicated area. The Authority will make reasonable attempts to ensure compliance with the existing Vibrio Management Plan.

(2) When the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or when cases exceed four (4) but not more than ten (10) over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest day from the implicated area, the Authority shall:

(a) Determine the extent of the implicated area; and

(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and

(c) As soon as determined by the Authority, transmit to the FDA and receiving States information identifying the dealers shipping the implicated shellfish.

(3) When the number of cases exceeds ten (10) illnesses within a thirty (30) day period from the implicated area or four (4) or more cases occurred from a single harvest date from the implicated area, The Authority shall:

(a) Determine the extent of the implicated area; and

(b) Immediately place the implicated portion(s) of the harvest area(s) in the closed status; and

(c) Promptly initiate a voluntary industry recall consistent with the Recall Enforcement Policy, Title 21 CFR Part 7 unless the Authority determines that a recall is not required where the implicated product is no longer available on the market or when the Authority determines that a recall would not be effective in preventing additional illnesses. The recall shall include all implicated products.

(d) Issue a consumer advisory for all shellfish (or species implicated in the illness).

(4) When a growing area has been closed as a result of *V.p.* cases, the Authority shall keep the area closed for the following periods of time to determine if additional illnesses have occurred:

(a) The area will remain closed for a minimum of fourteen (14) days when the risk exceeds one (1) illness per 100,000 servings within a thirty (30) day period or cases exceed four (4) but not more than ten (10) cases over a thirty (30) day period from the implicated area or two (2) or more cases but less than four (4) cases occur from a single harvest date from the implicated area.

(b) The area will remain closed for a minimum of twenty-one (21) days when the number of cases exceeds ten (10) illnesses within thirty (30) days or four (4) cases occur from a single harvest date from the implicated area

(5) Prior to reopening an area closed as a result of the number of cases exceeding ten (10) illnesses within thirty (30) days or four (4) cases from a single harvest date from the implicated area, the Authority shall:

(a) Collect and analyze samples to ensure that tdh does not exceed 10/g and trh does not exceed 10/g; or other such values as determined appropriate by the Authority based on studies.

(b) Ensure that environmental conditions have returned to levels not associated with *V.p.* cases.

(6) Shellfish harvesting may occur in an area closed as a result of *V.p.* illnesses when the Authority implements one (1) or more of the following controls:

(a) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and/or hard clams and a three (3) log reduction for Pacific Coast oysters and/or hard clams;

(b) Restricting oyster and/or hard clam harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(c) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

@. 03 Annual Assessment of *Vibrio vulnificus* and *Vibrio parahaemolyticus* Illnesses and Shellfish Production

A. The Authority shall assess annually *Vibrio vulnificus (V.v.)* and *Vibrio parahaemolyticus (V.p.)* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V.v.* and *V.p.* shellfish-associated illnesses reported within the State and from receiving States, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.

B. The Authority shall collect by month and report annually to the ISSC the volume of shellfish harvested in the State. The report shall include the volume of shellfish harvested for each species. Where available the volume breakdown of the production data will be reported by utilization type (raw, shucked, PHP, etc.).

@.04 Presence of Human Pathogens in Shellfish Meats

Additional Guidance: Section IV. Guidance Documents Chapter II. Section.16

A. Finding. Upon determination that human pathogens are present in shellfish meats, the Authority shall investigate the harvesting, the distribution, and the processing of the shellfish.
B. Growing Area Investigation.
   (1) The Authority shall review the following factors:
      (a) The documentation to trace the shellfish to its source;
      (b) The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and
      (c) The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.
   (2) The Authority shall take no further action when the Authority determines that:
      (a) The growing area is properly classified;
      (b) No illegal harvesting is taking place; and
      (c) There is no reason to believe that the growing area is the source of the pathogens.
   (3) When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:
      (a) Change the existing classification to the correct classification; or
      (b) Close the growing area until the correct classification can be determined; and
      (c) Determine whether to initiate a voluntary recall by firms. If a firm or firms is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.
   (4) When the Authority determines that the growing area may be the source of pathogens and the pathogens exceed tolerance levels, the Authority shall request a voluntary recall by firms. The firms will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.
   (5) When the Authority determines that illegal harvesting is taking place, the Authority shall determine whether to initiate a voluntary recall by firms. The firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.
C. Distribution and Processing Investigation.
   (1) The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.
   (2) The Authority shall take no further action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.
   (3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem and determine whether to initiate a voluntary recall by firms. If a firm(s) is requested by the Authority to recall, the firm will use procedures consistent with the Recall Enforcement Policy, Title 21 CFR Part 7. The recall shall include all implicated products.
D. Risk Management and Tolerance Levels.

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .08

(1) Pathogen Present. When a growing area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification for an area.

(2) Established Tolerance Levels.

(a) When the established tolerance level for a particular pathogen isolate is not exceeded, the Authority:

(i) Shall maintain a written summary of its finding and the data supporting its finding in its central file; and

(ii) May leave the growing area in its present classification.

(b) When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of shellfish associated disease caused by that pathogen in a particular growing area, the Authority shall:

(i) Leave the area in the open status of its classification when the tolerance level is not exceeded; and

(ii) Place the area in the closed status of its classification when the tolerance level is exceeded.

(c) When the tolerance level is exceeded, the Authority may:

(i) Maintain the growing area in the closed status of its current classification;

(ii) Reclassify the growing area to the restricted or prohibited classification; or

(iii) Reclassify the growing area to the conditionally restricted classification and establish a management plan.

(d) Any management plan based on shellstock exceeding established tolerance levels shall:

(i) Meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification;

(ii) Specify the additional criteria associated with the particular pathogen isolate that the growing area must meet to be in the open status of its classification;

(iii) Document the scientific basis for the additional criteria;

(iv) Provide for periodic retesting of the shellfish meats; and

(v) Provide for the growing area to be placed in the closed status if the criteria are exceeded.

(3) Established Tolerance Levels Not Known.

(a) When an established tolerance level does not exist for the particular pathogen isolated, the Authority shall assess the public health significance of the levels of the pathogen found in the growing area shellfish meats. The Authority may consider FDA recommended action levels or levels of concern in this determination. When the Authority determines that:

(i) The levels are acceptable, the growing area shall remain in the open status of its classification; or

(ii) The levels are unacceptable; the growing area shall be placed in the closed status of its classification.

(b) If a growing area is placed in the closed status, the Authority may elect to

(i) Maintain that status indefinitely;

(ii) Reclassify the area to the restricted or prohibited classification; or

(iii) Reclassify the area to the conditionally restricted classification and establish a management plan. The management plan shall meet the requirements of Section D. (2) (d).

@.05 Presence of Toxic Substances in Shellfish Meats

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .08

A. Upon determination that toxic substances, including heavy metals, chlorinated hydrocarbons, and natural toxins are present in levels of public health significance in shellfish meats, the Authority shall investigate the harvesting, distribution, and processing of shellfish and take necessary corrective action in accordance with the procedures described in Section @.04.
B. When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification of the area. The risk assessment and subsequent risk management shall follow the procedures outlined in Section @.04 D., Risk Management and Tolerance Levels.

@.06 *Vibrio vulnificus* Control Plan

A. Risk Evaluation
Each shellfish producing State that is not currently implementing a *V.v.* Control Plan shall conduct a *V.v.* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining the risk of *V.v.* infection from the consumption of shellfish harvested from the State's growing waters.
(1) In conducting the risk evaluation, the Authority will at a minimum consider the following:
(a) The number of *V.v.* cases etiologically confirmed and epidemiologically linked to the consumption of commercially harvested shellfish from the State; and
(b) Levels of *V.v.* in the growing waters and in shellfish, to the extent that such data exists; and
(c) The quantity of harvest from the area and its uses i.e. shucking, half shell, PHP.
B. States which have previously met the illness threshold requiring a *V.v.* Control Plan will continue to maintain and implement a *V.v.* Control Plan.
C. All States not currently implementing a *V.v.* Control Plan shall develop and implement a *V.v.* Control Plan should the risk evaluation indicate two (2) or more etiologically confirmed, and epidemiologically linked *V.v.* septicemia illnesses from the consumption of commercially harvested raw or undercooked oysters that originated from the growing waters of that State within the previous ten (10) years
D. The Authority shall develop a *V.v.* Contingency Plan should the risk evaluation indicate any etiologically confirmed shellfish-borne *V.v.* illness from the growing waters of that State but the number of cases does not reach the threshold established in @.06 C.
E. Control Plan
(1) The *V.v.* Control Plan shall include the following:
(a) Identification of triggers which address factors that affect risks. The triggers will be used to indicate when control measures are needed. One (1) or more of the following triggers will be used:
(i) The water temperatures in the area;
(ii) The air temperatures in the area;
(iii) Salinity in the area;
(iv) Harvesting techniques in the area; and
(v) Other factors which affect risk which can be used as a basis for reducing risk.
(b) Implementation of one (1) or more of the following control measures to reduce the

risk of *V.v.* illness:

(i) Labeling oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 70 °F.

(ii) Subjecting all oysters intended for the raw, half-shell market to Authority approved PHP when the Average Monthly Maximum Water Temperature exceeds 70 °F.

(iii) Reducing time of exposure to ambient air temperature prior to delivery to the initial certified dealer based on modeling or sampling, as determined by the Authority in consultation with FDA. For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged. When this control measure is selected, State *V.v.* plans will include controls when water temperature promotes *V.v.* levels and risk of illness increases. The controls will minimize risk to less than three (3) illnesses per 100,000 servings when Average Monthly Maximum Water Temperature exceeds 80 °F. Authority approved Best Management Practices (BMPs) will be applied to minimize *V.v.* growth to the extent possible when Average Monthly Maximum Water temperature exceeds 70 °F but is less than or equal to 80 °F. BMPs will ensure that when the water temperature exceeds 70 °F but is less than or equal to 75 °F risk is minimized to less than 1.75 illnesses per 100,000 servings and when water temperature exceeds 75 °F but is less than or equal 80 °F the risk will not exceed 2.5 illnesses per 100,000 servings. These risks per serving will be determined using the FDA developed *V.v.* calculator. A State is in compliance with the NSSP when it effectively implements the controls established in its plan using the FDA calculator to determine the risk per serving for the established water temperatures.

(iv) The State Authority may implement alternative controls that will reduce the risk to a level comparable to the risk per serving identified above in @.05 E. (1) (b) (iii) when water temperatures exceed 70 °F.

(c) When pre-harvest culture practices have the potential to elevate Vibrio levels in market size product intended for immediate harvest, the Authority shall establish Vibrio control measures and include the measures in the State Vibrio Control Plan. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.

(2) Control Plan Evaluation

(a) The State Authority will conduct an evaluation of the plan. At a minimum the Authority will consider:

(i) The annual number of *Vibrio vulnificus* cases associated with the State's growing waters and the amount of shellstock sold for half shell consumption to determine risk per servings for each temperature period.

(ii) Environmental changes which could affect total *V.v.* in shellfish pre and post-harvest.

(iii) Industry compliance with existing controls.

(iv) The Authorities enforcement of industries' implementation of the controls.

(b) For the purposes of determining Authority compliance the FDA will conduct

an annual Vibrio evaluation of the Authority to determine the following:

(i) Authority compliance with *V.v.* Risk Evaluation as required in Chapter II. @.06 A.

(ii) For States requiring the development of *V.v.* Plans, compliance with Control Plan requirements of Chapter II. @.06 E. (1). The evaluation should determine:

(a) Appropriate identification of triggers to determine when control measures are needed.

(b) Did the Authority implement one (1) or more of the control measures required in Chapter II. @.06 E. (1) (b).

(c) For Authorities implementing Chapter II. @.06 E. (1) (b) (i) and (ii), were the controls implemented adequately.

(d) For Authorities implementing Chapter II. @.06 E. (1) (b) (iii) (time and temperature control), did the Authority establish controls consistent with water temperature and was the FDA developed *V.v.* calculator used correctly.

(iii) For Authorities required to develop *V.v.* Contingency Plans the evaluation should determine:

a. Did the risk evaluation indicate the need for a Contingency Plan.

b. For States requiring the development of a Contingency Plan, does the plan include the regulatory steps to be implemented should the number of illnesses reach the threshold for a *V.v.* Plan

(c) Should the findings of the State evaluation indicate that the Authority was in compliance with the items audited in (2) (b) and the observed risk per servings exceeded established risk per serving for one (1) or more water temperature, the Authority will be deemed in compliance with the NSSP Model Ordinance. The FDA will include this finding in a report to the ISSC.

(d) The results of the State and FDA risk per serving evaluations will be shared with the ISSC Vibrio Management Committee for use in conducting trend evaluations as stated in the ISSC Constitution, Bylaws, and Procedures.

F. Contingency Plan

(1) The Contingency Plan shall include a detailed plan outlining the regulatory steps that will be implemented should the number of illnesses reach the threshold established for development and implementation of a *V.v.* Control Plan.

(2) Contingency Plan Evaluation
In consultation with FDA the Authority will evaluate the adequacy of their Contingency Plan.

@.07 *Vibrio parahaemolyticus* Control Plan

Additional Guidance: Section IV. Guidance Documents Chapter IV. Section .01 *V.p.* Control Plan

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio parahaemolyticus* (*V.p.*) illness during periods that have been historically associated with annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. Independent Species Specific Risk Evaluation.
Every State from which oysters or hard clams (*Mercenaria mercenaria*) are harvested shall conduct a *V.p.* risk evaluation annually. The evaluation shall consider each of the following

factors, including seasonal variations in the factors, in determining whether the risk of *V.p.* infection from the consumption of oysters or hard clams harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)

(1) The number of *V.p.* cases epidemiologically linked to the consumption of oysters or hard clams commercially harvested from the State;
(2) Levels of total and tdh+ *V.p.* in the area, to the extent that such data exists;
(3) The water temperatures in the area;
(4) The air temperatures in the area;
(5) Salinity in the area;
(6) Harvesting techniques in the area; and
(7) The quantity of harvest from the area and its uses i.e. shucking, half-shell, PHP.

B. Independent Species Specific Control Plan

(1) If a State's *V.p.* risk evaluation determines that the risk of *V.p.* illness from the consumption of oysters or hard clams harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *V.p.* Control Plan.
(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *V.p.* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:
(a) Waters bordering the Pacific Ocean: 60 °F.
(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south): 81 °F.
(c) Waters bordering the Atlantic Ocean (NY and north): 60 °F.
(d) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in Section A. that determines that it is not reasonably likely that *V.p.* illness will occur from the consumption of oysters or hard clams harvested from those areas.
(i) In conducting the evaluation, the State shall evaluate the factors listed in Section A. for the area during periods when the temperatures exceed those listed in this section;
(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in Section A. differ in the area being assessed from other areas in the State and adjoining States that have been the source of shellfish that have been epidemiologically linked to cases of *V.p.* illness; or
(3) If a State has a shellfish growing area that was the source of oysters or hard clams that were epidemiologically linked to an outbreak of *V.p.* within the prior five (5) years, the State shall develop and implement a *V.p.* Control Plan for the area.
(4) For States required to implement *V.p.* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:
(a) Establish one (1) or more triggers for when control measures are needed. These triggers shall be the temperatures in Section B. (2) where they apply, or other triggers as determined by the risk evaluation.
(b) Implement one (1) or more control measures to reduce the risk of *V.p.* illness at times when it is reasonably likely to occur. The control measures may include:
(i) PHP using a process that has been validated to achieve a two (2) log reduction in the levels of total *V.p.* for Gulf and Atlantic Coast oysters and hard clams and a three (3) log reduction for the Pacific Coast oysters;
(ii) Closing the area to oyster and/or hard clam harvest;
(iii) Restricting oyster and/or hard clam harvest to product that is labeled for

shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iv) Limiting time from harvest to refrigeration to no more than five (5) hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(v) Limiting time from harvest to refrigeration such that the levels of total *V.p.* after the completion of initial cooling to 60 °F (internal temperature of the oysters or hard clams) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *V.p.* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters and/or hard clams to an internal temperature of 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority after placement into refrigeration during periods when the risk of *V.p.* illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to ensure, document and verify that the internal temperature of oysters and/or hard clams has reached 50 °F (10 °C) or below within ten (10) hours or less as determined by the Authority of being placed into refrigeration. When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering. Oysters and/or hard clams without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.

(d) Evaluate the effectiveness of the Plan.

(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

(f) Optional cost benefit analysis of the *V.p.* Control Plan.

(5) When pre-harvest culture practices have the potential to elevate *V.p.* levels in market size product intended for immediate harvest, the Authority shall establish *V.p.* control measures and include the measures in the State Vibrio Control Plan. Such control measures may be implemented on a State-wide, regional, geographic, or farm or growing area-specific basis. When shellfish are re-immersed as a control measure the Authority should consider inclusion of record keeping requirements such as means of shellfish segregation/identification procedures, date re-immersed in water and date of final harvest. The Authority may require growers to have a control plan approved by the Authority.

C. The Time When Harvest Begins

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

Chapter III. Laboratory

Requirements for the Authority

Additional Guidance: Section IV Guidance Documents Chapter II. Section 15.

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

@.01 Quality Assurance

A. NSSP Conformance Required for all laboratories supporting the NSSP. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under the NSSP.

B. State Program Responsibilities. The Authority shall ensure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. Accordingly, the Authority shall:

(1) Require laboratories to develop a written quality assurance plan that:

(a) Describes the organization and management structure of the laboratory;

(b) Describes the laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised;

(c) Describes all procedures and methods used to analyze samples;

(d) Describes quality control measures, their frequency and tolerance limits, for determining equipment performance;

(e) Requires maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration;

(f) Includes an internal assessment and participation in a recognized annual proficiency test program (FDA, Northeast Laboratory Examination Officers and Managers (NELEOM), etc.); and

(g) Requires corrective action for any deficiencies found in the laboratory quality assurance program.

(2) Require laboratories to implement their quality assurance plan.

(3) Ensure that the laboratory has appropriate facilities and resources to effectively manage the workload.

(4) Require laboratories to participate in the laboratory evaluation process.

(5) Inform FDA Shellfish LEOs and/or the State Shellfish LEO as appropriate of major changes in laboratory personnel, laboratory workload or laboratory facilities.

(6) Require corrective action for any deficiencies/nonconformities found in the quality assurance program, laboratory operations, and laboratory performance.

C. FDA Responsibilities. The FDA will ensure that all laboratories generating data in support of the NSSP will be evaluated at a minimum frequency of once every three (3) years.

(1) Evaluations will be conducted by either an FDA Shellfish LEO or an FDA certified State Shellfish LEO as appropriate. Normally the initial evaluation of a laboratory will be conducted by FDA.

(2) Evaluations are generally onsite but can under certain circumstances be by desk audit (evaluation follow-up, action plan monitoring, nonconformity corrections, major changes in personnel, workload or facilities, etc.).

D. Wet Storage and Post-Harvest Processors. For any laboratory providing analytical testing services for depuration, wet storage or PHP, initial and subsequent triennial evaluations will be required and conducted in accordance with @.01 and @.03 of this Chapter by an FDA Shellfish LEO or an FDA certified State Shellfish LEO as appropriate. It is understood that academic laboratories involved in PHP Validation or Verification have special circumstances such as extended periods of inactivity resulting from university schedules or funding constraints; however, written documentation of Quality Control practices will be required for time periods in which they are preparing for or actively participating in a PHP Validation or Verification. Times in which the lab is inactive can be explained with a not applicable notation.

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .14

@.02 Methods

A. Microbiological. Methods for the analyses of shellfish and shellfish growing or harvest waters shall be:

(1) The Approved NSSP Methods validated for use in the NSSP under Procedure XV. of the Constitution, Bylaws and Procedures of the ISSC and/or cited in the Guidance Documents Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.

(2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, Bacteriological Analytical Manual (BAM), or EPA method;

(b) An Emergency Use Method pursuant to @ .02 D. (1) and (2) below.

B. Chemical and Physical. Methods for the analysis of shellfish and shellfish growing or harvest waters shall be:

(1) The Approved NSSP Methods validated for use in the NSSP under Procedure XV. of the Constitution, Bylaws, and Procedures of the ISSC and/or cited in the Guidance Documents Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.

(2) Results shall be expressed for chemical and physical measurements in standard units and not instrument readings.

(3) When there is an immediate or ongoing critical need for a Method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to @ .02 D. (1) and (2) below.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) The Approved NSSP Methods validated for use in the NSSP under Procedure XV. of the Constitution, Bylaws, and Procedures of the ISSC and/or cited in the Guidance Documents Chapter II. Growing Areas .14 Approved NSSP Laboratory Tests.

(2) When there is an immediate or ongoing critical need for a method and no Approved NSSP Method exists, the following may be used:

(a) A validated AOAC, BAM, or EPA method;

(b) An Emergency Use Method pursuant to @ .02 D. (1) and (2) below.

D. Emergency Use Methods.

(1) When there is an immediate or critical need and no Approved NSSP Method exists, an unapproved or non-validated method may be used for a specific purpose provided that:

(a) The appropriate FDA Office is notified within a reasonable period of time regarding the method employed; and

(b) The ISSC Executive Board is notified within a reasonable period of time regarding the method employed.

(2) When it is necessary to continue the use of the emergency method employed under D. (1) beyond the initial critical need, then the following minimum criteria shall be provided to the ISSC Executive Board for interim approval:

(a) Name of Method;

(b) Date of Submission;

(c) Specific purpose or intent of the method for use in the NSSP;

(d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method;

(e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable;

(f) Any peer reviewed articles detailing the method;

(g) Name of developer(s) or submitter; and

(h) Developer/submitter contact information.

(3) Within two (2) years of Executive Board interim approval of the Emergency Use Method, the entire Single Lab Validation Protocol should be submitted. The Laboratory Committee will report to the Executive Board on the status of the Single Lab Validation Protocol data submission.

Chapter IV. Shellstock Growing Areas

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .07

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .09

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .11

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.]

@.01 Sanitary Survey

A. General.

(1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:

(a) A shoreline survey;

(b) A survey of the microbiological quality of the water. In growing areas adjacent to waste water system discharge (WWSD)s the Authority may utilize male specific coliphage (MSC) results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report;

(c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area; and

(d) A determination of the appropriate growing area classification.

(2) The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with Section C. to assure that data are current and that conditions are unchanged.

(3) The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the central file shall include all data, results, and analyses from:

(a) The sanitary survey;

(b) The triennial reevaluation; and

(c) The annual review.

(4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey.

(5) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.

B. Sanitary Survey Required.

(1) A sanitary survey shall not be required to classify growing areas as prohibited. The findings of a sanitary survey, however, may result in a growing area being classified as

prohibited.

(2) A sanitary survey, including the triennial reevaluation, when available, of each growing area shall be required prior to:

(a) The harvest of shellstock for human consumption; and

(b) The classification of a growing area as approved, conditionally approved, restricted, or conditionally restricted.

C. Sanitary Survey Performance.

(1) A sanitary survey of each growing area shall be performed at least once every twelve (12) years and shall include the components in Section A. (1).

(2) When a written sanitary survey report is not completed, the area shall be placed in the closed status.

(3) The growing area classification and the supporting data from the sanitary survey shall be reviewed at least every three (3) years.

(a) This triennial reevaluation shall include:

(i) A water quality review in accordance with Section C. (5)(b)

(ii) Documentation of any new pollution sources and an evaluation of their effect on the growing area;

(iii) Reevaluation of all pollution sources, including the sources previously identified in the sanitary survey, as necessary to fully evaluate any changes in the sanitary conditions of the growing area. The reevaluation may or may not include a site visit;

(iv) A comprehensive report which analyzes the sanitary survey data and makes a determination that the existing growing area classification is correct or needs to be revised; and

(v) If the triennial reevaluation determines that conditions have changed based on the information and data collected during the triennial review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.

(b) When a written triennial reevaluation report is not completed, the Authority shall place the growing area in the closed status.

(4) The triennial reevaluation may include:

(a) Inspection of WWSD or collection of additional effluent samples to determine their impact on the growing area;

(b) Hydrodynamic studies;

(c) Additional field work to determine the actual impact of pollution sources; and

(d) Collection of additional water samples.

(5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include:

(a) A field observation of the pollution sources which may include:

(i) A drive-through survey;

(ii) Observations made during sample collection; and

(iii) Information from other sources.

(b) Review, at a minimum, of the past year's microbiological results by adding the year's sample results to the data base collected in accordance with the requirements for the microbiological standards and sample collection required in Section @.02;

(c) Review of available inspection reports and effluent samples collected from pollution sources;

(d) Review of available performance standards for various types of discharges that impact the growing area; and

(e) A brief report which documents the findings of the annual reevaluation.

(f) The Authority may use MSC meat sampling data and/or MSC waste water sampling

data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of WWSD impacts on shellfish growing areas. If MSC meat and/or water data are being used, the Authority shall conduct annual sample collection and analysis in determining performance standards.

(6) If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.

D. Shoreline Survey Requirements.

(1) In the shoreline survey for each growing area, the Authority shall:

(a) Identify and evaluate all actual and potential sources of pollution which may affect the growing area;

(b) Determine the distance from the pollution sources to the growing area and the impact of each source on the growing area;

(c) Assess the reliability and effectiveness of sewage or other waste treatment systems;

(d) Determine if poisonous or deleterious substances adversely affect the growing area; and

(e) Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas.

(2) The Authority shall assure that the shoreline survey meets the following minimum requirements:

(a) The boundaries, based on the area topography, of each shoreline survey area are determined by an in-field investigation which identifies only the properties with the potential to impact the shellfish waters;

(b) Each shoreline survey area is identified by a unique designation which results in identification of all data associated with each shoreline survey by the unique designation;

(c) Each shoreline survey area is investigated and pollution sources evaluated by qualified, trained personnel;

(d) Documentation for each pollution source identified by the Authority as affecting a growing area includes:

(i) The location of the site on a comprehensive map of the survey area; and

(ii) The determination that the pollution source has a direct or indirect impact on shellfish waters: and

(e) A written summary of the survey findings.

E. Sanitary surveys for Federal waters will be the responsibility of FDA. Sanitary surveys will be conducted in accordance with Chapter IV @.01, as applicable.

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .01 Total Coliform Standards

@.02 Microbiological Standards

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the State. The NSSP also allows for two (2) sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two (2) ways: a total coliform strategy and a fecal coliform strategy so that the State may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, an Authority may wish to adopt the use of both standards and both sampling

strategies for each standard. This codification represents the fecal coliform standards. Additionally, the Authority may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by WWSD.

A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The Authority may utilize MSC data in conjunction with bacteriological data to evaluate WWSD impacts on shellfish growing areas.

B. Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources.

C. Exceptions.

(1) Except for growing areas classified as prohibited, in growing areas where there are pollution sources having an impact on the water quality, a minimum of thirty (30) samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under Section @.03.

(2) Except for growing areas classified as prohibited or when the systematic random sampling standard is applied, in growing areas where there are no pollution sources having an impact on the water quality, a minimum of fifteen (15) samples shall be required to classify any growing area not previously classified under Section @.03.

D. Standard for the Approved Classification of Growing Areas in the Remote Status.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard below.

(2) Fecal Coliform Standard for the Remote Status. The fecal coliform median or geometric mean most probable number (MPN) or membrane filter (MF) (membrane-Thermotolerant *Escherichia coli* [mTEC]) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:

(a) 43 MPN per 100 ml for a five-tube decimal dilution test;
(b) 49 MPN per 100 ml for a three-tube decimal dilution test;
(c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
(d) 31 colony-forming units (CFU) per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection.

(a) A minimum of two (2) samples shall be collected annually.

(b) A minimum of the most recent fifteen (15) samples collected shall be used to calculate the median or geometric mean and percentage to determine compliance with the standard established for the approved classification of remote growing areas.

E. Standard for the Approved Classification of Growing Areas Affected By Point Sources.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:

(a) 43 MPN per 100 ml for a five-tube decimal dilution test;
(b) 49 MPN per 100 ml for a three-tube decimal dilution test;
(c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
(d) 31 CFU per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection.

(a) A minimum of five (5) samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.

(b) A minimum of the most recent fifteen (15) samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric

mean and percentage to determine compliance with this standard.

(c) Sample station locations shall be adjacent to actual or potential sources of pollution.

(4) For Authorities utilizing MSC data in conjunction with bacteriological data to evaluate WWSD impacts, the MSC level shall not exceed fifty (50) MSC per hundred (100) grams.

F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources.

(1) Exception. If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area.

(2) Pollution Sources. Growing areas shall be:

(a) Impacted only by randomly occurring, intermittent events; and

(b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.

(3) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section F. (4).

(4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed fourteen (14) per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

(a) 43 MPN per 100 ml for a five-tube decimal dilution test;

(b) 49 MPN per 100 ml for a three-tube decimal dilution test; or

(c) 31 CFU per 100 ml for a MF (mTEC) test.

(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:

(a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10);

(b) Multiplying the standard deviation in (a) by 1.28;

(c) Adding the product from (b) to the arithmetic mean;

(d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and

(e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number.

(6) Required Sample Collection.

(a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section E. (2).

(b) Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when:

(i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;

(ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical;

(iii) A minimum of six (6) random samples shall be collected annually from each sample station in the growing area;

(iv) A minimum of two (2) random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6) (b) (iii) must resume at least six (6) months before an area is reactivated; and

(v) A minimum of the thirty (30) most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.

(c) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority:

(i) Does not have thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) years; and

(ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section G. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:

(a) 260 MPN per 100 ml for a five-tube decimal dilution test;

(b) 300 MPN per 100 ml for a three-tube decimal dilution test;

(c) 173 MPN per 100 ml for a twelve-tube single dilution test; or

(d) 163 CFU per 100 ml for a MF (mTEC) test.

(3) Required Sample Collection. Samples shall be collected in accordance with Section E. (3).

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.

(2) Pollution Sources. Growing areas shall meet the requirements in Section F. (2).

(3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Section G. (2) or Section H. (4).

(4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:

(a) 260 MPN per 100 ml for a five-tube decimal dilution test;

(b) 300 MPN per 100 ml for a three-tube decimal dilution test; or

(c) 163 CFU per 100 ml for a MF (mTEC) test.

(5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in Section F. (5).

(6) Required Sample Collection.

(a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in Section E. (3) for application of the standard under Section G. (2).

(b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in Section F. (6) for the application of the standard under Section H. (4).

@.03 Growing Area Classification

A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.

(1) Emergency Conditions. A growing area shall be placed in the closed status under Section @.03 A. (5) when pollution conditions exist which were not included in the database used to classify the area. If it is determined that an emergency condition or situation exists, then the growing area will be immediately (within twenty-four (24) hours) placed in the closed status.

(2) Classification of All Growing Areas. All growing areas which:

(a) Are not subjected to a sanitary survey every twelve (12) years shall be classified as prohibited;

(b) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited classification established adjacent to the outfall in accordance with Section E. Prohibited Classification; and

(c) Are subjected to a sanitary survey shall be correctly classified based on the twelve (12) year sanitary survey, and its most recent triennial or annual reevaluation when available, as only one (1) of the following:

(i) Approved;
(ii) Conditionally Approved;
(iii) Restricted;
(iv) Conditionally Restricted; or
(v) Prohibited.

(3) Boundaries. The boundaries of each classified growing area shall be delineated on charts which are:

(a) Of sufficient scale and detail so as to adequately describe the boundaries; and
(b) Maintained in the central file by the Authority.

(4) Revision of Classifications.

(a) Any upward revision of a growing area classification shall be supported by an adequate sanitary survey.

(b) The appropriate FDA office shall be notified of any revision in growing area classification.

(5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open, closed or inactive for the harvesting of shellstock. Supporting information for all changes in the status of growing areas shall be documented by a written record in the central file.

(a) Open Status. Except for an area in the prohibited classification, any correctly classified growing area is normally open for the purposes of harvesting shellstock, subject to the limitations of its classification.

(b) Closed Status. Any classified growing area may be closed for a limited or temporary period because of:

(i) An emergency condition or situation;
(ii) The presence of biotoxins in concentrations of public health significance;
(iii) Conditions stipulated in the management plan of conditionally approved or conditionally restricted areas;
(iv) Failure of the Authority to complete a written sanitary survey or triennial review evaluation report; or
(v) The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met.

(c) Reopened Status. A growing area temporarily placed in the closed status as provided in

(b) above, shall be returned to the open status only when:

(i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or

(ii) For emergency closures of harvest areas caused by the occurrence of raw untreated sewage discharged from a large community sewage collection system or WWSD, the analytical sample results shall not exceed the levels established in Chapter IV @.02 E or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted or until the event is over and twenty-one (21) days have passed; or

(iii) The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met; and

(iv) Supporting information is documented by a written record in the central file.

(d) Inactive Status. The authority may place an approved or restricted growing area affected by non-point sources in the inactive status for up to five (5) years when shellstock harvest is suspended or no longer occurring. Shellstock harvesting shall be closed while an area is in the inactive status. The inactive status must continue for a minimum of one (1) year.

(i) While in inactive status, the required bacteriological sample collection under @.02 F. (6) (b) (iii) may be reduced to two (2) water samples per station per year collected under the systematic random sample collection strategy. Sanitary survey reports, triennial reevaluations, and annual updates must be completed as required under @.01 C.

(ii) The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6) (b) (iii) must resume at least six (6) months before an area is reactivated.

(iii) Before an area is reactivated, the results of the most recent thirty (30) samples must be reviewed and comply with the requirements under @.02 F.

(e) Remote Status. A growing area may be placed in the remote status if:

(i) A sanitary survey determines that the area has no human habitation, and is not impacted by any actual or potential pollution sources; and

(ii) The area is in the approved classification.

(f) Seasonally Remote/Approved Status. A growing area may be placed in a seasonally remote/approved status requiring two (2) water samples per year if the following criteria are met:

(i) The area is initially classified as approved;

(ii) The closure time period is defined; and

(iii) At least one (1) sample be taken upon reopening the area.

B. Approved Classification. Growing areas shall be classified as approved when the following criteria are met.

(1) Survey Required. A sanitary survey finds that the area is:

(a) Safe for the direct marketing of shellfish;

(b) Not subject to contamination from human or animal fecal matter at levels that, in the judgment of the Authority, presents an actual or potential public health hazard; and

(c) Not contaminated with:
(i) Pathogenic organisms;
(ii) Poisonous or deleterious substances;
(iii) Marine biotoxins; or
(iv) Bacteria concentrations exceeding the bacteriological standards for a growing area in this classification.

(2) Water Quality. The water quality in the growing area shall meet the bacteriological standards for an approved classification in Section @.02.

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(1) Survey Required. The sanitary survey meets the following criteria:
(a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;
(b) Each potential source of pollution that may adversely affect the growing area is evaluated;
(c) Microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and
(d) For Authorities utilizing MSC meat sample data, this data correlates with environmental conditions or other factors affecting the distribution and persistence of viral contaminants into the growing area.

(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:
(a) For management plans based on wastewater treatment plant function, performance standards that include:
(i) Peak effluent flow, average flow, and infiltration flow;
(ii) Microbiological quality of the effluent;
(iii) Physical and chemical quality of the effluent;
(iv) Conditions which cause plant failure;
(v) Plant or collection system bypasses;
(vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
(vii) Provisions for monitoring and inspecting the waste water treatment plant; and
(viii) Establishment of an area in the prohibited classification adjacent to a wastewater treatment plant outfall in accordance with Section E. Prohibited Classification;
(b) For management plans based on pollution sources other than waste water treatment plants:
(i) Performance standards that reliably predict when criteria for conditional classification are met; and
(ii) Discussion and data supporting the performance standards.
(c) For management plans based on WWSD function or pollution sources other than WWSD criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:
(i) Performance standards of the plan are fully met;
(ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
(iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to

pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water. The Authority may utilize MSC levels to establish that sufficient time has elapsed to allow the water quality to return to acceptable levels in growing areas adjacent to WWSD. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of viral levels in the shellstock. Analytical sample results shall not exceed the MSC levels established in Chapter IV@.02 E. or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in the shellfish meats or the area must be in the closed status until the event is over and twenty-one (21) days have passed; and

(iv) Shellstock feeding activity is sufficient to achieve microbial reduction.

(d) For management plans based on a risk assessment made in accordance with Chapter II. Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;

(e) For management systems based on marine biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;

(f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;

(g) Provisions for patrol to prevent illegal harvest; and

(h) Procedures to immediately place the growing area in the closed status in twenty-four (24) hours or less when the criteria established in the management plan are not met.

(3) Reevaluation of Conditional Classification.

(a) The classification shall be reevaluated at least once each year. The reevaluation shall include:

(i) Evaluation of compliance with the management plan;

(ii) Determination of adequacy of reporting of failure to meet performance standards;

(iii) Review of the cooperation of the persons involved;

(iv) Evaluation of water quality in the growing area with respect to the bacteriological standards for its classification;

(v) Field inspection of critical pollution sources, where necessary; and

(vi) Written findings, evaluations and recommendations.

(b) Water Sample Collection.

(i) When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three (3) of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.

(ii) When the conditional management plan is based on the operation and performance of a WWSD (s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification.

(iii) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.

(iv) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, storm water runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or six (6) sets of water samples (when the Systematic Random Sampling regimen is used) are required. The samples shall be collected when the growing area is in the open status.

(v) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events or storm water runoff, and the area is in the open status for less than six (6) months a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). At least one (1) sample shall be collected each month the area is placed in the open status. This sample shall be collected while the area is open. If closed status samples are used to meet the minimum sample requirements only two (2) sets of samples may be utilized and they must have been taken within five (5) days of when the Authority anticipates that the area will be placed in the open status. For growing areas in the open status less than two (2) months, at least one (1) sample must be collected while the area is in the open status. Samples collected during the closed status to meet the minimum five (5) sets of water samples shall be applied to annual and triennial reevaluations of the area.

(vi) When the conditional management plan is based on the seasonal opening and closing of the area, and the area is in the open status for a predetermined period of less than six (6) months, a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). All samples shall be collected while the area is in the open status unless the Authority has historical water quality data to demonstrate that the area meets open status criteria while in the closed status. If closed status samples are used to meet the minimum sample requirements they must be collected within thirty (30) days prior to the area being placed in the open status.

(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved.

(a) The management plan shall be developed by the Authority in coordination with:

(i) The local shellfish industry;

(ii) The individuals responsible for the operation of any WWSDs involved; and

(iii) Any local or State agencies; and

(b) Failure of any one party to agree shall constitute sufficient justification to deny the application of the conditional classification to a growing area.

(5) Conditional Area Types. There are two (2) types of conditional areas:

(a) Conditionally approved; and

(b) Conditionally restricted.

(6) Conditionally Approved Classification. Any growing area in the conditionally approved classification shall:

(a) Meet the requirements for:

(i) An approved area classification when the conditionally approved classification is in the open status; and

(ii) A restricted or prohibited classification when the conditionally approved classification is in the closed status; and

(b) If the closed status meets the criteria for the restricted classification, designate in its management plan whether the shellstock may be harvested for relaying or depuration.

(7) Conditionally Restricted Classification. Any growing area in the conditionally restricted classification shall:

(a) Meet the requirements for:

(i) A restricted classification when the conditionally restricted classification is in the open status; and

(ii) A prohibited classification when the conditionally restricted classification is in the closed status; and

(b) Designate in its management plan whether the harvested shellstock are to be relayed or depurated.

D. Restricted Classification.

(1) General

(a) A growing area may be classified as restricted when:

(i) A sanitary survey indicates a limited degree of pollution; and

(ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.

(b) The Authority shall have effective controls to assure that shellfish are harvested from restricted areas only:

(i) By special license; and

(ii) Under the supervision of the Authority.

(2) Water Quality. Water quality in the growing area shall meet the bacteriological standards in Section @.02 for a growing area in the restricted classification if the growing area is used for depuration.

(3) Shellstock Quality Criteria. The Authority shall establish shellstock quality criteria for use in placing an area in the restricted classification. Depending on the treatment process to be applied to the shellstock, the criteria shall be established in accordance with:

(a) Chapter V. Shellstock Relaying; or

(b) Chapter XV. Depuration.

E. Prohibited Classification.

(1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas. The Authority, however, may use the prohibited classification for these waters.

(2) General. The Authority shall:

(a) Not permit the harvest of shellstock from any area classified as prohibited, except for the gathering of seed or nursery culture for aquaculture or the depletion of the areas classified as prohibited; and

(b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it is seed to be cultured as outlined in the NSSP Model Ordinance Chapter VI. Shellfish Aquaculture @.02 Seed Shellstock.

(3) Sanitary Survey. A growing area shall be classified as prohibited if:

(a) No current sanitary survey exists;

(b) A sanitary survey determines:

(i) The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;

(ii) Pollution sources may unpredictably contaminate the growing area;

(iii) The growing area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms;

(iv) The concentration of biotoxin is sufficient to cause a public health risk as identified in Section @ .04. or

(v) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.

(4) Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II. Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption.

(5) Wastewater Discharges.

(a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.

(b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:

(i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the microbiological quality of the effluent. The Authority may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant;
(ii) The decay rate of the contaminants of public health significance in the wastewater discharged;
(iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and
(iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

F. FDA is responsible for the classification of growing areas in Federal waters. Federal waters are classified as Approved for shellfish harvesting unless such areas are known to be polluted (i.e., microbiological, chemical, or marine biotoxin hazards) and involve commercial shellfish resources.

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

@.04 Marine Biotoxin Control

A. Contingency Plan.

(1) The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas addressing the management of PSP, ASP, NSP, diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred or an illness outbreak caused by marine biotoxins.
(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:
(a) Initiate an emergency shellfish sampling and assay program;
(b) Close growing areas and embargo shellfish;
(c) Prevent harvesting of contaminated species;
(d) Provide for product recall;
(e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent States, shellfish industry, and local health agencies;
(f) Coordinate control actions taken by Authorities and Federal agencies; and
(g) Establish reopening criteria including the number of samples over what period of time.

NOTE: The plan may include other requirements, as deemed necessary by the Authority in the State of landing, to ensure adequate public health protection under the NSSP.

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .06

B. Marine Biotoxin Management Plan.

In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton are known to occur and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine biotoxins can be reasonably predicted to occur, representative samples of the water may be collected and shellfish shall be collected during harvest periods. The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples may be assayed for the presence of toxin-producing

phytoplankton and shellfish meat samples shall be assayed for the presence of toxins.

NOTE: In situations in which the toxin of concern has an established cell count standard, such as *Karenia brevis*, water and shellfish samples would not be required. Management decisions could be made on either water or shellfish sampling results.

(1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP, or AZP; if toxin-producing phytoplankton are known to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur.
(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:

(a) Maintain a routine shellfish sampling and assay program including;

i. Establishment of appropriate shellfish screening levels;
ii. Establishment of appropriate shellfish screening and testing methods;
iii. Establishment of appropriate laboratories/analysts to conduct shellfish screening and testing methods;
iv. Establishment of a sampling plan for both (i) and (ii) above; and
v. Other controls as necessary to ensure that shellstock are not harvested when levels of marine biotoxins meet or exceed the established criteria in Section C.

(b) Close growing areas and embargo shellfish;
(c) Prevent harvesting of contaminated species;
(d) Provide for product recall;
(e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent States, shellfish industry, and local health agencies;
(f) Coordinate control actions taken by Authorities and Federal agencies; and
(g) Establish reopening criteria.

(3) The Authority may use precautionary closures based on screening or phytoplankton sample results as defined in their marine biotoxin management program. Precautionary closures may be lifted immediately:

(a) if confirmatory testing using an approved method shows the level of biotoxin present in shellfish meats is not equal to or above established criteria in Section C; or
(b) when screening or phytoplankton sample results indicate that the precautionary closure was not necessary.

(4) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine biotoxins or so remote that adequate sampling cannot be achieved and thus the situation cannot be safely managed, the presence of marine biotoxins shall not affect the classification of the shellfish growing area under Section @.03. The Authority may use the conditionally approved classification for areas affected by marine biotoxins.
(5) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a State growing area while other parts of the same growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety. In State growing areas or designated portions of State growing waters that are closed, the Authority may allow for harvesting if an end product testing program is developed and samples of each lot are tested and found to be

below the action levels specified in Section C.

The program must include at a minimum:

(a) Establishment of appropriate pre-harvest screening levels;

(b) Establishment of appropriate screening and end product testing methods;

(c) Establishment of appropriate laboratories/analysts to conduct screening and end product testing methods;

(d) Establishment of representative sampling plan for both (a) and (b) above;

(e) Disposal of shellfish should end product test results meet or exceed established criteria specified in Section C; and

(f) Other controls as necessary to ensure that shellstock are not released prior to meeting all requirements of the program.

(6) Prior to allowing the landing of shellfish harvested from Federal waters where routine monitoring of toxin levels is not conducted, in addition to following State requirements in the Model Ordinance, the State Authority in the landing State, in cooperation with appropriate Federal agencies, shall develop agreements or memoranda of understanding between the Authority and individual shellfish harvesters or individual shellfish dealers. The agreements or memoranda of understanding shall provide strict safety assurances. At a minimum agreements or memoranda of understanding shall include provisions for:

(a) Harvest permit requirements;

(b) Training for individuals conducting onboard toxicity screening using NSSP methods;

(c) Vessel monitoring;

(d) Identification of shellfish for each harvesting trip to include:

(i) Vessel name and owner;

(ii) Captain's name;

(iii) Person conducting onboard screening tests;

(iv) Port of departure name and date;

(v) Port of landing name and date;

(vi) Latitude and longitude coordinates of designated harvest area;

(vii) Onboard screening test results;

(viii)Volume and species of shellfish harvested;

(ix) Intended processing facility name, address and certification number; and

(x) Captain's signature and date;

(e) Pre-harvested (onboard) sampling that includes a minimum of five (5) samples from the intended harvest area be tested for toxins that are likely to be present harvesting shall not be permitted if any of the pre-harvested samples contain toxin levels in excess of half of the established criteria listed in Chapter IV@.04(1) (e.g., 44 µg/l00 g when using a quantitative test or a positive at a limit of detection of 40 µg/100 g for the qualitative screening test for PSP toxins);

(f) Submittal of onboard screening homogenates and test results to the Authority in the State of landing;

(g) The collection of a minimum of seven (7) dockside samples by the Authority or designee and the testing of those samples for toxins using an NSSP method by an NSSP conforming laboratory; the Authority may require more samples based on the size of the vessel and the volume of shellfish harvested;

(h) Holding and providing separation until dockside samples verify that toxin levels are below the established criteria (e.g., 80 µg/100 g for PSP toxins);

(i) Disposal of shellfish when dockside test results meet or exceed the established criteria in Chapter IV@.04C.(1) (e.g., 80 µg /100 g for PSP toxins);

(j) Notification prior to unloading;
(k) Unloading schedule;
(l) Access for Dockside Sampling;
(m) Record Keeping; and
(n) Early Warning/Alert System.

NOTE: The plan may include other requirements, as deemed necessary by the Authority in the State of landing, to ensure adequate public health protection under the NSSP.

C. Closed Status of Growing Areas.
(1) A growing area, or portion(s) thereof as provided in Section A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the number of toxin-forming organisms in the growing waters and/or the level of biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:
(a) PSP - 80 µg saxitoxin equivalents/100 grams
(b) NSP - 5,000 cells/L or 20 MU/100 grams (0.8 mg brevetoxin-2 equivalents/kg)
(c) AZP - 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)
(d) DSP – 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)
(e) ASP - 2 mg domoic acid/100 grams (20 ppm)
(2) For any marine biotoxin producing organism for which criteria have not been established under this Ordinance, either cell counts in the water column or biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.
(3) When sufficient data exist to establish that certain shellfish species can be safely exempted from the marine biotoxin management plan, the closed status for harvesting may be applied selectively to some shellfish species and not others.
(4) The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area.
(5) The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.
(6) The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.

D. Heat Processing. If heat processing is practiced, a control procedure shall be developed. This procedure shall define the following:
(1) Toxicity limits for processing;
(2) Controls for harvesting and transporting the shellstock to processor;
(3) Special marking for unprocessed shellstock;
(4) Scheduled processes; and
(5) End product controls on the processed shellfish.

E. Records. The Authority shall maintain a copy of all of the following records.
(1) All information, including monitoring data, relating to the levels of marine biotoxins in the shellfish growing areas;
(2) Copies of notices placing growing areas in the closed status;
(3) Evaluation reports; and
(4) Copies of notices returning growing areas to the open status.

@.05 Marinas

A. Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as:
   (1) Conditionally approved;
   (2) Conditionally restricted; or
   (3) Prohibited.

B. Adjacent Waters. Waters adjacent to marina waters classified under Section A. may be impacted by pollution associated with the marina.
   (1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.
   (2) The dilution analysis shall be based on the volume of water in the vicinity of the marina.
   (3) The dilution analysis shall incorporate the following:
      (a) A slip occupancy rate for the marina;
      (b) An actual or assumed rate of boats which will discharge untreated waste;
      (c) An occupancy per boat rate (i.e., number of persons per boat);
      (d) A fecal coliform discharge rate of 2 x 10 fecal coliform per ninth power per day; and
      (e) The assumption that the wastes are completely mixed in the volume of water in and around the marina.
   (4) If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina shall be classified as:
      (a) Conditionally approved;
      (b) Restricted;
      (c) Conditionally restricted; or
      (d) Prohibited.
   (5) If the dilution analyses predict a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:
      (a) Approved; or
      (b) Conditionally approved.
   (6) If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two (2) persons per boat.

Chapter V. Shellstock Relaying

Additional Guidance: Section IV. Guidance Documents Chapter II. Growing Areas .10 Shellstock Relay

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 General

The Authority shall assure that:

A. The shellstock used in relaying activities is harvested from growing areas classified as conditionally approved, restricted, or conditionally restricted;
B. The level of contamination in the shellstock can be reduced to levels safe for human consumption;
C. The contaminated shellstock are held in growing areas classified as approved or conditionally approved for a sufficient time under adequate environmental conditions so as to allow reduction of pathogens as measured by total coliform or fecal coliform, or poisonous or deleterious substances that may be present in shellstock. For shellstock harvested from areas impacted by WWSD, MSC may be used as a measure for viral reduction that may be present in shellstock; and
D. If shellstock are relayed in containers:
    (1) The containers are:
        (a) Designed and constructed so that they allow free flow of water to the shellstock; and
        (b) Located so as to assure the contaminant reduction required in Section C.; and
    (2) The shellstock are washed and culled prior to placement in the containers.

@.02 Contaminant Reduction

A. The Authority shall establish species-specific critical values for water temperature, salinity, and other environmental factors which may affect the natural treatment process in the growing area to which shellstock will be relayed. The growing area to be used for the treatment process shall be monitored with sufficient frequency to identify when limiting critical values may be approached.
B. The effectiveness of species-specific contaminant reduction shall be determined based on a study. The study report shall demonstrate that, after the completion of the relay activity:
    (1) The microbiological quality of each shellfish species is the same microbiological quality as that of the same species already present in the approved or conditionally approved area; or
    (2) Contaminant levels of poisonous or deleterious substances in shellstock do not exceed FDA tolerance levels; or
    (3) When the source growing area is impacted by WWSD, the viral quality of each shellfish

species meets the MSC levels established in Chapter IV@.02 E. or pre-determined levels established by the Authority based on studies conducted on regional species under regional conditions.

C. The Authority may waive the requirements for a contaminant reduction study if:
   (1) Only microbial contaminants need to be reduced; and
   (2) The shellstock are relayed from a conditionally approved, restricted, or conditionally restricted area meeting the bacteriological water quality for restricted areas used for shellstock depuration per Chapter IV. @.02 G. and Chapter IV. @.02 H.; and
   (3)The treatment period exceeds sixty (60) days.

D. The time period shall be at least fourteen (14) consecutive days when environmental conditions are suitable for shellfish feeding and cleansing unless shorter time periods are demonstrated to be adequate.

E. When container relaying is used and the Authority allows a treatment time of less than fourteen (14) days, the Authority shall require more intensive sampling including:
   (1) Product sampling before and after relay;
   (2) Monitoring of critical environmental parameters such as temperature and salinity; and
   (3) For Authorities using MSC, monitoring before and after relay for shellstock relayed from areas impacted by WWSD.

F. The Authority shall establish the time period during the year when relaying may be conducted.

@.03 Licenses to Relay Shellstock or to Harvest Shellstock for Delivery to a Low Acid Canned Food Processing Facility

A. The Authority shall require that each harvester that relays or harvests shellstock for delivery to a low acid canned food processing facility from growing areas in the conditionally approved (in the closed status), restricted or conditionally restricted classification possesses a valid harvester or relay license.

B. The license conditions shall not be transferable.

C. A license shall be valid only when issued for:
   (1) A specific relay or harvest activity; and
   (2) Not more than 365 days.

D. The license conditions shall include:
   (1) The source, destination, and species to be relayed or harvested for low acid canned food processing;
   (2) The relayed or harvested for low acid canned food processing shellstock deposition method;
   (3) The method used to maintain adequate separation between different lots of shellfish;
   (4) A requirement for the licensee to keep records which:
      (a) Specify the dates on which the shellstock is harvested, deposited for treatment and harvested again, or delivered to a low acid canned food processing facility;
      (b) Identify the buyer and quantity of shellstock harvested for relaying or delivery to a low acid canned food processing facility; and
      (c) Are submitted to the Authority at a specified frequency, if required by the Authority, or made available to the Authority upon request; and
   (5) A provision for additional information at the discretion of the Authority.

E. If the relay harvester or harvester for low acid canned food processing fails to comply with the conditions of the license, the Authority shall revoke the license.

@.04 Management of Relaying Shellstock or the Harvesting for Delivery to a Low Acid Canned Food Processing Facility Activities

A. The Authority shall be authorized and equipped to enforce the State's procedures for relay and low acid canned food processing. The Authority shall develop and maintain an effective program to control the harvest, transport, replanting, and security of the shellstock until the end of the complete relay activity to prevent shellstock from being illegally diverted to direct marketing.
B. In the event that the control of relaying or harvesting for low acid canning activities is shared among two (2) or more agencies, the Authority shall develop written operating procedures for joint use among the agencies. These procedures shall provide for the achievement of all requirements specified in this Chapter and shall be reviewed annually and updated as necessary.
C. If shellstock from growing areas classified as conditionally approved or restricted are to be relayed or harvested for low acid canned food processing across State boundaries, a memorandum of understanding outlining the procedures to be used shall be developed between the appropriate Authorities in each State.
D. If a growing area in the conditionally approved classification meets the criteria for the restricted classification when the growing area is in the closed status, the Authority may permit shellstock to be harvested for relaying or low acid canned food processing during the period the area is in its closed status, provided that these activities are addressed in the management plan for the growing area classified as conditionally approved, and all other conditions of this Chapter are met.
E. Locations designated to receive relayed shellstock within growing areas which are classified as approved or conditionally approved shall:
    (1) Be placed in the closed status until the period of treatment is complete and the Authority returns the area to the open status; and
    (2) Be marked so that these areas are easily identified by harvesters transporting the relayed shellstock and by the Authority. These areas shall:
        (a) Be marked prior to the placing of any shellstock;
        (b) Remain marked until the Authority reopens the area and gives written permission to harvest shellstock; and
        (c) Be adequately separated from the shellstock in adjacent waters to prevent cross-contamination and commingling.

Requirement for Harvesters

.01 Harvester License Required

A. Any person who wants to relay shellstock or to harvest shellstock from a growing area classified as conditionally approved, restricted, or conditionally restricted shall make application to the Authority for a valid license to relay or to harvest shellstock.
B. No person shall relay shellstock or shall harvest shellstock for low acid canned food processing without a valid harvester license from the Authority.

Chapter VI. Shellfish Aquaculture

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 General

A. Aquaculture activities which may pose a significant public health concern and are regulated in this Chapter include, but are not limited to:
   (1) Seed production in waters classified as Prohibited or Unclassified;
   (2) Aquaculture structures that attract birds or mammals; and
   (3) Land based aquaculture.

B. The Authority shall:
   (1) Approve the written operational plan for operations as outlined in @.01A above;
   (2) Inspect operations outlined in @.01A above at least annually; and
   (3) At a minimum inspect operator records to verify that appropriate permits are up to date and operational plans required in @ .01 A (1). are being implemented.
   (4) Consistent with Chapter IV @ .01 D(1)(e) when aquaculture as defined in the Model Ordinance attracts birds or mammals, their presence should be considered for possible adverse effects on growing area water quality.

@ .02 Seed Shellstock

A. The Authority shall establish the maximum seed size for each species of shellfish that can be produced in prohibited waters. In determining the maximum seed size Authorities shall establish sizes that require a minimum of 120 days of growing to reach market size.
B. The Authority shall establish appropriate corrective actions for when seed exceeds the maximum seed size when it has been produced in waters classified as prohibited.
C. All sources of seed produced or collected in prohibited waters shall be sanctioned by the Authority.

@.03 Aquaculture in Federal Waters

A. Federal Agency Responsibilities. Once the appropriate permits for the construction of the aquaculture facility have been obtained,
   (1) NOAA is responsible for establishing a contract, in consultation with FDA, with the aquaculture facility describing requirements of the NSSP including:
      (a) the frequency with which NOAA will audit the aquaculture facility and vessels;
      (b) testing requirements of the aquaculture facility; and
      (c) the generation of product identification for traceability (i.e., tag numbers); and
   (2) FDA is responsible for reviewing the aquaculture facility operational plan prior to the start of operations, as well as the annual inspection of records, to ensure adherence to NSSP requirements. FDA is also responsible for the classification of the growing area(s) associated with the aquaculture facility.

Requirements for the Harvester/Dealer

.01 Exceptions

Hatcheries and nurseries rearing larvae and/or seed that are located in:

A. Approved or conditionally approved growing areas are exempt from these requirements; or
B. Restricted or Conditionally Restricted would be exempt from these requirements but subject to relay requirements in Chapter V for seed that exceeds the maximum seed size established by the Authority.

.02 General

A. Any person who performs aquaculture as defined in the Model Ordinance or operates an aquaculture facility to raise shellfish for human consumption shall obtain:
   (1)A permit from the Authority for the activity and functioning of his facility;
   (2)A harvester's license; and
   (3)Certification as a dealer, where necessary.
B. Shellfish aquaculture as defined in the Model Ordinance shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the aquaculture activity. Authorization shall be based on the operator's written operational plan.
C. Prior to beginning his activity, an operator shall obtain the permission of the Authority for use of his facility.
D. Any shellfish seed raised in aquaculture that exceeds the maximum seed size established by the Authority shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water which is in:
   (1)The closed status of the conditionally approved classification;
   (2)The restricted classification; or
   (3)The open status of the conditionally restricted classification.
E. Only drugs sanctioned by the FDA shall be used for shellfish treatment.
F. Harvesting, processing, storage, and shipping requirements for shellfish raised in a land-based aquaculture facility or a seed rearing facility or system that exceeds the maximum seed size established by the Authority shall be the same as the requirements for shellfish specified in Chapters V., VII., VIII., IX., X., XI., XII., XIII. and XIV.
G. Complete and accurate records shall be maintained for at least two (2) years by the operator of the aquaculture facility and shall include the:
   (1)Source of shellfish, including seed if the seed is from growing areas which are not in the approved or conditionally approved classification; and
   (2)Water source, its treatment method, if necessary, and its quality in land based systems.

.03 Seed Production in Water Classified as Prohibited or Unclassified

Seed may come from any growing area, or from any growing area in any classification, provided that:

A. The source of the seed, if from waters classified as prohibited or unclassified, is sanctioned by the Authority; and
B. Operational Plan. Each aquaculture site that cultures seed in waters classified as prohibited or unclassified shall have a written operational plan. The plan shall be approved by the Authority prior

to its implementation and shall include:
(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
(5) Procedures to assure that no poisonous or deleterious substances are introduced from the seed production activities; and
(6) Corrective actions for addressing seed exceeding the maximum seed size as defined by the Authority.

.04 Aquaculture That Attracts Birds or Mammals

A. Operational Plan. Each aquaculture site that the Authority determines may attract sufficient birds and/or mammals that their waste presents a human health risk shall have a written operational plan. The plan shall be approved by the Authority prior to its implementation and shall include:
(1) A description of the design and activities of the culture facility;
(2) The specific site and boundaries in which shellfish aquaculture activities will be conducted;
(3) The types and locations of any structures, including rafts, pens, cages, nets, or floats which will be placed in the waters;
(4) The species of shellfish to be cultured and harvested;
(5) Procedures to assure that no poisonous or deleterious substances are introduced from the aquaculture activities; and
(6) Maintenance of the required records.

.05 Land Based Aquaculture

A. Operational Plan. Each facility shall have a written operational plan. The facility must obtain approval from the Authority prior to its implementation and shall include:
(1)A description of the design and activities of the culture facility;
(2)The specific site and boundaries in which shellfish culture activities will be conducted;
(3)The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats which will be placed in the waters;
(4)The species of shellfish to be cultured and harvested;
(5)Procedures to assure that no poisonous or deleterious substances are introduced into the activities;
(6)A program of sanitation, maintenance, and supervision to prevent contamination of the shellfish products;
(7)A description of the water source, including the details of any water treatment process or method;
(8)A program to maintain water quality, which includes collection of microbial water samples and their method of analysis and routine temperature and salinity monitoring (the bacterial indicator monitored shall be the same as used for monitoring growing areas);
(9)If applicable, collection of data concerning the quality of food production (algae or other) used in the artificial harvest system; and
(10) Maintenance of the required records.

B. Each land-based facility conducting aquaculture as defined by the Model Ordinance shall maintain the following records while the aquaculture activity continues:

(1) Construction and remodeling plans for any permitted aquaculture facility;
(2) Aquaculture operational plans; and
(3) Aquaculture permits.

C. Water Systems.
If the land-based aquaculture system is of continuous flow through design, water from a growing area classified as approved, or in the open status of the conditionally approved classification at all times shellfish are held, may be used without treatment.

D. Water Quality.
(1) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and meets the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) may be used in direct marketing.
(2) Shellstock cultured in a closed or recirculating system that exceeds the maximum seed size and does not meet the requirements for water quality and testing in Chapter VII C. .04 (3) (a), (b), (c), and (d) shall be relayed or depurated consistent with Chapter IV prior to direct marketing.

.06 Polyculture Systems

A polyculture system shall:

A. Meet all requirements in Section .05 Land Based Systems;
B. Provide information concerning all sources and species of all organisms to be cultivated, cultured, and harvested; and
C. Include in its operational plan requirements to:
(1) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and
(2) Subject all harvested shellstock to relaying or depuration if human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances exist at levels of public health significance.

.07 Requirements for the Harvester in Aquaculture in Federal Waters

A. Prior to beginning any aquaculture activities, the person who performs aquaculture or operates an aquaculture facility to raise shellfish in Federal waters for human consumption shall obtain the appropriate permission(s) from Federal agencies as described in @.03.
B. Operational Plan. Each aquaculture facility shall have a written operational plan as described for Land Based Aquaculture in Section II Chapter VI .05(A). The operational plan shall also include:
(1) Description of harvest, tagging, handling, storage, transportation, and landing procedures;
(2) Description of a marine biotoxin management and contingency plan (Section II Chapter IV @.04) to include marine biotoxin sampling consistent with Section II Chapter IV @.04(B)(6) and ensure product segregation and control until biotoxin results confirm the shellfish do not contain biotoxins equal to or exceeding criteria established in Section IV Chapter II .08.;
(3) Description of a contingency in the event of an emergency situation or condition (e.g., sewage or oil spills); and
(4) Procedures for implementing product recalls.
C. Each aquaculture facility shall obtain a review from the FDA to ensure adherence to NSSP requirements prior to its implementation. If the aquaculture facility makes changes to the

operational plan, they shall obtain a new review from the FDA to ensure adherence to the NSSP requirements.

Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas

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 General

A. The Authority shall permit all wet storage activities to ensure that all wet storage activities are conducted by certified NSSP shellfish firms.
B. The Authority shall approve and maintain the following records while the wet storage activity continues:
    (1) Construction and remodeling plans for any permitted wet storage facility;
    (2) Wet storage operational plans;
    (3) Wet storage permits; and
    (4) Inspection documentation.
C. The Authority shall inspect wet storage activities at the following frequency:
    (1) Activities in offshore natural bodies of water at least annually;
    (2) Activities at land-based sites with flow-through systems at least every six (6) months; and
    (3) Activities at land-based sites with recirculating systems semi-annually.
D. The Authority shall immediately notify (within twenty-four (24) hours) all wet storage permit holders affected by a change in growing area classification or status.
E. Reshippers shall not engage in wet storage activities.

Requirements for the Dealer

.01 Source of Shellstock

A. Dealers shall wet store shellstock harvested only from areas classified as approved, or conditionally approved, in the open status.
B. Shellstock shall be harvested, identified and shipped to the wet storage activity in accordance with the requirements of Chapters VIII. and IX.

.02 General

A. Wet storage may be used to store, condition, remove sand or to add salt to shellstock. Wet storage shall be deemed a processing activity.
B. Wet storage of depurated product shall occur only within the facility in which it was depurated. The shellstock shall be packed and labeled according to the requirements in Chapter XV.

C. Wet storage shall be practiced only by a dealer in strict compliance with the provisions in the written approval for the wet storage activity given by the Authority.
D. While awaiting placement in a wet storage activity, shellstock shall be protected from physical, chemical or thermal conditions which may compromise shellstock survival, quality or activity during wet storage.
E. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.
F. Shellstock from a wet storage activity shall be harvested, handled, identified, processed and shipped according to the requirements of Chapters VIII., IX., and X.
G. The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the original harvest location and wet storage location, and include the dates the shellstock were held in wet storage. The records shall be maintained for a minimum of one (1) year.
H. Unless the dealer is in the Authority's commingling plan under Chapter I. .01 G., different lots of shellfish shall not be commingled during wet storage. If more than one (1) lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

.03 Wet Storage Sites in Natural Bodies of Water (Offshore)

A. Natural bodies of waters used for wet storage shall meet the requirements for classification as approved or conditionally approved while shellstock is being held in storage. Areas classified as conditionally approved may be used only when in the open status. When an area classified as conditionally approved is placed in a status other than its open status, any shellstock in wet storage in that area shall be:
    (1) Subjected to relaying or depuration prior to human consumption; or
    (2) Held in the wet storage site until the area is returned to the open status.
B. Site evaluations of natural bodies of water shall include:
    (1) The sanitary survey of the storage site, with special consideration of potential intermittent sources of pollution;
    (2) The location of storage sites and/or floats;
    (3) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock; and
    (4) A review of the operation's plan and operating procedures for an offshore activity as submitted by the dealer.
C. Different lots of shellstock shall not be commingled in wet storage. If more than one (1) lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

.04 Wet Storage in Artificial Bodies of Water (Land-Based)

A. General
    (1) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of Chapter VII. .01 and .02.
    (2) For the purpose of permitting, each wet storage site or activity shall be evaluated in accordance with @.01. B. The evaluation shall include a review of the plan and operating procedures for conducting land-based wet storage activity as submitted by the dealer.

(3) The wet storage facility evaluation shall include a review of:

(a) The purpose of the wet storage activity such as holding, conditioning or increasing the salt content of shellstock;

(b) Any species specific physiological factors that may affect design criteria; and

(c) The plan giving the design of the land-based wet storage facility, source and quantity of process water to be used for wet storage, and details of any process water treatment (disinfection) system.

B. Operation Specifications.

(1) General. Each land-based wet storage activity shall meet the following design, construction, and operating requirements.

(a) Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.

(b) Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:

(i) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from nontoxic, corrosion resistant materials; and

(ii) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.

(c) Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.

(d) Shellstock containers, if used, shall be designed and constructed so that the containers allow the free flow of water to all shellstock within a container.

(2) Outdoor Tank Operation. When the wet storage activity is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:

(a) Prevent entry of birds, animals or vermin; and

(b) Remain closed while the system is in operation except for periods of tank loading and unloading, or cleaning.

C. Wet Storage Source Water

(1) General.

(a) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification. Water classified as Prohibited or Conditionally Restricted when in the Closed Status shall not be used as source water.

(b) Any well used as source water for wet storage shall meet the requirements of Chapter XI. .02 (with the exception of the salt content in salt water wells).

(c) Except when the source of the water is a growing area in the approved classification, a water supply sampling schedule shall be included in the dealer's operating procedures and water shall be tested according to the schedule.

(d) Results of water samples and other tests to determine the suitability of the source water supply shall be maintained for at least two (2) years.

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) and do not interfere with the shellstock survival, quality or activity during wet storage.

(f) Disinfected process water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml for potable water and acceptable for use with marine water and follow the protocol of the Decision Tree (Section IV. Guidance Documents Chapter III. .05)

(g) When the laboratory analysis of a single sample of disinfected process water entering the wet storage tanks shows any positive result for the coliform group daily sampling shall be

immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected process water to show positive results for the coliform group is eliminated, the effectiveness of the correction shall be verified on the first operating day following correction through the collection, over a twenty-four (24) hour period, of a set of three (3) samples of disinfected process water.

(i) For water that is disinfected by ultra-violet treatment, turbidity shall not exceed twenty (20) nephelometric turbidity units (NTUs) measured in accordance with *Standard Methods for the Examination of Water and Wastewater*, APHA.

(j) The disinfection unit(s) for the process water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

(2) Continuous Flow-through System.

(a) If the system is of continuous flow-through design, water from a growing area classified as:

(i) Approved may be used, without disinfection, in wet storage tanks provided that the near shore water source used for supplying the system meets the approved classification bacteriological criteria at all times that shellstock are being held in wet storage; or

(ii) Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status may be used if the source water is continuously subjected to disinfection and it is sampled and analyzed daily following disinfection.

(b) When a source classified as Conditionally Approved in the Closed Status, Restricted or Conditionally Restricted in the Open Status is used, a study shall be required to demonstrate that the disinfection system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:

(i) Include five (5) sets of three (3) samples from each disinfection unit collected for five (5) consecutive days at the outlet from the disinfection unit or at the inlet to at least one (1) of the wet storage tanks served by the disinfection system;

(ii) Include one (1) sample daily for five (5) consecutive days from the source water prior to disinfection;

(iii) Use NSSP recognized methods to analyze the samples if determining coliform levels;

(iv) Require all samples of disinfected water to be negative for the coliform group; and

(v) Be repeated if any sample of disinfected process water during the study is positive for the coliform group.

(c) Once sanctioned for use, the water system shall be sampled daily to demonstrate that the disinfected water is negative for the coliform group.

(d) When other than approved water is located between the intake of a flow-through wet storage system and the land-based facility then the Authority may require periodic verification of the system's integrity to ensure that the other than approved water does not infiltrate into the intake pipe.

(3) Recirculating Water System.

(a) A study shall be required to demonstrate that disinfection for the recirculating system can consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in Section C. (2) (b) above.

(b) Once sanctioned for use, the recirculating process water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group

(c) When make-up water of more than ten (10) percent of the process water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three (3) samples of disinfected water and one (1) sample of the source water prior to disinfection shall be collected over a twenty-four (24) hour period to reaffirm the ability

of the system to produce process water free from the coliform group or viable bacteria.
(d) When ultra-violet treatment is used as the water disinfectant, each time a bulb change is required either to replace a burned out bulb or for servicing, new ultraviolet bulbs shall be installed and old bulbs discarded, and the weekly disinfected process water sample shall be collected and analyzed.

D. Shellstock Handling.

(1) Shellstock shall be thoroughly washed with water from a source authorized by the Authority and culled prior to wet storage in tanks. Any deviation to this requirement is subject to permission from the Authority.

(2) Unless the dealer is in the Authority's commingling plan under Chapter I. @.01 G., different lots of shellstock shall not be commingled during wet storage in tanks. If more than one (1) lot of shellstock is being held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

(3) Bivalve mollusks shall not be mixed with other species in the same tank. Where multiple tank systems use a common water supply system for bivalve mollusks and other species, wet storage process water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

Chapter VIII. Control of Shellfish Harvesting

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .12

Additional Guidance: Section IV. Guidance Documents Chapter II. Section .13

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 Control of Shellstock Growing Areas

A. General.

(1) The Authority shall maintain an effective program to control shellstock growing areas and to assure that shellstock are harvested only:

(a) From areas in an open status; and

(b) With approval from areas classified as restricted, conditionally restricted, or prohibited, or in the closed status of the approved or conditionally approved classification.

(2) This program shall include:

(a) The patrol of growing areas;

(b) The licensing of harvesters;

(c) Enforceable legal penalties sufficient to encourage compliance; and

(d) Appropriate identification of harvest areas where shellstock harvest is not allowed.

(3) At the time of issuance or renewal of a harvester's license or a dealer's certification, or an annual mail out to all licensed shellfish harvesters, the Authority shall provide each harvester or dealer with:

(a) Information which explains the public health risk associated with illegal harvesting shellstock in areas classified as restricted, conditionally restricted, or prohibited or in the closed status; and

(b) When requested, a current, comprehensive, itemized listing of all harvest areas including their geographic boundaries and their classification.

B. Patrol of Growing Areas.

(1) The Authority shall assure that shellstock are harvested only as provided in this Chapter.

(2) The Authority shall patrol harvest areas classified as restricted, conditionally restricted, or prohibited, or conditionally approved and approved when in the closed status at sufficient intervals to deter illegal harvesting. This patrol activity shall include consideration of the need for night, weekend, and holiday patrols. At a minimum, these growing areas shall be patrolled at the following frequencies, except as provided in B. (3), in order to ensure effective control:

Risk Category	Minimum Frequency of Patrol
Low	Four (4) times per thirty (30) harvestable days
Medium	Eight (8) times per thirty (30) harvestable days
High	Sixteen (16) times per thirty (30) harvestable days

A patrol is accomplished when the majority of an area is monitored. No more than two (2) patrols can be counted in a 24-hour period, and each must be a separate deliberate effort. A harvestable day refers to a day during which tidal, weather and other conditions make it possible to harvest shellfish. When tidal, weather, or other conditions prohibit harvesting on a particular day, that day is not included in the thirty (30) day period.

(3) Exceptions.

(a) Patrol is not required under the following conditions:

(i) There is no shellfish productivity, as demonstrated by one (1) of the following methods:

a. pH, salinity, temperature, or turbidity are not favorable to the growth of shellfish; or

b. The water bottom does not support shellfish growth; or

c. The area has been depleted of shellfish by dredging, disease, or other means;

(ii) The area meets all of the following conditions:

a. The area is unclassified;

b. Historically there has not been interest in commercial harvesting; and

c. The Authority has current evidence that commercial harvesting does not occur. This can be accomplished by information gathered from periodic patrols or reliable non-patrol sources.

(b) Where natural sets resulting in commercially harvestable quantities of shellfish do not exist and advanced aquaculture methods (e.g., racks, bags, lantern nets, long lines and/or floats) are used in the area: The area shall be patrolled at the frequencies specified in Section B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities that supplement the minimum required patrol frequency of one (1) time per thirty (30) harvestable days. The Risk Management Plan at least should include the following:

(i) Description of the area;

(ii) Classification of the area;

(iii) Description of adjacent growing areas;

(iv) Procedure used to prevent shellfish from prohibited or closed waters to be commingled with shellfish from an aquaculture area; and

(v) If, the patrol agency receives assistance from other State, Federal, or tribal agencies, a memorandum of agreement (MOA) must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.

(c) If the area is geographically remote, sparsely populated and has limited access (e.g., no or very poor roads) such that the potential for marketing the shellfish is severely restricted or not economically feasible:

(i) The area shall be patrolled at the frequencies specified in Section B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g., airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities, and the area should be patrolled at least one (1) time per thirty (30) harvestable days. The Risk Management Plan shall describe the administrative procedures and resources necessary

to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. Description of the area;

b. Classification of the area;

c. Description of adjacent growing areas; and

d. If the patrol agency receives assistance from other State, Federal, or tribal agencies, a MOA must be developed describing responsibilities of each agency. A copy of such MOA must be kept in a central file.

(ii) If the Authority has current evidence that commercial illegal harvesting is occurring, the Management Risk Plan should be reevaluated.

(d) Where the entire State is closed to harvesting during traditional non-harvesting seasons:

(i) The area shall be patrolled at the frequencies specified in Section B. (2) unless the Authority develops and implements a Risk Management Plan for the area for the prevention of illegal harvesting of shellfish. The Risk Management Plan shall include monitoring and control of surveillance activities (e.g., airport, dock, border, or truck surveillance) that will be used in lieu of traditional patrol activities. The Risk Management Plan shall describe the administrative procedures and resources necessary to prevent illegal harvesting and/ or the illegal commingling of the product and include at least the following:

a. Description of the area;

b. Classification of the area;

c. Description of adjacent growing areas; and

d. If the patrol agency receives assistance from other State, Federal, or tribal agencies, a MOA must be developed describing responsibilities from each agency. A copy of such MOA must be kept in a central file.

(ii) The area shall be patrolled in low risk areas at least once (1) per thirty (30) harvestable days, for medium risk areas at least twice (2) per thirty (30) harvestable days, and for high-risk areas at least four (4) times per thirty (30) harvestable days.

(iii) If the Authority has current evidence that commercial illegal harvesting is occurring, the State agency shall resume patrol at the frequency specified in B. (2).

(4) The Risk Category for an area shall be determined as follows:

(a) Shellfish Productivity. Estimate the abundance of shellfish based on density studies, historical information, and environmental conditions described in B. (3) (a). Consider only commercially marketable species. The descriptions below refer to the range of productivity within the State. The area shall be rated based on the highest density in any portion of the growing area.

(i) Low Production - 1

(ii) Medium Productivity - 3

(iii) High Productivity - 5

(b) Ease of Harvest. Determine the method used to harvest the shellfish. If multiple harvest techniques are used in an area, select the one (1) with the highest score.

(i) Highly mechanized requiring expensive equipment, deep water, difficult harvest - 1

(ii) Restricted access aquaculture relative shallow water dredging - 2

(iii) Scuba diving, tonging, bullraking - 3

(iv) Hand collection from a boat - 4

(v) Hand collection, no special tools or boat - 5

(c) Difficulty of Patrol. Determine the difficulty of patrol. If the difficulty varies in an area, select the description with the highest score.

(i) Resource within sight of population and a normal patrol route. Patrol Officer can observe illegal harvesting from the patrol vehicle - 1

(ii) Resource is near a shore and easily visible - 2

(iii) Moderate difficulty, deliberate effort is required to provide coverage to the area - 3

(iv) Long travel time to growing area, large open expanse of harvest area - 4

(v) Growing area is a marsh, short sight distance, canals system, extensive shoals - 5

(d) Using the values determined in B. (4) (a), (b), and (c), calculate the total score for the area as follows:

Risk Factors	**Score (1-5)**	**Weight**	**Rating**	**Explain Rating (optional)**	**Adjustment Of Rating (if needed)**
Shellfish Productivity (a)		0.40			
Ease of Harvest (b)		0.40			
Difficulty of Patrol (c)		0.20			
			Subtotal		

The rating for each risk factor is calculated by multiplying the risk factor score by the weight for that factor. The subtotal is calculated by adding all three (3) of the risk factor ratings.

(e) The following criteria should be used to adjust the rating, if warranted:

(i) If a community-policing program is in place, the subtotal may be reduced by up to 0.25 points. If such a program leads to frequent citations, the subtotal may be reduced by up to 0.5 points. Community policing may include but is not limited to telephone hot lines, out-reach programs, financial incentives, local law enforcement activities not covered by B. (5), or private security arrangements.

(ii) If specialized equipment is available to the patrol agency, the subtotal may be reduced by up to 0.40 points. The actual reduction should be dependent upon the type of equipment that is available and its frequency of use. For example, frequent use of an aircraft can warrant a 0.4 point reduction, and frequent use of night vision or periodic use of aircraft can warrant a 0.2 point reduction.

(iii) If the patrol agency implements a strategy for comprehensive monitoring and control of surveillance activities, the subtotal may be reduced by up to 1 point. Activities include, but are not limited to, airport, dock, border, truck, wholesale and retail inspections. The actual reduction should be dependent on the frequency and extent of the activities

(iv) If a growing area is conditionally managed or is poorly marked, the subtotal may be increased by up to 0.2 point. Adding or subtracting the appropriate adjustment(s) calculates the total score.

(f) The following risk categories shall be applied to the total score:

Total Score	**Risk Category**
Less than 3	Low
3 or less than 4	Medium
4 or greater	High

(5) The Authority may delegate patrol activity to any State or local enforcement authority. If patrol activities are delegated, the Authority shall:

(a) Develop a MOA with the delegated agency to assure that patrol requirements are met; and

(b) Require the delegated agency to maintain and file records of its patrol activities consistent with those required in B. (7).

(6) Officers responsible for the patrol of shellfish growing areas shall obtain the following

training:

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

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

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

(7) The Authority shall prepare and revise, as necessary, a patrol policy document which records the Authority's patrol organization and its activities to deter illegal shellstock harvesting. This documentation shall include:

(a) Citation of the law providing the legal basis for enforcement authority;

(b) Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;

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

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

(ii) The roster and chain of command;

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

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

(d) Summaries of training in shellfish patrol techniques;

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

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

(g) An identification of any patrol problems;

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

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

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

(i) The number of convictions or dismissals;

(ii) Fines in dollar amount;

(iii) Equipment or property confiscations and forfeitures;

(iv) License suspensions or revocations;

(v) Jail sentences; and

(vi) Written warnings.

(8) Upon request by FDA, the Authority shall provide any available documentation that is used to support the determination that the patrol program was effective in providing the required frequency of patrol. Ordinarily, this does not include providing reports not normally maintained by the Authority.

(9) To comply with the Standardized Evaluation Criteria, the Authority shall:

(a) Have a patrol policy document (Key item);

(b) Update patrol documents every year (Key item);

(c) Meet NSSP patrol training requirements (Key item);

(d) Patrol all areas that require patrol (Critical item);

(e) Meet NSSP requirements for frequency of patrol (Key item);

(f) Have a formalized MOA with other agency per Chapter VIII. @.01 B. (5) (Key item);

(g) Have a risk management plan per Chapter VIII. @.01 B. (3) (b), (c), and (d) (Critical item); and

(h) Have a complete risk management plan per Chapter VIII. @.01 B. (3) (b), (c), and (d) (Other item).

C. Licensing of Harvesting.

(1) The Authority shall assure that a license is required to commercially harvest shellstock,

including shellstock harvested from aquaculture.

(2) Each license shall:

(a) Not be valid for more than one (1) year;

(b) Require the harvester to sell only to dealers listed on the Interstate Certified Shellfish Shippers List; and

(c) Allow the harvester, at his discretion, to place shellstock in containers for transport of shellstock from a growing area to land or to a dealer.

(3) A license to harvest shall not allow a harvester to engage in shellstock packing or engage in independent wet storage activities as defined in this Ordinance unless the harvester is a certified shellfish dealer and has a Wet Storage Permit issued by the Authority.

(4) In the case of riparian or leased land, unless the riparian owner or lessee employs a licensed harvester, the Authority shall require a riparian owner or lessee to 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.

(5) When a person has a special license to harvest shellstock for depuration, the Authority may not require individuals working under the supervision of the licensed harvester to have their own license.

(6) The Authority shall inform each licensed harvester as to:

(a) The classification and current status assigned to each growing area; and

(b) The methods used to notify harvesters of changes in growing area status or classification.

(7) When the Authority authorizes shellstock relaying under Chapter V. or shellstock depuration under Chapter XV., the Authority shall issue special licenses to harvesters for the taking of shellfish from areas classified as restricted, conditionally restricted, or in the closed status of the approved or conditionally approved classification. The licenses shall specify the limitations and conditions for harvesting shellstock including requirements for the harvester to keep records which:

(a) For depuration:

(i) Specify the date and amount of shellstock harvested from each area; and

(ii) Record the name of the depuration facility to which the shellstock was consigned or sold; and

(b) For relaying, meet the requirements of Chapter V. @.03. D.

(8) The Authority shall maintain a record of all licenses and special licenses issued.

D. Identification of Certain Growing Areas.

(1) The Authority shall chart, describe, and mark the boundaries of growing areas classified as restricted, conditionally restricted, or prohibited, or in a closed status. The boundary descriptions shall:

(a) Be marked by fixed objects or landmarks; or

(b) Be described in a manner which allows easy recognition; and

(c) Allow successful prosecution of any illegal commercial harvesting activity.

(2) The Authority:

(a) Shall notify harvesters of the boundaries established under Section D. (1) by dissemination of information with licenses, publication, or direct notification including registered mail; and

(b) May use warning signs.

E. Prohibited Classification. The Authority shall exercise effective supervision over each depletion or seed gathering operation and maintain complete written documentation.

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .07

@.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 (1) of the following:
(1) The State *V.v.* Control Plan as outlined in Chapter II. @.06; or
(2) The State *V.p.* Plan as outlined in Chapter II. @.07; or
(3) All other shellstock shall comply with the matrix below:

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

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 Chapters 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. For States that establish and limit harvest times that assure compliance with the times outlined in the matrix of Chapter VIII. @.02 A. (3) recording the time harvest begins is not required.

F. Shellstock intended for Wet Storage, Depuration, PHP or "For Shucking Only by a Certified Dealer" must either be shucked, introduced into PHP, Wet Storage, or Depuration 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 *V.v.* or *V.p.* 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 *V.v.* and *V.p.* Control Plans. Shading shall be required when deemed appropriate by the Authority when implementing @.02 A. (1), (2), and (3).

I. Shellstock intended for a validated pathogen reduction process where refrigeration would reduce efficacy of the process (and appropriately labeled with name of the receiving dealer) is exempt from the requirements in Chapter VIII. @.02 A. (1) and (2).

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. Each harvester shall obtain Authority approved training at an interval to be determined by the Authority not to exceed five (5) years. The training shall include required harvest, handling, and transportation practices as determined by the Authority. A harvester shall be allowed ninety (90) days following initial licensing to obtain the required education.
    (1) A harvester shall obtain proof of completion of the required training. Proof of training obtained by the harvester shall be presented to the Authority prior to certification, recertification, or licensing.
    (2) At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.
C. Persons who are working in a boat crew under the supervision of a licensed harvester need not have a valid harvester's license.
D. 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.
E. Each harvester shall report harvest quantities by species to the Authority. The reporting shall be at a frequency not to exceed monthly. Should the State choose to collect production data from certified dealers, harvesters may be exempt from this requirement to avoid double counting.

.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) 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.

(3) 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.

(4) 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;

(b) Indelibly labeled “Human Waste” in contrasting letters at least three (3) inches in height; and

(c) Meet the requirements in Section 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 (1) 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. Section .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 cm^2) in size.

(5) The harvester's tag shall contain the following indelible, legible information in the order specified below:
(a) The harvesters' 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 Section .02 F.

(7) Bulk tagging of a lot of shellstock during transport from harvest area to the dealer facilities.
(a) When shellstock are harvested from one (1) harvest area on a single day by a single harvester or aquaculture leaseholder, multiple containers may be utilized on a wrapped pallet, in a tote, in a net brailer, in a single boat, vehicle, conveyance or other container and the unit tagged with a single tag in accordance with the requirements of Section .02 F.
(b) In addition to the information required in Section .02 F. the unit tag shall also include:
(i) A statement that "All shellstock containers in this lot have the same harvest data and area of harvest"; and
(ii) Number of individual containers in the unit or an estimate of the total weight, volume or count.

(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 Section .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 *V.v.* and *V.p.* Control Plans outlined in Chapter II. @.06 and @.07; 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 *V.v.* and *V.p.* Control Plans can be accessed on the ISSC web site using the following link: www.issc.org.

Chapter IX. Transportation

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .07

.01 Conveyances Used to Transport Shellstock to the Original Dealer

A. Any conveyance used to transport shellstock to the original dealer shall be properly constructed, operated, and maintained to prevent contamination, deterioration, and decomposition.
B. Storage bins on conveyances used in the transport of shellstock 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. 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 °F (10 °C).
D. When mechanical refrigeration units are used, the units shall be:
    (1) Equipped with automatic controls; and
    (2) Maintained at an ambient air temperature necessary to comply with .01 C. above.
E. Any ice used to cool shellstock during transport shall meet the requirements of Chapter XI. .02 A. (2).
F. Cats, dogs, and other animals shall not be allowed in any part of the conveyance where shellstock is stored.

.02 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.

.03 Cargo Protection From Cross Contamination

A. General. 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).

.04 Shipping Temperatures

Shellfish dealers shall ship shellfish adequately iced; or in a conveyance pre-chilled at or below 45 °F (7.2 °C) ambient air temperature. Geoduck clams (*Panopea generosa*) are exempt from these requirements

.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. Geoduck clams (*Panopea generosa*) are exempt from these requirements.

Chapter X. General Requirements for Dealers

.01 General HACCP Requirements

A. Hazard Analysis. Every dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventive measures that the dealer can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. A food safety hazard that is reasonably likely to occur is one for which a prudent dealer would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of shellfish product being processed in the absence of those controls. In the hazard analysis, the dealer shall consider the critical control points listed in Chapters XI., XII., XIII., XIV., and XV.

B. HACCP Plan. Every dealer shall have and implement a written HACCP plan. A HACCP plan shall be specific to:

(1) Each location where shellfish products are processed by that dealer; and

(2) Each kind of shellfish product processed by the dealer. The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in Section .01 C. are identical for all shellfish products so grouped or for all production methods so grouped.

C. Contents of the HACCP Plan. The HACCP plan shall, at a minimum:

(1) List the food safety hazards that are reasonably likely to occur, as identified in accordance with Section .01 A. and that thus must be controlled for each shellfish product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

(a) Natural toxins;
(b) Microbiological contamination;
(c) Chemical contamination;
(d) Pesticides;
(e) Drug residues;
(f) Unapproved use of direct or indirect food or color additives; and
(g) Physical hazards;

(2) List the critical control points for each of the identified food safety hazards, including as appropriate:

(a) Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during and after harvest. At a minimum, the critical control points shall include those identified in Chapter XI. .01, Chapter XII. .01, Chapter XIII. .01, Chapter XIV. .01 and Chapter XV. .01, as applicable. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis that the food safety hazard is not reasonably likely to occur, the critical control point is not required with the exception of receiving which shall always be considered as a critical control point.

(b) Critical control points designed to control food safety hazards that could be introduced in the processing plant environment. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Authority provide equivalent public health protection. If the dealer can demonstrate to the Authority through a hazard analysis

that the food safety hazard is not reasonably likely to occur, the critical control point is not required. At a minimum, the critical control points shall include those identified in Chapter XI. .01 A., Chapter XII. .01 A., Chapter XIII. .01 A., Chapter XIV. .01 A. and Chapter XV. .01 A., as applicable.

(c) Critical control points shall be designed to ensure that shellstock received with restricted use tags is processed consistent with the stated purpose. For Shellstock tagged for restricted use, critical control points shall be included in the Certified Dealer's HACCP plan to ensure that the shellstock is shipped to another Certified Dealer with the restricted use tag or processed consistent with the stated purpose.

(3) List the critical limits that must be met at each of the critical control points. At a minimum, the critical limits shall include those listed in Chapter XI. .01, Chapter XII. .01, Chapter XIII. .01, Chapter XIV. .01 and Chapter XV. .01, as applicable. As an alternative the dealer may establish other critical limits which the dealer has demonstrated provide equivalent public health protection with the exception of receiving which shall always be considered as a critical control point. In any case, the critical limits identified in Chapter XI. .01, Chapter XII. .01, Chapter XIII. .01, Chapter XIV. .01 and Chapter XV. .01 shall be met as components of good manufacturing practices.

(4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

(5) Include any corrective action plans that have been developed in accordance with Section .01 F. (2), to be followed in response to deviations from critical limits at critical control points.

(6) Provide for a record keeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

(7) List the verification procedures, and frequency thereof, that the dealer will use in accordance with Section .01 G. (1).

D. Signing and Dating the HACCP Plan.

(1) The HACCP plan shall be signed and dated, either by the most responsible individual on site at the processing facility or by a higher-level official of the dealer. This signature shall signify that the HACCP plan has been accepted for implementation by the dealer.

(2) The HACCP plan shall be signed and dated:

(a) Upon initial acceptance;

(b) Upon any modification; and

(c) Upon verification of the plan in accordance with Section .01 G. (1) (a).

E. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with Section .02 they need not be included in the HACCP plan, and vice versa.

F. Corrective Actions.

(1) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:

(a) Following a corrective action plan that is appropriate for the particular deviation, or

(b) Following the procedures in Section .01 F. (3).

(2) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with Section .01 C. (5), by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

(a) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(b) The cause of the deviation is corrected.

(3) When a deviation from a critical limit occurs and the dealer does not have a corrective

action plan that is appropriate for that deviation, the dealer shall:

(a) Segregate and hold the affected product until:

(i) There is a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review. Adequate training may or may not include training in accordance with Section .01 I.; and

(ii) Corrective action i s taken when necessary, to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.

(b) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with Section .01 I., to determine whether the HACCP plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

(4) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with Section .01 G. and the record keeping requirements of Section .01 H.

G. Verification.

(1) Every processor shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include, at a minimum:

(a) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. These changes may include: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Section .01.I. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of Section .01.C.

(b) Ongoing verification activities including:

(i) A review of any consumer complaints that have been received by the dealer to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;

(ii) The calibration of process-monitoring instruments; and

(iii) At the option of the dealer, the performing of periodic end product or in-process testing.

(c) A review, including signing and dating, by an individual who has been trained in accordance with Section .01 I., of the records that document:

(i) The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within one (1) week of the day that the records are made;

(ii) The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Section .01 F. This review shall occur within one (1) week of the day that the records are made; and

(iii) The calibrating of any process monitoring instruments used at critical control points and the performing of any periodic end product or in process testing that is part of the dealer's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the processor's written procedures. These reviews shall occur within a

reasonable time after the records are made.

(2) Dealers shall immediately follow the procedures in Section .01 F. whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(3) The calibration of process-monitoring instruments, and the performing of any periodic end- product and in-process testing, in accordance with Section .01 G. (1) (b) (ii) and (iii) shall be documented in records that are subject to the record keeping requirements of Section .01 H.

H. Records.

(1) All records required by Section .01 and Section .02 shall include:

(a) The name and location of the dealer;

(b) The date and time of the activity that the record reflects;

(c) The signature or initials of the person performing the operation; and

(d) Where appropriate, the identity of the product and the production code, if any.

Processing and other information shall be entered on records at the time that it is observed.

(2) All records required by Section .01 and Section .02 shall be retained at the processing facility for at least one (1) year after the date they were prepared in the case of refrigerated products and for at least two (2) years after the date they were prepared in the case of frozen products.

(3) Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing facility for at least two (2) years after their applicability to the product being produced at the facility.

(4) If the processing facility is closed for a prolonged period between seasonal operations, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal operations but shall be immediately returned for official review upon request.

(5) All records required by Section .01 and Section .02 and HACCP plans required by Section .01 B. and Section .01 C. shall be available for official review and copying at reasonable times.

(6) Tags on containers of shellstock are not subject to the requirements of this section unless they are used to fulfill the requirements of Chapter X. .05.

(7) The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and electronic signatures.

I. Training.

(1) At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to shellfish processing at least equivalent to that received under standardized curriculum recognized as adequate by the Authority or who is otherwise qualified through job experience to perform these functions:

(a) Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan that is appropriate for a specific processor, in order to meet the requirements of Section .01 C.;

(b) Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Section .01 F. (3) (b), and the HACCP plan in accordance with the verification activities specified in Section .01 G. (1) (a); and

(c) Performing the record review required by Section .01 G. (1) (c).

(2) Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum as determined by the Authority.

(3) The trained individual need not be an employee of the dealer.

Additional Guidance: Section IV Guidance Documents Chapter III. Section.01

.02 General Sanitation Requirements

A. Sanitation Monitoring. Each dealer shall monitor conditions and practices that are both appropriate to the plant and the food being processed with sufficient frequency to ensure, at a minimum, conformance with the requirements specified in Chapter XI. .02, Chapter XII. .02, Chapter XIII. .02, Chapter XIV. .02 and Chapter XV. .02. The requirements specified in these Sections relate to the following sanitation items:

(1) Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice, hereinafter referred to as: Safety of Water for Processing and Ice Production;

(2) Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Condition and Cleanliness of Food Contact Surfaces;

(3) Prevention of cross contamination from unsanitary objects to food, food packaging materials, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product, hereinafter referred to as: Prevention of Cross Contamination;

(4) Maintenance of hand washing, hand sanitizing, and toilet facilities, hereinafter referred to as: Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities;

(5) Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants, hereinafter referred to as: Protection from Adulterants;

(6) Proper labeling, storage, and use of toxic compounds, hereinafter referred to as: Proper Labeling, Storage, and Use of Toxic Compounds;

(7) Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces, hereinafter referred to as: Control of Employees with Adverse Health Conditions; and

(8) Exclusion of pests from the food plant hereinafter referred to as “Exclusion of Pests”.

While monitoring of those specified conditions and practices (listed in 1-8) that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.

B. Sanitation Monitoring Records. Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by Section .02 A. These records are subject to the requirements of Section .01 H.

C. Relationship to HACCP Plan. Sanitation controls may be included in the HACCP Plan, required by Section .01 B. However, to the extent that they are monitored in accordance with Section .02 A. they need not be included in the HACCP Plan, and vice versa.

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

.03 Other Model Ordinance Requirements

A. Each dealer shall comply with the requirements specified in Chapter XI. .03, Chapter XII. .03, Chapter XIII. .03, Chapter XIV. .03, and Chapter XV. .03 that are appropriate to the plant and

the food being processed. However, monitoring and record keeping for these conditions and practices is not required, unless specifically stated.

B. Recalls.

(1) Dealers shall adopt written procedures for conducting recalls of adulterated misbranded shellfish products. These written procedures for conducting recalls shall be based on, and complementary to, the FDA Enforcement Policy on Recalls, CFR Title 21, Chapter 1, Subchapter A., Part 7-Enforcement Policy, (NSSP Guide for the Control of Molluscan Shellfish, Federal Regulations).

(2) Dealers shall follow their written recall procedures to include timely notification of the Authority of a situation requiring recall, timely notification of consignee who received the affected product, and effective removal or correction of the affected product.

C. Each dealer shall report harvest quantities by species to the Authority. The reporting shall be at a frequency not to exceed monthly. Should the State choose to collect production data from harvesters, certified dealers are exempt from this requirement to avoid double counting.

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .04 Shellstock Tagging

.04 Certification Requirements

A. General.

(1) No person shall act as a dealer prior to obtaining certification.

(2) Any person who wants to be a dealer shall:

(a) Make application to the Authority for certification;

(b) Have and implement a HACCP Plan, and have a program of sanitation monitoring and record keeping in compliance with 21 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.

(c) Ensure that all individuals who manufacture, process, pack, or hold food obtain training in accordance with 21 CFR 117.4. A dealer shall be allowed thirty (30) days following initial hiring of a new employee to provide the required education.

(i) Proof of training for all employees shall be presented to the Authority prior to certification, recertification, or licensing.

(ii) The dealer shall maintain the record of the completed training.

(3) Each dealer shall have a business address at which inspections of facilities, activities, or equipment can be conducted.

B. Types of Certification.

(1) Shucker-packer. Any person who shucks shellfish shall be certified as a shucker-packer.

(2) Repacker.

(a) Any person who repacks shucked shellfish shall be certified as a shucker-packer or repacker;

(b) Any person who repacks shellstock shall be certified as a shellstock shipper, shucker-packer, or repacker;

(c) A repacker shall not shuck shellfish.

(3) Shellstock Shipper. Any person who ships and receives shellstock in interstate commerce shall be certified as a shellstock shipper, repacker, or shucker-packer.

(4) Reshipper. Any person who purchases shellstock or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers shall be certified as a reshipper.

.05 Shellstock Identification

[Note: All Federally allocated shellfish (surf and quahog) caught in Federally regulated waters must follow the National Marine Fisheries Service tagging protocol. These Federal sequential tags will supersede the tagging requirements in Section 05.*]*

A. General.

(1) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:

(a) Shipped with his/her dealer tag affixed to each container of shellstock; or

(b) Emptied to wash, grade, or pack the shellstock.

(2) When the dealer is also the harvester and he elects not to use a harvest tag, the dealer shall affix his dealer tag to each container of shellstock prior to shipment.

B. Tags.

(1) The dealers' 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 cm^2) in size.

(2) The dealer's tag shall contain the following indelible, legible information in the order specified below:

(a) The dealer's name and address.

(b) The dealer's certification number as assigned by the Authority.

(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required.

(d) The harvest date; or if depurated, the date of depuration processing, or if wet stored, the original harvest date, and the final harvest date which is the date removed from wet storage.

(e) If wet stored or depurated, the wet storage or depuration cycle or lot number. The wet storage lot number shall begin with the letter "w".

(f) The most precise identification of the harvest location 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 the Authority has not indexed growing areas, then an appropriated geographical or administrative designation must be used (e.g., Long Bay, Decadent County, lease number, bed, or lot number).

(g) The type and quantity of shellstock.

(h) 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, IN CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)**_____."**

Note: Shellstock tagged for restricted should not include the retailer guidance language "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED **(INSERT DATE)_____**."

(i) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all shellstock: "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if

you have certain medical conditions."

(j) The statement "Keep Refrigerated" or an equivalent statement.

(3) When both the dealer and harvester tags appear on the container, the dealer's tag is not required to duplicate the information on the harvester's tag.

(4) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in Section .05 B. If the shellstock is received bearing a restricted use tag all specific use language shall be transferred to the new shipping tag until processed consistent with the stated purpose.

(5) Country of origin information (USDA 2004) may be included on the dealer tag.

(6) When shellstock intended for retail sale are packed in containers of five (5) pounds or less and shipped in a master container which includes a tag in compliance with Chapter X. .05 B. (1) the individual containers of five (5) pounds or less shall not require tags as specified in Chapter X. .05 B. (1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the shellfish back to the lot of shellstock it is part of.

(7) If a shellfish producing State selects to implement Chapter II. @.06 E. (1) (b) (i), the statement "For shucking by a certified dealer" or an equivalent statement shall be included on the tag. When this statement is included, the shellstock shall ultimately be sold to or processed by a certified shucker-packer for the purpose of shucking only.

C. Bulk Tagging Lots of Shellstock for Sales between Dealers.

(1) When a single lot of shellstock is sold, multiple containers may be used on a wrapped pallet, in a tote, in a net bailer, or other container and the unit tagged with a single tag in accordance with Section .05 B. (1) through (4).

(a) This bulk tagging provision shall not apply to sales to reshippers;

(b) The shipment must be accompanied by a transaction record stating the name of the consignee who must be a certified dealer;

(c) In addition to the information required in Section .05 B. (1) through (4) 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.

D. Tagging of a Lot of Shellstock during Intermediate Processing.

(1) When the shellstock is removed from the original container, the dealer shall:

(a) Keep the harvester tag for ninety (90) days;

(b) Keep track of the growing area and date of harvest for shellstock; and

(c) Maintain the lot identity of all shellstock during any intermediate stage of processing.

(2) A dealer receiving bulk tagged lots of shellstock must have an intermediate processing plan approved by the Authority to ensure that each lot of shellstock is kept separate and identified in a way which prevents commingling or misidentification.

(3) In order for a dealer to tag a lot container (e.g., a pallet) of shellstock in lieu of meeting the requirement in Section .05 B. for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the Authority, which establishes the procedures, the dealer shall use to tag the lot during the washing, packing or staging of shellfish.

(4) Unless the dealer is included in the Authority's commingling plan under Chapter I. @.01 F., the dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. The identification shall be provided by:

(a) A harvester's or dealer's tag which meets the requirements of Section .05 B.; or

(b) A tag for each lot of shellstock that contains the following information:

(i) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest";
(ii) Harvest date;
(iii) Growing area;
(iv) Original dealer certification number; and
(v) Number of individual containers in each lot of shellstock container (e.g., a pallet) after washing, packing or staging has been completed.

(5) When a dealer has an approved intermediate processing plan, the dealer shall tag each lot of shellstock in accordance with the intermediate processing plan while the lot of shellstock is being processed in the plant.

E. All restricted use shellstock shall include a tag containing all information required in Section .05 of Model Ordinance Chapter X. In addition, the tag will include specific language detailing the intended use of the shellstock until processed consistent with the stated purpose.

F. Transaction Record. If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in Section .07 B. with the addition of the name of the consignee.

.06 Shucked Shellfish Labeling

A. Shellfish Labeling.

(1) The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers.

(2) If the shucker-packer uses returnable containers to transport shucked shellfish between dealers for the purpose of further processing or packing, the returnable containers are exempt from the labeling requirements in this section of the regulation. When returnable containers are used, the shipment shall be accompanied by a transaction record containing:

(a) The original shucker-packer's name and certification number;
(b) The shucking date; and
(c) The quantity of shellfish per container and the total number of containers.

(3) If the dealer uses master shipping cartons, the master cartons are exempt from these labeling requirements when the individual containers within the carton are properly labeled.

(4) At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.130, and 161.136) and the Federal Fair Packaging and Labeling Act.

(5) The dealer shall assure that the shucker-packer's or repacker's certification number is on the label of each package of fresh or frozen shellfish.

(6) The dealer shall label each individual package containing less than sixty-four (64) fluid ounces of fresh or fresh frozen shellfish with the following:

(a) The words "SELL BY" or "BEST IF USED BY" followed by a reasonable date when the product would be expected to reach the end of its shelf life;
(b) The date shall consist of the abbreviation for the month and number of the day of the month; and
(c) For fresh frozen shellfish, the year shall be added to the date.

(7) The dealer shall label each individual package containing sixty-four (64) fluid ounces or more of fresh or fresh frozen shellfish with the following:

(a) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container;
(b) The date shall consist of either the abbreviation for the month and number of the day of

the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; and

(c) For fresh frozen shellfish, the year shall be added to the date (for non-Julian format).

(8) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.

(9) If the dealer freezes fresh shucked shellfish, the dealer shall label all frozen shellfish as frozen in type of equal prominence immediately adjacent to the type of the shellfish and the year shall be added to the date (for non-Julian format).

(10) If the dealer uses lot codes to track shellfish containers, the lot codes shall be distinct and set apart from any date listed on the container.

(11) The dealer shall assure that each package of fresh or frozen shucked shellfish shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all packages: "Consuming raw or undercooked meats, poultry, seafood, shellfish, or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

B. Shucked Shellfish. If the dealer elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with Section .06 except that the original date of shucking shall be added to the new repacked container as specified in Section A. (7) or the original date of shucking shall be used in establishing the SELL BY DATE as specified in Section A. (6).

.07 In-Shell Product or Post-Harvest Processed In-Shell Labeling

A. The dealer shall tag or label all in-shell product with tags meeting the requirements of Chapter X. 05 B. (1).

B. In-Shell Product Tags or Labels.

(1) The dealer tag or label on in-shell product shall contain the following indelible, legible information in the order specified below:

(a) The dealer's name and address;

(b) The dealer's certification number as assigned by the Authority;

(c) The original shellstock shipper's certification number. If depurated the original shellstock shipper's certification number is not required;

(d) A "SELL BY DATE" which is a reasonable subsequent shelf-life or the words "BEST IF USED BY" followed by a date when the product would be expected to reach the end of its shelf-life. The date shall include, month, day and year;

(e) If depurated, the depuration cycle number or lot number;

(f) The most precise identification of the harvest location 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 the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g., Long Bay, Decadent County, lease number, bed, or lot number).

(g) The type and quantity of in-shell product; and

(h) The following statement in bold capitalized type on each tag or label: **"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS." "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____." OR "THIS LABEL IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RELABELED AND THEREAFTER**

KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS."
"RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)_____."

(i) All in-shell product intended for raw consumption shall include a consumer advisory. The following statement, from Section 3-603.11 of the Current Food Code, or an equivalent statement, shall be included on all shellstock: "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."

(j) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag or label.

(k) At a minimum the dealer shall tag or label each individual container in a legible and indelible form in accordance with CFR 21, Part 101; Part 161. Subpart B (161.130 and 161.136) and the Federal Fair Packaging and Labeling Act.

(i) If the in-shell product is removed from the original container, the tag or label on the new container shall meet the requirements in Section .07.B.

(ii) Country of origin information (USDA 2004) may be included on the shucker-packer or reshipper tag or label.

(iii) When in-shell product intended for retail sale are packed in containers of five (5) pounds or less and shipped in a master container which includes a tag in compliance with Chapter X. .05 B. (1), the individual containers of five (5) pounds or less shall not require tags as specified in Chapter X. .05. .B. (1) but may be labeled in some other manner with indelible, legible, information which at a minimum is adequate to trace the in-shell shellfish back to the lot of in-shell product it is part of. Consumer advisory information identified in Chapter X. .07 B. (1) (i) shall be included on each retail package.

NOTE: Implementation will be delayed until January 1, 2019 to allow shellfish dealers adequate time to use up existing tag inventories.
NOTE: The Consumer Advisory shall be required for both A. and B.

.08 Shipping Documents and Records

A. Shipping Documents.
   (1) Each shellfish shipment shall be accompanied by a shipping document.
   (2) The shipping document shall contain:
      (a) The name, address, and certification number of the shipping dealer;
      (b) The name and address of the major consignee; and
      (c) The kind and quantity of the shellfish product.
   (3) The receiving dealer shall:
      (a) Maintain in his files a copy of the completed shipping document; and
      (b) Make the shipping document available to the Authority upon request.
   (4) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment.
B. Transaction and Shipping Records.
   (1) Each dealer shall have a business address at which transaction records are maintained.
   (2) Each dealer shall maintain accurate and legible transaction records that are sufficient to:
      (a) Document that the shellfish are from a source authorized under this Ordinance;
      (b) Permit a container of shellfish to be traced back to the specific incoming lot of shucked

shellfish from which it was taken;

(c) Permit a lot (or commingled lots as per Chapter I. @.01 F.) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s), date(s) of harvest, date and location of wet storage, if applicable, and if possible, the harvester or group of harvesters.

(d) Trace the wet storage history of the shellstock including, original harvest site, original harvest date, wet storage site(s) and dates.

(3) Purchase and sales shall be recorded:

(a) In a permanently bound ledger book; or

(b) Using other recording methods acceptable to and authorized by the Authority. Entries of purchases or sales of shellfish shall be made into a permanently bound ledger book, computer record, or other method acceptable to and authorized by the Authority within seventy-two (72) hours of any purchase or sales.

(4) The transaction records shall be retained:

(a) In the case of fresh shellfish, for a minimum of one (1) year; and

(b) In the case of frozen shellfish, for at least two (2) years or the shelf life of the product, whichever is longer.

(5) If computer records are maintained, the Authority shall approve the format and its use.

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 schedule 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. Section .18

Requirements for Dealers

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .07

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(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 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 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. .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) 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 shuck and pack only in-shell product obtained from a dealer who has:

(a) Shipped the in-shell product adequately iced; or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature; or 45 °F (7.2 °C) internal temperature 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 VII. .04; and **[C]**

(2) Once placed under temperature control and until shucked the shellstock shall;

(a) Be iced; or **[C]**

(b) Be placed 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 Section .01 B. (1) or Section .01 B. (2) (a) or (b) 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. Processing Critical Control Point - Critical Limits. The dealer shall ensure that:

(1) For shellstock which has not been refrigerated prior to processing:

(a) Shucked meats are chilled to an internal temperature of 45 °F (7.2 °C) or less within three (3) hours of shucking. **[C]**

(b) In-shell product is chilled to an internal temperature of 45 °F (7.2 °C) or less within three (3) hours of processing. **[C]**

(2) For shellstock refrigerated prior to processing:

(a) 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]**

(b) In-shell product is 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]**

.02 Sanitation

A. Safety of Water for Processing and Ice Production.

Additional Guidance: Section IV Guidance Documents - Chapter III. Section .01

(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 (6) 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:

(a) Be made on-site from potable water in a commercial ice machine; **[C] or**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**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 twenty (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; **[$S^{C/K}$]**

(ii) Prevent any cross-connection between the pressurized potable water supply and water from unacceptable source. **[$S^{C/K}$]** 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) 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 °F for use in monitoring product temperatures. **[K]**

(f) All equipment used in heat shock processing shall meet the requirements of Chapter XI. .02 B. (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 (3) 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; and **[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) Properly stored until used; and **[K]**

(iv) 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) 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 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. **[$S^{K/0}$]**
(2) Hand washing facilities shall be provided which are:
(a) Convenient to work areas; **[O]**
(b) Separate from the three (3) 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 (1) 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; and **[K]**
(c) Each toilet facility with an adequate supply of toilet paper **[K]** in a suitable holder. **[$S^{K/0}$]**

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. **[$S^{C/K}$]**
(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**
(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. Section .06

(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]**

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 U.S. 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 twenty-four (24) hours of the last exposure:

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

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

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

(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 twenty-four (24) hours of the last exposure;

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

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

(iv) Hepatitis A virus within the past thirty (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 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]**

.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 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 fifteen (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; and **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water. **[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 (e.g., refrigeration units) **[K]**;

(c) Cleaned by hosing, flooding, or similar methods**]**; and **[K**

(d) Subject to the discharge of water or other liquid waste including three (3) 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. **[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; **[O]**
(b) Stands or stalls and stools for shucker; and **[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 Section 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) Assure that shellfish are maintained frozen during storage frozen. **[$S^{K/O}$]**
(10) Not commingle shellstock during shucking unless the dealer is included in the Authority's commingling plan. **[K]**
(11) Ensure that all shellstock obtained from a licensed harvester are
(a) Adequately iced within two (2) hours of receipt;

(b) Placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt; or

(c) Shucked within two (2) hours of receipt. **[$S^{C/K}$]**

(d) Product intended for relay, wet storage or depuration, or either geoduck clams (*Panopea generosa*), or *Mercenaria* spp. which are being cooled utilizing an Authority approved tempering plan are exempt from the requirements listed above in .03 F. (11).

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; **[K]**

(b) Make sure all responsible persons are familiar with requirements; and **[K]**

(c) Cool all hot dipped shellstock immediately after the heat shock process **[K], which** shall be accomplished by:

(i) Dipping in an 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 (3) 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 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 to 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) All employees to be trained in proper food handling and personal hygiene practices. **[K]**

Chapter XII. Repacking of Shucked Shellfish

Additional Guidance: Section IV Guidance Documents Chapter II. Section .18

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits. The dealer shall repack only shellfish which originated from a dealer who has:
   (1) Shipped the shellfish iced, or in a conveyance at or below 45 °F (7.2 °C) ambient air temperature; **[C]** and
   (2) Identified the shellfish with a label as outlined in Chapter X. .06. **[C]**

B. Processing Critical Control Point - Critical Limits. The dealer shall ensure that repacked shucked shellfish do not exceed an internal temperature of 45 °F (7.2 °C) for more than two (2) hours. **[C]**

C. Shucked Meat Storage Critical Control Point - Critical Limit.
The dealer shall store repacked shellfish in covered containers at an ambient temperature of 45 °F (7.2 °C) or less or covered with ice. **[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 (6) 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:
      a. Be made on-site from potable water in a commercial ice machine; **[C]** or
      b. Come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C]**
   (3) 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 and [$S^{C/K}$]
         (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [$S^{C/K}$]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. Section .01

B. Condition and Cleanliness of Food Contact Surfaces.

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

(a) 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) The dealer shall provide a temperature measuring device accurate to +/- 2 °F for use in monitoring product temperatures.

(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 (3) 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; and **[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]**

(c) Shucked shellfish shall be packed in clean covered containers:

(i) Fabricated from food grade materials; and **[K]**

(ii) Stored in a manner which assures their protection from contamination. **[K]**

(d) 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 shellfish.

(a) Shucked shellfish shall be protected from contamination. **[$S^{C/K}$]**

(b) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/O}$]**

(2) Employee practices

(a) The dealer shall assure that all employees working in direct contact with shellfish

processing activities or food contact surfaces maintain a high level of personal hygiene and cleanliness. **[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; **[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 repacked 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. **[$S^{K/O}$]**

(a) Hand washing facilities shall be provided which are:

(i) Convenient to work areas; **[O]**

(ii) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; **[K]**

(iii) Directly plumbed to an approved sewage disposal system, and **[$S^{K/O}$]**

(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 least one (1) hand sink in the packing room. **[O]**

(c) 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 **[C]** 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; and **[K]**

(c) An adequate supply of toilet paper at each toilet facility **[K]** in a suitable holder. **[$S^{K/0}$]**

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 area 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. **[$S^{C/K}$]**

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**

(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]**

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 Chapter III. Section .06

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 U.S. 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,

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(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 twenty-four (24) hours of the last exposure:

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

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

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

(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:

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

(iv) Hepatitis A virus within the past thirty (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 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]**

.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 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 the 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 that insects and vermin are not present in the facility.

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

(b) Screening of not less than fifteen (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; **[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; and **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water, **[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 prevention 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 (3) 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. **[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 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 non-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) Not commingle shellfish from different lots; **[K]**

(b) Repack shucked shellfish meats only into containers labeled with the authorized certification number; **[K]**

(c) 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]**

(d) Wash, blow, and rinse all shellfish meats in accordance with 21 CFR 161 Section 130; **[K]**

(e) Thoroughly drain, clean as necessary, and repack shucked shellfish meats promptly; **[K]**

(f) Conduct repacking activities so as to conform to applicable food additive regulations; and [K]

(g) During storage frozen shellfish shall be maintained frozen. **[$S^{K/0}$]**

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 to 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; and**[K]**
(d) All employees to be trained in proper food handling and personal hygiene practices; **[K]**

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.

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .07

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.

(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:

(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. .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) 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 requirement of Chapter XIII. .01 A. (2) (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 VII. .04; and **[C]**

(2) Once placed under temperature control and until sale to the processor or final consumer,

shellstock shall:

(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 Section .01 B. (1) or Section .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 *V.v.* Control Plans. **[C]**

(b) Cooled to an internal temperature of 50 °F (10 °C) within the time periods outlined in the State *V.p.* Control Plans. Shellstock cooled to an internal temperature of 55 °F (12.7 °C) to comply with a *V.v.* 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 or depuration, or either geoduck clams (*Panopea generosa*), or *Mercenaria* spp. which are 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. The transaction record shall indicate the quantity of restricted use shellstock containers.**[C]**

(2) 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 (6) 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:
(a) Be made on-site from potable water in a commercial ice machine; **[C]** or
(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**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 twenty (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; [$S^{C/K}$]
(b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source [$S^{C/K}$] 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. Section .01

B. Condition, and Cleanliness, of Food Contact Surfaces.
(1) Equipment and utensil construction for food contact surfaces.
(a) 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 (3) 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; and **[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. **[$S^{K/O}$]**

(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 handwashing 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) Handwashing 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. **[$S^{K/O}$]**

(a) Handwashing facilities shall be provided which are:

(i) Convenient to work areas; **[O]**

(ii) Separate from the three (3) 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 handwashing 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) Handwashing signs in a language understood by the employees. **[O]**

(2) Sewage **[C]** 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; and **[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$^{C/K}$]**

(6) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[S$^{C/K}$]**

(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 Chapter III. Section .06

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 twenty-four (24) hours of the last exposure:

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

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

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

(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 twenty-four (24) hours of the last exposure;

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

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

(iv) Hepatitis A virus within the past thirty (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 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]**

.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 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 the 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 that insects and vermin are not present in the facility.

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

(b) Screening of not less than fifteen (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; **[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; and**[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water. **[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 (e.g., refrigeration units) **[K]**;

(c) Cleaned by hosing, flooding, or similar methods; and **[K]**

(d) Subject to the discharge of water or other liquid waste including three (3) 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. **[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 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 assure that shellstock is:

(a) Alive; **[K]**

(b) Reasonably free of sediment **[O]**; and

(c) 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 within two (2) hours of receipt; or

(b) Placed in a storage area maintained at 45 °F (7.2 °C) within two (2) hours of receipt;

(c) Product intended for relay, wet storage or depuration, or either geoduck clams (*Panopea generosa*), or *Mercenaria* spp. which are being cooled utilizing an Authority approved tempering plan are exempt from the requirements listed above in .03 F. (6).

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 to 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; and **[K]**

(d) All employees to be trained in proper food handling and personal hygiene practices. **[K]**

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.*

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .07

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.
   (1) The dealer shall reship only shellfish obtained and transported from a dealer who has:
      (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. .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]** or
      (f) Shipped the shucked shellfish and/or in-shell product adequately iced or in a conveyance at or below 45 ºF (7.2 ºC) ambient air temperature. **[C]**
   (2) 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:
   (1) Be iced; or **[C]**
   (2) Be 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 or covered with ice. **[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. The

transaction record shall indicate the quantity of restricted use shellstock containers. **[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]**

.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 (6) 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:
(a) Be made on-site from potable water in a commercial ice machine; **[C]** or
(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**C**]
(3) 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; **[$S^{C/K}$]**
(b) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[$S^{C/K}$]**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.
Equipment and utensil construction for food contact surfaces. 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]**

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) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination. **[$S^{K/O}$]**
(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. **[$S^{K/O}$]**

(a) Hand washing facilities shall be provided which are:
(i) Convenient to work areas; **[O]**
(ii) Separate from the three (3) compartment sinks used for cleaning equipment and utensils; **[K]**
(iii) Directly plumbed to an approved sewage disposal system; and **[$S^{K/O}$]**
(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 **[C]** and liquid disposable wastes shall be properly removed from the facility. **[K]**

(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; and **[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 reshipping.
(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. **[$S^{C/K}$]**

(5) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed. **[$S^{C/K}$]**

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]**

Additional Guidance: Section IV Guidance Documents Chapter III. Section .06

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 U.S. 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 twenty-four (24) hours of the last exposure;
(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. within the past three (3) days of the last exposure;
(iii) *Salmonella typhi* within the past fourteen (14) days of the last exposure;
(iv) Hepatitis A virus within the past thirty (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 twenty-four (24) hours of the last exposure;
(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. within the past three (3) days of the last exposure;
(iii) *Salmonella typhi* within the past fourteen (14) days of the last exposure; or
(iv) Hepatitis A virus within the past thirty (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 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]**

.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 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 fifteen (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. **[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; and **[O]**

(iii) Have sealed junctions between floors and walls to render them impervious to water. **[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 preventer such as air gaps, shall be provided where floors are:

(a) Used in shellfish 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 three (3) 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. **[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 non-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 buy shellfish only from sources certified by the Authority or listed in the ICSSL. **[K]**

(2) The dealer shall not:

(a) Commingle, sort, or repack shellfish; or **[K]**

(b) Remove or alter any existing tag or label. **[K]**

(3) A dealer whose activity consists of trucks only shall:

(a) Have his own facility for the storage of shellfish; or **[K]**

(b) Have arrangements with a facility approved by the Authority for the storage of shellfish; and **[K]**

(c) Have a permanent business address at which records are maintained and inspections can be performed. **[K]**

(4) During storage frozen shellfish shall be maintained frozen. **[$S^{K/O}$]**

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 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 to 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) All employees to be trained in proper food handling and personal hygiene practices. **[K]**

Chapter XV. Depuration

[Note: In those States where depuration is not practiced, this Chapter may be deleted from the Model Ordinance, as well as references to depuration throughout the Model 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; and
   (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 inspection reports and reviews of the plant performance in accordance to Section D. (above) for each facility shall be kept for the period of five (5) years.
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

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .07

.01 Critical Control Points

A. Receiving Critical Control Point - Critical Limits.
   (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. .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]**

(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 forty-four (44) hours; **[C]**

(2) The water treatment system is operating to design specifications; and **[C]**

(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 VII. .04; **[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 °F (7.2 °C) or less; **[C]** and

(c) Not permitted to remain outside temperature control for more than two (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 (6) 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:

(a) Be made on-site from potable water in a commercial ice machine; or **[C]**

(b) Come from a facility sanctioned by the Authority or the appropriate regulatory agency. [**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; and **[$S^{C/K}$]**

(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 twenty (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; and **[C]**

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; **[S$^{C/K}$]** and

(ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. **[S$^{C/K}$]** 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; and **[K]**

(iii) Shellfish containers allow process water to flow freely and uniformly to all shellfish within each container. **[K]**

(6) Depuration unit. 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:

(a) Is easily accessible for cleaning and inspection; **[K]**

(b) Is self-draining; **[K]** and

(c) Meets the requirements for food contact surfaces. **[K]**

Additional Guidance: Section IV Guidance Documents Chapter III. Section .01

B. Condition and Cleanliness of Food Contact Surfaces.

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

(a) 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; 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 Section .02 B. 1 (a), (b), and (c). **[K]**

(e) Shellstock washing tanks and related plumbing shall be fabricated from safe materials which:

(i) Are easily accessible for cleaning and inspection; and: **[K]**

(ii) Meet 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. Depuration tanks and trays are not considered to be 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)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; and **[K]**

(iii) Wash and rinse equipment at the end of each day. [**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 (3) 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; and **[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. **[$S^{C/K}$]**

(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. **[$S^{C/K}$]**

(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) The dealer shall 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. Section .06

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 twenty-four (24) hours of the last exposure:
(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. within the past three (3) days of the last exposure;
(iii) *Salmonella typhi* within the past fourteen (14) days of the last exposure;
(iv) Hepatitis A virus within the past thirty (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 twenty-four (24) hours of the last exposure;
(ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. within the past three (3) days of the last exposure;
(iii) *Salmonella typhi* within the past fourteen (14) days of the last exposure; or
(iv) Hepatitis A virus within the past thirty (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 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; and **[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 fifteen (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; and **[O]**
(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 (3) 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; and **[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 non-depurated
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 (1) 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 °F (7.2 °C). **[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; 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, 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; and **[K]**

(iii) Shellstock protection from contamination. **[K]**

(c) Supervisors to 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; and **[K]**

(d) All Employees

(i) To be trained in proper food handling and personal hygiene practices; and **[K]**

(ii) To 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 Section 01 B. (3);

(e) Statement that construction materials and fabrication will meet the requirements of Section 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 Section .04 and Section .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 non-depurated 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 including a list of categories of information that will be recorded and 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); and
(d) Laboratory records.

J. Process Verification.

The Dealer shall continually:

(1) Perform process verification on a continuous basis (i.e., routine verification) according to the following protocol:
(a) Following completion of a minimum of forty-four (44) hours of depuration, collect and assay at least one (1) end-product sample:
(i) From each lot of restricted shellstock to be depurated in the depuration unit; or
(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 90^{th} 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 results become available, the depuration performance indices with the Critical Limits for the Indices of Depuration Plant Performance in the table

below.

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

Species	Geometric Mean	90th Percentile
Soft Clams (*Mya arenaria*)	50	130
Hard Clams (*Mercenaria mercenaria*)	20	70
Oysters	20	70
Manila 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, FC counts that signify the upper or lower limit of sensitivity of the test (MPN or elevated temperature coliform plates [ETCP]) shall be increased or decreased by one (1) 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 ten (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 (1) zero hour and three (3) 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 CCPs 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 (3) samples) of soft clams not to exceed 110 and no single sample to exceed 170; or

(ii) Geometric mean (from three (3) samples) of other clam species, mussels, or oysters not to exceed forty-five (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 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 Section 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 ten (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 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 Section XV.03.J.(1).

(iii) If less than ten (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 ten (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 found to conform to the NSSP pursuant to the requirements in Chapter III, using an NSSP-Approved Method;

(b) Sample size consists of a pool of at least twelve (12) shellfish selected at random from

each designated container (more than twelve (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.

Chapter XVI. Processes and Procedures for Pathogen Reduction

.01 Processes and Procedures Involving Labeling Claims

A. If a dealer elects to use a process to reduce the level(s) of one (1) 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. Section .11

(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 .02 and be approved by the Authority, with concurrence of FDA.

(a) The dealer must demonstrate that the process reduces the level of *V.v.* and/or *V.p.* in the process to non-detectable (<30 MPN/g) and the process achieves a minimum 3.52 log reduction. Determination of *V.v.* and/or *V.p.* levels must be done using the MPN protocols described in Guidance Documents, Chapter IV., Naturally Occurring Pathogens, Section .02 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 .02 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. .08.

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 (1) 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 (1) 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).

Additional Guidance: Section IV. Guidance Documents Chapter III. Section .07

C. For the purpose of 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.

.02 Processes and Procedures Not Involving Labeling Claims

D. If a dealer elects to use PHP to reduce the levels of a naturally occurring pathogen(s) of public health concern in shellfish, the dealer shall:
   1. Have a HACCP plan (approved by the Authority) for the control(s) that reduces the target pathogen(s).
      a. The dealer must validate that the PHP reduces naturally occurring pathogen(s). The validation study must be approved by the Authority with FDA concurrence.
      b. The ability of the PHP to reliably achieve the appropriate reduction in the target pathogen(s) shall be verified at a frequency determined by the Authority.
   2. Package and label all shellfish in accordance with the requirements of this Ordinance.
   3. Keep records in accordance with Chapter X. 08.

Chapter XVII Shellfish Gardening

@ .01 Shellfish Gardening

If a State recognizes shellfish gardening the Authority:

A. Shall permit or register shellfish gardening activities;
B. Shall establish permit or registration conditions and determine classification of waters where shellfish gardening can take place prior to its implementation;
C. Shall provide information to the shellfish gardener on the risk of consuming shellfish from private docks, piers, and shellfish floats attached to piers or docks and from waters not classified and open to harvest for direct consumption; and
D. May require that the shellfish gardener maintain records on the disposition of the shellfish product and provide these records to the Authority.

.01 Requirements for the Shellfish Gardener

A. Shellfish gardening shall be practiced only in strict compliance with the provisions of the permit issued by the Authority for the oyster/shellfish gardening activity.
B. Shellfish gardeners shall document that they understand the risks associated with consumption for shellfish grown from docks or private piers.
C. If required by the Authority, shellfish gardeners shall keep accurate records on the fate or final destination of all shellfish grown at their shellfish garden site and provide these records to the Authority upon request.