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TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 50 – ENVIRONMENTAL HEALTH

SUBCHAPTER 10 – FOOD PROTECTION

PART 6 – Processing and Distribution of Shellfish

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6.1 Authority and Purpose

6.1.1 Authority

These Regulations are amended pursuant to the authority of R.I. Gen. Laws [§Chapters 23-1](#) and [§21-14](#) and are established for the purpose of updating minimum standards and requirements related to the processing and distribution of shellfish, to adopt requirements of National Shellfish Sanitation Program (NSSP) 20195 Model Ordinance, to assure the safety of shellfish brought into the State of Rhode Island for sale, and to protect the health, safety, and welfare of the public.

6.1.2 Purpose

This Part establishes the minimum requirements necessary to regulate the intrastate 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 processing, shipping, or handling.

6.1.3 Applicability

The terms and provisions of these Rules and Regulations shall be liberally construed to permit the Rhode Island Department of Health to effectuate the purposes of State law, goals, and policies.

6.2 Definitions

- A. For the purpose of these Regulations, these terms shall have the following meaning:
1. "Approved" means approved by the Director.
 2. "Buy boat" means a boat that is considered to be an extension of the shellfish business facility. Boats can only operate in open harvest areas.
 3. "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 Director to conduct the activity; and
 - b. Compliance with the requirements of this Part.

4. "Certification number" means the unique identification number issued by the Director 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 (2) 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 Part using the following terms: shellstock shipper (SS), shucker-packer (SP), repacker (RP), and reshipper (RS).
5. "Commingle or commingling" means the act of combining different lots of shellfish or shucked shellfish.
6. "Compliance schedule" means a written schedule that provides a correction time period to eliminate Key and Other deficiencies.
7. "Critical control point" 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.
8. "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.
9. "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.
10. "Dealer" means any individual, trust or estate, partnership, corporation (including associations, joint stock companies), or limited liability company engaged in shellfish business as defined in § 6.2 of this Part.
11. "Department" means the Rhode Island Department of Health.
12. "Director" means the Director of the Rhode Island Department of Health or the Director's duly appointed agents.
13. "Dry storage" means the storage of shellstock out of water.
14. "Food contact surface" means an equipment surface or utensil which normally comes into direct or indirect contact with shucked shellfish.
15. "Food safety hazard" means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

16. "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 (7) principles identified by the National Advisory Committee on Microbiological Criteria for Foods (1992).
17. "HACCP pPlan" means a written document that delineates the formal procedures that a dealer follows to implement the HACCP requirements set forth in 21 C.F.R. § 123.6 as adopted by the Interstate Shellfish Sanitation Conference.
18. "Harvest area" means an area that contains commercial quantities of shellstock and may include aquaculture sites and facilities.
19. "Harvest tTime" means the time when the first shellstock in a lot is taken from the water or, in the case of intertidal harvest, the time of first exposure.
20. "Key deficiency" means a condition or practice which may result in adulterated, decomposed, misbranded or unwholesome product.
21. "License" means the document issued by the Director to a person to harvest or transport shellstock for commercial sale.
22. "Operational plan" means a written description of the design and activities of the facility specific to, but not limited to, the species of shellfish to be processed, the source of the shellfish to be processed, how the shellfish will be processed, and how the required records will be maintained.
23. "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 Part.
24. "Person" means any individual, firm, co-partnership, association, or private or municipal corporation.
25. "Preventive measure" means physical, chemical, or other factors that can be used to control an identified food safety hazard.
26. "Primary dealer" means a dealer who purchases shellfish directly from the harvester.
27. "Processing" means any activity associated with the handling, shucking, freezing, packing, labeling or storing of shellfish in preparation for distribution.

28. "Raw" means shellfish that have not been thermally processed:
- a. To an internal temperature of one hundred forty-five degrees Fahrenheit (145° F) (sixty-two and eight tenths degrees Centigrade (62.8° C)) or greater for fifteen (15) seconds (or equivalent); or
 - b. Altering the organoleptic characteristics.
29. "Repacker" or "{RP}" means:
- a. Any person who repacks shucked shellfish; and
 - b. Any person who repacks shellstock.
30. "Repacking sShellfish" means the practice of removing shellfish from containers and placing it into other containers.
31. "Reshipper" or "{RS}" means any person who purchases shellfish or shucked shellfish from dealers and sells the product without repacking or relabeling to other dealers, wholesalers or retailers.
32. "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.
33. "Secondary dealer", as used in this Part, means a dealer who does not buy from harvesters.
34. "Shellfish" means and include oysters, mussels, and all varieties of clams and scallops except where the final product will be the adductor muscle only whether:
- a. Shucked or in the shell;
 - b. Raw, including post-harvest processed;
 - c. Frozen or unfrozen; or
 - d. Whole or in part.

35. "Shellfish business" means and include one (1) of the following: processing, labeling, storing, or transporting except by common carrier, shellfish which are to be offered for sale or sold.
36. "Shellstock" means raw, in-shell molluscan shellfish.
37. "Shellstock shipper" or "~~SS~~" means any person who buys, repacks, sells, ships or receives shellstock.-
38. "Shucked shellfish" means molluscan shellfish that have one (1) or both shells removed.
39. "Shucker-packer" or "~~SP~~" means any person who shucks shellfish. A shucker-packer may act as a shellstock shipper or reshipper or may repack shellfish originating from other certified dealers.
40. "Tag" means a record of harvesting information attached to a container of shellstock by the harvester, processor or dealer.
41. "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.
42. "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.

6.3 Licensure Requirements

6.3.1 License for a Shellfish Business

- A. The provisions of R.I. Gen. Laws Chapter 21-14 and this Part shall not apply to retail operators offering for sale to the consumer only shellfish which have been obtained from persons licensed to operate a shellfish business.
- B. No person shall conduct within the State of Rhode Island any shellfish business until that person shall have obtained a license from the Department and any and all necessary permits or licenses from such agencies as the Department of Environmental Management (DEM), and in some instances from the Coastal Resources Management Council (CRMC).

- C. As a condition of initial and continued licensure, shellfish businesses licensed in the State of Rhode Island shall meet the requirements of 21 C.F.R. [Part§ 123](#) (2012) entitled “Fish and Fishery Products” (not to include later amendments thereof), where applicable.
- D. The Director shall, upon receipt of application for a license to conduct a shellfish business, cause the applicant's shellfish business facilities to be investigated and, if they are found to comply with the provisions of the Act and these Rules and Regulations herein, shall issue a license upon receipt of a fee as set forth in [Part 10-05-2 of this Title, the “Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services”](#) ~~Provided by the Department of Health,~~ for a shipper/reshipper or a fee as set forth for a shucker packer/repacker.
- E. Any person who wants to be a dealer shall have and implement a HACCP plan, and have a program of sanitation monitoring and record keeping in compliance with 21 C.F.R. [Part§ 123](#) (2012) (not to include later amendments thereof), except for the requirement for harvester identification on a dealer’s tag.
- F. Any license so issued shall apply only to those phases of the shellfish business as approved by the Department and as defined in this Part.
- G. The license period shall be for twelve (12) months, unless sooner suspended or revoked for cause, commencing on January 1st, and the license fee shall be at the full annual rate regardless of the date of application or the date of issuance of license. -The fee for renewal of a license to conduct a shellfish business shall be as set forth in [Part 10-05-2 of this Title, Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health, the “Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services”](#) ~~provided by the Department of Health~~ for a shipper/reshipper or as set forth for a shucker packer/repacker.
- H. Licenses issued pursuant to this Part may be suspended or revoked for violation of the provisions of R.I. Gen Laws Chapter 21-14 and this Part.
- I. The Director may, after a hearing, refuse to issue any such license to any person who has been convicted of any violation of R.I. Gen Laws Chapter 21-14 or this Part.
- J. Each dealer shall have a business facility address or aquaculture lease at which inspections of facilities, activities, equipment, or records can be conducted.
- K. Facility Plan

1. A licensee shall submit to the Department properly prepared plans and specifications for review and approval a minimum of thirty (30) days before:
 - a. The construction of a structure for use as a shellfish business;
 - b. The conversion of an existing structure for use as a shellfish business; or
 - c. The remodeling of a shellfish business or a change of type of shellfish business if the Department determines that plans and specifications are necessary to assure compliance with these Regulations.

L. Operational Plan

~~1.~~ An operational plan shall be submitted with a licensure application or when there is a change in operations of a shellfish business.

6.3.2 Sale of Non-Complying Shellfish Prohibited

- A. No person shall sell or possess with intent to sell within the State of Rhode Island for human consumption any shellfish which have not been processed, labeled, transported, or sold in compliance with the provisions of R.I. Gen. Laws Chapter 21-14 and this Part.
- B. Any shellfish which the Director shall have reasonable cause to believe have been taken from unapproved areas or which have not been processed, labeled, transported, or sold in compliance with the provisions of the Act and this Part shall be confiscated. Search warrants may be issued by any district court upon complaint of the Director or the Director's duly authorized agents relating to violations of R.I. Gen. Laws Chapter 21-14 and this Part.

6.3.3 Inspection of Business Premises

- A. The Director shall make regular inspections of the business premises of licensees and no person shall interfere with or obstruct the entrance of the Director to any dealer or structural appurtenance thereto, vessel, or vehicle, for the purpose of making inspection related to compliance with R.I. Gen. Laws Chapter 21-14 and this Part during reasonable business hours and no person shall obstruct the conduct of this inspection; provided, however, that inspections as to sanitary conditions shall be made only by the Director or employees of the Department.

- B. In accordance with R.I. Gen Laws § 21-14-14, all such agents, so appointed by the Director, by virtue of their appointment and until these appointments shall be cancelled and revoked, may seize all shellfish in possession of any person violating the provisions of R.I. Gen. Laws Chapter 21-14, and may make complaints for all such violations, and in any such complaint they shall not be required at the time of complaint or thereafter to enter into recognizance or in any way to become liable for the costs that may accrue thereon.

6.3.4 Certification Program

- A. Any shellfish business which requests to be included on the Interstate Certified Shellfish Shippers List (ICSSL) issued by the Department shall meet all requirements of the National Shellfish Sanitation Program's Guide for Control of Molluscan Shellfish: 2019⁹⁵ Revision (*not to include later amendments or editions thereof*) <https://www.fda.gov/media/143238/download>.
- B. No dealer shall ship shellfish out of the State of Rhode Island prior to obtaining certification from the Department.

6.4 General Requirements

6.4.1 General Requirements

- A. Licensure Requirements
 - 1. Types of Licensure Activities
 - a. Shucker-packer (SP). Any person who shucks shellfish shall be licensed as a shucker-packer.
 - b. Repacker (RP)
 - (1) Any person who repacks shucked shellfish shall be licensed as a shucker-packer or repacker;
 - (2) Any person who repacks shellstock shall be licensed as a shellstock shipper, shucker-packer, or repacker;
 - (3) A repacker shall not shuck shellfish.
 - c. Shellstock Shipper (SS). Any person who ships and receives shellstock in interstate commerce shall be licensed as a shellstock shipper, repacker, or shucker-packer.

- d. Reshipper (RS). 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 licensed as a reshipper. Reshippers are not required to have a business facility address as required in § 6.3.1(J) of this Part.

2. General Licensure Requirements

- a. No person shall act as a dealer prior to obtaining licensing.
- b. Any person who wants to be a dealer shall:
 - (1) Make application to the Director for licensing; and
 - (2) Have and implement a HACCP Plan.

B. Shellstock Identification

1. General

- a. The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:
 - (1) Shipped; or
 - (2) Emptied to wash, grade or pack the shellstock.
- b. 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.

2. Tags

- a. The dealers' tags shall:
 - (1) Be durable, waterproof and sanctioned by the Department prior to use; and
 - (2) Be at least 13.8 square inches [89.03 square cm] in size.
- b. The dealer's tag shall contain the following indelible, legible information in the order specified below:
 - (1) The dealer's name and address;

- (2) The dealer's license number or certification number as assigned by the Department and the original shellstock shipper's license number, if applicable;
- (3) The date of harvest;
- (4) The time of harvest (when appropriate);
- (5) The harvest location, as designated in the Rhode Island Department of Environmental Management [Regulations 250-RICR-90-00-4, entitled "Part 4 Shellfish."](#) and tagging map located at:
<http://www.dem.ri.gov/programs/bnatres/fishwild/pdf/tagmap.pdf>, including the initials for the State of Rhode Island (RI), or the harvest area it appears on the original dealer's tag, including the initials of the State of origin; and-
- (6) When the shellstock has been taken cross State lines and has been placed in wet storage in a dealer's operation, the statement: "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY LICENSE NUMBER) FROM (DATE) TO (DATE);"
- (7) The type and quantity of shellfish; and
- (8) 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." ~~And~~ "RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)"
- (9) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from § 3-603.11 of the 2017~~3~~ FDA Food Code, or an equivalent statement, shall be included on all shellstockfish:
~~"RETAILERS, INFORM YOUR CUSTOMERS"~~ "Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions."
- (10) The statement "Keep Refrigerated" or an equivalent statement must be included on the tag.

- (11) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in §§ 6.4.1(B) through (D) in this part.

C. Tagging 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 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 Department 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 shellfish in lieu of meeting the requirement in §§ 6.4.1(B), (C), and (D) of this part for a harvester or dealer tag on each individual container, the dealer shall have an intermediate processing plan approved by the Department 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 Department's commingling plan, the dealer's intermediate processing plan for tagging a lot of shellfish during the intermediate stage of processing shall ensure that each lot of shellfish 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 §§ 6.4.1(B), (C), and (D) of this part; or
 - b. A tag for each lot of shellstock which contains the following information:
 - (1) A statement that "All shellstock containers in this lot have the same harvest date and area of harvest";
 - (2) Harvest date;

- (3) Harvest time (when appropriate);
 - (4) Growing area;
 - (5) Original dealer license or certification number (if applicable);
and
 - (6) 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.
- D. 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 § 6.4.1(E) of this Part with the addition of the name of the consignee.
- E. Shucked Shellfish Labeling
1. All shellfish intended for raw consumption shall include a consumer advisory. The following statement, from § 3-603.11 of the 2017 FDA Food Code, or an equivalent statement, shall be included on all shellfish:
 - a. “RETAILERS, INFORM YOUR CUSTOMERS” “Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.”
 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 license or certification (if applicable);
 - 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 21 C.F.R. § 161.130 (2012) (*not to include later amendments thereof*) and the Federal Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451-1461.
5. The dealer shall assure that each package containing less than sixty-four (64) fluid ounces of fresh or frozen shellfish shall have:
 - a. The shucker-packer's or repacker's license or certification number (if applicable) on the label; and
 - b. A "SELL BY DATE" which provides 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 consist of the abbreviation for the month and number of the day of the month. For frozen shellfish, the year will be added to the date.
6. The dealer shall assure that each package containing more than sixty-four (64) fluid ounces of fresh or frozen shellfish shall have:
 - a. The shucker-packer's or repacker's license or certification number (if applicable) on the label; and
 - b. A "DATE SHUCKED" which shall:
 - (1) For fresh shellfish, consist of the number of the day of the year or the month and the number of the day of the month;
 - (2) For frozen shellfish, include the year; and
 - (3) Appear on the lid and sidewall or bottom of single-use containers.
7. If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.
8. The dealer shall provide all label information in a legible and indelible form.

9. The dealer shall maintain lot integrity when shucked shellfish are stored using in-plant reusable containers.

F. Shucked Shellfish

~~1.~~ If the dealer (SP, RP) elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with §§ 6.4.1(E), (F), and (G) of this Part, except that the original date of shucking shall be used in establishing the SELL BY DATE.

G. Buy Boats

1. Boats used to purchase shellfish must be operated in compliance with all applicable requirements of R.I. Gen. Laws Chapter 21-14 and this Part, including but not limited to:
 - a. Hand washing equipment, such as sanitizing baby wipes or potable water and soap, must be provided on the vessel and used any time the hands have become contaminated.
 - b. Boats shall provide overhead protection of shellstock from exposure to sun, birds, and other adverse conditions.
 - c. Boats may be cleaned with water from open harvest areas or a potable water supply.
 - d. Shellstock shall be placed under temperature control of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) ambient air temperature (or below) as soon as possible not to exceed two (2) hours from the time the boat leaves the harvest area in which it was operating; and
 - e. § 6.4.1(G)(2) of this Part, outlined below.
2. Disposal of Human Sewage from Vessels
 - a. 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.
 - b. As required by the Department, 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.
 - c. Portable toilets shall:

- (1) Be used only for the purpose intended
 - (2) Be secured while on board and located to prevent contamination of shellshock by spillage or leakage
 - (3) Be emptied only into a sewage disposal system
 - (4) Be cleaned before being returned to the boat
 - (5) Not be cleaned in equipment used for washing or processing food
- d. Use of other receptacles for sewage disposal may be approved by the Department if the receptacles are:
- (6) Constructed of impervious, cleanable materials and have a tight-fitting lid;
 - (7) Indelibly labeled "Human Waste" in contrasting letters at least three inches (3") in height; and
 - (8). Meet the requirements of § 6.4.1(G)(2)(c) of this Part.

6.4.2 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 this Part.
- 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 § 6.4.2 (C) of this Part 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 §6.4.2(A) of this Part 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 § 6.4 of this Part, as applicable. As an alternative, the dealer may establish other critical control points which the dealer can demonstrate to the Department provide equivalent public health protection. If the dealer can demonstrate to the Department 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 Department provide equivalent public health protection. If the dealer can demonstrate to the Department 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 § 6.4 of this Part, as applicable.

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 § 6.4 of this Part, 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 § 6.4 of this Part, 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 § 6.4.2 of this Part 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 § 6.4.2 of this Part.

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.

E. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with this Part, they do not need to 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 § 6.4.2 of this Part.
2. Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with § 6.4.2 of this Part, 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, at least until the requirements of § 6.4.2 of this Part are met;
 - b. Perform or obtain 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 § 6.4.2 of this Part;
 - c. Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

- d. Take corrective action, when necessary, to correct the cause of the deviation;
 - e. Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with § 6.4.2 of this Part, 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 § 6.4.2 of this Part and the record keeping requirements of § 6.4.2 of this Part.

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 § 6.4.2 of this Part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of § 6.4.2 of this Part.
 - b. Ongoing verification activities including:
 - (1) 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;
 - (2) The calibration of process-monitoring instruments; and
 - (3) 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 § 6.4.2 of this Part, of the records that document:
 - (1) 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;
 - (2) 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 § 6.4.2 of this Part. This review shall occur within one (1) week of the day that the records are made; and
 - (3) 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.
- d. Dealers shall immediately follow the procedures in § 6.4.2 of this Part whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.
- e. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with § 6.4.2 of this Part shall be documented in records that are subject to the record keeping requirements of § 6.4.2 of this Part.

H. Records

- 1. All records required by § 6.4.2 of this Part 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 § 6.4.2 of this Part 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 and HACCP plans required by § 6.4.2 of this Part 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 § 6.4.1 of this Part.
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. All dealers shall obtain Department-approved training every five (5) years. The training shall include required processing, handling, and transportation practices as determined by the Department.
 - a. A dealer shall receive proof of completion of the required training. Proof of training obtained by the dealer within the past two (2) years shall be presented to the Department prior to certification, recertification, or licensing.
 - b. At a minimum, one (1) individual involved in the shellfish operations shall obtain the required training.

- c. The dealer shall maintain the record of the completed training.
 2. 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 Department 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 § 6.4.2 of this Part.
 - b. Reassessing and modifying the HACCP plan in accordance within the corrective action procedures specified in § 6.4.2 of this Part and the HACCP plan in accordance with the verification activities specified in § 6.4.2 of this Part; and.
 - c. Performing the record review required by § 6.4.2 of this Part.
 3. 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 Department.
 4. The trained individual need not be an employee of the dealer.
- J. 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 § 6.4.3 of this Part. 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, 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.
 9. While monitoring of those specified conditions and practices (listed in §§ 6.10(a) through (h) of this Part) that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.
- K. Sanitation Monitoring Records. Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by § 6.4.2 of this Part.
- L. Relationship to HACCP Plan. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with § 6.4.2 of this Part, they need not be included in the HACCP plan, and vice versa.

6.4.3 Sanitation Requirements (HACCP Key Points of Sanitation)

- A. Each dealer shall comply with the requirements specified in this section that are appropriate to the plant and the food being processed. Monitoring and record keeping for these conditions and practices is required.
- B. 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.
 - 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 Department and tested at laboratories sanctioned or certified by the Department:
 - (1) Prior to use of the water supply;
 - (2) Every six (6) months while the water supply is in use; and
 - (3) After the water supply has been repaired and disinfected.
 - c. 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.
2. Ice Production. Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:
 - a. Be made on-site from potable water in a commercial ice machine; or
 - b. Come from a facility sanctioned by the Department or the appropriate regulatory agency.
3. Shellstock Washing. Water from either a potable water supply or a growing area in the Approved classification shall be used to wash shellstock.
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;
 - b. Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage.
5. Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials and tank construction shall be such that it:
 - a. Is easily accessible for cleaning and inspection;

- b. Is self-draining; and
- c. Meets the requirements for food contact surfaces.

C. Condition and Cleanliness of Food Contact Surfaces. Equipment and utensil construction for food contact surfaces

1. The dealer shall use only equipment and utensils, including approved plastic ware and finished product containers which are:
 - a. Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products;
 - b. Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and
 - c. Fabricated from food grade materials.
2. The dealer shall assure that all joints on food contact surfaces:
 - a. Have smooth easily cleanable surfaces; and
 - b. Are welded.
3. Shucking blocks shall be provided which are:
 - a. Easily cleanable;
 - b. Fabricated from safe material;
 - c. Solid, one (1) piece construction; and
 - d. Easily removed from the shucking bench, unless the block is an integral part of the bench.
 - e. The dealer shall provide a temperature measuring device accurate to +/- two degrees Fahrenheit (2° F) for use in monitoring product temperatures.
4. All equipment used in heat shock processing shall meet the requirements of § 6.4.3 of this Part.
5. All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in § 6.4.3 of this Part.

6. Wet storage tanks and all containers used in wet storage tanks shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in § 6.4.3 of this Part.

D. Cleaning and Sanitizing of Food Contact Surfaces

1. Food contact surfaces of equipment, utensils (including ice shovels), and containers shall be cleaned and sanitized to prevent contamination of shellfish and other food contact surfaces. The dealer shall:
 - a. 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;
 - b. 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
 - c. Wash and rinse equipment and utensils at the end of each day.
 - d. Provide a test kit or other device that accurately measures the parts per million concentration of sanitizing solutions.
2. 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.
3. Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling.
4. Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded.
5. Shucked shellfish shall be packed in clean containers and stored in a manner which assures their protection from contamination.
6. 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;
 - b. Sanitized at least twice daily;
 - c. Cleaned more often, if necessary;
 - d. Properly stored until used; and

- e. Maintained in a clean, intact, and sanitary condition.

E. 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.
- b. Shucked shellfish shall be protected from contamination.
- c. Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment.
- d. Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.

2. Employee Practices

- a. Where the same employee works in both the shucking and packing activities, the employee shall wash his hands thoroughly after entering.
- b. The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility:
 - (1) Before starting work;
 - (2) After each absence from the work station;
 - (3) After each work interruption; and
 - (4) Any time when their hands may have become soiled or contaminated.
- c. Any employee handling shucked shellfish shall be required to:
 - (1) Wear effective hair restraints;
 - (2) Remove any hand jewelry that cannot be sanitized or secured;
 - (3) Wear finger cots or gloves if jewelry cannot be removed;
 - (4) Wear clean outer garments, which are rinsed or changed as necessary to be kept clean.

- (5) 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: store clothing or other personal belongings; eat or drink; spit; and use tobacco in any form.

d. Separation of Operations

- (1) Facilities for shucking and packing activities shall be separated by use of: separate rooms; partitions; or sufficient spacing.
- (2) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers.
- (3) The dealer shall provide toilet room doors which are tight fitting, self-closing, and do not open directly into a processing area.

F. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities

1. Handwashing facilities with warm water at a minimum temperature of one hundred ten degrees Fahrenheit (110° F) (forty-three degrees Centigrade (43° C)), dispensed from a hot and cold mixing or combination faucet, shall be provided.
2. Handwashing facilities shall be provided which are:
 - a. Convenient to work areas;
 - b. Separate from the three (3) compartment sinks used for cleaning equipment and utensils;
 - c. Directly plumbed to an approved sewage disposal system.
 - d. Adequate in number and size for the number of employees.
3. The dealer shall provide at least one (1) hand sink in the packing room.
4. The dealer shall provide at each handwashing facility:
 - a. A supply of hand cleansing soap or detergent;
 - b. A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;

- c. An easily cleanable waste receptacle; and
 - d. Handwashing signs in a language understood by the employees.
5. Sewage and liquid disposable wastes shall be properly removed from the facility.
 6. An adequate number of conveniently located, toilets shall be provided.
 7. The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.

G. Protection from Adulterants

1. Shellfish shall be protected from contamination while being transferred from one (1) point to another during handling and processing.
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.
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.
4. 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.
5. 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.

H. Protection of Ice Used in Shellfish Processing

1. 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.
2. Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.
3. Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed.

I. Proper Labeling of Storage of Toxic Compounds

1. The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.
2. Each of the following categories of toxic substances shall be stored separately:
 - a. Insecticides and rodenticides;
 - b. Detergents, sanitizers, and related cleaning agents; and
 - c. Caustic acids, polishes, and other chemicals.
3. The dealer shall not store toxic substances above shellfish or food contact surfaces.

J. Use and Labeling of Toxic Compounds

1. 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.
2. Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable Federal and State laws and Regulations.
3. Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

K. Control of Employees with Adverse Health Conditions

1. The dealer 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 diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with 42 U.S.C. Chapter 126 § 12101 *et seq.*, the Americans with Disabilities Act, and published in the Federal Register. These include:
 - 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:
- a. Has any of the following symptoms:
 - (1) Vomiting,
 - (2) Diarrhea,
 - (3) Jaundice,
 - (4) Sore throat with fever, or
 - (5) 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:
 - (1) Norovirus
 - (2) Hepatitis A virus,
 - (3) *Shigella spp.*,
 - (4) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
 - (5) *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:

- (1) Norovirus within the past twenty-four (24) hours of the last exposure;
 - (2) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella spp.* Within the past three (3) days of the last exposure;
 - (3) *Salmonella typhi* within the past fourteen (14) days of the last exposure;
 - (4) 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:
- (1) Norovirus within the past twenty-four (24) hours of the last exposure;
 - (2) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella spp.* Within the past three (3) days of the last exposure;
 - (3) *Salmonella typhi* within the past fourteen (14) days of the last exposure; or
 - (4) Hepatitis A virus within the past thirty (30) days of the last exposure.
3. If an employee with an infected wound keeps it covered with a proper bandage, an impermeable barrier, and a single-use glove for a hand lesion, the dealer may allow the employee to work in the shellfish processing facility without additional restrictions.
 4. The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact

with the shellfish or with food contact surfaces or that may transmit the illness to other employees.

- L. Exclusion of Pests. The dealer shall operate his facility to assure that insects, rodents, and other pests are excluded from the facility and processing activities. Dogs, cats, birds, and other animals shall also be excluded.

6.4.4 Other Requirements

- A. Each dealer shall comply with the requirements specified in § 6.4.4 of this Part 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.
 - 2. Dealers shall follow their written recall procedures to include timely notification to the Department of a situation requiring recall, timely notification of consignee who received the affected product, and effective removal or correction of the affected product.
- C. Plants and Grounds
 - 1. General
 - a. The physical facilities shall be maintained in good repair.
 - b. Animals or unauthorized persons 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.
- D. Flooding
 - 1. 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.
 - 2. If facilities are flooded:

- a. 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.
 - b. Any shellfish coming in contact with the flood waters while in storage shall be destroyed; or discarded in non-food use.
3. The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded.

E. Plant Interior

1. Sanitary conditions shall be maintained throughout the facility.
 - a. All dry area floors shall be hard, smooth, easily cleanable; and
 - b. All wet area floors used in areas to store shellstock, process food, and clean equipment and utensils shall be constructed of easily cleanable, impervious, and corrosion resistant materials which:
 - (1) Are graded to provide adequate drainage;
 - (2) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;
 - (3) Have sealed junctions between floors and walls to render them impervious to water; and
2. 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.
3. Grounds. Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include, but not be limited to:
 - a. Excessively dirty or dusty parking lots, grounds or roads;
 - (1) Rodent, insect, or bird attraction and harborage; and
 - (2) Inadequate drainage.
4. Plumbing and Related Facilities

- a. All plumbing and plumbing fixtures shall be designed, installed, modified, repaired, and maintained to provide a water system that is adequate in quantity and under pressure, and includes:
 - (1) Cold and warm water at all sinks; and
 - (2) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use;
- b. Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - (1) Used in shellstock storage;
 - (2) Used for food holding units (e.g. refrigeration units); and
 - (3) Cleaned by hosing, flooding, or similar methods.
- c. A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable Federal and State laws and Regulations;
- d. 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.

5. Utilities

- a. Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.
- b. The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices.

F. Insect and Vermin Control

- 1. The dealer shall employ necessary internal and external insect and vermin control measures to ensure that insects and vermin are not present in his facility including:
 - a. Tight fitting, self-closing doors;
 - b. Screening of not less than fifteen (15) mesh per inch; and
 - c. Controlled air current.

G. Disposal of Other Wastes

1. Disposal of waste materials shall be conducted in accordance with appropriate Federal and State laws and Regulations.
2. Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table.
3. All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin; and

H. Equipment Construction and Design for 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.
2. The dealer shall use easily cleanable, corrosion-resistant, durable, impervious materials, free from cracks to construct:
 - a. Shucking benches and contiguous walls; and
 - b. Stands or stalls and stools for shucker.
 - c. Any non-food contact surfaces in shellfish storage or handling areas.
3. Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches.
4. Dealers shall have sufficient refrigeration, capable of cooling and holding shellfish, as required by this Part.

I. Cleaning Non-food Contact Surfaces

1. Cleaning activities for equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellfish and food contact surfaces.
2. 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.

J. Shellfish Storage and Handling

1. The dealer shall:
 - a. Assure that shellstock is:
 - (1) Reasonably free of sediment; and
 - (2) Culled.
 - b. Completely empty shucking buckets at the packing room so that no overage is returned to the shucker;
 - c. Inspect incoming shipments and shall reject dead or inadequately protected shellstock;
 - d. Not allow the use of dip buckets for hand or knife rinsing;
 - e. 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;
 - f. Wash, blow, and rinse all shellfish meats in accordance with § 130 of 21 C.F.R. Part 161.
 - g. Thoroughly drain, clean as necessary, and pack shucked shellfish meats promptly after delivery to the packing room;
 - h. Conduct packing activities so as to conform to applicable food additive Regulations;
 - i. Store packaged shellfish, if they are to be frozen, at an ambient temperature of zero degrees Fahrenheit (0° F) (negative seventeen and eight tenths degrees Centigrade (-17.8° C)) or less; and frozen solid within twelve (12) hours following the initiation of freezing.
 - j. Not commingle shellstock during shucking unless the dealer is included in the Department's commingling plan.
 - k. Shellstock shall not remain outside of temperature control for two (2) or more hours during processing.
 - l. Cool oysters and/or hard clams to an internal temperature of fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) or below within ten (10) hours after placement into refrigeration during periods when the risk of Vibrio illness is reasonably likely to occur.

When deemed appropriate by the Authority an exception may be permitted for hard clams to allow for tempering.

K. Heat Shock

1. A dealer may elect to use heat shock to prepare shellstock for shucking. The dealer shall:
 - a. Post the schedule for the heat shock process in a conspicuous location; and
 - b. Make sure all responsible persons are familiar with the requirements.
 - c. Cool all hot dipped shellstock immediately after the heat shock process. This cooling shall be accomplished by:
 - (1) Dipping in an ice bath; or
 - (2) Use of flowing potable water.
2. If a heat shock water tank is used and the water temperature is maintained at or above one hundred forty degrees Fahrenheit (140° F) (sixty degrees Centigrade (60° C)), the dealer shall completely drain and flush the tank at the end of each day's operation so that all mud and debris which have accumulated in the dip tank are eliminated.
 - a. If the tank is maintained at or below one hundred forty degrees Fahrenheit (140° F) (sixty degrees Centigrade (60° C)), the tank shall be drained and flushed at three (3) hour intervals.

L. Supervision

1. Supervisors shall not allow unauthorized persons in those portions of the facilities where shellfish are stored, handled, processed, or packaged or food handling equipment, utensils, and packaging materials are cleaned or stored. A reliable, competent individual shall be designated to supervise general plant management and activities;
2. Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces.
3. All supervisors shall be:

- a. Trained in proper food handling techniques and food protection principles; and
 - b. Knowledgeable of personal hygiene and sanitary practices.
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.
 - b. Supervisors to assure that proper sanitary practices are implemented, including:
 - (1) Plant and equipment clean-up;
 - (2) Rapid product handling; and
 - (3) Shellfish protection from contamination.
 - c. Employees:
 - (1) To be trained in proper food handling and personal hygiene practices, and
 - (2) To report any symptoms of illness to their supervisor.

6.4.5 Shipping Documents, Records and Written Recall Procedure/Transportation and Receiving

- A. Trucks or Other Vehicles Used to Transport Shellfish
- 1. The dealer who transports shellstock shall assure that all trucks and other conveyances used to transport shellstock are properly constructed, operated, and maintained to prevent contamination, adulteration, cross contamination, deterioration, and decomposition.
 - a. Shellfish shall be transported in refrigerated trucks.
 - 2. Prechilling trucks or other vehicles shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.
 - 3. Refrigeration trucks or other conveyances shall be:
 - a. Equipped with automatic controls; and

- b. Capable of maintaining the ambient air temperature in the storage area at temperatures of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less.
4. Any ice used to cool shellstock during transport shall meet the requirements of § 6.4.3(B)(4).
5. Cats, dogs, and other animals shall not be allowed in any part of the vessel, buy boat, truck or other vehicle where shellstock is stored.

B. Transportation Containers

1. All containers used to transport shellstock shall be:
 - a. Constructed to allow for easy cleaning; and
 - b. Operated and maintained to prevent product contamination.

C. All containers shall be cleaned with:

1. Potable water; and
2. Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

D. 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 Department 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.

E. Shipment Acceptability

1. Shellfish shipments shall be considered acceptable when:
 - a. Shipments are properly identified with tags and shipping documents;
 - b. Shellstock is alive and in a conveyance with an ambient air temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less;
 - c. Shucked shellfish is cooled to a temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less, or packed in ice; and
 - d. The time-temperature indicating device shows that the ambient air temperature has exceeded forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) but the shellstock internal body temperature is fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) or less; and
 - e. All other conditions of shipment in this Part are met.

F. Receiving Shellfish

1. The dealer shall reject or discard any shellfish shipments which:
 - a. Do not originate from a licensed harvester or certified dealer; and/or
 - b. Shellfish are not properly identified with tags and shipping documents;
 - c. The internal shellstock body temperature exceeds fifty degrees Fahrenheit (50° F) (fifteen and six tenths Centigrade (15.6° C)) unless the harvest initiation time is documented and is in compliance with Rhode Island Department of Environmental Management Regulations, [250-RICR-40-00-1](#) entitled "Aquaculture of Marine Species in Rhode Island Waters," and ~~,"Shellfish, Rhode Island Marine Fisheries Regulations Shellfish"~~
 - d. Shucked shellfish exceeds forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)); or

- e. Are unwholesome, inadequately protected, or whose source cannot be identified.
- 2. Transportation agents or common carriers used by a dealer are not required to be certified.
- 3. The dealer shall:
 - a. Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in this Part;
 - b. Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved methods of storage, as required [wet storage, iced, at or below forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C))] for more than two (2) hours at points of processing or transfer such as loading docks;
 - c. Ensure that shucked shellfish are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less;
 - d. Ensure that frozen shellfish remain frozen.

G. Shipping Times

- 1. Shipping Time is No More Than Four (4) Hours
 - a. When the shipping time is four (4) hours or less, the dealer shall ship under temperature control.
 - b. When mechanical refrigeration units are used, the units shall be equipped with automatic controls and shall be capable of maintaining the ambient air in the storage area at temperatures of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less.
 - c. The dealer shall not be required to provide thermal recorders during shipment.
- 2. Shipping Time is Greater Than Four (4) Hours
 - a. When the shipping time is greater than four (4) hours, the dealer shall ship all shellfish in mechanically refrigerated conveyances

which are equipped with automatic controls and capable of maintaining the ambient air in the storage area at temperatures of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less; or

- b. Unless the dealer has an approved HACCP plan with an alternate means of monitoring time-temperature, the initial dealer shall assure that a suitable time-temperature recording device accompanies each shipment of shellfish.
- c. The initial dealer shall note the date and time on the temperature indicating device, if appropriate.
- d. Each receiving dealer shall write the date and time on the temperature indicating device, if appropriate, when the shipment is received and the doors of the conveyance or the containers are opened.
- e. The final receiving dealer shall keep the time-temperature recording chart or other record of time and temperature in his files and shall make it available to the Department upon request.
- f. An inoperative temperature indicating device shall be considered as no recording device.

3. Transaction and Shipping Records

- a. Each dealer shall have a business address at which transaction records are maintained.
- b. Each dealer shall maintain complete, accurate and legible records of the Department's required information in a form authorized by the Department.
- c. Transaction records shall be sufficient to:
 - (1) Document that the shellfish are from a source authorized under these requirements;
 - (2) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;
 - (3) Permit a lot (or commingled lots) of shucked shellfish or a lot of shellstock to be traced back to the growing area(s),

date(s) of harvest, harvest time (when directed by the Department) and the harvester or group of harvesters.

- (4) Trace the wet storage history of the shellfish including, original harvest site, original harvest date, original harvest time (when directed by the Department) wet storage site(s) and dates.
- d. Purchase and sales shall be recorded:
- (1) In a permanently bound ledger book; or
 - (2) Using shipping/sales documents as required in § 6.4.5(D) of this Part and to include the harvest area, harvest date and harvest time (when directed by the Department); or
 - (3) Using other recording methods acceptable to and authorized by the Department within seventy-two (72) hours of any purchase or sales.
- e. The transaction records shall be retained:
- (1) In the case of fresh shellfish, for a minimum of one (1) year; and
 - (2) In the case of frozen shellfish, for at least two (2) years or the shelf-life of the product, whichever is longer.
- f. If computer records are maintained, the Department shall approve the format and its use.

6.4.6 Post-Harvest Processing

- A. A dealer may elect to use a process to reduce *Vibrio vulnificus* levels in shellfish. The dealer shall have a HACCP plan approved by the Department for the process which includes:
1. An end point criteria for the process as non-detectable (less than three (< 3) MPN/gram) to be determined by use of the *Vibrio vulnificus* FDA approved EIA procedure of Tamplin, *et al*, as described in Chapter 9 of the "Bacteriological Analytical Manual," 8th Edition, Revision A (2004) as required by the 2019⁹⁵ Model Ordinance available online at: <http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm070830.htm>; and
 2. A sampling program to demonstrate that the end point criteria is met.

- B. Package and label all shellfish in accordance with all requirements contained in this part. This includes the labeling all shellfish which has been subjected to the process but which is not frozen in accordance with applicable shellfish tagging and labeling requirements in §§ 6.4.1(B) through (F) of this Part.
- C. Keep records in accordance with §§ 6.4.1(E) and (F) of this Part.
- D. A dealer who meets the requirements of § 6.4.6 of this Part may label product which has been subjected to the reduction process as "Processed to reduce *Vibrio vulnificus* to non-detectable levels."
- E. Processed Products with Labeling Claims for Safety. All certified dealers processing products with labeling claims for safety shall:
 - 1. Consult with and adhere to advice from the U.S. Food and Drug Administration for all special labeling claims.
 - 2. Meet all applicable requirements of R.I. Gen. Laws Chapter 21-14.3. For the purposes of refrigeration, if the end product is dead, treat the product as shucked product. If the end product is live it shall be treated as shellstock for the purposes of refrigeration; and,
 - 3. Shall ensure through controls in their HACCP Plan that claims are met.

6.4.7 Shucking and Packing

- A. Heat Shock
 - 1. The dealer shall submit for approval the scheduled process for heat shock. The schedule may be developed by the Department or qualified persons with adequate facilities for conducting the appropriate studies.
 - 2. The dealer 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:
 - a. Type and size of shellfish;
 - b. Time and temperature of exposure;
 - c. Type of process;
 - d. Size of tank, tunnel or retort;
 - e. Water to shellfish ratios in tanks; and

- f. Temperature and pressure monitoring devices;
- 3. The dealer shall assure that heat shock process does not:
 - a. Change the physical and organoleptic properties of the species;
 - b. Kill the shellfish prior to shucking; and
 - c. Increase microbial deterioration of the shucked shellfish.
- 4. The dealer shall retain records covering all aspects of the establishment of the heat shock process.

B. Critical Control Points

- 1. Receiving Critical Control Point – Critical Limits. The dealer shall shuck and pack only shellstock which is:
 - a. Obtained from a licensed harvester who has:
 - (1) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and
 - (2) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or
 - b. Obtained from a dealer other than the original harvester who has identified the shellstock with a tag on each container or transaction record with each bulk shipment.
 - (1) Shipped the shellstock in a conveyance at or below forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) ambient air temperature; or fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) internal temperature or less;
 - (2) Identified the shellstock with a tag on each container or transaction record with each bulk shipment.
 - (3) All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of § 6.4.7 of this Part.

- c. Shucked shellfish is received in a conveyance with an ambient temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less or adequately iced.
 - d. Harvested ~~the shellstock~~ in compliance with the time temperature requirements as described in [Rhode Island Department of Environmental Management Regulations, 250-RICR-40-00-1 Aquaculture of Marine Species in Rhode Island Waters, and 250-RICR-90-00-4, Shellfish](#). ~~Rhode Island Department of Environmental Management regulations “Aquaculture of Marine Species in Rhode Island Waters” and “Rhode Island Marine Fisheries Regulations Shellfish”~~
2. Shellstock Storage Critical Control Point – Critical Limits. The dealer shall ensure that:
 - a. If wet storage is practiced, water quality meets the requirements outlined in § 6.4.11 of this Part; and
 - b. Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;
 - (1) Iced; or
 - (2) Placed and stored in a storage area or conveyance maintained at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less; and
 - (3) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in §§ 6.4.9(B)(1) and (2) of this Part, for more than two (2) hours at points of transfer such as loading docks.
3. Processing Critical Control Point – Critical Limits. The dealer shall ensure that:
 - a. For shellstock which has not been refrigerated prior to shucking, shucked meats are chilled to an internal temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less within three (3) hours of shucking.
 - b. For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less within four (4) hours of removal from refrigeration.

- c. If heat shock is used, once heat shocked shellstock is shucked, the shucked shellfish meats shall be cooled to forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less within two (2) hours after the heat shock process.
 - d. 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 forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) within two (2) hours from time of heat shock.
4. Shucked Meat Storage Critical Control Point – Critical Limit. The dealer shall store shucked and packed shellfish in covered containers at an ambient air temperature in the storage area of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less or covered with ice.

6.4.8 Repacking of Shucked Shellfish

- A. Receiving Critical Control Point – Critical Limits. The dealer shall repack only shellfish which:
 1. Originated from a dealer; and
 2. Shipped the shellfish in a conveyance at or below forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) ambient air temperature or covered in ice; and
 3. Are identified with a label as outlined in §§ 6.4.1(E) and (F) of this Part.
 4. Was harvested in compliance with the time temperature requirements as described in Rhode Island [Department of Environmental Management Regulations, 250-RICR-40-00-1 Aquaculture of Marine Species in Rhode Island Waters, and 250-RICR-90-00-4, Shellfish](#).~~Department of Environmental Management regulations “Aquaculture of Marine Species in Rhode Island Waters” and “Rhode Island Marine Fisheries Regulations-Shellfish”.~~
 5. Are accompanied with documentation indicating the time of shipment, that shellfish has been shipped adequately iced or in a conveyance pre-chilled at or below forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) ambient air temperature.
- B. Processing Critical Control Point – Critical Limits. The dealer shall ensure that repacked shellfish do not exceed an internal temperature of forty-five degrees

Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) for more than two (2) hours.

- C. Shucked Meat Storage Critical Control Point – Critical Limit. The dealer shall store repacked shellfish in covered containers at an ambient air temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less or covered with ice.

6.4.9 Shellstock Shipping

A. Receiving Critical Control Point – Critical Limits

- 1. The dealer shall ship or repack 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 identified by the tag; and
 - b. Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or
 - c. Obtained from a dealer who has identified the shellstock with a tag on each container.
 - d. Harvested the shellstock in compliance with the time temperature requirements as described In [Rhode Island Department of Environmental Management Regulations, 250-RICR-40-00-1 Aquaculture of Marine Species in Rhode Island Waters, and 250-RICR-90-00-4, Shellfish, Rhode Island Department of Environmental Management regulations “Aquaculture of Marine Species in Rhode Island Waters” and “Rhode Island Marine Fisheries Regulations Shellfish”](#)
- 2. Obtained from a dealer other than the original harvester who has:-
 - a. Identified the shellstock with a tag on each container or transaction record with each bulk shipment.-
 - b. Shipped the shellstock in a conveyance at or below forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) ambient air temperature; or fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) internal temperature or less;

- c. All shipments of shellstock shall be accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of § 6.4.7 of this Part.
- 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 §§ 6.4.11(C) and (D)(1) of this Part; and
 2. Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
 - a. Iced; or
 - b. Placed in a storage area or conveyance maintained at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less; and
 - c. Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in § 6.4.9(A) of this Part for more than two (2) hours at points of transfer such as loading docks.
 3. The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less or covered with ice.
 4. A dealer may receive shellstock from a dealer who has elected to ship shellstock without the shellstock meeting the receiving requirements of § 6.4.8 of this Part if the product is accompanied with documentation indicating:
 - a. Shellstock has been cooled to an internal temperature of fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) or less; or
 - b. All shipments of shellstock have been accompanied with documentation indicating the time of shipment and that all shipping conveyances comply with the requirements of § 6.4.8 of this Part. This documentation must include a notice of all shellstock harvested under the requirements of § 6.4.9(A)(4) of this Part.
 5. A dealer may receive shellstock from a dealer who has elected to ship shellstock without the shellstock meeting the receiving requirements of §

6.4.9 of this Part if the product is accompanied with a time/temperature recording device indicating and documenting that continuing cooling has occurred. Shipments of four (4) hours or less will not be required to have a time/temperature device.

6. 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.
7. All oysters harvested under State Vibrio Control Plans other than those labeled for a restricted use shall meet the following temperature requirements:
 - a. Oysters and/or hard clams must be cooled to an internal temperature of fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) or below within ten (10) hours or less after placement into refrigeration during periods when the risk of *Vibrio* illness is reasonably likely to occur.
 - b. 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 fifty degrees Fahrenheit (50° F) (ten degrees Centigrade (10° C)) or below within ten (10) hours or less after placement into refrigeration.
 - c. When deemed appropriate by the Department 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.
8. The effectiveness of the Plan should be evaluated yearly. The Vibrio Control Plan may be modified when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Department.
9. Product intended for relay, wet storage or depuration, or either geoduck clams (*Panopea generose*), or *Mercenaria sp* which are being cooled utilizing a Department-approved tempering plan are exempt from the Vibrio Control Plan requirement.

6.4.10 Reshipping

- A. Receiving Critical Control Point – Critical Limits. The dealer shall reship only shellfish which:
 - 1. Originated from a dealer;
 - 2. Are identified with a tag as outlined in § 6.4.1 of this Part or a label as outlined in § 6.4.1 of this Part.
 - 3. Has been shipped in compliance with § 6.4.9 of this Part.

- B. Shellstock Storage Critical Control Point – Critical Limits. The dealer shall ensure that once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:
 - 1. Iced; or
 - 2. Placed in a storage area or conveyance maintained at forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less; and
 - 3. Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than two (2) hours at points of transfer such as loading docks.

- C. Shucked Meat Storage Critical Control Point – Critical Limit. The dealer shall store shucked shellfish at a temperature of forty-five degrees Fahrenheit (45° F) (seven and two tenths degrees Centigrade (7.2° C)) or less or covered with ice.

6.4.11 Wet Storage in Approved and Conditionally Approved Growing Areas

- A. Requirements for the Dealer: Source of Shellstock
 - 1. The dealer shall wet store shellstock harvested only from areas classified as Approved, or Conditionally Approved, when in the open status.
 - 2. Shellstock shall be harvested, identified and shipped to the wet storage operation in accordance with the requirements of § 6.4.5 of this Part.

- B. General Requirements
 - 1. Wet storage may be used to store, condition, remove sand or to add salt to shellstock. Wet storage shall be deemed a processing activity, however licensees are not subject to any additional license fees and therefore not required to obtain a separate Department food processor license.

2. 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 of this Part.
3. 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 Department.
4. While awaiting placement in a wet storage operation, shellstock shall be protected from physical, chemical or thermal conditions which may compromise the shellstock's survival, quality or activity during wet storage.
5. Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.
6. For the purpose of certification, each wet storage site or operation shall be evaluated annually. The evaluation shall include an inspection of the near shore storage site and floats, or the wet storage operation.
7. Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of §§ 6.4.2 and 6.4.5 of this Part. Any dealer who wet stores shellstock from another State and ships the shellstock as a product of the State where the shellstock was wet stored shall be required to:
 - a. Have an operational plan approved by the Department which describes how this labeling change will be employed in assuring that shellstock can be traced to its source; and
 - b. Meet the requirements of § 6.4.5 of this Part.
8. 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 at least one (1) year.
 - a. 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.

C. Wet Storage Sites in Natural Bodies of Water

1. Natural bodies of waters used for wet storage in containers and floats 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:
 - a. Subjected to relaying or depuration prior to human consumption; or
 - b. Held in the wet storage site until the area is returned to the open status.
2. Site evaluations of natural bodies of water shall include:
 - a. The sanitary survey of the storage site, with special consideration of potential intermittent sources of pollution;
 - b. The location of near shore storage sites and floats; and
 - c. The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock; and
 - d. A review of the operation's plan and operating procedures for an offshore activity as submitted by the dealer.

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

1. General
 - a. If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall also meet the requirements of §§ 6.4.11(A) through (C) of this Part
 - b. For the purpose of permitting, each wet storage site or operation shall be evaluated at intervals not to exceed six (6) months. The evaluation shall include the operation's plan and operating procedures for an onshore activity as submitted by the dealer.
 - c. Prior to commencing construction, all plans for construction or remodeling of onshore wet storage facilities or operations shall be reviewed and authorized by the Department.
 - d. The wet storage facility or operation evaluation shall include a review of:

- (1) The purpose of the wet storage activity, such as holding, conditioning or increasing the salt content of shellstock;
- (2) Any species specific physiological factors that may affect design criteria; and
- (3) 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 system.

2. Operation Specifications

- a. Each land-based wet storage activity shall meet the following design, construction, and operating requirements.
- b. Effective barriers shall be provided to prevent entry of birds, animals, and vermin into the area.
- c. Storage tanks and related plumbing shall be fabricated of safe material and shall be easily cleanable. This requirement shall include:
 - (1) Tanks constructed so as to be easily accessible for cleaning and inspection, self-draining and fabricated from non-toxic, corrosion resistant materials; and
 - (2) Plumbing designed and installed so that it can be cleaned and sanitized on a regular schedule, as specified in the operating procedures.
- d. Storage tank design, dimensions, and construction are such that adequate clearance between shellstock and the tank bottom shall be maintained.
- e. 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.
- f. When a building is used for the wet storage activity:
 - (1) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of § 6.4.4 of this Part; and

(2) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of § 6.4.4 of this Part.

g. When the wet storage activity is outdoors or in a structure other than a building, tank covers shall be used. Tank covers shall:

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

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

3. Wet Storage Source Water

a. General

(1) 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 and water classified as Prohibited or Conditionally Restricted when in the Closed Status shall not be used as source water.

(2) Any well used as source water for wet storage shall meet the requirements (with the exception of the salt content in saltwater wells).

(3) 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.

(4) 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.

(5) 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's survival, quality or activity during wet storage.

(6) 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 one hundred (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. 056. of the 20195 NSSP Model Ordinance).

- (7) 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.
- (8) 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.
- (9) 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 (Jenkins, David, Joseph J. Connors, and Arnold E. Greenberg. Standard Methods for the Examination of Water and Wastewater. Washington, D.C: American Public Health Association, 1981) (not to include later amendments thereof)).
- (10) The disinfection unit(s) for the process water supply shall be cleaned and serviced as frequently as necessary to assure effective water treatment.

4. Continuous Flow-through System

- a. If the system is of continuous flow-through design, water from a growing area classified as:
 - (1) 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
 - (2) 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 other than Approved is used, a study shall be required to demonstrate that the disinfection system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:
 - (1) 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;
 - (2) Include one (1) sample daily for five (5) consecutive days from the source water prior to disinfection;
 - (3) Use NSSP recognized methods to analyze the samples to determine coliform levels;
 - (4) Require all samples of disinfected water to be negative for the coliform group; and
 - (5) Be repeated if any sample of disinfected 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 Department may require periodic verification of the system's integrity to ensure that the other than approved water does not infiltrate into the intake pipe.

5. Recirculating Water System

- a. A study shall be required to demonstrate that the disinfection system for the recirculating system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall meet the requirements in § 6.4.11(D)(4)(b) of this Part.
- b. Once sanctioned for use, the recirculating 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 percent (10%) of the 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 within a twenty-four (24) hour period to reaffirm the ability of the system to produce 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.
 - e. Failure to meet the weekly water sampling requirements of § 6.4.11(D)(5)(b) of this Part may result in termination of the system, pending approval of the Department.
6. Shellstock Handling
- a. Shellstock shall be thoroughly washed with water from an approved source and culled prior to wet storage in tanks. Due to the adverse effects of culling on mussel physiology, culling of mussels may be done after wet storage, subject to permission from the Department.
 - b. Unless the dealer is in the Department's commingling plan, 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.
 - c. 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 water shall be effectively disinfected prior to entering tanks containing the bivalve mollusks.

6.5 Enforcement, Variances, and Practices/Procedures

A. Enforcement, Inspections, Penalties

- 1. Documenting Information and Observations. The Department shall document, on an inspection report form, specific factual observations of conditions that violate R.I. Gen. Laws Chapter 21-14 and the requirements of this Part that require correction by the permit holder.

2. Specifying Time Frame for Corrections. The Department shall specify on the inspection report form the time frame for correction of the violations.
3. Issuing Report and Obtaining Acknowledgment of Receipt. At the conclusion of the inspection and according to law, the Department shall provide a copy of the completed inspection report and the notice to correct violations to the person in charge, and request a signed acknowledgment of receipt.

B. Refusal to Sign Acknowledgment

1. The Department shall:
 - a. Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in § 6.5(A)(3) of this Part that:
 - (1) An acknowledgment of receipt is not an agreement with findings,
 - (2) Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the violations noted in the inspection report within the time frames specified, and
 - (3) A refusal to sign an acknowledgment of receipt is noted in the inspection report and conveyed to the Department's historical record for the dealer; and
 - b. Make a final request that the person in charge signs an acknowledgment of receipt of inspectional findings.
2. Ceasing Operations and Reporting: Imminent Health Hazard
 - a. Except as specified in § 6.5(B)(2)(b) of this Part, a permit holder shall immediately discontinue operations and notify the Department if an imminent health hazard may exist because of an emergency such as a fire, flood, extended interruption of electrical or water service, sewage backup, misuse of poisonous or toxic materials, onset of an apparent foodborne illness outbreak, gross unsanitary occurrence or condition, or other circumstance that may endanger public health;
 - b. A permit holder need not discontinue operations in an area of an establishment that is unaffected by the imminent health hazard.

C. Resumption of Operations

1. If operations are discontinued as specified under § 6.5(B)(2) of this Part or otherwise according to law, the permit holder shall obtain approval from the Department before resuming operations.
2. Timely Correction
 - a. Except as specified in § 6.5(C)(2)(b) of this Part, a permit holder shall at the time of inspection correct a critical violation of R.I. Gen. Laws Chapter 21-14 and this Part and implement corrective actions for a HACCP plan provision that is not in compliance with its critical limit.
 - b. Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the Department may agree to or specify a longer time frame, not to exceed ten (10) calendar days after the inspection, for the permit holder to correct critical violations of R.I. Gen. Laws Chapter 21-14 or this Part or HACCP plan deviations.

D. Verification and Documentation of Correction

1. After observing at the time of inspection a correction of a critical violation or deviation, the Department shall enter the violation and information about the corrective action on the inspection report.
2. As specified under § 6.5(D) of this Part, after receiving notification that the permit holder has corrected a critical violation or HACCP plan deviation, or at the end of the specified period of time, the Department may verify correction of the violation, document the information on an inspection report, and enter the report in the Department's records.

E. Time Frame for Correction

1. Except as specified in § 6.5(E)(2) of this Part, the permit holder shall correct noncritical violations by a date and time agreed to or specified by the Department but no later than ninety (90) calendar days after the inspection.
2. The Department may approve a compliance schedule that extends beyond the time limits specified under § 6.5(E)(1) of this Part if a written schedule of compliance is submitted by the permit holder and no health hazard exists or will result from allowing an extended schedule for compliance.

F. Grounds for Discipline without Hearing

~~1.~~ The Director may, temporarily, suspend the license of a shellfish business without a hearing if the Director finds that evidence in his or her possession substantiates that continuation in practice would constitute an immediate danger to the health, safety, and welfare of the public. In the event that the Director temporarily suspends the license of a shellfish business without a hearing, a hearing by the Department must be held within ten (10) days after the suspension has occurred.

G. Variances Procedure

1. The Department may grant a variance upon request of the applicant from the provisions of this Part, if it finds in specific cases, that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such a variance will not be contrary to the public interest.
 - a. A request for a variance shall be filed by an applicant in writing, setting forth in detail the basis upon which the request is made, citing the relevant regulation and the alternative(s).

H. Commingling

1. Shellfish from different harvest areas or different harvest days can only be comingled by a primary dealer under the following conditions:
 - a. Only partial containers that are left over at the end of the day's production;
 - b. Shellfish from no more than two (2) different harvest areas; or
 - c. No more than two (2) different harvest days;
 - d. The tag must identify the two (2) harvest areas or the two (2) dates of harvest.
2. Aquacultured shellstock cannot be comingled under any circumstances.

I. Rules Governing Practices and Procedures

~~1.~~ All hearings and reviews required under the provisions of R.I. Gen. Laws Chapter 21-14 shall be held in accordance with the provisions of ~~216-RICR-10-05-Part 4 of this Subchapter~~ entitled "~~Rules and Regulations Pertaining to Practices and Procedures Before the Rhode Island Department of Health.~~"