Rhode Island Department of Health

PUBLIC NOTICE

The Director of the Rhode Island Department of Health has determined to amend the rules and regulations listed below to remove the specific dollar value of all fees for licensing, laboratory and administrative services provided by the Department of Health from the individual regulations and reference all such fees to a new consolidated fee regulation (to be promulgated separately). These amendments are proposed pursuant to the authority contained in Public Law 2012-241, enacted by the General Assembly on 15 June 2012, and the relevant sections of the respective professional practice and licensure acts.

The following seventy-five (75) regulations are proposed to be amended:

1. Food Code
2. Rules and Regulations Establishing Educational and Experience Requirements for Registration as a Sanitarian
3. Rules and Regulations for Asbestos Control
4. Rules and Regulations for Bottled Water
5. Rules and Regulations for Certifying Analytical Laboratories
6. Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services
7. Rules and Regulations for Lead Poisoning Prevention
8. Rules and Regulations for Licensing Assisted Living Residences
9. Rules and Regulations for Licensing Athletic Trainers
10. Rules and Regulations for Licensing Birth Centers
11. Rules and Regulations for Licensing Chemical Dependency Professionals
12. Rules and Regulations for Licensing Clinical Laboratories and Stations
13. Rules and Regulations for Licensing Clinical Social Workers and Independent Clinical Social Workers
14. Rules and Regulations for Licensing Doctors of Acupuncture and Acupuncture Assistants
15. Rules and Regulations for Licensing Home Nursing Care Providers and Home Care Providers
16. Rules and Regulations for Licensing Hospice Care
17. Rules and Regulations for Licensing Interpreters for the Deaf
18. Rules and Regulations for Licensing Kidney Disease Treatment Centers
19. Rules and Regulations for Licensing Massage Therapists
20. Rules and Regulations for Licensing Mental Health Counselors and Marriage and Family Therapists
21. Rules and Regulations for Licensing Occupational Therapists and Occupational Therapy Assistants
22. Rules and Regulations for Licensing of Hospitals
23. Rules and Regulations for Licensing of Midwives
24. Rules and Regulations for Licensing of Nursing Facilities
25. Rules and Regulations for Licensing of Nursing Home Administrators
26. Rules and Regulations for Licensing Physical Therapists and Physical Therapist Assistants
27. Rules and Regulations for Licensing Psychologists
28. Rules and Regulations for Licensing Rehabilitation Hospital Centers

29. Rules and Regulations for Licensing Respiratory Care Practitioners
30. Rules and Regulations for Licensing Speech Pathologists and Audiologists
31. Rules and Regulations for Licensing Swimming and Wading Pools, Hot Tubs, and Spas
32. Rules and Regulations for Licensure and Discipline of Chiropractic Physicians
33. Rules and Regulations for Limited Medical Registration
34. Rules and Regulations for Radon Control
35. Rules and Regulations for the Certification of Administrators of Assisted Living Residences
36. Rules and Regulations for the Certification of Health Plans
37. Rules and Regulations for the Control of Radiation
38. Rules and Regulations for the Licensing of Freestanding Ambulatory Surgical Centers
39. Rules and Regulations for the Licensing of Freestanding Emergency Care Facilities
40. Rules and Regulations for the Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs
41. Rules and Regulations for the Licensing of Nursing Service Agencies
42. Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities
43. Rules and Regulations for the Licensing of Podiatrists
44. Rules and Regulations for the Licensing of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants
45. Rules and Regulations for the Licensure and Discipline of Physicians
46. Rules and Regulations for the Licensure of Barbers, Hairdressers/Cosmeticians, Manicurists, Estheticians, and Instructors
47. Rules and Regulations for the Licensure of Clinical Laboratory Science Practitioners
48. Rules and Regulations for the Licensure of Physician Ambulatory Surgery Centers and Podiatry Ambulatory Surgery Centers
49. Rules and Regulations for the Licensure of Physician Assistants
50. Rules and Regulations for the Licensure of Veterinarians
51. Rules and Regulations for the Registration of Body Piercing Technicians and Body Piercing Establishments
52. Rules and Regulations for the Registration of Distributors of Controlled Substances in Rhode Island
53. Rules and Regulations for the Registration of Tanning Facilities
54. Rules and Regulations for the Registration of Tattoo Artists and Tattoo Parlors
55. Rules and Regulations for the Utilization Review of Health Care Services
56. Rules and Regulations Governing Vital Statistics
57. Rules and Regulations Pertaining to Certification of Managers in Food Safety
58. Rules and Regulations Pertaining to Dentists, Dental Hygienists, and Dental Assistants
59. Rules and Regulations Pertaining to Embalmers, Funeral Directors, and Funeral Service Establishments
60. Rules and Regulations Pertaining to Opticians
61. Rules and Regulations Pertaining to Optometrists
62. Rules and Regulations Pertaining to Permits for Screening Programs
63. Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors
64. Rules and Regulations Pertaining to Public Drinking Water
65. Rules and Regulations Pertaining to Rhode Island Certificates of Registration for Nursing Assistants, Medication Aides, and the Approval of Nursing Assistant and Medication Aide Training Programs
66. Rules and Regulations Pertaining to the Certification of Public Drinking Water Supply Treatment and Public Water Supply Transmission and Distribution Operators

67. Rules and Regulations Pertaining to the Licensing of Dietitians/Nutritionists
68. Rules and Regulations Pertaining to the Medical Examiner System
69. Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program
70. Rules and Regulations Pertaining to the Processing and Distribution of Shellfish
71. Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products
72. Rules and Regulations Related to the Licensure of Hearing Aid Dealers and Fitters
73. Rules and Regulations Related to the Medical Marijuana Program
74. Rules and Regulations Related to the Practice of Electrolysis
75. Rules and Regulations Relating to Emergency Medical Services

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Notice is hereby given in accordance with the provisions of §42-35-3(a)(2) of the Rhode Island General Laws, as amended, that the Director is affording all interested persons the opportunity to submit data, views, or arguments in writing on this matter. Opportunity for public hearing shall be granted if requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members. *Otherwise, no hearing shall be convened*. Should a hearing be requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members, *a hearing shall be scheduled only for the regulation(s) for which the request for hearing was received*. All regulations for which a public hearing is not requested will be filed with the Rhode Island Secretary of State pursuant to Chapter 42-35 of the Rhode Island General Laws, as amended, shortly after the 10 September 2012 deadline (as below).

Such input or requests for public hearing must be received in writing **no later than Monday, 10 September 2012**. Such input or requests should be addressed to: Michael Fine, M.D., Director, Rhode Island Department of Health, Three Capitol Hill, Room #401, Providence, Rhode Island 02908-5097.

In the development of these amendments, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach, duplication, or overlap was identified based upon available information.

Copies of all regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, Three Capitol Hill, Providence, Rhode Island 02908-5097, on the Secretary of State's website: http://www.sos.ri.gov/rules/, by calling 401-222-7767, or by e-mail to Bill.Dundulis@health.ri.gov.

Signed this 3rd day of August 2012

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

RULES AND REGULATIONS PERTAINING TO THE PROCESSING AND DISTRIBUTION OF SHELLFISH

[R21-14-SB]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

September 2002

AS AMENDED:

January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

September 2007

January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

August 2012 (Proposed)

COMPILER'S NOTES:
Proposed Additions: Underlined
Proposed Deletions: ~~Strikeouts~~

INTRODUCTION

These amended *Rules and Regulations Pertaining to the Processing and Distribution of Shellfish [R21-14-SB]* are promulgated under the authority of Chapters 23-1 and 21-14 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimum standards and requirements related to the processing and distribution of shellfish to assure the safety of shellfish brought into this state for sale, and to protect the health, safety, and welfare of the public.

Pursuant to the provisions of section 42-35-3(c) of the General Laws of Rhode Island, as amended, consideration was given to: (1) alternative approaches to the regulations; and (2) duplication or overlap with other state regulations. Based on the available information, no known alternative approach, overlap or duplication was identified.

These amended regulations shall supersede all previous *Rules and Regulations Pertaining to the Processing and Distribution of Shellfish* promulgated by the Department of Health and filed with the Secretary of State.

TABLE OF CONTENTS

		Page
PART I:	***Definitions and Licensure Requirements***	1
1.0	Definitions	1
2.0	License for a Shellfish Business	3
3.0	Sale of Non-complying Shellfish Prohibited	4
4.0	Inspection of Business Premises	4
5.0	Certification Program	5
PART II:	***General Requirements***	6
6.0	General Requirements	6
7.0	General HACCP Requirements	11
8.0	Sanitation Requirements (HACCP Key Points of Sanitation)	18
9.0	Other Requirements	23
10.0	Shipping Documents and Records / Transportation and Receiving	30
11.0	Post-Harvest Processing	35
12.0	Shucking and Packing	35
13.0	Repacking of Shucked Shellfish	37
14.0	Shellstock Shipping	38
15.0	Reshipping	39
16.0	Wet Storage in Approved and Conditionally Approved Growing Areas	39
PART III:	***Enforcement, Inspection, and Penalties***	46
17.0	Enforcement, Inspection, and Penalties	46
18.0	Variance Procedure	48
19.0	Practices and Procedures	48
20.0	Severability	48
References		49
Appendix "A":	Map of Harvest Areas	50
Appendix "B":	State Comingling Plan	51

PART I: ***DEFINITIONS AND LICENSURE REQUIREMENTS***

Section 1.0 ***Definitions***

Wherever used in these rules and regulations, the following terms shall be construed as follows:

1.1 "***Act"*** means Chapter 21-14 of the Rhode Island General Laws, as amended.

1.2 "***Approved***" shall be construed to mean approved by the Director.

1.3 ***"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.

1.4 ***"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.

1.5 ***"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.

1.6 "***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 section 1.19 herein.

1.7 "***Department"*** shall be construed to mean the state Department of Health.

1.8 "***Director"*** shall be construed to mean the Director of the state Department of Health or the Director's duly appointed agents.

1.9 ***"Food safety hazard"*** means any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

1.10 "***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.

1.11 ***"Person***" shall be construed to mean any individual, firm, co-partnership, association, or private or municipal corporation.

1.12 "***Preventive measure"*** means physical, chemical, or other factors that can be used to control an identified food safety hazard.

1.13 ***"Primary dealer***" means a dealer who purchases shellfish directly from the harvester.

1.14 "***Processing***" shall be construed to mean and include cleansing, mixing, opening, or packing shellfish which are to be offered for sale or sold.

1.15 ***"Repacker***" means (a) any person who repacks shucked shellfish shall be licensed as a shucker-packer or repacker; (b) any person who repacks shellstock shall be licensed as a shellstock shipper, shucker-packer, or repacker; and (c) a repacker shall not shuck shellfish.

1.16 "***Reshipper***" means 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.

1.17 "***Secondary dealer",*** as used herein, means a dealer who does not buy from harvesters.

1.18 "***Shellfish***" shall be construed to mean and include oysters, mussels, and all varieties of clams and scallops except where the final product will be the adductor muscle only.

1.19 "***Shellfish business***" shall be construed to mean and include one of the following: processing, labeling, storing except in commercial warehouses, or transporting except by common carrier, shellfish which are to be offered for sale or sold.

1.20 ***"Shellstock"*** means raw, in-shell molluscan shellfish.

1.21 ***"Shellstock shipper***" means any person who ships and receives shellstock in interstate commerce shall be licensed as a shellstock shipper, repacker, or shucker-packer.

1.22 ***"Shucked shellfish"*** means molluscan shellfish that have one or both shells removed.

1.23 "***Shucker-packer"*** means any person who shucks shellfish shall be licensed as a shucker-packer.

1.24 ***"Tag"*** means a record of harvesting information attached to a container of shellstock by the harvester or processor.

Section 2.0 ***License for a Shellfish Business***

2.1 The provisions of the Act and the rules and regulations herein 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.

2.2 No person shall conduct within this state any shellfish business until that person shall have obtained a license from the Department.

2.3 As a condition of initial and continued licensure, shellfish businesses licensed in this state shall meet the requirements of 21 *Code of Federal Regulations,* Part 123 of reference 2 herein, where applicable.

2.4 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 the rules and regulations herein, shall issue a license upon receipt of a fee ~~of three hundred twenty dollars ($320.00)~~ as set forth in 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 ~~of three hundred ninety dollars ($390.00)~~ as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* for a shucker packer/repacker.

2.5 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 CFR 123 as it appears in the *Federal Register* of December 18, 1995, except for the requirement for harvester identification on a dealer's tag.

2.6 Any license so issued shall apply only to those phases of the shellfish business as approved by the Department and as defined herein.

2.7 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 ~~three hundred twenty dollars ($320.00)~~ as set forth in 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 ~~three hundred ninety dollars ($390.00)~~ as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* for a shucker packer/repacker.

2.8 Licenses issued hereunder may be suspended or revoked for violation of the provisions of the Act and the rules and regulations herein.

2.9 The Director may, after a hearing, refuse to issue any such license to any person who has been convicted of any violation of the Act or the rules and regulations herein.

2.10 Each dealer shall have a business facility address or aquaculture lease at which inspections of facilities, activities, equipment, or records can be conducted.

Facility and Operating Plans

2.11 A licensee shall submit to the Department properly prepared plans and specifications for review and approval 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.

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

Section 3.0 ***Sale of Non-complying Shellfish Prohibited***

3.1 No person shall sell or possess with intent to sell within this state for human consumption any shellfish which have not been processed, labeled, transported, or sold in compliance with the provisions of the Act and the regulations adopted herein.

3.2 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 the regulations adopted herein 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 the Act and the rules and regulations herein.

Section 4.0 ***Inspection of Business Premises***

4.1 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 the Act and these rules and regulations herein 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 state Department of Health.

4.1.1 In accordance with § 21-14-14 of the Rhode Island General Laws, as amended, 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 the Act, 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.

Section 5.0 ***Certification Program***

5.1 Any shellfish business voluntarily requesting to receive federal Food and Drug Administration (FDA) certification from the Department shall also meet all of the requirements of the National Shellfish Sanitation Program of reference 1 herein.

5.2 No dealer shall ship shellfish out of this state prior to obtaining certification from the Department.

PART II: ***GENERAL REQUIREMENTS***

Section 6.0 ***General Requirements***

Licensure Requirements

6.1 ***Types of Licensure Activities***

(a) ***Shucker-packer (SP):*** Any person who shucks shellfish shall be licensed as a shucker-packer.

(b) ***Repacker (RP)***

(i) Any person who repacks shucked shellfish shall be licensed as a shucker-packer or repacker;

(ii) Any person who repacks shellstock shall be licensed as a shellstock shipper, shucker-packer, or repacker;

(iii) 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 section 2.10 herein.

Shellstock Identification

6.2 ***General***

(a) The dealer shall keep the harvester's tag affixed to each container of shellstock until the container is:

(i) Shipped; or

(ii) 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.

6.3 ***Tags***

(a) The dealers' tags shall:

(i) Be durable, waterproof and sanctioned by the Department prior to use; and

(ii) Be at least 2 5/8 inches by 5 1/4 inches (6.7 x 13.3 cm) in size.

(b) The dealer's tag shall contain the following indelible, legible information in the order specified below:

(i) The dealer’s name and address;

(ii) The dealer’s license number as assigned by the Department and the original shellstock shipper’s license number, if applicable;

(iii) The date of harvest;

(iv) The harvest location, as designated in Appendix "A", 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

(v) When the shellstock 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)";

(vi) The type and quantity of shellstock; and

(vii) The following statement in bold capitalized type on each tag:

"THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS."

(viii) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, from section 3-602.11 of the 1999 federal Food Code, or an equivalent statement, shall be included on all shellstock:

"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."

(d) If the shellstock is removed from the original container, the tag on the new container shall meet the requirements in sections 6.2--6.5 herein.

6.4 ***Tagging Shellstock During Intermediate Processing***

(a) When the shellstock is removed from the original container, the dealer shall:

(i) Keep the harvester tag for 90 days;

(ii) Keep track of the growing area and date of harvest for shellstock; and

(iii) Maintain identity of all shellstock during any intermediate stage of processing.

(b) 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.

(c) In order for a dealer to tag a lot container (e.g. a pallet) of shellstock in lieu of meeting the requirement in sections 6.2--6.5 herein 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.

(d) Unless the dealer is included in the Department's commingling plan, the dealer's intermediate processing plan for tagging a lot of shellstock during the intermediate stage of processing shall ensure that each lot of shellstock is separated and identified in a way which prevents commingling or misidentification. The identification shall be provided by:

(i) A harvester's or dealer's tag which meets the requirements of sections 6.2 --6.5 herein.; or

(ii) 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) Growing area;
(4) Original dealer license number; and
(5) Number of individual containers in each lot of shellstock container (e.g. a pallet) after washing, packing or staging has been completed.

(e) 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.

6.5 ***Transaction Record.*** If shellstock are sold in bulk, the dealer shall provide a transaction record prior to shipment. This transaction record shall contain all the information required in section 6.6 herein with the addition of the name of the consignee.

Shucked Shellfish Labeling

6.6 ***Shellfish Labeling***

(a) 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:

(i) The original shuckers-packer's name and license number;
(ii) The shucking date; and
(iii) The quantity of shellfish per container and the total number of containers.

(b) 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.

(c) At a minimum the dealer shall label each individual package containing fresh or frozen shucked shellfish meat in a legible and indelible form in accordance with CFR 21, Part 101; Part 161, Subpart B (161.30, and 161.136) and the Federal Fair Packaging and Labeling Act.

(d) The dealer shall assure that each package containing less than 64 fluid ounces of fresh or frozen shellfish shall have:

(i) The shucker-packer's or repacker's license number on the label; and

(ii) 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.

(e) The dealer shall assure that each package containing more than 64 fluid ounces of fresh or frozen shellfish shall have:

(i) The shucker-packer's or repacker's license number on the label; and

(ii) 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 disposable containers.

(f) If the dealer thaws and repacks frozen shellfish, the dealer shall label the shellfish container as previously frozen.

(g) The dealer shall provide all label information in a legible and indelible form.

6.7 ***Shucked Shellfish.*** If the dealer (SP, RP) elects to repack shellfish, the dealer shall pack and label all shellfish in accordance with sections 6.6; 6.7; and 6.8 herein except that the original date of shucking shall be used in establishing the **SELL BY DATE.**

Buy Boats

6.8 Boats used to purchase shellfish must be operated in compliance with all applicable requirements of the Act and the rules and regulations herein, including but not limited to:

a) Overboard discharge of sewage is prohibited. Buy boats that are in use for more than four (4) hours continuously shall have an approved marine sanitation device and hand washing equipment with a warm water supply.

b) Boats shall provide overhead protection 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 45° Fahrenheit (7.2° Centigrade) 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.

Section 7.0 ***General HACCP Requirements***

Secondary dealers and re-shippers shall be exempt from the HACCP requirements contained in this section unless such dealers/re-shippers choose to be certified in accordance with the requirements of section 5.0 herein.

7.1 ***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 sections 12.0, 13.0, 14.0 and 15.0 herein.

7.2 ***HACCP Plan***. Every dealer shall have and implement a written HACCP plan. A HACCP plan shall be specific to:

(a) Each location where shellfish products are processed by that dealer; and

(b) Each kind of shellfish product processed by the dealer. The plan may group kinds of shellfish products together, or group kinds of production methods together, if the food safety hazard, critical control points, critical limits, and procedures required to be identified and performed in section 7.3 herein are identical for all shellfish products so grouped or for all production methods so grouped.

7.3 ***Contents of the HACCP Plan***. The HACCP plan shall, at a minimum:

(a) List the food safety hazards that are reasonably likely to occur, as identified in accordance with section 7.1 herein 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:

(i) Natural toxins;

(ii) Microbiological contamination;

(iii) Chemical contamination;

(iv) Pesticides;

(v) Drug residues;

(vi) Unapproved use of direct or indirect food or color additives; and

(vii) Physical hazards;

(b) List the critical control points for each of the identified food safety hazards, including as appropriate:

(i) 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 section 12.5 (SP); section 13.1 (RP); section 14.1 (SS); and section 15.1 herein, 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.

(ii) 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 sections 12.6--12.8, 13.2--13.3, 14.2--14.3, and 15.2--15.3 herein, as applicable.

(c) 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 sections 12.5--12.8, 13.1--13.3, 14.1--14.3, and 15.1--15.3 herein, 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 sections 12.5--12.8, 13.1--13.3, 14.1--14.3, and 15.1--15.3 herein, shall be met as components of good manufacturing practices.

(d) 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.

(e) Include any corrective action plans that have been developed in accordance with section 7.6 (b) to be followed in response to deviations from critical limits at critical control points.

(f) 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.

(g) List the verification procedures, and frequency thereof, that the dealer will use in accordance with section 7.7 (a).

7.4 ***Signing and Dating the HACCP Plan***

(a) 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.

(b) The HACCP plan shall be signed and dated:

(i) Upon initial acceptance;

(ii) Upon any modification; and

(iii)Upon verification of the plan in accordance with section 7.7(a)(i).

7.5 ***Sanitation.*** Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with sections 7.10, 7.11, 7.12 herein, they need not be included in the HACCP plan, and vice versa.

7.6 ***Corrective Actions***

(a) Whenever a deviation from a critical limit occurs, a dealer shall take corrective action either by:

(i) Following a corrective action plan that is appropriate for the particular deviation, or

(b) Following the procedures in section 7.6 (c).

(b) Dealers may develop written corrective action plans, which become part of their HACCP plans in accordance with section 7.3 (e)**,** 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:

(i) No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation; and

(ii) The cause of the deviation is corrected.

(c) 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:

(i) Segregate and hold the affected product, at least until the requirements of sections 7.6 (c)(ii)(iii) are met;

(ii) 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 section 7.9;

(iii) 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;

(iv) Take corrective action, when necessary, to correct the cause of the deviation;

(v) Perform or obtain timely reassessment by an individual or individuals who have been trained in accordance with section 7.9 herein**,** 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.

(d) All corrective actions taken in accordance with this section shall be fully documented in records that are subject to verification in accordance with section 7.7 herein and the record keeping requirements of section 7.8 herein.

7.7 ***Verification***

(a) 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:

(i) A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. These changes may include: Raw materials or source of raw materials, product formulation, processing methods or systems, finished product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with section 7.9 herein. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements of section 7.3 herein.

(ii) 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.

(iii) A review, including signing and dating, by an individual who has been trained in accordance with section 7.9 herein, 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 section 7.6 herein. 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.

(b) Dealers shall immediately follow the procedures in 7.6 herein whenever any verification procedure, including the review of a consumer complaint, reveals the need to take a corrective action.

(c) The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing, in accordance with sections 7.7(a)(ii)(1)(2) herein shall be documented in records that are subject to the record keeping requirements of section 7.8 herein.

7.8 ***Records***

(a) All records required by section 7.0 herein shall include:

(i) The name and location of the dealer;

(ii) The date and time of the activity that the record reflects;

(iii) The signature or initials of the person performing the operation; and

(iv) 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.

(b) All records required by section 7.0 herein 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.

(c) 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.

(d) 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.

(e) All records required by section 7.0 and HACCP plans required by sections 7.2 and 7.3 herein shall be available for official review and copying at reasonable times.

(f) Tags on containers of shellstock are not subject to the requirements of this section unless they are used to fulfill the requirements of sections 6.2 --6.5 herein.

(g) 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.

7.9 ***Training***

(a) 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:

(i) 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 section 7.3 herein.

(ii) Reassessing and modifying the HACCP plan in accordance within the corrective action procedures specified in sections 7.6 (c) (v) herein and the HACCP plan in accordance with the verification activities specified in sections 7.7(a)(i) herein**;** and.

(iii) Performing the record review required by section 7.7(a)(iii).

(b) 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.

(c) The trained individual need not be an employee of the dealer.

General Sanitation Requirements

7.10 ***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 section 8.0 herein. The requirements specified in these sections relate to the following sanitation items:

(a) 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;

(b) 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;

(c) 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;

(d) Maintenance of hand washing, hand sanitizing, and toilet facilities, hereinafter referred to as: Maintenance of hand washing, hand sanitizing and toilet facilities;

(e) 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;

(f) Proper labeling, storage, and use of toxic compounds, hereinafter referred to as: Proper labeling, storage, use of toxic compounds;

(g) 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

(h) Exclusion of pests from the food plant, hereinafter referred to as: Exclusion of pests.

While monitoring of those specified conditions and practices (listed in subsections a--h above) that are not appropriate to the plant and the food being processed is not required, compliance with such conditions and practices remains mandatory.

7.11 ***Sanitation Monitoring Records.*** Each dealer shall maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by section 7.10 herein. These records are subject to the requirements of section 7.8 herein.

7.12 ***Relationship to HACCP Plan***. Sanitation controls may be included in the HACCP plan, required by section 7.2 herein. However, to the extent that they are monitored in accordance with section 7.10 herein**,** they need not be included in the HACCP plan, and vice versa.

Section 8.0 ***Sanitation Requirements (HACCP Key Points of Sanitation)***

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.

Safety of Water for Processing and Ice Production

8.1 ***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:

(i) Prior to use of the water supply;

(ii) Every six months while the water supply is in use; and

(iii) 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.

Ice Production

(d) Any ice used in the processing, storage, or transport of shellstock or shucked shellfish shall:

(i) Be made on-site from potable water in a commercial ice machine; or

(ii) Come from a facility sanctioned by the Department or the appropriate regulatory agency.

Shellstock Washing

(e) Water from either a potable water supply or a growing area in the approved classification shall be used to wash shellstock.

Plumbing and Related Facilities

(f) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:

(i) Prevent contamination of water supplies;

(ii) 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.

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

(i) Is easily accessible for cleaning and inspection;

(ii) Is self-draining; and

(iii) Meets the requirements for food contact surfaces.

8.2 ***Condition and Cleanliness of Food Contact Surfaces***

Equipment and utensil construction for food contact surfaces.

(a) The dealer shall use only equipment and utensils, including approved plasticware and finished product containers which are:

(i) Constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellfish products**;**

(ii) Free from any exposed screws, bolts, or rivet heads on food contact surfaces; and

(iii) Fabricated from food grade materials.

(b) The dealer shall assure that all joints on food contact surfaces:

(i) Have smooth easily cleanable surfaces; and

(ii) Are welded.

(c) Shucking blocks shall be provided which are:

(i) Easily cleanable;

(ii) Fabricated from safe material;

(iii) Solid, one piece construction; and

(iv) Easily removed from the shucking bench, unless the block is an integral part of the bench.

(v)The dealer shall provide a temperature measuring device accurate to +/- 2°F for use in monitoring product temperatures.

(d) All equipment used in heat shock processing shall meet the requirements of section 8.2 (a)(b) herein**.**

(e) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in sections 8.2 (a)(b) herein**.**

Cleaning And Sanitizing Of Food Contact Surfaces

(f) 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:

(i) Provide adequate cleaning supplies and equipment, including three compartment sinks, brushes, detergents, and sanitizers, hot water and pressure hoses shall be available within the plant;

(ii) Sanitize equipment and utensils prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; and

(iii)Wash and rinse equipment and utensils at the end of each day.

(iv)Provide a test kit or other device that accurately measures the parts per million concentration of sanitizing solutions.

(g) 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.

(h) Shellfish shall be protected from contamination by washing and rinsing shucking containers and sanitizing before each filling.

(i) Containers which may have become contaminated during storage shall be washed, rinsed, and sanitized prior to use or shall be discarded.

(j) Shucked shellfish shall be packed in clean containers and stored in a manner which assures their protection from contamination.

(k) If used, the finger cots or gloves shall be:

(i) Made of impermeable materials except where the use of such material is inappropriate or incompatible with the work being done;

(ii) Sanitized at least twice daily;

(iii) Cleaned more often, if necessary;

(iv) Properly stored until used; and

(v) Maintained in a clean, intact, and sanitary condition.

8.3 ***Prevention of Cross Contamination***

(a) ***Protection of Shellfish***

(i) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer.

(ii) Shucked shellfish shall be protected from contamination.

(iii) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment.

(iv) Equipment and utensils shall be stored in a manner to prevent splash, dust, and contamination.

(b) ***Employee Practices***

(i) Where the same employee works in both the shucking and packing activities, the employee shall wash his hands thoroughly after entering.

(ii) 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.

8.4 ***Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities***

(a) Handwashing facilities with warm water at a minimum temperature of 110 ^{o} Fahrenheit (43° Centigrade), dispensed from a hot and cold mixing or combination faucet, shall be provided.

(b) Sewage and liquid disposable wastes shall be properly removed from the facility.

(c) An adequate number of conveniently located, toilets shall be provided.

(d) The dealer shall provide each toilet facility with an adequate supply of toilet paper in a suitable holder.

8.5 ***Protection from Adulterants***

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

(b) 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.

(c) 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.

Protection of Ice Used in Shellfish Processing

(d) 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.

(e) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice.

(f) Adequate ventilation shall be provided to minimize condensation in areas where food is stored, processed or packed.

8.6 ***Proper Labeling, Storage and Use of Toxic Compounds***

Storage of toxic compounds

(a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility.

(b) Each of the following categories of toxic substances shall be stored separately:

(i) Insecticides and rodenticides;

(ii) Detergents, sanitizers, and related cleaning agents; and

(iii) Caustic acids, polishes, and other chemicals.

(c) The dealer shall not store toxic substances above shellfish or food contact surfaces.

Use and labeling of toxic compounds

(d) 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.

(e) Cleaning compounds and sanitizing agents shall be labeled and used only in accordance with applicable federal and state laws and regulations.

(f) Toxic substances shall be labeled and used in accordance with the manufacturer's label directions.

8.7 ***Control of Employees with Adverse Health Conditions***

(a) 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 the Americans with Disabilities Act, and published in the *Federal Register.*

(b) 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.

8.8 ***Exclusion of Pests.*** The dealer shall operate his facility to assure that pests are excluded from the facility and processing activities.

Section 9.0 ***Other Requirements***

Each dealer shall comply with the requirements specified in section 9.0 herein 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.

9.1 ***Plants and Grounds***

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.

(c) 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.

Flooding:

(d) 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.

(e) If facilities are flooded:.

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

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

(f)The dealer shall operate his facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from his facility and activities.

Separation of Operations

(g) Facilities for shucking and packing activities shall be separated by use of

(i) Separate rooms;

(ii) Partitions; or

(iii) Sufficient spacing.

(h) Manufacturing activities which could result in the contamination of the shellfish shall be separated by adequate barriers.

(i) The dealer shall provide toilet room doors which are tight fitting, self closing, and do not open directly into a processing area.

Plant Interior

(j) Sanitary conditions shall be maintained throughout the facility.

(i) All dry area floors shall be hard, smooth, easily cleanable; and

(ii) 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:

(A) Are graded to provide adequate drainage;

(B) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage;

(C) Have sealed junctions between floors and walls to render them impervious to water; and

(k) ***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.

(l) ***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;

(b) Rodent, insect, or bird attraction and harborage; and

(c) Inadequate drainage.

9.2 ***Plumbing and Related Facilities***

Handwashing facilities shall be provided which are:

(a) Convenient to work areas;

(b) Separate from the three compartment sinks used for cleaning equipment and utensils; and

(c) Directly plumbed to an approved sewage disposal system.

(d)The dealer shall provide at least one handsink in the packing room.

(e)The dealer shall provide at each handwashing facility:

(i) A supply of hand cleansing soap or detergent;

(ii) A conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air;

(iii) An easily cleanable waste receptacle; and

(iv) Handwashing signs in a language understood by the employees;

(f) 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:

(i) Cold and warm water at all sinks; and

(ii) Handwashing facilities adequate in number and size for the number of employees, and located where supervisors can observe employee use;

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

(i) Used in shellstock storage;

(ii) Used for food holding units (e.g. refrigeration units); and

(iii) Cleaned by hosing, flooding, or similar methods.

(h) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations;

(i) 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.

9.3 ***Utilities.*** Ventilation, heating, or cooling systems shall not create conditions that may cause the shellfish products to become contaminated.

Insect and Vermin Control

9.4 The dealer shall employ necessary internal and external insect and vermin control measures to insure that insects and vermin are not present in his facility including:

(a) Tight fitting, self-closing doors;

(b) Screening of not less than 15 mesh per inch; and.

(c) Controlled air current.

9.5 ***Disposal of Other Wastes***

(a) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations.

(b) Shell and other non-edible materials shall be promptly and effectively removed from the shucking bench or table.

(c) 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

9.6 ***Equipment Construction and Design for Non-food Contact Surfaces***

(a) 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.

(b) The dealer shall use easily cleanable, corrosion-resistant, durable, impervious materials, free from cracks to construct:

(i) Shucking benches and contiguous walls; and

(ii) Stands or stalls and stools for shucker.

(iii) Any non-food contact surfaces in shellfish storage or handling areas.

(c) Shucking benches shall drain completely and rapidly, and shall drain away from any shellfish on the benches.

(d) Dealers shall have sufficient refrigeration, capable of cooling and holding shellfish, as required herein.

9.7 ***Cleaning Non-food Contact Surfaces***

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

(b) 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.

9.8 ***Shellfish Storage and Handling***

The dealer shall:

(a) Assure that shellstock is:

(i) Reasonably free of sediment; and

(ii) 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 21 CFR 161§130.

(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 0 ^{o} Fahrenheit (-17.8 ^{o} Centigrade) or less; and frozen solid within twelve 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.

9.9 ***Heat Shock***. 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:

(i) Dipping in a ice bath; or

(ii) Use of flowing potable water.

(A) If a heat shock water tank is used and the water temperature is maintained at or above 140 ^{o} Fahrenheit, 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.

(B) If the tank is maintained at or below 139 ^{o} Fahrenheit, the tank shall be drained and flushed at three (3) hour intervals.

9.10 ***Personnel.*** Any employee handling shucked shellfish shall be required to:

(a) Wear effective hair restraints;

(b) Remove any hand jewelry that cannot be sanitized or secured;

(c) Wear finger cots or gloves if jewelry cannot be removed.;

(d)Wear clean outer garments, which are rinsed or changed as necessary to be kept clean.

(e) 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:

(i) Store clothing or other personal belongings;

(ii) Eat or drink;

(iii) Spit; and

(iv) Use tobacco in any form.

9.11 ***Supervision***

(a) A reliable, competent individual shall be designated to supervise general plant management and activities;

(b) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellfish or food contact surfaces.

(c) All supervisors shall be:

(i) Trained in proper food handling techniques and food protection principles; and

(ii) Knowledgeable of personal hygiene and sanitary practices.

(d) The dealer shall require:

(i) Supervisors to monitor employee hygiene practices, including handwashing, eating, and smoking at work stations, and storing personal items or clothing.

(ii) 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.

(iii) Employees

(1) to be trained in proper food handling and personal hygiene practices, and

(2) to report any symptoms of illness to their supervisor.

Section 10.0 ***Shipping Documents and Records / Transportation and Receiving***

Trucks or Other Vehicles Used to Transport Shellfish

10.1 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.

10.2 Prechilling trucks or other vehicles shall be required when ambient air temperatures are such that unacceptable bacterial growth or deterioration may occur.

10.3 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 45° Fahrenheit (7.2^{o} Centigrade) or less.

10.4 Any ice used to cool shellstock during transport shall meet the requirements of section 8.1(d) herein**.**

10.5 Cats, dogs, and other animals shall not be allowed in any part of the truck or other vehicle where shellstock is stored.

Transportation Containers

10.6 All containers used to transport shellstock shall be:

(a) Constructed to allow for easy cleaning; and

(b) Operated and maintained to prevent product contamination.

10.7 All containers shall be cleaned with:

(a) Potable water; and

(b) Detergents, sanitizers, and other supplies acceptable for food contact surfaces.

10.8 ***Shipping Documents***

(a) Each shellfish shipment shall be accompanied by a shipping document.

(b) The shipping document shall contain:

(i) The name, address, and certification number of the shipping dealer;
(ii) The name and address of the major consignee; and
(iii) The kind and quantity of the shellfish product.

(c) The receiving dealer shall:

(i) Maintain in his files a copy of the completed shipping document; and
(ii) Make the shipping document available to the Department upon request.

(d) If the shipment is subdivided to different dealers, each receiving dealer shall maintain records sufficient to trace his portion back to the original shipment.

Shipment Acceptability

10.9 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 45° Fahrenheit (7.2^{o} Centigrade) or less;

(c) Shucked shellfish is cooled to a temperature of 45° Fahrenheit (7.2^{o} Centigrade) or less; and

(d) The time-temperature indicating device shows that the ambient air temperature has exceeded 45° Fahrenheit (7.2^{o} Centigrade) but the shellstock internal body temperature is 50° Fahrenheit (l0 Centigrade) or less; and

(e) All other conditions of shipment in these requirements are met.

Receiving Shellfish

10.10 The dealer shall reject or discard any shellfish shipments which:

(a) Do not originate from a licensed harvester or dealer; and/or

(b) Shellfish are not properly identified with tags and shipping documents;

(c) The internal shellstock body temperature exceeds 50° Fahrenheit (15.6 Centigrade) unless the harvest initiation time can be documented and indicates that the time from harvest has not exceeded the requirements stated herein;

(d) Shucked shellfish exceeds 50° Fahrenheit (10° Centigrade); or

(e) Are unwholesome, inadequately protected, or whose source cannot be identified.

10.11 Transportation agents or common carriers used by a dealer are not required to be certified.

10.12 The dealer shall:

(a) Inspect incoming shellfish shipments to assure that the shipments are received under the conditions required in the regulations contained herein**;**

(b) Ensure that shellstock are not permitted to remain without ice, mechanical refrigeration, or other approved means of lowering the internal body temperature of the shellstock to, or maintaining it at, 50° Fahrenheit (10° Centigrade) or less for more than two (2) hours;

(c) Ensure that shucked shellfish are not permitted to remain without ice, mechanical refrigeration, or other approved means of maintaining shellfish temperature at 45° Fahrenheit (7.2° Centigrade) or less; and

(d) Ensure that frozen shellfish remain frozen.

Shipping Times

10.13 ***Shipping Time is No More Than Four Hours***

(a) When the shipping time is four hours or less, the dealer shall ship all shellfish using an acceptable means of 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 45° Fahrenheit (7.2^o Centigrade) or less.

(c) The dealer shall not be required to provide thermal recorders during shipment.

10.14 ***Shipping Time is Greater Than Four Hours***

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

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

(ii)Containers with an internal ambient air temperature maintained at or below temperatures of 45° Fahrenheit (7.2^{o} Centigrade) or less.

(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.

10.15 ***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:

(i) Document that the shellfish are from a source authorized under these requirements;

(ii) Permit a container of shellfish to be traced back to the specific incoming lot of shucked shellfish from which it was taken;

(iii)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, and if possible, the harvester or group of harvesters.

(d) Purchase and sales shall be recorded:

(i) In a permanently bound ledger book; or

(ii) Using shipping/sales documents as required in section 10.8 herein and to include the harvest area and harvest date; or

(iii) Using other recording methods acceptable to and authorized by the Department.

(e) The transaction records shall be retained:

(i) In the case of fresh shellfish, for a minimum of one year; and

(ii) In the case of frozen shellfish, for at least two 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.

Section 11.0 ***Post-Harvest Processing***

11.1 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:

(a) An end point criteria for the process as non-detectable (<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 FDA *Bacteriological Analytical Manua*l, 7th edition, 1992; and

(b) A sampling program to demonstrate that the end point criteria is met.

11.2 Package and label all shellfish in accordance with all requirements contained herein. 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 sections 6.2---6.7 herein.

11.3 Keep records in accordance with sections 6.6 and 6.7 herein.

11.4 A dealer who meets the requirements of this section may label product which has been subjected to the reduction process as "Processed to reduce *Vibrio vulnificus* to non-detectable levels."

Processed Products with Labeling Claims for Safety

11.5 All certified dealers processing products with labeling claims for safety shall:

(a) Consult with and adhere to advice from the U.S. Food and Drug Administration for all special labeling claims.

(b) Meet all applicable requirements of this chapter.

(c) 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,

(d) Shall ensure through controls in their HACCP Plan that claims are met.

Section 12.0 ***Shucking and Packing***

Heat Shock

12.1 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.

12.2 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;

12.3 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.

12.4 The dealer shall retain records covering all aspects of the establishment of the heat shock process.

Critical Control Points

12.5 ***Receiving Critical Control Point - Critical Limits***. The dealer shall shuck and pack only shellstock which is:

(a) Obtained from a licensed harvester who has:

(i) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; and

(ii) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; or

(b) Obtained from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment.

(c) Shucked shellfish is received in a conveyance with an ambient temperature of 45°F (7.2°C) or less or is adequately packed in ice or other approved method of refrigeration.

12.6 ***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 section 16.0 herein**;** and

(b) Once placed under temperature control and until sale to the processor or final consumer, shellstock shall be;

(i) Iced; or

(ii) Placed and stored in a storage area or conveyance maintained at 45° Fahrenheit (7.2^{o} Centigrade) or less; and

(iii) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in sections 12.6 (a)(b) (above) for more than 2 hours at points of transfer such as loading docks.

12.7 ***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 45 ^{o} F (7.2 ^{o} Centigrade) or less within three hours of shucking.

(b) For shellstock refrigerated prior to shucking, shucked meats are chilled to an internal temperature of 45 ^{o} F (7.2 ^{o} Centigrade) or less within four 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 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less within two hours after the heat shock process.

12.8 ***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 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less or covered with ice.

Section 13.0 ***Repacking Of Shucked Shellfish***

Critical Control Points

13.1 ***Receiving Critical Control Point - Critical Limits.*** The dealer shall repack only shellfish which:

(a) Originated from a dealer; and

(b) Are identified with a label as outlined in sections 6.6--6.7 herein.

13.2 ***Processing Critical Control Point - Critical Limits.*** The dealer shall ensure that repacked shellfish do not exceed an internal temperature of 45° Fahrenheit (7.2 ^{o}Centigrade) for more than two (2) hours.

13.3 ***Shucked Meat Storage Critical Control Point - Critical Limit.*** The dealer shall store repacked shellfish in covered containers at an ambient air temperature of 45° Fahrenheit (7.2° Centigrade) or less or covered with ice.

Section 14.0 ***Shellstock Shipping***

Critical Control Points

14.1 ***Receiving Critical Control Point - Critical Limits.*** 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.

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

(a) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in sections 16.11--16.14 herein; and

(b) once placed under temperature control and until sale to the processor or final consumer, shellstock shall be:

(i) Iced; or

(ii) Placed in a storage area or conveyance maintained at 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less; and

(iii) Not permitted to remain without ice, mechanical refrigeration or other approved methods of refrigeration, as required in section 14.2 (above) for more than 2 hours at points of transfer such as loading docks.

14.3 The dealer shall store shucked and packed shellfish in covered containers at an ambient temperature of 45°F (7.2°C) or less or covered with ice.

Section 15.0 ***Reshipping***

Critical Control Points

15.1 ***Receiving Critical Control Point - Critical Limits***. The dealer shall reship only shellfish which:

(a) Originated from a dealer;

(b) Are identified with a tag as outlined in sections 6.2--6.5 herein or a label as outlined in sections 6.6 and 6.7 herein.

15.2 ***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:

(a) Iced; or

(b) Placed in a storage area or conveyance maintained at 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less; and

(c) Not permitted to remain without ice, mechanical refrigeration, or other approved means of refrigeration for more than 2 hours at points of transfer such as loading docks.

15.3 ***Shucked Meat Storage Critical Control Point - Critical Limit***. The dealer shall store shucked shellfish at a temperature of 45 ^{o} Fahrenheit (7.2 ^{o} Centigrade) or less or covered with ice.

Section 16.0 ***Wet Storage in Approved and Conditionally Approved Growing Areas***

Dealers who practice wet storage shall be in compliance with all Rhode Island Department of Environmental Management and Rhode Island Coastal Resources Management Council statutes and regulations.

Requirements for the Dealer: Source of Shellstock

16.1 The dealer shall wet store shellstock harvested only from areas classified as approved, or conditionally approved, when in the open status.

16.2 Shellstock shall be harvested, identified and shipped to the wet storage operation in accordance with the requirements of section 10.0 herein.

General Requirements

16.3 Wet storage may be used to store, condition, remove sand or to add salt to shellstock.

16.4 Wet storage of depurated product shall occur only within the facility in which it was depurated.

16.5 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.

16.6 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.

16.7 Conditions and water quality during wet storage shall be sufficient to minimize the potential for compromising the sanitary quality of the shellstock during storage.

16.8 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.

16.9 Shellstock from a wet storage operation shall be harvested, identified and shipped according to the requirements of sections 7.0 and 10.0 herein. 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 section 10.0 herein.

16.10 The wet storage operator shall keep complete and accurate records to enable a lot of shellstock to be traced back to the wet storage location. The records shall be maintained for at least one (1) year.

Wet Storage Sites

16.11 Near shore 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 held in the wet storage site until the area is returned to the open status.

16.12 The near shore site evaluation shall include:

(a) The location of near shore storage sites and floats; and

(b) The examination of the construction of shellstock containers, if used, to ensure the free flow of water to all shellstock.

16.13 Different lots of shellstock shall not be commingled in wet storage. If more than one lot of shellstock is held in wet storage at the same time, the identity of each lot of shellstock shall be maintained.

Wet Storage in Artificial Bodies of Water

16.14 ***General***

(a) If the dealer chooses to practice wet storage in artificial bodies of water, the dealer shall meet the requirements of sections 16.1--16.11 herein.

(b) For the purpose of permitting, each wet storage site or operation shall be evaluated annually. 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:

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

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

(iii) The plan giving the design of the onshore storage facility, source and quantity of water to be used for wet storage, and details of any water treatment system.

Continuous Flow-through System

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

(a) 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

(b) Other than approved may be used if the source water is continuously subjected to disinfection and it is sampled daily following disinfection.

16.16 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:

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

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

(c) Use NSSP recognized methods to analyze the samples to determine coliform levels;

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

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

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

Recirculating Water System

16.18 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 section 16.16 herein **(**above).

16.19 Once sanctioned for use, the recirculating water system shall be sampled weekly to demonstrate that the disinfected water is negative for the coliform group.

16.20 When make-up water of more than 10 percent of the water volume in the recirculating system is added from a growing area source classified as other than approved, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

16.21 When ultra-violet treatment is used as the water disinfectant, each time new ultraviolet bulbs are installed, a set of three samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a 24 hour period to reaffirm the ability of the system to produce water free from the coliform group.

16.22 Failure to meet the weekly water sampling requirements of section 16.19 above may result in termination of the system, pending approval of the Department.

16.23 ***Operation Specifications***

(a) ***General.*** Each onshore wet storage operation shall meet the following design, construction, and operating requirements..

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

(ii) 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 nontoxic, 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.

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

(iv) 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.

(b) ***Buildings.*** When a building is used for the wet storage operation:

(i) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of section 9.0 herein; and

(ii) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of section 9.0 herein**.**

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

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

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

16.24 ***Water Supply***

(a) ***General***

(i) Except for wells, the quality of the surface source water prior to treatment shall meet, at a minimum, the bacteriological standards for the approved or conditionally approved when in the open status classification.

(ii) Any well used as source water for wet storage shall meet the requirements of section 8.0 herein.

(iii) 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.

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

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

(vi) Disinfected water entering the wet storage tanks shall have no detectable levels of the coliform group as measured by a recognized multi-tube MPN test per 100 ml. for potable water.

(vii) When the laboratory analysis of a single sample of disinfected 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.

(viii) Daily sampling shall continue until the elimination of the problem is demonstrated by three (3) consecutive negative results. Process water shall not adversely affect shellfish. If any sample detects fecal coliform greater than or equal to (≥) 14 MPN per 100 ml, the dealer shall immediately cease use of the system. Shellfish that is in or has gone through the system since the violative sample was taken shall be evaluated by the Department. Any shellstock adversely affected may be subject to recall, embargo, or destruction.

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

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

16.25 ***Shellstock Handling***

(a) Shellstock shall be thoroughly washed with water from a source authorized by the Department 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 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.

PART III: *ENFORCEMENT, VARIANCES, AND PRACTICES/PROCEDURES*

Section 17.0 *Enforcement, Inspections, Penalties*

Documenting Information and Observations

17.1 The Department shall document on an inspection report form specific factual observations of violative conditions or other deviations from the Act and the rules and regulations herein that require correction by the permit holder.

Specifying Time Frame for Corrections

17.2 The Department shall specify on the inspection report form the time frame for correction of the violations.

Issuing Report and Obtaining Acknowledgment of Receipt

17.3 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.

Refusal to Sign Acknowledgment

17.4 The Department shall:

(a) Inform a person who declines to sign an acknowledgment of receipt of inspectional findings as specified in section 17.3 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.

17.5 ***Ceasing Operations and Reporting: Imminent Health Hazard***

(a) Except as specified in subsection (b) of this section, 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.

Resumption of Operations

17.6 If operations are discontinued as specified under section 17.5 or otherwise according to law, the permit holder shall obtain approval from the Department before resuming operations.

17.7 ***Timely Correction***

(a) Except as specified in subsection (b) of this section, a permit holder shall at the time of inspection correct a critical violation of the Act and the rules and regulations herein 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 the Act or the rules and regulations herein or HACCP plan deviations.

17.8 ***Verification and Documentation of Correction***

(a) 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.

(b) As specified under section 17.8, 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.

17.9 ***Time Frame for Correction***

(a) Except as specified in subsection (b) of this section, the permit holder shall correct noncritical violations by a date and time agreed to or specified by the Department but no later than 90 calendar days after the inspection.

(b) The Department may approve a compliance schedule that extends beyond the time limits specified under subsection (a) of this section 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.

Grounds for Discipline Without Hearing

17.10 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.

Section 18.0 ***Variances Procedure***

18.1 The Department may grant a variance upon request of the applicant from the provisions of any rules and regulations herein, 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.

18.1.1 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).

Section 19.0 ***Rules Governing Practices and Procedures***

19.1 All hearings and reviews required under the provisions of Chapter 21-14 of the General Laws of Rhode Island, as amended, shall be held in accordance with the provisions of the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)* of reference 3 herein.

Section 20.0 ***Severability***

20.1 If any provision of these rules and regulations or the application thereof to any person or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.

REFERENCES

1. *National Shellfish Sanitation Program Manual of Operations, Sanitation of the Harvesting, Processing and Distribution of Shellfish*, 1999 revision, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Seafood, Shellfish Sanitation Branch, Washington, DC, 20204. Available online at**: www.issc.org/on-line_docs/onlinedocs.htm.**

2. 21 *Code of Federal Regulations* (CFR), Part 123, "Fish and Fishery Products," Subparts A and C: "General Provisions" and "Raw Molluscan Shellfish" respectively. Revised as of April 1, 2001. Available online at: **http://frwebgate4.access.gpo.gov/c...09331154+6+0+0&WAISaaction=retrieve**

3. *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*, Rhode Island Department of Health, October 2000 and subsequent amendments thereto.

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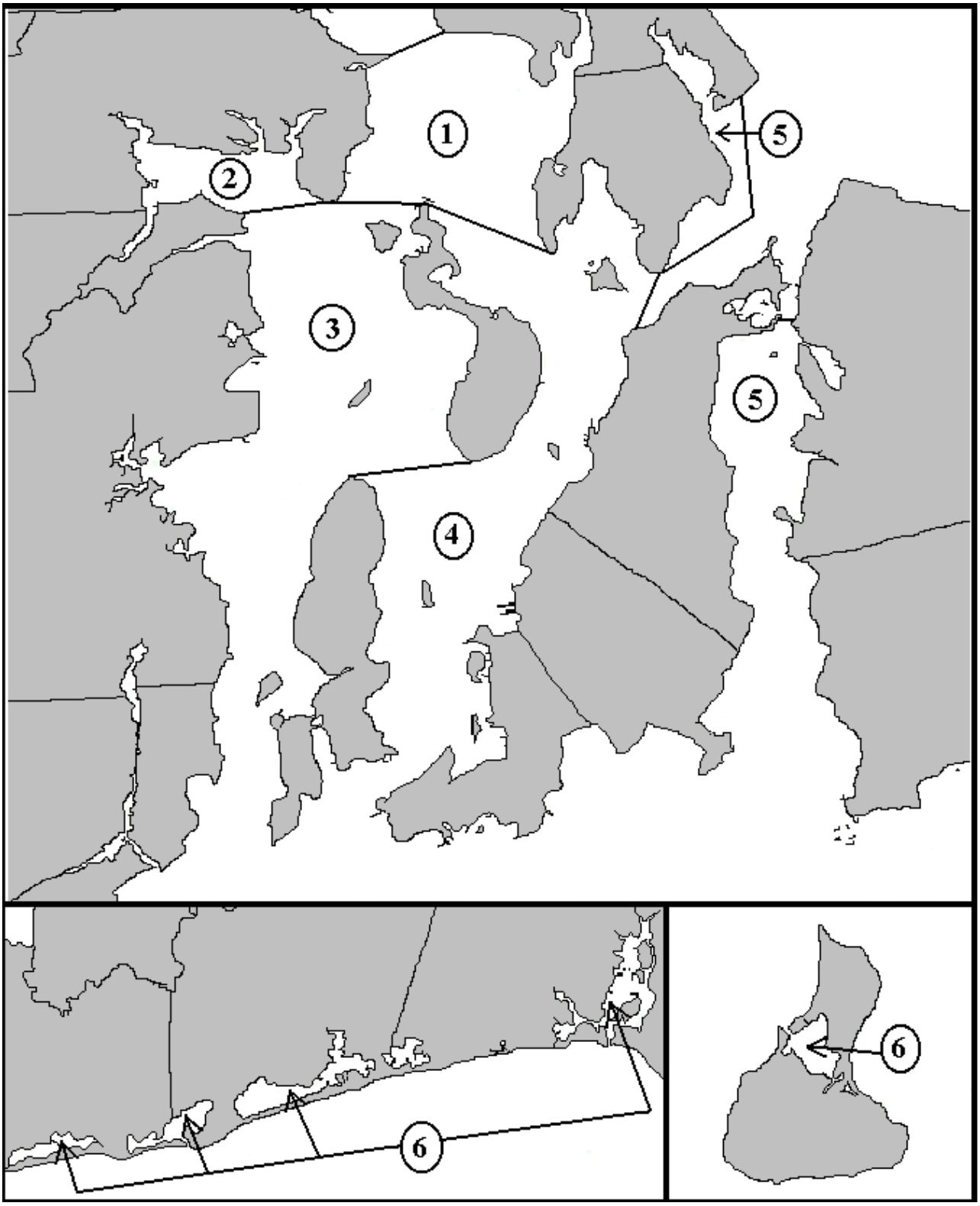
Wednesday, 01 August 2012

APPENDIX "A"

MAP OF HARVEST AREAS



APPENDIX "B"

STATE OF RHODE ISLAND
STATE SHELLFISH CONTROL AGENCY
SHELLFISH COMINGLING PLAN

Shellfish from different harvest areas or different harvest days can only be comingled by a primary dealer under the following conditions:

- Only partial containers that are left over at the end of the day's production;
- Shellfish from no more than two (2) different harvest areas; or
- No more than two (2) different harvest days;
- The tag must identify the two (2) harvest areas or the two (2) dates of harvest.

Aqacultured shellstock can not be comingled under any circumstances.