

COMPREHENSIVE SHELLFISH CONTROL CODE

5L-1

SEPTEMBER 2008

CHARLES H. BRONSON, Commissioner



1203 Governor's Square Boulevard, 5th Floor
Tallahassee, Florida 32301
www.floridaaquaculture.com
(850)488-4033

CHAPTER 5L-1 COMPREHENSIVE SHELLFISH CONTROL CODE

5L-1.001	General Requirements and Intent.
5L-1.002	Definitions.
5L-1.003	Shellfish Harvesting Area Standards.
5L-1.004	Production and Market Standards.
5L-1.005	Shellfish Processing Plant Certification License.
5L-1.006	Compliance and Penalties.
5L-1.007	Container Identification, Terminal Sale Date; Prohibitions.
5L-1.008	Shellfish Handling.
5L-1.009	Shellfish Relaying.
5L-1.010	Buildings and Facilities.
5L-1.011	Equipment for Shellfish Processing.
5L-1.012	Sanitary Operations.
5L-1.013	Plant Operation.
5L-1.014	Heat Shock Method.
5L-1.015	Depuration Plant Operations.
5L-1.016	Depuration Shellfish Sampling Procedures.
5L-1.017	Depuration – Process Water Treatment Standards.
5L-1.018	Depuration – Ultraviolet (UV) Unit.
5L-1.019	Laboratory Procedures and Sample Testing.

5L-1.001 General Requirements and Intent.

- (1) A shellfish processing plant certification is required to operate any shellfish processing facility.
- (2) It is the intent of the Department to establish regulations and specifications to be known as the “Comprehensive Shellfish Control Code”, relating to sanitary practices for the catching, handling, relaying, depuration, packaging, preserving and storing of shellfish products.
- (3) The Department, as a participant in the Interstate Shellfish Sanitation Conference, recognizes and endorses the following principles:
 - (a) Shellfish are a renewable, manageable natural and aquacultured resource of significant economic value to many coastal communities, and should be managed as carefully as are other natural resources such as forests, water, and agricultural lands.
 - (b) Shellfish culture and harvesting represents a beneficial use of water in the estuaries. This use should be recognized by local, state and federal agencies in planning and carrying out pollution prevention and abatement programs and in comprehensive planning for the use of these areas.
 - (c) The goals of the Interstate Shellfish Sanitation Conference are: 1. the continued safe use of this natural and aquacultured resource, and 2. active encouragement of water quality programs which will preserve all possible coastal areas for this beneficial use.
- (4) The Department recognizes that the shellfish industry is subject to change as technological data becomes available; accordingly, it is the intent of the Department that the Comprehensive Shellfish Control Code be revised as necessary so that the technological data and industrial practices contained therein shall be consistent with good health and safety practices.
- (5) The enforcement of the provisions of this code by the Department shall be coordinated with and be in conjunction with any and all other state, local and federal agencies exercising jurisdiction over the sanitary practices of the shellfish industry.

(6) Adoption of Federal Regulations and Standards – To the extent not inconsistent with the rules herein, the following are hereby adopted as rules under Section 597.020, F.S.:

(a) The following parts of Title 21, Code of Federal Regulations:

1. Part 7 – Enforcement Policy, revised as of April 1, 2000;
2. Part 101 – Food Labeling, revised as of April 1, 2000;
3. Part 109 – Unavoidable Contaminants in Food for Human Consumption and Food Packaging Material, revised as of April 1, 2000;
4. Part 110 – Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, revised as of April 1, 2000;
5. Part 123 – Fish and Fishery Products, revised as of April 1, 2000;
6. Part 161 – Fish and Shellfish, revised as of April 1, 2000;
7. Part 509 – Unavoidable Contaminants in Animal Food and Food Packaging Material, revised as of April 1, 2000.

(b) The Purpose, the Definitions, and Chapters 1 through 13, and 15 of the “Model Ordinance 1999” of the National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration 1999, except for:

1. Definition number (14)(d) Reshipper; and
2. Definition number (84) Reshipper.

Interested persons may obtain copies of the pertinent sections of the Codes of Federal Regulations referenced in paragraph (a) above by contacting the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Copies of the Pertinent sections of the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Guide For The Control Of Molluscan Shellfish referenced in paragraph (b) above may be obtained by contacting the U.S. Government Printing Office. Copies of all referenced documents are available for examination at the Florida Department of Agriculture and Consumer Services, Division of Aquaculture, 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History–New 1-4-87, Amended 8-10-88, 7-9-89, 11-5-92, Formerly 16R-7.001, Amended 7-3-95, 2-6-97, 6-23-99, Formerly 62R-7.001, Amended 8-9-00, 5-29-02.

5L-1.002 Definitions.

(1) Adulterated – any shellfish harvested from closed waters; any shellfish shucked, packed, or otherwise processed in a plant which has not been certified and licensed by the Department in accordance with the requirements of these rules; any shellfish contaminated as determined by microbiological or other analysis; any shellfish consisting in whole or in part of any filthy, putrid or decomposed substance, or otherwise unfit for food; any shellfish prepared, packed, or held under unsanitary conditions where it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(2) Alternative Processing – any processing done to shellfish which does not follow the time-temperature matrix as stated in subsection 5L-1.008(5), F.A.C.

(3) Approved area – an area in which it is indicated by a sanitary survey or other monitoring program data that fecal material, pathogenic microorganisms, radio nuclides, harmful chemicals, and marine biotoxins are not present in dangerous concentrations.

(4) Certification period – the period of time between July 1 and June 30 of a year.

(5) Certified shellfish dealer – a shellstock shipper, shucker-packer, repacker, or depuration processor who possesses a shellfish processing plant certification license from the Department. The certified shellfish dealer shall be held accountable for compliance with all laws, rules, and permits applicable to the shellfish business operation.

(6) Closed area (closed waters) – a growing area where the harvesting of shellfish is not permitted. Closed areas include prohibited and unclassified areas as well as temporarily closed approved, conditionally approved, restricted, and conditionally restricted areas.

(7) Code – the Comprehensive Shellfish Control Code, Chapter 5L-1, F.A.C.

(8) Commercial harvester – a person that harvests with the intent to sell.

(9) Conditionally approved area – an area in which it is indicated by a sanitary survey or other monitoring program data that the area is subjected to intermittent microbiological pollution and, under such conditions, is temporarily unsuitable as a source of shellfish for direct marketing. Such an area shall be managed by an operating procedure that will assure that shellfish from the area are not harvested from waters not meeting approved area criteria.

(10) Conditionally restricted area – an area in which it is indicated by a sanitary survey or other monitoring program data that the area is subjected to intermittent microbiological pollution and, under such conditions, is temporarily unsuitable as a source of shellfish for relaying or depuration. Such an area shall be managed by an operating procedure that will assure that shellfish from the area are not harvested from waters not meeting restricted area criteria.

(11) Corrective action plan – is a brief outline of the deficiency(ies) found during an inspection of a licensed facility with the corresponding rule deficiencies cited and the time frame in which the deficiency(ies) must be corrected.

(12) Critical control point – 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.

(13) Critical deficiency – a condition or practice which results in the production of a product which is adulterated. A critical deficiency is not a minor violation

(14) Critical limit – 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.

(15) Deficiency – a violation.

(16) Department – the Department of Agriculture and Consumer Services.

(17) Depuration processor (depuration plant; controlled purification plant) (DP) – a certified shellfish dealer who obtains shellstock from approved, conditionally approved, restricted or conditionally restricted growing area(s) and submits such shellstock to a Department approved controlled purification process as described in Chapter XV of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance 1999 as incorporated herein under paragraph 5L-1.001(6)(b), F.A.C. The treatment process is designed to purge shellfish of bacterial and viral contamination to the extent that such shellfish are rendered safe for human consumption.

(18) Designated representative – in the absence of the plant supervisor or certified shellfish dealer the individual who supervises all activities associated with the operation of the certified shellfish dealer's plant. The designated representative shall be held accountable for compliance with all laws, rules, and permits applicable to the shellfish business operation.

(19) Emergency – any unusual incident resulting from natural or unnatural causes which endangers the health, safety, or resources of the state, including, but not limited to, a hurricane, storm, or red tide; petroleum spill; toxic substance discharge; inability of a sewage treatment plant to comply with permit conditions due to a breakdown of equipment, power outage, destruction by fire, wind, or by other cause.

(20) Firm – a certified shellfish dealer who is a shellstock shipper, shucker-packer, repacker, or depuration processor who possesses a shellfish processing plant certification license from the Department.

(21) Food – any raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption. Shellfish in the shell are considered food.

(22) Food contact surface – a surface of equipment or utensil which food normally comes into contact; or a surface of equipment or utensil from which food may drain, drip, or splash into food or onto a surface

normally in contact with food.

(23) Food packaging materials – any material or container which food normally comes into contact.

(24) Food safety hazard – any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

(25) Free liquor – that liquid portion of a container that passes through a porous straining device when the contents (oyster or clam meats) of the container are drained.

(26) Growing area – an area in which market or seed shellfish are growing either naturally or artificially.

(27) HACCP – Hazard Analysis and Critical Control Points – A system of inspection, control, and monitoring measures initiated by a certified dealer to identify and control microbiological, chemical, or physical food safety hazards which are likely to occur in shellfish products produced by the firm.

(28) Harvester – a person engaged in the harvesting of shellfish.

(29) Health authority – the Department or its authorized representative.

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

(31) High density aquaculture lease areas – legally-defined parcels that are surveyed and properly marked, describing and indicating corners and boundaries, that have been subdivided into individual aquaculture leases issued pursuant to Section 253.68, F.S., and paragraph 18-21.004(2)(l), F.A.C.

(32) ICWW – Intracoastal Waterway.

(33) Key deficiency – a condition or practice which may result in adulterated, or misbranded product. A Key deficiency is not a minor violation.

(34) Lot of shellstock – a single type of bulk shellstock or container of shellstock of no more than one day's harvest from a single harvest area gathered by one or more harvesters.

(35) Lot of shucked shellfish – a collection of containers of no more than one day's shucked product from a single harvest area produced under conditions as nearly uniform as possible, and designated by a common container code or marking.

(36) Lot wet storage/depuration – all shellfish from a single depuration or wet storage tank or series of tanks serviced by a common treatment system.

(37) Mechanical refrigeration – refrigeration provided by an electric compressor in a system where temperature can be adjusted with a thermostat and the unit will maintain a temperature of 45 degrees F or less.

(38) Misbranded – any shellfish product whose labeling is false or misleading; any shellfish product in package form unless it bears labeling including (1) the name and place of business of the manufacturer, packer, or distributor; (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and (3) meets labeling requirements of the Department within this chapter.

(39) NSSP Model Ordinance – the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, published by the U.S. Department of Health and Human Services.

(40) Other deficiency – a condition or practice that is not in accordance with rule requirements and is considered a minor deficiency but is not a key or critical deficiency.

(41) Pest – refers to any objectionable animals or insects, including, but not limited to, dogs, cats, birds, rodents, flies, and larvae.

(42) Plant supervisor – an individual, so designated in writing to the Department, who supervises all activities associated with the operation of the shellfish depuration plant. The plant supervisor shall be held accountable for compliance with all laws, rules, and permits applicable to the shellfish business operation.

(43) Processing – is the handling, unloading, storing, transporting, shucking, freezing, preparing, changing into different market form, manufacturing, preserving, packing, or labeling of shellfish or shellfish products.

(44) Prohibited area – an area from which the taking of shellfish is not permitted.

(45) Public Water System – a system for the provision to the public of water for human consumption through pipes or other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year. Such term includes: any collection, treatment, storage, and distribution facilities under control of the operator of such system and used primarily in connection with such system; and any collection or pretreatment storage facilities not under such control which are used primarily in connection with such system. Such term does not include any “special irrigation district.” A public water system is either a “community water system” or a “non-community water system.” See the Code of Federal Regulations (C.F.R.), Title 40, Part 141, Section 2, revised as of July 1, 2000.

(46) Repacker/Repacking plant (RP) – a certified shellfish dealer, other than the original certified shucker-packer, who repacks shucked shellfish into other containers for distribution or sale. A repacker may also repack and ship shellstock. A repacker shall not shuck shellfish.

(47) Repeat Critical deficiency – is the same “critical” deficiency that has been listed on the corrective action plans for the same facility during the most recent consecutive inspection.

(48) Repeat Key deficiency – is the same “key” deficiency that has been listed on the corrective action plans for the same facility during the most recent consecutive inspection.

(49) Repeat Other deficiency – is the same “other” deficiency that has been listed on the corrective action plans for the same facility during the most recent consecutive inspection.

(50) Restricted area – an area in which it is indicated by a sanitary survey or other monitoring program data that fecal material, pathogenic microorganisms, radio nuclides, harmful chemicals, and marine biotoxins are not present in dangerous concentrations such that shellfish harvested from such an area and subjected to a suitable and effective purification process are safe for human consumption.

(51) Retail sale – sale to the ultimate consumer or to a person who will not resell the product.

(52) Sanitize – the effective bactericidal treatment of clean food contact surfaces of equipment and utensils by a process using only those safe sanitizing agents that have an available field test for strength and effectiveness, and is effective to yield a reduction of 5 logs, which is equal to a 99.999% reduction of representative disease microorganisms of public health importance. Such treatment shall not adversely affect the product and shall be safe for the consumer.

(53) Scheduled Depuration Process (SDP) – a process which places shellfish harvested from restricted or approved waters into a controlled aquatic environment selected by the processor as adequate to effectively reduce the level of bacteria and viruses in live shellfish.

(54) Scheduled Heat Shock Process (SHSP) – the process selected by the processor to heat shock a shellfish species in order to facilitate shucking without adversely affecting the microbial quality or altering the organoleptic characteristics of the species.

(55) Scheduled Wet Storage Process (SWSP) – a process which places shellfish harvested from approved waters in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater for product enhancement.

(56) Shellfish – all edible species of oysters, clams, mussels, and whole or roe-on scallops either shucked or in the shell, fresh, or frozen.

(57) Shellfish Relaying – the transfer of shellfish from one water bottom to another water bottom which activity would otherwise be prohibited; or the transfer of shellfish from a restricted or conditionally restricted area or an area otherwise closed for the harvesting of shellfish to a certified depuration plant.

(58) Shellstock – shellfish which remain in their shells.

(59) Shellstock plant – any establishment or place where shellstock are washed and packed or otherwise prepared for sale or shipment.

(60) Shellstock shipper/Shellstock shipping plant (SS) – a certified shellfish dealer who grows, harvests, buys, or repacks and sells shellstock. A shellstock shipper is not authorized to act as a shucker-packer or repacker. A shellstock shipper may also ship sealed containers of shucked shellfish.

(61) Shuck date – the date shucked shellfish are initially removed from their shells.

(62) Shucked shellfish – shellfish or parts thereof which have been removed from their shells.

(63) Shucker-packer/Shucker-packer plant (SP) – a certified shellfish dealer who shucks and packs shellfish and who may act as a shellstock shipper and/or repacker.

(64) Swing deficiency – a deficiency that could either be a “critical” or a “key” deficiency, or it could be either a “key” or an “other” deficiency, depending on the location, severity and circumstances.

(65) Terminal sale date – the last day freshly packed shellfish shall be offered for sale; that being no more than 14 calendar days subsequent to the date the product was shucked, or for oyster shellstock harvested from the Gulf of Mexico, no more than 14 days subsequent to the date shellstock was harvested.

(66) Time of Harvest – is defined as that time when shellfish are first removed from growing waters and placed on or in a manmade conveyance or other means of transport.

(67) Time of Refrigeration – is defined as the time when shellfish are first placed within an ambient environment of 45 degrees F or less.

(68) Unclassified area – an area for which no recent sanitary survey exists.

(69) UV – Ultraviolet.

(70) Violation and deficiency – are used interchangeably within these rules. The meaning of both is that a facility is not in compliance with the rules governing their operation as outlined in Chapter 5L-1, F.A.C., “The Comprehensive Shellfish Control Code”.

(71) Warning letter – a warning letter includes a notice of non-compliance.

(72) Wet storage – the temporary storage of shellfish received from permitted or approved sources and intended for marketing, on privately-owned or leased bottom, in tanks containing seawater, or on floating facilities in natural bodies of water.

(73) Wholesale – any sale to any person other than the final consumer.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History–New 1-4-87, Amended 5-21-87, 8-10-88, 7-9-89, 11-5-92, 5-20-93, Formerly 16R-7.003, Amended 7-3-95, 5-8-96, 2-6-97, 6-23-99, Formerly 62R-7.003, Amended 8-9-00, 5-29-02.

5L-1.003 Shellfish Harvesting Area Standards.

(1) The Department shall describe and/or illustrate harvesting areas and provide harvesting area classifications as approved, conditionally approved, restricted, conditionally restricted, prohibited, or unclassified as defined herein, including criteria for opening and closing shellfish harvesting areas in accordance with Chapters II and IV of the National Shellfish Sanitation Program Model Ordinance. Copies of the document Shellfish Harvesting Area Classification Maps, revised July 28, 2008, and the document Shellfish Harvesting Area Classification Boundaries and Management Plans, revised July 28, 2008, containing shellfish harvesting area descriptions, references to shellfish harvesting area map numbers, and operating criteria herein incorporated by reference may be obtained by writing to the Department at 1203 Governor’s Square Boulevard, 5th Floor, Tallahassee, Florida 32301.

(2) Approved Areas – Growing areas shall be classified as approved when a sanitary survey, conducted in accordance with Chapter IV of the National Shellfish Sanitation Program Model Ordinance, indicates that pathogenic microorganisms, radionuclides, and/or harmful industrial wastes do not reach the area in dangerous concentrations and this is verified by laboratory findings whenever the sanitary survey indicates the need. Shellfish may be harvested from such areas for direct marketing. This classification is based on the following criteria:

(a) The area is not so contaminated with fecal material or poisonous or deleterious substances that consumption of the shellfish might be hazardous; and

(b) The bacteriological quality of every sampling station in those portions of the area most probably exposed to fecal contamination shall meet one of the following standards during the most unfavorable meteorological, hydrographic, seasonal, and point source pollution conditions: 1) The median or geometric mean fecal coliform Most Probable Number (MPN) of water shall not exceed 14 per 100 ml., and not more

than 10 percent of the samples shall exceed a fecal coliform MPN of 43 per 100 ml. (per 5-tube, 3-dilution test) or 2) The median or geometric mean fecal coliform Most Probable Number (MPN) of water shall not exceed 14 per 100 ml., and not more than 10 percent of the samples shall exceed a fecal coliform MPN of 33 per 100 ml. (per 12-tube, single-dilution test) or 3) The median or geometric mean fecal coliform Membrane Filter (MF) colony forming units of water shall not exceed 14 per 100 ml., and not more than 10 percent of the samples shall exceed a fecal coliform MF colony forming unit of 31 per 100 ml. Harvest from temporarily closed approved areas shall be unlawful.

(3) Conditionally approved areas – A growing area shall be classified as conditionally approved when a sanitary survey, conducted in accordance with Chapter IV of the National Shellfish Sanitation Program Model Ordinance, indicates that the area is subjected to intermittent microbiological pollution. The suitability of such an area for harvesting shellfish for direct marketing may be dependent upon attainment of established performance standards by wastewater treatment facilities discharging effluent directly or indirectly into the area. In other instances, the sanitary quality of the area may be affected by seasonal populations, climatic and/ or hydrographic conditions, non-point source pollution, or sporadic use of a dock, marina, or harbor facility. Such areas shall be managed by an operating procedure that will assure that shellfish from the area are not harvested from waters not meeting approved area criteria. In order to develop effective operating procedures, these intermittent pollution events shall be predictable. Harvest from temporarily closed conditionally approved areas shall be unlawful.

(4) Restricted Areas – A growing area shall be classified as restricted when a sanitary survey, conducted in accordance with Chapter IV of the National Shellfish Sanitation Program Model Ordinance, indicates that fecal material, pathogenic microorganisms, radionuclides, harmful chemicals, and marine biotoxins are not present in dangerous concentrations after shellfish from such an area are subjected to a suitable and effective purification process. The bacteriological quality of every sampling station in those portions of the area most probably exposed to fecal contamination shall meet the following standard: The median or geometric mean fecal coliform Most Probable Number (MPN) of water shall not exceed 88 per 100 ml. and not more than 10 percent of the samples shall exceed a fecal coliform MPN of 260 per 100 ml. (per 5-tube, 3-dilution test) or the median or geometric mean fecal coliform Membrane Filter (MF) colony forming units of water shall not exceed 88 per 100 ml., and not more than 10 percent of the samples shall exceed a fecal coliform MF colony forming unit of 163 per 100 ml. in those portions of the area most probably exposed to fecal contamination during the most unfavorable meteorological, hydrographic, seasonal, and point source pollution conditions. Harvest is permitted according to permit conditions specified in Rule 5L-1.009, F.A.C. Harvest from temporarily closed restricted areas shall be unlawful.

(5) Conditionally Restricted Area – A growing area shall be classified as conditionally restricted when a sanitary survey or other monitoring program data, conducted in accordance with Chapter IV of the National Shellfish Sanitation Program Model Ordinance, indicates that the area is subjected to intermittent microbiological pollution. The suitability of such an area for harvest of shellfish for relaying or depuration activities is dependent upon the attainment of established performance standards by wastewater treatment facilities discharging effluent, directly or indirectly, into the area. In other instances, the sanitary quality of such an area may be affected by seasonal population, non-point sources of pollution, or sporadic use of a dock, marina, or harbor facility, and these intermittent pollution events are predictable. Such areas shall be managed by an operating procedure that will assure that shellfish from the area are not harvested from waters not meeting restricted area criteria. Harvest is permitted according to permit conditions specified in Rule 5L-1.009, F.A.C. Harvest from temporarily closed conditionally restricted areas shall be unlawful.

(6) Prohibited Area – A growing area shall be classified as prohibited if a sanitary survey indicates that the area does not meet the approved, conditionally approved, restricted, or conditionally restricted classifications. Harvest of shellfish from such areas shall be unlawful. The waters of all man-made canals and marinas are classified prohibited regardless of their location.

(7) Unclassified Area – A growing area for which no recent sanitary survey exists, and it has not been classified as any area described in subsection (2), (3), (4), (5), or (6) above. Harvest of shellfish from such

areas shall be unlawful.

(8) Approved, conditionally approved, restricted, or conditionally restricted waters shall be temporarily closed to the harvesting of shellfish when counts of the red tide organism *Gymnodinium breve* exceed 5000 cells per liter in bays, estuaries, passes or inlets adjacent to shellfish harvesting areas. Areas closed to harvesting because of presence of the red tide organism shall not be reopened until counts are less than or equal to 5000 cells per liter inshore and offshore of the affected shellfish harvesting area, and shellfish meats have been shown to be free of toxin by laboratory analysis.

(9) The Department is authorized to open and temporarily close approved, conditionally approved, restricted, or conditionally restricted waters for harvesting of shellfish in emergencies as defined herein, in accordance with specific criteria established in operating procedures for predictively closing individual growing areas, or when growing areas do not meet the standards and guidelines established by the National Shellfish Sanitation Program.

(10) Operating procedures for predictively closing each growing area shall be developed by the Department; local agencies, including those responsible for operation of sewerage systems, and the local shellfish industry may be consulted for technical information during operating procedure development. The predictive procedure shall be based on evaluation of potential sources of pollution which may affect the area and should establish performance standards, specify necessary safety devices and measures, and define inspection and check procedures.

(11) Shellfish harvesting area numbers are as follows:

AREA NUMBER	HARVEST AREA NAME
0212	Pensacola Bay Conditionally Approved Escambia Bay Shellfish Aquaculture Lease Areas managed during the Summer months of Jul – Sep
0222	Pensacola Bay Conditionally Approved Escambia Bay
0232	Pensacola Bay Conditionally Approved East Bay
0216	Pensacola Bay Conditionally Restricted Escambia Bay
0226	Pensacola Bay Conditionally Restricted East Bay
0622	Choctawhatchee Bay Conditionally Approved Central
0632	Choctawhatchee Bay Conditionally Approved Eastern
0806	West Bay Conditionally Restricted Spring/Fall Apr – Jun, Oct – Nov
0812	West Bay Conditionally Approved Winter Dec - Mar
0822	West Bay Conditionally Approved Spring/Fall Apr – Jun, Oct – Nov
1012	North Bay Conditionally Approved Western
1022	North Bay Conditionally Approved Eastern
1006	North Bay Conditionally Restricted Eastern
1206	East Bay Conditionally Restricted
1212	East Bay Conditionally Approved Section 1
1222	East Bay Conditionally Approved Section 2
1401	St. Joe Bay Approved
1506	Indian Lagoon Conditionally Restricted
1512	Indian Lagoon Conditionally Approved Spring/Fall Mar – Jun, Oct
1542	Indian Lagoon Conditionally Approved Zone A Winter Nov – Feb
1552	Indian Lagoon Conditionally Approved Zone B Winter Nov – Feb
1572	Indian Lagoon Conditionally Approved Summer Jul – Sep
1611	Apalachicola Bay Approved Winter Jan - May, Sept – Dec
1621	Apalachicola Bay Approved Summer June – Aug
1631	Apalachicola Bay Approved, Shellfish lease numbers 525, 551, 551B, 580, 582, 609, 672, and 981
	Summer June – Aug

1612	Apalachicola Bay Conditionally Approved West 1 Winter Jan – May, Sept – Dec
1622	Apalachicola Bay Conditionally Approved West 2 Winter Jan – May, Sept – Dec
1632	Apalachicola Bay Conditionally Approved West 3 Winter Jan – May, Sept – Dec
1642	Apalachicola Bay Conditionally Approved East Winter Jan – May, Sept – Dec or Apalachicola Bay
	Approved East Hole Summer June – Aug
1652	Apalachicola Bay Conditionally Approved North Summer June – Aug
1662	Apalachicola Bay Conditionally Approved South Summer June – Aug
1606	Apalachicola Bay Conditionally Restricted
1802	Alligator Harbor Conditionally Approved
2002	Ochlockonee Bay Conditionally Approved
2006	Ochlockonee Bay Conditionally Restricted
2206	Wakulla County Conditionally Restricted
2212	Wakulla County Conditionally Approved Zone 1 Winter
2222	Wakulla County Conditionally Approved Zone 2 Winter
2232	Wakulla County Conditionally Approved Zone 1 Spring
2242	Wakulla County Conditionally Approved Zone 2 Spring
2501	Horseshoe Beach Approved Summer Apr – Sep
2502	Horseshoe Beach Conditionally Approved Winter Oct – Mar
2506	Horseshoe Beach Conditionally Restricted Winter Oct – Mar
2802	Suwannee Sound Conditionally Approved Spring Summer Feb-May and Sept or Suwannee Sound
	Conditionally Approved Winter Oct-Jan
2806	Suwannee Sound Conditionally Restricted Spring Summer Feb-May and Sept or Suwannee Sound
	Conditionally Restricted Winter Oct-Jan
3012	Cedar Key Conditionally Approved Zone A
3022	Cedar Key Conditionally Approved Zone B
3006	Cedar Key Conditionally Restricted
3202	Waccasassa Bay Conditionally Approved
3206	Waccasassa Bay Conditionally Restricted
3402	Withlacoochee Bay Conditionally Approved
3406	Withlacoochee Bay Conditionally Restricted
3701	Citrus County Approved Spring / Fall Mar. – June and Oct.
3702	Citrus County Conditionally Approved Winter Nov. – Feb.
3705	Citrus County Restricted Spring / Fall Mar. – June and Oct.
3706	Citrus County Conditionally Restricted Winter Nov. – Feb.
4202	Boca Ciega Bay Conditionally Approved
4802	Lower Tampa Bay Conditionally Approved
5402	Sarasota Bay Conditionally Approved
5602	Lemon Bay Conditionally Approved
5802	Gasparilla Sound Conditionally Approved
6002	Myakka River Conditionally Approved
6006	Myakka River Conditionally Restricted
6212	Pine Island Sound Conditionally Approved Western Section
6222	Pine Island Sound Conditionally Approved Eastern Section

6602	Ten Thousand Islands Conditionally Approved
7001	Indian River/St. Lucie Approved
7006	Indian River/St. Lucie Restricted
7202	North Indian River Conditionally Approved
7206	North Indian River Conditionally Restricted
7412	Body F Conditionally Approved
7416	Body F Conditionally Restricted
7506	Body E Conditionally Restricted
7602	Body D Conditionally Approved
7606	Body D Conditionally Restricted
7712	Body C Conditionally Approved Zone 1 Spring/Summer/Fall Mar – Nov
7722	Body C Conditionally Approved Zone 2 Spring/Summer/Fall Mar – Nov
7732	Body C Conditionally Approved Winter Dec – Feb
7716	Body C Conditionally Restricted Winter Dec – Feb
7726	Body C Conditionally Restricted Spring/Summer/Fall Mar – Nov
7812	Body B Conditionally Approved Zone 1
7822	Body B Conditionally Approved Zone 2
7902	South Banana River Conditionally Approved
7906	South Banana River Conditionally Restricted
8001	Body A Approved
8005	Body A Restricted
8201	South Volusia Approved
8212	South Volusia Conditionally Approved Zone 1
8222	South Volusia Conditionally Approved Zone 2
8206	South Volusia Conditionally Restricted
8802	St. Johns South Conditionally Approved
8806	St. Johns South Conditionally Restricted
9202	St. Johns North Conditionally Approved
9206	St. Johns North Conditionally Restricted

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 8-10-88, 7-9-89, 12-23-91, Formerly 16R-7.004, Amended 7-3-95, 6-18-97, 7-1-97, 7-22-97, 10-12-97, 12-16-97, 12-28-97, 2-12-98, 2-25-98, 7-1-98, 7-20-98, 11-13-98, 12-28-98, 3-18-99, 7-1-99, Formerly 62R-7.004, Amended 6-19-00, 8-9-00, 10-14-01(1), 10-14-01(1), 8-17-04, 9-28-04, 9-5-05, 6-11-06, 3-11-07, 10-2-07, 4-14-08, 7-28-08.

5L-1.004 Production and Market Standards.

(1) Shellfish offered for sale at the wholesale market level shall be deemed to be “adulterated” as defined in subsection 5L-1.002(1), F.A.C., and Section 500.10, F.S., and will be subject to rejection or seizure by the Department when it exceeds the following bacteriological criteria. Fecal coliform density of not more than 230 MPN per 100 grams; and a 35° C plate count of not more than 500,000 per gram.

(2) Shucked and packed shellfish shall not contain more than 15% by volume of free liquor until the product reaches the consumer.

(3) No shucked shellfish shall be sold, offered for sale, processed, packed, or repacked after the terminal sale date.

(4) No frozen shellfish products shall be thawed to be processed or sold as fresh shellfish products. Thawed frozen shellfish shall be labeled as “previously frozen” in accordance with Rule 5L-1.007, F.A.C.

(5) Shellfish having undergone a deuration process shall not be released for sale prior to laboratory analysis and approval by the plant supervisor or representative. Shellfish shall not be released if the geometric mean of three samples exceeds a fecal coliform MPN of 45 per 100 grams of sample, or if any sample’s fecal coliform MPN exceeds 100 per 100 grams of sample.

(6) The use of the elevated temperature coliform plate count is authorized for the bacteriological evaluation of hard clams, *Mercenaria* spp. only from a depuration facility.

(7) Should the Department suspect contamination of shellfish by metallic ions and compounds, pesticides, detergents, radionuclides, marine toxins, or any toxic substance or adulterate, the Department shall require that shellfish meat be analyzed for such contaminants before suspect shellfish are released for sale.

(8) Shellfish or shellfish products determined to be adulterated, or misbranded shall be subject to recall by the certified shellfish dealer responsible for distribution of the products. For a first offense in a certification license year, the Department will apply mitigation measures if applicable. Mitigation measures include on-the-spot correction and reconditioning. For repeat violations, and where mitigation measures are not approved by the Department, the Department shall issue an order to stop the sale or to condemn, and destroy, shellfish or shellfish containers found to be adulterated, misbranded, or found to be held in non-compliance with any of the provisions of this chapter. Reconditioning shall be a mitigation option only if the products will meet the safety standards of Rule 5L-1.004, F.A.C., and the labeling standards of Rule 5L-1.007, F.A.C. Stop sale, condemnation, or reconditioning of products or containers shall be based on individual conditions found during inspections and shall be conducted using a Seizure and Destruction Order, DACS Form 15001, Revision 05/01. This form is herein incorporated by reference, and available for inspection at the Department's offices located at 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301.

Specific Authority 500.09, 597.020 FS. Law Implemented 500.10, 500.172, 597.020 FS. History--New 1-4-87, Amended 8-10-88, 7-9-89, Formerly 16R-7.006, Amended 7-3-95, 5-8-96, 2-6-97, Formerly 62R-7.006, Amended 8-9-00, 5-29-02.

5L-1.005 Shellfish Processing Plant Certification License.

(1) Upon request, the Department shall provide an application form entitled Shellfish Processing Plant Certification License Application, Form Number DACS 15007, Revision 05/01, herein incorporated by reference, and obtainable by writing the Department of Agriculture and Consumer Services, Division of Aquaculture, 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301. This completed application form is required for certification or recertification licensing of shellfish establishments. The following information shall be requested on the application form:

- (a) The name and address of the firm;
- (b) The name and address of the legal entity that owns the establishment in (a) above;
- (c) Name of the registered agent;
- (d) The name of the designated representative, person in charge, or plant supervisor that will officially represent the firm on site;
- (e) The plant classification; and
- (f) The type of product to be processed.

(2) Possession of a wholesale license to sell saltwater products issued under provisions of Section 370.07, F.S., shall be required for certification licensing under this chapter. A copy of the current wholesale license to sell saltwater products shall be submitted with the Shellfish Processing Plant Certification License Application.

(3) If the water supply is not from a public water system, possession of satisfactory bacteriological water analysis results, which shall not equal or exceed two cfu (colony forming units) per 100 mls for total coliform bacteria on any consecutive samples, and shall not equal or exceed two cfu per 100 mls for fecal coliform or *E. coli* bacteria on any samples shall be required for certification under this chapter. Analysis shall be from the source water and an outlet location within the plant, and ice if any is used. The water shall be sampled and approved prior to use of the water supply, every six months while the water supply is in use, and immediately after the water supply has been repaired and disinfected. If the source is a public

water system, only a sample from an outlet in the plant and ice, if used, is required prior to certification. The water sample shall be taken and acceptable results provided to the Department within 90 days prior to certification. A copy of the current acceptable water analysis shall be submitted with the Shellfish Processing Plant Certification License Application.

(4) A shellfish processing plant certification license number will be assigned by the Department after receipt of a completed Shellfish Processing Plant Certification License Application. Upon receipt of a completed application, an inspection of the physical facility will be conducted within 30 calendar days.

(5) Certification is granted only to firms who meet the following inspection requirements: the firm has no "Critical" item deficiencies, the firm does not have more than two (2) "Key" item deficiencies and the firm does not have more than three (3) "Other" item deficiencies. Failure of a certification inspection requires reapplication by the applicant. After successful inspection of the facility and the applicant's meeting the requirements of Rule 5L-1.005, F.A.C., a Shellfish Processing Certification License, DACS Form 15002, Revision 02/01, will be issued. After a firm is certified, unannounced inspections using the DACS plant inspection Forms 15009, Revision 06/01, and 15012, Revision 06/01, shall be conducted during periods of operation and at such frequency as necessary to assure that adequate operational and sanitary conditions are maintained. These forms are herein incorporated by reference, and obtainable by writing the Department of Agriculture and Consumer Services, Division of Aquaculture, 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301. Upon completion of the initial inspection where the applicant has met the requirements for licensure, he/she will be given a corrective action plan by the Department, if there are any "key" or "other" deficiencies cited. The licensee must comply with the corrective action plan outlined on Form DACS-15012, Revision 06/01, that is given to the certified dealer, plant supervisor or the designated representative of the plant at the end of the inspection. At the completion of each inspection, a copy of the completed inspection forms shall be issued to the plant supervisor or the plant's designated representative.

(6) Renewal certification – A dealer shall make application by completing the Shellfish Processing Plant Certification License Application form for certification renewal annually. The license year starts on July 1 and ends on June 30. The certification shall not be renewed for any dealer until the dealer has: eliminated any "Critical" deficiencies, does not have more than two (2) "Key" item deficiencies, and does not have more than three (3) "Other" item deficiencies. The application (Shellfish Processing Plant Certification License Application Form) for renewal must be received by the agency by April 1 to have an inspection for recertification for the next certification period of a shellfish processor prior to June 30. The application for renewal certification will be denied to any dealer not meeting the above.

(7) The Shellfish Processing Plant Certification License will be issued to a licensee at a specific location. The legal entity will be the licensee at that specific location as listed on the Shellfish Processing Plant Certification License.

(8) One shellfish processing plant certification license shall be issued to a shellfish processing plant owner operating at a single location, regardless of whether the location may qualify for two or more licenses or permits.

(9) In the event that a licensed certified shellfish processing plant changes its name, changes owners, changes location, changes address, or changes classifications, a new application, DACS Form 15007, Revision 05/01 must be completed and submitted to the Department. The firm will be required to go through the complete certification process.

(10) Possession of a mechanical refrigeration unit that is non-portable and is able to maintain an ambient temperature of 45° F or below and be of sufficient size to handle one day's production, shall be required for certification under this chapter.

(11) Each applicant for a shellfish certification license shall have conducted a Hazard Analysis to determine whether there are food safety hazards that are reasonably likely to occur for shellfish products produced at the location listed on DACS Form 15007, Revision 05/01 Shellfish Processing Plant Certification License Application. Each certified shellfish dealer shall have someone with adequate

HACCP training, knowledge or experience to develop a HACCP plan, reassess and modify the HACCP plan and perform the records review. Each certified shellfish dealer shall prepare a written HACCP plan. The HACCP plan shall incorporate critical control points that will eliminate, prevent, or reduce to an acceptable level the hazards identified in the hazard analysis. Critical control points shall have established critical limits for parameters to ensure when exceeded the dealer takes corrective actions. The HACCP plan shall include the procedures, and frequency thereof that will be used to monitor each of the critical control points to ensure compliance with the critical limits. The HACCP plan shall provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring. The plan shall be signed and dated by the owner or corporate officers of the firm at the time of its implementation, and after any modification. Each establishment shall develop or adopt acceptable sanitation monitoring records to meet the requirements in subsection 5L-1.013(12), F.A.C.

(12) Each owner or corporate officer who is a certified shellfish dealer shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented. Verification shall include at a minimum:

(a) Reassessment of the HACCP plan on an annual basis, or when changes occur that could affect the hazard analysis; and

(b) Ongoing verification including a review of any consumer complaints received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points, or the calibration of process-monitoring instruments.

(13) All persons who commercially engage in purchasing shellfish from harvesters, shucking, packing, repacking or transporting shellfish are subject to inspection and shall allow inspection by the Department or its duly authorized representatives during normal operating hours and any time there is shellfish processing, in order to determine compliance with sections of this rule. The Department shall inspect all licensed certified shellfish processing plants. Denial of access for such inspection will automatically institute agency administrative action for immediate suspension of the shellfish processing plant certification license.

(14) It is unlawful for persons to commercially engage in purchasing from harvesters, shucking, packing, or repacking shellfish without having complied with these rules and applied for and obtained a shellfish processing plant certification license from the Department.

(15) Upon issuance of a processing plant certification license, the Department shall notify the U.S. Food and Drug Administration of the certified shellfish dealer's business name and certification license number to be published in the Interstate Certified Shellfish Shippers List.

(16) The shellfish processing plant certification license shall be posted in a conspicuous location on the premises.

(17) No person shall attempt, by means of any threat or violence, to deter or prevent an agent of the Department from performing any duties imposed by law.

(18) All licensed certified shellfish processing plants shall maintain on the premises a current copy of this rule Chapter 5L-1, F.A.C., entitled "The Comprehensive Shellfish Control Code" and a current copy of the "Model Ordinance" of the National Shellfish Sanitation Program, Guide for the Control of Molluscan Shellfish published by the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 8-10-88, Formerly 16R-7.007, Amended 7-3-95, 5-8-96, 2-6-97, 6-23-99, Formerly 62R-7.007, Amended 8-9-00, 5-29-02.

5L-1.006 Compliance and Penalties.

(1) The Department shall initiate enforcement action as follows:

(a) The Department shall inspect and re-inspect all licensed certified shellfish processing plants as necessary. The deficiency(ies) cited in an inspection report is not determined by the type of inspection

being conducted.

(b) At the completion of an inspection where the Department finds a deficiency(ies) at a facility, the Department will do a corrective action plan. The Department will solicit input from the certified shellfish dealer, plant supervisor or the designated representative. The consent and cooperation of the certified shellfish dealer, plant supervisor or the designated representative is not necessary for the creation of a corrective action plan by the Department nor will the lack of cooperation from the certified shellfish dealer, plant supervisor or the designated representative affect the plans' validity or requirement that the plan be implemented. A copy of the inspection report (DACS 15009, Revision 06/01) and the corrective action plan (DACS 15012, Revision 06/01) will be given to one of the following individuals who is present in the facility at the time the inspection is concluded: the plant supervisor, the certified shellfish dealer, or the designated representative. The certified shellfish dealer, plant supervisor, and the designated representative shall comply with the corrective action plan as outlined on Form DACS-15012, Revision 06/01 that is given to the certified shellfish dealer, plant supervisor or the designated representative of the plant at the end of the inspection. The certified shellfish dealer, plant supervisor, or the designated representative's failure to comply with the corrective action plan outlined on Form DACS-15012, Revision 06/01 will lead to a fine, suspension, or revocation of the certified dealer's certificate.

(c) If upon inspection of a facility by an employee of the Department it is determined that there are "Critical", "Key", or "Other" deficiency(ies) of the facility, the following schedule will be used by the Department with respect to the administrative actions to be taken:

Critical deficiency(ies)

When a "Critical" deficiency(ies) is detected, operations affected by the "Critical" deficiency will be suspended and the deficiency will be corrected during the inspection or the firm's certification license to operate shall be immediately suspended as a public health threat. If the certification license to operate is suspended, it will remain suspended until corrections are made and verified by Department inspection. Product affected by the "Critical" deficiency will be controlled to prevent contaminated or adulterated product from reaching consumers. The Department will mandate a recall of the product from the market by the certified shellfish dealer and notify necessary officials of the recall.

In addition to these actions the sanction to be imposed on a certified shellfish dealer upon the finding of repeat "critical" deficiency(ies), after the initial inspection that leads to the certificate being issued, will be as follows:

Repeat "Critical" deficiency(ies)	The certified shellfish dealer will be fined \$500.00 per violation.
2nd repeat "Critical" deficiency(ies)	The certified shellfish dealer will be fined \$1,000.00 per violation.
3rd repeat "Critical" deficiency(ies)	The certified shellfish dealer will be suspended for 7 days.
4th repeat "Critical" deficiency(ies)	The certified shellfish dealer license will be revoked for the remainder of the certification period.

Key deficiency(ies)

The sanction to be imposed on a certified shellfish dealer upon the finding of repeat "Key" deficiency(ies), after the initial inspection that leads to the certificate being issued, will be as follows:

Repeat "Key" deficiency(ies)	The certified shellfish dealer will be fined \$100.00 per violation.
2nd repeat "Key" deficiency(ies)	The certified shellfish dealer will be fined \$200.00 per violation.
3rd repeat "Key" deficiency(ies)	The certified shellfish dealer will be suspended for 7 days.
4th repeat "Key" deficiency(ies)	The certified shellfish dealer will be

5th repeat "Key" deficiency(ies) suspended for 14 days.
The certified shellfish dealer license will be revoked for the remainder of the certification period.

Other deficiency(ies)

A warning letter will be sent to a certified shellfish dealer upon the finding of 5 or more "Other" deficiencies. The sanction to be imposed on a certified shellfish dealer upon the finding of repeat "Other" deficiency(ies), after the initial inspection that leads to the certificate being issued, will be as follows; after 5 or more "other" item deficiencies:

Repeat "Other" deficiency(ies) The certified shellfish dealer will be fined \$25.00 per violation.

2nd repeat "Other" deficiency(ies) The certified shellfish dealer will be fined \$50.00 per violation.

3rd repeat "Other" deficiency(ies) The certified shellfish dealer will be fined \$75.00 per violation.

4th or subsequent repeat "Other" deficiency(ies) The certified shellfish dealer will be fined \$100.00 per violation.

(d) In those cases involving no fine, suspension or revocation, a warning letter will be sent to the certified dealer along with a notice of rights, which states that a dealer may contest the warning letter by requesting an administrative hearing to be conducted in accordance with Sections 120.569 and 120.57, F.S., when the establishment has 3 or more "Key" item deficiencies cited in violation of Chapter 5L-1, F.A.C., or when an establishment has 2 "Key" item deficiencies and 3 "Other" item deficiencies cited in violation of Chapter 5L-1, F.A.C., or 1 "Key" item deficiency and 4 "Other" item deficiencies cited in violation of Chapter 5L-1, F.A.C. In cases involving the imposition of a fine the Department will forward an administrative complaint to the certified shellfish dealer, a proposed settlement offer and a statement of rights. In cases involving the imposition of a suspension or revocation of a certified shellfish dealer's license the Department will forward an administrative complaint, a statement of rights and a proposed settlement agreement to the certified shellfish dealer except when the Department has to immediately suspend a certification license because of an immediate public health threat. Payment of fines owed to the Department must be made within 22 days of the receipt by the certificate holder of the notice imposing the fine absent a request for a hearing on the matter pursuant to Chapter 120, F.S.

(e) A renewal of a firm's certificate will not be made if there are any unpaid fines with respect to prior certification periods.

(2) The Department or its agents shall summarily suspend a certification license if it is determined that there is an immediate serious danger to the public health, safety, or welfare requiring such emergency action. The Department shall, at the time the emergency action is taken, initiate proceedings as provided in Section 120.60, F.S.

(3) Upon suspension or revocation of a certification license, the Department shall notify the U.S. Food and Drug Administration so that the dealer's business name and certification license number may be removed from the Interstate Certified Shellfish Shippers List. Upon reinstatement of the license, the Department shall notify the U.S. Food and Drug Administration so that the dealer's business name and certification license number may be reinstated on the Interstate Certified Shellfish Shippers List.

(4) When an employee of the Department finds, or has reason to believe, that any equipment which is located at a licensed facility is in violation of this chapter so as to be dangerous or unsanitary within the meaning of this chapter, an employee of the Department may issue and enforce a stop-sale, stop-use, removal, or hold order, which order gives notice that such equipment is, or is suspected of being, in violation and has been detained or embargoed and which order warns all persons not to remove, use, or dispose of such equipment by sale or otherwise until permission for removal, use, or disposal is given by the Department or the court. It is unlawful for any person to remove, use, or dispose of such detained or

embargoed equipment by sale or otherwise without such permission.

(5) Settlement and Additional Enforcement Remedies. In determining the appropriate disciplinary penalty the Department will consider the compliance record of the violator. The provisions of this rule shall not be construed to limit the authority of the Department to enter into settlement with any party per Section 120.57(4), F.S., or to prohibit additional administrative remedies or civil actions. Settlement agreements can provide for installment payments and costs for up to six months. The Department will enforce a failure to comply with a settlement agreement with the penalties and remedies provided in the settlement agreement or as authorized by law.

Specific Authority 500.121(1), 500.172, 597.020 FS. Law Implemented 500.121(1), 500.172, 597.020 FS. History--New 1-4-87, Amended 8-10-88, 7-9-89, Formerly 16R-7.009, Amended 7-3-95, 2-6-97, Formerly 62R-7.009, Amended 8-9-00, 5-29-02.

5L-1.007 Container Identification, Terminal Sale Date; Prohibitions.

(1) Shucked shellfish container – The packer’s or repacker’s shellfish processing plant certification license number preceded by the state abbreviation must be embossed, imprinted, lithographed, or otherwise permanently and legibly recorded on the external body of containers or on the lid if the lid becomes an integral part of the container during the sealing process (Example: FL-872-SP). Containers shall permanently indicate type of product, quantity, and name and address of packer, repacker, or distributor. Containers of fresh shellfish, with a capacity of less than 64 ounces, shall further clearly and permanently bear the terminal sale date, by the numerical month, day, and last digit of the year. Containers of fresh shellfish with a capacity of 64 ounces or more, shall bear the actual shucking date by numerical month, day, and last digit of the year, in that order (Example: 01015). Reusable bulk storage containers shall be identified with state of origin, harvest date, and shuck date. Containers of frozen or previously frozen shellfish shall further clearly and permanently bear the date of shucking by numerical month, day, and last digit of the year, in that order (Example: 02097). Previously frozen shucked shellfish shall also have the freeze date and the thaw date following the same format. The terminal sale date for previously frozen shucked shellfish will be calculated by adding the day of shucking plus amount of time under refrigeration if not frozen, and adding the days that the product has been held thawed. Repacked shellfish containers shall also bear an appropriate code identifying the original packer. If oysters exceed the time limit for refrigeration found in subsections 5L-1.008(5), (6), F.A.C., the shucked shellfish container may be identified with the language “FOR COOKING ONLY”.

(2) Each commercial harvester or each certified shellfish dealer shall affix a durable, waterproof tag of minimal size – 2 5/8 by 5 1/4 inches – to each container of shellstock; for commercial harvesters this shall be done at each harvest location; for certified shellfish dealers this shall be done after final packing. In the case where a certified shellfish dealer is also the harvester, that dealer’s tag may also be used as the harvester’s tag.

(3) The commercial harvester’s tags shall contain legible waterproof indelible information arranged in the specific order as follows:

- (a) The harvester’s saltwater product license number or aquaculture certificate number;
- (b) The date of harvesting;
- (c) The time of harvest;
- (d) The time of refrigeration, if applicable;
- (e) The identification of the harvest area using the four digit area number or name of the harvest area listed in subsection 5L-1.003(11), F.A.C., as well as the most precise identification within that area as practicable;
- (f) Common name of shellfish and quantity of shellfish;
- (g) The following statement will appear in bold capitalized type “THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.”

(4) Bulk tagging is allowed for those aquaculturists operating with an aquaculture certificate. A bulk tag, containing the information required in paragraphs (3)(a)-(g), along with the name of the certified shellfish dealer which the product is consigned to, shall be completed at each harvest location.

(5) Bulk tagging, by a certified shellfish dealer, while washing, packing, during depuration, wet storing, staging and intrastate transport of shellfish is permissible up to final packaging only when the lot container (i.e., pallet), contains shellfish which are harvested on the same day, from the same harvest area, and have the same intended use (i.e., for halfshell consumption, for shucking, or for further processing), and is tagged as follows:

(a) The statement “All Shellfish containers in this lot have the same date and area of harvest, as well as the same intended use”,

(b) Harvest date,

(c) Harvest area,

(d) Original Dealer/Shipper identification,

(e) Number of units in this lot container.

(6) The dealer’s tag shall contain legible, waterproof, indelible information arranged in the specific order as follows:

(a) The shellfish shipper, shucker-packer, repacker, depurator, or distributors name, address, processing plant certification number;

(b) The original shipper’s certification number including the state abbreviation;

(c) The date of harvesting;

(d) The identification of the harvest area, and for Florida harvest areas the four digit code or name of the harvest area found in paragraph (3)(e) above;

(e) Common name of shellfish and quantity of shellfish; and

(f) The following statement will appear in bold capitalized type “THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS.”

(g) For oyster shellstock harvested from the Gulf of Mexico, the terminal sale date as a numeric date depicting month, day, and last digit of the year, not to exceed 14 days after the harvest date, or the statement “Sell Within 14 days of the Harvest Date”.

(h) If shellstock exceeds the time limit for refrigeration found in subsections 5L-1.008(5) and (6), F.A.C., the shellstock dealer tag shall be identified with the language “FOR SHUCKING ONLY BY A CERTIFIED DEALER” or “FOR COOKING ONLY”.

(i) For depuration processors, paragraphs (a), (d), (e), and (f) are required as well as the date of processing, and the depuration cycle number.

(j) For shellstock wet stored the following statement: “This product was wet stored on or at (Lease # or Facility certification number) from (date) to (date)”.

(7) Containers of treated shellfish from depuration facilities shall be tagged in accordance with item (6) in addition to the lot number and date shellfish were released from the treatment plant.

(8) Shellfish identification, out-of-state – No shellfish from sources outside of Florida shall be brought into the state for purpose of resale or public distribution unless the product bears evidence of certification from the state or nation of origin and certification is based on requirements similar to those outlined in this chapter.

(9) In addition to the identification and labeling requirements of subsections (1) and (2), containers of fresh, frozen, previously frozen or repacked shellfish or containers of shellstock must indicate the state of origin of the shellfish, e.g., LA, MS, TX. For shellstock this requirement can be by paragraphs (6)(a) and (b) above.

(10) Shellstock and shucked shellfish containers shall be labeled with the following statement: “CONSUMER INFORMATION There is a risk associated with consuming raw shellfish. If you have chronic illness of the liver, stomach or blood or have immune disorders, you are at greater risk of serious illness from raw shellfish and should eat shellfish fully cooked. If unsure of your risk, consult a physician.”

(11) It shall be unlawful for any person, firm, corporation, wholesale or retail dealer to sell or offer for sale any fresh shellfish after the terminal sale date has expired, or sell or offer for sale any fresh, frozen, or previously frozen shellfish not in compliance with any and all requirements of Chapter 5L-1, F.A.C.

(12) Whoever knowingly or willfully alters or damages in any manner, or loans or transfers to another person any certification license number or shellfish tags, or any person who uses the certification license or shellfish tags, other than the person to whom they were issued, shall be in violation of this section and shall be subject to certification license suspension or revocation in addition to any other penalty for violation of Chapter 5L-1, F.A.C.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 5-21-87, 8-10-88, 7-9-89, 8-30-89, 5-6-93, 9-14-93, 8-21-94, Formerly 16R-7.010, Amended 9-1-95, 5-8-96, 2-6-97, 10-12-97, 2-12-98, 2-25-98, 7-1-98, 11-13-98, 12-28-98, 3-18-99, 7-1-99, Formerly 62R-7.010, Amended 6-19-00, 8-9-00, 10-14-01, 5-29-02, 8-17-04, 9-28-04, 7-28-08, 7-29-08.

5L-1.008 Shellfish Handling.

(1) Wet storage shall be conducted upon execution of an agreement between a person, firm, or corporation possessing a shellfish processing plant certification license and the Department. Each agreement shall include the following provisions:

(a) The coordinates in Latitude and Longitude where the facility is to be located.

(b) A description of all facilities and equipment to be used to wet-store shellfish.

(c) A listing of the species to be wet-stored.

(d) If the wet storage facility is to be located upon or in waters of the state, the facility shall be marked and lighted so as not to be a hazard to navigation.

(e) If the wet storage facility is to be located on or in waters of the state, and is to be a manned structure, it shall be equipped with a U.S. Coast Guard approved Type III marine sanitation device; this device shall be maintained in working order and be used by all personnel for disposal of bodily wastes.

(f) All solid wastes shall be removed from the wet storage facility daily and disposed of in a shore-based receptacle.

(g) No anti-fouling paints or finishes shall be used on any portion of the wet storage facility.

(h) No shellfish shall be removed from a wet storage facility when the shellfish harvesting area in which such shellfish are stored is closed pursuant to Rule 5L-1.003, F.A.C., or because of emergency conditions as defined by Rule 5L-1.002, F.A.C.

(i) Should maintenance of the wet storage facility require that the facility be relocated, written notification shall be provided to the Department, by certified mail, a minimum of 10 working days prior to such relocation. All shellfish shall be removed from the facility prior to relocation.

(j) If wet storage is to be practiced using a shore-based facility, the applicable provisions of Rules 5L-1.002, 5L-1.010, 5L-1.011, 5L-1.012, 5L-1.013, subsections 5L-1.015(2), (3), (4), (5), (6) and (7), and Rules 5L-1.017 and 5L-1.018, F.A.C., shall apply. All shore-based facilities shall employ ultraviolet light treatment of all incoming and recirculated seawater. All water quality measurements required by Rule 5L-1.017, F.A.C., shall be documented and such data retained for inspection by the Department for a minimum of one year. Paragraphs 5L-1.008(1)(a), (b), (d), (e), (f), (h), and (i), F.A.C., shall not apply to a shore-based facility.

(k) The agreement shall be valid for no more than 1 year from the date it is signed by the Department.

(2) Boats and vehicles – Boats and vehicles used in harvesting or transporting shellfish shall be constructed, operated, and maintained, so as to protect the shellfish from contamination. Fuel tanks or other sources of contamination shall not be permitted to come into contact with shellfish. All boats used for commercial harvesting and handling shellfish shall be designed in such a way to prevent shellfish from coming in contact with any bilge water. No dogs or other animals or pets shall be allowed at any time on vessels or vehicles used to harvest or transport shellfish. No bodily wastes shall be discharged overboard from a harvest vessel. Shellstock harvested with commercial intent shall be protected by effective shading

on harvest boats and vehicles to protect shellstock from exposure to sun, birds, and other adverse conditions. Shellfish shall be held under conditions which allows air circulation and promotes evaporative cooling.

(3) Boats engaged in harvesting or transporting shellfish shall have on board an approved Type III marine sanitation device, portable toilet or other sewage disposal receptacle. Portable toilets shall:

(a) Be constructed of high quality plastic that is durable, easy to clean and will not spill;

(b) Be used only for the purpose intended;

(c) Be secured while on board the vessel and located to prevent contamination of shellstock by spillage or leakage;

(d) Be emptied only into an appropriate sewage disposal system;

(e) Be cleaned before being returned to the boat; and

(f) Not be cleaned with equipment used for washing or processing food.

(4) Use of other receptacles for sewage disposal are approved if the receptacles are constructed of impervious, cleanable materials, have tight fitting lids, and meet the requirements of paragraphs 5L-1.008(3)(a)-(e), F.A.C.

(5) Throughout the year, it is harvester's responsibility that shellfish shall be harvested between sunrise and sunset as established by the U.S. Weather Service. During the months of November, December, January, February, and March, the harvester shall assure that shellfish shall be delivered to a certified shellfish dealer by 10:00 p.m. of the same day as harvest. During the months of April, May, and October, harvesters shall assure that oysters or clams shall be delivered to a certified shellfish dealer within twelve (12) hours of the time of harvest. During the months of June, July, August, and September, the harvesters shall assure that oysters shall be delivered to a certified shellfish dealer within five (5) hours of the time of harvest. During the months of June, July, August, and September, the harvester shall assure that clams shall be delivered to a certified shellfish dealer within ten (10) hours of the time of harvest, or within the same day as harvest, whichever is earlier. All shellfish shall be delivered directly to a certified shellfish dealer possessing a shellfish processing plant certification license.

(6) Once received by a certified shellfish dealer, the shellstock lot shall be immediately processed and placed under temperature control and until sale to final consumer, the shellstock shall be maintained at an environmental temperature of 45° F or less and not be permitted to remain outside of temperature control for more than 2 hours cumulative at points of transfer within the processing plant such as loading docks or in the plant during processing except for the process described in paragraph 5L-1.013(3)(b), F.A.C.

(7) Shellfish leaving a certified shellfish dealer must be transported in an enclosed, refrigerated conveyance with doors closed securely. The refrigeration unit must be capable of maintaining an ambient temperature of 45 degrees F or less at all times.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 5-21-87, 8-10-88, 7-9-89, Formerly 16R-7.011, Amended 7-3-95, 2-6-97, 3-18-99, 6-23-99, Formerly 62R-7.011, Amended 8-9-00, 5-29-02, 7-29-08.

5L-1.009 Shellfish Relaying.

(1) No person, firm, corporation, municipality, association, or other governmental body shall engage in shellfish relay operations without first obtaining a "Special Activity License to Relay Shellfish" from the Department.

(2) A Special Activity License to Relay Shellfish may be issued to any person, firm, corporation, municipality, or other governmental body or agency holding a shellfish lease, aquaculture lease, or owning or operating a depuration plant, and whose past record indicates that they can be bonded and are responsible to oversee and assure compliance with all rules and licenses. A Special Activity License to Relay Shellfish may be issued to an association when the Department has public funds appropriated for relaying shellfish to public areas.

(3) Anyone wishing to conduct shellfish relaying operations shall provide the Department, upon application form entitled "Application for A Special Activity License to Relay Shellfish", Form Number DACS 15109, Revision 05/01, available from the Department of Agriculture and Consumer Services, 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301, and herein incorporated by reference, with the following information:

(a) Name, address, telephone number, and instructions for contacting person or persons responsible for relaying operations;

(b) Species of shellfish to be moved;

(c) Anticipated amount of shellfish to be moved;

(d) Method of harvesting, that is raking, tonging, treading, or diving;

(e) Areas from which shellfish will be moved;

(f) Areas to which shellfish will be moved;

(g) Method of transportation;

(h) Number of crews to be involved in the relay operation;

(i) The colors and design of flags to be used pursuant to paragraph 5L-1.009(4)(r), F.A.C.; and

(j) Laboratory secured for collection and laboratory analysis according to paragraph 5L-1.009(4)(p), F.A.C., for shellfish leases and aquaculture leases and according to Rules 5L-1.016 and 5L-1.017, F.A.C., for depuration facilities.

(4) The Department, after reviewing the application and finding the plan in compliance with all applicable rules and regulations, and determining that the activity will not degrade, destroy or affect marine resources, shall issue a Special Activity License to Relay Shellfish within the general conditions set forth below:

(a) The Department is authorized to establish the effective date and expiration date of the "Special Activity License to Relay Shellfish". In no case shall the expiration date be greater than one year from the effective date.

(b) Shellfish relaying shall be conducted only during daylight hours, commencing at official sunrise and ending at official sunset, as established by the U.S. Weather Service, except as defined by subparagraph 5L-1.009(4)(n)5., F.A.C., under approved law enforcement, licensed security guard monitoring, or under the supervision of the Department. All persons involved in harvest, transport, and relaying shall comply with these rules and license conditions. Harvesters shall remain within the immediate control and observation of a monitor at all times. No more than 15 watercraft shall be under the supervision of a monitor at any time. The requirement for a monitor is not necessary when an association is conducting shellfish relaying to public areas in conjunction with Department supervision using public funds.

(c) All persons operating under a "Special Activity License to Relay Shellfish", shall comply with all applicable shellfish rules, regulations, and specific license conditions listed on the "Special Activity License to Relay Shellfish", under which he/she is operating.

(d) The licensee and person named as being responsible, shall be lawfully responsible for all activities conducted under the conditions of the "Special Activity License to Relay Shellfish" and applicable rules and regulations.

(e) The licensee must notify the local Marine Enforcement District Office of the Florida Fish and Wildlife Conservation Commission and the Department within twelve (12) hours by telephone and in writing by certified mail or hand delivery, within three days of any changes in ownership or person named as being responsible for the activities conducted under the conditions of the "Special Activity License to Relay Shellfish".

(f) The Licensee shall use only Department approved monitors, as specified by subsection 5L-1.009(5), F.A.C., to supervise relay harvesting, relay transport operations, placement on permitted site, and completion of required relay reports.

(g) Approved monitors must have completed the Department monitor training course and have a current "Department Approved Monitor Identification Card" showing successful completion of the course.

(h) Approved monitors shall have in their possession and available for immediate inspection, a current "Department Approved Monitor Identification Card" and a valid picture identification card during relay operations, available for immediate inspection.

(i) Approved monitors shall have in their possession a complete copy of the valid "Special Activity License to Relay Shellfish", including complete copies of all licenses of each licensee who participates in a relay crew when the relay crew is comprised of more than one licensee, available for immediate inspection during any phase of relay operation. The copy(ies) shall be supplied by the licensee(s) or person(s) named as being responsible.

(j) Harvesters shall harvest shellfish within one hundred yards of the approved monitor, and remain under the immediate supervision and unobstructed view of the approved monitor, except as described in subparagraph 5L-1.009(4)(n)13., F.A.C.

(k) No more than fifteen (15) harvesters shall comprise one crew and not more than one crew shall be under the immediate supervision of an approved monitor, except as described in subparagraph 5L-1.009(4)(n)3., F.A.C.

(l) Relay teams that are treading or using rakes and/or tongs shall remain at a distance greater than 100 yards from any diving relay team that is in operation.

(m) Seagrasses shall not be disturbed.

(n) If relay harvesting is to be conducted by divers, the following additional conditions shall apply:

1. Any harvester who wishes to engage in a diving operation shall be required to obtain an "Underwater Shellfish Harvester Certificate" from the Florida Marine Enforcement District Office of the Florida Fish and Wildlife Conservation Commission, in which geographic area the harvester works. No certificate shall be issued to any applicant with a conviction of harvesting in a restricted, conditionally restricted, prohibited, or unclassified area within one year prior to application. No certificate shall be issued to any applicant who is not a certified diver.

2. It shall be unlawful for a diver to harvest shellfish on a relay crew without an "Underwater Shellfish Harvester Certificate" issued by the Florida Marine Enforcement District Office in which geographic area harvesting occurs.

3. A diver relay crew shall not be comprised of more than five divers, and not more than one crew shall be under the immediate supervision of an approved monitor.

4. Diving shall be the only method used by a team. Other harvesting methods, such as raking or tonging from a vessel or treading, shall not be permitted by a team employing diving.

5. The use of self contained underwater breathing apparatus (SCUBA) is not permitted.

6. The air supply shall come from the surface and consist of an apparatus which is supported by flotation, and used by no more than two harvesters at a time.

7. The air line from the apparatus to each diver shall not exceed 150 feet in length.

8. A designated diver's apparatus must be tethered to the approved monitor's vessel to provide a means of communication. The designated diver will provide communication for the approved monitor to the other divers.

9. Diver down flags shall be utilized as prescribed by Section 861.065, F.S. In addition, each diver shall have a diver's down flag on any flotation device designating the diver's approximate location.

10. Flags, as required by paragraph 5L-1.009(4)(r), F.A.C., shall be flown on the vessels and not on the flotation device used to support a compressor.

11. Each diver shall have in his possession, while in the water, a maximum of one container at any time. No other container of any type shall be allowed with the diver while in the water.

12. Harvesters shall remain within 100 yards of the approved monitor's vessel.

13. Relay teams shall remain more than 100 yards from any other relay team.

(o) Relayed shellfish shall be delivered directly to the designated license location on the same day of harvest. Diverting shellfish to any other source or location is prohibited.

(p) If shellfish are relayed to a lease in Approved or Conditionally Approved areas, they shall not be

harvested without written permission from the Department. Permission will be granted only after a minimum of 15 days have elapsed to allow the shellfish to cleanse themselves, and this cleansing is verified by laboratory analysis. The fifteen days will commence when the Department receives the licensee's "Special Activity License to Relay Shellfish" for cancellation. The fifteen day period does not include days that shellfish harvesting areas have been temporarily closed to harvest. Laboratory analysis shall consist of a minimum of five samples (each sample to consist of a minimum of 12 individual shellfish), collected by an employee of a laboratory with a current Department certification letter or staff of the Department. Four samples are to be collected from four corners of the lease and one sample collected from approximately the center of the lease. High-density aquaculture lease areas will be treated as a single entity pursuant to subparagraphs 5L-1.009(4)(s)3. and 8., F.A.C., for sampling. The Department will collect and analyze samples for shellfish relaying to public areas in conjunction with Department supervision using public funds. The laboratory must be certified by the Department State Laboratory Certification Officer pursuant to Guidance document A.11 of the National Shellfish Sanitation Program Model Ordinance and the Shellfish Laboratory Evaluation Checklist (1995), published by the U.S. Food and Drug Administration, which is hereby incorporated by reference and available for inspection at the Department's offices located at 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301. Laboratory analysis shall include approved methods for fecal coliform bacteria and standard plate count. The bacteriological quality of the relayed shellfish shall be equal to or better than shellfish of the same species harvested from nearby Approved or Conditionally Approved areas. If shellfish are being relayed due to marine biotoxins, laboratory analyses shall include mouse bioassays for toxin. The toxin level must be less than 20 mouse units. Aquacultured shellfish are the only shellfish allowed to be relayed due to marine biotoxins. Relaying for marine biotoxins is only allowed within the following four specific geographic regions of the state: (1) Escambia County through Jefferson County; (2) Taylor County through Levy County; (3) Citrus County through Monroe County; (4) Dade County through Nassau County. Relaying due to marine biotoxins between these specific geographic regions is prohibited. The holder of the "Special Activity License to Relay Shellfish" must coordinate with the certified laboratory and other persons or agencies that these criteria are met and communicate this information to the Department. Upon verification that the criteria have been met the Department will issue the written permission in the form of a letter.

(q) Shellfish relaying from Florida waters to another state or country, or from the waters of another state or country to Florida waters or a licensed depuration plant, is prohibited.

(r) Persons engaged in relaying operations shall fly a flag on their vessel, the color of which was applied for and approved by the Department in the "Special Activity License to Relay Shellfish". The flag will be a rigid flag, minimum size of 12 inches high by 18 inches wide. Only one color design will be approved for each license, except as provided in sub-subparagraph 5L-1.009(4)(s)4.a.-d., F.A.C. The flags will be free standing and identifiable from the air and the water. The vessel which contains the Department approved monitor will fly a flag of the same description as before described but differentiated by two, three (3) inch wide strips, of contrasting color to the flag, extending diagonally from corner to corner, forming an X. Individual flags shall be mounted such that the entire flag extends a minimum of 2 feet higher than the highest point on the craft.

(s) Special conditions shall apply to high-density aquaculture lease areas, to relaying and transport operations, laboratory sampling, and harvesting when more than one person or licensee participates on a relay crew composed of other persons or licensees from the same high-density aquaculture lease area.

1. The "Application for a Special Activity License to Relay Shellfish" pursuant to subsection 5L-1.009(3), F.A.C., shall incorporate the following additional information:

- a. The description of the high-density aquaculture lease area, and
- b. The description of the aquaculture lease in the high-density aquaculture lease area.

2. The Department shall establish an expiration date pursuant to paragraph 5L-1.009(4)(a), F.A.C., which shall be the same for all applicants for Special Activity Licenses to Relay Shellfish who participate in relays to high-density aquaculture lease areas.

3. For a high-density aquaculture lease area to be considered as a single entity for laboratory sampling and harvesting, all relaying activity must be terminated by the designated expiration date. The number of participating licensees shall be determined by the number of applicants using the same expiration date and the number of participants is limited by the number of individual aquaculture leases located in the high-density aquaculture lease area. When an expiration date has been established for relaying to a high-density aquaculture lease area, all applicants shall terminate relay activities on or before the established expiration date regardless of the effective date of the Special Activity License to Relay Shellfish; except when a single licensee surrenders the Special Activity License to Relay Shellfish for cancellation and harvests shellfish pursuant to paragraph 5L-1.009(4)(p), F.A.C.

4. Persons or licensees participating on relay crews composed of other persons or licensees from the same high-density aquaculture lease area shall fly a flag on their vessel pursuant to paragraph 5L-1.009(4)(r), F.A.C., except:

a. Only one color design will be approved for each high-density aquaculture lease area when relay crews are composed of more than one licensee.

b. Each vessel shall also fly a flag or banner, the color and design of which is designated and provided by the approved monitor.

c. The licensee shall maintain possession of the flag designated in the Special Activity License to Relay Shellfish.

d. The approved monitor shall maintain possession and have available the designated monitor flag and provide such flags or banners to all persons or licensees participating on relay crews under his/her immediate supervision during the days activity.

5. No more than 15 boats or licensees shall comprise a relay crew from the same high-density aquaculture lease area and not more than one crew shall be under the immediate supervision of an approved monitor, except as described in subparagraph 5L-1.009(4)(n)3., F.A.C.

6. All participating licensees shall surrender their Special Activity License to Relay Shellfish to the Department for cancellation on the same date.

7. Shellfish relayed to high-density aquaculture lease areas in Approved or Conditionally Approved areas shall not be harvested without written permission from the Department pursuant to paragraph 5L-1.009(4)(p), F.A.C., except the 15 days will commence when the Department receives all participating licensees' "Special Activity License to Relay Shellfish" for cancellation.

8. High-density aquaculture lease areas will be treated as a single entity pursuant to subparagraph 5L-1.009(4)(s)3., F.A.C., for laboratory sampling when all participating licensees have surrendered their Special Activity License to Relay Shellfish pursuant to subparagraph 5L-1.009(4)(s)6., F.A.C. Laboratory analysis shall consist of a minimum of five samples (each sample to consist of a minimum of 12 individual shellfish), collected by an employee of a laboratory with a current Department certification letter or staff of the Department. Four samples are to be collected from individual aquaculture leases located most proximate to the four corners of the high-density aquaculture lease area and one sample collected from an individual lease located near the center of the high-density aquaculture lease area.

9. Shellfish relayed under the provisions of paragraph 5L-1.009(4)(s), F.A.C., shall not be harvested without written permission from the Department as defined in paragraph 5L-1.009(4)(p), F.A.C., and permission to harvest by individual licensees shall be denied until all participating licensees receive written permission to harvest.

(5) Requirements for Department approved monitors include the following:

(a) Department approved monitors must be current "Certified Law Enforcement Officers" or licensed "Class D Security Guards" working for a licensed "Class B Security Agency", hired by a "Special Activity License to Relay Shellfish" licensee, or staff of the Department. Staff of the Department, who are not "Certified Law Enforcement Officers", shall monitor only relay operations directed and supervised by the Department during cooperative shellfish resource development programs. Staff of the Department shall monitor shellfish relays to licensed leases pursuant to paragraphs 5L-1.009(4)(g)-(i), subsection 5L-

1.009(5) and paragraph 5L-1.009(6)(b), F.A.C.

(b) Applicants shall not possess a current Shellfish License or upon application for training they must surrender their Shellfish License.

(c) It shall be unlawful for any approved monitor to be involved in any other activities within the commercial shellfish industry.

(d) Department approved monitor training will consist of a course developed and approved by the Florida Marine Enforcement and the Division of Aquaculture. The course shall cover the responsibilities of the approved monitor, shellfish laws, shellfish relay license rules, water classifications, health issues and other information deemed necessary by the Department. Training shall be conducted by Department personnel, as follows:

1. Initial training will consist of weekly courses for a period of two months if sufficient applicants apply to fill classes of twenty students. Applicants need to attend only one of the weekly courses.

2. A training course will be scheduled every six months.

3. Contracted licensed security agencies and licensees to relay shellfish will receive written notification of training dates and where the courses will be conducted.

4. An applicant who completes the course satisfactorily will be issued a "Department Approved Monitor Identification Card" in his or her name. The Identification Card will bear an expiration date that coincides with eligibility requirements established for a Department approved monitor. This identification card will expire on the expiration date printed on the identification card, or in no case longer than one year from the date of issue. The identification card will be renewed only after satisfactory completion of the training course.

(e) A Department approved monitor whose identification card has expired may reapply and will be issued a new identification card with a new expiration date if he or she meets the eligibility requirements established for a Department approved monitor.

(6) Penalty for violation of Rule 5L-1.009, F.A.C.

(a) An approved monitor's failure to supervise shellfish relay operations, complete required reports, and comply with the requirements of Rule 5L-1.009, F.A.C., and the "Special Activity License to Relay Shellfish", will result in the suspension of his authorization to act as a Department approved monitor.

(b) A diver, who is permitted by the Florida Marine Enforcement to harvest shellfish on a relay crew, will have his "Underwater Shellfish Harvester Certificate" suspended for any conviction of violating subparagraphs 5L-1.009(4)(n)1.-13., F.A.C. The suspension will be for one year from the date of conviction.

(c) A "Special Activity License to Relay Shellfish" will be revoked for:

1. Any conviction for violation of diverting shellfish to any location other than specified on the license.

2. Any conviction for violation of depuration periods specified by law for relayed shellfish or sale of relayed shellfish prior to written authorization by the Division of Aquaculture.

3. Second conviction for violation of harvesting shellfish from any waters not approved by the license.

4. Four separate instances involving convictions for violations, other than subparagraphs 5L-1.009(6)(d)1., 2., and 3., F.A.C., within any six month period.

(d) Pursuant to Section 120.60(7), F.S., prior to the entry of a final order revoking a "Special Activity License to Relay Shellfish", the Department will serve an administrative complaint which affords reasonable notice to the licensee of facts or conduct which warrant the intended action and the licensee is given an adequate opportunity to request a proceeding pursuant to Section 120.57, F.S.

(e) A "Special Activity License to Relay Shellfish" will be revoked for the following periods:

1. First revocation of license will be for a minimum of thirty days.

2. Second revocation of license will be for a minimum of sixty days and continue until such time the licensee can show to the satisfaction of the Department that corrective measures have been taken to control violations.

3. Third revocation of license will be permanent. No other "Special Activity License to Relay

Shellfish” will be issued to a person, firm, corporation, municipality, or other governmental body holding a shellfish lease, aquaculture lease, or owning or operating a depuration plant whose “Special Activity License to Relay Shellfish” was revoked three times. After a six month period a new lease holder or owner or operator of a depuration plant must show to the satisfaction of the Department that corrective measures to control violations will be implemented prior to having an application considered.

(f) During periods of revocation no further “Special Activity License to Relay Shellfish” will be issued to a person, firm, corporation, municipality, or other governmental body holding a shellfish lease, aquaculture lease, or owning or operating a depuration plant who had their “Special Activity License to Relay Shellfish” revoked.

Specific Authority 597.020 FS. Law Implemented 597.010(15), (19), 597.020 FS. History—New 1-4-87, Amended 5-21-87, 8-10-88, 7-9-89, 12-23-91, 4-21-93, 5-20-93, 6-9-94, Formerly 16R-7.012, Amended 1-1-98, Formerly 62R-7.012, Amended 8-9-00, 5-29-02.

5L-1.010 Buildings and Facilities.

(1) Plant construction and design. Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food manufacturing purposes. At a minimum for shellstock, depuration and on shore wet storage operations, the structure shall have a sealed roof and screened walls. At a minimum, shucker-packer and repacker operators shall have a sealed roof, solid walls, and sealed flooring. The plant and facilities shall:

(a) Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food.

(b) Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.

(c) Be constructed in such a manner that floors, walls, and ceilings may be cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials; and that aisles or working spaces are provided between equipment and walls and are of such width to permit employees to perform their duties and to protect against contaminating food or food-contact surfaces with clothing or personal contact.

(d) Provide at least 110 lux (10 foot candles) in walk in refrigeration units, dry food storage areas and single service storage areas; at least 220 lux (20 foot candles) at any handwashing lavatory, warewashing and equipment and utensil storage, and in toilet rooms; at least 540 lux (50 foot candles) at the surface where a food employee is working with food or equipment or utensils such as knives or grinders where employee safety is a factor. This is considered adequate lighting for hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned. Light bulbs shall be shielded, coated or otherwise shatter resistant in areas where there is exposed food, clean equipment and utensils or unwrapped single service and single-use articles. Shielded, coated or otherwise shatter resistant bulbs need not be used in areas used only for storing food in unopened packages if the integrity of the packages can not be affected by broken glass falling onto the packages and the packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

(e) Provide adequate ventilation or control equipment to minimize air borne dust and particulates, odors and vapors in areas where they may contaminate food; and locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food, food-packaging

materials, and food contact surfaces.

(f) Provide screening or other protection to prevent the entrance of pests.

(2) Grounds about a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for maintenance of grounds include, but are not limited to:

(a) Storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant building or structures that may constitute an attractant, breeding place, or harborage for pests.

(b) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed.

(c) Draining areas that may contribute contamination to food by seepage, foot-borne filth, or providing a breeding place for pests.

(d) Operating systems for waste treatment and disposal in such a manner that they do not constitute a source of contamination in areas where food is exposed. If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in paragraphs (2)(a) through (c) of this section, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.

(3) The water supply shall be sufficient for the operations intended. Any water that contacts food or food contact surfaces shall be safe and of sanitary quality. Running water at a suitable temperature of 110° F or above, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food-packaging materials, or for employee sanitary facilities. Sanitary quality shall be maintained by the following steps:

(a) In plants that are not on a public water system, routine microbiological monitoring shall be conducted on water, and ice used in the plant, at least once every six months by the operator of the certified processing plant. The sample collected shall be from a tap that provides water for use in processing shellfish. When treatment includes disinfection, a source water standard bacterial sample must also be collected on the same day.

(b) Microbiological results from testing shall not equal or exceed two cfu (colony forming units) per 100 mls for total coliform bacteria on any consecutive samples, and shall not equal or exceed two cfu per 100 mls for fecal coliform or E. coli bacteria on any samples.

(4) Plumbing shall be of size and design and installed and maintained to:

(a) Carry sufficient quantities of water to required locations throughout the plant.

(b) Convey sewage and liquid disposable waste from the plant.

(c) Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition.

(d) Provide floor drainage in all areas where floors are subject to flooding-type cleaning.

(e) Provide that there is no backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.

(5) Sewage and all in-plant wastewater shall be discharged into a public sewage treatment system or other approved sewage treatment system in accordance with provisions of Chapter 64E-6, F.A.C.

(6) Each plant shall provide its employees with readily accessible toilet facilities. Compliance with this requirement shall be accomplished by:

(a) Maintaining the facilities in a sanitary condition.

(b) Keeping the facilities in good repair at all times.

(c) Providing self-closing doors.

(d) Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination, such as double doors or positive air flow systems.

(e) Providing toilet tissue.

(7) Handwashing facilities shall be furnished and easily accessible, where persons handle food, food packaging materials, or food contact surfaces, and include the following:

(a) Running water at a minimum temperature of 110 degrees F.

(b) Where persons handle food, food packaging materials, or food contact surfaces, hand-sanitizing facilities shall be furnished.

(c) Effective hand-cleaning and sanitizing preparations.

(d) Sanitary towels or drying devices.

(e) Readily understandable signs directing employees handling exposed food, unprotected food-packaging materials, or food-contact surfaces, to wash and sanitize their hands prior to handling these items. These signs shall be posted in the processing room at all hand wash stations and in all other areas where employees may handle such food, materials, or surfaces.

(8) Refuse receptacles shall be constructed and maintained in a manner that protects against contamination of food. Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pest, and protect against contamination of food, food-contact surfaces, water supplies, and ground surfaces.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 5-21-87, 8-10-88, Formerly 16R-7.013, Amended 7-3-95, 2-6-97, Formerly 62R-7.013, Amended 8-9-00, 5-29-02.

5L-1.011 Equipment for Shellfish Processing.

(1) All plant equipment and utensils shall be so designed and of such material and workmanship as to be cleanable, and shall be properly maintained. The design, construction, and use of equipment and utensils shall preclude the adulteration of food with contaminants. All equipment shall be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Food-contact surfaces shall be corrosion-resistant, made of nontoxic materials, and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds and sanitizing agents. Food-contact surfaces shall be maintained to protect food from being contaminated by any source.

(2) Seams on food-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

(3) Equipment that is used in the manufacturing or food-handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.

(4) Three compartment sinks shall be properly installed, maintained and provided with hot and cold running water to all three compartments in establishments required to wash, rinse and sanitize food contact surfaces. Signs shall be posted indicating proper use of the three compartment sink. A three compartment sink shall be used for washing, rinsing and sanitizing food contact surfaces and shall not be used for hand washing.

(5) Each freezer and cold storage compartment used to store and hold shellfish shall be mechanically refrigerated, nonportable and shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment, and should be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change.

(6) Compressed air or other gases mechanically introduced into food or used to clean food-contact surfaces or equipment shall be treated in such a way that food is not contaminated.

(7) Blowers – devices which use compressed air to circulate wash water around and through shucked shellfish shall be properly designed and constructed as to be easily dismantled for cleaning, examination, and repair.

(8) Blowing time – blowing time shall not exceed 15 minutes.

(9) Depuration tanks shall be designed to allow for good water circulation and prevent short-circuiting of the seawater. Tanks shall be designed so that scum and sludge, including shellfish feces and pseudo-feces, sand, and grit can be easily removed or flushed out. The bottom shall be sloped longitudinally at least 1/4 to 1/2 inch per foot toward the outlet end.

(10) To facilitate proper cleaning and sanitation, as well as proper treatment of shellfish, tanks shall be constructed from impervious, non-toxic, and inert materials. Coatings, when used, may include epoxy resins, powdered polyesters, vinyl bituminous water-tank paint, and paraffin. These coatings are not only for waterproofing but should provide a smooth, hard, non-porous surface to facilitate cleaning.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History--New 1-4-87, Amended 8-10-88, Formerly 16R-7.014, Amended 7-3-95, 5-8-96, 2-6-97, Formerly 62R-7.014, Amended 8-9-00, 5-29-02.

5L-1.012 Sanitary Operations.

(1) General maintenance. Buildings, fixtures, and other physical facilities of the plant shall be maintained and kept in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of this rule. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials.

(2) Cleaning compounds used in cleaning procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination.

(3) Only sanitizing agents found in Title 21, Code of Federal Regulations, Section 178.1010, revised as of April 1, 2000, hereby incorporated by reference and available for inspection at the Department's offices located at 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301, will be used at recommended levels in shellfish processing plants.

(4) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, used and stored in a manner that protects against contamination of food, food-contact surfaces, or food-packaging materials. Test kits that measure the concentration of sanitizing solutions shall be provided and used for verifying the proper sanitizing solution concentration.

(5) No pests shall be allowed in any area of a food plant. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions of product labeling.

(6) All food-contact surfaces, including utensils and food-contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.

(7) Non-food contact surfaces of equipment used in the operation of food plants shall be cleaned as frequently as necessary to protect against contamination of food.

(8) Single-service articles shall be stored in appropriate containers and/or in a clean dry location where they are not exposed to splash, dust or other contamination. Single-service articles shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food-contact surfaces.

(9) Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and sanitized.

(10) Cleaned and sanitized portable equipment with food-contact surfaces and utensils shall be stored in a location and manner that protects food-contact surfaces from contamination.

(11) 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.

(a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate handwashing facility before starting work, after each absence from the work station, after each work interruption and any time when their hands may have been soiled or contaminated.

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

(c) Any employee handling shucked shellfish shall be required to wear an effective hair restraint, remove any hand jewelry that cannot be sanitized and secured, wear finger cots or gloves if jewelry cannot be removed, wear clean outer garments which are rinsed or changed as necessary to be kept clean.

(d) In any area where shellfish are shucked or packed and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to store clothing or other personal belongings, eat or drink, spit and use tobacco in any form.

(12) Each certified dealer shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in subsection 5L-1.005(7), paragraphs 5L-1.010(1)(a) and (b), subsections 5L-1.010(6) and (7), 5L-1.011(1), 5L-1.012(1)-(11), 5L-1.013(6), (7), (8) and (9), and 5L-1.014(5), F.A.C.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History--New 1-4-87, Amended 8-10-88, Formerly 16R-7.015, Amended 7-3-95, Amended 2-6-97, 6-23-99, Formerly 62R-7.015, Amended 8-9-00, 5-29-02.

5L-1.013 Plant Operation.

(1) The plant shall operate in accordance with the HACCP plan designed and approved by the owner or corporate officers.

(2) Prior to acceptance of shellstock from a licensed harvester, certified shellfish dealer and/or certified aquaculturist, the certified shellfish dealer will ensure that shellstock are properly identified as specified in subsection 5L-1.007(3), F.A.C., are clean, wholesome, and alive.

(3) Upon acceptance of shellstock from a licensed harvester, certified aquaculturist or certified shellfish dealer, the receiving certified shellfish dealer shall determine the appropriate use of the shellfish through examination of shellfish labeling as follows:

(a) Shellfish which fails to meet the requirements of subsection 5L-1.008(5), F.A.C., or is labeled in compliance with paragraph 5L-1.007(6)(h), F.A.C., shall only be used for shucking by a certified shellfish dealer, or labeled "For Cooking Only", or shall undergo an alternative post harvest processing method to assure a safety level equivalent to product meeting subsection 5L-1.008(5), F.A.C.

(b) Tempering, as an alternative process shall consist of those methods which have demonstrated through verification studies that the process renders hard clams which are as safe as hard clams meeting subsection 5L-1.008(5), F.A.C. Prior to initiating tempering a certified shellfish dealer shall have written approval from the Department. The certified shellfish dealer must provide the following:

1. A description of all facilities, equipment and methods to be used in the alternative process. This process must be included in the firm's HACCP plan.

2. The source of hard clams and the maximum capacity of hard clams to undergo the process at any one time.

3. The process to be followed shall not exceed 16 hours total time between hard clam harvest and refrigeration at 45 degrees F or less. Product harvest, processing, tempering and food storage at 45 degrees F or less must be scheduled to occur as a continuous procedure.

4. Upon initiation, the tempering process must have temperature control of 68 degrees F or less and be maintained until hard clams are placed into refrigeration of 45 degrees F or less.

5. If facilities, equipment or methods change, the Department must be notified.

(c) Post Harvest Processing, including but not limited to such processes as frozen storage, hydrostatic

high pressure, mild pasteurization, and irradiation, shall consist of those methods which have demonstrated through validation studies that the process renders shellfish at least as safe as shellfish meeting subsection 5L-1.008(5) and (6), F.A.C. Prior to initiating post harvest processing, a certified shellfish dealer shall provide validation and obtain written approval from the Department.

(4) Shellfish shall be segregated by the certified shellfish dealer in accordance with its intended use as determined in paragraphs (3)(a) and (b) above and identified per subsection 5L-1.007(5) or (6), F.A.C.

(5) Unidentified, adulterated, unwholesome, dead, or contaminated shellstock shall be discarded.

(6) Shucking of shellfish – Shellfish shall be shucked in a manner such that they are not subjected to possible contamination. Only live shellfish shall be shucked.

(a) Shucked meats shall be delivered to the packing room within one hour.

(b) Shucked meats shall be thoroughly drained, cleaned as necessary, and packed promptly after delivery to the packing room. Packing operations shall be scheduled and conducted so as to chill all meats to an internal temperature of 45° F or less within two hours of delivery to the packing room. Shucked meats which are packed into containers having a capacity of more than one gallon shall be pre-chilled to 45° F or less prior to packing.

(7) Shucked shellfish shall be held and transported at temperatures of 45° F or less.

(8) Ice shall be manufactured from potable water in a commercial machine which has been properly installed and maintained without connections to nonpotable water sources.

(9) Ice shall be stored so as not to come into contact with non-clean surfaces and is handled in such a manner that it will not be contaminated.

(10) Records – Complete, legible, and accurate dated records of purchase and sale of all shellfish shall be kept by all shellfish establishments operating in the state. Records shall indicate:

(a) From whom shellfish were purchased;

(b) Areas from which shellstock were harvested;

(c) State from which shucked shellfish were harvested;

(d) Harvesting date;

(e) The date of receipt by the processor;

(f) Names and addresses of persons to whom shellfish were sold; and

(g) Date sold.

(h) Records shall remain on file for not less than one year and shall be made available for inspection and copying by Department personnel during plant inspections.

(i) Production records shall be maintained for shucked meats which provide the amount of shellstock used, the harvest area, harvest date of the shellstock, and the amount of shucked meats produced.

(j) Production records shall be maintained for shellstock which provides for the amount of shellstock used, the harvest area, harvest date, harvest state, and the units of shellstock produces.

(k) Records covering purchases and sales of frozen or previously frozen shellfish shall be retained for at least two years or for a period of time that exceeds the shelf-life of the product.

(l) Records for shellfish lots having completed a depuration or wet storage treatment process shall include:

1. Counties from which shellfish were harvested;

2. Name or location of harvesting areas;

3. Relaying permit numbers, if applicable;

4. Date received in plant;

5. Date released from the plant;

6. Date and time of initiation of treatment;

7. Date and time of termination of treatment;

8. Ending UV unit meter readings;

9. Number of hours treated; and

10. All laboratory results as specified.

(11) Monitoring records of HACCP plan critical control points shall be maintained and reviewed at least weekly as specified in the firm's HACCP plan. Records shall be reviewed to ensure that the records are complete and to verify that they document values that are within the critical limits. The review shall occur within one week of the day that the records are made. The reviewed records shall be signed and dated by an individual who is in a supervisory position in the firm and is knowledgeable of HACCP.

(12) Sanitation monitoring records shall be maintained for those conditions identified in subsection 5L-1.012(11), F.A.C., per the schedule of the activity, e.g. daily, weekly, monthly.

(13) Whenever a deviation from a critical limit occurs, a certified shellfish dealer shall take corrective action either by following a corrective action that is appropriate for the particular deviation, or by segregating and holding the affected product until a review can determine the acceptability of the affected product for distribution. Corrective actions include, when necessary, reconditioning, seizure, or destruction of 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. Corrective action also include, when necessary, correcting the cause of the deviation. All corrective actions shall be documented in writing.

(14) Responsibility – It shall be the duty and responsibility of each owner, manager, and operator of a shellfish plant to insure that all regulations pertaining thereto are strictly adhered to and that only safe, wholesome, unadulterated shellfish shall be produced. It shall be his or her duty and responsibility to see that the plant is properly supervised at all times and all shellfish can be identified, whether shellstock or shucked shellfish, to insure that they were harvested from approved growing waters and that they have been handled and processed in a sanitary manner.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History–New 1-4-87, Amended 5-21-87, 8-10-88, Formerly 16R-7.016, Amended 7-3-95, 5-8-96, 2-6-97, 6-23-99, Formerly 62R-7.016, Amended 8-9-00, 5-29-02, 7-29-08.

5L-1.014 Heat Shock Method.

(1) Washing of shellstock – Shellstock subjected to the heat shock process shall be washed immediately prior to the heat shock operation in potable water. Washing shall be accomplished by spraying water under pressure. Immersing shellfish for washing purposes is prohibited. Shellstock shall be protected from contamination prior to and during the prewash cycle.

(2) Temperature and change of dip water – During the heat shock process the water shall be maintained at a temperature not less than 145° F or more than 150° F. The water shall be completely drained or removed from the heat shock tank when it becomes dirty or at the end of each working day. An accurate indicating or recording thermometer shall be used during the heat shock process for temperature measurements.

(3) Time interval of immersion – Shellstock subjected to the heat shock process shall not be immersed in the heat shock water for periods longer than 5 minutes. An accurate timing device shall be available and used to control the time of immersion.

(4) Dip tank volume – At least 8 gallons of heat shock water shall be maintained in the dip tank for each one-half bushel container of shellstock being heat shocked.

(5) Cooling of heat shocked shellstock – Upon removal from shock immersion water, all heat shocked shellstock shall be subjected to an immediate cooldown with potable tap water, or ice. Heat shocked shellstock shall be handled in a manner which prevents contamination from reaching the shellstock and shucked product during the cooling operation.

(6) Refrigeration of heat shocked shellfish – Shucked meat from all shellstock which has been subjected to the heat shock process shall be cooled to an internal temperature of 45° F or less within 2 hours after the heat shocking process. Shucked meats shall be immediately cooled by placing ice in shucking containers prior to and during the shucking process.

(7) Records of heat shock time and temperatures – Each plant operating the heat shock process shall maintain an accurate daily record of the time and temperature of the immersion of all lots of shellfish

during each day of operation as well as recording the time of change of heat shock water. These records shall be maintained for at least one year.

(8) Shucker-packers may submit, for department review and written approval, a written processing schedule together with all validation and supporting documents for their alternative heat shock operation. The written processing schedule must address these factors:

- (a) No changes in the physical and organoleptic properties of the species shall occur;
- (b) Process shall not kill the shellfish;
- (c) No increase in microbial deterioration of the shucked shellfish shall occur;
- (d) Type and size of shellfish;
- (e) Time and temperature of exposure;
- (f) Type of process;
- (g) Size of tank, tunnel or retort;
- (h) Water to shellfish ratios in tanks; and
- (i) Temperature and pressure monitoring devices.

(9) The written heat shock process shall be on display in the processing area. All responsible persons involved with the heat shock process must be aware of the requirements.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History--New 1-4-87, Amended 8-10-88, Formerly 16R-7.017, Amended 7-3-95, 2-6-97, Formerly 62R-7.017, Amended 8-9-00.

5L-1.015 Depuration Plant Operations.

(1) Source of shellfish – Shellfish shall be accepted for treatment at a shellfish treatment plant only from areas specified by the Department pursuant to Rule 5L-1.009, F.A.C. The plant supervisor or representative shall inspect all containers of untreated shellfish upon arrival at the plant to verify that they contain the species and quantity stated on the monitor's reports.

(2) Shellfish containers – Shellfish shall be accepted for treatment and released after treatment in clean containers only. All containers shall be constructed of non-absorbent and rust-proof material, and kept clean and free from foreign matter. Burlap bags or similar absorbent material shall not be used for transporting shellfish to the treatment plant nor for the removal of shellfish from the plant.

(3) Culling – All untreated shellfish, prior to, or upon arrival at the plant, shall be thoroughly inspected and culled by personnel under the supervision of the plant supervisor or representative. All dead shellfish or shellfish in broken or cracked shells shall be destroyed. The plant supervisor or representative shall be responsible for the culling and the removal and disposal of dead shellfish or shellfish with broken or cracked shells both before and after depuration.

(4) Washing shellfish – All shellfish shall be thoroughly washed prior to and after treatment. Immersion of shellfish for washing purposes is prohibited.

(5) Baskets used in treatment process – All baskets used in the treatment process shall be of suitable size, designed for easy handling, and made of impervious material. Baskets shall be of such design to allow water to flow freely over the shellfish in the treatment tanks. Baskets shall not be filled beyond the level which will allow free circulation of water during the treatment process. The height of the shellfish in the baskets shall not exceed 6 inches. Baskets shall be stacked in such a manner as to allow free circulation of water. Containers used for treatment purposes shall not be used for any other purpose, and no containers or other equipment shall be placed in the treatment tanks.

(6) Shellfish treatment – All shellfish, upon receipt at the treatment plant, shall be promptly treated or placed in controlled storage. Shellfish from approved growing waters which are to undergo wet storage shall be segregated from shellfish from restricted or conditional restricted waters. Shellfish for wet storage shall be treated by a Department approved scheduled wet storage process (SWSP). Shellfish from restricted or conditionally restricted waters shall undergo a Department approved scheduled depuration process (SDP).

(7) Washing treatment tanks – After each 24 hours that the shellfish are in the treatment tanks, the seawater in the tanks shall be drained out and the shellfish hosed down thoroughly. Feces, pseudo-feces, and any other waste matter must be flushed out of the tank. Immediately after hosing, the tanks shall again be filled with treated seawater. Treatment tanks employing some form of refrigeration shall be drained and thoroughly washed after each depuration period or lot of shellfish depurated.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History–New 1-4-87, Amended 8-10-88, Formerly 16R-7.021, Amended 7-3-95, Formerly 62R-7.021, Amended 8-9-00.

5L-1.016 Depuration Shellfish Sampling Procedures.

(1) Start-up phase sampling procedures – When shellfish are delivered to the treatment plant, the following schedule shall be followed:

(a) One or more shellfish samples (12 or more shellfish per sample) shall be collected for bacterial examination before the shellfish are submitted to the treatment process.

(b) Three or more shellfish samples (12 or more shellfish per sample), randomly selected from 3 or more locations in each tank, shall be collected for bacterial examination after 24 hours of depuration.

(c) Three or more shellfish samples (12 or more shellfish per sample), randomly selected from 3 or more locations in each tank, shall be collected for bacterial examination after the shellfish have completed the treatment process.

(2) Routine Sampling Procedures.

(a) Start-up phase sampling procedures shall be followed until such time as the Department and the plant supervisor, after review of start-up phase results, determine that the shellfish are responding properly to the treatment process, and that the treatment process is successfully reducing bacterial levels in the shellfish and providing process water quality pursuant to Rule 5L-1.017, F.A.C. After such a determination, the routine sampling procedures shall be followed. Written permission from the Department shall be obtained before the initiation of the following routine monitoring procedures:

1. One or more shellfish samples (12 or more shellfish per sample) shall be collected for bacterial examination before the shellfish are submitted to the treatment process.

2. Three or more shellfish samples (12 or more shellfish per sample), randomly selected from each lot, shall be collected for bacterial examination after 24 hours of depuration.

3. Three or more shellfish samples (12 or more shellfish per sample), randomly selected from each lot, shall be collected for bacterial examination after 48 hours of depuration.

(b) In the event of the installation of a new laboratory, new laboratory equipment, employment of new laboratory personnel, initiation of new laboratory procedures, or the alteration of treatment procedures, the Department may require reinitiation of start-up phase sampling procedures until such time as the Department and the plant supervisor, after review of the results, determine that the laboratory and treatment procedures are providing valid results. Written permission from the Department shall be obtained before routine monitoring procedures are again followed.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History–New 1-4-87, Amended 8-10-88, Formerly 16R-7.022, Formerly 62R-7.022.

5L-1.017 Depuration - Process Water Treatment Standards.

(1) All controlled processes require quality tests to determine if standards are being met and if controls are effective. The treatment of shellfish is a controlled process designed to reduce bacterial contamination to an acceptable level, as defined in subsection 5L-1.004(6), F.A.C., for depuration, or in the case of wet storage, enhance the product quality without degradation of market standards as defined in Rule 5L-1.004, F.A.C. To insure the continuing effectiveness of the shellfish treatment process, the minimum sampling procedure as described below shall be followed.

(2) Incoming seawater.

(a) Type of test – temperature, turbidity, salinity, dissolved oxygen.

(b) Frequency – each time seawater is withdrawn.

(3) Effluent from UV light treatment unit.

(a) Type of test – bacteriological.

(b) Frequency – once per day per unit.

(4) Bacteriological – All water to be used in shellfish treatment tanks shall be subjected to UV light treatment. The water discharged from the UV unit shall be of bacterial quality equal to or better than the quality of water required in the U. S. P. H. S. Drinking Water Standards, as stated in the NSSP Model Ordinance.

(5) Dissolved oxygen – The amount of dissolved oxygen in the water in the treatment tanks shall be at least 5 mg/l and shall be measured daily.

(6) Temperature – Treatment tank water temperature shall be measured daily during the treatment process. Temperature of seawater used in the treatment process shall be suitable for depuration.

(7) Turbidity – Turbidity in the treatment process water shall not exceed 20 N.T.U. (Nephelos Turbidity Units) and shall be measured daily.

(8) Salinity – Salinity of the treatment process water shall be suitable for depuration and shall be measured daily.

(9) pH – pH of the treatment process water shall range from greater than or equal to 7.0 to less than or equal to 8.4 and shall be measured daily.

(10) Metallic ions and compounds – Levels of metallic ions and compounds shall not exceed levels found in approved shellfish harvesting areas and shall be measured if required by the Department.

(11) Pesticides, detergents, and radionuclides – Levels of pesticides, detergents, and radionuclides shall not exceed levels found in approved shellfish harvesting areas and shall be measured if required by the Department.

(12) Marine toxins (*Gymnodinium breve*) – Levels of *Gymnodinium breve* in the incoming seawater and in the source water shall not exceed 1,000 cells/liter. Estuarine and/or marine waters adjacent to the source waters with salinities of at least 26 parts per thousand shall also be examined for the presence of *Gymnodinium breve*. Only Department personnel, or personnel approved by the Department, shall determine levels of *Gymnodinium breve*.

The following table provides a summary of the depuration treatment process water standards:

Table 1. DEPURATION TREATMENT PROCESS WATER STANDARDS

Parameter	Minimum	Maximum
Bacteriological	0	Less than 1
Dissolved Oxygen (Milligrams/liter)	5.0	Saturation
Temperature	Suitable	Suitable
Turbidity (Nephelos Turbidity Units)	0	20 units
Salinity	Suitable	Suitable
pH	7.0	8.4
Metallic Ions and Compounds	Not exceeding levels found in approved shellfish harvesting areas.	

Pesticides, Detergents and Radionuclides	Not exceeding levels found in approved shellfish harvesting areas.	
Marine Toxins (<i>Gymnodinium breve</i>)	0 cells/liter	1,000 cells/liter

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 8-10-88, Formerly 16R-7.024, Amended 7-3-95, 5-8-96, 2-6-97, Formerly 62R-7.024, Amended 8-9-00.

5L-1.018 Depuration - Ultraviolet (UV) Unit.

(1) Any UV unit which provides the required treatment and desired results may be used for the purification of water to be used in the treatment process. The unit shall be designed to deliver, at peak load, at least 1 gallon per minute of treated water per bushel of shellfish.

(2) Cautions and maintenance.

(a) UV tubes shall be checked for intensity on a monthly basis and shall be replaced when they reach a point of 60% efficiency. A log of intensity shall be kept and an orderly numbering procedure for UV units and bulbs established.

(b) UV tubes and reflectors shall be cleaned daily. Cleaning may be done with a clean damp cloth or sponge.

(c) Signs stating “Ultraviolet Light Danger to Eyes – Do Not Look at Bulbs Without Eye Protection” shall be displayed in full view of personnel and authorized visitors. Skin protection, especially for the face and hands, shall be provided for personnel monitoring the bulbs. Eye protection may be accomplished by use of ordinary glasses with solid side pieces or special goggles made for this purpose. Protection for the head may be afforded by a hat and hand protection may be accomplished by the use of gloves. Face protection may be afforded by the use of certain clear plastics.

(d) An automatic shutoff switch shall be provided to break the electric circuit, thus shutting off the current to the UV bulb when the lid of the UV unit is raised.

(e) A tamper-proof hour meter shall be installed in line with all UV units to measure continuity of operation as well as to measure bulb life. A log which documents meter readings taken at the beginning and end of each depuration cycle shall be maintained for each UV unit.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History—New 1-4-87, Amended 8-10-88, Formerly 16R-7.026, Formerly 62R-7.026.

5L-1.019 Laboratory Procedures and Sample Testing.

(1) Samples of shellfish, processing water, or ice, may be taken at any reasonable time or place by the Department and examined for compliance with sections of this Chapter. Samples of shellfish shall be furnished by processors of such shellfish upon request of the Department. Samples will be collected and appropriate sample collection and receipt forms will be used by Department staff to document sample collections. Forms include DACS 15005, Collection/Analysis Water Report, revision 7/2000, DACS 15004, Shellfish Sample Collection Report, revision 7/2000, and DACS 15013, Receipt for Samples, revision 7/2000. These forms are herein incorporated by reference, and obtainable by writing the Department of Agriculture and Consumer Services, Division of Aquaculture, 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301.

(2) Bacterial examinations of shellfish and seawater shall be conducted in accordance with *The Recommended Procedures for Bacterial Examination of Seawater and Shellfish* Fifth Edition, 1985 published by the American Public Health Association which is hereby incorporated herein by reference and is available for inspection at the Department’s office, located at 1203 Governors Square Boulevard, 5th

Floor, Tallahassee, Florida 32301. Bacteriological examinations of seawater employing the fecal coliform Membrane Filter (MF) colony forming unit procedure referenced in paragraph 5L-1.003(2)(b) and subsection 5L-1.003(4), F.A.C., shall be conducted in accordance with *Enumeration of fecal coliforms and E. coli in marine and estuarine waters: an alternative to the APHA-MPN approach* written by Scott R. Rippey, Willard N. Adams, and William D. Watkins and published in the *Journal Water Pollution Control Federation Volume 59, Number 8*, pages 795 – 798, August 1987, which is hereby incorporated herein by reference. This procedure is terminated at the fecal coliform stage. The urease step is not required. This reference is available for inspection at the Department's office, located at 1203 Governors Square Boulevard, 5th Floor, Tallahassee, Florida 32301.

(3) Laboratory staff shall, upon request of the Department, allow observation of analytical techniques to determine compliance with (2) above.

(4) The laboratory must be certified by the Department in accordance with Appendix L of the National Shellfish Sanitation Program Model Ordinance.

Specific Authority 597.020 FS. Law Implemented 597.020 FS. History--New 1-4-87, Amended 8-10-88, Formerly 16R-7.030, Amended 7-3-95, 5-8-96, 2-6-97, Formerly 62R-7.030, Amended 8-9-00, 8-17-04.