



R.61-47, Shellfish

Effective June 27, 2008

(This regulation replaces and supercedes any former regulations)

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DISCLAIMER

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PREAMBLE

Pursuant to South Carolina Code Section 44-1-140 (1976 Code of Laws, as amended), the Department is authorized to promulgate and enforce rules and regulations for public health for the classification of waters and for the safety and sanitation in the harvesting, storing, processing, handling and transportation of mollusks, fin fish and crustaceans. R.61-47, Shellfish prescribes requirements for producers, processors, harvesters, and transporters of shellfish and is intended to protect the health of consumers of shellfish.

Regulation History

Promulgated pursuant to South Carolina Code Section 44-1-140 (1976 Code of Laws, as amended)

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South Carolina Regulation 61-47, Shellfish

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A. GENERAL PROVISIONS.

1. Purpose and Scope. This regulation outlines requirements for producers, harvesters, processors, and transporters of shellfish and is intended to protect the health of consumers of shellfish. The requirements, standards, and implementation methods outlined herein are consistent with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, published by the United States Department of Health and Human Services, U.S. Food and Drug Administration. The National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish is partially incorporated by reference within these regulations. This Regulation is intended to protect the health of consumers of shellfish by:

(a) Establishing sanitary controls for the production, processing, harvesting, handling, distribution, and transportation of shellfish;

(b) Classifying coastal shellstock growing areas in accordance with accepted public health standards;

(c) Prohibiting the distribution of adulterated shellfish; and

(d) Establishing permit and certification requirements for commercial shellfish activities.

2. Definitions. For the purpose of this regulation:

(a) Adulterated means any one of the following:

(1) Shellfish that have been harvested from closed areas;

(2) Shellfish that have not been grown, harvested, stored, treated, transported, handled, shucked, packed, tagged, labeled, or offered for sale in compliance with this Regulation.

(3) Shellfish deemed unsafe as outlined in E.2;

(4) Shellfish that are putrid or unfit for human consumption;

(5) Shellfish that have been exposed to any unsanitary conditions;

(6) Shellfish which that contain any added substance, unless the substance is authorized by the Department or the United States Food and Drug Administration;

(7) determined to contain any poisonous or deleterious substance at a level or concentration likely injurious to public health.

(b) Adverse Pollution Condition means a state or situation caused by meteorological, hydrological or seasonal events or point source discharges that has historically resulted in elevated fecal coliform levels in a particular harvest area.

(c) Approved means a shellfish water quality classification that allows shellfish harvest for direct marketing for human consumption.

(d) Approved Area means a growing area where the water quality has been classified by the Department for harvesting shellfish for direct marketing for human consumption.

(e) Aquaculture means the cultivation of shellfish in land-based artificial growing or harvest areas, or confined cultivation in South Carolina Department of Natural Resources-permitted natural growing or harvest areas.

(f) Bulk means any of the following:

(1) A single lot of shellstock stored or shipped in individual packages which are contained within a sealed master carton or on a wrapped pallet;

(2) A single lot of unpackaged shellstock shipped in a single large-volume container such as a vehicle or vessel;

(3) A single lot of shellstock held in multiple large capacity tubs, totes, net brailers, or other holding units when being transported from a growing area to a certified shipper.

(g) Certified Shipper means a person engaged in the business of selling, distributing or otherwise transporting shellfish and who has a valid certification as a Depuration Processor(DP), Shucker-Packer(SP), Repacker(RP), Shellstock Shipper(SS), or Reshipper(RS) issued by the state in which his facility is located.

(h) Certification Number means the unique identification number assigned by the Department to each certified shipper.

(i) Classification or Classify means the designation of a growing area harvest category or categories. A growing area may be classified as any combination of approved, conditionally approved, restricted, conditionally restricted, or prohibited.

(j) Classified Growing Area means a growing area for which the Department has completed a sanitary survey report and assigned classifications of approved, conditionally approved, restricted, conditionally restricted, or prohibited.

(k) Closed Area means a growing area where the harvesting of shellfish is temporarily or permanently not allowed. The Department may place any growing area in a closed area status.

(l) Coliform Group means all of the aerobic and facultative anaerobic, gram negative, nonspore forming, rod shaped bacilli that ferment lactose broth with gas formation within forty-eight (48) hours at ninety-five (95) degrees Fahrenheit (35 degrees \pm 0.5 degrees Centigrade).

(m) Commingle or Commingling means the act of combining different lots of shellstock or shucked shellfish.

(n) Conditionally Approved means a shellfish water quality classification used to identify a growing area that meets approved criteria except under conditions described in a management plan.

(o) Conditionally Approved Area means a growing area that meets approved area criteria under certain environmental conditions determined by the Department. Direct harvesting of shellfish for human consumption is allowed at times and under conditions determined by the Department through collection of water quality and pollution source data. Conditionally approved area management employs criteria specified in a management plan.

(p) Conditionally Restricted means a shellfish water quality classification used to identify a growing area that meets restricted criteria except under conditions described in a management plan.

(q) Conditionally Restricted Area means a growing area that meets Restricted Area criteria under specific conditions determined by the Department. Conditionally restricted area management employs criteria specified in a management plan.

(r) Container means any bag, box, crate, tub, carton, or other conveyance in which shellfish may be held, carried or transported.

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

(t) Critical deficiency means a condition or practice that results in the production of a product that is unwholesome or presents a threat to the health or safety of the consumer.

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

(v) Department means the South Carolina Department of Health and Environmental Control or agents thereof having responsibility for enforcing these regulations.

(w) Depletion means the removal and disposal of all market-size shellfish from a growing area in a manner to prevent human consumption.

(x) Depuration means the process of using a controlled aquatic environment to reduce the level of bacteria and viruses in live shellfish.

(y) Depuration Facility means the physical structure wherein depuration is accomplished, including all the appurtenances necessary to the effective operation thereof.

(z) Depuration Processor (DP) means a person who is certified to receive shellstock from approved or restricted growing areas and submit such shellstock to a depuration process.

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

(bb) Employee means an individual who handles, stores, transports, sells, or distributes shellfish and is employed by someone with a shellfish certificate or permit.

(cc) Fecal Coliform means that portion of the coliform group that will produce gas from lactose in an EC or A-1 multiple tube procedure liquid medium within twenty-four (24) (+ 2) hours in a water bath maintained at one hundred twelve (112) degrees Fahrenheit [forty-four and one-half (44.5) ±0.2 degrees Centigrade].

(dd) Growing Area means an estuary or coastal river area delineated by the Department that supports or could support live shellfish. For purposes of this regulation, growing waters shall be synonymous with growing area.

(ee) HACCP is an acronym that stands for Hazard Analysis Critical Control Point, a systematic, science based approach used in food production as a means to assure food safety.

(ff) HACCP Plan means a written document that delineates the formal procedures that a processor follows to implement the HACCP requirements set forth in 21 CFR § 123.6 (April 1, 2007) as adopted by the Interstate Shellfish Sanitation Conference.

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

(hh) Harvester means a person who gathers shellfish by any means from a growing area.

(ii) Lot means any of the following:

(1) A single type of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area;

(2) A collection of containers of no more than one day's shucked shellfish product produced under conditions as nearly uniform as possible, and designated by a common container code;

(3) Shellstock harvested for depuration from a particular area during a single day's harvest and delivered to one depuration facility.

(jj) Marina means any of the following:

(1) locked harbor facility;

(2) any facility which provides fueling, pump-out, maintenance or repair services (regardless of length);

(3) any facility which has effective docking space of greater than 250 linear feet or provides moorage for more than 10 boats;

(4) any water area with a structure which is used for docking or otherwise mooring vessels and constructed to provide temporary or permanent docking space for more than ten boats, such as a mooring field; or

(5) a dry stack facility.

(kk) National Shellfish Sanitation Program means the program cooperatively developed by state, United States Food and Drug Administration, and shellfish industry representatives resulting in sanitary control guidelines that ensure that the shellfish produced in accordance with guidelines will be safe and sanitary.

(ll) National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish means the 2005 version of the United States Food and Drug Administration document with that title that consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the National Shellfish Sanitation Program. Portions of the document are incorporated by reference herein and such referenced sections shall have effect as if fully recited within the text of this regulation. Copies can be obtained through the U.S. Food and Drug Administration or the S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201.

(mm) Person means any individual, partnership, company, corporation, trustee, association, agency, or any public or private entity.

(nn) Poisonous or Deleterious Substance means a toxic compound occurring naturally or added to the environment that may be found in shellfish or shellfish growing waters for which a regulatory tolerance limit or action level has been established or may be considered harmful to public health. Examples of naturally occurring substances would include paralytic shellfish toxins and trace elements geologically leached from the environment, such as mercury; examples of added substances would include agricultural pesticides and polynuclear aromatics.

(oo) Post Harvest Processing means processing of shellfish for the purpose of added safety or quality that involve hazards not addressed by controls in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance for shucker-packers, repackers, shellstock shippers, or reshippers.

(pp) Process means those actions related to the operation of the Certified Shipper facilities of Depuration Processors(DP), Shucker-Packers(SP), Repackers(RP), Shellstock Shippers(SS), and Reshippers(RS).

(qq) Processor means a certified shipper.

(rr) Prohibited means an administrative classification that disallows shellfish harvest for human consumption.

(ss) Prohibited Area means a growing area that has been closed by the Department for the harvesting of shellfish for any purpose related to direct human consumption.

(tt) Raw means shellfish that have not been thermally processed:

(1) to an internal temperature of one hundred and forty-five (145) degrees Fahrenheit or greater for fifteen (15) seconds (or equivalent); or

(2) to alter the organoleptic characteristics.

(uu) Relaying means the transfer of shellstock from restricted areas or conditionally restricted areas to approved or conditionally approved areas for natural biological cleansing using the ambient environment as a treatment system.

(vv) Repacker (RP) means a certified shipper who packs shucked shellfish into containers other than those in which they were originally packaged. A repacker may act as a shellstock shipper.

(ww) Repacking means the transfer of shucked shellfish into containers other than those in which they were originally packaged.

(xx) Reshipper (RS) means certified shippers who purchase shellfish from other certified shippers and sell or distribute the shellfish without repackaging.

(yy) Restricted means a shellfish water quality classification that does not meet approved water quality criteria, disallows direct marketing of shellfish, and allows shellfish harvest only by special permit.

(zz) Restricted Area means a growing area that has been classified by the Department as not meeting water quality criteria that would allow harvesting shellfish for direct marketing for human consumption. In a restricted area, shellfish may be harvested only by special permit and direct marketing of harvested shellfish is not allowed.

(aaa) Sanitary Survey Report means a written evaluation of all actual and potential pollution sources and environmental factors that affect shellfish growing area water quality.

(bbb) Sanitize means adequate treatment of food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing the number of other microorganisms. Such treatment shall be safe and not adversely affect shellfish.

(ccc) Scheduled Depuration Process means the process that places shellfish harvested from conditionally restricted, restricted, or approved waters into a controlled aquatic environment selected by the processor and that has been demonstrated to the Department to effectively reduce the level of fecal coliform bacteria in live shellfish.

(ddd) Seed means juvenile shellstock intended for growth to market size.

(eee) Shellfish means all edible species of oysters, clams, mussels, and scallops; either shucked or in the shell; fresh or fresh frozen; whole or in part, except that scallops shall be excluded when the final product is the adductor muscle only.

(fff) Shellstock means live molluscan shellfish in the shell.

(ggg) Shellstock Shipper (SS) means a certified shipper who grows, harvests, buys, or sells shellstock. A shellstock shipper is not certified to shuck shellfish or repack shucked shellfish. A shellstock shipper may repack shellstock or act as a reshipper.

(hhh) Shucked Shellfish means shellfish that have been removed from their shells.

(iii) Shucker-Packer (SP) means a certified shipper who shucks and packs shellfish. A shucker-packer may act as a repacker, shellstock shipper, or reshipper.

(jjj) State Shellfish Control Authority or Authority means the South Carolina Department of Health and Environmental Control or, if in reference to another state, the state agency having the primary authority to implement public health-related shellfish regulations.

(kkk) Systematic Random Sampling is a field sampling and data analysis design that employs a preestablished sampling schedule and assumes that a statistically representative cross section of all meteorological, hydrographic, and/or other pollution events will be included in the data set.

(lll) Vehicle means any truck, car, bus, trailer, railcar, aircraft, boat, ship, barge, dredge, or other means of conveyance by which shellfish is transported from one location to another.

(mmm) Vessel means any boat, ship, barge, dredge, or other type of watercraft used for the commercial harvest or transport of shellfish for human consumption.

(nnn) Wet Storage means storage of marketable shellfish in water after initial harvest.

3. Severability. In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

B. GROWING AREA SURVEY AND CLASSIFICATION

1. Sanitary Survey. A sanitary survey of shellfish growing areas shall be conducted by the Department, and each area shall be classified prior to its approval for shellfish harvesting. Sanitary Surveys and reports will be conducted and prepared consistent with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish.

2. Classification of Growing Area. Shellfish growing areas shall be identified and assigned harvesting classifications of approved, conditionally approved, restricted, conditionally restricted, or prohibited. The assigned classification will be based upon a sanitary survey conducted by the Department. Growing areas for which a sanitary survey has not been completed shall be classified as prohibited. The Department may also designate a growing area as a closed area and prohibit harvesting when it determines that conditions have occurred that may potentially render shellfish unsafe for human consumption.

3. Approved Area. Growing areas shall be classified approved when the sanitary survey concludes that fecal material, pathogenic microorganisms, and poisonous or deleterious substances are not present in concentrations that would render shellfish unsafe for human consumption. Approved classifications shall be determined upon a sanitary survey that includes water samples collected from stations in the designated area adjacent to actual or potential sources of pollution. For waters sampled under adverse pollution conditions, the median fecal coliform Most Probable Number (MPN) or the geometric mean MPN shall not exceed fourteen per one hundred milliliters, nor shall more than ten percent of the samples exceed a fecal coliform MPN of forty-three per one hundred milliliters (per five tube decimal dilution). For waters sampled under a systematic random sampling plan, the geometric mean fecal coliform MPN shall not exceed fourteen per one hundred milliliters, nor shall the estimated ninetieth percentile exceed an MPN of forty three per one hundred milliliters (per five tube decimal dilution). Computation of the estimated ninetieth percentile shall be determined using National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish methodology.

4. Conditionally Approved Area.

(a) Growing areas may be classified conditionally approved when they are subject to temporary conditions of actual or potential pollution. When such events are predictable, as in non-point source pollution from rainfall runoff or discharge of a major river, a management plan describing conditions under which harvesting will be allowed shall be adopted by the Department prior to classifying an area as conditionally approved. Where appropriate, the management plan for each conditionally approved area shall include performance standards for sources of controllable pollution (e.g., wastewater treatment and collection systems), evaluation of each source of pollution, and means of rapidly closing and subsequently reopening areas to shellfish harvesting. Memorandums of agreements shall be a part of these management plans where appropriate.

(b) Shellfish shall not be directly marketed from a conditionally approved area until conditions for an approved classification have been met for a period of time likely to ensure the shellfish are safe for consumption.

(c) Shellstock from conditionally approved areas that have been subjected to temporary conditions of actual or potential pollution may be relayed to approved areas for purification or depuration through controlled purification operations only by special permit issued by the Department.

5. Restricted Area

(a) Growing areas shall be classified restricted when sanitary survey data show a moderate degree of pollution or the presence of deleterious or poisonous substances to a degree that may cause the water quality to fluctuate unpredictably or at such a frequency that a conditionally approved classification is not feasible. Shellfish may be harvested from areas classified as restricted only for the purposes of relaying or depuration and only by special permit issued by the Department and under Department supervision.

(b) The suitability of restricted areas for harvesting of shellstock for relay or depuration purposes may be determined through the use of comparison studies of background tissue samples with post-process tissue samples, as well as other process verification techniques deemed appropriate by the Department.

(c) For restricted areas to be utilized as a source of shellstock for depuration, or as source water for depuration, the fecal coliform geometric mean MPN of restricted waters sampled under adverse pollution conditions shall not exceed eighty-eight per one hundred milliliters nor shall more than ten percent of the samples exceed a MPN of two hundred and sixty per one hundred milliliters for a five tube decimal dilution test. For waters sampled under a systematic random sampling plan, the fecal coliform geometric mean MPN shall not exceed eighty-eight per one hundred milliliters nor shall the estimated ninetieth percentile exceed an MPN of two hundred and sixty (five tube decimal dilution). Computation of the estimated ninetieth percentile shall be obtained using National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish methodology.

6. Conditionally Restricted Area.

(a) Growing areas may be classified conditionally restricted when they are subject to temporary conditions of actual or potential pollution. When such events are predictable, as in the malfunction of wastewater treatment facilities, non-point source pollution from rainfall runoff, discharge of a major river or potential discharges from dock or harbor facilities that may affect water quality, a management plan describing conditions under which harvesting will be allowed shall be prepared by the Department prior to classifying an area as conditionally restricted. Where appropriate, the management plan for each conditionally restricted area shall include performance standards for sources of controllable pollution, e.g., wastewater treatment and collection systems and an evaluation of each source of pollution, and description of the means of rapidly closing and subsequent reopening areas to shellfish harvesting. Memorandums of agreements shall be a part of these management plans where appropriate.

(b) Shellfish may be harvested from areas classified as conditionally restricted only for the purposes of relaying or depuration and only by permit issued by the Department and under Department supervision.

(c) For conditionally restricted areas to be utilized as a source of shellstock for depuration, the fecal coliform geometric mean MPN of conditionally restricted waters sampled under adverse pollution conditions shall not exceed eighty-eight per one hundred milliliters nor shall more than ten percent of the samples exceed a MPN of two hundred and sixty per one hundred milliliters for a five tube decimal dilution test. For waters sampled under a systematic random sampling plan, the fecal coliform geometric mean MPN shall not exceed eighty-eight per one hundred milliliters nor shall the estimated ninetieth percentile exceed an MPN of two hundred and sixty per one hundred milliliters (five tube decimal

dilution). Computation of the estimated ninetieth percentile shall be obtained using National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish methodology.

7. Prohibited Area.

(a) Growing areas shall be classified prohibited if there is no current sanitary survey report or if the sanitary survey report or monitoring data show unsafe levels of fecal material, pathogenic microorganisms, or poisonous or deleterious substances in the growing area or otherwise indicate that such substances could potentially reach quantities that could render shellfish unfit or unsafe for human consumption.

(b) Harvesting of shellfish from prohibited areas for human consumption shall not be allowed by the Department. This item shall not be construed to prohibit seed hatchery or nursery operations, provided such operations comply with applicable provisions of this regulation.

(c) Shellfish may be depleted for non-food use from prohibited areas upon approval of the Department and under specified conditions as outlined in D.4.

(d) Growing areas receiving sewage treatment plant and other waste discharges shall be classified as prohibited. The following assumptions and criteria will be considered in determining the area that could be potentially impacted:

(1) Pollution Conditions;

(a) Flow rate;

(b) Sewage treatment plant performance;

(c) Location of shellfish resources.

(2) Dispersion, dilution, and time of travel;

(a) Current velocity and net transport velocity;

(b) Volume;

(c) Depth of water;

(d) Direction of travel and stratification;

(e) Location of discharge;

(f) Tidal characteristics;

(g) Receiving area geometry.

(3) Decay rate (bacteriological die-off);

(4) Bacteriological quality required;

(5) Adjacent harvest use classification;

(6) Identifiable landmarks for boundaries.

(e) Growing waters within and adjacent to marinas shall be classified as prohibited. The size and extent of closures within and adjacent to marinas shall be determined using a dilution analysis that incorporates the following assumptions:

(1) An occupancy rate of the marina;

(2) An assumed rate of boats that will discharge untreated waste;

(3) An occupancy rate of two (2) persons per boat;

(4) A rate of discharge of 2×10^9 fecal coliform per person per day;

(5) Wastes are completely mixed in and around the marina;

(6) The volume of water in the vicinity of the marina;

(7) A theoretical calculated fecal coliform level of fourteen (14) MPN per one hundred (100) milliliters.

(f) Nothing in this regulation shall be construed to require that a dilution analysis be conducted for any existing marina historically encompassed by a prohibited closure of one thousand (1000) feet; provided however, that in the event a request or application is made seeking authorization to increase the marina's potential boat occupancy rate, the Department shall calculate the prohibited closure area in accordance with B.7.(e).

(g) Any proposed or existing dry stack or fueling facility having effective docking space of two hundred and fifty (250) linear feet or less and providing moorage for ten (10) or less boats shall not constitute sole cause for classification or closure in accordance with item B.7.(e) of this Regulation.

C. HARVESTING, HANDLING, AND TRANSPORTATION OF SHELLFISH.

1. Harvesting.

(a) Harvesting of Shellfish from Closed Waters. It shall be unlawful to harvest, remove, take, buy, sell, offer for sale, or possess shellfish from areas closed by the Department. This Section shall not be construed to prevent harvesting as permitted by the Department.

(b) Harvesting Vessels. It shall be unlawful for any person engaged in commercial shellfish activities to harvest, handle, or transport shellstock in a vessel that has not been constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of the shellstock.

(1) Decks and storage bins shall be constructed and located to prevent bilge water, fuel, oil, or polluted overboard water from coming into contact with the shellstock;

(2) Bilge pump discharges shall be located so that the discharge shall not contaminate shellstock;

(3) Containers used for storing shellstock shall be clean and fabricated from safe materials;

(4) Decks and storage bins used in the harvest or transport of shellstock for direct marketing shall be provided with effective drainage and kept clean with potable water or with water from a growing area in the open status;

(5) All vessels and equipment coming in contact with shellstock during handling or transport for relaying or depuration shall be thoroughly cleaned before the boat and equipment are used to transport or handle shellfish for direct marketing;

(6) Coverings shall be provided on unattended vessels to protect shellstock from exposure to hot sun, birds, and other adverse conditions.

(c) Identification of Shellstock During Harvest.

(1) Commercial harvesters shall affix a harvest identification tag to containers of shellstock prior to removal of the shellstock from the area in which it was harvested. Harvest identification tags shall:

(a) Be prominently labeled "Harvest Tag";

(b) Be durable and waterproof;

(c) Be at least 13.8 square inches in size;

(d) Contain the following accurate, indelible and legible information:

(1) Harvester's commercial saltwater fishing license number, as issued by the South Carolina Department of Natural Resources;

(2) Date and harvest start time;

(3) Harvest area;

(4) Name and certificate number of the certified shipper to whom the shellfish are being delivered;

(5) Type and quantity of shellstock.

(e) Not be altered in any manner.

(2) When shellstock are harvested from more than one harvest area on any single harvest day, each container of shellstock shall be tagged with an individual harvest identification tag.

(3) When shellstock are harvested from a single harvest area on a single day, multiple containers of shellstock may be held on a wrapped pallet, in a tub or tote, in a net brailer, or in other types of holding units, provided each individual wrapped pallet, tub or tote, net brailer, or other holding unit shall be tagged with a harvest identification tag meeting all requirements included in item C.1.(c)(1).

(4) When shellstock are harvested from a single harvest area on a single day, and a harvest vessel utilizes open decks or holds, tubs or totes, or other similar large-capacity holding units for the transport of loose, bulk shellstock, the vessel may utilize a single harvest identification tag. This tag shall be affixed to the vessel.

(5) In addition to the requirements of item C.1.(c)(1), a harvest identification tag used for tagging a holding unit shall include the following statement; "All shellstock containers in this lot have the same harvest date and area of harvest".

(6) In addition to the requirements of item C.1.(c)(1) and item C.1.(c)(5), a harvest identification tag used to identify a holding unit shall include documentation of the number of individual containers in the unit.

(d) Disposal of Body Waste.

(1) No person shall discharge untreated human fecal waste into any shellfish growing area.

(2) An approved marine sanitation device (MSD) or portable toilet shall be required on any commercial shellfish harvest vessel utilizing mechanical harvesting equipment. Use of other receptacles for sewage disposal may be allowed by the Department if the receptacles are:

(a) Constructed of impervious, cleanable materials and have tight fitting lids; and

(b) Used only for the purpose intended;

(c) Secured while on board and located, operated, and maintained to prevent contamination of shellstock by spillage or leakage.

2. Handling.

(a) Shellstock shall be protected from contamination at all times.

(b) Shellstock Temperature Management. Within two (2) hours of receiving shellstock from a harvester, certified shippers shall implement procedures to manage shellstock temperature. For purposes of this item, shellstock shall be considered received when the shellstock are located in any portion of a certified shipper facility. Nothing in this item shall be construed to reduce the maximum allowable time period for shellstock temperature control. Acceptable methods of temperature management for the period from two hours after receipt of shellstock to the maximum allowable time period for temperature control are:

(1) Mechanical refrigeration;

(2) Icing;

(3) Mechanical air conditioning, at conditioned temperatures no greater than sixty-eight (68) degrees Fahrenheit;

(4) Evaporative cooling, including, but not limited to equipment such as fans, blowers, and/or potable water sprays;

(5) Shading, however, the use of shading alone is only acceptable when ambient (surrounding) air temperatures are no greater than sixty-eight (68) degrees Fahrenheit.

(c) Shellstock Temperature Control. For purposes of initial processing, shellstock temperature control shall be defined as the management of the environmental temperature of shellstock by means of

ice, mechanical refrigeration or other approved means which is capable of lowering the temperature of the shellstock and will maintain it at fifty (50) degrees Fahrenheit [ten (10) degrees Centigrade] or less. Shellstock shall;

(1) Be placed under temperature control by the receiving certified shipper within twenty (20) hours from the time of harvest; and

(2) in the event waters of the State are confirmed as the source of two (2) or more *Vibrio vulnificus* illnesses, maximum hours to temperature control for shellfish intended for raw consumption shall, upon notice provided by the Department, be in accordance with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance, VIII. Control of Shellfish Harvesting, 03 Shellstock Temperature Control, Option 1, Action Level 2, Action Level 3, or Action Level 4 (as applicable); and

(3) in the event a growing area is confirmed as the original source of product associated with two (2) or more *Vibrio parahaemolyticus* illness within the past three (3) years, the maximum hours to temperature control for shellstock harvested from the affected growing area(s) shall, upon notice provided by the Department, be in accordance with the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance, VIII. Control of Shellfish Harvesting, .03 Shellstock Temperature Control, Option 2, Action Level 2 or Action Level 3 (as applicable); and

(4) in the event that a *Vibrio parahaemolyticus* risk evaluation determines that illness is reasonably likely to occur from the consumption of oysters harvested from an aquaculture facility during times when the average monthly daytime water temperature exceeds 81 degrees Fahrenheit, the maximum allowable time from harvest to temperature control for oysters harvested from the facility shall be five (5) hours.

(d) Identification of Shellstock in the Marketplace.

(1) When at the facilities of a certified shipper, shellstock shall be tagged in accordance with the provisions of item C.1.(c) or item C.2.(d)(2) at all times.

(2) Shellstock distributed or offered for sale within the State shall be identified with tags that are:

(a) Labeled as "Sale Tag";

(b) Durable and waterproof;

(c) At least 13.8 square inches (89.03cm²) in size;

(d) Legible and indelible, and contains accurate, unaltered information in the order specified below:

(1) The dealer's name and address;

(2) The dealer's certification number as assigned by the Authority;

(3) The original shellstock shipper's certification number. If depurated, the original shellstock shipper's certification number is not required;

(4) The date and, when shellstock have been harvested in South Carolina, the time of harvest shall be included. All depurated shellstock shall include the date and time of depuration processing;

(5) If depurated, the depuration cycle number or lot number;

(6) The most precise identification of the harvest location as is practicable including the initials of the state of harvest, and the Authority's designation of the growing area by indexing, administrative or geographic designation. If the Authority has not indexed growing areas, then an appropriate geographical or administrative designation must be used (e.g. Long Bay, Decadent County, lease number, bed, or lot number);

(7) When the shellstock has been transported across state lines and placed in wet storage in a dealer's operation, the statement: "THIS PRODUCT IS A PRODUCT OF (NAME OF STATE) AND WAS WET STORED AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";

(8) The type and quantity of shellstock;

(9) The following statement in bold capitalized type on each tag: "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE FOR 90 DAYS.";

(10) All shellstock intended for raw consumption shall include a consumer advisory. The following statement, based upon guidance provided in Section 3-603.11 of the United States Food and Drug Administration 2005 Food Code (Copies can be obtained through the U.S. Food and Drug Administration or the S.C. Department of Health and Environmental Control, 2600 Bull Street, Columbia, SC 29201.), or an equivalent statement, shall be included on all shellstock: "RETAILERS, INFORM YOUR CUSTOMERS: Consuming raw or undercooked meats, poultry, seafood, shellfish or eggs may increase your risk of foodborne illness, especially if you have certain medical conditions.";

(11) The statement "Keep Refrigerated" or an equivalent statement.

(e) Shucked Shellfish Temperature Control. Shucked shellfish shall be stored and maintained in accordance with the following:

(1) Within two (2) hours of shucking, shucked shellfish shall be stored and maintained at temperatures of forty-five (45) degrees Fahrenheit or below;

(2) Frozen shucked shellfish shall be stored and maintained at temperatures of zero (0) degrees Fahrenheit or below.

(f) Shucked Shellfish Labeling. Prior to sale or distribution, each individual container of shucked shellfish shall be labeled as follows:

(1) The shucker-packer's or repacker's certification number shall be displayed on the label of each package of shucked shellfish;

(2) Packages containing less than sixty-four (64) fluid ounces shall include:

(a) The words "SELL BY" or "BEST IF USED BY" followed by a reasonable date when the product would be expected to reach the end of its shelf life;

(b) The date as a month and day of the month; and

(c) For fresh frozen shellfish, the year shall be added to the date.

(3) Packages containing sixty-four (64) fluid ounces or more shall be labeled in the following manner:

(a) The words "DATE SHUCKED" followed by the date shucked located on both the lid and sidewall or bottom of the container;

(b) The date shall consist of either the abbreviation for the month and number of the day of the month or in Julian format (YDDD), the last digit of the four digit year and the three digit number corresponding the day of the year; and

(c) For fresh frozen shellfish, the year shall be added to the date (for non-Julian format).

(4) Frozen shucked shellfish shall be labeled as frozen in type-size of equal prominence to the type of shellfish;

(5) Repacked shellfish shall:

(a) Include the original date of shucking on packages of sixty-four (64) fluid ounces or more;

(b) Use the original date of shucking to establish the "Sell By Date" on packages containing less than sixty-four (64) fluid ounces;

(c) If thawed for repacking, be labeled as previously frozen.

3. Transportation.

(a) Shellfish in transportation shall be protected from contamination at all times.

(b) Vehicles used to transport shellfish shall be constructed, operated, and maintained to prevent contamination, deterioration, and decomposition of shellfish. Shellfish transported in unenclosed vehicles shall at all times be protected by effective coverings, provided, however, that this requirement shall not apply to an occupied vessel during shellstock harvest and delivery by water route to a certified shipper.

(c) Commercial shellstock shipments, intended or offered for human consumption shall:

(1) Include a Bill of Sale; and

(2) Be properly identified or labeled in accordance with this regulation; and

(3) Be transported in accordance with the following protocols:

(a) When shipping time is no more than four (4) hours:

(1) Shellstock shall be alive and transported under mechanical refrigeration, equipped with automatic controls, at ambient air temperatures of forty-five (45) degrees Fahrenheit or less; or

(2) Shellstock shall be alive and transported using ice; and

(3) Shellstock shall be cooled to an internal shellstock body temperature of fifty (50) degrees Fahrenheit or less.

(b) When shipping time is greater than four (4) hours:

(1) Shellstock shall be alive and transported under mechanical refrigeration, equipped with automatic controls, at ambient air temperatures of forty-five (45) degrees Fahrenheit or less; or

(2) Shellstock shall be shipped in containers having an internal ambient air temperature of forty-five (45) degrees Fahrenheit or less; and

(3) Shellstock shall be shipped alive and cooled to an internal shellstock body temperature of fifty (50) degrees Fahrenheit or less.

(4) Nothing in item C.3.(c)(3) shall be construed to make unlawful the intrastate shipment of shellstock harvested from within the State provided such shellstock have not exceeded any maximum allowable time period for temperature control as established by item C.2.(c).

(d) Commercial shipments of non-frozen shucked or post harvest processed shellfish shall;

(1) Include a Bill of Sale; and

(2) Be properly identified in accordance with this regulation; and

(3) Be transported in accordance with the following temperature protocols:

(a) When shipping time is no more than four (4) hours:

(1) Non-frozen shucked or post-harvest processed shellfish shall be transported under mechanical refrigeration, equipped with automatic controls, at ambient air temperatures or forty-five (45) degrees Fahrenheit or less; or

(2) Transported well iced; and

(3) Be cooled to an internal temperature of forty-five (45) degrees Fahrenheit or less.

(b) When shipping time is greater than four (4) hours:

(1) Non-frozen shucked or post-harvest processed shellfish shall be transported under mechanical refrigeration, equipped with automatic controls, at ambient air temperatures of forty-five (45) degrees Fahrenheit or less; or

(2) Non-frozen shucked or post-harvest processed shellfish shall be shipped in containers having an internal ambient air temperature of forty-five (45) degrees Fahrenheit or less; and

(3) Non-frozen shucked or post-harvest processed shellfish shall be cooled to an internal shellstock body temperature of forty-five (45) degrees Fahrenheit or less.

(4) An operative time-temperature indicating device shall accompany each shipment

(e) Ice used to cool shellfish during transport shall:

(1) Be produced from potable water in a commercial ice machine inspected by the Department;
or

(2) Be produced at a facility sanctioned by an appropriate regulatory agency.

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

(g) Containers used to transport shellstock shall not be constructed, used, or maintained in any manner that would result in product contamination.

D. SPECIAL SHELLSTOCK HANDLING.

1. Relaying.

(a) Shellstock may be harvested and relayed from restricted or conditionally restricted areas to approved or conditionally approved areas for natural biological purification. The shellstock for relaying shall be of such quality that purification will be effective in reducing contaminants to safe levels.

(b) Following approval by the South Carolina Department of Natural Resources, relaying operations may be permitted and supervised by the Department. Only shellfish harvested from waters meeting approved area criteria as defined in B.3 shall be certified for marketing.

(c) Applications for Relay Permits must designate whether the shellfish are being relayed for direct marketing or for South Carolina Department of Natural Resources planting credit purposes.

(d) Shellfish relayed from a restricted or conditionally restricted area to an approved area for subsequent harvesting for direct marketing purposes shall remain planted for a period of not less than fourteen (14) consecutive days when the water temperature is above fifty (50) degrees Fahrenheit [ten (10) degrees Centigrade]. If the water temperature is less than fifty (50) degrees Fahrenheit, the Department shall make a determination as to an adequate time period to ensure natural purification. Shellfish relayed from a restricted area to a conditionally approved area for direct marketing purposes shall remain planted for a period of not less than fourteen (14) consecutive days when the water temperature is above fifty (50) degrees Fahrenheit and the area is in an open status. If the water temperature is less than fifty (50) degrees Fahrenheit, or if the area is downgraded to a closed status, the Department shall make a determination as to an adequate time period to ensure natural purification.

(e) Shellfish relayed for planting credit purposes shall remain planted for a minimum of four months.

(f) Shellfish relayed to approved or conditionally approved areas shall not be re-harvested until authorized by the Department.

(g) Areas to which shellstock are relayed shall be readily identified and marked. These areas shall be situated in a manner to avoid contamination of shellstock in adjacent growing areas.

2. Interstate Relaying. Shellstock shall not be relayed from the State to another state without prior approval of the Department and the responsible state agency that will receive the shellstock. The United

States Department of Health and Human Services, Food and Drug Administration, shall be informed of such interstate activities.

3. Wet Storage. Harvested shellstock may be held in wet storage in approved shellfish growing waters or land-based ponds or tanks where effective control measures are enforced to keep shellfish fresh and protected from contamination. Proper shellstock identification as outlined in item C.1.(c)(1) must be maintained during wet storage.

(a) Permit Requirements. Prior to the wet storage of molluscan shellfish in approved near-shore growing waters, application for a Wet Storage Facility Operating Permit shall be made to and obtained from the Department. Prior to the construction, expansion or modification of any land-based wet storage facility, application for a Wet Storage Facility Construction Permit shall be made to, and a Wet Storage Facility Construction Permit obtained from, the Department. Prior to operating any land-based wet storage facility, application for a Wet Storage Facility Operating Permit shall be made to and obtained from the Department. Wet Storage Operating Permits shall be issued only in conjunction with a Certified Shipper Certificate.

(b) Wet Storage in approved near-shore shellfish growing waters - Operating Permit Requirements. Information related to the proposed construction and operation of a near-shore wet storage facility shall be submitted for Department review and approval. This information shall be provided in the form of a written operational plan detailing the scope and extent of the proposed activity, including, but not necessarily limited to location, type of construction, and species of shellfish stored. The operational plan shall address the following:

(1) the purpose of the wet storage activity, such as holding, conditioning, or increasing the salt content of shellstock.

(2) any species specific physiological factors that may affect design criteria

(3) location of near-shore storage structures

(4) details of the design and proposed construction of the storage structures that address the following minimum construction standards to:

(a) allow the free flow of water to shellfish; and

(b) be constructed of non-toxic materials; and

(c) be constructed so as to protect shellfish from physical, chemical or thermal conditions that may compromise shellfish survival, quality or biological activity.

(c) The Department shall issue an operating permit after approval of the operational plan and completion of a satisfactory Department inspection of the constructed facility.

(d) Wet Storage in land-based ponds or tanks.

(1) Construction Permit Requirements. An Operational Plan shall be provided in conjunction with the Wet Storage Facility Construction Permit application. The Operational Plan shall address the following:

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

content of shellstock;

(b) any species-specific physiological factors that may affect design criteria;

(c) details of the design and proposed construction of the onshore storage facility as required by item D.3(d)(2), source, quantity and quality of water to be used for wet storage as required by item D.3(d)(3), and details of the design and proposed construction of any water treatment system.

(2) Construction Requirements. Each land-based wet storage operation shall meet the following design, construction, and operating requirements:

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

(b) Storage tanks and related plumbing shall be fabricated of non-toxic material and shall be easily cleanable.

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

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

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

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

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

(i) Floors, walls, and ceilings shall be constructed in compliance with the applicable provisions of Chapter I;

(ii) Lighting, plumbing, water and sewage disposal systems shall be installed in compliance with applicable provisions of Chapter I.

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

(i) Be constructed of a light colored material;

(ii) Prevent entry of birds, animals or vermin;

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

(3) Water Supply.

(a) The quality of source water prior to treatment shall meet, at a minimum, the bacteriological standards for the restricted classification.

(b) Any well used as source water for wet storage shall be constructed, operated and maintained in accordance with all applicable Departmental regulations.

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

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

(e) Disinfection or other water treatment such as the addition of salt cannot leave residues unless they are Generally Recognized as Safe (GRAS) [see Title 21 Code of Federal Register (21CFR) (April 1, 2007)] and unless they do not interfere with the shellstock's survival, quality or activity during wet storage.

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

(g) When the laboratory analysis of a single sample of disinfected water entering the wet storage tanks shows any positive result for the coliform group, daily sampling shall be immediately instituted until the problem is identified and eliminated.

(h) When the problem that is causing disinfected water to show a positive result for the coliform group is eliminated, the effectiveness of the correction shall be shown on the first operating day following correction through the immediate collection, within a 24-hour period, of a set of three samples of disinfected water and one sample of the source water prior to disinfection.

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

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

(i) Continuous Flow-through Systems.

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

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

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

(ii) When a source classified as other than approved is used, a study shall be required to demonstrate that the disinfection system will consistently produce water that tests negative for the coliform group under normal operating conditions. The study shall:

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

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

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

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

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

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

(j) Recirculating Water System.

(i) A water disinfection system shall be required for all recirculating wet storage systems. A study shall be required to demonstrate that the disinfection system for the recirculating system will consistently produce water that tests negative for the coliform group under all operating conditions. The study shall meet the requirements in item D.3(d)(3)(i)(ii) above.

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

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

(iv) When multiple tube ultra-violet treatment with redundant capacity is used as a water disinfectant, each time a bulb change is required to replace a burned out bulb, or for periodic servicing, new ultra-violet bulbs shall be installed and old bulbs discarded. When a single tube ultra-violet treatment unit or a multi tube unit without redundancy is utilized, each time a bulb change is required either to replace a burned out bulb or for periodic servicing, new ultra-violet bulbs shall be installed and old bulbs discarded, a set of three (3) samples of disinfected water and one sample of the source water prior to disinfection shall be collected within a twenty four (24) hour period to reaffirm the ability of the system to produce water free from the coliform group. Ultra-violet systems using either a single tube or multiple-tube unit with no redundancy as their disinfections system may utilize an approved ultra-violet wavelength intensity monitoring unit to demonstrate bulb integrity.

4. Depletion of Closed Areas. If depletion of shellfish in a Prohibited Area is more economical than patrolling, all shellfish of market size and as many of smaller size as can be gathered by reasonable methods may be removed from the area by the Department or under direct supervision of the Department.

5. Shellfish Habitat Preservation. For purposes of shellfish habitat preservation, the Department may, in limited instances and with special conditions, authorize the translocation of viable shellfish beds

within prohibited areas. Authorization shall be considered only upon official request from the South Carolina Department of Natural Resources.

E. SHELLFISH SAMPLING AND STANDARDS.

1. Sampling and Testing. Samples of shellfish may be taken for scientific examination for public health purposes at any reasonable time or place by agents of the Department. Samples of shellfish shall be furnished as necessary by processors and operators of facilities, trucks, carriers, stores, restaurants, and other places where shellfish are sold. Receipt for shellfish used for sampling shall be given upon request. The type of test to be performed shall be included on the receipt.

2. Adulteration Standards. In determining bacteriological adulteration of shellfish, the Department shall use an *Escherichia coli* Most Probable Number (MPN) of two hundred and thirty per one hundred grams of sample and a total bacteria count of five hundred thousand per gram. Shellfish containing levels of pathogenic organisms or other substances that render the shellfish potentially unsafe for human consumption shall also be deemed adulterated by the Department.

F. LABORATORY PROCEDURES.

1. General. Laboratory analyses shall be performed by a State laboratory or a laboratory authorized by the Department. Laboratories shall conform to requirements of National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapter) III. Laboratory.

2. Microbiological. Methods, practices, and procedures for the analysis of shellfish and shellfish growing or harvest waters shall be the methods required by the National Shellfish Sanitation Program.

3. Physical and Chemical.

(a) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:

(1) Be the current Association of Analytical Chemists (AOAC) or American Public Health Association (APHA) method for all physical and chemical measurements; and

(2) Express results of all chemical and physical measurements in standard units, and not instrument readings.

(b) When an AOAC or APHA method is not available, EPA methods may be used.

4. Biotoxin. Methods for the analysis of shellfish and shellfish harvest waters shall be:

(a) The current Association of Analytical Chemists (AOAC) and American Public Health Association (APHA) methods used in the bioassay for paralytic shellfish poisoning toxins;

(b) The current APHA method used in the bioassay for *Karenia brevis* toxins.

G. CERTIFICATION AND PERMITTING PROCEDURES.

1. General.

(a) It shall be unlawful for any person to shuck, pack, repack, dehydrate, transport in interstate commerce, or purchase from harvesters or growers, shellfish, who does not possess the appropriate valid

certified shipper certificate issued by the Department or other appropriate state shellfish control authority. This item shall not be construed to prevent the transport of non-adulterated shellfish products by common carriers in the hire of a certified shipper, provided shellfish products shall be transported and handled in accordance with applicable provisions of this Regulation.

(b) Certified shipper certificates shall be of the following types:

- (1) Shucker-Packer;
- (2) Repacker;
- (3) Shellstock Shipper;
- (4) Reshipper;
- (5) Depuration Processor.

(c) It shall be unlawful for any person to sell, offer for sale, distribute for financial consideration, or market shellfish for any purpose related to human consumption that have not been processed by a certified shipper.

(d) Nothing in this section shall be construed to prevent the intrastate distribution or sale of shellfish products for human consumption by persons not possessing a certified shipper certificate issued by the Department, provided, however, that it shall be unlawful for any person who has not been issued a valid certified shipper certificate to:

(1) Sell or offer for sale any shellfish that have not been obtained from a certified shipper;

(2) Sell or offer for sale any shellfish in non-original packaging, and without original tags or labels as affixed by the certified shipper from which the shellfish were obtained, provided, however, that this item shall not apply to persons possessing a valid operating permit issued under authority of South Carolina R.61-25 Retail Food Establishments, provided shellfish have been obtained from a certified shipper;

(3) Transport or store shellfish offered or intended for sale in vehicles that are not constructed, operated, and maintained to prevent contamination and deterioration of shellfish;

(4) Sell or offer for sale adulterated shellfish;

(5) Sell or re-distribute shellfish to certified shippers.

(e) It shall be unlawful for any person to relay, construct or operate a wet storage facility, construct or operate an aquaculture facility, construct a depuration facility, or harvest for depuration who does not possess the appropriate valid permit issued by the Department. Permits shall be of the following types:

- (1) Relaying Permit;
- (2) Wet Storage Facility Operating Permit;
- (3) Wet Storage Facility Construction Permit;

- (4) Depuration Harvest Permit;
- (5) Depuration Facility Construction Permit
- (6) Aquaculture Facility Construction Permit;
- (7) Aquaculture Facility Operating Permit.

2. Application Requirements.

(a) Application for certificates and permits shall be made on forms provided by the Department. Application forms may be obtained by contacting the S.C. Department of Health and Environmental Control, Environmental Quality Control Bureau of Water, 2600 Bull St., Columbia, S.C. 29201.

(b) A construction permit shall be required prior to the construction, expansion, or modification of any depuration, land-based aquaculture, or land-based wet storage facility. Issuance of a valid construction permit shall be required prior to issuance of the associated operating permit;

(c) Application for any activity requiring a construction permit shall include a written operations plan, including construction and site plan, detailing the scope and extent of the proposed construction and associated activity.

(d) Application for aquaculture and wet storage operating permits shall include a written operations plan detailing the scope and extent of the proposed operation.

(e) Application for certification as a depuration processor shall include a scheduled depuration process (operations plan and manual).

(f) Certificates and permits shall be non-transferable

(g) Certificates and permits, unless otherwise specified, shall expire on June 30 of each year.

(h) Only persons who comply with the requirements of this Regulation shall be entitled to receive and retain a certificate or permit.

3. Issuance of Certificates and Permits.

(a) Certified Shipper Certificates.

(1) Upon receipt of a completed application package, including any required operations plan, the Department shall make comprehensive onsite inspections of the proposed certified shipper facility/operation as may be necessary to determine compliance with the applicable provisions of this Regulation. Inspections shall be conducted within the one hundred twenty (120) day period immediately prior to the issuance or renewal of the certification. Certification shall be issued only for facilities that meet the following requirements:

(a) Have a Hazard Analysis Critical Control Point (HACCP) plan accepted by the Authority;

(b) During inspection for certification, have no critical deficiencies (see section H.);

(c) During inspection for certification, have no more than two key deficiencies (see section H.);

(d) During inspection for certification, have no more than three other deficiencies (see section H.).

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

(b) Construction and Operating Permits.

(1) Upon receipt of a completed application package, including any required written operations plan, the Department shall, as necessary, make comprehensive onsite inspections of the proposed facility or activity to determine compliance with the applicable provisions of this Regulation.

(2) Permits shall be issued only for facilities and activities meeting applicable requirements of this Regulation.

(3) Any operations plan accepted by the Department in conjunction with the issuance of a construction or operating permit shall not be modified without Department authorization.

H. INSPECTION AND COMPLIANCE.

1. Inspections.

(a) Access. For the purpose of determining compliance with this Regulation, authorized representatives of the Department shall, upon display of proper identification, be permitted to enter at any reasonable time any facility, establishment, market, vessel, or vehicle used to harvest, handle, process, store, sell, or transport shellfish.

(b) Inspection Frequency.

(1) Certified Shippers. Following issuance of a certified shipper certificate, unannounced performance-based inspections shall be made during periods of activity. Inspections and re-inspections shall be made, as determined necessary by the Department, for the effective enforcement of this Regulation. At a minimum, certified shipper facilities shall be inspected in accordance with the following frequencies:

(a) monthly for Depuration Processors;

(b) quarterly for Shucker-Packers or Repackers;

(c) semi-annually for Shellstock Shippers or Reshippers

(2) Permits. Following issuance of any permit, inspections shall be made during periods of activity as necessary for the effective enforcement of this Regulation.

(c) Records. Authorized representatives of the Department shall, upon display of proper identification, be permitted to examine the records of any facility, establishment, or operation certified or permitted by the Department in accordance with this Regulation, for the purpose of obtaining information

pertaining to shellfish grown or harvested, purchased, received, sold, shipped, distributed, shucked, packed, depurated or processed in any manner.

2. Compliance.

(a) National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapter) X. General Requirements For Dealers shall be used in establishing and determining Hazard Analysis Critical Control Point (HACCP) and general sanitation requirements.

(b) National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapters) XI. Shucking and Packing, XII. Repacking Of Shucked Shellfish, XIII. Shellstock Shipping, XIV. Reshipping, and XV. Depuration shall be utilized in determining certified shipper inspection item deficiency levels. Deficiencies documented during the inspection of certified shipper facilities shall be corrected in accordance with the following procedures:

(1) When any inspection detects a critical deficiency:

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

(b) The certified shipper shall immediately cease production affected by the deficiency.

(c) If the certified shipper facility fails to correct the critical deficiency during the inspection, the Department shall provide notice of intent to suspend or revoke the certificate.

(2) Shellfish products affected by a critical deficiency shall be controlled to prevent contamination or adulterated product from reaching consumers. The Department shall:

(a) Condemn and destroy adulterated shellfish;

(b) Initiate a recall of adulterated shellfish;

(c) Notify enforcement officials for the United States Food and Drug Administration, as well as shellfish control authorities in states that are known to have received adulterated shellfish.

(3) When any inspection detects key or other deficiencies not currently covered in a compliance schedule, the Department, working with the certified shipper, shall develop a compliance and correction schedule.

(4) When any inspection detects four or more new key deficiencies, the Department shall consider the following options and document the reasons for selection of one of the following options:

(a) Revise the existing compliance schedule;

(b) Commence action to suspend or revoke certification; or

(c) Seek other administrative remedies.

(c) Nothing in sub-section H.2 shall be construed to limit or make null any option for remedy as provided for in Section P. of this Regulation.

(d) Stop Sale or Disposal of Shellfish.

(1) If it has been determined by the Department that shellfish have not been grown, harvested, stored, treated, transported, handled, shucked, packed, processed, sold, or offered for sale in compliance with this Regulation, those shellfish shall be deemed adulterated.

(2) Shellfish or shellfish products determined to be adulterated shall be subject to stop sale or disposal by the Department. The Department may temporarily or permanently issue an order to stop sale, condemn, destroy, recall, or otherwise dispose of all shellfish or shellfish containers found to be adulterated.

(3) Adulterated shellfish shall be disposed of at the discretion of the Department.

(e) Suspension or Revocation of Permits or Certificates.

(1) If the Department has evidence that an operator of a shellfish activity or facility has created or is responsible for conditions that may cause shellfish to become adulterated, the permit or certificate may be suspended or revoked.

(2) Serious or repeated violations of any of the requirements of this Regulation, failure to cooperate, or interference with Department personnel in the performance of their duties shall be cause for a permit or certificate to be revoked.

(3) Decisions involving the issuance, denial, renewal, modification, suspension, or revocation of permits, licenses, certification, or other actions of the Department shall be in accordance with the provisions of S.C. Code Section 44-1-60, 1976 Code of Laws, as amended.

(f) Appeal. A Department decision involving the issuance, denial, renewal, modification, suspension, or revocation of permits, licenses, certification, or other actions of the Department may be appealed by the affected person with standing pursuant to applicable law, including S.C. Code Title 44, Chapter 1; and Title 1, Chapter 23.

I. CERTIFIED SHIPPER FACILITIES.

1. General Requirements. In addition to and to the extent not inconsistent with other applicable provisions of this Regulation, certified shippers shall comply with the following sections of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapter) X. General Requirements For Dealers:

- (a) .01 General HACCP Requirements;
- (b) .02 General Sanitation Requirements;
- (c) .03 Other Model Ordinance Requirements;
- (d) .07 Post Harvest Process Labeling; and
- (e) .08 Shipping Documents and Records.

2. Shellfish Source. Certified shippers shall receive and/or process shellfish in accordance with the following:

(a) Shucker-packers, repackers, shellstock shippers, and depuration processors shall only receive or process shellfish that have been:

(1) Harvested from approved or conditionally approved growing areas in the open status, provided that this item shall not apply when closed area harvest has been conducted in conjunction with a special permit issued by the Department; or

(2) Obtained from a certified shipper that has obtained, handled, processed, and transported the shellfish in accordance with the provisions of this Regulation, or another state's substantially equivalent regulation.

(b) Reshippers shall receive shellfish only from certified shippers that have obtained, handled, processed, and transported the shellfish in accordance with the provisions of this Regulation, or another state's substantially equivalent regulation.

3. Shellfish Refrigeration. Certified Shipper facilities shall have non-mobile, mechanically refrigerated storage rooms capable of maintaining all non-frozen shellfish at a temperature of forty-five (45) degrees Fahrenheit (7.2 degrees Centigrade) or less.

4. Shellstock Temperature Management. Certified shippers shall manage shellstock temperature in accordance with the provisions of item C.2.(b).

5. Temperature Control. Certified shippers shall control shellfish temperatures in accordance with the provisions of items C.2.(c) and C.2.(e).

6. Shellstock Identification. Certified shippers shall identify shellstock in accordance with item C.2.(d)(1) of this Regulation.

7. Shucked Shellfish Labeling. Certified shippers shall label shucked shellfish in accordance with item C.2.(f)(1) of this Regulation.

8. Bulk Receiving. When bulk tagged lots of shellfish are received, certified shippers shall use an intermediate processing plan authorized by the Department to ensure shellfish are controlled to prevent commingling or misidentification.

J. SHUCKER-PACKERS.

1. General Requirements. In addition to and to the extent not inconsistent with other applicable provisions of this Regulation, shucker-packers shall comply with dealer requirements of the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapter) XI. Shucking and Packing.

2. Heat Shock. Heat shock shall only be conducted in accordance with a scheduled heat shock process authorized by the Department.

K. REPACKERS.

General Requirements. In addition to and to the extent not inconsistent with other applicable provisions of this Regulation, repackers shall comply with National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapter) XII. Repacking Of Shucked Shellfish.

L. SHELLSTOCK SHIPPERS.

General Requirements. In addition to and to the extent not inconsistent with other applicable provisions of this Regulation, shellstock shippers shall comply with National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapter) XIII. Shellstock Shipping.

M. RESHIPPIERS

General Requirements. In addition to and to the extent not inconsistent with other applicable provisions of this Regulation, reshippers shall comply with National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish (chapter) XIV. Reshipping.

N. DEPURATION.

General Requirements. In addition to and to the extent not inconsistent with other applicable provisions of this Regulation, depuration processors shall comply with the dealer requirements of National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (chapter) XV. Depuration.

O. SHELLFISH AQUACULTURE.

1. General.

(a) For purposes of this Regulation, aquaculture encompasses the following:

(1) Open-water and/or Land-based operations, other than shellfish seed hatchery operations;

(2) Monoculture (molluscan shellfish) or Polyculture (molluscan shellfish combined with non-molluscan organisms) production.

(b) Any person operating a land based aquaculture facility that grows or produces molluscan shellfish for sale shall obtain the following from the Department prior to commencing operations or harvesting shellfish for human consumption:

(1) An Aquaculture Facility Construction Permit based upon criteria described in the facility's operational plan as required by Section O.4(a); and

(2) An Aquaculture Operating Permit based upon successfully meeting the requirements of all applicable portions of this Regulation; and

(3) Certification as a processor, unless the permitted aquaculturist provides the Department with prior notice that harvested shellfish are to be delivered to a Shucker-Packer (SP), Repacker (RP), Shellstock Shipper (SS), or Depuration Processor (DP) within the State.

(c) Any person operating an open water aquaculture facility that grows or produces molluscan shellfish for sale shall obtain the following from the Department prior to commencing operations or harvesting shellfish for human consumption:

(1) An Aquaculture Operating Permit based upon successfully meeting the requirements of all applicable portions of this Regulation; and

(2) Certification as a processor, unless the permitted aquaculturist provides the Department with prior notice that harvested shellfish are to be delivered to a Shucker-Packer (SP), Repacker (RP), Shellstock Shipper (SS), or Depuration Processor (DP) within the State.

(d) Shellfish aquaculture shall be practiced only in strict compliance with the specific provisions of the Aquaculture Permit;

(e) Applications for Aquaculture Permits must contain a written operational plan detailing the scope and extent of the operation.

(f) Water quality at any site used for aquaculture shall meet the criteria for an approved, conditionally approved, or restricted area classification provided, however, this item shall not apply to shellfish seed operations when:

(1) The use of a prohibited growing area is sanctioned for seed culture operations by the Department;

(2) Prior to relocation, seed cultured in any prohibited area are demonstrated to the Department to have acceptable levels of poisonous or deleterious substances;

(3) Seed cultured in prohibited growing areas are relocated with Department authorization and cultured for a minimum of six months in areas exhibiting approved area criteria; and

(4) Shellfish relocated in accordance with this section shall not be harvested without Department authorization.

(g) Shellfish cultured in any land-based system meeting the criteria for an approved area classification throughout the culture period may be immediately marketed.

(h) Any shellfish raised in aquaculture shall be subjected to relaying or depuration prior to direct marketing if the culture area or facility is located in or using water that is in one of the following:

(1) A conditionally approved area classification in a "closed" status; or

(2) A restricted area classification.

(i) Only drugs authorized by the United States Food and Drug Administration shall be used for shellfish treatment.

(j) Complete and accurate records shall be maintained for at least two years by the aquaculturist and shall include the:

(1) Source of shellfish, including seed;

(2) Dates of transplanting and harvest; and

(3) Water source, its treatment method, if necessary, and its quality in land based systems.

(k) Harvesting, processing, storage, and transportation of shellfish shall comply with all other applicable requirements of this Regulation.

2. Seed Source. Aquaculture Permit holders shall provide the Department with documentation concerning the source of seed shellstock.

3. Open Water Operations. Open-water aquaculture operations shall comply with all applicable requirements of this Regulation.

4. Land-Based Operations. Applicants for land-based aquaculture permits shall provide the following to the Department:

(a) A written operational plan that shall include:

(1) A description of the design and activities of the aquaculture facility;

(2) The specific site and boundaries in which shellfish culture activities will be conducted;

(3) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats utilized in the aquaculture operation;

(4) The species and source of shellfish, including seed, to be cultured and harvested;

(5) If appropriate, the source and species of other organisms to be cultured in any polyculture systems;

(6) Procedures to assure that no poisonous or deleterious substances are introduced into the activities;

(7) A program of sanitation, maintenance, and supervision to prevent contamination of the final shellfish products;

(8) A description of the water source, including the details of any water treatment process or method, if necessary;

(9) A program to maintain water quality that includes collection of water samples for microbial analysis, temperature and salinity monitoring, and analytical methods used. The bacterial indicator monitored shall be the same as used for monitoring growing areas;

(10) Collection of information on the microbial and chemical quality of shellfish harvested from the aquaculture site;

(11) Collection of data concerning the quality of food produced for use in the artificial harvest system;

(12) Maintenance of the required records; and

(13) How shellstock will be harvested, processed if applicable, and sold.

(b) Water Systems.

(1) Water disinfection will not be required if shellfish are held at all times in continuous flow through systems that utilize water from an approved growing area, or from a conditionally approved area in the open status.

(2) Closed or recirculating systems shall:

(a) Not contaminate shellfish with residues that are not Generally Recognized As Safe (GRAS) [see Title 21 CFR (April 1, 2007)]; and

(b) Utilize waters classified as approved, conditionally approved or restricted; and

(c) Be maintained, at a minimum, at the bacteriological quality of the restricted classification.

(3) If the water in the closed or recirculating system is from water classified as conditionally approved, the operational plan shall include a sampling schedule and shellfish shall not be harvested until:

(a) a total of three water samples have been collected from the system a minimum of three days apart over a 14 day period; and

(b) fecal coliform levels in each sample are not greater than fourteen (14) MPN per one hundred (100) ml.

(c) Water Quality.

(1) Shellstock held at all times in waters meeting the criteria for an approved area may be used for direct marketing;

(2) If the water in a closed or recirculating system is from a source classified as conditionally approved and in the open status, shellstock may be marketed directly if the water quality meets a fecal coliform level of less than fourteen (14) MPN per one hundred (100) ml. in each sample collected in the 14 days prior to harvest.

(3) Shellstock in a closed or recirculating system that does not meet the water quality requirements of items O.4(c)(1) or O.4(c)(2) shall be relayed or deperated prior to direct marketing.

5. Polyculture Activities. Aquaculture permit applicants engaging in Polyculture activities shall include in an operational plan provisions to:

(a) Provide information concerning all sources and species of all organisms to be cultivated, cultured, and harvested;

(b) Monitor for human pathogens, unacceptable levels of animal drugs, and other poisonous or deleterious substances that might be associated with polyculture activities; and

(c) Subject all harvested shellstock to relaying or deperation:

6. Mariculture Permit Areas. Operators of shellfish mariculture permit areas permitted by the South Carolina Department of Natural Resources shall provide the Department with a written operational plan that shall include:

(a) A description of activities associated with the operation;

(b) The specific site and boundaries in which shellfish culture activities will be conducted;

(c) The types and locations of any structures, including rafts, pens, cages, nets, tanks, ponds, or floats utilized in the aquaculture operation;

(d) The type and source of shellfish, including seed, to be cultured and harvested;

(e) Documentation of the source of seed shellstock.

P. REMEDIES.

1. General. In addition to the provisions herein for administrative suspension or revocation of operating permits, the Department may, at its discretion, bring civil court proceedings to enforce provisions of this Regulation, and may also seek to impose criminal sanctions for violation of this Regulation.

2. Criminal Liability. Violation of any provision of this Regulation shall be punishable in accordance with Section 44-1-150 and Section 44-1-151, Code of Laws of South Carolina, 1976, and any subsequent amendments.