

SECTION .0300 – SANITATION OF SHELLFISH - GENERAL

15A NCAC 18A .0301 DEFINITIONS

The following definitions shall apply throughout Sections .0300 to .0900 of this Subchapter:

- (1) "Adulterated" means the following:
 - (a) Any shellfish that have been harvested from prohibited areas;
 - (b) Any shellfish that have been shucked, packed, or otherwise processed in a plant which has not been permitted by the Division in accordance with these Rules;
 - (c) Any shellfish which exceed the bacteriological standards in Rule .0430 of this Subchapter; and
 - (d) Any shellfish which are deemed to be an imminent hazard;
- (2) "Approved area" means an area determined suitable for the harvest of shellfish for direct market purposes.
- (3) "Bulk shipment" means a shipment of loose shellstock.
- (4) "Buy boat or buy truck" means any boat which complies with Rule .0419 of this Subchapter or truck which complies with Rule .0420 of this Subchapter that is used by a person permitted under these Rules to transport shellstock from one or more harvesters to a facility permitted under these Rules.
- (5) "Certification number" means the number assigned by the state shellfish control agency to each certified shellfish dealer. It consists of a one to five digit number preceded by the two letter state abbreviation and followed by the two letter symbol designating the type of operation certified.
- (6) "Critical control point" means a point, step or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated or reduced to acceptable levels.
- (7) "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.
- (8) "Depuration" means mechanical purification or the removal of adulteration from live shellstock by any artificially controlled means.
- (9) "Depuration facility" means the physical structure wherein depuration is accomplished, including all the appurtenances necessary to the effective operation thereof.
- (10) "Division" means the Division of Environmental Health or its authorized agent.
- (11) "Food safety hazard" means any biological, chemical or physical property that may cause a food to be unsafe for human consumption.
- (12) "HACCP plan" means a written document that delineates the procedures a dealer follows to implement food safety controls.
- (13) "Hazard analysis critical control point (HACCP)" means a system of inspection, control and monitoring measures initiated by a dealer to identify microbiological, chemical or physical food safety hazards which are likely to occur in shellfish products produced by the dealer.
- (14) "Heat shock process" means the practice of heating shellstock to facilitate removal of the shellfish meat from the shell.
- (15) "Imminent hazard" means a situation which is likely to cause an immediate threat to human life, and immediate threat of serious physical injury, an immediate threat of serious physical adverse health effects, or a serious risk of irreparable damage to the environment if no immediate action is taken.
- (16) "Misbranded" means the following:
 - (a) Any shellfish which are not labeled with a valid identification number awarded by regulatory authority of the state or territory of origin of the shellfish; or
 - (b) Any shellfish which are not labeled as required by these Rules.
- (17) "Operating season" means the season of the year during which a shellfish product is processed.
- (18) "Person" means an individual, corporation, company, association, partnership, unit of government or other legal entity.
- (19) "Prohibited area" means an area unsuitable for the harvesting of shellfish for direct market purposes.
- (20) "Recall procedure" means the detailed procedure the permitted dealer will use to retrieve product from the market when it is determined that the product may not be safe for human consumption as determined by the State Health Director.
- (21) "Relaying or transplanting" means the act of removing shellfish from one growing area or shellfish grounds to another area or ground for any purpose.

- (22) "Repacking plant" means a shipper, other than the original shucker-packer, who repacks shucked shellfish into containers for delivery to the consumer.
- (23) "Reshipper" means a shipper who ships shucked shellfish in original containers, or shellstock, from permitted shellstock dealers to other dealers or to consumers.
- (24) "Sanitary survey" means the evaluation of factors having a bearing on the sanitary quality of a shellfish growing area including sources of pollution, the effects of wind, tides and currents in the distribution and dilution of polluting materials, and the bacteriological quality of water.
- (25) "Sanitize" means the a bactericidal treatment by a process which meets the temperature and chemical concentration levels in 15A NCAC 18A .2619.
- (26) "SELL BY date" means a date conspicuously placed on a container or tag by which a consumer is informed of the latest date the product will remain suitable for sale.
- (27) "Shellfish" means oysters, mussels, scallops and all varieties of clams. However, the term shall not include scallops when the final product is the shucked adductor muscle only.
- (28) "Shellstock" means any shellfish which remain in their shells.
- (29) "Shellstock conveyance" means all trucks, trailers, or other conveyances used to transport shellstock.
- (30) "Shellstock dealer" means a person who buys, sells, stores, or transports or causes to be transported shellstock which was not obtained from a person permitted under these Rules.
- (31) "Shellstock plant" means any establishment where shellstock are washed, packed, or otherwise prepared for sale.
- (32) "Shucking and packing plant" means any establishment or place where shellfish are shucked and packed for sale.
- (33) "Wet storage" means the temporary placement of shellstock from approved areas, in containers or floats in natural bodies of water or in tanks containing natural sea water.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. August 1, 2000; August 1, 1998; February 1, 1997; January 4, 1994; September 1, 1990;
December 1, 1987.*

15A NCAC 18A .0302 PERMITS

- (a) No person shall operate any of the following facilities without a permit issued by the Division:
 - (1) Depuration facilities;
 - (2) Shellstock plants;
 - (3) Shucking and packing plants;
 - (4) Repacking plants.
- (b) No person shall operate as a shellstock dealer without a permit issued by the Division.
- (c) A permit may be issued to a reshipper when required for out of state shipment.
- (d) Approval for wet storage of shellstock shall be granted only to persons permitted pursuant to this Rule.
- (e) Application for a permit shall be submitted in writing to the Division at the Shellfish Sanitation Office, Fisheries Building, Arendell Street, Morehead City, North Carolina, 28557. Application forms are available from the Division.
- (f) No permit shall be issued by the Division until an inspection shows that the facilities and equipment comply with all applicable rules of this Subchapter.
- (g) All permits shall be posted in a conspicuous place in the facilities. All permits shall expire on April 30 of each year.
- (h) Plans and specifications for proposed new construction or remodeling shall be submitted to the Division for review and approval.
- (i) A permit may be revoked or suspended pursuant to G.S. 130A-23.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. April 1, 1997.*

15A NCAC 18A .0303 RELAYING PERMITS

If a person is granted a relaying permit by the Division and the Division of Marine Fisheries, shellfish may be removed from certain designated prohibited areas for conditioning and purification prior to marketing and marketed after relaying in a large body of clean water, but only under the following conditions:

- (1) Application for relaying must be received by the North Carolina Division of Marine Fisheries and the Division 15 days prior to relaying.
- (2) Removal and relaying shall be under the supervision of the Division and the Division of Marine Fisheries.
- (3) Shellfish relayed from a prohibited area to a designated area of approved water shall remain down for a period of not less than fourteen days when the water in which shellfish are relayed has a temperature above 50°F (10°C). When the water temperature is below 50°F (10°C), shellfish shall not be relayed.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

15A NCAC 18A .0304 DEPURATION HARVESTING PERMITS

If a person is granted a depuration harvesting permit by the Division and the Division of Marine Fisheries, shellfish may be removed from certain designated prohibited areas for depuration prior to marketing and marketed after depuration in a permitted facility, but only under the following conditions:

- (1) Application for a depuration harvesting permit must be received by the Division of Marine Fisheries and the Division 15 days prior to harvesting for depuration purposes.
- (2) Harvesting for depuration purposes shall be under the supervision of the Division and the Division of Marine Fisheries.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

15A NCAC 18A .0305 APPEALS PROCEDURE

Appeals concerning the interpretation and enforcement of the rules in this Subchapter shall be made in accordance with G.S. 150B.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

SECTION .0400 - SANITATION OF SHELLFISH - GENERAL OPERATION STANDARDS

Rules .0401 - .0431 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0401 - .0431); has been transferred and recodified from Rules .0901 - .0931 of Title 10 Subchapter 10B of the North Carolina Administrative Code (T10.10B .0901 - .0931), effective April 4, 1990.

15A NCAC 18A .0401 APPLICABILITY OF RULES

The rules in this Section shall apply to the operation of all facilities and persons permitted in Rule .0302 and all other businesses and persons that buy, sell, transport, or ship shellfish. These Rules do not apply to persons possessing shellfish for personal use.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. April 1, 1997; December 1, 1987.*

15A NCAC 18A .0402 GENERAL REQUIREMENTS FOR OPERATION

- (a) During the operating season the plant shall be used for no purpose other than the handling of shellfish. All unnecessary equipment and materials shall be removed from the plant and the floors kept clear for thorough cleaning.
- (b) All floors, walls, shucking benches and stools, shucking blocks, tables, skimmers, blowers, colanders, buckets, or any other equipment or utensils used in the processing operation shall be cleaned and sanitized daily, or more frequently as may be necessary during the day's operation to prevent the introduction of undesirable microbiological organisms and filth into the shellfish product.
- (c) Ceilings and windows shall also be kept clean. Refrigerators, refrigeration rooms, and ice boxes shall be washed and sanitized.
- (d) Wheelbarrows, measures, baskets, shovels, and other implements used in the handling of shellstock shall not be used for any other purpose and shall be cleaned and stored in the shellstock room when not in use.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0403 SUPERVISION

The owner shall personally supervise or shall designate an individual whose principal duty shall be to supervise and be responsible for compliance with the Rules of this Subchapter. No unauthorized persons shall be allowed in the plant during periods of operation.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0404 CONSTRUCTION

Shellfish plants shall be adequate in size and construction to permit compliance with the operational provisions of this Subchapter.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0405 PLANT LOCATION

Shellfish plants shall be located so that they will not be subject to flooding by high tides.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0406 FLOORS

Floors shall be of concrete or other equally impervious material, constructed so that they may be easily and thoroughly cleaned and shall be sloped so that water drains completely and rapidly. For new construction, the joints between walls and floors shall be rounded to expedite cleaning.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0407 WALLS AND CEILINGS

Walls to a height of at least two feet above the floor shall be constructed of smooth concrete or other equally impervious material. The remainder of the walls and ceilings shall be smooth concrete, cement plaster, or other material approved by the Division and shall be painted with a light color washable paint.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0408 LIGHTING

Natural or artificial lighting shall be provided in all parts of the plant. Light bulbs, fixtures, or other glass suspended within the plant shall be safety type or otherwise protected to prevent contamination in case of breakage. Lighting intensities shall be a minimum of 25 foot candles on working surfaces in packing and shucking rooms.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0409 VENTILATION

Ventilation shall be provided to eliminate odors and condensation.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0410 FLY CONTROL

All outside openings shall be screened, provided with wind curtains or be provided with other fly control methods approved by the Division. All screens shall be kept in good repair. All outside doors shall open outward and shall be self-closing. The use and storage of pesticides shall comply with all applicable state and federal guidelines.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0411 RODENT AND ANIMAL CONTROL

The plant shall be constructed to prevent entrance of rodents and other vermin. The storage and use of rodenticides shall comply with all applicable state and federal guidelines. No animals shall be allowed in the plant at any time.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0412 PLUMBING

All plumbing shall be in compliance with applicable plumbing codes.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0413 WATER SUPPLY

- (a) The water supply shall be from a source approved by the Division.
- (b) The water supply used shall be located, constructed, maintained, and operated in accordance with the Commission for Health Services' rules governing water supplies. Copies of 15A NCAC 18A .1700 and 15A NCAC 18C may be obtained from the Division.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

15A NCAC 18A .0414 TOILET FACILITIES

Separate and convenient toilet facilities shall be provided for each sex employed and shall comply with the N.C. State Building Code, Volume 2, Plumbing. Floors, walls, and ceilings shall be smooth, easily cleanable and kept clean. Fixtures shall be kept clean. All toilet wastes and other sewage shall be disposed of in a public sewer system or in the absence of a public sewer system, by an on site sewage disposal system approved by the Department in accordance with G.S. 130A-335.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

15A NCAC 18A .0415 WASTE DISPOSAL

Shells, washings, and other wastes shall be disposed of in a sanitary landfill or in a sanitary manner approved by the Division.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0416 PERSONAL HYGIENE

- (a) All employees shall wash their hands thoroughly with soap and running water before beginning work and again after each interruption. Signs to this effect shall be posted in conspicuous places in the plant by the operator.
- (b) All persons handling shucked shellfish shall sanitize their hands before beginning work and again after each interruption.
- (c) All persons employed or engaged in the handling, shucking, or packing of shellfish shall wear clean, washable outer clothing. Clean plastic or rubber aprons, overalls, and rubber gloves shall be considered satisfactory.
- (d) Employees shall not use tobacco in any form in the rooms where shellfish are stored, processed, or handled.
- (e) All persons known to be a carrier of any disease which can be transmitted through the handling of shellfish or who have an infected wound or open lesion on any exposed portion of their bodies shall be prohibited from handling shellfish.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0417 LOCKERS

A separate room or locker shall be provided for storing employees' street clothing, aprons, gloves, and personal articles.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0418 SUPPLY STORAGE

Storage room shall be provided for storing shipping containers, tags, and other supplies.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0419 HARVEST BOATS

All boats used in the harvesting and handling of shellstock shall be kept clean and repaired such that the shellstock thereon shall not be subject to adulteration by bilge water, by leakage of water from prohibited areas, or by other means. Decks, holds, or bins used for shellstock on boats shall not be washed with water from prohibited areas. Human wastes shall not be discharged into shellfish waters.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0420 TRANSPORTING SHELLSTOCK

(a) All shellstock storage areas in trucks, buy boats, buy trucks, trailers, and other conveyances used for transporting shellstock shall be enclosed, tightly constructed, painted with a light color washable paint, kept clean, and shall be subject to inspection by the Division.

(b) Shellstock shall be shipped under temperature and sanitary conditions in accordance with these Rules which will keep them alive and clean and will prevent adulteration or deterioration. All shellstock shall be kept under mechanical refrigeration at a temperature of 45°F (7.1°C) or below. All conveyances used to transport shellstock shall be equipped with an operating thermometer.

(c) Buy boats and buy trucks shall be kept clean with water from a source approved by the Division under Rule .0413 of this Subchapter. Buy boats and buy trucks shall provide storage space for clean shipping containers, identification tags, and records.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. May 1, 1994.*

15A NCAC 18A .0421 DAILY RECORD

All permitted persons who conduct any business of buying, selling, or shipping shellfish shall keep an accurate, daily record which shall show the names and addresses of all persons from whom shellfish are received, the location of the source of shellfish, and the names and addresses of all persons to whom shellfish are sold or shipped. These records shall be recorded and shall be kept on file for one year. All records shall be open to inspection by the Division at any time during business hours.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. August 1, 1998.*

15A NCAC 18A .0422 SHELLSTOCK CLEANING

No person shall offer for sale any shellstock which have not been washed free of bottom sediments and detritus.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0423 SALE OF LIVE SHELLSTOCK

Only live shellstock shall be offered for sale.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0424 SHELLFISH RECEIVING

No person shall receive or accept any shellfish unless the container or package bears the tag or label required by these Rules.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. April 1, 1997.*

15A NCAC 18A .0425 TAGGING

(a) In order that information may be available to the Division with reference to the origin of shellstock, containers holding shellstock shall be identified with a uniform tag or label. The tag shall be durable, waterproof and measure at least 2-5/8 by 5-1/4 inches (6.7 by 13.3 centimeters). The tag shall contain legible information arranged in specific order as follows:

- (1) the dealer's name, address and certification number assigned by the appropriate shellfish control agency;
- (2) the original shipper's certification number;
- (3) the harvest date;
- (4) the harvest location, including the country or state abbreviation;
- (5) when the shellstock has been in wet storage, the statement "THIS PRODUCT WAS IN WET STORAGE AT (FACILITY CERTIFICATION NUMBER) FROM (DATE) TO (DATE)";
- (6) the type and quantity of shellfish;
- (7) the following statement shall appear in bold capitalized type "THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY AND THEREAFTER KEPT ON FILE FOR 90 DAYS."; and
- (8) the following statement, or equivalent,
"Consumer Advisory
Eating raw oysters, clams or mussels may cause severe illness. People with the following conditions are at especially high risk: liver disease, alcoholism, diabetes, cancer, stomach or blood disorder, or weakened immune system. Ask your doctor if you are unsure of your risk. If you eat raw shellfish and become sick, see a doctor immediately."

(b) The uniform tag or label shall remain attached to the shellstock container until the container is empty and thereafter shall be kept on file for 90 days.

(c) All shellstock from a depuration facility must be identified as having been cleansed by a depuration facility identified by a name and permit number on the tag.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. April 1, 1997; January 4, 1994; December 1, 1987;
Temporary Amendment Eff. October 12, 1998; February 1, 1998;
Amended Eff. April 1, 1999.*

15A NCAC 18A .0426 BULK SHIPMENTS

Shipment in bulk shall not be made except where the shipment is from only one consignor to one consignee and accompanied by the uniform shipping tag.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0427 SHELLSTOCK STORAGE

Shellstock held in wet or dry storage must be kept so that they will not become adulterated. All shellstock held in dry storage shall be kept under mechanical refrigeration at a temperature of 45°F (7.1°C) or below. All refrigerated shellstock storage areas shall be equipped with an operating thermometer.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. May 1, 1994; December 1, 1987.*

15A NCAC 18A .0428 SAMPLING AND TESTING

Samples of shellfish may be taken and bacteriologically examined for any public health reason by agents of the Division at any time or place. Samples of shellfish shall be furnished, upon request, by operators of plants, trucks, carriers, stores, restaurants, and other places where shellfish are sold.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0429 STOPSALE OR DISPOSAL OF SHELLFISH

(a) When it has been determined by the Division that shellfish have not been grown, harvested, stored, treated, transported, handled, shucked, packed or offered for sale in compliance with 15A NCAC 18A .0300 through .0900 of this Subchapter, those shellfish shall be deemed adulterated.

(b) Shellfish or shellfish products processed or prepared for sale to the public determined to be adulterated or misbranded shall be subject to stopsale or disposal by the Division. The Division may temporarily or permanently issue an order to stop sale or condemn, destroy, or otherwise dispose of all shellfish or shellfish containers found to be adulterated or misbranded.

(c) All shellfish shall be disposed of in a manner prescribed by the Division or by a court of appropriate jurisdiction.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0430 BACTERIOLOGICAL STANDARDS

Shellfish shucked or in the shell and intended or offered for sale in North Carolina that exceed an Escherichia coli Most Probable Number of 230 per 100 grams of sample or a total bacteria count of more than 500,000 per gram or contain pathogenic organisms in sufficient numbers to be hazardous to the public health shall be deemed adulterated by the Division. Shellfish contaminated by any other substance which renders it unsafe for human consumption shall be deemed adulterated by the Division.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0431 STANDARDS FOR AN APPROVED SHELLFISH GROWING AREA

In order that an area be approved for shellfish harvesting for direct market purposes the following criteria must be satisfied as indicated by sanitary survey:

- (1) the shoreline survey has indicated that there is no significant point source contamination;
- (2) the area is not so contaminated with fecal material that consumption of the shellfish might be hazardous;
- (3) the area is not so contaminated with radionuclides or industrial wastes that consumption of the shellfish might be hazardous; and
- (4) the median fecal coliform Most Probable Number (MPN) or the geometric mean MPN of water shall not exceed 14 per 100 milliliters, and not more than 10 percent of the samples shall exceed a fecal coliform MPN of 43 per 100 milliliters (per five tube decimal dilution) in those portions of areas most probably exposed to fecal contamination during most unfavorable hydrographic conditions.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0432 PUBLIC DISPLAY OF CONSUMER ADVISORY

All facilities and persons permitted in Rule .0302 of this Subchapter and all other businesses and persons that sell raw shellfish shall post in a conspicuous place where it may be readily observed by the public the following consumer advisory:

"Consumer Advisory

Eating raw oysters, clams or mussels may cause severe illness. People with the following conditions are at especially high risk: liver disease, alcoholism, diabetes, cancer, stomach or blood disorder, or weakened immune system. Ask your doctor if you are unsure of your risk. If you eat shellfish and become sick, see a doctor immediately."

*History Note: Authority G.S. 130A-230;
Temporary Adoption Eff. October 12, 1998; February 1, 1998;
Eff. April 1, 1999.*

15A NCAC 18A .0433 HAZARD ANALYSIS

Each dealer shall conduct a hazard analysis to determine the food safety hazards that are reasonably likely to occur for each kind of shellfish product processed by that dealer and to identify the preventative measures that the dealer can apply to control those hazards.

*History Note: Authority G.S. 130A-230;
Eff. August 1, 2000.*

15A NCAC 18A .0434 HACCP PLAN

Each dealer shall have and implement a written HACCP Plan. The owner or authorized designee shall sign the plan when implemented and after any modification. The plan shall be reviewed and updated, if necessary, at least annually. The plan shall, at a minimum:

- (1) List the food safety hazards that are reasonably likely to occur;
- (2) List the critical control points for each of the food safety hazards;
- (3) List the critical limits that must be met for each of the critical control points;
- (4) List the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
- (5) List any corrective action plans to be followed in response to deviations from critical limits at critical control points;
- (6) Provide a record keeping system that documents critical control point monitoring; and
- (7) List the verification procedures, and frequency thereof, that the dealer will use.

*History Note: Authority G.S. 130A-230;
Eff. August 1, 2000.*

15A NCAC 18A .0435 SANITATION MONITORING REQUIREMENTS

Each dealer shall monitor, at a minimum, the following sanitation items:

- (1) Safety of water;
- (2) Condition and cleanliness of food contact surfaces;
- (3) Prevention of cross contamination;
- (4) Maintenance of hand washing, hand sanitizing and toilet facilities;
- (5) Protection of shellfish, shellfish packaging materials and food contact surfaces from adulteration;
- (6) Proper labeling, storage and use of toxic compounds;
- (7) Control of employees with adverse health conditions; and
- (8) Exclusion of pests from the facility.

*History Note: Authority G.S. 130A-230;
Eff. August 1, 2000.*

15A NCAC 18A .0436 MONITORING RECORDS

Monitoring records of critical control points and general sanitation requirements shall be recorded, as specified in plan, signed and dated when recorded. The records shall be reviewed by owner or designee within one week of recording.

*History Note: Authority G.S. 130A-230;
Eff. August 1, 2002.*

SECTION .0500 - OPERATION OF SHELLSTOCK PLANTS AND RESHIPPERS

Rules .0501 - .0504 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0501 - .0504); has been transferred and recodified from Rules .1001 - .1004 of Title 10 Subchapter 10B of the North Carolina Administrative Code (T10.10B .1001 - .1004), effective April 4, 1990.

15A NCAC 18A .0501 GENERAL REQUIREMENTS

The rules in Section .0400 shall apply for the operation of shellstock plants and reshippers.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0502 GRADING SHELLSTOCK

- (a) The grading of shellstock shall be conducted only in a permitted shellstock plant.
- (b) A separate grading room or area shall be required for the grading of shellstock.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0503 GRADER

The grader used to grade shellstock, and any other accessories or tables used in the grading operation, shall be constructed for ease of cleaning and shall be properly maintained.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0504 RESHIPPERS

- (a) Reshippers shall meet all applicable requirements for shellstock plants. When shucked shellfish are reshipped, they shall be obtained from a permitted shipper. The shucked shellfish shall be received in approved shipping containers at a temperature of 40°F (4°C) or below. The temperature of the shellfish shall not exceed 40°F (4°C) during the holding and shipping periods.
- (b) Reshippers shall keep adequate and accurate records indicating the source from which shellfish were purchased, the date purchased, the name of the waters from which the shellfish were harvested, and the names and addresses of persons to whom the shellfish were sold for a period of one year.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

**SECTION .0600 - OPERATION OF SHELLFISH SHUCKING AND PACKING PLANTS AND
REPACKING PLANTS**

Rules .0601 - .0619 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0601 - .0619); has been transferred and recodified from Rules .1101 - .1119 of Title 10 Subchapter 10B of the North Carolina Administrative Code (T10.10B .1101 - .1119), effective April 4, 1990.

15A NCAC 18A .0601 GENERAL REQUIREMENTS

The rules in Section .0400 shall apply for the operation of shucking and packing plants and repacking plants.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0602 SEPARATION OF OPERATIONS

A shucking and packing plant shall provide separate rooms for shellstock storage, shucking, heat shock, and general storage. A separate packing area with delivery shelf shall be required.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0603 HOT WATER SYSTEM

An automatically regulated hot water system shall be provided which has sufficient capacity to furnish water at a temperature of at least 130°F (54°C) during all hours of plant operation.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0604 HANDWASHING FACILITIES

Handwashing facilities, including lavatories, hot and cold running water (combination supply faucet), soap, and individual towels shall be provided in a convenient place in the shucking and packing rooms. Signs requiring handwashing shall be conspicuously displayed within the plant.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0605 DELIVERY WINDOW OR SHELF

A delivery window or a non-corrosive shelf shall be installed in the partition between the shucking room and packing area. No shuckers or unauthorized personnel shall be allowed in the packing room or area. The delivery window shall be equipped with a shelf completely covered with smooth, non-corrosive metal or other material approved by the Division for such purpose, sloped to drain towards the shucking room.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0606 NON-FOOD CONTACT SURFACES

All non-food contact surfaces of equipment shall be non-absorbent, and constructed to be easily cleaned.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0607 SHUCKING BENCHES

Shucking benches, tables, and contiguous walls to a height of at least two feet above the bench top, shall be of smooth concrete, non-corrosive metal, or other durable non-absorbent material, free from cracks and pits, and so constructed that drainage is complete and rapid and is directed away from the stored shellfish. Shucking blocks shall be solid, one-piece construction, removable, and easily cleanable. The stands, stalls and stools shall be of smooth material and shall be painted with a light colored washable paint.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0608 EQUIPMENT CONSTRUCTION

(a) All pails, skimmers, measures, tanks, tubs, blowers, paddles, and other equipment, which come into contact with shucked shellfish or with ice used for direct cooling of shellfish, shall be made of smooth, non-corrosive, impervious materials and constructed so as to be easily cleanable and shall be kept clean and in good repair.

(b) All equipment, including external and internal blower lines and hoses below a point two inches above the overflow level of the tank and blower drain valves, shall be constructed as to be easily cleanable; and there shall be no V-type threads in the food-product zone of the blower.

(c) The blower and skimmer drain shall not be directly connected with the sewer. There shall be an air gap, approved by the Division, between the blower and skimmer outlets. A floor drain shall be provided.

(d) Air-pump intakes shall be located in a place protected from dirt and other contamination, and shall be equipped with filters.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

15A NCAC 18A .0609 SANITIZING EQUIPMENT

Washing and sanitizing facilities, including a three-compartment wash sink of adequate size to wash the largest utensils used in the plant shall be provided in a section of the plant convenient to the work areas. The sink shall be kept in good repair. Permanent hot and cold water connections, with combination supply faucets, shall be installed so that all vats may receive hot and cold water. Either steam, hot water, or a sanitizing solution shall be used to sanitize utensils and equipment.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. December 1, 1987.*

15A NCAC 18A .0610 EQUIPMENT SANITATION

All utensils and tools, such as opening knives, shucking pails, measures, skimmers, colanders, tanks, tubs, paddles, and containers which come in contact with the shellfish shall be thoroughly cleaned and then sanitized:

- (1) by steam in a steam chamber or box equipped with an indicating thermometer located in the coldest zone, by exposure to a temperature of 170°F (76°C) for at least 15 minutes, or to a temperature of 200°F (93°C) for at least five minutes;
- (2) by immersion in hot water at a temperature of 170°F (76°C) for at least two minutes (a thermometer is required);
- (3) by immersion for at least one minute in, or exposure for at least one minute to, a constant flow of a solution containing not less than 100 parts per million chlorine residual. Utensils and equipment which have to be washed in place will require washing, rinsing, and sanitizing; or
- (4) by a bactericidal treatment method which will provide equivalent sanitization to that provided by the methods authorized in (1), (2), or (3), as determined by the Division. If the bactericidal immersion or spray treatment is employed, testing kits shall be used to ensure that minimum solution strengths are maintained throughout the cleaning process.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0611 EQUIPMENT STORAGE

Equipment and utensils which have been cleaned and given bactericidal treatment shall be stored to protect against contamination.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0612 ICE

Ice shall be obtained from a water supply approved by the Division pursuant to Rule .0413 of this Subchapter and shall be stored and handled in a sanitary manner.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0613 SHELLFISH SHUCKING

- (a) Shellfish shall be shucked in a manner that they are not subject to adulteration. Shellstock shall be reasonably free of mud when shucked. Only live shellstock shall be shucked.
- (b) Shucking of shellstock shall only be permitted on approved shucking tables or benches. Floors used by shuckers shall not be used for the storage of shellfish or the retention of shucking pails or other food contact containers.
- (c) When shellstock are stored in the shucking room, protection shall be provided for the storage space to prevent possible adulteration from wash water wastes and from the feet of the employees.
- (d) Shucking pails shall be placed so as to exclude the drippings from shells and from the hands of shuckers. The pails shall be rinsed with running tap water before each filling.
- (e) Shucked shellfish, when washed, shall be thoroughly washed on a skimmer or a container approved by the Division with cold running water from a source approved by the Division under Rule .0413 of this Subchapter.
- (f) The return of excess shucked shellfish from the packing room shall not be allowed. All shucked shellfish shall be packed before leaving the packing room.
- (g) If blowers are used for cleansing, the total time that shellfish are in contact with water after leaving the shucker, including the time of washing, rinsing, and any other contact with water shall not be more than 30 minutes. In computing the time of contact with water, the length of time that shellfish are in contact with water that is agitated, shall be calculated at twice its actual length. Before packing into containers for shipment or delivery for consumption, the shellfish shall be drained and packed without any added substance.
- (h) Pre-cooling of shucked shellfish shall be done in equipment which meets National Sanitation Foundation standards or the equivalent.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

15A NCAC 18A .0614 CONTAINERS

- (a) Containers used for transporting shucked shellfish shall be made from food safe materials approved by the United States Food and Drug Administration. These containers shall not be reused for packing shellfish.
- (b) Shucked shellfish shall be packed and shipped in containers, sealed so that tampering can be detected. Each individual container shall have permanently recorded on the container, so as to be conspicuous, the shucker-packer's, repacker's, or distributor's name and address, and the shucker-packer's or repacker's certification number.
- (c) Any container of shucked shellfish which has a capacity of 64 fluid ounces or more shall be dated as of the date shucked on both the lid and sidewall or bottom. Any container of shucked shellfish which has a capacity of less than 64 fluid ounces shall indicate a SELL BY date.
- (d) No person shall use containers bearing a certification number other than the number assigned to him.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. August 1, 1998; February 1, 1997; December 1, 1987.*

15A NCAC 18A .0615 SHELLFISH COOLING

Shucked shellfish shall be cooled to an internal temperature of 45°F (7°C) or less within two hours after delivery to the packing room. Storage temperatures shall be 40° F (4° C) or below. No ice or other foreign substance shall be allowed to come into contact with the shellfish after processing has been completed.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. April 1, 1997.*

15A NCAC 18A .0616 SHELLFISH FREEZING

- (a) If shellfish are to be frozen, they shall be frozen within three days of shucking and packing and the shucked date shall be preceded by the letter (F).
- (b) A temperature of 0° F (-18° C) or less shall be maintained in the frozen storage rooms.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. April 1, 1997; December 1, 1987.*

15A NCAC 18A .0617 SHIPPING

- (a) Shucked shellfish shall be stored and shipped at 40° F (4° C) or below.
- (b) Shipments shall be tagged or labeled to show the name and address of the consignee, the name and address of the shipper, the name of the state or territory of origin, and the permit number of the shipper.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. April 1, 1997.*

15A NCAC 18A.0618 HEAT SHOCK METHOD OF PREPARATION OF SHELLFISH

- (a) Facilities. If a shucking and packing plant uses the heat shock process, it shall be done in a separate room adjacent to the shellstock storage room and the shucking room.
- (b) Tank construction. The heat shock tank shall be constructed of smooth, non-corrosive metal, designed to drain quickly and completely and to be easily and thoroughly cleaned.
- (c) Booster heaters. All heat shock tanks shall be equipped with booster heaters that are thermostatically controlled.
- (d) Shellstock washing. All shellstock subjected to the heat shock process shall be thoroughly washed with flowing potable water immediately prior to the heat shock operation.
- (e) Water temperature. During the heat shock process the water shall be maintained at not less than 140°F (60°C) or more than 150°F (65°C). An accurate thermometer shall be available and used to determine the temperature during the heat shock process. The heat shock tanks shall be drained and cleaned at the end of each day's operation.
- (f) Alternatives to heat shock method. Nothing in these Rules shall be construed to prohibit any other process which has been found equally effective.
- (g) Water requirements. At least eight gallons of heat shock water shall be maintained in the tank for each one half bushel of shellstock being treated. All water used in the heat shock process shall be from a source approved by the Division under Rule .0413 of this Subchapter.
- (h) Cooling. Immediately after the heat shock process, all treated shellstock shall be subjected to a cool-down with potable tap water. All heat shocked shellstock shall be handled in a manner to prevent adulteration of the product. Shellfish which have been subjected to the heat shock process shall be cooled to an internal temperature of 45°F (7°C) or below within two hours after this process and shall be placed in storage at 40°F (4°C) or below.
- (i) Cleaning. At the close of each day's operation, the heat shock tank shall be completely emptied of all water, mud, detritus, and thoroughly cleaned and then rinsed with flowing potable water.
- (j) Sanitizing. All heat shock tanks shall be sanitized immediately before starting each day's operation.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. August 1, 2002, August 1, 1998; February 1, 1997; September 1, 1990.*

15A NCAC 18A .0619 REPACKING OF SHELLFISH

- (a) If repacking is practiced, it shall be done strictly in accordance with all the requirements stipulated for shucking and packing plants except those related to shucking.
- (b) The shucked shellfish to be repacked shall be received at the repacking plant in approved shipping containers at a temperature of 32° - 40°F (0° - 4°C) or less.
- (c) Shellfish shall not be repacked more than one time.
- (d) The temperature of the shellfish shall not exceed 45°F (7°C) during the repacking process.
- (e) Containers with a capacity of 64 fluid ounces or less in which shucked shellfish are repacked shall indicate a SELL BY date preceded by the letter R. Containers with a capacity above 64 fluid ounces in which shucked shellfish are repacked shall be dated to show the original shucking date and repacking date, which will be preceded by the letter (R).
- (f) Packers shall keep accurate records indicating source from which shellfish were purchased, the date packed, the date of purchase, the area within the state or territory from which the shellfish were harvested, and the names and addresses of persons to whom the shellfish were sold.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. December 1, 1987.*

15A NCAC 18A .0620 SHELLFISH THAWING AND REPACKING

- (a) Frozen shellfish shall be thawed under temperatures not to exceed 45° F (7° C).
- (b) Shellfish held for thawing shall be separated from other shellfish.
- (c) Thawed shellfish shall not exceed 45° F (7° C) during the repacking process.
- (d) Containers of repacked, thawed shellfish shall be labeled as required in Rule .0619 of this Section and shall also be labeled as "PREVIOUSLY FROZEN", or equivalent.
- (e) Thawed shellfish, which remain in original containers, shall be labeled as required in Rule .0614 of this Section and shall also be labeled as "PREVIOUSLY FROZEN", or equivalent.

*History Note: Authority G.S. 130A-230;
Eff. April 1, 1997.*

15A NCAC 18A .0621 RECALL PROCEDURE

Each owner of a shellfish facility shall keep on file a written shellfish recall procedure. A copy of this procedure shall be provided to the Division.

*History Note: Authority G.S. 130A-230;
Eff. August 1, 1998.*

SECTION .0700 - OPERATION OF DEPURATION (MECHANICAL PURIFICATION) FACILITIES

Rules .0701 - .0713 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0701 - .0713); has been transferred and recodified from Rules .1201 - .1213 of Title 10 Subchapter 10B of the North Carolina Administrative Code (T10.10B .1201 - .1213), effective April 4, 1990.

15A NCAC 18A .0701 GENERAL REQUIREMENTS

The Rules in Section .0400 shall apply for the operation of depuration facilities.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0702 FACILITY SUPERVISION

- (a) The owner shall either personally supervise or designate an individual to be responsible for compliance with the rules of this Subchapter.
- (b) The depuration facility shall be used for no purpose other than the treatment of shellfish and research activities related thereto. No unauthorized persons shall be allowed in the depuration facility.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0703 FACILITY DESIGN AND SANITATION

- (a) The plant layout shall be designed to physically separate undepurated shellstock from depurated shellstock and be approved by the Division.
- (b) Tank design and construction. The tank shall be designed to allow for good water circulation. The tank shall be of sufficient size to allow at least eight cubic feet of sea water per bushel of shellstock in the tank except for soft clams (*Mya arenaria*), which requires at least five cubic feet of sea water per bushel. If the tank is rectangular in shape, length to width ratio shall be from two to one (2:1) to four to one (4:1).
- (c) The tank shall be designed so that scum and sludge (shellfish feces, pseudo feces, sand grit, etc.), can be easily removed or flushed out. The bottom shall be sloped longitudinally at least one fourth to one half inch per foot toward the outlet end.
- (d) To facilitate proper cleaning and sanitation, as well as proper depuration of shellfish, tanks shall be constructed from impervious, non-toxic, and inert materials. Coatings, when used, shall be approved by the Division. Pipes conveying process water throughout the plant shall be so constructed as to be easily disassembled to facilitate cleaning and sanitizing.
- (e) Facility sanitation. The general sanitation requirement of the facility, physical structure, equipment and utensils, and the sanitary requirements for operations, processes, and personnel shall be approved by the Division.
- (f) Material. The equipment in the food product zone shall be made of smooth, corrosion resistant, impervious, non-toxic material and shall meet National Sanitation Foundation standards or the equivalent.
- (g) Plumbing and related facilities. Plumbing shall be installed in compliance with state and local plumbing ordinances. Lavatories shall have running hot and cold water. Lavatories, other than those located in restrooms, shall be located so that their use by personnel can be readily observed. An automatically regulated hot water system shall be provided which has sufficient capacity to furnish water at a temperature of at least 130°F (54°C) during all hours of plant operation. Signs shall be posted in toilet rooms and near lavatories, directing employees to wash their hands before starting work and after each interruption. Pump volutes and impellers shall be of material which is non-toxic. The facilities domestic sewage shall be discharged into a sewage disposal system constructed in accordance with state and local requirements.
- (h) Floors. Floors of rooms in which shellstock are handled or stored shall be constructed of concrete or other material impervious to water; shall be graded to drain quickly; shall be free from cracks and uneven surfaces that interfere with proper cleaning or drainage; and shall be maintained in good repair.
- (i) Walls and ceilings. The interior surfaces of rooms in which shellstock are handled or stored shall be smooth, washable, a light color, and kept in good repair.

- (j) Lighting. Natural or artificial light shall be provided in all working and storage rooms. Light bulbs, fixtures, or other glass suspended within the facility shall be of safety-type or otherwise protected to prevent contamination in case of breakage. The water surface of the depuration tanks shall not be subjected to direct sunlight.
- (k) Heating and ventilation. Working rooms shall be ventilated. Working rooms shall be equipped with heating equipment for use as necessary during the months of September to April.
- (l) Water supply. The water supply for non-depuration uses shall be from a source approved by the Division under Rule .0413 of this Subchapter.
- (m) Rodent control. The depuration facility shall comply with the provisions of Rule .0411 of this Subchapter.
- (n) General cleanliness. The depuration facility shall be kept clean and free of litter and rubbish. Miscellaneous and unused equipment and articles which are not necessary to the facility operations shall not be stored in rooms used for depuration or shellstock storage. Culled shellstock shall be removed promptly from the facility.
- (o) Health of personnel. Any person known to be infected with any disease in a communicable form, or to be a carrier of any disease which can be transmitted through the handling of shellfish, or who has an infected wound or open lesion on any exposed portion of his body, shall be excluded from handling shellfish in the facility.
- (p) Disposal of all waste water shall be permitted by the appropriate agency.

History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.

15A NCAC 18A .0704 LABORATORY PROCEDURES

- (a) The laboratory and the laboratory operator shall be approved by the Division.
- (b) The laboratory shall conduct routine bacterial examinations of process water and shellfish, and special examinations when necessary or required in accordance with Rule .0706 of this Subchapter.
- (c) Bacterial examinations of shellfish and sea water shall be made in accordance with "Recommended Procedures for Examination of Sea Water and Shellfish", American Public Health Association, Inc., which is adopted by reference in accordance with G.S. 150B-14(c), or other methods approved by the Division. A copy of this publication is available for inspection at the Shellfish Sanitation Office, Marine Fisheries Building, Arendell Street, Morehead City, North Carolina 28557.
- (d) All other physical, chemical, or biological tests shall be conducted according to "Standard Methods for the Examination of Water and Waste Water", prepared and published by American Public Health Association, American Water Works Association, and Water Pollution Control Federation, which is adopted by reference in accordance with G.S. 150B-14(c), or other methods approved by the Division. A copy of this publication is available for inspection at the Shellfish Sanitation Office, Fisheries Building, Arendell Street, Morehead City, North Carolina 28557.

History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1991; September 1, 1990.

15A NCAC 18A .0705 FACILITY OPERATIONS

- (a) Source of shellfish. Shellfish shall be accepted for treatment at a shellfish depuration facility only from areas designated for this purpose by the Division and the Division of Marine Fisheries. A detailed description of all areas from which shellfish may be taken for depuration purposes, updated as necessary, shall be prepared by the Division and the Division of Marine Fisheries, and kept on file by the facility owner or operator. The facility operator shall inspect all containers of raw shellstock upon arrival at the facility to verify that they contain the shellfish species and quantity stated on the surveillance officer's reports.
- (b) Shellstock containers. Shellstock shall be accepted for treatment and released after depuration 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 shellstock to the depuration facility nor for the removal of shellstock from the facility.
- (c) Culling. All untreated shellstock prior to, or upon arrival at the facility, shall be thoroughly inspected and culled. All dead shellfish, or shellfish in broken or cracked shells shall be disposed of in a manner approved by the Division. The owner or operator shall be held responsible for suitable culling and for the removal and disposal of dead shellfish or shellfish in broken or cracked shells after depuration.

(d) Washing shellstock. Before and after depuration all shellstock shall be thoroughly washed or hosed with water taken from a source approved by the Division under Rule .0413 of this Subchapter. Immersion of shellstock for washing purposes is prohibited.

(e) Depuration Baskets. All baskets used in the depuration process shall be made of impervious material and shall not be more than four inches deep. Baskets shall be of a design to allow water to flow freely over the shellstock in the depuration tanks. Shellstock shall not be placed more than three inches deep in the baskets. Baskets shall be stacked in a manner to allow free circulation of water. There shall be at least three inches clearance separating containers of shellfish in tanks and between the containers and the bottom and sides of the tank. Containers used for depuration purposes shall not be used for any other purpose and no containers or other equipment shall be placed in the depuration tanks.

(f) Depuration. All shellstock upon receipt at the depuration facility, shall be immediately placed in depuration or placed in controlled storage. Shellstock shall be depurated for a period of 48 hours or longer as required to meet the bacteriological standards established in Rule .0709 of this Subchapter.

(g) Washing depuration tanks. After each 24 hours the sea water in the tanks shall be drained out and the shellstock hosed down thoroughly with water from a supply approved by the Division under Rule .0413 of this Subchapter. All waste matter must be flushed out of the tank. Immediately after hosing, the tanks shall again be filled with treated sea water.

(h) Scheduled process. A scheduled control purification process shall be established outlining the critical parameters for each depuration facility. This scheduled process shall be written and posted conspicuously at the depuration site.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990; December 1, 1987.*

15A NCAC 18A .0706 SHELLFISH SAMPLING PROCEDURES

(a) Start-up phase. When shellfish are delivered to the depuration facility, the following schedule shall be followed:

- (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 depuration process.
- (2) Three or more shellfish samples, randomly selected from three or more locations in each tank, shall be collected for bacterial examination after 24 hours of depuration.
- (3) Three or more shellfish samples, randomly selected from three or more locations in each tank, shall be collected for bacterial examination after the shellfish have completed the depuration process.

(b) The above schedule shall be followed until the time that the Division and the facility operator, after review of the results, determine that the shellfish from the area(s) are responding properly to the depuration process, and that the depuration process is successfully reducing bacterial levels. After the determination, the routine sampling procedures shall be followed. A routine sampling procedure defining a program of daily sampling shall be established by the Division. Written permission from the Division must be obtained before the initiation of routine monitoring procedures.

(c) Any change in laboratory equipment, operators, or procedures, shall be approved by the Division.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987;
Amended Eff. September 1, 1990.*

15A NCAC 18A .0707 DEPURATION PROCESS WATER CONTROL - SAMPLING PROCEDURES

The treatment of shellfish is a controlled process designed to reduce bacterial contamination to an acceptable level. To insure the continuing effectiveness of the shellfish depuration process, the minimum sampling procedure as described below shall be followed:

- (1) Incoming sea water;
 - (a) type of test: temperature, turbidity, salinity, dissolved oxygen, bacteriological;
 - (b) frequency: each time sea water is withdrawn;
- (2) Tank water;
 - (a) type of test: bacteriological;
 - (b) frequency: once per day per tank.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0708 DEPURATION TREATMENT PROCESS WATER - STANDARDS

- (a) Water Source. Depuration process water shall not exceed fourteen fecal coliform Most Probable Number (MPN) per 100 milliliters of water prior to treatment.
- (b) Bacteriological. All water to be used in shellfish depuration tanks shall be subjected to ultraviolet light treatment. The tank water bacterial quality shall not exceed one total coliform Most Probable Number (MPN) per 100 milliliters of water.
- (c) Dissolved oxygen. The amount of dissolved oxygen in the water in the depuration tanks shall be at least five milligrams per liter and shall be measured daily.
- (d) Temperature. Depuration tank temperature shall be measured daily during the depuration process. Temperatures of sea water used in the depuration process shall not be below 50°F (10°C) nor above 77°F (25°C).
- (e) Turbidity. Turbidity in the depuration water shall not exceed 20 Jackson Turbidity Units or other equivalent methods and shall be measured daily.
- (f) Salinity. Salinity of the depuration water shall deviate no more than plus or minus 20 percent of the value of the harvest area and shall be measured daily.
- (g) pH. pH of the depuration water shall range from 7.0 to 8.4 and shall be measured daily.
- (h) 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 Division.
- (i) Pesticides, detergents, and radionuclides. Levels of pesticides, detergents, and radionuclides shall not exceed levels found in approved harvesting areas and shall be measured if required by the Division.
- (j) Marine toxins. Levels of marine toxins in the incoming sea water and in the source water shall not exceed levels found in approved shellfish harvesting areas and shall be measured if required by the Division.

History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.

15A NCAC 18A .0709 DEPURATION - SHELLFISH MEAT STANDARDS

Shellfish shall not be released for sale if the geometric mean of the fecal coliform MPN of the treated shellfish samples exceeds 20 per 100 grams of sample, or if more than 10 percent of the samples exceed a fecal coliform MPN of 70 per 100 grams of sample, or if any sample fecal coliform MPN exceeds 100 per 100 grams of sample.

- (1) The use of the Elevated Temperature Coliform Plate Count is authorized for the bacteriological evaluation of hard clams, Mercenaria species, and soft clam, Mya arenaria.
- (2) Should the Division suspect adulteration of shellfish by metallic ions and compounds, pesticides, detergents, radionuclides, marine toxins, or any toxic substance or adulterate, the Division shall require that shellfish meats be analyzed for these adulterants before suspect shellfish are released for sale.

History Note: Authority G.A. 130A-230;
Eff. February 1, 1987.

15A NCAC 18A .0710 ULTRAVIOLET UNIT

Any ultraviolet unit which provides the required treatment and desired results may be used for the purification of water to be used in the depuration process. The unit shall be designed to deliver, at peak load, at least one gallon per minute of treated water per bushel of shellfish, measured by an approved measuring device or method.

- (1) Cautions and maintenance. Ultraviolet tubes shall be checked for intensity on a monthly basis and shall be replaced when they reach a point of 60 percent efficiency. A log of intensity shall be kept and an orderly numbering procedure for units and bulb established.
- (2) Ultraviolet tubes and reflectors shall be cleaned as necessary. Cleaning may be done with a clean damp cloth or sponge.
- (3) 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.

- (4) An automatic shutoff switch shall be provided to break the electric current, this shutting off the current to the ultraviolet bulb when the lid of the ultraviolet unit is raised.
- (5) A clock, off-on current recorder, or other device approved by the Division, shall be installed in line with all ultraviolet units to measure continuity of operation as well as to measure bulb life.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0711 SHELLSTOCK STORAGE

(a) Refrigeration of shellstock. Treated shellstock shall be placed in cold storage if they are not released immediately. The temperature for cold storage shall be 50°F (10°C) or lower. A refrigerated storage room shall be provided for depurated shellstock. All untreated shellstock shall be kept in a separate shellstock storage room. Measures shall be taken to prevent the unauthorized removal of any shellstock. All shellstock shall be handled and stored under sanitary conditions in accordance with the rules in this Subchapter.

(b) Controlled storage. Shellstock which is received at the depuration facility which cannot be processed immediately shall be placed in controlled storage. In controlled storage the temperature shall be 50°F (10°C) or lower. A gradual change of temperature from the storage temperature to the depuration water temperature may then be necessary to insure proper treatment. Any shellstock which has been held under refrigeration at a depuration facility for more than 48 hours shall not be depurated.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0712 DEPURATION - TAGGING AND RELEASE OF SHELLFISH

No shellstock shall be removed from the depuration facility until approved for release by the operator of the facility as provided in these Rules. All containers of depurated shellstock shall be tagged before being released from the shellstock depuration facility. The tag shall contain the name and permit number given the depuration facility by the Division, the quantity of shellstock, and the date the shellstock were released from the depuration facility.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0713 DEPURATION - RECORDS

Records containing the following information shall be available at the depuration facility at all times:

- (1) For shellstock presently undergoing the depuration process:
 - (a) name and location of harvesting area(s);
 - (b) depuration harvesting permit number(s);
 - (c) date received;
 - (d) quantity of shellstock in tank(s); and
 - (e) date and time of initiation of depuration.
- (2) For each lot of shellstock which have completed the depuration process:
 - (a) name and location of harvesting area(s);
 - (b) depuration harvesting permit number(s);
 - (c) date received into facility;
 - (d) date released from the facility;
 - (e) date and time of initiation of depuration;
 - (f) date and time of termination of depuration;
 - (g) number of hours depurated; and
 - (h) all laboratory results as specified.
- (3) Every two weeks the facility operator shall send to the Division a copy of the daily records required under this Rule and the results of all shellfish and water samples analyzed during that biweekly period.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

SECTION .0800 - WET STORAGE OF SHELLSTOCK

Rules .0801 - .0806 of Title 15A Subchapter 10B of the North Carolina Administrative Code (T15A.10B .0801 - .0806); has been transferred and recodified from Rules .1301 - .1306 of Title 10 Subchapter 10B of the North Carolina Administrative Code (T10.10B .1301 - .1306), effective April 4, 1990.

15A NCAC 18A .0801 GENERAL REQUIREMENTS

The rules in Section .0400 shall apply for wet storage of shellstock.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0802 PLANT DESIGN: SANITATION: AND WET STORAGE

Plant design, sanitation, and wet storage shall be approved by the Division.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0803 WET STORAGE WATER

Water used for wet storage shall be approved by the Division.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0804 SHELLSTOCK CLEANING

Shellstock shall be thoroughly washed with water from an approved source and culled to remove dead, broken, or cracked shellstock prior to wet storage in tanks.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0805 WET STORAGE TANKS

Wet storage tanks shall be constructed of smooth, impervious materials approved by the Division and shall be kept clean.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

15A NCAC 18A .0806 SHELLSTOCK CONTAINERS

All containers used during wet storage shall be constructed of non-absorbant and rust-proof material, and shall be kept clean.

*History Note: Authority G.S. 130A-230;
Eff. February 1, 1987.*

SECTION .0900 - CLASSIFICATION OF SHELLFISH GROWING WATERS

Rules .0901 - .0914 of Title 15A Subchapter 18A of the North Carolina Administrative Code (T15A.18A .0901 - .0914); has been transferred and recodified from Rules .1401 - .1414 of Title 10 Subchapter 10B of the North Carolina Administrative Code (T10.10B .1401 - .1414), effective April 4, 1990.

15A NCAC 18A .0901 DEFINITIONS

The following definitions shall apply throughout this Section.

- (1) "Approved area" means an area determined suitable for the harvesting of shellfish for direct market purposes.
- (2) "Closed - system marina" means a marina constructed in canals, basins, tributaries or any other area with restricted tidal flow.
- (3) "Commercial marina" means marinas that offer one or more of the following services: fuel, transient dockage, haul-out facilities, or repair services.
- (4) "Conditionally approved area" means an area subject to predictable intermittent pollution that may be used for harvesting shellfish for direct market purposes when management plan criteria are met.
- (5) "Depuration" means mechanical purification or the removal of adulteration from live shellstock by any artificially controlled method.
- (6) "Division" means the Division of Environmental Health or its authorized agent.
- (7) "Fecal coliform" means bacteria of the coliform group which will produce gas from lactose in a multiple tube procedure liquid medium (EC or A-1) within 24 plus or minus two hours at 44.5°C plus or minus 0.2°C in a water bath.
- (8) "Growing waters" means waters which support or could support shellfish life.
- (9) "Marina" means any water area with a structure (dock, basin, floating dock, etc.) which is utilized for docking or otherwise mooring vessels and constructed to provide temporary or permanent docking space for more than 10 boats.
- (10) "Marine biotoxins" means a poisonous substance accumulated by shellfish feeding upon dinoflagellates containing toxins.
- (11) "Most probable number (MPN)" means a statistical estimate of the number of bacteria per unit volume and is determined from the number of positive results in a series of fermentation tubes.
- (12) "Open - system marina" means a marina constructed in an area where tidal currents have not been impeded by natural or man-made barriers.
- (13) "Private marina" means any marina that is not a commercial marina as defined in this Rule.
- (14) "Prohibited area" means an area unsuitable for the harvesting of shellfish for direct market purposes.
- (15) "Public health emergency" means any condition that may immediately cause shellfish waters to be unsafe for the harvest of shellfish for human consumption.
- (16) "Relaying" means the act of removing shellfish from one growing area or shellfish grounds to another area or ground for any purpose.
- (17) "Restricted area" means an area from which shellfish may be harvested only by permit and subjected to an approved depuration process or relayed to an approved area.
- (18) "Sanitary survey" means the evaluation of factors that affect the sanitary quality of a shellfish growing area including sources of pollution, the effects of wind, tides and currents in the distribution and dilution of polluting materials, and the bacteriological quality of water.
- (19) "Shellfish" means oysters, mussels, scallops and all varieties of clams. However, the term shall not include scallops when the final product is the shucked adductor muscle only.
- (20) "Shoreline survey" means a visual inspection of the environmental factors that affect the sanitary quality of a growing area and identifies sources of pollution when possible.

History Note: Authority G.S. 130A-230;
Eff. June 1, 1989;
Amended Eff. August 1, 1998; February 1, 1997; September 1, 1990.

15A NCAC 18A .0902 CLASSIFICATION OF SHELLFISH GROWING WATERS

(a) All actual and potential shellfish growing areas shall be classified as to their suitability for shellfish harvesting. Growing waters shall be designated with one of the following classifications:

- (1) Approved area,
- (2) Conditionally approved area,
- (3) Restricted area, or
- (4) Prohibited area.

(b) Maps showing the boundaries and classification of growing areas shall be maintained by the Division.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0903 SANITARY SURVEY

(a) Growing waters shall be divided into growing areas by the Division.

(b) A sanitary survey shall be conducted for each growing area every three years except growing areas that are totally prohibited, and shall include the following:

- (1) A shoreline survey to evaluate pollution sources that may affect the area.
- (2) A hydrographic survey to evaluate meteorological and hydrographic factors that may affect distribution of pollutants.
- (3) A bacteriological survey to assess water quality. A bacteriological survey shall include the collection of growing area water samples and their analysis for fecal coliforms. The number and location of sampling stations shall be selected to produce the data necessary to effectively evaluate point and non-point pollution sources. A minimum of 15 sets of samples shall be collected from growing areas during the three year evaluation period. Areas without a shoreline may be sampled less frequently.

(c) Sanitary survey reports shall be prepared every three years.

(d) All sanitary survey reports shall be maintained by the Division.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0904 APPROVED AREAS

An area classified as approved for shellfish harvesting for direct market purposes, must satisfy the following criteria as indicated by a sanitary survey:

- (1) the shoreline survey has indicated that there is no significant point source contamination;
- (2) the area is not contaminated with fecal material, pathogenic microorganisms, poisonous and deleterious substances, or marine biotoxins that may render consumption of the shellfish hazardous;
- (3) the median fecal coliform Most Probable Number (MPN) or the geometric mean MPN of water shall not exceed 14 per 100 milliliters, and not more than ten percent of the samples shall exceed a fecal coliform MPN of 43 per 100 milliliters (per five tube decimal dilution) in those portions of areas most probably exposed to fecal contamination during adverse pollution conditions.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0905 CONDITIONALLY APPROVED AREAS

(a) An area may be classified as conditionally approved if the sanitary survey indicates the area will meet approved area classification criteria for a reasonable period of time and the factors determining these periods are known and predictable.

(b) A written management plan shall be developed by the Division for conditionally approved areas.

(c) When management plan criteria are met the Division may recommend to the Division of Marine Fisheries the area may be opened to shellfish harvesting on a temporary basis.

(d) When management plan criteria are no longer met or public health appears to be jeopardized, the Division will recommend to the Division of Marine Fisheries immediate closure of the area to shellfish harvesting.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0906 RESTRICTED AREAS

(a) An area may be classified as restricted when a sanitary survey indicates a limited degree of pollution and the area is not contaminated to the extent that indicates that consumption of shellfish could be hazardous after controlled depuration or relaying.

(b) Relaying of shellfish shall be conducted in accordance with 15A NCAC 18A, Rules Governing the Sanitation of Shellfish.

(c) Depuration of shellfish shall be conducted in accordance with 15A NCAC 18A, Rules Governing the Sanitation of Shellfish.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0907 PROHIBITED AREAS

A growing area shall be classified prohibited if there is no current sanitary survey or if the sanitary survey or other monitoring program data indicate that the area does not meet the criteria as specified in approved, conditionally approved or restricted classifications. The taking of shellfish for any human food purposes from such areas shall be prohibited.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0908 UNSURVEYED AREAS

Growing areas which have not been subjected to a sanitary survey shall be classified as prohibited.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0909 BUFFER ZONE

A prohibited area shall be established as a buffer zone around each wastewater treatment plant outfall.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0910 RECLASSIFICATION

(a) Any upward revision of an area classification shall be supported by a sanitary survey and documented in the sanitary survey report.

(b) A downward revision of an area classification may be made without a sanitary survey.

(c) When growing waters are reclassified, appropriate recommendations shall be made to the Division of Marine Fisheries regarding the opening and closure of the waters for the harvest of shellfish for human consumption.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0911 MARINAS: DOCKING FACILITIES: OTHER MOORING AREAS

Classification of shellfish growing waters with respect to marinas, docking facilities, and other mooring areas shall be done in accordance with the following:

- (1) All waters within the immediate vicinity of a marina shall be classified as prohibited to the harvesting of shellfish for human consumption. Excluded from this classification are marinas with less than 30 slips, having no boats over 24 feet in length, no boats with heads and no boats with cabins. Marinas permitted

prior to the effective date of this Rule may continue to have boats up to 21 feet in length with cabins and not be subject to the mandatory water classification of prohibited in the immediate vicinity of the marina.

- (2) Owners of marinas conforming to the exclusion provisions in Item (1) of this Rule shall make quarterly reports to the Division. These reports shall include the following information:
- (a) number of slips;
 - (b) number and length of boats;
 - (c) number and length of boats with cabins;
 - (d) number of boats with heads; and
 - (e) number of boats with "porta-potties."

Reports to the Division shall cover the occupancy of the marina on the fifth day of the first month of each quarter of the calendar year and shall be post marked on or before the fifteenth day of the reporting month.

- (3) The minimum requirement for the prohibited area beyond the marina shall be based on the number of slips and the type of marina (open or closed system). The prohibited area shall extend beyond the marina from all boat slips, docks, and docking facilities, according to the following:

Number of Slips in Marina	Size of Prohibited Area (Feet)	
	Open System	Closed System
11 - 25	100	200
26 - 50	150	275
51 - 75	175	325
76 - 100	200	400

Open system marinas exceeding 100 slips shall require an additional 25 feet for each 25 slips or portion thereof over 100. A closed system marina shall require 50 feet for each 25 slips or portion thereof over 100. Closed system private or residential marinas with more than 75 slips shall require a prohibited area of the number of feet determined above, or 100 feet outside the entrance canal, whichever is greater. Closed system commercial marinas with more than 50 slips shall require a prohibited area of the number of feet determined above, or 100 feet outside the entrance canal, whichever is greater.

- (4) After a marina is put in use water quality impacts of marina facilities may require a change in classification. In determining if a change in classification is necessary, marina design, marina usage, dilution, dispersion, bacteriological, hydrographic, meteorological, and chemical factors will be considered.
- (5) Areas, other than marinas, where boats are moored or docked may be considered on a case-by-case basis with respect to sanitary significance relative to actual or potential contamination and classification shall be made as necessary.
- (6) The cumulative impacts of multiple marinas, entrance canals, or other mooring areas, in close proximity to each other are expected to adversely affect public trust waters. When these situations occur the Division will recommend closures exceeding those outlined in Item (3) of this Rule. The following guides will be used in determining close proximity:
- (a) marina entrance canals within 225 feet of each other;
 - (b) open system marinas within 450 feet of each other (Mooring areas shall be considered open system marinas);
 - (c) where closure areas meet or overlap; and
 - (d) open system marinas within 300 feet of a marina entrance canal.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989;
Amended Eff. July 1, 1993.*

15A NCAC 18A .0912 SHELLFISH MANAGEMENT AREAS

When the Division of Marine Fisheries begins operations to relocate shellfish from a restricted or conditionally approved area to an approved area, the Division will recommend to the Division of Marine Fisheries that the area of relocation be closed until cleansing requirements for relayed shellfish have been satisfied.

History Note: Authority G.S. 130A-230;

Eff. June 1, 1989.

15A NCAC 18A .0913 PUBLIC HEALTH EMERGENCY

(a) The Division shall recommend to the Division of Marine Fisheries immediate closure of shellfish waters to the harvesting of shellfish in the event of a public health emergency.

(b) The Division shall recommend to the Division of Marine Fisheries re-opening shellfish waters when the condition causing the public health emergency no longer exists and shellfish have had sufficient time to purify naturally from possible contamination.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989.*

15A NCAC 18A .0914 LABORATORY PROCEDURES

All laboratory examinations for water and shellfish used for the evaluation of growing areas shall be made in accordance with the latest approved edition by the Food and Drug Administration of "Recommended Procedures for Examination of Sea Water and Shellfish", American Public Health Association, Inc., which is adopted by reference in accordance with G.S. 150B-14(c).

A copy of this publication is available for inspection at the Shellfish Sanitation Office, Marine Fisheries Building, Arendell Street, Morehead City, North Carolina 28557.

*History Note: Authority G.S. 130A-230;
Eff. June 1, 1989;
Amended Eff. September 1, 1991; September 1, 1990.*