

**National Shellfish Sanitation Program
2009 NSSP Guide for the Control of Molluscan Shellfish****Section II. Model Ordinance
Chapter XV. Depuration**

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Note: In those States where depuration is not practiced, this Chapter may be deleted from the Ordinance, as well as references to depuration throughout the Ordinance.

Requirements for the Authority

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this Chapter in regulation.]

- A. Prior to authorizing depuration, the Authority shall develop and maintain an effective program to:
 - (1) Control shellstock harvesting by special license in accordance with Chapter VIII. @.01 C.;
 - (2) Control shellstock transportation between the harvest area and the depuration facility to prevent shellstock from being illegally diverted to direct marketing;
 - (3) Approve the design and construction of the depuration facility or activity including subsequent changes;
- B. If shellstock is transported interstate to be depurated, the Authorities in both States shall execute a memorandum of agreement to provide adequate control measures to prevent diversion prior to depuration.
- C. The Authority shall review and approve the Depuration Plant Operating Manual prior to granting depuration certification.
- D. The Authority shall review the depuration plant performance index and other records as part of the monthly inspections to verify that the process and CCP are effective and the process verification analysis is being performed properly.
- E. The Authority shall maintain adequate records for each depuration facility. The following records for each facility shall be kept for the period of five years:
 - (1) Inspection reports and reviews of the plant performance in accordance to §D. (above);
 - (2) Current Depuration Plant Operations Manual for each dealer (§.03).
- F. The Authority shall assure that each dealer has procedures to assure that no shellstock which has not been depurated is removed from the depuration facility without the direct supervision of the Authority.

Requirements for the Dealer**.01 Critical Control Points.**

- A. Receiving Critical Control Point - Critical Limits. The dealer shall receive and depurate only shellstock which is:
 - (1) Obtained from a licensed harvester who has:
 - (a) Harvested the shellstock from an Approved or Conditionally Approved area in the open status as indicated by the tag; [C] and
 - (b) Identified the shellstock with a tag on each container or transaction record on each bulk shipment; [C] and
 - (2) Originates from a dealer who has identified the shellstock with a tag on each container or transaction record with each bulk shipment; [C] and
 - (3) Obtained from a special licensed harvester who has:

- (a) Harvested or supervised the harvest of shellstock from a Restricted or Conditionally Restricted area in the open status; [C] and
 - (b) Identified the shellstock by transaction records which include the harvest area, the special-licensed harvester's name, harvester license number(s), the harvest date, and the amount of shellstock shipped in each lot. [C]
- B. Processing Critical Control Points - Critical Limits. The dealer shall assure that:
- (1) All depuration lots are treated for a minimum of 44 hours; [C] and
 - (2) The water treatment system is operating to design specifications; [C] and
 - (3) All critical limits established during verification of the specific depuration process are being met. [C]
- C. Finished Shellstock Storage Critical Control Point - Critical Limits. The dealer shall assure that:
- (1) If wet storage in artificial bodies of water is practiced, water quality meets the requirements outlined in Chapter X.08; [C] and
 - (2) Once placed under temperature control while in the possession of the dealer, shellstock shall be:
 - (a) Iced; [C] or
 - (b) Placed in a storage area or conveyance maintained at 45 °Fahrenheit (7.2 °Centigrade) or less; [C] and
 - (c) Not permitted to remain outside temperature control for more than 2 hours at points of transfer such as loading docks. [C]

.02 Sanitation

- A. Safety of Water for Processing and Ice Production
- (1) Water Supply.
 - (a) Dealers shall provide a potable water supply in accordance with applicable federal, state and local regulations. [C]
 - (b) If the water supply is from a private source, the dealer shall make arrangements to have the water supply sampled by persons recognized by the Authority and tested at laboratories sanctioned or certified by the Authority: [K]
 - (i) Prior to use of the water supply; [C]
 - (ii) Every six months while the water supply is in use; [K] and
 - (iii) After any water supply has been repaired and disinfected. [S^{C/K}]
 - (2) Ice production. Any ice used in the processing or storage of shellfish shall:
 - (a) Be made on-site from potable water in a commercial ice machine; [C] or
 - (3) Shellstock washing
 - (a) Water from either a potable water supply, a growing area in the approved classification, a saltwater well approved by the authority, or the restricted area at the time and place of harvest, shall be used to wash shellstock. [C]
 - (b) If the dealer uses any system to wash shellstock which recirculates water, the dealer shall:
 - (i) Obtain approval for the construction or remodeling of the system from the Authority; [K]
 - (ii) Provide a water treatment and disinfection system to treat an adequate quantity of water to a quality acceptable for shellstock washing, which, after disinfection, meets the coliform standards for drinking water; and does not leave any unacceptable residues in the shellstock; [C]
 - (iii) Test wash water daily for bacteriological water quality; [S^{C/K}]
 - (iv) Clean, service, and test disinfection units at the frequency necessary to ensure effective disinfection. [K]

- (c) The dealer may use ultra-violet (UV) disinfection in his recirculating wash water system, provided that the turbidity of the water to be disinfected:
 - (i) shall not exceed 20 nephelometric turbidity units (NTUs); [K] and
 - (ii) Is measured using the method in the APHA *Standard Methods for the Examination of Water and Wastewater*. [K]
- (d) Food contact plumbing which is designed and installed to permit effective cleaning and sanitization shall be used. [C]
- (4) Depuration Process Water. The dealer shall:
 - (a) Continuously treat process water with a disinfection system approved by the Authority that does not leave any unacceptable residue in the shellstock; [C] and
 - (b) Verify that the disinfection system produces process seawater with no detectable coliform organisms as measured using an NSSP approved method in the tank influent according to the following sampling protocols.
 - (i) If the source water is an approved growing area, approved well, or other approved source, then the tank influent produced by each disinfection unit is evaluated once per process batch; [C]
 - (ii) If the source water is a restricted growing area, then:
 - a. A study meeting the requirements of Chapter VII. 04. C. is required; [C]
 - b. The tank influent produced by each disinfection unit is evaluated daily; [C] and
 - c. Source water prior to final disinfection must meet the water quality criteria for restricted for depuration in accordance with Chapter IV.02. G-H. [C]
 - (iii) If the source water is a recirculating water system, then:
 - a. A study meeting the requirements of Chapter VII. 04. C. [C] is required; and
 - b. The tank influent produced by each disinfection unit is verified daily. [C]
 - c. A prohibited growing area may not be used for source water. [C]
- (5) Plumbing and Related Facilities.
 - (a) The dealer shall design, install, modify, repair, and maintain all plumbing and plumbing fixtures to:
 - (i) Prevent contamination of water supplies; [C] and
 - (ii) Prevent any cross-connection between the pressurized potable water supply and water from an unacceptable source. [C] The dealer shall install and maintain in good working order devices to protect against backflow and back siphonage. [K]
 - (b) Depuration Plant Design and Construction. The dealer shall ensure that:
 - (i) Depuration tanks, processing containers, and piping are fabricated from non-toxic corrosion-resistant materials and are easily cleanable; [K]
 - (ii) Depuration tank design, hydraulics, and typical container configuration are such that process water is evenly circulated throughout all the shellfish containers within a given tank; [K]
 - (iii) Shellfish containers allow process water to flow freely and uniformly to all shellfish within each container. [K]
- (6) Depuration unit
 - (a) Depuration unit including depuration tanks, all reservoir tanks, and related piping shall be fabricated from safe materials, and depuration unit construction is such that it:
 - (i) Is easily accessible for cleaning and inspection; [K]
 - (ii) Is self-draining; [K] and
 - (iii) Meets the requirements for food contact surfaces. [K]

Additional Guidance - Section IV Guidance Documents

[Chapter III Harvesting, Handling, Processing, and Distribution .01 Shellfish Industry Equipment Guide](#)

B. Condition and Cleanliness of Food Contact Surfaces.

(1) Equipment and utensil construction for food contact surfaces.

(a) Except for equipment in continuous use and placed in service prior to January 1, 1989, the dealer shall use only equipment which conforms to Shellfish Industry Equipment Construction Guides (August 1993), U.S. Department of Health and Human Services. [K]

(b) The dealer shall use only equipment and utensils, including approved plastic ware which is:

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

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

(iii) Fabricated from food grade materials. [K]

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

(i) have smooth easily cleanable surfaces; [K] and

(ii) are welded. [K]

(d) All equipment used to handle ice shall be kept clean and stored in a sanitary manner, and shall meet the construction requirements in §.02 B (1) (a), (b), and (c). [K]

(e) Shellstock washing tanks and related plumbing shall be fabricated from safe materials.

(i) Is easily accessible for cleaning and inspection: [K]

(ii) Meets requirements for food contact surfaces [K]

(2) Cleaning and sanitizing of food contact surfaces.

(a) Food contact surfaces of the depuration units, equipment and containers shall be cleaned and sanitized to prevent contamination of shellstock and food contact surfaces.

The dealer shall:

(i) Provide applicable adequate cleaning supplies and equipment, brushes, detergents, and sanitizers, hot water and pressure hoses. [K]

(ii) Wash, rinse and sanitize equipment prior to the start-up of each day's activities and following any interruption during which food contact surfaces may have been contaminated; [K]

(b) Containers which may have become contaminated during storage shall be properly washed, rinsed and sanitized prior to use or are discarded. [K]

(c) Shellstock depuration tanks shall be cleaned and sanitized on a regular schedule as part of a plant sanitation standard operating procedure. [K]

B. Prevention of Cross Contamination.

(1) Protection of shellfish.

(a) Shellstock shall be stored in a manner to protect shellstock from contamination in dry storage and at points of transfer. [S^{C/K}]

(b) Shellstock shall not be placed in containers with standing water for the purposes of washing shellstock or loosening sediment; [K]

(2) Separation of Operations: Manufacturing activities which could result in the contamination of the shellstock shall be separated by adequate barriers. [K]

- (3) Employee practices.
 - (a) The dealer shall require all employees to wash their hands thoroughly with soap and water and sanitize their hands in an adequate hand washing facility:
 - (i) Before starting work; [K]
 - (ii) After each absence from the work station; [K]
 - (iii) After each work interruption; [K] and
 - (iv) Any time when their hands may have become soiled or contaminated. [K]
 - (b) In any area where shellfish are stored and in any area which is used for the cleaning or storage of utensils, the dealer shall not allow employees to:
 - (i) Store clothing or other personal belongings [O]
 - (ii) Eat or drink; [K]
 - (iii) Spit; and [K]
 - (iv) Use tobacco in any form. [K]
- C. Maintenance of Hand Washing, Hand Sanitizing and Toilet Facilities
 - (1) Hand washing facilities with warm water at a minimum temperature of 100 °F (37.8 °C), dispensed from a hot and cold mixing or combination faucet, shall be provided; [S^{K/O}]
 - (2) Handwashing facilities shall be provided which are:
 - (a) Convenient to work areas; [O]
 - (b) Separate from the three compartment sinks used for cleaning equipment and utensils; [K]
 - (c) Directly plumbed to an approved sewage disposal system, and [S^{K/O}]
 - (d) Adequate in number and size for the number of employees, and located where supervisors can observe employee use; [K]
 - (3) The dealer shall provide at each handwashing facility;
 - (a) Supply of hand cleansing soap or detergent; [K]
 - (b) Conveniently located supply of single service towels in a suitable dispenser or a hand drying device that provides heated air; [O]
 - (c) Easily cleanable waste receptacle; and [O]
 - (d) Handwashing signs in a language understood by the employees; [O]
 - (4) Sewage [C] and liquid disposable wastes [K] shall be properly removed from the facility.
 - (5) The dealer shall provide:
 - (a) Toilet room doors that are tight fitting, self closing, and do not open directly into a processing area; [K]
 - (b) An adequate number of conveniently located toilets. [K]
 - (c) Each toilet facility with an adequate supply of toilet paper [K] in a suitable holder. [S^{K/O}]
- D. Protection from Adulterants.
 - (1) Shellstock shall be protected from contamination while being transferred from one point to another during handling and processing; [K]
 - (2) Any lighting fixtures, light bulbs, skylights, or other glass suspended over food storage or processing activities in areas where shellstock are exposed shall be of the safety type or protected to prevent food contamination in case of breakage. [O]
 - (3) Conveyances or devices used to transport shellstock shall be constructed, maintained and operated to prevent contamination of the shellstock. If overhead monorails or conveyors are used, the dealer shall take precautions to assure that hydraulic fluids or lubricants do not leak or drip onto the shellstock or conveyance surfaces. [K]
 - (4) Adequate ventilation shall be provided to minimize condensation in areas where shellfish are stored, processed or packed. [S^{K/C}]
 - (5) Shellstock packing activities shall be conducted to provide adequate protection from contamination and adulteration. [K]
 - (6) Protection of ice used in shellstock shipping.

- (a) Any ice which is not made on-site in the depuration facility shall be inspected upon receipt and rejected if the ice is not delivered in a way so as to be protected from contamination. [S^{C/K}]
- (b) Ice shall be stored in a safe and sanitary manner to prevent contamination of the ice. [S^{C/K}]
- (c) Any ice used in the processing, storage, or transport of shellstock shall come from a facility sanctioned by the Authority or the appropriate regulatory agency. [C]
- (7) The dealer shall assure that any steam used in food processing or that comes in contact with food contact surfaces is free from any additives, or deleterious substances consistent with federal and state laws and regulations; [K]
- (8) Air pump intakes shall be located in a protected place. Air filters shall be installed on all blower air pump intakes. Oil bath type filters are not allowed. [O]
- E. Proper Labeling, Storage and Use of Toxic Compounds.
 - (1) Storage of toxic compounds.
 - (a) The dealer shall assure that only toxic substances necessary for plant activities are present in the facility. [K]
 - (b) Each of the following categories of toxic substances shall be stored separately:
 - (i) Insecticides and rodenticides; [K]
 - (ii) Detergents, sanitizers, and related cleaning agents; [K] and
 - (iii) Caustic acids, polishes, and other chemicals. [K]
 - (c) The dealer shall not store toxic substances above shellfish or food contact surfaces. [K]
 - (2) Use and labeling of toxic compounds.
 - (a) When pesticides are used, the dealer shall apply pesticides in accordance with applicable federal and state regulations to control insects and rodents in such a manner to prevent the contamination of any shellfish or packaging materials with residues. [K]
 - (b) Cleaning compounds/supplies, detergents and sanitizing agents shall be used only in strict accordance with the manufacturer's label instructions and all applicable federal and state laws and regulations. [K]
 - (c) Toxic substances shall be used only in strict accordance with the manufacturer's label instructions. [K]
 - (d) Provide a test kit, strips or other device that accurately measures the parts per million concentration of the chemical sanitizing agent in use. [K]

Additional Guidance - Section IV Guidance Documents
[Chapter III.07 Guidance for Reinstating a Previously Infected Employee](#)

- F. Control of Employees with Adverse Health Conditions.
 - (1) The dealer and the supervisor shall take all reasonable precautions to assure that any employee with a disease in the communicable stage which might be transmissible through food shall be excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces. The pathogens causing diseases which are transmissible from food workers through food are those determined by the US Centers for Disease Control and Prevention, in compliance with the Americans with Disabilities Act, and published in the *Federal Register*. These include: [K]
 - (a) Norovirus
 - (b) Hepatitis A virus,
 - (c) *Shigella* spp.,
 - (d) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or

- (e) *Salmonella typhi*;
- (2) All employees shall immediately report to the dealer and/or the supervisor information about their health and activities as they relate to diseases that are transmissible through food. All employees shall report the information in a manner that allows the dealer and/or supervisor to reduce the risk of shellfish-borne disease transmission, including providing necessary additional information, such as the date of onset of symptoms of an illness, or of a diagnosis without symptoms, or if the employee: [K]
- (a) Has any of the following symptoms:
- (i) Vomiting
 - (ii) Diarrhea,
 - (iii) Jaundice,
 - (iv) Sore throat with fever, or
 - (v) A lesion containing pus such as a boil or infected wound that is open or draining on any part of the body, or
- (b) Has an illness diagnosed by a health practitioner due to:
- (i) Norovirus
 - (ii) Hepatitis A virus,
 - (iii) *Shigella* spp.,
 - (iv) Enterohemorrhagic or Shiga Toxin-producing *Escherichia coli*, or
 - (v) *Salmonella typhi*;
- (c) Had a previous illness, diagnosed by a health practitioner, within the past 3 months due to *Salmonella typhi*, without having received antibiotic therapy, as determined by a health practitioner;
- (d) Has been exposed to, or is the suspected source of, a confirmed disease outbreak, because the employee consumed or prepared food implicated in the outbreak, or consumed food at an event prepared by a person who is infected or ill with:
- (i) Norovirus within the past 24 hours of the last exposure;
 - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli* or *Shigella* spp. Within the past 3 days of the last exposure;
 - (iii) *Salmonella typhi* within the past 14 days of the last exposure;
 - (iv) Hepatitis A virus within the past 30 days of the last exposure; or
- (e) Has been exposed by attending or working in a setting where there is a confirmed disease outbreak, or living in the same household as, and has knowledge about, an individual that works or attends a setting where there is a confirmed disease outbreak or living in the same household as, and has knowledge about, an individual diagnosed with an illness caused by:
- (i) Norovirus within the past 24 hours of the last exposure;
 - (ii) Enterohemorrhagic or Shiga toxin-producing *Escherichia coli*, or *Shigella* spp. within the past 3 days of the last exposure;
 - (iii) *Salmonella typhi* within the past 14 days of the last exposure; or
 - (iv) Hepatitis A virus within the past 30 days of the last exposure.
- (3) If an employee with an infected wound protects the lesion by keeping it covered with a proper bandage, a dry, durable, tight-fitting impermeable barrier, and a single-use glove for a hand lesion, the dealer and/or supervisor may allow the employee to work in the shellfish processing facility without additional restrictions. [K]
- (4) The dealer shall notify the State Shellfish Control Authority and Health Department when notified by an employee of a diagnosis or exhibits symptoms of hepatitis, and shall ensure that the employee is excluded from working in any capacity in which the employee may come in contact with the shellfish or with food contact surfaces or that may transmit the illness to other employees. [K]

- G. Exclusion of Pests. The dealer shall operate his facility to assure that pests are excluded from his facility and his activities. Animals shall not be allowed in those portions of the facilities where shellfish are stored, handled, processed, or packaged or where food handling equipment, utensils, and packaging materials are cleaned and stored. [K]

.03 Other Model Ordinance Requirements

A. Plants and Grounds.

(1) General

- (a) The physical facilities shall be maintained in good repair. [O]

(2) Flooding.

- (a) Facilities in which shellstock are stored, packed, or repacked shall be located so that these facilities are not subject to flooding during ordinary high tides. [C]

(b) If facilities are flooded:

- (i) Shellstock processing or repacking activities shall be discontinued until the floodwaters have receded from the building; and the building is cleaned and sanitized. [C]

- (ii) Any shellstock coming in contact with the floodwaters while in storage shall be destroyed; or discarded in non-food use. [C]

- (3) The dealer shall operate his/her facility to provide adequate protection from contamination and adulteration by assuring that dirt and other filth are excluded from the facility and activities. [S^{C/K}]

- (4) The dealer shall employ necessary internal and external insect and vermin control measures to insure insects and vermin are not present in the facility.

- (a) Tight fitting, self closing doors; [K]

- (b) Screening of not less than 15 mesh per inch; [K] and

- (c) Controlled air current. [K]

(5) Plant Interior.

- (a) Sanitary conditions shall be maintained throughout the facility. [O]

- (b) Interior surfaces are kept in good repair. [O]

- (c) All dry area floors are hard, smooth, easily cleanable and in good repair; [O] and

- (d) All wet area floors used in areas to store shellstock, food processing, and cleaning equipment are constructed of easily cleanable, impervious, and corrosion resistant materials which:

- (i) Are graded to provide adequate drainage; [O]

- (ii) Have even surfaces, and are free from cracks that create sanitary problems and interfere with drainage; [O] and

- (iii) Have sealed junctions between floors and walls to render them impervious to water. [O]

- (e) Walls and ceilings. Interior surfaces of rooms where shellstock are stored, handled, processed, or packaged and food handling equipment and packaging materials shall be constructed of easily cleanable, corrosion resistant, impervious and light colored materials. [O]

- (6) Grounds around the facility shall be maintained to be free from conditions which may result in shellfish contamination. These conditions may include:

- (a) Rodent attraction and harborage; [O]

- (b) Inadequate drainage. [O]

B. Plumbing and Related Facilities.

- (1) All plumbing and plumbing fixtures shall be properly designed, installed, modified, repaired, and maintained. The water system shall provide an adequate quantity of water under pressure, and includes cold and warm water at all sinks. [K]

- (2) Adequate floor drainage, including backflow preventers such as air gaps, shall be provided where floors are:
 - (a) Used in shellstock storage; [K]
 - (b) Used for food holding units (e.g. refrigeration units); [K]
 - (c) Cleaned by hosing, flooding, or similar methods; [K] and
 - (d) Subject to the discharge of water or other liquid waste, including, if applicable, three compartment sinks, on the floor during normal activities; [K]
 - (3) A safe, effective means of sewage disposal for the facility shall be provided in accordance with applicable federal and state laws and regulations; [S^{C/K}]
 - (4) Installation of drainage or waste pipes over processing or storage areas, or over areas in which containers and utensils are washed or stored shall not be permitted. [K]
 - (5) Shellstock washing storage tanks and related plumbing shall be fabricated from safe materials such that it:
 - (a) Is easily accessible for inspection. [K]
 - (b) Is self draining. [K]
- C. Utilities.
- (1) The dealer shall ensure that ventilation, heating, or cooling systems do not create conditions that may cause the shellfish products to become contaminated. [S^{C/K}]
 - (2) The dealer shall provide lighting throughout the facility that is sufficient to promote good manufacturing practices. [S^{C/K}]
- D. Disposal of Wastes.
- (1) Disposal of waste materials shall be conducted in accordance with appropriate federal and state laws and regulations. [O]
 - (2) All areas and receptacles used for the storage or conveyance of waste shall be operated and maintained to prevent attraction, harborage, or breeding places for insects and vermin. [O]
- E. Equipment Condition, Cleaning, Maintenance and Construction of Non-food Contact Surfaces.
- (1) The dealer shall use only equipment which is constructed in a manner and with materials that can be cleaned, sanitized, maintained or replaced in a manner to prevent contamination of shellstock. [O]
 - (2) The dealer shall use easily cleanable, corrosion resistant, impervious materials, free from cracks, to construct any non-food contact surfaces in shellfish storage or handling areas. [O]
 - (3) Cleaning activities for the depuration unit and equipment shall be conducted in a manner and at a frequency appropriate to prevent contamination of shellstock and food contact surfaces. [K]
 - (4) All conveyances and equipment which come into contact with stored shellstock shall be cleaned and maintained in a manner and frequency as necessary to prevent shellstock contamination. [O]
- F. Shellstock Storage and Handling.
- (1) The dealer shall assure that shellstock is:
 - (a) Reasonably free of sediment; [O] and
 - (b) Culled. [K]
 - (2) Shellstock shall be stored in a protected location which assures complete and rapid drainage of water away from the shellstock by:
 - (a) Placing shellstock at an adequate height off the floor; [K] or
 - (b) Grading the floor. [O]
 - (3) Any mechanical refrigeration equipment used for shellstock storage shall be adequate in size and are equipped with:
 - (a) An automatic temperature regulating control; [K] and
 - (b) Installed thermometers to accurately measure temperature within the storage compartments. [K]

- (4) Inspect incoming shipments and shall reject dead or inadequately protected shellstock. [K]
 - (5) Ensure that separate dry storage facilities are provided for depurated and undepurated shellfish. [K]
 - (6) Cull and wash the shellstock prior to loading into the depuration tanks. This process may occur before the shellstock is received at the facility by;
 - (a) Licensed harvester(s) at the harvest site; [K] or
 - (b) Certified dealer(s) at their certified facility. [K]
 - (7) Assure that culled shellfish are destroyed or disposed of in such a manner as to prevent their use for human food. [K]
 - (8) Transport, store, and handle shellstock so that:
 - (a) Shellstock potential for normal physiological activity during depuration is not compromised; [K] and
 - (b) Shellstock quality is not degraded. [K]
 - (9) Assure that different harvest lots of shellfish are not commingled during washing, culling, processing, or packing. If more than one harvest lot of shellfish is being processed at the same time, the identity of each harvest lot is maintained throughout the stages of depuration. [K]
 - (10) Wash and cull shellstock after depuration and pack the shellstock in clean shipping containers fabricated from safe materials. [K]
 - (11) Depurated packaged shellstock shall be protected from contamination at all times and be held at an ambient temperature not to exceed 45 °Fahrenheit (7.2 °Centigrade). [K]
- G. Heat Shock. N/A
- H. Supervision.
- (1) A reliable, competent individual shall be designated to supervise general plant management and activities; [K]
 - (2) Cleaning procedures shall be developed and supervised to assure cleaning activities do not result in contamination of shellstock or food contact surfaces. [K]
 - (3) All supervisors shall be:
 - (a) Trained in proper food handling techniques and food protection principles; [K] and
 - (b) Knowledgeable of personal hygiene and sanitary practices. [K]
 - (4) The dealer shall require:
 - (a) Supervisors to monitor employee hygiene practices, including handwashing, eating, smoking and/or storing personal items and clothing at work stations. [K]
 - (b) Supervisors to assure that proper sanitary practices are implemented, including:
 - (i) Plant equipment clean up; [K]
 - (ii) Rapid product handling; [K] and
 - (iii) Shellstock protection from contamination. [K]
 - (c) Supervisors shall not allow unauthorized persons in those portions of the facility where shellfish are processed, handled, stored or packaged or where food handling equipment, utensils, and packaging materials are cleaned or stored. [K]
 - (d) Employees
 - (i) shall be trained in proper food handling and personal hygiene practices, [K] and
 - (ii) shall report any symptoms of illness to their supervisor. [K]
- I. Plant Operations Manual. The dealer shall prepare a written Depuration Plant Operations Manual (DPOM) according to Minimum Requirements of a Depuration Plant Operations Manual (below); and update the DPOM as necessary. A copy of the DPOM shall be kept in a location readily accessible to the trained personnel responsible for the depuration activity. The minimum requirements for a Depuration Plant Operations Manual shall address:
- (1) Introduction including;
 - (a) Status of document (to create, revise, or update DPOM);

- (b) Ownership and principal(s) involved with operation of facility;
 - (c) Address and phone number of owners and principles; and
 - (d) Summary of proposed use of the depuration facility including statement of objectives of the operation of the plant, species to be processed, proposed periods of facility operation, proposed sources of shellfish, including potential harvest areas, and maximum capacity of plant.
- (2) Description of the Facility including:
- (a) Site plan drawings;
 - (b) Facility layout including detailed schematic of the entire depuration system;
 - (c) Schematic drawing of process;
 - (d) Product flow diagram showing product movement through facility (may be combined with §01.B.(3));
 - (e) Statement that construction materials and fabrication will meet the requirements of §.03.E. (1) and (2); and
 - (f) Schematic of seawater delivery and distribution system.
- (3) Design Specifications of Depuration Unit including:
- (a) Depuration tank diagram including tank dimensions and construction details, influent and effluent locations, operating water level, and typical container configuration;
 - (b) Process water system describing type of system (flow-through or recirculating), pretreatment and filtration systems, disinfection system, and hydraulic schematic;
 - (c) Shellfish containers construction and material meets §.04 and §.08 of this Chapter; and
 - (d) List of equipment including washing, culling, and packing equipment, material handling equipment, and cleaning and sanitation equipment.
- (4) Laboratory to be utilized for microbial analyses (in house, government agency, private commercial);
- (5) Depuration process monitoring including:
- (a) Sampling protocols including frequency of sampling, number of samples, sampling locations, and methodology for process water analyzing, incoming shellstock, depurated shellstock, and growing waters;
 - (b) Monitoring equipment maintenance and calibration procedures and copy of activity log forms that will be used for data entry;
 - (c) Process water monitoring protocol for physical and chemical parameters; and
 - (d) Data analysis and evaluation.
- (6) Standard Operating Procedure for:
- (a) Receiving and holding;
 - (b) Washing, culling, and placement of undepurated product in process tanks;
 - (c) Depuration unit operation;
 - (d) Monitoring of depuration unit operation;
 - (e) Removal of depurated product from process tanks;
 - (f) Storage parameters and procedures;
 - (g) Labeling/tagging procedures;
 - (h) Plant cleaning and sanitation; and
 - (i) Data analysis.
 - (j) Recall procedures.
- (7) Record Keeping. List categories of information that will be recorded. Include copies of proposed forms to be used in each category. A single form may be used for several categories if properly designed.
- (a) Shipping and receiving records;
 - (b) Plant Operation Log, including provisions for recording the values for chemical and physical parameters;

- (c) Maintenance and Sanitation Log(s);
- (d) Laboratory records;

J. Process

Verification.

The Dealer shall continually:

- (1) Routine Verification. Perform process verification on a continuous basis according to the following protocol:
 - (a) Following completion of a minimum of 44 hours of depuration, collect and assay at least one end-product sample;
 - (i) from each lot of restricted shellstock to be depurated in the depuration unit.
 - (ii) weekly from each lot of approved shellfish to be depurated in the depuration unit.
 - (b) Determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.
 - (c) Compare daily, or as a results become available, the depuration performance indices with the following Critical Limits for the Indices of Depuration Plant Performance.

Limits for Verification of Depuration Plant Performance		
Fecal coliform per 100 grams		
Species	Geometric Mean	90th Percentile
Soft Clams (<i>Mya arenaria</i>)	50	130
Hard Clams (<i>Mercenaria mercenaria</i>)	20	70
Oysters	20	70
Manilla Clams	20	70
Mussels	20	70

- (d) If the depuration performance indices for a specific species from a specific growing area are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance, then the process is considered verified for that species from that growing area.
- (e) For the purpose of making calculations, fecal coliform counts that signify the upper or lower limit of sensitivity of the test (MPN or ETCP) shall be increased or decreased by one significant figure. Thus, <9.0 becomes 8.9, <17 becomes 16 and >248 becomes 250. Individual plates which are too numerous to count (TNTC) are considered to have >100 colonies per plate. A sample containing "TNTC" plates is collectively rendered as having a count of 10,000.
- (2) Conditional Protocol Verification. If the depuration performance indices for a specific growing area fail to meet the Critical Limits for the Indices of Depuration Plant Performance, or if a new restricted growing area is used as a source of shellfish for depuration, or if a new depuration process has generated less than 10 process batches of data, the process is considered to be unverified and the dealer shall adhere to the following conditional protocols:
 - (a) The depuration processor shall collect and assay at least one zero hour and three end-product samples from each harvest lot;
 - (b) Environmental parameters including process water temperature, salinity, dissolved oxygen, and turbidity and/or other operational conditions may inhibit the physiological process and must be identified. The condition(s), once identified and quantified, become critical control points (CCP) for specific species in the specific plant and the hazard analysis and HACCP plan shall be revised accordingly;

- (c) Shellstock which are processed during this conditional protocol must meet the following release criteria before they may be released to market:
- (i) Geometric mean (from three samples) of soft clams not to exceed 110 and no single sample to exceed 170; or
 - (ii) Geometric mean (from three samples) of other clam species, mussels, or oysters not to exceed 45 and no single sample to exceed 100.
- (d) If the harvest lot fails to meet the release criteria, the depuration processor may choose to subject the product to additional depuration processing whereupon the shellfish can be resampled for release criteria or the disposition of the shellfish shall be as follows:
- (i) The Authority, in consultation with the depuration processor, may order the destruction of the shellfish; or
 - (ii) The Authority, in consultation with the depuration processor, may allow non-food use of the shellfish; or
 - (iii) The Authority, in consultation with the depuration processor, may allow the shellfish to be relayed in accordance with Chapter V.
- (e) When in Conditional Protocol Verification due to a failure of an established harvest area to meet the above Indices for Depuration Plant Performance, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive end product samples for each species depurated and for each harvest area used
- (i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.
 - (ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in XV§.03 J. (1).
 - (iii) If either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until the above Indices of Depuration Plant Performance are attained.
- (f) When in Conditional Protocol Verification due to the use of a new harvest area as the source of shellfish or if a new depuration process has generated less than 10 process batches of data, determine daily, or as results become available, the depuration performance indices defined as the geometric mean and 90th percentile of fecal coliform (FC) from assay data of the most recent ten (10) consecutive harvest lots for each species depurated and for each harvest area used.
- (i) Compare these depuration performance indices with the above Critical Limits for the Indices of Depuration Plant Performance for this species.
 - (ii) If these depuration performance indices are less than or equal to the above Critical Limits for the Indices of Depuration Plant Performance for this species, the process is then considered to be verified for this species from this particular harvest area; and the process reverts to the Process Verification protocol in §XV.03 J. (1).
 - (iii) If less than 10 process batches of data have been collected or either the geometric mean or the 90th percentile values exceed the above Critical Limits for the Indices of Depuration Plant Performance for this species, from this particular harvest area, the process shall remain in Conditional Protocol Verification for this species from this particular harvest area until 10 batches of data have been collected and the above Indices of Depuration Plant Performance are attained.

- (3) When depuration units with multiple tanks are used, it is necessary to determine whether the individual tanks are similar.
 - (a) Tanks are considered similar if the difference between physical tank dimensions and process water flow rate is less than 10%.
 - (b) If they are not similar, then the process verification protocols contained in Section .03 J. (1) - (2) must be employed for each tank.
- (4) The dealer shall ensure that all microbiological assays of end-point samples of shellstock:
 - (a) Are analyzed by a laboratory which has been evaluated and approved pursuant to the requirements in Chapter III, using an NSSP-approved method;
 - (b) Sample size consists of a pool of at least 12 shellfish selected at random from each designated container (more than 12 individuals may be required in the case of smaller shellfish); and
 - (c) Samples are collected at locations within the depuration unit that are considered to be most compromised as regards shellfish activity, based on the sampling plan contained in the Depuration Plant Operations Manual.