Introduction

Oysters, clams, and mussels are unique foods that have been enjoyed by consumers for many years. The popularity of shellfish as a food can be traced through several centuries of American history. The value of these renewable natural resources to the early settlers was reflected in colonial legislation designed to encourage their wise use.

Public health controls of shellfish became a national concern in the U.S. in the late 19th and early 20th century when public health authorities noted a large number of illnesses associated with consuming raw oysters, clams, and mussels. During the winter of 1924, there occurred a widespread typhoid fever outbreak, which resulted in a request that the Surgeon General of the United States Public Health Service develop necessary control measures to ensure a safe shellfish supply to the consuming public. In accordance with this request, the Surgeon General called a conference, which was held in Washington, D.C., on February 19, 1925.

The members of the conference recommended eight resolutions for the sanitary control of the oyster industry, which formed the basis for development of the National Shellfish Sanitation Program. The conference also established a committee to develop further necessary guidelines to recommend practices for the sanitary control of the shellfish industry.

The basic concepts in formulating a program of national public health controls were reiterated by the Surgeon General in his letter of August 12, 1925, to State health officers and all others concerned. This letter set forth the following understandings:

1. "The Public Health Service considers that the responsibility for the sanitary control of the shellfish industry rests chiefly upon the individual States; and that the requisite coordination and uniformity of control may best be achieved by mutual agreement among the States, with the assistance and cooperation of the Public Health Service..."
2. "In accordance with this principle, it is considered that each producing State is directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens, but equally for safeguarding such of its product as goes to other States..."
3. "In order that each state may have full information concerning the measures carried out in other States, the Public Health Service will undertake systematic surveys of the machinery and efficiency of sanitary control as actually established in each producing State, and will report thereon for the information of the authorities of other States. It is believed that, in addition to furnishing valuable information, these reports will have an important influence in stimulating the development of better sanitary control and in promoting substantial uniformity on a higher plane." "The officers of the Public Health Service assigned to this survey work will assist the State agencies in determining their sanitary problems, in formulating plans for adequate sanitary control, and in making actual sanitary surveys as far as practicable."
4. "In addition to the above, the Public Health Service will continue to extend the services which it is already rendering, especially in conducting scientific investigations of fundamental importance to control, and in serving as a clearinghouse for the interchange of information and the discussion of policies between State authorities."

To implement this program, the members of the 1925 conference agreed that the producing states would issue "Certificates," i.e., a permit to operate, to shellfish shippers that met agreed upon sanitary standards. The Public Health Service would serve as a clearinghouse for information on the effectiveness of the State control programs.

The procedures used by the Public Health Service in fulfillment of its obligations under the Public Health Service Act resulted from an understanding that implementation and enforcement of the necessary public health controls could best be accomplished under State laws with federal technical support and industry participation. The National Shellfish Sanitation Program is dependent entirely upon the States adopting the recommended requirements and the cooperative and voluntary efforts of State regulatory agencies and the shellfish industry.

The NSSP went beyond the original objective set forth in the 1925 Conference of insuring that shellfish shipped interstate would not be the cause of communicable disease. In the 1940's paralytic shellfish poison became a matter of public health concern and steps were taken to protect the public against this hazard. In 1957 it was recognized that shellfish might concentrate certain radionuclides and that a radiation surveillance activity might become a necessary addition to the established procedures. In the 1960's and 1970's it became apparent that shellfish have the ability to concentrate poisonous and deleterious substances such as metals, pesticides, hydrocarbons, etc. to potentially unsafe levels. To ensure the safety of shellfish, the State must supervise the growing, harvesting, relaying and transportation of shellfish. It is also important that shellfish be protected against contamination.

If State supervision is to be effective, the activity must be supported by legal authority. This authority may be either a specific law or a regulation. The success with which the State is able to regulate the several components of the shellfish industry provides a measure of the adequacy of the statutory authority. The unique nature of shellfish as a food consumed whole and raw also makes it necessary for the State shellfish control agency to have authority to take immediate emergency action without recourse to lengthy administrative procedures, to halt harvesting and processing of shellfish. This authority should include placing restrictions on harvesting on the basis of a potential as well as an actual public health hazard. As examples, a State may find it necessary to close a shellfish growing area following a breakdown of a wastewater treatment plant or the unexpected finding of marine toxin(s), or when a growing area is implicated in confirmed illnesses.

Periodic revisions of State shellfish laws or regulations may be necessary to cope with new public health hazards and to reflect new knowledge. Examples of changes or developments which have called for revision of State laws include: (1) the increased use of pleasure boats with the resulting probability of contamination of shellfish growing areas with fresh untreated fecal material, (2) the conditionally approved area concept resulting from the construction of wastewater treatment facilities, (3) the effect of non-point source pollution, and (4) the ability of shellfish to concentrate certain radionuclides and hazardous chemicals. Experience has demonstrated that all actual and potential shellfish growing waters of the State must be classified by their sanitary suitability for shellfish harvesting. Harvesting should be permitted only from those areas that have been found by sanitary survey to meet the criteria of this Manual. Harvesting should accordingly be specifically prohibited from areas which do not meet the criteria, or which have not been surveyed, or which have outdated survey information.

The National Shellfish Sanitation Program (NSSP) is the federal/state cooperative program recognized by the U.S. Food and Drug Administration (FDA) and the Interstate Shellfish Sanitation Conference (ISSC) for the sanitary control of shellfish produced and sold for human consumption. The purpose of the NSSP is to promote and improve the sanitation of shellfish (oysters, clams, mussels and scallops in any form, except when the final product form is the adductor muscle only) moving in interstate commerce through federal/state cooperation and uniformity of State shellfish programs. Participants in the NSSP include agencies from shellfish producing States, FDA, and the shellfish industry. Under international agreements with FDA, foreign governments also participate in the NSSP. Other components of the NSSP include program guidelines, State growing area classification and dealer certification programs, and FDA evaluation of State program elements.

In 1984, the FDA entered into a Memorandum of Understanding (MOU) with the Interstate Shellfish Sanitation Conference recognizing the ISSC as the primary voluntary national organization of State shellfish regulatory officials that provides guidance and counsel on matters for the sanitary control of shellfish. The purpose of the ISSC is to provide a formal structure for State regulatory authorities to participate in establishing updated regulatory guidelines and procedures for uniform state application of the Program. The ISSC has adopted formal procedures for state representatives to review shellfish sanction issues and develop regulatory guidelines. Following FDA concurrence, these guidelines are published in revision of the NSSP Model Ordinance.

The NSSP Guide for the Control of Molluscan Shellfish consists of a Model Ordinance, supporting guidance documents, recommended forms, and other related materials associated with the Program. The Model Ordinance includes guidelines to ensure that the shellfish produced in States in compliance with the guidelines are safe and sanitary. The Model Ordinance provides readily adoptable standards and administrative practices necessary for the sanitary control of molluscan shellfish.

Chapter I. Shellfish Sanitation Program

Requirements for the Authority

@01. Administration

A. Scope. Because shellfish can be contaminated either in the growing area before harvest or during activities involved in harvesting, processing, distribution, or shipping, State laws or regulations must provide an adequate legal basis for sanitary control of all of these phases of handling shellfish. This legal authority must enable one or more departments or agencies of the state to regulate and supervise the classification of growing areas, harvest, relaying and transport of shellstock at its source; the shipment, tagging and storage of shellstock; the operation of depuration plants; and the shucking, packing, labeling and repacking of shellfish. The State must be able to apply the NSSP requirements to every actual and potential growing area, and to all shellfish harvesters to insure that shellfish available to certified dealers have been produced and harvested under acceptable sanitary conditions. The state must also have the authority to certify and suspend or revoke the certification of interstate shellfish shippers; to conduct laboratory examinations of shellfish; to prevent the sale of unsafe shellfish or shellfish from uncertified dealers by such legal means as detention, monetary fines, seizure, embargo and destruction; and to suspend harvesting and certificates of interstate shippers in public health emergencies.

B. Records. States must maintain data and files that will provide evidence and demonstrate the effective administrative management of the shellfish sanitary control program as part of their participation in the NSSP. States must keep records in a central file to facilitate the FDA review of their shellfish sanitation programs and must assist the FDA in making such reviews. The purpose of this FDA review is to evaluate the adequacy of each state program in meeting the requirements of the NSSP Model Ordinance. The maintenance of proper records, organized files and adoption of accepted public administrative procedures provides the State control agencies with the means to conduct an effective program. The State program should have clearly written administrative procedures to affect the controls specified in the NSSP Model Ordinance.

C. Shared Responsibilities. When two or more State agencies are involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed.

D. Administrative Procedures. If state supervision is to be effective, the activity must be supported by legal authority applied through law, regulation or appropriate administrative procedures. Periodic revisions of state shellfish laws, regulations or administrative procedures may be necessary to cope with new public health hazards and to reflect new knowledge. The success with which the State is able to regulate the several components of the shellfish industry provides a measure of the adequacy of the statutory authority.

E. Epidemiologically Implicated Outbreaks of Shellfish-Related Illness. The intrinsic risk associated with consumption of raw or partially cooked shellfish products compels the shellfish control authority to act quickly and effectively when shellfish are implicated in a food-borne outbreak. Development of administrative procedures in advance of outbreaks supports quick effective action and avoids costly mistakes and inadvertent destruction of evidence through delay.

F. Commingling. Commingling means the act of combining different lots of shellstock or shellfish from different days in the same growing area, or combining different lots of shellstock from different growing areas. Health departments and other appropriate state and federal agencies must be able to determine the source of shellfish contamination when an outbreak of disease attributable to shellfish occurs so they can prevent any further illnesses from this source. Separating shellfish from different sources is necessary to maintain lot identity during harvest, transport, storage, shucking, and repacking operations. This lot separation assists in tracing shellfish back to its source when questions of public health safety arise. Maintaining lot identity will prevent implication of sources that are not associated with the outbreak and can prevent unnecessary regulatory action and liability. When commingling is allowed under any state management plan, the objective is to minimize the commingling of different dates of harvest and different growing areas. For additional information concerning commingling, see the NSSP Model Ordinance Guidance Document: *Shellstock Tagging* (ISSC/FDA, 2007).

@.02 Dealer Certification

A. - D. General, Initial Certification, Renewal of Certification, and Revocation or Suspension of Certification. A principal objective of the NSSP has been to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria. This NSSP objective is achieved through establishment of criteria and procedures to allow a producing or processing state to "certify" to receiving states that the product from a specific dealer has been grown, harvested, transported, processed, or shipped in compliance with the NSSP Model Ordinance guidelines. Dealer certification is dependent on a dealer maintaining acceptable operational and sanitary conditions and is determined through uniform inspections by standardized inspectors. For more information concerning standardized inspections, see the NSSP Model Ordinance Guidance Document: *Shellfish Plant Inspection Standardization Procedures* (ISSC/FDA, 2007).

State officials who certify dealers must fully comply with the administrative requirements for certification for the process to remain viable. For the certification process to be effective, dealers must fully comply with the applicable Model Ordinance sanitation guidelines pertaining to the type of operation involved. For a full discussion of the certification process, see the NSSP Model Ordinance Guidance Document: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2007).

E. Interstate Certified Shellfish Shippers List (ICSSL). Placement of a dealer on the ICSSL serves as nationwide notification to receiving states and the shellfish industry of dealer certification. Food control officials throughout the United States use the ICSSL to determine that shellfish offered for sale at the wholesale or retail level have been produced under the sanitary guidelines of the NSSP Model Ordinance. These officials generally rely upon the certification process instead of holding up shipments or sales of shellfish lots pending examination. The ICSSL is also used by the seafood and other food industries to find sources of safe shellfish. For a full discussion of the ICSSL purpose and use, see the NSSP Model Ordinance Guidance Documents: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2007).

F. Inspections. Through inspections by both the shellfish control agency and the dealer, as part of the dealer's HACCP plan, unsanitary conditions may be detected and corrected. Unannounced shellfish control agency inspections serve to verify that NSSP Model Ordinance guidelines are being met by the dealer. For additional information concerning inspections, see the NSSP Model Ordinance Guidance Documents: *Shellfish Plant Inspection Standardization Procedures* (ISSC/FDA, 2007).

G. Performance Based Inspection Program (PIP). Performance based inspections for dealers with a significant history of satisfactory compliance result in improved regulatory efficiency. Regulatory inspections can be concentrated on more high-risk shellfish operations or operations with poor performance histories. Dealers recognized as having a record of excellent performance may be rewarded with the privilege of a reduced number of inspections.

H. Enforcement. The unique nature of shellfish as a food consumed whole and raw in the form as it comes from the growing area requires the state shellfish control authority to have sufficient growing area patrol capacity to enforce the public health based restrictions on harvesting and to obtain meaningful penalties for violation of those harvesting restrictions. Information concerning enforcement activities at the growing area level can be found in the NSSP Model Ordinance, Chapter V, @04 and Chapter VIII, @01, B., *Patrol of Growing Areas* (ISSC/FDA, 2007) and in Guidance Documents: *Growing Area Patrol and Enforcement* and *Shellstock Relay* (ISSC/FDA, 2007). Dealer certification is intended to provide an unbroken chain of sanitation control to a lot of shellfish from the moment of harvest to its sale at the wholesale or retail level. Dealers having major non-conformities with the NSSP Model Ordinance should not be certified. Certified dealers found to have major non-conformities should have their licenses or permits suspended or certifications revoked. Information concerning enforcement activities at the dealer certification level can be found in the NSSP Model Ordinance Guidance Documents: *Dealer Certification and the Interstate Certified Shellfish Shippers List (ICSSL)* (ISSC/FDA, 2007).

Chapter II. Risk Assessment and Risk Management

Requirements for the Authority

@.01 Outbreaks of Shellfish-Related Illness.

Shellfish are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, from the water column if these organisms are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result.

When illness has occurred, immediate closure of the implicated growing area and/or recall of implicated product will significantly reduce the chance of additional illnesses. Additional information concerning investigation of an outbreak of shellfish related illness believed to be associated with a naturally occurring pathogen can be found in the NSSP Model Ordinance Guidance Documents: *Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak* (ISSC/FDA, 2007). Additional information concerning the disease causing potential of shellfish can be found in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Guidance for Developing Marine Biotoxin Contingency Plans*, and *Shellstock Relay* (ISSC/FDA, 2007).

Documentation of the information supporting growing area classification, proper tagging and record keeping, expeditious follow-up on reported illnesses, effective recall of implicated product and public warning announcements are all requisite to protecting public health. Shellfish growing areas implicated through epidemiological association between illness and shellfish consumption must be closed immediately to prevent additional implicated product from reaching the consumer. Broad closures of Growing Areas, in addition to reducing the chance of additional illnesses, will: improve identification of specific sites where harvesting is taking place; reduce the size of areas available to harvest; reduce the practice of mixing together shellstock from different growing areas; and reduce illegal harvesting because legitimate harvesters will self-police their ranks to prevent false tagging. In addition, shellfish product from the implicated growing areas should be detained and an effective recall of product initiated.

When the source of the illness is found to be the distribution and processing system, shellfish product should be also detained and an effective recall of product initiated, and the problem immediately corrected.

@.02 Presence of Human Pathogens in Shellfish Meats.

Human pathogens have been found in shellfish in the absence of human illness. These pathogens can be present at levels below that of an infectious dose, and may originate either as naturally occurring organisms in the growing area or from contamination of the growing area or of the shellfish during its handling, storage, transport or processing. Continued finding of the presence of human pathogens in shellfish from a specific growing area with no evidence of illness in the consumers may or may not constitute a human health risk. In these circumstances, the shellfish control authority needs to act quickly to initiate a thorough investigation to determine if the pathogen source is either the growing area or the system used for distributing and processing the product. If the source can be determined, the authority needs to take immediate steps to correct the problem through appropriate actions such as eliminating the source, reclassifying the growing area or changing a distribution or processing procedure.

When the source of the organism cannot be identified or if the organism is naturally occurring, the authority should conduct a risk assessment using all available information to determine if the human consumer is at risk. When the risk is determined to be negligible, no further action is required. A determination that some risk exists may prompt further action to protect the consumer such as allowing the shellfish to be harvested with an advisory to immunologically compromised individuals, allowing shellfish to be used only for cooked product, or closing the growing area.

@.03 Presence of Toxic Substances in Shellfish Meats

Because shellfish are filter feeders, they can readily accumulate toxigenic micro-algae and other substances from the water column. These substances include heavy metals, chlorinated hydrocarbons and other poisonous or deleterious substances. The presence of these substances does not necessarily constitute a health risk, as toxicity is dependent on both concentration (dose) and length of exposure.

To protect the consumer, the shellfish control authority needs to evaluate the levels of toxic substances that may be present in the shellfish against known tolerance levels in human foods or other appropriate information, and determine what action, if any, should be taken. Additional information concerning this topic can be found in the NSSP Model Ordinance Guidance Documents: *Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood* (ISSC/FDA, 2007); and *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2007).

Chapter III. Laboratory

Requirements for the Authority

@.01 Quality Assurance.

Laboratory results from the bacteriological and chemical testing of shellfish growing waters and meats are widely used in the National Shellfish Sanitation Program to determine the safety of shellfish for human consumption. Experience with the bacteriological and toxicological examination of shellfish and shellstock growing waters has indicated that minor differences in laboratory procedures or techniques might cause wide variations in the results. Improper handling of the sample may also cause variations in results during collection or transportation to the laboratory. The APHA *Recommended Procedures for the Examination of Seawater and Shellfish*, which are revised periodically, offer reliable information for minimizing these variations. Assuring uniformity nationwide in the application of a laboratory quality assurance program is necessary to substantiate the validity of analytical results. Integral to laboratory quality assurance is a strong program for the evaluation of laboratory performance.

@.02 Methods.

American Public Health Association (APHA) *Recommended Procedures for the Examination of Seawater and Shellfish* shall be followed for the collection, transportation, and examination of samples of shellfish and shellfish waters. The official reference of the NSSP for the examination of shellfish for *Vibrio cholerae, V. vulnificus, and V. parahaemolyticus* is Section IV, Guidance Documents, Chapter II, Growing Areas: .10 Approved National Shellfish Sanitation Program Laboratory Tests: Microbiological and Biotoxin Analytical Methods. State laboratories should conduct the test for these organisms when routine tests of marine foods implicated in foodborne outbreaks fail to demonstrate other enteric pathogens or bacterial toxins.

Use of standardized laboratory methods and procedures produces results acceptable to all regulatory agencies and allows comparative evaluation of data across laboratories. The APHA reference and FDA's BAM contain procedures for the virological examination of seawater and shellfish. However, the use of these procedures should be limited to special studies such as the development of new approaches for assessing, controlling, or improving shellfish sanitary quality, investigation of shellfish-borne disease outbreaks and other research studies. Routine virus monitoring of shellfish or their waters is not recommended due to the technical complexity, time required, high cost, and limitations of the detection and recovery method. For methods used in the NSSP, see the NSSP Model Ordinance Guidance Document: *Approved NSSP Laboratory Test* (ISSC/FDA, 2007).

Chapter IV. Shellstock Growing Areas

Requirements for the Authority

@.01 Sanitary Survey

A. General. One of the goals of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. The positive relationship between sewage pollution of shellfish growing areas and disease has been demonstrated many times. Shellfish-borne infectious diseases are generally transmitted via a fecal-oral route. The pathway can become quite circuitous. The cycle usually begins with fecal contamination of the growing waters. Feces deposited on land surfaces can release pathogens into surface waters via runoff. Most freshwater streams eventually empty into an estuary where fecal bacteria and viruses may accumulate in sediment and subsequently can be re-suspended.

Shellfish pump large quantities of water through their bodies during the normal feeding process. During this process the shellfish also concentrate microorganisms, which may include pathogenic microorganisms. Epidemiological investigations of shellfish-caused disease outbreaks have found difficulty in establishing a direct numerical correlation between the bacteriological quality of water and the degree of hazard to health. Investigations made from 1914 to 1925 by the states and the Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc portions of water examined were positive for coliforms (an MPN of approximately 70 per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed by bacteriological examination.

Following the oyster-borne typhoid outbreaks during the winter of 1924-25 in the United States, the National Shellfish Sanitation Program was initiated by the States, the Public Health Service, and the shellfish industry. Water quality criteria were then stated as: (1) the area is sufficiently removed from major sources of pollution so that the shellfish would not be subjected to fecal contamination in quantities which might be dangerous to the public health, (2) the area is free from pollution by even small quantities of fresh sewage, and (3) bacteriological examination does not ordinarily show the presence of the coli-aerogenes group of bacteria in 1 cc dilution of the growing area water. Once the standards were adopted in the United States in 1925, reliance on this three-part standard for evaluating the safety of shellfish harvesting areas has generally proven effective in preventing major outbreaks of disease transmitted by the fecal-oral route. Similar water quality criteria have been used in other countries with favorable results.

Nevertheless, some indicators and pathogens are capable of persisting in terrestrial soil, fresh and marine waters, and aquatic sediment for many days while others are even capable of growth external to a host. A small number of shellfish-borne illnesses have also been associated with bacteria of the genus *Vibrio*. The vibrios are free-living aquatic microorganisms, generally inhabiting marine and estuarine waters. Among the marine vibrios classified as pathogenic are strains of non-01 *Vibrio cholerae*, *V. parahaemolyticus*, and *V. vulnificus*. All three species have been recovered from coastal waters in the United States and other parts of the world. These and other vibrios have been detected in some environmental samples recovered from areas free of overt sewage contamination and coliform.

In general, shellfish-borne vibrio infections have tended to occur in coastal areas in the summer and fall when the water was warmer and vibrio counts were higher. *V. parahaemolyticus* and non-01 *V. cholerae* are commonly reported as causing diarrhea illness associated with the consumption of seafood including shellfish. In contrast, *V. vulnificus* has been related to two distinct syndromes: wound infections, often with tissue necrosis and bacteremia, and primary septicemia characterized by fulminant illness in individuals with severe chronic illnesses such as liver disease, hemochromatosis, thalassemia major, alcoholism or malignancy. Increasing evidence shows that individuals with such chronic diseases are susceptible to septicemia and death from raw seafoods, especially raw oysters. Shellfish-borne vibrio infections can be prevented by cooking seafood thoroughly, keeping them from cross contamination after cooking, and eating them promptly or storing them at hot (60°C or higher) or cold (4°C or lower) temperatures. If oysters and other seafoods are to be eaten raw, consumers are probably at lower risk to vibrio infection during months when seawater is cold than when it is warm.

In addition to pathogenic microorganisms, poisonous or deleterious substances may enter shellfish growing areas via industrial or domestic waste discharges, seepage from waste disposal sites, agricultural land or geochemical reactions. The potential public health hazard posed by these substances must also be considered in assessing the safety of shellfish growing areas.

The primary responsibility of the shellfish control authority is to ensure the public health safety of the shellfish growing areas through compliance with the NSSP Model Ordinance. The Authority must perform a sanitary survey that collects and evaluates information concerning actual and potential pollution sources that may adversely affect the water quality in each growing area. Based on the sanitary survey information, the authority determines what use can be made of the shellstock from the growing area and assigns the growing area to one of five classifications. The survey information must be updated periodically to ensure that it remains current and must be readily accessible to both the Authority and the harvester. Experience has shown that the minimum sanitary survey components required in this chapter are necessary for a reliable sanitary survey. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2007).

B. Sanitary Survey Required. The findings of the sanitary survey represent a comprehensive analysis of data from several sources used to determine the proper classification of a growing area. Therefore, the Authority is required to complete the survey before determining the classification of a growing area and the appropriate use of shellstock from the area. If no harvesting is to be permitted in a growing area, the sanitary survey is unnecessary.

C. Sanitary Survey Performance. Since the sanitary survey must be kept current to routinely verify the classification of the growing area, specified frequencies for updating the various survey components are necessary. Lack of written documentation precludes accurate assessment on a routine basis, and requires that, to protect the public health, the growing area be placed in the prohibited classification or closed status of its classification. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2007).

D. Shoreline Survey Requirements. The shoreline survey (also known as the pollution source survey) is the sanitary survey component in which the actual and potential pollution sources that may adversely affect the growing area are identified. These sources may introduce infectious disease agents or poisonous and deleterious substances to the growing waters where they may be taken up and concentrated by shellfish. Detailed and accurate information concerning the pollution sources is necessary for a proper growing area classification. A more detailed explanation is provided in the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2007).

The key to the accurate classification of shellfish growing areas is the sanitary survey. The principal components of a sanitary survey include: (1) an evaluation of the pollution sources that may affect the areas, (2) an evaluation of the meteorological factors, (3) a review of hydrographic factors that may affect distribution of pollutants throughout the area, and (4) an assessment of water quality.

A pollution source survey should be conducted of the shoreline area and watershed to locate direct discharges (e.g., municipal and industrial waste discharges, package treatment units, and malfunctioning septic tanks) and non-point sources of pollution (e.g., storm water runoff and agricultural and wildlife area runoff). Municipal and industrial wastewater treatment facilities should be evaluated in terms of design capacity versus actual loading, type and concentration of pollutants discharged, and the type and effectiveness of pollution control devices.

Following these evaluations, hydrographic and meteorological characteristics that may affect the distribution of pollutants to the area should be determined. Examples of these are tidal amplitude and type, water circulation patterns, depth, salinity, stratification characteristics, rainfall patterns and intensity, and prevailing winds.

Information from pollution source evaluations and hydrographic studies should be considered in developing an evaluation of the water quality in a growing area. The purpose of this evaluation is to develop specific information to assist in defining classification boundaries. In many instances, bacteriological and related salinity data can be used to develop information on hydrographic characteristics of the area.

In designing a water quality evaluation, the following should be considered. Most water samples should be collected from the surface, since pollution discharged into freshwater streams or brackish estuarine waters usually tends to remain near the surface or above the denser seawater. Sample collection should be timed to be representative of the major pollution impacts, since shellfish respond rapidly to an increase in the number of bacteria in their surrounding waters. A sanitary survey report is needed to integrate data from several sources into a comprehensive analysis to determine the proper classification for the area. This report should include a compilation of relevant data, a data analysis utilizing recognized statistical techniques, conclusions as to the appropriate classification of the area, and recommendations for necessary follow-up actions. The report may also consider relevant resource management, social, economic, or political factors that may influence the establishment of boundaries and open and closed periods for conditionally approved and restricted areas.

Maintaining the sanitary survey consists primarily of routinely evaluating major pollution sources, collecting water quality data from key stations under adverse conditions, and analyzing the data to assure that the sanitary survey continues to be representative of current sanitary conditions in the growing area. The growing area must be subjected promptly to a more intense and comprehensive sanitary survey reevaluation when routine monitoring reveals a substantial change in the sanitary conditions. A reevaluation report is then needed and a determination must be made as to the proper classification of the area.

Experience with the shellfish certification program indicates a tendency to omit or de-emphasize some components of the sanitary survey unless a central state file of all shellfish sanitary survey reports, maintenance data and analysis, and reevaluation reports is maintained. This is particularly true where responsibility for shellfish sanitation is divided between two or more state agencies. Maintenance of a central state file for all shellfish sanitary survey information will also simplify the appraisal of state programs by the FDA and will prevent loss of historical data which may be useful in evaluating the sanitary quality of an area.

@.02 Bacteriological Standards

A. General. The NSSP recognizes the use of two different indicator organisms for evaluating shellfish growing water quality. The water quality standards for the two indicators are numerically different from one another but are believed to afford the same level of public health protection (Hunt and Springer, 1974). The Authority may use either indicator and its companion water quality standard in any growing area.

B. Water Sample Stations. The location of water sample collection stations can markedly affect the water quality detected. The NSSP requires that stations be of sufficient number and located to capture the effect of pollution sources so that the water quality affecting the shellfish can be adequately evaluated.

C. Exceptions. Application of the water quality standards under the NSSP is based on the collection of a specified minimum number of samples at a specified frequency over a 3-year period. When a new growing area is under evaluation for classification, 3 years of historic data may not exist. This section sets the minimum number of samples that must be collected as part of the required sanitary survey to determine the appropriate growing area classification for these new growing areas. The requirements are more stringent for growing areas that have pollution sources that affect water quality. No water quality samples are required to place a growing area in the prohibited classification.

D. - F. Standards for the Approved Classification of Growing Areas in the Remote Status, Affected by Point Sources, or Affected by Nonpoint Sources. Based on the information gathered in the sanitary survey, the shellfish authority determines the appropriate classification of the shellfish growing area. The shellfish authority makes a decision to place a growing area in either the approved, conditionally approved, restricted, or conditionally restricted growing area classification. The growing area classification determines how the shellstock may be used following harvest. Water samples collected as part of the sanitary survey or as a required update of the sanitary survey are used to determine if the water quality meets the water quality standards for the growing area classification. The NSSP recognizes two water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition sampling strategy to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the water sample monitoring strategy used dictate the frequency of samples that must be collected. If the water quality meets approved classification water quality standards, the growing area is placed in the approved classification. If the water quality does not meet the water quality standards for the approved classification or meets the water quality standards only under certain conditions, the Authority places the area in another more suitable classification. For a fuller explanation of the classification of growing waters and the water quality monitoring strategies, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters, Systematic Random Sampling Monitoring Strategy*, and *Management Plans for Growing Areas in the Conditional Classification* (ISSC/FDA, 2007).

A field sampling and data analysis design that employs a systematic random sampling plan, assumes that a statistically representative cross section of all meteorological, hydrographic, and/or other pollution events will be included in the data set. Therefore, all shellfish growing area data collected shall be used during classification. This sampling and data analysis design may be applied to approved and restricted shellfish growing areas that are affected by only randomly occurring pollution events. Additionally, this sampling strategy may be used to classify shellfish growing areas where water quality is influenced by seasonal water uses or where harvesting is controlled by seasonal resource management restrictions.

Systematic random sampling cannot be applied to areas impacted by point source pollution. This field sampling and data analysis design presumes that if intermittent, unfavorable changes in water quality occur, they will be revealed in the bacteriological sampling results. These unfavorable sampling results will then contribute to the variation of the data set. Data sets displaying greater levels of variation will consequently exhibit an elevated estimated 90th percentile. The Authority's option to use a systematic random sampling strategy is therefore, contingent upon the acceptance of the estimated 90th percentile, as the statistic to measure the variance of a data set. This statistic shall, along with the geometric mean or median, be used when evaluating each sampling station for compliance with NSSP growing area criteria.

An example of an acceptable systematic sampling plan is one that documents a preestablished sampling schedule in the growing area central file. Monthly or bimonthly sampling regimes are acceptable as long as there is no avoidance of unfavorable conditions and a reasonable attempt is made to collect samples on the preestablished days. Field sampling crews will *not* be required to take unnecessary risks to sample on any particular day. The sampling plan will address unsafe sampling (boating) conditions by designating an alternate sampling day or by allocating extra sampling days in the schedule that may be used when needed.

If the growing area is intended for year-round harvesting, the sampling regime should stipulate the collection of samples throughout the year. If the growing area is intended to be approved for direct harvest for only part of the year, the random sampling plan would need only to address that period when the area is available for harvest. The only exception to this obligation to a random sampling regime is that the Authority will direct sampling to a particular tidal condition, if that condition unfavorably impacts the quality of the growing area.

The estimated 90th percentile was suggested in ISSC issue 8109 and its addendum, to address the public health concerns associated with variation in shellfish growing water-monitoring data. The estimated 90th percentile will weigh every MPN value in the data set. This statistic will aid the evaluation of the growing water data by accurately describing the results of the field sampling. When environmental events (such as rainfall) produce unfavorable effects on water quality, a randomly collected set of growing water data may, while still meeting the "10 percent above 43" criterion, display a greater level of variance than that associated with NSSP criteria. The "percentage factor" was not intended to allow for variation in the data caused by changes in environmental conditions at the time of sampling. The "percentage factor" was intended for use with a normally distributed data set, and reflects the inherent variation of the MPN analytical method.

If growing water data collected following unfavorable pollution events are combined with data collected under normal conditions, variation is increased. The estimated 90th percentile will reflect this variation. Therefore, the estimated 90th percentile will facilitate the use of a systematic random sampling strategy, while protecting against the potential public health problems that may result when shellfish are consumed from growing waters that are adversely affected by intermittent pollution events. For more information on systematic random sampling, see the NSSP Model Ordinance Guidance Documents: *Systematic Random Sampling Monitoring Strategy* (ISSC/FDA, 2007).

G. - H. Standard for the Restricted Classification of Growing Areas Affected by Point Sources or Nonpoint Sources and Used as a Shellstock Source for Depuration. Classification as a restricted growing area used as a shellstock source for depuration is an option available to the Authority as an alternative to placing a growing area in the prohibited classification. Shellstock harvested from these waters are subjected to depuration, which is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment as a treatment process. Following successful depuration, the shellfish are safe to eat.

Water samples are collected to determine if the water quality meets the water quality standards for this growing area classification. The NSSP recognizes two water quality-monitoring strategies: adverse pollution condition and systematic random sampling. Presence of point sources of pollution requires the use of the adverse pollution condition monitoring system to collect data for the application of the water quality standard. In growing areas not affected by point sources, the Authority may elect to use either system. The presence or absence of point sources of pollution and the monitoring system used dictate the frequency of samples that must be collected for application of the water quality standards. If the water quality meets the water quality standard for this classification, the growing area is placed in the restricted classification. If the water quality does not meet this water quality standard, or meets the water quality standard only under certain conditions, the Authority places the area in either the prohibited or the conditionally restricted classifications. For a fuller explanation of the classification of growing waters and the water quality monitoring strategies, see the NSSP Model Ordinance Guidance Documents: *Sanitary*

Survey and the Classification of Growing Waters, Systematic Random Sampling Monitoring Strategy, and *Management Plans for Growing Areas in the Conditional Classification* (ISSC/FDA, 2007).

@.03 Growing Area Classification

A. General. The probable presence or absence of pathogenic microorganisms in shellfish waters is important in deciding how shellfish obtained from an area may be used. All actual and potential growing waters should thus be classified according to the information developed in the sanitary survey. Classification should not be revised upward without careful consideration of trends and currently available data. Included in the sanitary survey file should be a written report with analysis supporting the classification.

The classification in which a growing area is placed dictates how the shellstock from that area may be used i.e. sold directly to the consumer to eat or required to be subjected to natural or artificial cleansing prior to sale to the consumer. Therefore, the Authority must make every effort to use the sanitary survey information to determine the correct classification in which to place the growing area to minimize public health risk to the consumer. Any change from a more restrictive growing area classification to a less restrictive classification requires a written sanitary survey report that carefully and thoughtfully evaluates the changes in the information and data supporting the current classification to justify the less restrictive classification.

The status of a growing area is different from its classification. A growing area is generally in the open status for harvest subject to the limitations of its classification. When the conditions for the open status are not satisfied, the growing area may be placed in the closed status of its classification. For example, in a public health emergency such as deterioration of growing area water quality following a hurricane, a growing area in the approved classification would be placed in the closed status until the water quality is determined to meet the water quality standards for its classification. After a closure, a reevaluation must be made prior to reopening. The growing area would be returned to its open status when the water quality returns to normal provided it continues to meet all other criteria for the approved classification.

Some growing areas are so remote that there is no possibility of contamination. If an area qualifies for remote status, less restrictive monitoring requirements are imposed.

B. Approved Classification. A review of epidemiological investigations of disease and marine biotoxin outbreaks attributable to the consumption of shellfish reveals that three general situations prevail insofar as contamination of approved growing areas are concerned.

Firstly, improperly conducted or outdated sanitary surveys or misapplication of approved area criteria have unwittingly allowed sewage contamination of approved areas. Such areas have been shown to be the source of shellfish involved in shellfish associated disease outbreaks. The misapplication of approved area criteria includes the improper interpretation of the upper 10 percentile criteria to permit an area that is contaminated 10 percent of the time to be classified as approved.

A report of a 1910 outbreak of typhoid fever involving 41 persons notes that raw sewage from a city with a population of 30,000 was discharged only a few hundred feet away from clam beds and floats. In 1947, a case of typhoid fever was attributed to clams harvested 200 yards from the outlet of a municipal sewage treatment plant. In the latter case, the coliform MPN of the harbor water exceeded 12,000 per 100 ml and the area had been posted as closed to shellfish harvesting. In 1961, clams were responsible for at least 15 cases of infectious hepatitis. Subsequent water quality samples from the area found total coliform levels ranged between 900 to 2,400 MPN per 100 ml. The highest fecal coliform level observed was 2,100 MPN per 100 ml.

In 1978, at least 2,000 persons were victims of oyster-associated food poisoning. The causative agent was determined to be the Norwalk virus. The oysters were contaminated by sewage and runoff during periods of heavy rainfall. In 1977, there were over 700 cases of viral gastroenteritis associated with the consumption of sewage-contaminated cockles. Between November 1, 1980 and April 30, 1981, 450 cases of infectious hepatitis A were reported from the consumption of cockles.

Secondly, shellfish associated illnesses have been caused by chance contamination of growing areas. These growing areas were contaminated by fresh fecal material, which was not diffused throughout the entire area and was not readily detectable by ordinary bacteriological sampling procedures. This possibility of chance contamination was recognized by Dr. Gurion in his report on a 1902 typhoid outbreak in which he noted "There is a zone of pollution established by the mere fact of the existence of a populated city upon the banks of a stream or tidal estuary which makes the laying down of oysters and clams in these waters a pernicious custom if persisted in, because it renders these articles of food dangerous at times, and always suspicious."

In 1956, an outbreak of infectious hepatitis (691 cases) attributed to oysters, which were contaminated in a wet storage area, is another example of chance contamination. Similarly in 1939, 87 cases of typhoid were attributed to fecal contamination of a storage area by a typhoid carrier.

Finally, shellfish illnesses have been traced back to areas where an intermittent pollution source contaminated the shellfish. These areas should have been managed and classified as conditionally approved, or classified as restricted.

Shellfish from waters meeting approved area criteria are unlikely to be involved in the spread of disease that can be attributed to fecal contamination of the shellfish. This is because, in part, a total coliform MPN of 70/100 ml is equivalent to the fecal material contributed from one person diluted in about 2.27×10^8 liters (8 million cubic feet) of coliform-free water. In addition, such a small amount of sewage reaching the growing area is likely to have been so treated, diluted, or aged that it will be of negligible public health significance. This also means an element of time and distance to permit mixing of sewage or fecal material with large volumes of diluting water. An increasing amount of saltwater will increase the rate at which many terrestrial microorganisms die out. Many reports have been published on the natural die-off of microorganisms in the marine environment.

In general, microbial inactivation in seawater occurs by two different processes -physical dilution by diffusion and a process of biological inactivation. The inactivation process appears to be associated with the following factors: specific bacteriophages, sunlight and solar radiation, temperature, absorption and sedimentation, predation, antibiosis, action of inorganic salts, nutrient deficiencies, and action of heavy metals and other substances.

Studies have shown that enteric bacteria in seawater may survive from a few hours to five days and longer. Field and laboratory studies have demonstrated that enteric viruses can survive in marine water and shellfish from a few days to over 130 days. The survival of viruses in seawater becomes greatly prolonged once they become associated with sediments. Virus concentrations may be many-fold greater in sediments than in overlying water. In general, viruses survive longer at lower temperatures, at low salinity, and in waters contaminated by sewage. Evidence from many field studies indicates that a constant relationship does not exist between either pathogen (bacterial or viral) or coliform content of shellfish and overlying water.

The effectiveness of sewage treatment processes must be considered in evaluating the sanitary quality of a growing area since the bacterial and viral content of the effluent will be determined by the degree of treatment which is obtained. The results of bacteriological sampling must also be correlated with sewage treatment plant operation and evaluated in terms of the minimum treatment which can be expected with the possibility of malfunctioning, overloading, or poor operations.

The ability of shellfish to concentrate chemical pollutants from water and sediment may lead to accumulation of these poisonous and deleterious substances to levels that may constitute a public health hazard. The degree to which these added substances are concentrated depends upon such variables as the species of shellfish, water temperature and salinity, the level of contaminants in the waters, and the physiological conditions of the shellfish. Concentration factors in oysters may range from near unity for Strontium 90 to as high as 10^4 for DDT. Anatomical distribution in shellfish and biological half-life of the substances are also highly variable.

Although there have been at least nine closures of shellfish growing areas in the United States due to findings of added poisonous or deleterious substances, there have been no documented illnesses attributed to consumption of shellfish from these areas. The level of surveillance for these substances in a shellfish control program may vary widely. Review of existing background data derived from national and international monitoring programs and assessment of potential sources of the substances should enable program managers to determine if a potential problem exists that may indicate a need for further field study. Sampling for specific chemical contaminants in shellfish is recommended only when the pollution source survey reveals a potential problem, or if there is concern due to lack of information.

Limiting maximum permissible concentrations of radioisotopes and unidentified mixtures in water and food has been established. Current standards should be consulted in evaluating public health significance in market shellfish. The NSSP Model Ordinance Guidance Documents: *Action Levels, Tolerances, and Guidance Levels for Poisonous or Deleterious Substances in Seafood*, (ISSC/FDA, 2007) contains current FDA action levels and tolerances for poisonous and deleterious substances in seafood. Existing data are insufficient to establish levels for other substances at this time. Information on procedures for developing action levels and guidelines may be found in the September 30, 1977 *Federal Register*. In the absence of specific levels, decisions must be made on a case-by-case basis utilizing the best available knowledge.

The approved classification for a growing area requires that the sanitary survey has determined that there are no unacceptable concentrations of fecal material, pathogenic microorganisms, or poisonous and deleterious substances. There are no NSSP limitations on the harvest of shellstock from growing areas placed in this classification.

C. Conditional Classification. The basic concept of the NSSP is to control the safety of shellfish by preventing their harvest from contaminated growing areas. In reviewing growing area classifications and sanitary surveys conducted by national and international control officials, it appears that a common misinterpretation is the classification of an area as *approved* when in fact the area should have been classified as *conditionally approved*. Critical investigations usually reveal that the area is subject to intermittent pollution events. Careful consideration of an intermittent pollution event, development and application of a management plan, and cooperation and compliance by all parties may also allow upgrading of an area to a *conditionally approved* or *conditionally restricted* classification instead of requiring the area to be *restricted* or *prohibited* at all times.

Intermittent pollution to shellfish growing waters has been a significant cause of shellfish-borne infectious disease outbreaks worldwide. In 1978, at least 20,000 persons were involved in an outbreak of oyster-associated gastroenteritis attributed to Norwalk virus. The investigation of the outbreak indicated that a combination of meteorological and hydrographic events had caused inadequately treated and diluted sewage from a nearby municipal facility to reach the area. In an incident in 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters when a combination of raw sewage bypasses, high rainfall, strong winds, and abnormally low tides caused contamination of an area that was classified as approved. In both of these instances, application of the conditionally approved area concept probably could have prevented the outbreaks.

A common situation where this classification might be appropriate is when water quality is, to some degree, dependent upon the operation of a wastewater treatment plant. For example, the boundaries of an approved shellfish area might be improperly determined during a period when a wastewater treatment plant is operating at a satisfactory level. If there is some interruption in treatment, it follows that there will be some degradation of water quality in the growing area which may require a relocation of the boundaries. The degree of relocation would depend upon such items as the distance between the pollution source and the growing area, hydrography, the amount of water, and the amount of pollution.

The concept is also applicable to other situations in which there may be a rapid or seasonal change in water quality. Examples of such situations include:

The water quality in a growing area adjacent to a resort community may vary according to seasons of the year. During the summer months, when the community experiences a significant population increase, water quality may be adversely affected. However, during the winter when there are few people in the community, water quality might improve sufficiently to allow approval of the area. In some states, this is known as a seasonal closure.

The water quality in a protected harbor in a sparsely settled area, which provides anchorage for a fishing fleet, several months a year might vary. When the fishing fleet is in, the harbor water might be of poor sanitary quality. However, during the remainder of the year the quality of the harbor water might be satisfactory. The area would be closed for shellfish harvesting when the fishing fleet is using the harbor.

The water quality in an area may fluctuate with the discharge of a major river, or rainfall in the area may cause runoff of pollutants into the growing area. This type of pollution is often referred to as non-point pollution. During periods of low runoff, such an area might be of satisfactory quality and thus be approved for shellfish harvesting.

The first step in determining whether an area should be classified as conditionally approved or conditionally restricted is to determine whether sufficient state resources are available to manage, survey, monitor, control harvesting, affect closures, and reopen the area as required. It should be noted that sources of pollution must be routinely monitored; coordination between state, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. States electing to classify areas as conditionally approved have found the public resource investment to be substantial.

The second step in determining whether an area should be placed in the conditionally approved or conditionally restricted classification is to evaluate the potential sources of pollution in terms of their effect on water quality in the area. Some potential sources of pollution include: bypasses and overflows within a sewage collection and treatment system, intermittent discharges from boats, seasonally used areas, animals, land runoff, and freshwater flows.

The third step in establishing a conditionally approved or conditionally restricted area is to evaluate each source of pollution in terms of the water quality standards to be maintained, and to formulate performance standards for each pollution source having a significant effect on the sanitary quality of the area. The following are examples of different types of performance standards that might be developed:

Performance standards or closure criteria may be based upon the bacteriological quality of effluent from sewage treatment plants. This might be stated in terms of chlorine residual if the bacteriological quality of the effluent can be positively related to chlorine residual. The following is an example of a performance standard for an effluent discharge: "The median coliform MPN, in any one month, shall not exceed 500 per 100 ml, based on not less than 16 composite samples per month, and not more than 10 percent of the samples shall have an MPN in excess of 10,000 per 100 ml. Determinations of the chlorine residual of the effluent should be made hourly and recorded in the permanent plant records."

A performance standard may be based upon total quality of sewage, which can be discharged from any given unit, or from a combination of units, without causing the basic water quality standards to be exceeded.

A performance standard may be based upon the amount of vessel traffic in the area and the concomitant amount of sewage, which can be expected.

Performance standards may be based upon the amount of rainfall in the immediate area. An example could be: "The area will be closed when there has been 5 cm (2 inches) or more rainfall registered at a rain gauge at (specified area within a 24-hour period)."

Performance standards may be based upon the height of a river stage. An example could be: "When the river at (a specified area) reaches 3.66 meters (12 feet) or above, the area will be closed."

The design of a waste treatment plant and the plant effluent specifications may be critical to the designation of an area classified as conditionally approved or conditionally restricted. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (coliform) of sewage, predicted survival of coliform in seawater, effectiveness of chlorination and the total quality of clean dilution water in an area. Results of many studies on the survival of bacteria in seawater have been published.

The mechanical equipment at critical sewage treatment or pumping units should be such that interruptions will be minimized. Wherever possible, operations should be automatically recorded on charts. Requirements that might be imposed depend upon the importance of the unit's relationship to water quality. Important design features of a sanitary waste collection system that should be considered include:

Storm water should be excluded from the sanitary system. There should be stand-by equipment to insure that treatment or pumping will not be interrupted. It should be taken into account that interruptions may occur because of damage to a single unit or a power failure.

The pumps and critical units should be fitted with meters or gauges so the regulatory agency can monitor performance standards.

Installation of recording scales to indicate rate of chlorine use is helpful. Chlorine flow meters are available that integrate hydraulic flow with chlorine demand.

Liquid level recording gauges fitted with alarms and located in overflow channels of sewage treatment plants and wet wells of lift stations are useful. They can be set to indicate when overflow takes place. It is good operating procedure to date recording charts. Gauges should be calibrated and maintained so that indicated discharge rates are accurate.

Automatic devices to warn of failure or malfunctioning at self-operated pumping stations or treatment plants can be an important control.

Another factor to consider in developing a conditionally approved or conditionally restricted area is that a prohibited area must be interposed between the conditionally approved or restricted area and the source of pollution. The size of such area should be based on the total time it would take for the operating agency to detect a failure, notify the state shellfish control agency, and for the latter agency to issue a notice to stop shellfish harvesting. It is recommended that the area be of such size that the flow time through the safety area is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that closure actions might be necessary on holidays or at night.

The length of time a conditionally approved or conditionally restricted area should be closed following a temporary closure will depend upon several factors including the species of shellfish, water temperature, shellfish activity and cleansing rates, presence of silt or other chemicals that might interfere with the physiological activity of the shellfish, and the degree of pollution of the area.

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These optional classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection and the control of shellfish safety in the use of the conditional classifications are afforded through the use of a management plan. The management plan for each growing area placed in a conditional classification is based on the information gathered during the sanitary survey. The plan establishes a strict set of criteria that must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two of the most important components of the management plan are: the acceptance of and the agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of compliance with the plan to assure public health protection. Use of the conditional classification requires more intense monitoring and more frequent reevaluation because of the intermittent nature of the pollution event.

When the Authority has sufficient resources to manage a conditional classification, the use of the conditional classification could allow the safe use of growing areas that might otherwise not be available to the shellfish industry. For a complete discussion of the conditional classification, see the NSSP Model Ordinance Guidance Documents: *Management Plans for Growing Areas in the Conditional Classification* (ISSC/FDA, 2007). For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2007).

D. Restricted Classification. The restricted area classification is an option available to state shellfish control agencies to use instead of a prohibited classification. The establishment of a restricted area might be considered in instances where an area does not meet approved area criteria but is not grossly polluted. Another common situation where this classification might be appropriate is for areas affected by non-point pollution from either urban or rural sources that cause the water quality to fluctuate unpredictably or of sufficient frequency that a conditionally approved area is not feasible. In such instances, the state may, at its option, classify these areas as restricted and may limit the use of the shellfish to relaying, container relaying, or depuration operations.

Relaying is a process of reducing the levels of microorganisms that may be present in the shellstock by moving the shellstock to growing areas in the approved classification and using the shellstock's ability to cleanse itself naturally as a treatment process. Depuration is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment (i.e. a land based facility) as a treatment process.

The sanitary and bacteriological criteria to be applied by the state for classifying restricted areas are to be developed by the state shellfish control agency. The criteria may vary according to the use to be made of the shellfish and according to the effectiveness of the relay and/or depuration process to which the shellfish will be subjected. The effectiveness of the process is determined by a study as provided for in the Model Ordinance, Chapter V, Shellstock Relaying and Chapter XV, Depuration. The purpose of this study is to establish the bacteriological quality requirements for the shellfish processing. Effectiveness of the process is likely to vary from one cleansing area to another, from one species of shellfish to another, and from one depuration plant to another. The classification criteria may be based upon the quality of the shellfish or the water in the restricted area in addition to other sanitary parameters.

Before classifying an area as restricted, the state shellfish control agency should make a determination of whether sufficient state resources are available to monitor pollution sources; to provide coordination between state, local and industry officials; to issue special harvesting permits; and to supervise harvesting and transportation of shellfish to depuration facilities or relay sites. Some states that have classified areas as restricted have found the resource investment to be substantial. For a complete discussion of relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2007). For a complete discussion of depuration, see the NSSP Model Ordinance Public Health Reasons and Explanations Chapter XV Depuration (ISSC/FDA, 2007).

E. Prohibited Classification. The positive relationship between disease and consuming contaminated shellfish has been clearly established. Prevention of consumption of contaminated shellfish is the primary objective of the NSSP. The prohibited area classification is the most restrictive growing area classification, used for areas subject to gross pollution. The use of this classification is also required, as a precautionary measure, for any growing area where the shellfish authority has not performed a sanitary survey, and for a growing area immediately adjacent to a sewage treatment plant outfall, irrespective of the level of effluent treatment provided. The harvesting of shellstock is not allowed for any human food use. For additional information concerning the classification of growing waters and the sanitary survey, see the NSSP Model Ordinance Guidance Documents: *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2007)

@.04 Marine Biotoxin Control

Marine biotoxins may be ingested by molluscan shellfish feeding on toxic dinoflagellates. Dinoflagellates in their vegetative stage flourish seasonally when water conditions are favorable. Toxic blooms of dinoflagellates can occur unexpectedly or may follow predictable patterns. Paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP) and domoic acid poisoning, also known as amnesic shellfish poisoning (ASP) are the three types of poisonings most commonly associated with oysters, clams, mussels and scallops in the United States.

Cases of paralytic shellfish poisoning, including several fatalities resulting from poisonous shellfish, have been reported from both the Atlantic and Pacific coasts. The minimum quantity of poison, which will cause intoxication in the susceptible person, is not known. Epidemiological investigations of paralytic shellfish poisoning in Canada have indicated 200 to 600 micrograms of poison will produce symptoms in susceptible persons. A death has been attributed to the ingestion of a probable 480 micrograms of poison. Investigations indicate that lesser amounts of the poison have no deleterious effects on humans. Growing areas should be closed at a level to provide an adequate margin of safety, since in many instances, toxicity levels will change rapidly.

A review of the literature and research dealing with the source of the poison, the occurrences and distribution of poisonous shellfish physiology and toxicology, characteristics of the poison, and prevention and control of poisoning has been prepared.

In Gulf coast areas, toxicity in shellfish has been associated with red tide outbreaks caused by massive blooms of the toxic dinoflagellate, *Karemia brevis* (formerly *Ptychodiscus brevis*). Toxic symptoms in mice suggest a type of neurotoxic shellfish poisoning rather than symptoms of paralytic shellfish poisoning. The most common public health problem associated with *Karemia brevis* blooms is respiratory irritation; however, neurotoxic shellfish poisonings associated with *Karemia brevis* blooms have been reported in Florida. Uncooked clams from a batch eaten by a patient with neurotoxic symptoms were found to contain 118 mouse units per 100 grams of shellfish meat.

Toxic dinoflagellates are indigenous to most coastal and estuarine waters on the Atlantic, Gulf, and Pacific coasts of America, as well as in many other parts of the world. Blooms of these organisms can occur unexpectedly and rapidly. This phenomenon occurred in New England in 1972 when shellfish suddenly became toxic in a previously unaffected portion of the coastline and resulted in many illnesses. During 1991 and 1992, there was a spread of domoic acid producing organisms throughout the world including the detection of high numbers of *Pseudonitzschia pseudodellcatissima* in Australia and *Pseudonitzschia pseudoseratia* in California. Domoic acid was also recovered from shellfish in Washington and Oregon. All shellfish producing states or MOU countries must have a contingency plan that defines administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of shellfish toxins. A model state contingency plan for control of marine biotoxins is provided in the NSSP Model Ordinance Guidance Documents, A.2., *Guidance for Developing Marine Biotoxin Contingency Plans* (ISSC/FDA, 2007).

All states or MOU countries must monitor toxin levels to establish a baseline historical reference. Thereafter, states or MOU countries where shellfish toxins are likely to occur must monitor toxin levels on a routine basis to meet the approved area requirements for direct market harvesting. Experience with monitoring for shellfish toxins suggests that an effective program should include the following:

Sampling stations should be located at sites where past experience has shown toxin is most likely to appear first.

Samples should be collected of shellfish species which are most likely to reveal the early presence of toxin and which are most likely to show the highest toxin levels. For example, mussels have been found to be useful for early PSP detection.

The frequency and period for collection of samples should be based upon historical patterns. This assumes several years of baseline data in order to establish stations and sampling plans.

An information network should be established between the health and marine resource communities and the state shellfish control agency. Any toxin-like illnesses related to shellfish and environmental phenomena such as dinoflagellate blooms, fish kills, or bird kills, which might indicate the early stages of an increase in toxin levels should be rapidly communicated over the network.

Sampling stations and frequency of sampling should be increased when monitoring data or other information suggests that toxin levels are increasing.

Sample collection, sample transportation, and sample analysis procedures should be developed so that in an emergency sample results will be known within 12 hours.

When monitoring data or other information indicates that toxin levels have increased to the quarantine levels, growing area closures must be immediately implemented. The determination of which growing areas should be closed should include consideration of the rapidity with which toxin levels can increase to excessive levels and the inherent delays in the state sample collection procedures. It may be appropriate to close growing areas adjacent to known toxic areas until increased sampling can establish which areas are toxin free and that toxin levels have stabilized.

Shellfish growing areas closed because marine biotoxins have exceeded quarantine levels may be reopened for growing after a sufficient number of samples and other environmental indices, if used, have established that the level of toxin will remain below quarantine levels for an extended period. For example, experience has shown that appropriate reopening criteria include a minimum of three samples collected over a period of at least 14 days. These samples should show the absence of PSP or levels below 80 micrograms per 100 grams.

A. Contingency Plan. The suitability of some areas for harvesting shellstock is periodically influenced by the presence of toxigenic micro-algae. Recent increases in toxigenic micro-algae distribution dictate that a more comprehensive series of public health controls be adopted. The need exists to make contingency plans to address the contamination of a growing area by toxigenic micro-algae or a disease outbreak caused by marine biotoxin. This contingency plan must describe administrative procedures, laboratory support, sample collection procedures, and patrol procedures to be implemented on an emergency basis in the event of the occurrence of marine biotoxin in shellstock. The primary goal of this planning should be to ensure that maximum public health protection is provided in growing areas subject to marine biotoxin contamination. For a fuller discussion of marine biotoxin disease and its management in shellfish growing areas, see the NSSP Model Ordinance Guidance Documents: *Guidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2007).

B. Marine Biotoxin Monitoring. The primary purpose of a marine biotoxin-monitoring program is to prevent illness or death among the shellfish consuming public. The monitoring program should use the "indicator station" and "critical species" concepts to develop an early warning system to prevent harvest of biotoxin contaminated shellstock. For a full discussion, see the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2007).

C. Closed Status of Growing Areas. In the event of a toxigenic micro-algae bloom, shellstock-growing areas shall be placed in the closed status for harvesting to prevent human consumption of biotoxin-contaminated shellfish. The biotoxin level governing the need to place the growing area in the closed status will vary depending on the species of toxigenic micro-algae and the species of bivalve shellfish. Since the ability to concentrate biotoxins varies among species, it is possible for one species in a growing area to have safe levels of biotoxin while another species in the same growing area will have dangerous biotoxin concentrations. In this situation, the Authority may permit the harvesting of one species with no adverse public health consequences while prohibiting the harvest of another species. In these situations, the Authority must closely monitor the growing area and develop a sufficient database for use in making this determination.

The Authority must develop criteria, which must be met before a growing area can be returned to the open status for harvesting. These criteria should integrate public health, conservation, and economic considerations. The criteria should also employ a sufficient number of samples and other environmental indices, if used, to establish that the level of toxin will remain, for an extended period of time, at levels safe for human consumption. For additional discussion concerning biotoxin contamination of shellstock, see the NSSP Model Ordinance Guidance Documents:G*uidance for Developing Marine Biotoxin Contingency Plan* (ISSC/FDA, 2007).

D. Heat Processing. Heat treatment can reduce the toxicity of some biotoxins. When heat treatment is used, the Authority must require that the processor provide adequate demonstration of the destruction of the biotoxin and adequate controls to assure that the end product is safe for human consumption.

E. Records. Good record keeping is essential to the successful management of a marine biotoxin contingency plan. Appropriate records of monitoring data, evaluation reports, and closure and reopening notices should be compiled and maintained by the Authority. This information is important in defining the severity of the problem, as well as for a retrospective evaluation of the adequacy of the entire control program.

@.05 Marinas

A. Marina Proper. Under the NSSP, any growing area within the confines of the marina proper is presumed to be contaminated for some period of time. Therefore, no growing area within the marina proper can be placed in the approved classification.

B. Adjacent Waters. The microbiological and chemical contamination associated with marina facilities may result in the contamination of adjacent shellfish growing waters. The NSSP has developed a set of evaluation criteria to be used in determining if the growing waters adjacent to a marina are affected by microbiological contaminants associated with sewage. Since there are significant regional differences in all factors that affect pollution loading from marinas, sufficient flexibility must be allowed to account for these differences. The Authority has the option of applying the specified occupancy and discharge rates necessary to conduct a dilution analysis. The Authority may also opt to conduct studies to document different rates for specific areas. Best professional judgment of qualified individuals and best available technology must be applied to determine adequate restrictions on harvesting in and around marinas.

Chapter V. Shellstock Relaying

Requirements for the Authority

@.01 General. Relaying is the practice of harvesting bivalve shellstock from polluted growing or growing areas and placing them in unpolluted bodies of water for a sufficient time for the shellstock to reduce contaminating microorganisms or chemicals to safe levels. Through the natural cleansing process in relaying, shellstock resource that would otherwise not be available for human consumption is made safe and becomes accessible to the shellfish industry and the consumer. As early as 1911, public health officials were investigating the use of natural cleansing through relaying to reduce pathogenic organism levels in oysters. For a complete discussion of relaying activities, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2007).

@.02 Contaminant Reduction. Research has shown that shellfish have the ability to purge themselves of certain microbial and chemical contaminants when placed in clean saline water. The rate of purging depends on the specific contaminants, species of shellfish, and environmental factors such as temperature and salinity. The shape of the containers used to hold the shellstock may also affect the purging rate. Because of the differences in purging rates among shellfish species and contaminants, a specific study must be performed in each growing area used for relaying to determine the purging rates, and the relay activity must be carried out in strict conformance with criteria established from the study. For a fuller discussion of the factors effecting contaminant reduction during relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2007).

@.03 Licenses to Relay Shellstock. Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. Special permits must be issued to licensed harvesters for taking shellstock from contaminated growing areas and transporting them to other growing areas for the purpose of natural cleansing. Use of special permits with special harvesting conditions facilitates the shellfish authority's prevention of contaminated product being diverted for sale to the consumer prior to treatment rendering the shellstock safe for consumption. For more information concerning relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2007).

@.04 Management of Relaying Activities. Because shellstock relaying involves the harvesting and transport of contaminated shellstock and its treatment to render it safe for human consumption, great care must be taken to assure that contaminated product does not inadvertently reach the consumer. This requires direct supervision of the operation and good enforcement by the shellfish authority. Techniques such as special licenses, testing of shellstock before and after relay activities, special tagging of shellstock during relay, special marking of the growing areas used for natural cleansing, record keeping, and additional patrol activities are used to ensure that effective contaminant purging is completed before the shellstock is marketed to the consumer. For additional information concerning the management of shellstock relaying, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2007).

Requirements for Harvesters

.01 Harvester License Required. Licensing of each person who harvests shellstock is an important control measure to help protect against contaminated shellstock reaching the consumer and to help maintain accurate source identity records. Harvesters must work with the shellfish authority to foster the use and enforcement of special permits to prevent bypassing of the natural cleansing treatment process. Compliance with permit requirements is extremely important. Prevention of sale of contaminated shellstock to the consumer is the primary objective of the NSSP. Use of special permits with special harvesting conditions facilitates the shellfish authority's prevention of contaminated product being diverted for sale to the consumer prior to treatment rendering the shellstock safe for consumption. For more information concerning relay, see the NSSP Model Ordinance Guidance Documents: *Shellstock Relay* (ISSC/FDA, 2007).

Chapter VI. Shellfish Aquaculture

Oysters, clams, mussels and scallops are filter feeders and therefore have the ability to concentrate microorganisms, including human pathogens and toxigenic micro-algae, and poisonous or deleterious substances from the water column if these organisms or substances are present in the growing area. Concentrations in the shellfish may be as much as 100 times that found in the water column. If the microorganisms concentrated are harmful to humans, and if, in the case of human pathogens, the shellfish are consumed raw or partially cooked, human disease can result. Poisonous or deleterious substances can induce illness or death immediately or through long-term exposure, may contribute to the development of cancer in humans. Additional information concerning the disease causing potential of shellfish can be found in the NSSP Model Ordinance Guidance Documents: G*uidance for Developing Marine Biotoxin Contingency Plan, Sanitary Survey and the Classification of Growing Waters*, and *Shellstock Relay* (ISSC/FDA, 2007).

The culturing of molluscan shellfish in natural and artificial growing areas is known as aquaculture. This may include the cultivation of molluscan shellfish with non-molluscan species in a common aquaculture system known as polyculture. Oysters, clams, mussels and scallops raised in aquaculture operations are subject to the same potential for contamination as they are growing in the wild. In land-based operations, there may be some additional risk of accumulation in the shellstock of animal drugs used to stimulate growth and control mollusk diseases, or fish diseases in the case of polyculture. Since some components of aquaculture such as relaying, wet storage, depuration, growing water classification and tagging, are similar to other activities covered in the NSSP Model Ordinance, they are regulated under those Model Ordinance chapters. The shellfish authority must have an adequate legal basis and sufficient resources to regulate public health concerns pertinent to bivalve shellstock aquaculture.

Polyculture and land-based monoculture operations must be under adequate control to assure the shellstock product harvested will be acceptable for human consumption. The shellstock authority must establish detailed procedures for issuing permits for shellfish aquaculture, approving culturing sites and boundaries, controlling of harvesting, sampling of shellstock, monitoring environmental parameters, keeping records, imposing quarantine measures, controlling the use of animal drugs to stimulate growth or treat diseases, and developing other control measures as may be necessary. The shellfish authority should work with FDA in its review of the plans for a land based aquaculture operation.

Of particular concern in land-based systems is the use of a closed or recirculating water system. Potential exists for shellstock contamination through the failure of the water treatment system to sufficiently disinfect the water to control levels of human pathogens that might be introduced through the water supply or other means. There is also potential for the increased concentration of poisonous and deleterious substances such as animal drugs or antifouling agents in the water supply and subsequently the shellstock over time.

Prior to its harvest for sale in interstate commerce, the aquaculturist must demonstrate that the water in the land-based system met the NSSP Model Ordinance criteria for direct sale of shellstock to the consumer. If the water supply does not meet those criteria, the aquaculturist must subject the shellstock to relaying or depuration prior to sale. Relay is a process of reducing the levels of microorganisms that may be present in the shellstock by moving the shellstock to growing areas in the approved classification and using the shellstock's ability to cleanse itself naturally over time as a treatment process. Depuration is a process of reducing the levels of pathogenic organisms that may be present in the shellstock by using a controlled aquatic environment (i.e. a land based facility) as a treatment process.

The cultivation of shellfish with other species in a common aquaculture system is known as polyculture. There are some additional public health concerns related to polyculture. Greater potential may exist for contamination of oysters, clams, mussels and scallops with human pathogens and animal drugs in polyculture. However, the extent of that potential is not known. The extensive use of tanks, sea enclosures, floating rafts, ponds, etc. in polyculture makes the oysters, clams, mussels or scallops highly vulnerable to pollution from various sources, including their association with the other species present in the polyculture operation. The usage of anti-fouling agents (tributyltin, copper, etc.), hormones, and antibiotics in finfish aquaculture has evoked concern about its environmental effects and potential threat to human health through bioaccumulation in shellfish. Therefore, a conservative approach to polyculture is provided in the NSSP Model Ordinance requirements.

Chapter VII. Wet Storage in Approved and Conditionally Approved Growing Areas

The purpose of wet storage is to improve palatability of shellfish by desanding or increasing their salt content, or to provide temporary storage for depurated shellfish or shellfish from approved or conditionally approved harvest areas. Wet storage facilities are not designed and operated to increase the safety of shellfish. Therefore, all controls pertaining to shellfish for direct consumption must be applied.

Effective control measures must be established and implemented by the Authority to ensure that wet stored shellfish are protected from becoming contaminated. These control measures include review of the plans for proposed wet storage areas or flats; review of the design and operating procedures for onshore facilities; periodic inspections of wet storage facilities; and, evaluation of the water quality for compliance with the requirements of the *Model Ordinance*.

The types, location, and uses of wet storage operations are highly variable and may range from temporary storage near shore in approved areas to onshore tanks using recirculating natural or synthetic seawater for the purpose of desanding, temporary storage, or salt uptake. Consequently, it is not possible to provide detailed guidelines in the *Model Ordinance* and it is necessary for each separate operation to be developed and evaluated on its own merit with respect to overall Program guidelines.

Removing shellfish from growing beds for storage in areas close to shore may subject such shellfish to constant or intermittent pollution. Shellfish in wet storage tanks are similarly subjected to pollution if the tank water is obtained from a polluted source. An example of health consequences due to such contamination is the outbreak (691cases) of infectious hepatitis in Sweden in 1956 attributed to oysters contaminated in a wet storage area.

Shellfish on floats near shore may be more directly exposed to potential contamination from boats and surface runoff than are shellfish in their natural growing areas. Therefore, particular emphasis should be placed on a sanitary survey of the vicinity to ensure that chance contamination does not occur.

Careful consideration must be given to designing and operating onshore wet storage tanks to ensure that shellfish are not contaminated during holding or do not die from physiological stresses such as low dissolved oxygen and unsuitable temperatures or salinity. Excessive mud on the shells and dead shellfish may increase bacterial loads in the tanks and lead to increased microbial levels in the shellfish during wet storage. Hence, washing and culling the shellfish prior to wet storage is essential.

Chapter VIII. Control of Shellfish Harvesting

Requirements for the Authority. Other portions of this section of the Guide have described the public health reasons for limiting shellfish harvesting to areas free of contamination and shellfish toxins. Methods have been described for the evaluation and classification of such areas. However, classification is not effective unless the State can prevent illegal harvesting of shellfish from closed areas. For a full discussion of control activities, see the NSSP Model Ordinance Guidance Documents: *Growing Area Patrol and Enforcement* (ISSC/FDA, 2007).

For the most part, control of illegal harvesting depends upon the police activities as described in this chapter. Adequate delineation of closed areas is fundamental to effective patrol. The type of area identification will be determined by the structure of the local shellfish industry and the legal requirements for each State to permit successful prosecution. Posting a warning sign is one method of informing shellfish harvesters that an area is closed to the taking of shellfish for public health reasons.

Other methods for identification of closures include telephone, maps issued at checkpoints, or with harvesting licenses, direct mail, and news media. It is recommended that the advice of the State's legal counsel be obtained to insure that the marking of closed areas and notifications to shellfish harvesters are such that persons harvesting from closed areas can be successfully prosecuted.

The primary objective of the NSSP is to ensure that shellfish are only harvested from areas free of excessive concentrations of pathogenic microorganisms and poisonous or deleterious substances. Growing areas may be classified as to their public-health suitability for shellfish harvesting on the basis of information obtained by sanitary surveys in accordance with Chapter IV., @01. However, if local shellfish harvesters are not convinced of the need for restrictions, shellfish may be harvested surreptitiously from closed areas. *Thus, the patrol element of the NSSP is important to ensure compliance with the public-health safeguards resulting from the sanitary survey.* The fact that the law prohibits the removal of shellfish from certain areas will deter the majority of the population from attempting to harvest such shellfish, provided they are aware of the law and of the areas which are closed. Where traditional gathering practices have prevailed, local public opinion may not support the need for such closures. In such cases, favorable opinion may be developed through an educational program or a locally demonstrated need resulting from an outbreak of shellfish-associated illness or intoxication.

The type of patrol needed for any particular situation cannot be specified and is determined by the nature of areas to be patrolled, means of access, methods of harvesting, and species. Patrol equipment should be such that the officers can apprehend persons illegally harvesting shellfish in a closed area. Equipment that has proven effective for apprehension of illegal harvesters includes: small, high-speed, readily transportable boats capable of operating in open waters; automobiles; aircraft; communications for coordinating patrol activities; radar surveillance systems; and night scopes.

Organization of the patrol activity must take into consideration the need for night, weekend, holiday, undercover and surprise patrols. Various patrol methods may be used depending on the nature of the area to be patrolled and the type of industry.

Complete removal of shellfish from polluted areas provides a safeguard against contaminated shellfish reaching the market. In some cases, depletion may be the method selected to eliminate an irresistible temptation for harvesters. Depletion may be more economical and effective than patrol of closed areas and will serve to protect public health.

Educational programs should be developed for both industry and the public describing the public health necessity for eliminating shellfish harvesting from closed areas. Programs developed specifically for participation of key industry people may be especially helpful in eliciting cooperative efforts of the entire industry. Such programs should focus on incentives to eliminate harvesting and marketing of shellfish from closed areas.

The adequacy of state laws as a basis for prosecution is an important component of this activity. Shellfish patrol will be ineffective and or compromised if State laws are so written or interpreted that violators can not successfully be prosecuted and if penalties are so small that they are economically unimportant. It is important that periodic assessments are made by the State control or patrol agency of the degree of success of court actions taken in response to illegal harvesting. Information of this nature is necessary for both the analysis of the effectiveness of the program and for education purposes. Prosecution will be difficult where local public opinion does not support the need for the restriction or the courts are not fully aware of the public health hazards associated with the crime.

Requirements for Harvesters. Precautions exercised in gathering shellfish from approved growing areas may be nullified if shellfish are contaminated with bilge water or polluted overboard water, or in the case of trucks, with contaminated water on the floor or hazardous materials on or adjacent to the shellstock. Also, several investigations have been conducted by States and the FDA regarding shipments of shellfish where product deterioration resulted when shellstock was held or shipped under adverse conditions such as direct sunlight and warm temperatures. These studies reaffirm the critical role that adequate shellstock protection and refrigeration plays when ambient temperatures are high. Product deterioration and bacterial growth occurs when shellstock is left exposed for several hours on harvest boats. If this shellstock is transported in trucks without adequate prechilling and in-transit refrigeration, product deterioration continues.

The majority of studies on microbiological quality of shellfish point up the need to refrigerate shellstock quickly after harvesting and maintain the product below 10°C (50°F) throughout processing, distribution and storage. It should be noted that a study by Cook and Ruple reported in 1989, showed that 10°C (50°F) storage of summer harvested Eastern oyster shellstock from the U.S. Gulf Coast, prevented the multiplication of fecal coliforms and vibrios, including *Vibrio vulnificus*. Universally, food control officials consider shellfish as a potentially hazardous food that is capable of supporting rapid and progressive growth of infectious or toxigenic microorganisms. Other foods in this category are milk, milk products, eggs, meat, poultry and fish. Generally, FDA recommends that potentially hazardous food be held at 5°C (41°F) or below, and if large volumes are involved in processing, methods be employed to rapidly cool the product to an internal temperature of 5°C (41°F) within four hours.

Several studies have established that some pathogenic *Vibrio* species and other autochthonous bacteria may be present in marine sediments throughout the year. One study of *Vibrio* species and *Aeromonas hydrophila* in sediments of Apalachicola Bay, Florida, routinely detected *V. parahaemolyticus*, *V. alginolyticus*, and *A. hydrophila* and during some portions of the year at relatively high levels (up to 46,000 organisms per gram). Additionally, *V. vulnificus*, *V. cholerae*, *V. fluvialis* were detected at levels up to 2,400 organisms per gram of sediment.

Furthermore, there is evidence that some pathogenic organisms will survive in shellfish for a considerable length of time after harvesting and that some bacterial pathogens may multiply in the absence of adequate refrigeration. Vibrio species can also survive on inadequately cleaned equipment in a processing plant. Washing sediments from shellstock at the time of harvest helps to protect the shellfish and the processing equipment from becoming contaminated. Washing shellstock also helps to prevent quantities of mud and other bacteria from being mixed with the shucked shellfish, thereby contributing to high bacteria counts in the finished product. Muddy shellstock also makes it difficult to maintain shucking rooms in a clean, sanitary condition.

Water used for shellstock washing should be of good sanitary quality, to avoid possible contamination of the shellstock. There are instances when shellstock washing by the harvester might introduce a sanitary hazard because of the possible tendency of the harvester to wash the shellstock with polluted water from a harbor area, rather than with clean water from a growing area. Therefore, the Authority may waive the requirement for shellstock washing by the harvester when there are climatic, technical, or sanitary reasons for such action. In such event, the processor becomes responsible for washing shellstock.

It is necessary to protect the shellfish from pollution by disease-causing organisms that may be present in body wastes discharged from boats. This item is intended to protect the shellfish from chance pollution during harvesting. The likelihood of body wastes being discharged from boats will be considered in evaluating the sanitary quality of the harvesting area. If discharges are not adequately controlled, the area cannot meet the classification requirements for an approved harvesting area.

Licensing of each person who harvests shellfish for sale to a certified dealer is an important control measure to help protect against illegally harvested shellfish and to help maintain accurate source identity records. Harvesters must provide information necessary to create a record of the origin, quantity, and date of harvest that can be used to trace lots of questionable shellstock back to the source(s). Investigation of disease outbreaks can be severely hindered if the source of the shellfish cannot be readily identified. This can result in shellfish from the unacceptable source continuing to be used and continuing to cause illness. Health authorities may be forced to close safe areas, to ban safe shipments or to seize safe lots as a public health precaution if the source of contaminated shellfish cannot be accurately and rapidly determined.

Chapter IX. Transportation

Requirements for the Authority. Studies conducted during the period from pre-1925 to 1989 showed that the bacteriological examination of shellfish is an important *tool* in detecting: product mishandling; temperature abuse; and gross errors in growing area classification. The studies also demonstrated that shellfish will generally reflect the bacteriological quality of the water in which they have grown. However, this relationship is not consistent. Variation reflects differences in species and product forms and seasonal conditions at the time of harvest. Some studies concluded that there is no single uniform bacteriological standard which could be applied to all species of shellfish.

Efforts to develop satisfactory bacteriological criteria for interstate shipments of shellfish (especially oysters) as received at the wholesale market level were begun in 1950. During the period from 1950 to 1964, there were many studies conducted to determine the bacteriological changes associated with shellfish harvesting, shucking - packing and marketing. Throughout this period various coliform and plate count standards were developed under the NSSP. However, it wasn't until 1965, that the fecal coliform and standard plate count criteria were applied to all species of shucked oysters at the "wholesale market level" (wholesale market level not defined). In 1968, the NSSP Workshop adopted these criteria, presumably for all species and product forms of oysters, clams and mussels.

Certified dealers are responsible to assure that shellfish purchased for direct sales, further shipments, or processing are safe and wholesome. The safety of shellfish is predicated on the cleanliness of the growing area waters from which they are obtained, and the sanitary practices applied during harvesting and shipping.

The positive relationship between sewage-polluted shellfish and enteric disease has been demonstrated many times. Because physiologically active shellfish pump and filter large quantities of water as part of their feeding process, rapid intake and concentration of bacteria, viruses, marine toxins, and other poisonous and deleterious substances may occur. Therefore, the shellfish may contain higher levels of chemical contaminants or pathogens than are found in the water in which they grow.

The shellfish-water bacteria ratio depends upon the shellfish species, water temperature, presence of certain chemicals, and varying physiological capabilities of the individual animals. If the water in which the shellfish are grown is polluted, it may be assumed that the shellfish will also contain pathogenic bacteria or viruses capable of causing disease in man.

In addition, shellfish contaminated by added trace metals can result in illness to man if consumed in sufficient quantities. Health hazards also may result from the presence of naturally occurring biotoxins produced by certain marine dinoflagellates. The occurrence of these poisons is related to the concentration of toxic dinoflagellates in the growing area. The contamination of shellfish by these dinoflagellates usually occurs in well-defined areas and, in some instances, only during certain seasons not widespread over all shellfish producing areas.

Cooking does not necessarily ensure safety of contaminated shellfish since, in ordinary cooking processes; shellfish may not be heated sufficiently to ensure a kill of pathogenic organisms, although a considerable reduction will take place. Also, normal cooking processes cannot be relied upon to destroy paralytic shellfish poison.

Certified dealers have three principal responsibilities to assure that the consumer receives a safe product. The first is to purchase only safe and wholesome raw products. The second is to maintain the product in a sanitary manner. The final responsibility is to ship the product under sanitary conditions. The tagging and shipping records requirements, the sanitary shipping practices requirements, and the raw product inspection requirements are necessary to fulfill these responsibilities.

Chapter X. General Requirements for Dealers

.01 General HACCP Requirements.

HACCP is a preventive system of hazard control. It consists first of an identification of the likely hazards that could be presented by a specific product, followed by the identification of the critical control points in a specific production process where a failure to control would likely result in a hazard being created or allowed to persist. These critical control points (CCP) are then systematically monitored, and records are kept of that monitoring. Corrective actions are also documented when problems occur.

The application of HACCP controls by the molluscan shellfish industry, coupled with inspections by Shellfish Control Authorities based on the HACCP system, are a more effective and efficient system for ensuring the safety of molluscan shellfish products than the traditional Good Manufacturing Practices-based system. Adoption of HACCP controls by the molluscan shellfish industry will provide a basis for enhanced consumer confidence in the safety of molluscan shellfish.

The first step in the HACCP process, called Hazard Analysis, should include an assessment of both the likelihood that a food safety hazard will occur and its severity if it does occur. To be addressed by the HACCP system, the hazards must be such that their prevention, elimination, or reduction to acceptable levels is essential to the production of safe food. Even factors beyond the control of the processor, such as how the food will be distributed and how it will be consumed, must be considered because these factors could influence how it should be processed. A hazard is a biological, chemical, or physical property that may cause a food to be unsafe.

All dealers must conduct a hazard analysis or have one conducted on their behalf. The hazard analysis need not be performed according to a standardized regime, nor must it be documented in writing for review by the State Shellfish Control Authority.

The hazard analysis must identify the hazard of pathogen contamination at the receiving CCP as a significant hazard for all raw, molluscan shellfish products. For this reason, all dealers must have and implement a written HACCP plan. Other hazards may also be identified (e.g., natural toxins, pesticides and environmental contaminants) at receiving and at other CCPs. In general, the CCPs identified in chapters XI.01, XII.01, XIII.01, XIV.01 and XV.01 must be listed in HACCP plans for molluscan shellfish products. However, a dealer has the option to demonstrate, through the performance of a hazard analysis, that a particular hazard does not exist for a particular product or processing method, or that it can be controlled at another CCP in a manner that provides an equivalent level of public health protection. This option is not provided for the hazard of pathogen contamination at the receiving step.

In addition to listing the food safety hazards that are reasonably likely to occur in the food and the critical control points necessary to control these hazards, the HACCP plan must establish the critical limits for the preventive measures at each CCP. Critical limits can be thought of as boundaries of safety for each CCP. They may be derived from sources such as regulatory standards and guidelines, literature surveys, experimental studies, and experts. In general, the critical limits listed in chapters XI.01, XII.01, XIII.01, XIV.01 and XV.01 must be listed in HACCP plans for molluscan shellfish products. However, a dealer has the option to demonstrate that another critical limit provides an equivalent level of public health protection. This option is not provided for the hazard of pathogen contamination at the receiving step.

Monitoring procedures must also be included in the plan. Monitoring is a planned sequence of observations or measurements to assess whether a critical control point is under control and to produce an accurate record for future use in verification. Monitoring: 1) tracks the system's operation so that a trend toward a loss of control can be recognized, and a process adjustment can be made before a deviation occurs; and 2) indicates when loss of control and a deviation has actually occurred, and corrective action must be taken. Monitoring intervals must be frequent enough to permit the dealer to determine whether the hazard is under control.

While the HACCP system is intended to prevent deviations from a planned process from occurring, perfection is rarely, if ever achievable. When a deviation from a critical limit occurs, corrective action must be sufficient to: 1) ensure that no product enters commerce that is injurious to health or is otherwise adulterated as a result of the deviation; and 2) correct the cause of the deviation. These goals can be achieved by either predetermining what corrective actions will be taken when a critical limit failure occurs and then following those procedures, or following the minimum generic-type procedures described in X.01F(3).

The HACCP plan must also list the records that are necessary to document the result of monitoring at CCPs. These records must contain the actual values and observations obtained during monitoring. This requirement ensures that preventive monitoring is occurring in a systematic way.

.02 General Sanitation Requirements. General Sanitation Requirements apply to Chapters XI, XII, XIII, XIV, and XV as appropriate to the activity being conducted and as required in the Model Ordinance: (1) Safety of Water for Processing and Ice Production; (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 from Adulterants; (6) Proper Labeling, Storage, and Use of Toxin Compounds; (7) Control of Employees with Adverse Health Conditions; (8) Exclusion of Pests.

.03 Other Model Ordinance Requirements. Other Model Ordinance Requirements apply to Chapters XI, XII, XIII, XIV, and XV as appropriate to the activity being conducted: (1) Plants and Grounds; (2) Plumbing and Related Facilities; (3) Utilities; (4) Disposal of Other Wastes; (5) Equipment Condition, Cleaning, Maintenance and Construction of Non-Food Contact Surfaces; (6) Shellfish Storage and Handling; (7) Heat Shock; (8) Supervision.

.04 Certification Requirements. A principal objective of the NSSP has been to provide a mechanism for health officials and consumers to receive information as to whether lots of shellfish shipped in interstate commerce meet acceptable and agreed upon sanitation and quality criteria. Although these requirements pertain only to interstate shipments, it is recommended that the same requirements be imposed on intrastate operations. To accomplish this, the NSSP includes criteria and procedures to assure that producing and processing states receive only product that has been grown, harvested, transported, processed, and/or shipped in compliance with NSSP guidelines. Certification is dependent on a dealer maintaining acceptable operational and sanitary conditions. The state must have adequate legal authority to regulate the sanitary requirements for harvesting, transporting, shucking-packing, and repacking of shellfish to be shipped interstate. This authority may be either a specific law or a regulation. The success with which the state is able to regulate all components of the shellfish industry provides a measure of the adequacy of the statutory authority.

The unique nature of shellfish as a food eaten whole and raw also makes it necessary that the Authority have authority to take immediate emergency action to halt sale and distribution of shellfish without recourse to lengthy administrative procedures. As an example, a state may find it necessary to detain lots of shellfish following reports of illness traced to a certain source of shellfish before confirmatory laboratory analysis can be conducted to document the causative agent. In taking such action, the responsible regulatory agency should be cognizant of the need to use rapid analytical methods for determining status of these highly perishable products. Periodic revisions of state shellfish laws or regulations may be necessary to cope with new public health hazards and to reflect new knowledge. Examples of changes or developments that have called for revision of state laws include the construction of depuration plants, changes in conservation laws, or the exploitation of a new resource.

State officials who certify dealers must fully comply with the requirements for certification for the process to remain viable. Certification is intended to provide an unbroken chain of sanitation control to a lot of shellfish from the moment of harvest to its sale at the wholesale or retail level. For the certification process to be effective, certified dealers must fully comply with the applicable sanitation requirements pertaining to the type of operation involved.

The minimum plant sanitation and management guidelines for interstate shellfish shippers are described in Model Ordinance Chapters XI., XII., XIII., XIV., and XV. Only those shellfish firms that meet the guidelines are eligible for certification as Interstate Shellfish Shippers and may be listed in FDA's monthly publication of the ICSSL. Plants having major non-conformities should not be certified and certified plants found to have major non-conformities should have their license or permits suspended or certification canceled. This "List" is mailed to a comprehensive list of interested agencies, industry and or persons to inform them of approved sources of shellfish. Food control officials throughout the United States use the "List" to determine that shellfish offered for sale or used in food service establishments have been produced under the sanitary guidelines of the NSSP. These officials are asked to rely upon the certification process by not holding up shipments or sales of shellfish lots pending examination.

Inspections of certified shellfish dealers should be conducted at such frequency as is necessary to assure compliance with NSSP requirements. The recommended frequency of inspection of certified shellfish dealers is:
Depuration plants (when operating) at least monthly
Shucker packers and repackers: at least quarterly
Shellstock shippers and reshippers: at least semi-annually
To conduct effective inspections, it is necessary that inspectors have adequate equipment and supplies to measure compliance with applicable requirements. Since the type of equipment and supplies required for an inspection will vary with the type of establishment, it is recommended that a checklist of equipment be developed for each dealer classification.

.05-.07 Shellstock Identification, Shucked Shellfish Labeling, Shipping Documents and Records.

The NSSP requires that the product be identified with certain information showing that the shellfish were harvested by licensed diggers and shipped and processed by certified dealers. This information assists in tracing the product back through the distribution system to the growing area in the event the shellfish are associated with a disease outbreak. The requirement for placing the certificate number and shucked marking on the lid or bottom of packages holding 1873 ml (64 fluid ounces) or more is to discourage re-use of these containers for illegal purposes.

In case of an outbreak of disease attributable to shellfish, it is necessary that health departments and other appropriate state and federal agencies be able to determine the source of contamination, and thereby to prevent any further outbreaks from this source. This can be done most effectively by following the course of a shipment, through all the various dealers who have handled it, back to the point of origin by means of records kept by the shellfish dealers. Maintaining adequate records is considered by some industry members to be a burden. This has resulted in various unacceptable practices being encountered by health officials, including no written records of purchase, undated shippers tags maintained in an unordered manner, new shipping tags being placed on a lot without records to correlate the original identity of the lot with the new identity, and shellfish on the premises with no tags. Although these dealers often have "records" in the most general sense, these records are not in the form that meets the intent of the NSSP certification requirement to provide traceability on a lot-by-lot basis. As a result, follow-up investigations of disease outbreaks have been stymied, identification of the cause of the outbreak has been delayed, and outbreaks have continued. The NSSP Guide Section V, Suggested Forms, contains an example of a typical ledger that may be used to provide the required information.

An example where the failure to maintain adequate records was identified as one of the principal contributing factors to a series of continuing disease outbreaks was in 1981 and 1982. The outbreaks continued for several months and affected thousands of people. An investigation by the states involved and FDA revealed that some states were unable to enforce the record keeping and tagging requirements of the NSSP. FDA found in one state that approximately one-third or the certified dealers inspected failed to maintain adequate records. State officials realized that an improved labeling or manifest system was needed to track shellfish in the marketplace back to the distributor and to the digger. However, they also recognized that no single source identity and record keeping system would be applicable to all situations in each state. Therefore, specific requirements should be developed by each state to achieve the NSSP requirements.

Additionally, the Federal Food, Drug and Cosmetic Act requires that food labels provide an accurate statement which includes the name and address of either the manufacturer, packer, or distributor; the net amount of food in the package; the common or usual name of the food; and the ingredients, unless the product conforms to standard of identity requirements. Foods shipped in interstate commerce having labels that do not meet these requirements are deemed misbranded and in violation of Section 405 of the Food, Drug and Cosmetic Act.

.08 Wet Storage in Artificial Bodies of Water.

The purposes of wet storage are the temporary storage of approved shellfish, desanding and improving palatability. Wet storage facilities are not designed and operated to increase safety of the shellfish. Therefore, all controls pertaining to shellfish for direct consumption should be applied.

The types, locations, and purposes of wet storage operation are highly variable and may range from temporary storage near shore in approved areas to onshore tanks using recirculating, synthetic seawater for the purpose of desanding and salt uptake. Consequently, it is not possible to provide detailed guidelines in the Model Ordinance and it is necessary for each separate operation to be developed and evaluated on its own merit with respect to overall program guidelines.

Removing shellfish from growing beds to storage areas close to shore and habitations may subject such shellfish to constant or intermittent pollution. Shellfish in wet storage tanks are similarly subjected to pollution if the tank water is obtained from a polluted source. An example of such contamination is the 1956 outbreak of infectious hepatitis in Sweden (691 cases) attributed to oysters contaminated in a wet storage area.

Shellfish on floats nearshore may be more directly exposed to potential contamination from boats and surface runoff than are shellfish in their natural growing areas. Therefore, particular emphasis should be placed on a sanitary survey of the vicinity to assure that chance contamination does not occur.

Careful consideration must be given to designing and operating onshore wet storage tanks to assure that shellfish are not contaminated during holding or do not die from physiological stresses such as low dissolved oxygen and unsuitable temperatures or salinity. Excessive mud on the shells and dead shellfish may increase bacterial loads in the tanks and lead to increased microbial levels in the shellfish during storage. Hence, washing and culling the shellfish prior to storage is essential.

Proper hydraulic design of the tank is important to assure an adequate quantity and quality of water with minimum turbulence at suitable temperatures to achieve the intended purpose of the storage operation. Inadequate flow or "dead spots" can lead to oxygen deficiency and shellfish mortality if the shellfish are physiologically active. Minimum turbulence will permit feces and pseudo feces generated by active shellfish to settle out without being resuspended and ingested. Tanks fabricated with safe material, which are easily cleanable, will prevent possible adulteration with chemicals migrating from the tank into the water and will facilitate cleaning and sanitizing.

Commingling of bivalve mollusks with other species in tanks may subject the bivalve mollusks to contamination from pathogenic organisms from the non-molluscan animals. Fish, crabs, lobsters, and other marine species may be harvested from polluted areas and may have ingested pathogens or accumulated them on their body surfaces. Therefore, holding such animals in the same tank with bivalve mollusks presents a risk of cross contamination. This risk can be avoided by using separate tanks for non-bivalve molluscan species. Where the same water is used for all tanks, effective disinfection must be provided prior to entering the tank holding the bivalve species.

Chapters XI, XII, XIII, and XIV. - SHELLFISH PROCESSING AND HANDLING

Requirements for Dealers.

.01 Critical Control Points. [NOTE: these Critical Control Points apply to Chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance.]

A. Receiving Critical Control Point. Certified dealers are responsible to assure that shellfish purchased for direct sales, further shipments, or processing are safe and wholesome. The safety of shellfish is predicated on the cleanliness of the growing area waters from which they are obtained and the sanitary practices applied during harvesting and shipping. The positive relationship between sewage-polluted shellfish and enteric disease has been demonstrated many times. If the water in which shellfish are grown is polluted, it may be assumed that the shellfish will also contain pathogenic bacteria or viruses capable of causing disease in man. Harvesters and shippers must provide information necessary to create a record of the origin, quantity, and date of harvest, which can be used to trace lots of questionable shellfish back to the sources(s).

B. Shellstock Storage Critical Control Point. There is evidence that some pathogenic organisms will survive in shellfish for a considerable length of time after harvesting and that some bacterial pathogens may multiply in the absence of adequate refrigeration.

C. Processing Critical Control Point. The bacteria count of the final pack is related to the elapsed time after shucking when the shellfish are held at temperatures favorable to the rapid growth of bacteria. Factors which influence the length of time required to lower the temperature of shucked shellfish to 7.2°C (45°F) include the temperature of blower or other process water, the speed of the individual shucker or shucking machinery, the frequency with which the shucking containers are delivered to the packing room, ambient air temperature in the plant, and the temperature of the shellstock being shucked. To maintain optimum bacteriological quality, it is preferable that the elapsed time between shucking and cooling to a temperature of 7.2°C (45°F) does not exceed four hours. More rapid processing is very desirable.

D. Shucked Meat Storage Critical Control Point. Shucked shellfish are an excellent medium for the growth of bacteria. Thus, it is very important that the packaged shellfish be cooled and refrigerated promptly so that bacteria growth is minimized. Studies have shown that bacterial growth is significantly reduced at storage temperatures of less than 7.2°C (45°F) and that storage in wet ice is the most effective method for refrigeration of shucked meats.

.02 Sanitation Requirements. [NOTE: these General Sanitation Requirements apply to chapters XI, XII, XIII, and XIV as appropriate to the activity being conducted and as required in the Model Ordinance.]

A. Safety of Water for Processing and Ice Production. Water should be safe and sanitary to avoid contamination of food-contact surfaces and the product. Ice may become contaminated by non-potable water or may become contaminated during freezing or in subsequent storage or handling. When non-hermetically sealed containers of shellfish are stored in unsanitary ice, a partial vacuum may form within the containers and draw water from the melting ice into the container and contaminate packed shellfish. Special attention should be given to ice used for direct contact chilling of shellfish meats to assure that the ice is of acceptable quality. Water used for shellstock washing should be of good quality, to avoid possible contamination of the shellstock. The organisms causing typhoid fever, hepatitis, and other gastrointestinal diseases may be present in the body discharges of cases or carriers, and thus be present in the drainpipes in the plants. Correctly installed plumbing protects the water supplies against cross connections and back siphonage.

B. Condition and Cleanliness of Food Contact Surfaces. Colanders, shucking pails, skimmers, blowers, and other equipment or utensils which come into contact with the shucked shellfish and which have cracked, rough, or inaccessible surfaces or are easily cracked or chipped, or which are made of improper material, are apt to harbor accumulations of organic material in which bacteria or other microorganisms may grow. These microorganisms may later cause illness among those who eat the shellfish, or spoilage in the shucked shellfish. Slime and foreign material, which accumulate in blower pipes below the liquid level, afford an excellent breeding place for bacteria. This material may be dislodged and forced into the batch of shellfish in the blower, thus increasing the bacterial content of the shellfish. Cleaned and sanitized equipment and utensils reduce the chance of contaminating shellfish during shucking and processing. Shellfish furnish an excellent growth medium for spoilage microorganisms, and small numbers of these microorganisms on improperly sanitized equipment may multiply to very high levels in the finished pack. Use of sanitizers is not effective unless the equipment is first thoroughly cleaned and rinsed.

C. Prevention of Cross Contamination. The nature of shellfish operations is such that the shellfish require protection from undesirable microorganisms, chemicals, filth, or other extraneous materials. This protection is achieved by properly selecting the plant location so that it is not contaminated by floodwaters. It is normal during shucking operations for shucker's clothing to become very soiled. If shuckers enter the packing room, shucked stock, cans, and other equipment may become contaminated. A delivery window has proven to be an effective means of keeping shuckers out of the packing room. If shellstock are stored where polluted ground or surface water or floor drainage can accumulate, the shellstock may become contaminated.

D. Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the sanitizing of the hands. Disease-causing microorganisms may be present in body discharges of employees that are cases or carriers of communicable disease organisms. When sewage disposal facilities are of a satisfactory type, there is less possibility that the shellfish being processed may become contaminated with fecal material carried by flies, rodents, or by other means.

E. Protection from Adulterants. Shielded light fixtures help protect the food, equipment, and employees from glass fragments should the fixture break. Ventilation, plumbing, and air intakes for blowers can all introduce adulterants into the area where shellfish are stored or processed. Care must be exercised to prevent the entrance or leakage of adulterants. Shellfish can also be contaminated by hydraulic fluid or other lubricants, dirt or other filth, or contaminated ice. Care must be used to prevent adulterants in these items from contacting shellfish.

F. Proper Labeling, Storage, and Use of Toxic Compounds. In order to reduce the potential for contamination, stored poisonous or toxic materials should be limited to those necessary to maintain the establishment. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to assure the safety of workers and the consumer.

G. Control of Employees with Adverse Health Conditions. It is considered good public health practice for any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food-contact surfaces, or food-packaging materials becoming contaminated, to be excluded from any operations which may be expected to result in such contamination until the condition is corrected. Personnel should be instructed to report such health conditions to their supervisors.

H. Exclusion of Pests. Controlling flies, cockroaches, and other insects may prevent shellfish and food-contact surfaces from being contaminated with disease organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the building, and at depriving them of food, water, and shelter.

.03 Other Model Ordinance Requirements.

A. Plants and Grounds. The plant and building facilities should be kept clean so as to minimize the chance of contamination of shellfish during processing. Rooms or lockers should be provided for clothing, aprons, and gloves to eliminate the tendency to store such articles on the shucking benches or in packing rooms, where they interfere with plant clean up and operations. Properly graded floors, of durable, impervious material, maintained in good condition, permit rapid disposing of liquid and solid wastes, and facilitate easy cleaning of the plant. Smooth, washable walls and ceilings are more easily kept clean and are, therefore, more likely to be kept clean. A light colored paint or finish aids in the distribution of light and in the detection of unclean surfaces. Clean walls and ceilings are conducive to sanitary handling of shellfish. Maintaining the plant grounds and using physical barriers provides protection from filth, chemicals, microorganisms, or other extraneous materials. Miscellaneous equipment and articles may interfere with plant operations and make clean up more difficult.

B. Plumbing and Related Facilities. Adequate toilet and Hand washing facilities, including running water, soap, and sanitary drying facilities also are essential to personal cleanliness of the workers.

C. Utilities. Adequate lighting encourages and facilitates keeping rooms, equipment, and the product clean by making dirt and unsanitary conditions conspicuous. Comfortable working conditions increase the efficiency of the workers, and may promote sanitary practices. Adequate ventilation reduces condensation and aids in retarding the growth of mold. Excessive temperatures also promote growth of spoilage microorganisms in shellfish and on food-contact surfaces.

D. Insect and Vermin Control. Controlling flies, cockroaches, and other insects may prevent shellfish and food-contact surfaces from becoming contaminated with disease organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the building, and at depriving them of food, water, and shelter. Fly control measures, such as insecticide spraying, may also be necessary on the shell pile.

E. Disposal of Other Wastes. Shellstock shipping and shucking facilities can protect against infestation by vermin if building entrances are protected, the grounds do not provide harborage, and there is no food available in the buildings or on the grounds. Removing shell and organic processing wastes from the plant and properly disposing of these wastes can play a key role in controlling vermin. Methods found to be suitable for removing these materials without contaminating the shucked product include conveyors, baskets, barrels, wheelbarrows, and shell drop-holes. When shells are to be temporarily piled or stored on the premises, special controls may be needed. Organic wastes, including culled shellfish, clam siphons, and surf and ocean quahog viscera, need to be discarded into separate containers from the shells in the plant during shucking. These wastes can then be disposed of separately from the shell at, for example, a landfill. Proper disposal and prompt removal of shell and non-edible wastes from the plant also makes it possible to keep the premises clean, and decreases the likelihood that any product or food-contact surfaces will become contaminated.

F. Equipment Construction for Non-Food Contact Surfaces. Unless shucking benches, stands, blocks, and stalls are made of smooth material and are easily cleaned, they will become very dirty and may contaminate the shellfish.

G. Cleaning of Non-Food Contact Surfaces. Determining an adequate cleaning procedure for facilities and equipment will depend upon which method of sanitizing is selected and what equipment and utensils are identified to be washed in a sink or washed "in place." Detergents and brushes, including special brushes that may be needed for cleaning equipment, such as blower lines, should be available. Cleaning and sanitizing of equipment and utensils should be initiated immediately after processing operations are finished. Postponing clean-up operations results in more difficult cleaning, creates conditions conducive to growth of bacteria and mold, which may not be completely removed, and may result in product contamination.

H. Shellfish Storage and Handling. The sanitary requirements for individual shellfish dealers are variable since they may engage in several different phases of processing and distribution. Some shellstock shippers may have only a truck that is used to ship shellstock from a harvester to a processor or the market. Other shippers must have a building where shellstock is stored, repacked, or labeled. Consequently, the applicable sanitary controls must be based on an evaluation of the individual characteristics of the operation. Single-service and single-use containers, which have not been stored and handled in a sanitary manner, may become contaminated and thus may contaminate the packaged shellfish. Unacceptable practices that can interfere with the prompt handling, packing, and refrigerating of shellfish include holding shucked meats at the shucking station for prolonged periods, return of overage to the shucker, and bench grading of shucked meat. Another frequently encountered unacceptable practice is soaking of shucked meats for prolonged periods in water for the purpose of increasing yield through uptake of fresh water by the shellfish.

I. Heat Shock. The primary objective of heat shock is to facilitate shucking of shellfish. Due consideration in developing the scheduled process must be given to a large number of factors which affect the heat shock process. Heat penetration into the shellfish will vary with species and size. Even regional variations in shell thickness and shape may affect the length of time required to reach the desired internal temperature. The temperature and time of exposure must be such that the adductor muscle is sufficiently relaxed to open easily but must allow the shellfish to remain alive. The scheduled process may be developed from studies conducted by the state, by a knowledgeable processor in cooperation with state shellfish control authorities, by shellfish experts such as university biologists, or by any other person with adequate knowledge of the technical control procedures. The person responsible for developing the scheduled process should retain all records of process operations so the FDA may review them and state shellfish control authority if questions arise regarding the adequacy of the scheduled process or its use.

J. Post-Harvest Processing. *Vibrio vulnificus* has been identified as an organism of concern to at-risk consumers of shellfish. Post-harvest treatments which can demonstrate that the process achieves end point criteria of non-detectable (<30 MPN/gram) for *Vibrio vulnificus* can provide a product that has a reduced level of risk for these at-risk consumers. Applying those processes enables the dealer to label treated products "Processed to reduce *Vibrio vulnificus* to non-detectable levels."

K. Toxic Materials. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to ensure the safety of workers and the consumer.

L. Personnel. Disease producing agents may be carried on the hands of shuckers and packers unless proper Hand washing is practiced. Finger cots, gloves, and shields, unless effectively sanitized periodically, will accumulate bacteria that may contaminate the shucked shellfish. Employees handling shucked shellfish need to sanitize their hands as an added public health control practice.

M. Supervision. Hand washing by employees is an important public health measure. Unless someone is made specifically responsible for this practice, it is apt to be forgotten or overlooked. Similarly, one person must be responsible for plant clean up. In general, it is considered to be good practice to clearly assign supervisory personnel the responsibility for assuring compliance by all personnel with all requirements.

Chapter XV. Depuration

Requirements for the Authority

.01 Administration

Depuration is intended to reduce the number of pathogenic organisms that may be present in shellfish harvested from moderately polluted (restricted) waters to such levels that the shellfish will be acceptable for human consumption without further processing. The process is not intended for shellfish from heavily polluted (prohibited) waters nor to reduce the levels of poisonous or deleterious substances that the shellfish may have accumulated from their environment. The acceptability of the depuration process is contingent upon the Authority exercising very stringent supervision over all phases of the process.

The depuration process shall be under the effective supervision of the Authority. The Authority shall have a management plan which details procedures for regulating the harvesting from restricted areas; controlling the transport of shellfish between the harvest area and to the depuration plant; approving plant design and operation, including subsequent changes; certifying and inspecting plants in accordance with the requirements of the *Model Ordinance*; and, prohibiting interstate shipments in the event that nonconformities are found which compromise the validity of the process. A Memorandum of Understanding (MOU) shall be developed between appropriate Authorities when more than one Authority is involved in the management plan.

Extensive administrative procedures are essential if the Authority is to adequately control a very complex operation such as depuration. There are numerous critical control points where significant deviation can result in the distribution of contaminated shellfish. Control over the harvesting areas is needed to ensure that the shellfish are not so contaminated that cleansing will be inadequate. Adequate control measures must be taken to prevent diversion of undepurated shellfish into the marketplace. Shellstock delivered to the depuration plant must be properly identified with information necessary to trace each harvest lot back to the harvest area, date of harvest, and harvester or group of harvesters.

Shellfish destined for depuration plants shall be protected as necessary during harvesting and transporting to prevent further contamination and undue physiological stress that could reduce the effectiveness of the depuration process. Thermal and physical shock can adversely affect the pumping action of shellfish and reduce the rate of elimination of microorganisms. Additional contamination of the shellfish during harvest could raise bacterial levels to such a point that adequate depuration will not occur. Thermal abuse may also cause bacterial levels to reach the point that depuration may not be effective in 48 hours. The types of protection that may be provided to prevent thermal abuse include; but, are not limited to: furnishing shade in warm weather; providing refrigeration in transit; ensuring rapid transit to the depuration plant; preventing freezing in cold weather; preventing breakage of shells; and, optimizing holding or storage time before depuration.

Depurated shellfish require an increased level of control compared to shellfish from approved areas because of the increased potential for contamination. These controls must include packaging and labeling that will serve to help identify the deputation cycle of each harvest lot and to deter illegal commingling of undepurated shellfish with depurated shellfish. Such controls include prohibition against commingling of harvest lots during packing, tags that identify the shellfish as being depurated, and a prohibition against repackaging after the shellfish leave the depuration plant. It is recommended that tamper-evident seals be used on the packages as a further deterrent. Design, construction and operation of the plant must adhere to guidelines established in the *Model Ordinance*. Finally, the inspection program must be adequate to detect critical deviations and to effect immediate correction or prevent the sale of suspect shellfish.

Requirements for the Depuration Processor

.01 Critical Control Points

A. Receiving Critical Control Point

Shellfish intended for deputation must be harvested only from growing areas meeting the water quality requirements for approved, conditionally approved, restricted, or conditionally restricted areas in the open status.

It has been amply demonstrated that shellfish harvested from prohibited areas should not be used for depuration. Depuration studies have been conducted on the relationship of initial levels of indicator bacteria and viruses to the levels of these indicators after varying lengths of time. These studies have indicated that consistent reductions of both bacteria and viruses to low levels can be achieved with moderately polluted shellfish, but satisfactory results cannot be obtained with heavily contaminated shellfish.

It is also essential that shellfish harvested from restricted or conditionally restricted areas be controlled so these shellfish are not illegally diverted and sold. This usually necessitates special procedures for monitoring harvest operations and tagging the shellfish. Methods that may be employed include the use of specially designed, labeled, or colored containers; or the use of colored or distinctly shaped tags. If shellfish are transported in bulk, other methods to distinguish the shellfish as originating from restricted or conditionally restricted areas may need to be employed. Recommended measures include continuous surveillance of the boat or truck, transporting in trucks sealed with a serially numbered, tamper-evident seal, or a count by the Authority of the quantity shipped and quantity received at the depuration plant.

B. Processing Critical Control Points

Depuration is a complex biological process. Individual species respond in different ways to various combinations of operational criteria including water turbidity, salinity and temperature, depth of shellfish in the baskets, and tank design. Consequently, it is necessary to establish process effectiveness on a continuous basis. Continuous process verification is accomplished by comparing the means and variability of end-product data from consecutive harvest lots for each species of shellfish harvested with species-specific critical limits for these parameters established empirically through extensive field work. The depuration process is considered to be verified or operating effectively for the harvest lot and species harvested if the end-product data meets these established species-specific critical limits. New harvest areas, harvest areas having little end-product data, and harvest areas which have failed process verification are all subject to addition, more rigorous requirements under the conditional protocol. This process is designed to prevent potentially adulterated shellfish from unproven or ineffective depuration from reaching the marketplace.

C. Finished Shellstock Storage Critical Control Point

Depurated shellfish must be stored in a manner that maintains quality and prevents the shellfish from becoming contaminated. Two options are available to meet this requirement. The first is to bring and maintain the product under appropriate temperature control (45°F) by icing or refrigeration. In this way any low levels of bacteria that remain in the shellfish after depuration will be prevented from growing and reaching the point at which they may become harmful. The second option is to wet store depurated shellfish in waters of appropriate sanitary quality which meet the requirements of Chapters VII or X in the *Model Ordinance*.

.02 Sanitation

A. Safety of Water for Processing and Ice Production. The source of the process water and the water treatment system must be such that an adequate volume and quality of process water can be provided to accomplish effective depuration. Currently all plants in the United States use ultraviolet light (UV) for disinfection of process water. Numerous studies have shown UV treatment to be highly effective for inactivating bacteria and viruses provided the units are properly operated and maintained. In choosing a UV treatment system, consideration should be given as to whether the process water will be recirculating or flow through and whether the type of plant and flow rate are compatible with the UV treatment system.

As with any disinfection system, microbial inactivation is strongly dependent on the dose-time relationship which, for UV treatment is primarily a function of water depth and turbidity. Contact time is a function of the flow rate of the water and cross-sectional area or volume of the unit. In order for the UV lights to remain effective, the tubes must be kept clean to prevent build-up of materials which reduce radiation intensity. The amount of radiation must be monitored and the UV tubes replaced when they are no longer effective.

Ozone has been used for many years in Europe for treating depuration process water. Care must be taken in using ozone or other chemicals which may react with organic and inorganic components in the water to form compounds which adversely affect physiological activity. Disinfection with ozone and other chemicals could constitute a food additive situation requiring FDA approval before use.

Ice should be produced using potable water to avoid contamination. Care should also be exercised to avoid contamination of the ice during freezing or in subsequent storage and handling.

Shellfish washing should make use of water of good sanitary quality to avoid possible contamination or added contamination of the shellfish. Whatever the source, shellfish wash water must be of the sanitary quality of potable or drinking water .

B. Condition and Cleanliness of Food Contact Surfaces. The need to effectively clean and sanitize processing tanks, containers and pipes carrying process water is well established. The inadequate cleaning and sanitizing of process equipment can result in microorganisms being resuspended in the process water and increasing the bacterial loading to such a level that adequate depuration will not occur.

Processing tanks and containers used to hold shellfish that have cracked, rough or inaccessible surfaces, or made of improper material, are apt to harbor accumulations of organic material in which bacteria, including pathogens, may reside and grow. Such organisms can be regularly introduced into the system and these potentially may contaminate the shellfish. Surfaces, therefore, must be smooth and easily cleanable if bacteria are to be flushed out in the cleaning and sanitizing process. Uncleanable surfaces can result in inconsistent depuration effectiveness, and, possibly, the reintroduction of pathogens into the shellfish.

C. Prevention of Cross Contamination. Shellfish must be stored in a manner that will protect them from contamination while in dry storage and at transfer points. Employees should be encouraged to practice good personal hygiene, as they may be a source of cross-contamination.

D. Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities. Adequate toilet, hand washing and sanitizing facilities must be provided. Hand washing by employees is an important public health measure. Providing convenient, properly constructed and plumbed facilities, supplied with soap and towels encourages employees to wash their hands frequently and correctly. Washing of hands with soap and drying with single service towels or a hand-drying device improves the sanitizing of the hands.

E. Protection from Adulterants. Shielded light fixtures help protect the shellfish from contamination with glass fragments should the fixture break. Ventilation, plumbing, and air intakes can all introduce adulterants into the area where shellfish are stored or processed. Shellfish can also be contaminated by hydraulic fluid or other lubricants, dirt or other filth, or contaminated ice. Care must be used to prevent adulterants from any source from contacting the shellfish or shellfish contact surfaces.

F. Proper Labeling, Storage, and Use of Toxic Compounds. In order to reduce the potential for contamination, stored poisonous or toxic materials should be limited to those necessary to maintain the plant. Proper labeling, use, storage, and handling are essential to prevent accidental contamination of shellfish and to assure the safety of workers and the consumer. Only those chemical agents necessary for plant operations shall be present in the plant and shall be used only in accordance with labeling.

G. Control of Employees with Adverse Health Conditions. It is considered good public health practice for any person who, by medical examination or supervisory observation, is shown to have, or appears to have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of shellfish, shellfish contact surfaces, or shellfish packaging materials becoming contaminated, to be excluded from any operations which could be expected to result in such contamination until the condition is corrected. Personnel should be instructed to report such health conditions to their supervisors.

H. Exclusion of Pests. Controlling flies, cockroaches, and other insects may prevent shellfish and shellfish contact surfaces from being contaminated with disease causing organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the plant and at depriving them of food, water, and shelter.

. 03 Other Model Ordinance Requirements.

A. Plants and Grounds. Physical facilities of the plant including the processing system shall be kept in good repair, and are cleaned and sanitized as necessary. No miscellaneous equipment is stored in processing or holding areas. The plant and building facilities should be kept clean so as to minimize the chance of contamination of shellfish during processing. Rooms or lockers should be provided for clothing, aprons and gloves to eliminate the tendency to store such articles where they may interfere with plant cleanup and operations. Properly graded floors, of durable, impervious material, maintained in good condition, permit rapid disposing of liquid and solid wastes, and facilitate easy cleaning of the plant. Smooth, washable walls and ceilings are more easily kept clean and, therefore, are more likely to be kept clean. A light colored paint or finish aids in the distribution of light and in the detection of unclean surfaces. Clean walls and ceilings are conducive to sanitary handling of shellfish. Maintaining the plant grounds and using physical barriers provides protection from filth, chemicals, microorganisms, or other extraneous materials. Miscellaneous equipment and articles may interfere with plant operations and make cleanup more difficult.

The grounds about a depuration plant must be free from conditions that may result in contamination of shellfish at any time during processing and storage. The plant building or structure shall be suitable in size, construction, and design to prevent contamination of shellfish by animals and other pests; to keep untreated and treated shellfish separate; and to facilitate adequate cleaning, sanitizing, operation, and maintenance of the depuration facilities. Processing tanks, containers, piping and conveyances must be enclosed within a protective structure.

It is essential that depuration plants be designed and constructed so shellfish will be adequately protected and consistently depurated. Research on the depuration process and experience gained in commercial facilities has led to some generally accepted standards that are critical for effective depuration. Other design and construction criteria are less clearly defined, and only general guidance is available. Additionally, the plant must be designed and constructed so adequate cleaning and sanitizing can be accomplished, and to facilitate proper operation.

B. Plumbing and Related Facilities. Adequate toilet and hand washing facilities, including running water, soap, and sanitary drying facilities are essential to personal cleanliness of the workers. Adequate floor drainage and backflow preventers are installed where appropriate. Drainage or waste pipes are not installed over shellfish processing or storage areas; nor, are they installed in areas in which shellfish containers and utensils are stored. Such precautions will minimize the potential for cross contamination.

C. Utilities. Adequate lighting encourages and facilitates keeping rooms, equipment, and the product clean by making dirt and unsanitary conditions conspicuous. Comfortable working conditions increase the efficiency of the workers, and may promote sanitary practices. Adequate ventilation reduces condensation and aids in retarding the growth of mold. Adequate ambient temperature control prevents excessive temperatures that promote growth of spoilage microorganisms and potential pathogens in shellfish and on shellfish contact surfaces.

D. Insect and Vermin Control. Controlling flies, cockroaches, and other insects may prevent shellfish and shellfish contact surfaces from becoming contaminated with disease causing organisms. Controls should be directed at preventing the entrance of insects, rodents, and other vermin into the plant and at depriving them of food, water, and shelter.

E. Disposal of Wastes. Depuration facilities can protect against infestation by vermin if building entrances are protected, the grounds do not provide harborage, and there is no food available in the plant or on the grounds. Removing shell culled shellfish and organic processing wastes from the plant and properly disposing of these wastes can play a key role in controlling vermin. Proper disposal and prompt removal of shell and non-edible wastes from the plant make it possible to keep the premises clean and decreases the likelihood that any shellfish or shellfish contact surfaces will become contaminated.

F. Equipment Construction for Non-Food Contact Surfaces. Unless storage and handling equipment are made of smooth material and are easily cleaned, they will become very dirty and may contaminate the shellfish.

G. Cleaning of Non-Food Contact Surfaces. Cleaning of the depuration tanks and equipment must be performed in a manner and at a frequency that will preclude the potential for contamination of the shellfish or shellfish contact surfaces.

H. Shellfish Storage and Handling. Washing of shellfish prior to depuration rids shells of sand, mud, and detritus that may interfere with depuration and may make tank cleaning difficult. The type of harvest method may negate the need for additional washing however. At other times, thorough washing at the plant may be necessary to adequately remove mud. Depurated shellfish shall be washed and culled after depuration and packaged in clean containers fabricated from safe materials. Different harvest lots of shellfish must not be commingled during packing. After depuration, washing removes feces and pseudo-feces that may cling to shells and may recontaminate the shellfish meats during processing or consumption. Non-depurated shellfish must be stored in a manner that maintains their physiological ability to cleanse themselves and prevents post harvest contamination. Otherwise, depuration may not be effective. Depurated shellfish must be stored in a manner that will maintain their quality and prevent recontamination.

I. Personnel. Personnel are not allowed to store clothing or other belongings, eat, drink or smoke in areas where shellfish are processed or stored. Such activities could lead to cross contamination of the shellfish or shellfish contact surfaces.

J. Supervision. Management shall clearly designate a knowledgeable and competent individual to be present at the plant and be accountable that appropriate operating procedures and proper personal hygiene practices are followed. The supervisor will also maintain complete and accurate records that will permit each batch of depurated shellfish to be traced back to its source, and will account for all product sample results and measurements of critical parameters for each cycle. One person must be responsible for plant cleanup. In general, it is considered to be good practice to clearly assign supervisory personnel the responsibility for ensuring compliance by all personnel with all requirements.

K. Plant Operating Manual. The plant must prepare a written Depuration Plant Operations Manual (DPOM). A copy of this Manual must be kept in a location that is accessible to plant personnel responsible for the depuration activity. The DPOM will be kept current and contain all the information and records relevant to the operation of the depuration plant, and will be formatted to include the following:

(1) Introduction.

The introduction must contain information relative to the current status of the DPOM (create, revise, update, etc.), ownership of the plant, proposed schedule of operation, potential harvest areas and plant capacity.

(2) Description of the Facility.

The DPOM must contain site plan drawings for the plant, the facility layout including a detailed schematic of the entire depuration system, a schematic drawing of the process, shellfish flow diagram showing the movement of the shellfish throughout the plant, and a schematic of the process water delivery and distribution system. Essentially, the documentation provided should show that the plant has the capability to achieve effective depuration of the shellfish, provide adequate storage before and after depuration, and prevent commingling of both depurated and undepurated shellfish and treated shellfish from different harvest lots.

(3) Design Specifications of the Depuration Unit.

During design and construction of depuration systems, careful consideration must be given to hydraulic flow through the tank. Non-uniform flow may result in dead spots and oxygen depletion that lead to inadequate depuration at some locations in the tank. Choice of' design criteria may be based on existing studies or new studies which verify effectiveness of any new designs. Furfari reports accepted design criteria for tank loading rates, water flow, and container arrangement. Tank water volume is recommended to be at least 6,400 liters per cubic meter of shellfish (8 cubic feet of water per U.S. bushel) for hard clams and eastern oysters and 4,000 liters per cubic meter of shellfish (5 cubic feet per bushel) for soft clams. A minimum flow rate of 107 liters per minute per cubic meter of shellfish (1 gallon per bushel) is recommended to maintain adequate oxygen levels. A clearance space of at least 7.6 cm (3 inches) is recommended for separating containers of shellfish in the tanks and between the shellfish containers and the bottom and sides of the tanks.

(4) Laboratory to be Utilized for Microbial Analyses.

Sample analyses shall be conducted by a laboratory approved by the Authority pursuant to the requirements of Chapter III in the *Model Ordinance*. Use of an approved laboratory ensures the quality and reliability of the analytical results.

(5) Depuration Process Monitoring.

If shellfish are released for sale before they are adequately depurated, adulterated shellfish may reach the market. It is essential; therefore, to implement an adequate sampling program designed to determine if critical environmental conditions are being met and if the shellfish being released to the market meet accepted criteria. Extensive field-testing has resulted in a set of species-specific critical limits being established which indicate the effectiveness of depuration process. These limits are referred to as the Critical Limits for the Indices of Depuration Plant Performance.

(6) Standard Operating Procedures.

Since effective depuration is dependent upon the control of a wide range of interrelated variables, it is essential that a set of standard operating procedures (SOPs) be developed which specify the exact procedures to be used for every aspect of the depuration process from receipt of the shellfish to data analysis, labeling and tagging. Use of SOPs help to ensure that appropriate actions are taken at each stage in the depuration process. By so doing, the probability that effective depuration and safe handling will be achieved is considerably increased and the incidence of processing mistakes is minimized.

(7) Record Keeping.

It is essential that detailed identification information be maintained on all harvest lots and shipping containers of depurated shellfish. In the events that an outbreak of illness occurs, or a question arises concerning the product, responsible state and federal authorities must be able to trace the implicated shellfish back to a specific depuration cycle, and to the harvest area. Additionally, maintaining complete and accurate records of all transactions serves to promote business integrity wherein all harvesters, processors, and dealers are fully accountable for their product. Records of product samples and critical parameters within the plant are necessary to determine if the plant is operating in accordance with the DPOM. Plant records should be kept for at least two (2) years in order that adequate investigations can be conducted in the event of a suspected illness and in order that the Authority can make process reviews.

L. Process Verification

Depuration is a complex biological process. Individual species respond in different ways to various combinations of operational criteria including water turbidity, salinity and temperature, depth of shellfish in the baskets, and tank design. Consequently, it is necessary to establish process effectiveness on a continuous basis. Continuous process verification is accomplished by comparing the means and variability of end-product data for consecutive harvest lots for each species of shellfish with species-specific critical limits for these parameters established empirically through extensive fieldwork and referred to as the Critical Limits for the Indices of Depuration Plant Performance. The depuration process is considered to be verified or operating effectively for the harvest lot and species harvested if the end-product data meets the established species-specific critical limits for the Indices of Depuration Plant Performance.

New harvest areas, harvest areas having little end-product data, and harvest areas which have failed process verification are all subjected to additional, more rigorous requirements under what is known as the conditional protocol. This process is designed to prevent potentially adulterated shellfish from unproven or ineffective depuration from reaching the market.

Chapter XVI. Background & Performance of Post Harvest Processing (PHP) Validation/ Verification Protocols

BACKGROUND:

A post harvest process (PHP) to reduce the levels of pathogenic *vibrios* in shellfish, must be capable of reducing potentially high summer levels to a level that presents a negligible health risk. Cook et al 2002 indicated that a concentration of *Vibrio parahaemolyticus* or *Vibrio vulnificus* of 100,000 per gram was not uncommon in market oysters harvested from the Gulf Coast during summer months. A WHO/FAO (2005) risk assessment indicated that a *Vibrio vulnificus* concentration of below 30 per gram is a negligible health risk. Therefore, in an attempt to validate a post harvest process to be used throughout the year, the ISSC adopted as interim guidance, a protocol to assure that the process is capable of reducing levels of *vibrios* from an initial MPN level of 100,000/gram to <30/gram.

Obtaining an initial level of 100,000/gram was difficult to achieve consistently in some locations (even with temperature abuse) except during the hottest part of the summer. This limited the time that a validation could be conducted to 3 months of the year or less. In an attempt to allow validation during other times of the year, the ISSC proposed a validation procedure based upon a 3.52 log reduction (this is equivalent to reducing from 100,000 to 30) regardless of the initial level. A new validation protocol was developed which specified an initial level between 10,000 and 100,000 and reduction by 3.52 logs resulting in a final concentration of <30.

VALIDATION:

Validation is the initial check of a PHP to assure that the process can reduce the concentration of *V. vulnificus* and *V. parahaemolyticus* in shellfish by 3.52 logs and to levels <30 as shown in table 1. Determining the log reduction for validation uses knowledge of both the initial and final concentrations. The interval containing the initial concentration determines a test on a single sample for the final concentration. A multiple dilution test is preferred for finding a concentration and the single dilution for indicating whether the concentration is above a threshold. For the initial concentration, a serial dilution with three tubes at each of three or four dilutions was chosen. Four samples are taken to determine the initial concentration and the adjusted geometric mean is used to combine the MPN results. If four samples from a lot of shellfish with a true concentration of 100,000 per gram are examined by the MPN procedure, the probability of the geometric mean of the MPNs showing 100,000 or greater is about 50%. In an attempt to improve the probability of samples being accepted when the true concentration is 100,000 per gram, an adjustment factor of 1.3 was selected based upon examining tables of the probability of getting various results from simulated outcomes.

For a process to be validated, no more than three samples out of 30 may fail. Depending upon the initial load, failure of a single sample is determined according to the table below.

TABLE 1

AGM Interval	Grams Per Tube	Positive Tubes Allowed
59,995 or Greater	.01	2
37,174 – 59,994	.01	1
23,449 – 37,173	.1	4
12,785 – 23,448	.1	3
10,000 – 12,784	.1	2

The choice of intervals for each test in table 1 tried to keep the probabilities near the original test. The original test used .01 grams/tube and allowed 2 of the 5 tubes to have growth. It tried to test for 30 cfu/gram. At 30cfu/gram the probability of a tube with .01 grams of homogenate not having growth equals exp (-30*.01) from a Poisson. From putting this value into a binomial at a final concentration of 30 cfu/gram a single sample has a probability of passing the original test of .88656. The table gives initial concentrations which can be converted to target final concentrations by multiplying by 30/100,000 ≈ -3.52 log10.

A change from one test to another was done at a concentration where the probability of passing both tests was the same distance from the probability of passing the original test. For example, an initial concentration of 59,995 becomes a target final concentration of

$$(30/100,000) * 59,995 = 17.9985$$

At this target final concentration and .01 grams/tube the probability of 2 or fewer growth tubes equals .96562. The probability of 1 or fewer growth tubes equals .80751. Since .96562 - .88656 and .88656 - .80751 are equal up to rounding, the initial concentration of 59,995 was chosen as the value to change between these two tests.

Since validation tries to assure that a PHP gives the desired log reduction and gets the final concentration below 30 per gram, an operational characteristic curve is used to determine how well the process works. For an initial concentration, an operational characteristic curve indicates the probability of passing validation for various final concentrations.

The probability of passing validation for each pair depends on the initial and final concentrations. The initial concentration indicates which of the five tests in the validation procedure is used. The final concentration and the test used give the probability of the sample passing.

The probability of passing any of the five tests in the validation procedure is calculated from the final concentrations. In addition, simulations generated outcomes from the initial concentration. The adjusted geometric means for the MPNs of these outcomes indicate the probability of each of the five tests given the initial concentration. The product of the probability of each test times the probability of passing with the test were added over all five tests. This gives the probability a sample would pass. Calculating with a binomial gave the probability that at most 3 of the 30 samples would fail for a validation. The following table (table 2) gives the probability of passing validation with various combinations of initial and final concentrations.

TABLE 2																	
INITIAL CONC.	**FINAL CONCENTRATIONS**																
	3	**6**	**9**	**12**	**15**	**18**	**21**	**24**	**27**	**30**	**33**	**36**	**39**	**42**	**45**	**48**	**51**
10,000	**.96**	**.14**	**.00**														
20,000	**1**	**.93**	**.39**	**.04**	**.00**												
30,000	**1**	**.99**	**.89**	**.56**	**.21**	**.05**	**.01**	**.00**									
40,000		**1**	**.97**	**.85**	**.62**	**.36**	**.18**	**.07**	**.03**	**.01**	**.00**						
50,000		**1**	**.99**	**.96**	**.86**	**.69**	**.49**	**.31**	**.17**	**.09**	**.04**	**.02**	**.01**	**.00**			
60,000			**1**	**.99**	**.95**	**.87**	**.73**	**.56**	**.38**	**.24**	**.13**	**.06**	**.03**	**.01**	**.00**		
70,000				**1**	**.98**	**.93**	**.84**	**.70**	**.53**	**.36**	**.22**	**.12**	**.06**	**.03**	**.01**	**.00**	
80,000				**1**	**.99**	**.96**	**.90**	**.78**	**.63**	**.45**	**.29**	**.17**	**.09**	**.05**	**.02**	**.01**	**.00**
90,000				**1**	**.99**	**.97**	**.92**	**.82**	**.68**	**.51**	**.34**	**.20**	**.11**	**.06**	**.03**	**.01**	**.00**
100,000					**1**	**.98**	**.93**	**.84**	**.70**	**.53**	**.36**	**.23**	**.13**	**.06**	**.03**	**.01**	**.00**

Highlighted areas represent a 3.52 log reduction between initial concentration and final concentration.

The original reason for using 30 samples for validation was to be able to select one each week for 30 weeks during the warm weather. This would have given an idea how the post harvest process performed under various conditions throughout the summer. In order for this to be more feasible for industry, this arrangement was changed to 10 measurements on a single lot on each of 3 days.

VERIFICATION:

After initial validation of a PHP, verification of the process must be done monthly. In the verification process, the output of the PHP is tested to determine if it is below 30 per gram. If a PHP fails verification, then it has to be revalidated in order to use labeling claims as approved by the ISSC. Any verification that is not excessively burdensome may miss some problems with the process. Consequently, if other evidence indicates a problem then action may be needed regardless of verification results.

Samples can be taken throughout a month on different lots of product. Although testing different lots could help find intermittent problems, a small processor during a slow month may not be able to test many different lots. Consequently, the decision of how many lots are tested for verification may be left up to the processor with the approval of the state SSCA.

In order to determine the probability of verification failures that would result in revalidation, 1000 simulations were run with each simulation mimicking nine months and counting the number of passes. Nine months represents the number of months in a year that oysters might be expected to have high vibrio counts. The count for 9 months that passed indicates how likely the post harvest process would be of not needing revalidation.

Based upon a verification procedure that requires 30 tubes per month be tested with no more than 11 of the 30 tubes being positive for the process to be verified for that month and assuming that all months are independent and identically distributed, the table (table 3) below indicates the probability of failing verification in at least one of nine months and at least twice in nine months for various final concentrations.

TABLE 3

Final Concentration	**Probability of 1 failure in 9 months**	**Probability of 2 failures in 9 months**
20	**4**	**0**
25	**17**	**1**
30	**45**	**11**
35	**76**	**39**
40	**93**	**73**

Example: If a final concentration of 30 has been achieved by the Post Harvest Process, there is an 11% chance that revalidation will be required based upon two verification failures within a 9 month period. Likewise, at a final concentration of 30, there is a 45% chance that one failure would occur within 9 months.

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