Requirements for the Authority

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

@.01 Outbreaks of Shellfish-Related Illness.

A. When shellfish are implicated in an illness outbreak involving two (2) or more persons not from the same household (or one or more persons in the case of paralytic shellfish poisoning [PSP]), the Authority shall determine whether an epidemiological association exists between the illness and the shellfish consumption by reviewing:
   (1) Each consumer's food history;
   (2) Shellfish handling practices by the consumer and/or retailer;
   (3) Whether the disease has the potential or is known to be transmitted by shellfish; and
   (4) Whether the symptoms and incubation period of the illnesses are consistent with the suspected etiologic agent.

   NOTE: For additional guidance refer to the International Association of Milk, Food, and Environmental Sanitarians' *Procedures to Investigate Food Borne Illness*.

B. When the Authority has determined an epidemiological association between an illness outbreak and shellfish consumption, the Authority shall conduct an investigation of the illness outbreak within 24 hours to determine whether the illness is growing area related or is the result of post-harvest contamination or mishandling.
C. When the investigation outlined in §.02B. does not indicate a post-harvest contamination problem, or illegal harvesting from a closed area, the Authority shall:
   (1) Immediately place the implicated portion(s) of the harvest area(s) in the closed status;
   (2) Notify receiving states and the FDA Regional Shellfish Specialist that a potential health risk is associated with shellfish harvested from the implicated growing area;
   (3) As soon as determined by the Authority, transmit to the FDA and receiving states information identifying the dealers shipping the implicated shellfish; and
   (4) Promptly initiate recall procedures consistent with the Recall Enforcement Policy, Title 21 Code of Federal Regulations Part 7. The recall shall include all implicated products.
D. When the investigation outlined in §.02B demonstrates that the illnesses are related to post-harvesting contamination or mishandling, growing area closure is not required. However, the Authority shall:
   (1) Notify receiving states and the FDA Regional Shellfish Specialist of the problem; and
   (2) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7. The recall shall include all implicated products.
E. When the investigation outlined in §.02B. cannot be completed within 24 hours, the Authority shall:
   (1) Follow the closure procedure outlined in § .01C; and if the investigation does not indicate a growing area problem, the area shall be immediately reopened and product recall terminated.

F. Upon closing an implicated area for problems other than natural occurring pathogens and/or Biotoxins, the Authority shall review the growing area classification and determine if a growing area classification problem exists. The review shall include at a minimum:
   (1) A review of the growing area classification file records;
   (2) A field review of existing pollution sources;
   (3) A review of actual and potential intermittent pollution sources, such as vessel waste discharge and wastewater discharge from treatment plant collection systems; and
   (4) Examination of water quality subsequent to the illness outbreak.

G. Upon closing an implicated portion(s) of the harvest area(s) for naturally occurring pathogens and/or Biotoxins, the Authority:
   (1) Shall follow an existing marine Biotoxin contingency plan, if appropriate.
   (2) Shall collect and analyze samples relevant to the investigation, if appropriate.
   (3) Shall keep the area closed until it has been determined that levels of naturally occurring pathogens and/or Biotoxins are not a public health concern.
   (4) May limit the closure to specific shellfish species when FDA concurs that the threat of illness is species specific.

H. When the growing area is determined the problem, the Authority shall:
   (1) Place the growing area in the closed status until:
      (a) The Authority verifies that the area is properly classified, using current data, in compliance with the NSSP Model Ordinance; or
      (b) Shellfish from the growing area are confirmed as the cause of illness but it has been determined that the event which caused the contamination no longer exists;
   (2) Keep the area closed for a minimum of 21 days if the illness is consistent with viral etiology; and
   (3) Develop a written report summarizing the findings of the investigation and actions taken.

I. Whenever an Authority or dealer initiates a recall of shellfish products because of public health concerns, the Authority will monitor the progress and success of the recall. The Authority will immediately notify the FDA and the Authorities in other states involved in the recall. The Authority shall submit periodic recall status reports to the FDA Regional Shellfish Specialist consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7, Subpart C, §7.53 (b) (1-6) until such time that the Authority deems the recall to be completed. Each Authority involved in a recall will implement actions to ensure removal of recalled product from the market, issue public warnings if necessary to protect public health and provide periodic reports to the Authority in the state of product origin regarding recall efforts within their state until such time that the Authority in the state of product origin deems the recall to be completed. FDA will decide whether to audit or issue public warnings after consultation with the Authority/Authorities, and after taking into account the scope of the product distribution and other related factors. If the FDA determines that the Authority in any state involved in the recall fails to implement effective actions to protect public health, the FDA may classify, publish and audit the recall, including issuance of public warnings when appropriate.

Additional Guidance - Section IV Guidance Documents
Chapter IV .03 *Vibrio* Control Plan Guidance Template

J. The Authority shall assess annually *Vibrio parahaemolyticus* illnesses associated with the consumption of molluscan shellfish. The assessment will include a record of all *V. parahaemolyticus* shellfish-associated illnesses reported within the state and from receiving states, the numbers of illnesses per event, and actions taken by the Authority in response to the illnesses.

@. 02 Presence of Human Pathogens in Shellfish Meats.

Additional Guidance - Section IV Guidance Documents
Chapter II .13 Protocol for Reviewing Classification of Area Implicated by Pathogens in Shellfish Meat Samples

A. Finding. Upon determination that human pathogens are present in shellfish meats, the Authority shall investigate the harvesting, the distribution, and the processing of the shellfish.
B. Growing Area Investigation.
    (1) The Authority shall review the following factors:
        (a) The documentation to trace the shellfish to its source;
        (b) (The classification assigned to the growing area and whether the sanitary survey data supporting that classification is current; and
        (c) The probability of illegal harvesting from areas classified as restricted or prohibited, or in the closed status.
    (2) The Authority shall take no further action when the Authority determines that:
        (a) The growing area is properly classified;
        (b) No illegal harvesting is taking place; and
        (c) There is no reason to believe that the growing area is the source of the pathogens.
    (3) When the Authority determines that the growing area is not properly classified, the Authority shall take immediate action to:
        (a) Change the existing classification to the correct classification; or
        (b) Close the growing area until the correct classification can be determined; and
        (c) Promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.
    (4) When the Authority determines that the growing area may be the source of pathogens the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7 if the pathogens exceed tolerance levels.
    (5) When the Authority determines that illegal harvesting is taking place, the Authority shall promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 Code of Federal Regulations Part 7 for all shellfish that may be falsely represented.
C. Distribution and Processing Investigation.
    (1) The Authority shall evaluate the distribution and processing of the shellfish. This investigation may include collection of additional meat samples.
    (2) The Authority shall take no further action when the Authority determines that there is no reason to believe a problem exists in the distribution or processing of the shellfish.
    (3) When the Authority determines that a problem exists in the distribution or processing of the shellfish, the Authority shall take immediate steps to correct the problem and promptly initiate recall procedures consistent with the Recall Enforcement Policy Title 21 of Code of Federal Regulations Part 7.
D. Risk Management and Tolerance Levels.

Additional Guidance - Section IV Guidance Documents Chapter II @ .04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

(1) Pathogen Present. When a growing area continues to demonstrate the presence of human pathogen isolates in shellfish meats in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification for an area.

(2) Established Tolerance Levels.

(a) When the established tolerance level for a particular pathogen isolate is not exceeded, the Authority:

(i) Shall maintain a written summary of its finding and the data supporting its finding in its central file; and

(ii) May leave the growing area in its present classification.

(b) When the established tolerance level for a particular pathogen isolate is known and there are no known outbreaks of shellfish associated disease caused by that pathogen in a particular growing area, the Authority shall:

(i) Leave the area in the open status of its classification when the tolerance level is not exceeded; and

(ii) Place the area in the closed status of its classification when the tolerance level is exceeded.

(c) When the tolerance level is exceeded, the Authority may:

(i) Maintain the growing area in the closed status of its current classification;

(ii) Reclassify the growing area to the restricted or prohibited classification; or

(iii) Reclassify the growing area to the conditionally restricted classification and establish a management plan.

(d) Any management plan based on shellstock exceeding established tolerance levels shall:

(i) Meet all appropriate requirements for a management plan for the conditionally approved or conditionally restricted classification;

(ii) Specify the additional criteria associated with the particular pathogen isolate that the growing area must meet to be in the open status of its classification;

(iii) Document the scientific basis for the additional criteria;

(iv) Provide for periodic retesting of the shellfish meats; and

(v) Provide for the growing area to be placed in the closed status if the criteria are exceeded.

(3) Established Tolerance Levels Not Known.

(a) When an established tolerance level does not exist for the particular pathogen isolated, the Authority shall assess the public health significance of the levels of the pathogen found in the growing area shellfish meats. The Authority may consider FDA recommended action levels or levels of concern in this determination. When the Authority determines that:

(i) The levels are acceptable, the growing area shall remain in the open status of its classification; or

(ii) The levels are unacceptable, the growing area shall be placed in the closed status of its classification.

(b) If a growing area is placed in the closed status, the Authority may elect to

(i) Maintain that status indefinitely;

(ii) Reclassify the area to the restricted or prohibited classification; or

(iii) Reclassify the area to the conditionally restricted classification and establish a management plan. The management plan shall meet the requirements of §D.(2)(d).

@.03 Presence of Toxic Substances in Shellfish Meats.

Additional Guidance - Section IV Guidance Documents Chapter II @ .04 Action Levels, Tolerances and Guidance Levels for Poisonous or Deleterious Substances in Seafood

A. Upon determination that toxic substances, including heavy metals, chlorinated hydrocarbons, and natural toxins are present in levels of public health significance in shellfish meats, the Authority shall investigate the harvesting, distribution, and processing of shellfish and take necessary corrective action in accordance with the procedures described in § @.02.
B. When a growing area continues to demonstrate the presence of toxic substances in the absence of illness, the Authority shall perform a risk assessment to determine the correct classification of the area. The risk assessment and subsequent risk management shall follow the procedures outlined in § @.02D., Risk Management and Tolerance Levels.

@.04 *Vibrio vulnificus* Risk Management for Oysters.

Additional Guidance - Section IV Guidance Documents Chapter IV- Naturally Occurring Pathogens

A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* Management Plan.
B. The Source State's *Vibrio vulnificus* Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness reduction program. The goal of the *Vibrio vulnificus* Management Plan will be to reduce the rate of etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters by 40 percent for years 2005 and 2006 (average) and by 60 percent for years 2007 and 2008 (average) from the average illness rate for the years 1995 -1999 of 0.303/million. The list of states (California, Florida, Louisiana, Texas) used to calculate rate reduction may be adjusted if after a thorough review, epidemiological and statistical data demonstrates that it would be appropriate. The illness rate shall be calculated as the number of illnesses per unit of population. The goal may be reevaluated prior to the year 2006 and adjusted in the event that new science, data, or information becomes available. State's compliance with the Plan will require States to maintain a minimum of 60% reduction in years subsequent to 2008. Determination and compliance after 2008 will be based on two-year averages beginning in 2009.
C. The Source State's *Vibrio vulnificus* Management Plan shall include, at a minimum:
    (1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;
    (2) A process to collected standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;
    (3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses;

(4) Identification and preparation for achieving a goal of post harvest processing capacity of 25 percent of all oysters intended for the raw, half-shell market during the months of May through September harvested from a Source State by the end of the third year (December 31, 2004). The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction;
(5) Identification and preparation for implementation of required post harvest processing capacity of 50% of all oysters intended for the raw, half-shell market during the months of May through September, harvested from a Source State, which shall be implemented should the 40 percent illness reduction goal not be achieved by December 31, 2006. The percentage of post harvest processing will include the capacity of all operational plants and the capacity of plants under construction. In the alternative, the state may utilize the control measures, or equivalent control measures, listed in @.04, (C), (6) (a), (b), (c), and (d) below for such periods of time which, in combination with post harvest processing, will provide equivalent outcomes. This portion of the plan shall be completed no later than December 31, 2005; and
(6) Identification and preparation for implementation of one or more of the following controls, or equivalent controls, which shall be implemented should the 60 percent rate of illness reduction goal not be achieved collectively by 2008. The control measures identified in the plan shall be appropriate to the state and reflect that state's contribution to the number of Vv illnesses and the controls that have been implemented by each state. This portion of the Plan shall be completed no later than December 2007. The temperature and month-of the-year parameters identified in the following controls may be adjusted by the ISSC Executive Board as recommended by the Vibrio Management Committee (VMC) on a state by state basis, as needed to achieve the established illness reduction goal. The adjustment to the State's plan can take into account the illness rate reduction that has occurred since the last review of the plan.

(a) Labeling all oysters, "For shucking by a certified dealer", when the Average Monthly Maximum Water Temperature exceeds 75°F;
(b) Subjecting all oysters intended for the raw, half-shell market to an Authority-approved post harvest processing that reduces the *Vibrio vulnificus* levels to <30 MPN/gram when the Average Monthly Maximum Water Temperature exceeds 75°F;
(c) Closing shellfish growing areas for the purpose of harvest of oysters intended for the raw, half-shell market when the Average Monthly Maximum Water Temperature exceeds 75°F;
(d) Labeling all oysters, "For shucking by a certified dealer", during the months of May through September, inclusive;
(e) Subjecting all oysters intended for the raw, half-shell market to a post harvest processing that is both approved by the Authority and reduces the *Vibrio vulnificus* levels to <30 MPN/gram during the months of May through September, inclusive; and
(f) Closing shellfish growing areas for the purpose of harvesting oysters intended for the raw, half-shell market during the months of May through September, inclusive.

Effective January 1, 2012:

@.04 *Vibrio vulnificus* Risk Management for Oysters

A. For states having 2 or more etiologically confirmed shellfish-borne *Vibrio vulnificus* illnesses since 1995 traced to the consumption of commercially harvested raw or undercooked oysters that originated from the waters of that state (Source State), the Authority shall develop and implement *a Vibrio vulnificus* Risk Management Plan.

B. The Source State's *Vibrio vulnificus* Risk Management Plan shall define the administrative procedures and resources necessary to accomplish (i.e. establish and maintain) involvement by the state in a collective illness risk reduction program. The goal of the *Vibrio vulnificus* Risk Management Plan will be to reduce the risk per serving to a 60% illness rate reduction for etiologically confirmed shellfish-borne *Vibrio vulnificus* septicemia illnesses reported collectively by California, Florida, Louisiana, and Texas, from the consumption of commercially harvested raw or undercooked oysters to a level equivalent to a 60% illness rate reduction from 1995 – 1999 baseline average illness rate of 0.278 per million.

C. The Source State's *Vibrio vulnificus* Risk Management Plan shall include, at a minimum:

(1) The ISSC Consumer Education Program targeted toward individuals who consume raw oysters and whose health condition(s) increase their risk for *Vibrio vulnificus* illnesses;

(2) A process to collect standardized information for each *Vibrio vulnificus* illness: including underlying medical conditions; knowledge of disease status; prior counseling on avoidance of high risk foods, including raw oysters; existence of consumer advisories at point of purchase or consumption; and, if possible, whether consumer was aware and understood the advisories;

(3) A standardized process for tracking products implicated in *Vibrio vulnificus* illnesses; and

(4) Identification and implementation of the controls, or equivalent controls, which produced an illness per serving equivalent to a 60% illness rate reduction in the core states.

@.05 *Vibrio parahaemolyticus* Control Plan

The goal of the Control Plan is to reduce the probability of occurrence of *Vibrio parahaemolyticus* illness during periods that have been historically associated with annual illnesses. The Plan is to be implemented as part of a comprehensive program which includes all the time and temperature requirements contained in the Model Ordinance.

A. Risk Evaluation.

Every State from which oysters are harvested shall conduct a *Vibrio parahaemolyticus* risk evaluation annually. The evaluation shall consider each of the following factors, including seasonal variations in the factors, in determining whether the risk of *Vibrio parahaemolyticus* infection from the consumption of oysters harvested from an area (hydrological, geographical, or growing) is reasonably likely to occur: (For the purposes of this section, "reasonably likely to occur" shall mean that the risk constitutes an annual occurrence)

(1) The number of *Vibrio parahaemolyticus* cases epidemiologically linked to the consumption of oysters commercially harvested from the State; and

(2) Levels of total and tdh+ *Vibrio parahaemolyticus* in the area, to the extent that such data exists; and

(3) The water temperatures in the area; and

(4) The air temperatures in the area; and

(5) Salinity in the area; and

(6) Harvesting techniques in the area; and

(7) The quantity of harvest from the area and its uses i.e. shucking, halfshell, PHP.

B. Control Plan

(1) If a State's *Vibrio parahaemolyticus* risk evaluation determines that the risk of *Vibrio parahaemolyticus* illness from the consumption of oysters harvested from a growing area is reasonably likely to occur, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan; or

(2) If a State has a shellfish growing area in which harvesting occurs at a time when average monthly daytime water temperatures exceed those listed below, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan. The average water temperatures representative of harvesting conditions (for a period not to exceed thirty (30) days) that prompt the need for a Control Plan are:

(a) Waters bordering the Pacific Ocean - 60°F.

(b) Waters bordering the Gulf of Mexico and Atlantic Ocean (NJ and south) - 81°F.

(c) However, development of a Plan is not necessary if the State conducts a risk evaluation, as described in §A., that determines that it is not reasonably likely that *Vibrio parahaemolyticus* illness will occur from the consumption of oysters harvested from those areas.

(i) In conducting the evaluation, the State shall evaluate the factors listed in §A. for the area during periods when the temperatures exceed those listed in this section;

(ii) In concluding that the risk is not reasonably likely to occur, the State shall consider how the factors listed in §A differ in the area being assessed from other areas in the state and adjoining states that have been the source of shellfish that have been epidemiologically linked to cases of *Vibrio parahaemolyticus* illness; or

(3) If a State has a shellfish growing area that was the source of oysters that were epidemiologically linked to an outbreak of *Vibrio parahaemolyticus* within the prior five (5) years, the State shall develop and implement a *Vibrio parahaemolyticus* Control Plan for the area.

(4) For States required to implement *Vibrio parahaemolyticus* Control Plans, the Plan shall include the administrative procedures and resources necessary to accomplish the following:

(a) Establish one or more triggers for when control measures are needed. These triggers shall be the temperatures in § B. (2) where they apply, or other triggers as determined by the risk evaluation.

(b) Implement one or more control measures to reduce the risk of *Vibrio parahaemolyticus* illness at times when it is reasonably likely to occur. The control measures may include:

(i) Post harvest processing using a process that has been validated to achieve a 2 log reduction in the levels of total Vibrio parahaemolyticus for Gulf and Atlantic Coast oysters and a 3 log reduction for the Pacific Coast oysters;

(ii) Closing the area to oyster harvest;

(iii) Restricting oyster harvest to product that is labeled for shucking by a certified dealer, or other means to allow the hazard to be addressed by further processing;

(iv) Limiting time from harvest to refrigeration to no more than five hours, or other times based on modeling or sampling, as determined by the Authority in consultation with FDA;

(v) Limiting time from harvest to refrigeration such that the levels of total *Vibrio parahaemolyticus* after the completion of initial cooling to 60 °F (internal temperature of the oysters) do not exceed the average levels from the harvest water at time of harvest by more than 0.75 logarithms, based on sampling or modeling, as approved by the Authority;

(vi) Other control measures that based on appropriate scientific studies are designed to ensure that the risk of *Vp* illness is no longer reasonably likely to occur, as approved by the Authority.

(c) Require the original dealer to cool oysters to an internal temperature of 50°F (10°C) or below within 10 hours or less as determined by the Authority after placement into refrigeration during periods when the risk of Vibrio parahaemolyticus illness is reasonably likely to occur. The dealer's HACCP Plan shall include controls necessary to

ensure, document and verify that the internal temperature of oysters has reached 50°F (10°C) or below within 10 hours or less as determined by the Authority of being placed into refrigeration. Oysters without proper HACCP records demonstrating compliance with this cooling requirement shall be diverted to PHP or labeled *"for shucking only"*, or other means to allow the hazard to be addressed by further processing.

(d) Evaluate the effectiveness of the Plan.

(e) Modify the Control Plan when the evaluation shows the Plan is ineffective, or when new information is available or new technology makes this prudent as determined by the Authority.

(f) Optional cost benefit analysis of the *Vibrio parahaemolyticus* Control Plan.

C. The Time When Harvest Begins

For the purpose of time to temperature control, time begins once the first shellstock harvested is no longer submerged.