

National Shellfish Sanitation Program

Guide for the Control of Molluscan Shellfish

2007

Section II. Model Ordinance

Chapter IV. Shellstock Growing Areas

[Guide Contents](#)

Requirements for the Authority

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

@.01 Sanitary Survey.

A. General.

- (1) The sanitary survey is the written evaluation report of all environmental factors, including actual and potential pollution sources, which have a bearing on water quality in a shellfish growing area. The sanitary survey shall include the data and results of:
 - (a) A shoreline survey;
 - (b) A survey of the bacteriological quality of the water;
 - (c) An evaluation of the effect of any meteorological, hydrodynamic, and geographic characteristics on the growing area;
 - (d) An analysis of the data from the shoreline survey, the bacteriological and the hydrodynamic, meteorological and geographic evaluations; and
 - (e) A determination of the appropriate growing area classification.
- (2) The sanitary survey shall be periodically updated through the triennial reevaluation and the annual review in accordance with §C. to assure that data is current and that conditions are unchanged.
- (3) The documentation supporting each sanitary survey shall be maintained by the Authority. For each growing area, the central file shall include all data, results, and analyses from:
 - (a) The sanitary survey;

Additional Guidance - Section IV. Guidance Documents

[Chapter II.03 Sanitary Survey and the Classification of Growing Waters](#)

[Chapter II.05 Management Plans for Growing Areas in the Conditional Classification](#)

[Chapter II.07 Systematic Random Sampling Monitoring Strategy](#)

- (b) The triennial reevaluation; and
 - (c) The annual review.
- (4) Wherever possible, the Authority shall provide the necessary information to Federal, State, or local agencies which have the responsibility to minimize or eliminate pollution sources identified in the sanitary survey.
- (5) The Authority shall maintain a current comprehensive, itemized list of all growing areas, including maps showing the boundaries and classification of each shellstock growing area.

B. Sanitary Survey Required.

- (1) A sanitary survey shall not be required to classify growing areas as prohibited. The findings of a sanitary survey, however, may result in a growing area being classified as prohibited.
- (2) A sanitary survey, including the triennial reevaluation, when available, of each growing area shall be required prior to:
- (a) The harvest of shellstock for human consumption; and
 - (b) The classification of a growing area as approved, conditionally approved, restricted, or conditionally restricted.

C. Sanitary Survey Performance.

- (1) A sanitary survey of each growing area shall be performed at least once every twelve years and shall include the components in §A. (1).
- (2) When a written sanitary survey report is not completed, the area shall be placed in the closed status.
- (3) The growing area classification and the supporting data from the sanitary survey shall be reviewed at least every three years.
- (a) This triennial reevaluation shall include:
- (i) A review in accordance with §C. (5) and (6) of the water quality samples;
 - (ii) Documentation of any new pollution sources and an evaluation of their effect on the growing area;
 - (iii) Reevaluation of all pollution sources, including the sources previously identified in the sanitary survey, as necessary to fully evaluate any changes in the sanitary conditions of the growing area. The reevaluation may or may not include a site visit;
 - (iv) A comprehensive report which analyzes the sanitary survey data and

makes a determination that the existing growing area classification is correct or needs to be revised; and

(v) If the triennial reevaluation determines that conditions have changed based on the information and data collected during the triennial review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.

(b) When a written triennial reevaluation report is not completed, the Authority shall place the growing area in the closed status.

(4) The triennial reevaluation may include:

(a) Inspection of wastewater treatment plants or collection of additional effluent samples to determine their impact on the growing area;

(b) Hydrodynamic studies;

(c) Additional field work to determine the actual impact of pollution sources; and

(d) Collection of additional water samples.

(5) On an annual basis, the sanitary survey shall be updated to reflect changes in the conditions in the growing area. The annual reevaluation shall include:

(a) A field observation of the pollution sources which may include:

(i) A drive-through survey;

(ii) Observations made during sample collection; and

(iii) Information from other sources.

(b) Review, at a minimum, of the past year's water quality sample results by adding the year's sample results to the data base collected in accordance with the requirements for the bacteriological standards and sample collection required in §.02;

(c) Review of available inspection reports and effluent samples collected from pollution sources;

(d) Review of available performance standards for various types of discharges that impact the growing area; and

(e) A brief report which documents the findings of the annual reevaluation.

(6) If the annual reevaluation determines that conditions have changed based on the information and data collected during the annual review and that the growing area classification is incorrect, immediate action shall be initiated to reclassify the area.

D. Shoreline Survey Requirements.

- (1) In the shoreline survey for each growing area, the Authority shall:
 - (a) Identify and evaluate all actual and potential sources of pollution which may affect the growing area;
 - (b) Determine the distance from the pollution sources to the growing area and the impact of each source on the growing area;
 - (c) Assess the reliability and effectiveness of sewage or other waste treatment systems;
 - (d) Determine if poisonous or deleterious substances adversely affect the growing area; and
 - (e) Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas.
- (2) The Authority shall assure that the shoreline survey meets the following minimum requirements:
 - (a) The boundaries, based on the area topography, of each shoreline survey area are determined by an in-field investigation which identifies only the properties with the potential to impact the shellfish waters;
 - (b) Each shoreline survey area is identified by a unique designation which results in identification of all data associated with each shoreline survey by the unique designation;
 - (c) Each shoreline survey area is investigated and pollution sources evaluated by qualified, trained personnel; and
 - (d) Documentation for each pollution source identified by the Authority as affecting a growing area includes:
 - (i) The location of the site on a comprehensive map of the survey area; and
 - (ii) The determination that the pollution source has a direct or indirect impact on shellfish waters: and
 - (e) A written summary of the survey findings.

@.02 Bacteriological Standards.

Note: The NSSP allows for a growing area to be classified using either a total or fecal coliform standard. The NSSP further allows the application of either standard to different water bodies within the state. The NSSP also allows for two sample collection strategies for the application of the total or fecal coliform standard: adverse pollution condition and systematic random sampling. The 1992 Task Force II recommended that this portion of the Ordinance be codified in two ways: a total coliform strategy and a fecal coliform strategy so that the state

<p>Additional Guidance - Section IV. Guidance Documents Chapter II.01 Total Coliform Standards</p>

may choose sampling plans on a growing area basis. Within each strategy, provisions would appear for use of both systematic and adverse pollution condition sample collection. The Ordinance has been recodified in this manner. For maximum flexibility, a state may wish to adopt the use of both standards and both sampling strategies for each standard. This codification represents the fecal coliform standards.

- A. General. Either the total coliform or fecal coliform standard shall be applied to a growing area.
- B. Water Sample Stations. The Authority shall assure that the number and location of sampling stations is adequate to effectively evaluate all pollution sources.
- C. Exceptions.
 - (1) Except for growing areas classified as prohibited, in growing areas where there are pollution sources having an impact on the water quality, a minimum of 30 samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under §.03.
 - (2) Except for growing areas classified as prohibited or when the systematic random sampling standard is applied, in growing areas where there are no pollution sources having an impact on the water quality, a minimum of 15 samples shall be required to classify any growing area not previously classified under §.03.
- D. Standard for the Approved Classification of Growing Areas in the Remote Status.
 - (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard below.
 - (2) Fecal Coliform Standard for the Remote Status. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 14 per 100 ml, and not more than 10 percent of the samples shall exceed an MPN or MF (mTEC) of:
 - (a) 43 MPN per 100 ml for a five tube decimal dilution test;
 - (b) 49 MPN per 100 ml for a three-tube decimal dilution test;
 - (c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
 - (d) 31 CFU per 100 ml for a MF (mTEC) test.
 - (3) Required Sample Collection.
 - (a) A minimum of two samples shall be collected annually.
 - (b) A minimum of the most recent 15 samples collected shall be used to calculate the median or geometric mean and percentage to determine compliance with the standard established for the approved classification of remote growing areas.

E. Standard for the Approved Classification of Growing Areas Affected By Point Sources.

- (1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §E. (2).
- (2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 14 per 100 ml, and not more than 10 percent of the samples shall exceed an MPN or MF (mTEC) of:
 - (a) 43 MPN per 100 ml for a five tube decimal dilution test;
 - (b) 49 MPN per 100 ml for a three-tube decimal dilution test;
 - (c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
 - (d) 31 CFU per 100 ml for a MF (mTEC) test.
- (3) Required Sample Collection.
 - (a) A minimum of five samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.
 - (b) A minimum of the most recent 15 samples collected under adverse pollution conditions from each sample station shall be used to calculate the median or geometric mean and percentage to determine compliance with this standard.
 - (c) Sample station locations shall be adjacent to actual or potential sources of pollution.

F. Standard for the Approved Classification of Growing Areas Affected by Nonpoint Sources.

- (1) Exception. If the tidal stage increases the fecal coliform concentration, the authority shall use sample results collected during that tidal stage to classify the area.
- (2) Pollution Sources. Growing areas shall be:
 - (a) Impacted only by randomly occurring, intermittent events; and
 - (b) Not impacted by discharges from sewage treatment facilities or combined sewer overflows.
- (3) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §E.(2) or §F.(4).
- (4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median (or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 14 per 100 ml and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

- (a) 43 MPN per 100 ml for a five tube decimal dilution test;
 - (b) 49 MPN per 100 ml for a three-tube decimal dilution test; or
 - (c) 31 CFU per 100 ml for a MF (mTEC) test.
- (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by:
- (a) Calculating the arithmetic mean and standard deviation of the sample result logarithms (base 10);
 - (b) Multiplying the standard deviation in (a) by 1.28;
 - (c) Adding the product from (b) to the arithmetic mean;
 - (d) Taking the antilog (base 10) of the results in (c) to get the estimated 90th percentile; and
 - (e) The MPN values that signify the upper or lower range of sensitivity of the MPN tests in the 90th percentile calculation shall be increased or decreased by one significant number.
- (6) Required Sample Collection.
- (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in §E. (3) for application of the standard under §E.(2).
 - (b) Systematic Random Sampling Standard. The requirement for systematic random sample collection shall be met when:
 - (i) Sample station locations are adequate to produce the data to effectively evaluate all nonpoint sources of pollution;
 - (ii) Sample collection is scheduled sufficiently far in advance to support random collection with respect to environmental conditions. Compliance requires that, prior to implementation, the schedule for random sampling shall be documented in the master file for the growing area, and if conditions at the time of scheduled sample collection are believed to be hazardous to the safety of the individuals assigned to collect samples, sample collection shall be rescheduled at a later date as soon as practical;
 - (iii) A minimum of six random samples shall be collected annually from each sample station in the growing area;
 - (iv) A minimum of two random samples shall be collected annually from each sample station in the growing area while in the inactive status. The sample collection frequency of six random samples per station per year specified under @.02F(6)(b)(iii) must resume at least six months

before an area is reactivated; and

(v) A minimum of the 30 most recent randomly collected samples from each sample station shall be used to calculate the median or geometric mean and 90th percentile to determine compliance with this standard.

(c) Transition from Adverse Pollution Condition Standard to Systematic Random Sampling Standard. If the Authority:

(i) Does not have 30 recent randomly collected sample results from each station, then the previous 15 samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum 30 sample requirement for a transition period not to exceed three years; and

(ii) Uses the transition period described in (i), as additional random samples are collected; the random samples shall replace chronologically the samples collected under adverse pollution conditions (e.g. sample 31 replaces sample 1).

G. Standard for the Restricted Classification of Growing Areas Affected by Point Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in §G. (2).

(2) Fecal Coliform Standard for Adverse Pollution Conditions. The fecal coliform median or geometric mean MPN of the water sample results shall not exceed 88 per 100 ml and not more than 10 percent of the samples shall exceed an MPN of: (a) 260 MPN per 100 ml for a five tube decimal dilution test; or (b) 300 MPN per 100 ml for a three tube decimal dilution test; or (c) 173 MPN per 100 ml for a twelve tube single dilution test.

(3) Required Sample Collection. Samples shall be collected in accordance with §E. (3).

H. Standard for the Restricted Classification of Growing Areas Affected by Nonpoint Sources and Used as a Shellstock Source for Shellstock Depuration.

(1) Exception. If the tidal stage increases the fecal coliform concentration, the Authority shall use samples collected under that tidal stage to classify the area.

(2) Pollution Sources. Growing areas shall meet the requirements in §F. (2).

(3) Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in §G. (2) or §H. (4).

(4) Fecal Coliform Standard for Systematic Random Sampling. The fecal coliform median or geometric mean MPN of the water sample results shall not exceed 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN of:

(a) 260 MPN per 100 ml for a five tube decimal dilution test; or

- (b) 300 MPN per 100 ml for a three-tube decimal dilution test.
- (5) Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in §F. (5).
- (6) Required Sample Collection.
 - (a) Adverse Pollution Condition Standard. The Authority shall collect samples in the same intensity and frequency as described in §E. (3) for application of the standard under §G. (2).
 - (b) Systematic Random Sampling Standard. The Authority shall collect samples in the same intensity and frequency, and shall apply the sample results in the manner described in §F. (6) for the application of the standard under §H. (4).

@. 03 Growing Area Classification.

- A. General. Each growing area shall be correctly classified as approved, conditionally approved, restricted, conditionally restricted, or prohibited, as provided by this Ordinance.
 - (1) Emergency Conditions. A growing area shall be placed in the closed status under §.03A(5) when pollution conditions exist which were not included in the database used to classify the area. If it is determined that an emergency condition or situation exists, then the growing area will be immediately (within 24 hours) placed in the closed status.
 - (2) Classification of All Growing Areas. All growing areas which:
 - (a) Are not subjected to a sanitary survey every twelve years shall be classified as prohibited;
 - (b) Have a sewage treatment plant outfall or other point source outfall of public health significance within or adjacent to the growing area shall have an area in the prohibited classification established adjacent to the outfall in accordance with §E. Prohibited Classification; and
 - (c) Are subjected to a sanitary survey shall be correctly classified based on the twelve year sanitary survey, and its most recent triennial or annual reevaluation when available, as only one of the following:
 - (i) Approved;
 - (ii) Conditionally Approved;
 - (iii) Restricted;
 - (iv) Conditionally Restricted; or
 - (v) Prohibited.

- (3) Boundaries. The boundaries of each classified growing area shall be delineated on charts which are:
 - (a) Of sufficient scale and detail so as to adequately describe the boundaries; and
 - (b) Maintained in the central file by the Authority.
- (4) Revision of Classifications.
 - (a) Any upward revision of a growing area classification shall be supported by an adequate sanitary survey.
 - (b) The appropriate FDA regional office shall be notified of any revision in growing area classification.
- (5) Status of Growing Areas. The status of a growing area is separate and distinct from its classification and may be open, closed or inactive for the harvesting of shellstock.
 - (a) Open Status. Except for an area in the prohibited classification, any correctly classified growing area, is normally open for the purposes of harvesting shellstock, subject to the limitations of its classification.
 - (b) Closed Status. Any classified growing area may be closed for a limited or temporary period because of:
 - (i) An emergency condition or situation;
 - (ii) The presence of biotoxins in concentrations of public health significance; or
 - (iii) Conditions stipulated in the management plan of conditionally approved or conditionally restricted areas; or
 - (iv) Failure of the Authority to complete a written sanitary survey or triennial review evaluation report.
 - (c) Reopened Status. A growing area temporarily placed in the closed status as provided in (b) above, shall be returned to the open status only when:
 - (i) The emergency situation or condition has returned to normal and sufficient time has elapsed to allow the shellstock to reduce pathogens or poisonous or deleterious substances that may be present in the shellstock to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of contaminant levels in the shellstock to pre-closure levels. In addressing pathogen concerns, the study may establish criteria for reopening based on coliform levels in the water; or
 - (ii) The requirements for biotoxins or conditional area management plans as established in §.04 and §.03, respectively, are met; and

(iii) Supporting information is documented by a written record in the central file.

(d) Inactive Status. The authority may place an approved or restricted growing area affected by non-point sources in the inactive status for up to five years when shellstock harvest is suspended or no longer occurring. Shellstock harvesting shall be closed while an area is in the inactive status. The inactive status must continue for a minimum of one year.

(i) While in inactive status, the required bacteriological sample collection under @.02F (6)(b)(iii) may be reduced to two water samples per station per year collected under the systematic random sample collection strategy. Sanitary survey reports, triennial reevaluations, and annual updates must be completed as required under @.01C.

(ii) The sample collection frequency of six random samples per station per year specified under @.02F (6)(b)(iii) must resume at least six months before an area is reactivated.

(iii) Before an area is reactivated, the results of the most recent 30 samples must be reviewed and comply with the requirements under @.02F.

(e) Remote Status. A growing area may be placed in the remote status if:

(i) A sanitary survey determines that the area has no human habitation, and is not impacted by any actual or potential pollution sources; and

(ii) The area is in the approved classification.

(f) Seasonally Remote/Approved Status. A growing area may be placed in a seasonally remote/approved status requiring two water samples per year if the following criteria are met:

(i) The area is initially classified as approved;

(ii) The closure time period is defined; and

(iii) At least one sample be taken upon reopening the area.

B. Approved Classification. Growing areas shall be classified as approved when the following criteria are met.

(1) Survey Required. A sanitary survey finds that the area is:

(a) Safe for the direct marketing of shellfish;

(b) Not subject to contamination from human or animal fecal matter at levels that, in the judgement of the Authority, presents an actual or potential public health hazard; and

(c) Not contaminated with:

- (i) Pathogenic organisms;
- (ii) Poisonous or deleterious substances;
- (iii) Marine biotoxins; or
- (iv) Bacteria concentrations exceeding the bacteriological standards for a growing area in this classification.

(2) Water Quality. The water quality in the growing area shall meet the bacteriological standards for an approved classification in §.02.

C. Conditional Classifications. Growing areas may be classified as conditional when the following criteria are met:

(1) Survey Required. The sanitary survey meets the following criteria:

- (a) The area will be in the open status of the conditional classification for a reasonable period of time. The factors determining this period are known, are predictable, and are not so complex as to preclude a reasonable management approach;
- (b) Each potential source of pollution that may adversely affect the growing area is evaluated;
- (c) Bacteriological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area.

(2) Management Plan Required. For each growing area, a written management plan shall be developed and shall include:

- (a) For management plans based on wastewater treatment plant function, performance standards that include:
 - (i) Peak effluent flow, average flow, and infiltration flow;
 - (ii) Bacteriological or viral quality of the effluent;
 - (iii) Physical and chemical quality of the effluent;
 - (iv) Conditions which cause plant failure;
 - (v) Plant or collection system bypasses;
 - (vi) Design, construction, and maintenance to minimize mechanical failure, or overloading;
 - (vii) Provisions for monitoring and inspecting the waste water treatment plant; and
 - (viii) Establishment of an area in the prohibited classification adjacent to a

wastewater treatment plant outfall in accordance with §E. Prohibited Classification;

- (b) For management plans based on pollution sources other than waste water treatment plants:
 - (i) Performance standards that reliably predict when criteria for conditional classification are met; and
 - (ii) Discussion and data supporting the performance standards.
- (c) For management plans based on wastewater treatment plant function or pollution sources other than wastewater treatment plants, criteria that reliably predict when an area that was placed in the closed status because of failure to comply with its conditional management plan can be returned to the open status. The minimum criteria are:
 - (i) Performance standards of the plan are fully met;
 - (ii) Sufficient time has elapsed to allow the water quality in the growing area to return to acceptable levels;
 - (iii) Sufficient time has elapsed to allow the shellstock to reduce pathogens that might be present to acceptable levels. Studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. The study may establish criteria for reopening based on coliform levels in the water; and
 - (iv) Shellstock feeding activity is sufficient to achieve coliform reduction.
- (d) For management plans based on a risk assessment made in accordance with Chapter II, Risk Assessment and Risk Management, criteria that reliably determine when the growing area may be placed in the open status and shellfish may be harvested;
- (e) For management systems based on marine biotoxins, the procedures and criteria that reliably determine when the growing area may be placed in the open status;
- (f) Procedures for immediate notification to the Authority when performance standards or criteria are not met;
- (g) Provisions for patrol to prevent illegal harvest; and
- (h) Procedures to immediately place the growing area in the closed status in 24 hours or less when the criteria established in the management plan are not met.

(3) Reevaluation of Conditional Classification.

- (a) The classification shall be reevaluated at least once each year. The reevaluation shall include:
- (i) Evaluation of compliance with the management plan;
 - (ii) Determination of adequacy of reporting of failure to meet performance standards;
 - (iii) Review of the cooperation of the persons involved;
 - (iv) Evaluation of water quality in the growing area with respect to the bacteriological standards for its classification;
 - (v) Field inspection of critical pollution sources, where necessary; and
 - (vi) Written findings, evaluations and recommendations.
- (b) Water Sample Collection.
- (i) When the conditional management plan is based on the absence of pollution from marinas for certain times of the year, monthly water samples are not required when the growing area is in the open status of its conditional classification provided that at least three of the water samples collected to satisfy the bacteriological standard for the open status are collected when the growing area is in the open status.
 - (ii) When the conditional management plan is based on the operation and performance of a wastewater treatment plant(s); combined sewer overflow(s); or other point sources of pollution, monthly water samples are required when the growing area is in the open status of its conditional classification.
 - (iii) If a monthly sample cannot be collected due to environmental constraints, the monthly sampling requirement will be satisfied if an additional water sampling run is conducted the following month.
 - (iv) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events, stormwater runoff, and seasonal variations, a minimum of five (5) sets of water samples (when the Adverse Pollution Condition sampling regimen is used) or six (6) sets of water samples (when the Systematic Random Sampling regimen is used) are required. The samples shall be collected when the growing area is in the open status.
 - (v) When the conditional management plan is based on the effects of non-point sources of pollution, such as rainfall events or storm water runoff, and the area is in the open status for less than six months a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). At least one (1) sample shall be collected each month the area is placed in the open

status. This sample shall be collected while the area is open. If closed status samples are used to meet the minimum sample requirements only two (2) sets of samples may be utilized and they must have been taken within five (5) days of when the Authority anticipates that the area will be placed in the open status. For growing areas in the open status less than two (2) months, at least one (1) sample must be collected while the area is in the open status. Samples collected during the closed status to meet the minimum five (5) sets of water samples shall be applied to annual and triennial reevaluations of the area.

(vi) When the conditional management plan is based on the seasonal opening and closing of the area, and the area is in the open status for a predetermined period of less than six (6) months, a minimum of five (5) sets of water samples are required (Adverse Pollution Condition and Systematic Random Sampling). All samples shall be collected while the area is in the open status unless the Authority has historical water quality data to demonstrate that the area meets open status criteria while in the closed status. If closed status samples are used to meet the minimum sample requirements they must be collected within thirty (30) days prior to the area being placed in the open status.

(4) Understanding of and Agreement With the Purpose of the Conditional Classification and Conditions of Its Management Plan by All Parties Involved.

(a) The management plan shall be developed by the Authority in coordination with:

(i) The local shellfish industry;

(ii) The individuals responsible for the operation of any wastewater treatment plants involved; and

(iii) Any local or State agencies; and

(b) Failure of any one party to agree shall constitute sufficient justification to deny the application of the conditional classification to a growing area.

(5) Conditional Area Types. There are two types of conditional areas:

(a) Conditionally approved; and

(b) Conditionally restricted.

(6) Conditionally Approved Classification. Any growing area in the conditionally approved classification shall:

(a) Meet the requirements for:

(i) An approved area classification when the conditionally approved classification is in the open status; and

- (ii) A restricted or prohibited classification when the conditionally approved classification is in the closed status; and
 - (b) If the closed status meets the criteria for the restricted classification, designate in its management plan whether the shellstock may be harvested for relaying or depuration.
- (7) Conditionally Restricted Classification. Any growing area in the conditionally restricted classification shall:
- (a) Meet the requirements for:
 - (i) A restricted classification when the conditionally restricted classification is in the open status; and
 - (ii) A prohibited classification when the conditionally restricted classification is in the closed status; and
 - (b) Designate in its management plan whether the harvested shellstock are to be relayed or depurated.

D. Restricted Classification.

(1) General

- (a) A growing area may be classified as restricted when:
 - (i) A sanitary survey indicates a limited degree of pollution; and
 - (ii) Levels of fecal pollution, human pathogens, or poisonous or deleterious substances are at such levels that shellstock can be made safe for human consumption by either relaying, depuration or low acid-canned food processing.
 - (b) The Authority shall have effective controls to assure that shellfish are harvested from restricted areas only:
 - (i) By special license; and
 - (ii) Under the supervision of the Authority.
- (2) Water Quality. Water quality in the growing area shall meet the bacteriological standards in §.02 for a growing area in the restricted classification if the growing area is used for depuration.
- (3) Shellstock Quality Criteria. The Authority shall establish shellstock quality criteria for use in placing an area in the restricted classification. Depending on the treatment process to be applied to the shellstock, the criteria shall be established in accordance with:
- (a) Chapter V. Shellstock Relaying; or

(b) Chapter XV. Depuration.

E. Prohibited Classification.

- (1) Exception. The prohibited classification is not required for harvest waters within or adjacent to marinas. The Authority, however, may use the prohibited classification for these waters.
- (2) General. The Authority shall:
 - (a) Not permit the harvest of shellstock from any area classified as prohibited, except for the harvest of shellstock for the gathering of seed for aquaculture or the depletion of the areas classified as prohibited; and
 - (b) Ensure that shellstock removed from any growing area classified as prohibited is effectively excluded from human consumption unless it is seed to be cultured as outlined in NSSP MO Chapter VI. Shellfish Aquaculture.02 Seed Shellstock.
- (3) Sanitary Survey. A growing area shall be classified as prohibited if:
 - (a) No current sanitary survey exists;
 - (b) A sanitary survey determines:
 - (i) The growing area is adjacent to a sewage treatment plant outfall or other point source outfall with public health significance;
 - (ii) Pollution sources may unpredictably contaminate the growing area;
 - (iii) The growing area is contaminated with fecal waste so that the shellfish may be vectors for disease microorganisms;
 - (iv) The concentration of biotoxin is sufficient to cause a public health risk as identified in §.04. or
 - (v) The area is contaminated with poisonous or deleterious substances causing the shellfish to be adulterated.
- (4) Risk Assessment. A growing area shall be classified as prohibited if a risk assessment performed in accordance with Chapter II, Risk Assessment and Risk Management indicates the shellstock are not safe for human consumption.
- (5) Wastewater Discharges.
 - (a) An area classified as prohibited shall be established adjacent to each sewage treatment plant outfall or any other point source outfall of public health significance.
 - (b) The determination of the size of the area to be classified as prohibited adjacent to each outfall shall include the following minimum criteria:

- (i) The volume flow rate, location of discharge, performance of the wastewater treatment plant and the bacteriological or viral quality of the effluent;
- (ii) The decay rate of the contaminants of public health significance in the wastewater discharged;
- (iii) The wastewater's dispersion and dilution, and the time of waste transport to the area where shellstock may be harvested; and
- (iv) The location of the shellfish resources, classification of adjacent waters and identifiable landmarks or boundaries.

@.04 Marine Biotoxin Control.

A. Contingency Plan.

Additional Guidance - Section IV Guidance Documents
[II.02 Guidance for Developing Marine Biotoxin Contingency Plans](#)

- (1) The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas.
- (2) The plan shall define the administrative procedures and resources necessary to accomplish the following:
 - (a) Initiate an emergency shellfish sampling and assay program;
 - (b) Close growing areas and embargo shellfish;
 - (c) Prevent harvesting of contaminated species;
 - (d) Provide for product recall;
 - (e) Disseminate information on the occurrences of toxic algal blooms and/or toxicity in shellfish meats to adjacent states, shellfish industry, and local health agencies; and
 - (f) Coordinate control actions taken by Authorities and federal agencies.
- (3) Except that the Authority shall classify as prohibited any growing areas where shellfish are so highly or frequently affected by marine biotoxins that the situation cannot be safety managed, the presence of marine biotoxins shall not affect the classification of the shellfish growing area under §.03. The Authority may use the conditionally approved classification for areas affected by marine biotoxins.
- (4) The plan may include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters or individual shellfish dealers, to allow harvesting in designated parts of a growing area while other parts of the growing area are placed in the closed status. Such controlled harvesting shall be conducted with strict assurances of safety, such as by batch release of shellfish lots only after samples of each lot are tested and found to be below the action levels

specified in Section C.

B. Marine Biotoxin Monitoring.

In those areas where toxin-forming organisms are known to occur periodically and the toxins are prone to accumulate in shellfish, and when appropriate at those times when marine biotoxins can be reasonably predicted to occur, representative samples of the water and/or shellfish shall be collected during harvest periods. The samples shall be collected from indicator stations at intervals determined by the Authority. Water samples will be assayed for the presence of toxin-forming organisms and shellfish meat samples shall be assayed for the presence of toxins.

C. Closed Status of Growing Areas.

- (1) A growing area, or portion(s) thereof as provided in §A.(4), shall be placed in the closed status for the taking of shellstock when the Authority determines that the number of toxin-forming organisms in the growing waters and/or the level of biotoxin present in shellfish meats is sufficient to cause a health risk. The closed status shall be established based on the following criteria:

PSP - cells/L n/a; 80 µg/100 grams

NSP - 5,000 cells/L or 20 MU (approximate as 80 µg/100 g)

ASP - cells/L n/a; 2 mg/100 grams (20 ppm)

- (a) The concentration of paralytic shellfish poison (PSP) equals or exceeds 80 micrograms per 100 grams of edible portion of raw shellfish; or
- (b) For neurotoxic shellfish poisoning (NSP), the harvesting of shellstock shall not be allowed when:
- (i) The concentration of NSP equals or exceeds 20 mouse units per 100 grams of edible portion of raw shellfish; or
- (ii) The cell counts for *Karenia brevis* organisms in the water column exceed 5,000 per liter; or
- (c) For domoic acid, the toxin concentration shall not be equal to or exceed 20 ppm in the edible portion of raw shellfish.
- (2) For any marine biotoxin producing organism for which criteria have not been established under this Ordinance, either cell counts in the water column or biotoxin meat concentrations may be used by the Authority as the criteria for not allowing the harvest of shellstock.
- (3) When sufficient data exist to establish that certain shellfish species can be safely exempted from the marine biotoxin contingency plan, the closed status for harvesting may be applied selectively to some shellfish species and not others.
- (4) The closed status shall remain in effect until the Authority has data to show that the toxin content of the shellfish in the growing area is below the level established for closing the area.

- (5) The determination to return a growing area to the open status shall consider whether toxin levels in the shellfish from adjacent areas are declining.
 - (6) The analysis upon which a decision to return a growing area to the open status is based shall be adequately documented.
- D. Heat Processing. If heat processing is practiced, a control procedure shall be developed. This procedure shall define the following:
- (1) Toxicity limits for processing;
 - (2) Controls for harvesting and transporting the shellstock to processor;
 - (3) Special marking for unprocessed shellstock;
 - (4) Scheduled processes; and
 - (5) End product controls on the processed shellfish.
- E. Records. The Authority shall maintain a copy of all of the following records.
- (1) All information, including monitoring data, relating to the levels of marine biotoxins in the shellfish growing areas;
 - (2) Copies of notices placing growing areas in the closed status;
 - (3) Evaluation reports; and
 - (4) Copies of notices returning growing areas to the open status.

@.05 Marinas.

- A. Marina Proper. The area within any marina which is in or adjacent to a shellstock growing area shall be classified as:
- (1) Conditionally approved;
 - (2) Conditionally restricted; or
 - (3) Prohibited.
- B. Adjacent Waters. Waters adjacent to marina waters classified under §A. may be impacted by pollution associated with the marina.
- (1) A dilution analysis shall be used to determine if there is any impact to adjacent waters.
 - (2) The dilution analysis shall be based on the volume of water in the vicinity of the marina.
 - (3) The dilution analysis shall incorporate the following:

- (a) A slip occupancy rate for the marina;
 - (b) An actual or assumed rate of boats which will discharge untreated waste;
 - (c) An occupancy per boat rate (i.e., number of persons per boat);
 - (d) A fecal coliform discharge rate of 2×10^6 fecal coliform per ninth power per day; and
 - (e) The assumption that the wastes are completely mixed in the volume of water in and around the marina.
- (4) If the dilution analysis predicts a theoretical fecal coliform loading greater than 14 fecal coliform MPN per 100 ml, the waters adjacent to the marina shall be classified as:
- (a) Conditionally approved;
 - (b) Restricted;
 - (c) Conditionally restricted; or
 - (d) Prohibited.
- (5) If the dilution analyses predicts a theoretical fecal coliform loading less than or equal to 14 fecal coliform MPN per 100 ml, the waters adjacent to the marina may be classified as:
- (a) Approved; or
 - (b) Conditionally approved.
- (6) If the Authority chooses not to determine a specific occupancy per boat rate by investigation in specific areas or sites, the Authority shall assume a minimum occupancy rate of two persons per boat.