Proposal No. 2 7 - 1 1 8

Proposal for Task Force Consideration at the ISSC 2027 Biennial Meeting *(Tab to go to next field)*	1. a. ☐ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
2. Submitter	Model Ordinance Effectiveness Review Committee
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9. Proposal Subject	Model Ordinance Effectiveness
10. Specific NSSP Guide Reference	Chapter IV. Shellstock Growing Areas
11. Text of Proposal/ Requested Action	**@.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 microbiological quality of the water. In growing areas adjacent to waste water system discharge (WWSD)s the Authority may utilize male specific coliphage (MSC) results from analysis of shellfish meat samples and the analysis of the data will be included in the sanitary survey report;** **(c) An evaluation of the effect of any meteorological, hydrographic~~dynamic~~, and geographic characteristics on the growing area; and** **(d) 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 Section C. to assure that data are 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~~Authority's file system shall include all data, results, and analyses from:** **(a) The sanitary survey reviewed and signed by the Sanitary Survey Officer;** **(b) The triennial reevaluation; and** **(c) The annual review.**

(4) **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 (12) years and shall include the components in Section A. (1).**

(2) **When a written sanitary survey report is not completed within the twelve (12) year time frame, the area shall be immediately 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 (3) years.**

(a) **This triennial reevaluation shall include:**

(i) **A water quality review in accordance with Section C. (5)(b)**

(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 WWSD 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 microbiological results by adding the year's sample results to the data base collected in accordance with the requirements for the microbiological standards and sample collection required in Section @.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.** (f) **The Authority may use MSC meat sampling data and/or MSC waste water sampling data in the annual reevaluation of (5) (b), (c), and (d) above to evaluate the viral contributions of the performance standards of WWSD impacts on shellfish growing areas. If MSC meat and/or water data are being used, the Authority shall conduct annual sample collection and analysis in determining performance standards.** (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;**

(e) **Consider the presence of domestic, wild animal or resident and migrating bird populations for possible adverse effects on growing areas; and**

(f) Conduct an assessment of pollution sources which may include:

(i) A drive-through survey;

(ii) Observations made during sample collection;

(iii) Other in-field assessments; and/or

(iv) Information from other sources.

(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 investigation which identifies 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;**

(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~~ report of the survey findings.**

E. **Sanitary surveys for Federal waters will be the responsibility of FDA. Sanitary surveys will be conducted in accordance with Chapter IV @.01, as applicable.**

@.02 Microbiological 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 (2) 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 (2) ways: a total coliform strategy and a fecal coliform strategy so that the State 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, an Authority may wish to adopt the use of both standards and both sampling strategies for

each standard. This codification represents the fecal coliform standards. Additionally, the Authority may choose to use MSC sample data in conjunction with total or fecal coliform data to evaluate areas impacted by WWSD.

A. **General. Either the total coliform or fecal coliform standard shall be applied to a growing area. The Authority may utilize MSC data in conjunction with bacteriological data to evaluate WWSD impacts on shellfish growing areas.**

B. **Water Sample Stations. The Authority shall enassure 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 thirty (30) samples, collected under various environmental conditions, shall be required to classify any growing area not previously classified under Section @.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 fifteen (15) samples shall be required to classify any growing area not previously classified under Section @.03.**

(3) **Except for offshore state waters greater than three (3) nautical miles from shore where a sanitary survey shows that there are no pollution sources that will impact the microbiological quality of the water. Offshore state waters greater than three (3) nautical miles from shore may be classified as approved.**

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 most probable number (MPN) or membrane filter (MF) (membrane-Thermotolerant *Escherichia coli* [mTEC]) of the water sample results shall not exceed fourteen (14) per 100 ml, and not more than ten (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 colony-forming units (CFU) per 100 ml for a MF (mTEC) test.**

(3) **Required Sample Collection.**

(a) **A minimum of two (2) samples shall be collected annually.**

(b) **A minimum of the most recent fifteen (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 when Evaluated for Adverse Pollution Conditions.** (1) **Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section 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 fourteen (14) per 100 ml, and not more than ten (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 (5) samples shall be collected annually under adverse pollution conditions from each sample station in the growing area.** (b) **A minimum of the most recent fifteen (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.** (4) **For Authorities utilizing MSC data in conjunction with bacteriological data to evaluate WWSD impacts, the MSC level shall not exceed fifty (50) MSC per hundred (100) grams.** F. **Standard for the Approved Classification of Growing Areas when Evaluated for 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 impacted only by randomly occurring, intermittent events.** (3) **Water Quality. The bacteriological quality of every station in the growing area shall meet the fecal coliform standard in Section E. (2) or Section 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 fourteen (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 Section E. (3) for application of the standard under Section 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 (6) random samples shall be collected annually from each sample station in the growing area;** (iv) **A minimum of two (2) 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 (6) random samples per station per year specified under @.02 F. (6)** (b) **(iii) must resume at least six (6) months before an area is reactivated; and** (v) **A minimum of the thirty (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 thirty (30) recent randomly collected sample results from each station, then the previous fifteen (15) samples collected under adverse pollution conditions may be used with the most recent random samples to meet the minimum thirty (30) sample requirement for a transition period not to exceed three (3) 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 when Evaluated for Adverse Pollution Conditions 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 Section G. (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 88 per 100 ml and not more than ten (10) percent of the samples shall exceed an MPN or MF (mTEC) of:** (a) **260 MPN per 100 ml for a five-tube decimal dilution test;** (b) **300 MPN per 100 ml for a three-tube decimal dilution test;** (c) **173 MPN per 100 ml for a twelve-tube single dilution test; or** (d) **163 CFU per 100 ml for a MF (mTEC) test.** (3) **Required Sample Collection. Samples shall be collected in accordance with Section E. (3).** H. **Standard for the Restricted Classification of Growing Areas when Evaluated for 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 Section F. (2).** (3) **Water Quality. The bacteriological quality of every sample station in the growing area shall meet the fecal coliform standard in Section G. (2) or Section H. (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 88 per 100 ml and the estimated 90th percentile shall not exceed a MPN or MF (mTEC) of:** (a) **260 MPN per 100 ml for a five-tube decimal dilution test;** (b) **300 MPN per 100 ml for a three-tube decimal dilution test; or** (c) **163 CFU per 100 ml for a MF (mTEC) test.**

(5) **Estimated 90th Percentile. The estimated 90th percentile shall be calculated by the same method described in Section 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 Section E. (3) for application of the standard under Section 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 Section F. (6) for the application of the standard under Section 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 or a portion of a growing area (harvest area) shall be placed in the closed status under Section @.03 A. (5) when pollution conditions exist which were not included in the data used to classify the area. If it is determined that an emergency condition or situation exists, then the growing area or harvest area will be immediately (within twenty-four (24) hours) placed in the closed status.**

(2) **Classification of Growing Areas. Each growing area which:**

(a) **Is not subjected to a sanitary survey every twelve (12) years shall be classified as prohibited or, if unclassified, shall be treated as prohibited for NSSP purposes; or;**

(b) **Is subjected to a sanitary survey shall be correctly classified based on the twelve (12) year sanitary survey, and its most recent triennial or annual reevaluation when available, as one (1) or more of the following:**

(i) **Approved;**

(ii) **Conditionally Approved;**

(iii) **Restricted;**

(iv) **Conditionally Restricted; and/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 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. Supporting information for all changes in the status of growing areas shall be documented by a written record in the central file.** (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 or harvest area may be closed because of:** (i) **An emergency condition or situation;** (ii) **The presence of biotoxins in concentrations of public health significance;** (iii) **Conditions stipulated in the management plan of conditionally approved or conditionally restricted areas;** (iv) **Failure of the Authority to complete a written sanitary survey or triennial review evaluation report; or** (v) **The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met.** (c) **Controlled Access Status. This status can be applied to allow harvesting in areas with biotoxin concerns where routine monitoring or pre-harvest testing is not practical.** (d) **Reopened Status. A growing area or harvest 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.** (ii)**When pathogens are of concern and the area is not impacted by human sewage, studies establishing sufficient elapsed time shall document the interval necessary for reduction of coliform levels in the shellstock to pre-closure levels. Such coliform studies may establish criteria for reopening based on coliform levels in the water.** (iii) **When poisonous or deleterious substances are the concern, sampling shall establish that poisonous or deleterious substances in shellstock do not exceed FDA action levels, tolerances and/or guidance levels and/or levels that are deemed safe through risk evaluation; or** (iv) **For emergency closures of harvest areas caused by the occurrence of raw untreated sewage or partially treated sewage discharged from a sewage collection system or WWSD:**

	a. The MSC analytical sample results in shellfish shall not exceed MSC levels established in Chapter IV @.02 E (4) or **b. Pre-determined MSC levels in shellfish established by the Authority based on studies conducted on regional species under regional conditions from shellfish samples collected no sooner than seven (7) days after contamination has ceased and from representative locations in each growing area potentially impacted or** **c. Until the event is over and twenty-one (21) days have passed; or** (v) **The requirements for biotoxins or conditional area management plans as established in Section @.04 and Section @.03, respectively, are met; and** (vi) **Supporting information is documented by a written record in the central file.** (e) **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 (5) 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 (1) year.** (i) **While in inactive status, the required bacteriological sample collection under @.02 F. (6) (b) (iii) may be reduced to two (2) 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 @.01 C.** (ii) **The sample collection frequency of six (6) random samples per station per year specified under @.02 F. (6) (b) (iii) must resume at least six (6) months before an area is reactivated.** (iii) **Before an area is reactivated, the results of the most recent thirty (30) samples must be reviewed and comply with the requirements under @.02 F.** (f) **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.** (g) **Seasonally Remote/Approved Status. A growing area may be placed in a seasonally remote/approved status requiring two (2) 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 (1) 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 judgment 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 Section @.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 factors determining the period the growing area is in open status are known and predictable and are not so complex as to preclude a reasonable management approach as determined by the Authority;** (b) **Each potential source of pollution that may adversely affect the growing area is evaluated;** (c) **When conditional management is based at least in part on predicted changes in microbiological water quality, microbiological water quality correlates with environmental conditions or other factors affecting the distribution of pollutants into the growing area; and** (d) **For Authorities utilizing MSC meat sample data, when conditional management is based at least in part on predicted changes in MSC levels, those data correlate with environmental conditions or other factors affecting the distribution and persistence of viral contaminants 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) **Microbiological 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 Section 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 WWSD function or pollution sources other than WWSD 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 reopening criteria for conditional management plans 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.** (iv) **Shellstock feeding activity is sufficient to achieve pathogen reduction.** (v) **If (i-iv) are met and if the conditional management plan closure performance standard(s) is(are) based on effects of non-point sources of pollution such as rain events and/or storm water runoff, an area may be reopened when the water quality meets classification criteria without a shellstock cleansing study.** (vi) **For conditionally managed areas based on WWSD performance standards, the Authority may utilize MSC levels in shellstock to establish that sufficient time has elapsed to allow water quality and shellstock to return to acceptable levels in growing areas adjacent to WWSD.** **a. Analytical shellstock tissue sample results shall not exceed the MSC levels established in Chapter IV@.02 E.(4); or** **b. Pre-determined MSC shellstock tissue levels established by the Authority based on studies conducted on regional species under regional conditions. These studies may establish criteria for reopening based on viral levels in the shellfish meats; or** **c. The area must be in the closed status until the**

event is over and twenty-one (21) days have passed.

(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 twenty-four (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 (3) 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 WWSD (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 except when:**

(a) Hydrographic or dilution analysis has been completed to determine the impact of a WWSD performance failure and communication requirements are documented and the WWSD operator provides immediate notification to the Authority during a performance failure; or

	(b) Mooring assessment determines the mooring area is not a pollution source. (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, storm water 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 (6) 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 WWSDs 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 (2) 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 Section @.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 gathering of seed or nursery culture for aquaculture or resource enhancement 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 complies with the criteria in NSSP Model Ordinance 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 Section @ .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 microbiological quality of the effluent. The Authority may utilize MSC waste water sample data in the determination of the performance of the sewage treatment plant;**

(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.**

F. **FDA is responsible for the classification of growing areas in Federal waters. Federal waters are classified as Approved for shellfish harvesting unless such areas are known to be polluted (i.e., microbiological, chemical, or marine biotoxin hazards) and involve commercial shellfish resources. Should FDA allow harvesting in Federal waters with known marine biotoxin hazards, the FDA will classify the harvest area in a manner equivalent to the requirements of Model Ordinance Chapter IV.**

@.04 Marine Biotoxin Control

A. **Contingency Plan.**

(1) **The Authority shall develop and adopt a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas addressing the management of PSP, ASP, NSP, diarrhetic shellfish poisoning (DSP) and azaspiracid shellfish poisoning (AZP) in the event of the emergence of a toxin-producing phytoplankton that has not historically occurred or an illness outbreak caused by marine biotoxins.**

(2) **The plan shall define the administrative procedures and resources necessary to accomplish the following:**

(a) **Initiate an emergency shellfish sampling 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 and federal partners, shellfish industry, and local health agencies;**

(f) **Coordinate control actions taken by Authorities and Federal agencies; and**

(g) **Establish reopening criteria including the number of**

samples over what period of time.

B. **Marine Biotoxin Management Plan.**
In those areas that have been implicated in an illness outbreak or where toxin-producing phytoplankton have been documented to occur, the toxins are prone to accumulate in shellfish and during times when marine biotoxins are likely to occur, representative samples of water and/or shellfish shall be collected during harvest periods in accordance with one (1) or a combination of the marine biotoxin management strategies listed below in (4). and in accordance with Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.

(1) The Authority shall develop and adopt a marine biotoxin management plan for all marine and estuarine shellfish growing areas if there is a history of biotoxin closures related to PSP, ASP, NSP, DSP and/or AZP; if toxin-producing phytoplankton have been documented to occur in the growing area; or a reasonable likelihood that biotoxin closures could occur.
(2) The plan shall define the administrative procedures and resources necessary to accomplish the following:
(a) Maintain a toxin-producing phytoplankton and/or shellfish sampling program as described below in (4). It is necessary to recognize that different marine biotoxin management strategies are essential to address specific risks as well as geographic and logistical conditions. Marine biotoxin management strategies must include an appropriate number of samples to adequately address the specific risks. Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.
(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;
(f) Coordinate control actions taken by Authorities and Federal agencies;
(g) Establish reopening criteria; and
(h) Ensure that all shellfish harvested from growing areas or portion(s) of growing areas placed in the controlled access status meets all conditions of

	harvest restrictions prior to being placed in distribution. This would include all sampling, testing or product holds. **(3) The Authority may use precautionary closures based on shellfish toxicity screening or phytoplankton sample results as defined in their marine biotoxin management plan. Precautionary closures may be lifted immediately:** **(a) if confirmatory testing using an approved method shows the level of biotoxin present in shellfish meats is not equal to or above established criteria as described below in C; or** **(b) when shellfish toxicity screening or phytoplankton sample results indicate that the precautionary closure was not necessary.** **(4) Marine biotoxin management strategies are as follows:** (a) Phytoplankton monitoring: this strategy involves a routine program for sampling growing area waters for the presence of phytoplankton species known or suspected to produce marine biotoxins. This is a complementary management strategy that enhances predictive capabilities of anticipating toxicity in shellfish and must be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans. (b) Routine shellfish toxicity monitoring: this strategy involves a routine program for sampling and testing shellfish meats for the presence of marine biotoxins. Unless species specific shellfish testing is conducted, the highest risk species shall be used. This strategy may be used in combination with other management strategies. Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans. (c) Pre-harvest shellfish toxicity testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins in the intended harvest area specifically in advance of harvest. This strategy, if used independent of any other strategy, shall permit harvest for a short period of time following testing. This strategy may be used in combination with other management strategies.

Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.

(d) Shellfish lot testing: this strategy involves sampling and testing shellfish meats for the presence of marine biotoxins on a lot basis after harvest. This strategy may be combined with a pre-harvest shellfish toxicity testing strategy, the results of which permit harvest. Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans. Lot testing may also be used on a case by case basis to clear product harvested immediately prior to a biotoxin closure if the Authority determines it is necessary.

(e) Pre-harvest shellfish toxicity screening and lot testing: this strategy requires pre-harvest shellfish toxicity screening of the intended harvest area coupled with shellfish lot testing upon landing. Specific criteria are cited in Section IV. Guidance Documents Chapter IV. Growing Areas @.04 Marine Biotoxin Control .01 Guidance for Developing Marine Biotoxin Plans.

(5) The marine biotoxin management plan shall include agreements or memoranda of understanding, between the Authority and individual shellfish harvesters, individual growers or individual shellfish dealers, to allow harvesting in a growing area that is placed in the controlled access status. Such harvesting shall be conducted with strict assurances of safety and in accordance with the marine biotoxin management strategies listed in (4).

C. **Closed or Controlled Access Status of Growing Areas.**

(1) **A growing area, or portion(s) thereof as provided in Section 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:**

(a) **PSP - 80 µg saxitoxin equivalents/100 grams**
(b) **NSP - 20 MU/100 grams (0.8 mg brevetoxin-2 equivalents/kg)**
(c) **AZP - 0.16 mg azaspiracid-1 (AZA-1) equivalents/kg (0.16 ppm)**
(d) **DSP – 0.16 mg okadaic acid (OA) equivalents/kg (0.16 ppm)**
(e) **ASP - 2 mg domoic acid/100 grams (20 ppm)**

(2) **For any marine biotoxin for which criteria have not been established under this Ordinance, either cell counts of the toxin producing organism 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 , 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.**

(7) **A growing area, or portion(s) thereof, shall be placed in the controlled access status for the taking of shellstock when the Authority determines that additional requirements are necessary to ensure the safe harvest of product. Controlled access status is a designation of an approved area or a conditionally approved area in open status. Additional requirements shall be included in harvest permit conditions. All shellstock harvested from growing areas in the controlled access status shall be tagged with Restricted Shellstock tags.**

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 conditionally approved, conditionally restricted or prohibited.**

(1) **Prior to the Authority establishing a classification of conditionally**

approved or conditionally restricted in the marina proper, a pollution assessment supporting the classification will be conducted by the authority.

(2) **The assignment of a prohibited classification within the marina proper does not require a pollution assessment by the Authority.**

B. **Adjacent Waters. Waters adjacent to marina waters classified under Section 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 x 10^9 fecal coliforms per day; and**

(e) **The assumption that the wastes are completely mixed in the volume of water in and around the marina.**

(f) **Documentation, verification and enforcement of Federal No Discharge Zones and locally well enforced no discharge and occupancy by-laws and regulations.**

(g) **Availability and documented use of pump out boats or facilities.**

(4) **If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (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 fourteen (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 (2) persons per boat.**

@.06 Mooring Areas

A. Mooring Area. The area within any designated mooring area, where there is anchoring of boats, which is in or adjacent to a shellstock growing area shall be classified as conditionally approved, conditionally restricted, restricted or prohibited.

(1) Prior to the Authority establishing a classification of conditionally approved or conditionally restricted or restricted in the mooring area proper, a pollution assessment supporting the classification will be conducted by the authority. The assessment shall include:

	(a) Boat type and usage (b) Density of boats (c) Accessibility to boats which could reduce likelihood of overnight occupancy. (d) Occupancy rates (e) Seasonal Use Pattern (f) An actual or assumed rate of boats which will discharge untreated waste (g) Documentation, verification and enforcement of federal No Discharge Zones, and locally well enforced no discharge and occupancy regulations or by-laws. (h) Availability and documented use of pump out boats. (2) After assessment determines that the mooring area is not a pollution source and it is documented in the Conditional Area Management Plan, the area can be placed in the open status. **(3) The assignment of a prohibited classification within the mooring area proper does not require a pollution assessment by the Authority.** B. Adjacent Waters. Waters adjacent to open water mooring areas classified under Section A. may be impacted by pollution associated with the mooring areas. If determined a pollution source: (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 mooring areas. (3) The dilution analysis shall incorporate the following: (a) An occupancy rate for the mooring areas; (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 2×10^9 fecal coliform per day; and (e) The assumption that the wastes are completely mixed in the volume of water in and around the open water mooring areas. (4) If the dilution analysis predicts a theoretical fecal coliform loading greater than fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas shall be classified as: (a) Conditionally approved; (b) Restricted; (c) Conditionally restricted; or (d) Prohibited. (5) If the dilution analyses predict a theoretical fecal coliform loading less than or equal to fourteen (14) fecal coliform MPN per 100 ml, the waters adjacent to the mooring areas may be classified as: (a) Approved; or (b) Conditionally approved.
12. Public Health Significance	N/A

13. Cost Information	N/A
14. Changes Needed to Guidance (if proposed change is adopted)	N/A