

Section IV. Guidance Documents**Chapter II. Growing Areas**

Page 1 of 7

.05 Management Plans for Growing Areas in the Conditional Classification

NSSP guidance documents provide the public health principles supporting major components of the NSSP and its Model Ordinance, and summaries of the requirements for that component. NSSP Model Ordinance requirements apply only to interstate commerce although most states apply the requirements intrastate. For the most up to date and detailed listing of requirements, the reader should consult the most recent edition of the Model Ordinance.

The goal of the NSSP is to control the safety of shellfish for human consumption by preventing its harvest from contaminated growing areas. In implementing this goal, the NSSP uses five classifications for growing areas: approved, conditionally approved, restricted, conditionally restricted, and prohibited. The placement of a growing area in any one classification is based upon the growing area's conformance with the requirements established for that classification. For a full explanation of this concept, see the public health explanation in NSSP Guidance Document, *Sanitary Survey and the Classification of Growing Waters* (ISSC/FDA, 2002).

The conditional classifications are designed to address growing areas that are subject to intermittent microbiological pollution. These classifications offer the Authority an alternative to placing the area in the restricted or prohibited classification year round when during certain times of the year or under certain conditions, the shellstock from the growing area may be safely harvested. Public health protection from unsafe shellfish in the use of the conditional classifications is afforded through the use of a management plan. Using a thorough investigation conducted as part of the sanitary survey, the Authority determines that the growing area will be in the open status of its conditional classification for a reasonable period of time; that the factors which determine this period of time are known, predictable and are not so complex that the factors cannot be reasonably managed; and that the bacteriological water quality can be correlated with the factors affecting the distribution of pollutants in the growing area. The management plan for each growing area placed in a conditional classification is based on the information gathered during the investigation. The plan establishes a strict set of criteria, which must be met for the growing area to remain in the open status. Failure to meet the criteria automatically places the growing area in the closed status, with immediate notice to the public, the affected industry, and the plan's participants. Two of the most important components of the management plan are the acceptance of and the agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved; and the annual reevaluation of the compliance with the plan to assure public health protection.

The criteria for the approved classification of the NSSP require that the growing area not be subject to human or animal fecal matter at levels that present an actual or potential public health risk, and not be contaminated with pathogenic organisms, poisonous or deleterious substances or marine biotoxin. From the review of growing area classifications and sanitary surveys conducted by national and international Authorities, it appears that a common misuse of the approved classification is the placement of a growing area in the approved classification when the use of the conditionally approved classification would have been more appropriate. Critical investigation usually reveals that the growing area is improperly classified

because it is subject to intermittent pollution events, which is a contravention of the criteria for the approved classification.

Intermittent pollution events have been identified as a significant cause of shellfish-borne infectious disease outbreaks worldwide. As an example, in the fall of 1982, at least 471 persons developed gastroenteritis after consumption of sewage contaminated oysters from a growing area that had been placed in the approved classification (Casper, 1982). An investigation into the outbreak demonstrated that the growing area could probably be safely open to harvesting in the summer when the prevailing winds are southerly and tides are high. In the late fall, the arrival of cold fronts can cause high rainfall, strong winds and abnormally low tides and raw sewage bypasses from overloaded sewage treatment plants. Under these conditions, sewage reached the growing area causing the outbreak. As a result of the investigation, the Authority learned that it should have placed the growing area in the conditionally approved classification and developed a management plan to automatically close the area in the late fall through spring when climatic conditions were likely to render the growing area unsafe. Under the management plan, the area would be reopened to harvesting in the summer when favorable conditions prevailed and would be intensively monitored to ensure that the summer conditions were met. In this instance, application of the conditionally approved area concept probably could have prevented the outbreak.

Use of the Conditional Classification

Use of the conditional classifications is a voluntary option for the Authority. There are two types of conditional areas: conditionally approved and conditionally restricted. Any growing area in the conditionally approved classification must meet the criteria for the approved classification when it is in the open status of this classification. When the growing area is in the closed status of this classification, it may be used for relaying or depuration if it meets the requirements for the restricted classification and if this use is specified in its management plan, or it may be closed to any use. Any growing area in the conditionally restricted classification must meet the criteria for the restricted classification when it is in the open status of this classification and no harvesting is permitted when it is in its closed status.

Growing areas that are subject to intermittent microbiological pollution from predictable pollution events may be placed in the conditionally approved or conditionally restricted classification under the NSSP. Examples of predictable pollution events include the failure of wastewater treatment facilities to maintain a performance standard needed to maintain an established effluent quality; changes in seasonal populations affecting growing area water quality; and nonpoint source pollution events such as caused by as certain rainfall intensities. Conditional classifications may also be used to manage growing areas affected by toxigenic micro-algae that produce marine biotoxins.

An example of a common situation where use of the conditionally approved classification might be appropriate is when water quality is dependent upon the operation and performance of a sewage treatment plant. In this example, the growing area would meet the criteria for the approved classification when the sewage treatment plant is performing satisfactorily. If there is some interruption in sewage treatment, the likely result will be degradation of water quality in the growing area. This degradation would require the establishment of a prohibited area large enough to dilute and assimilate the effluent discharged during the interruption in treatment. If an interruption can be predicted and is at a manageable frequency necessitating repeated closings (e.g. one or two times a year), the Authority may consider a conditionally approved classification for a portion of the growing area classified as prohibited. Interruptions could include a disinfection failure or certain climatic conditions which are known to affect the wastewater treatment facility's performance). Although many Authorities are burdened by administrative procedures, the use of a management plan for the conditional classification allows the Authority to act quickly to

implement closures, and avoid unnecessary delays in returning the conditionally approved portion of the growing area to the open status. The added administrative burden might be offset by the shellfish resource gained by upgrading a prohibited portion of a growing area to the conditionally approved classification.

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

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

* The water quality in a protected harbor in a sparsely settled area, which provides anchorage for a fishing fleet several months a year, might vary. When the fishing fleet is in the harbor, the water might be of poor sanitary quality. The area would be closed for shellstock harvesting when the fishing fleet is using the harbor. During the remainder of the year, however, the quality of the harbor water might meet the criteria for the approved classification and be opened to shellstock harvesting.

* The water quality in an area may fluctuate with the discharge of a major river, or rainfall in the area may cause runoff of pollutants from adjacent land surfaces (non-point pollution) into the growing area. During periods of low runoff or river discharge, the area might meet the criteria for the approved classification.

The use of the conditional classification option offers the Authority the ability to increase the availability of water for shellfishing that would otherwise be closed. The management plan dictates the circumstances and procedures for immediate response to situations requiring closure. The administrative procedures included in the management plan allows the Authority to reopen the area to harvesting as soon as the pollution condition is over and the water quality and shellstock have returned to acceptable quality.

Suitability of the Conditional Classification

The first step is to determine, through a thorough investigation conducted as part of the sanitary survey, if the growing area is suitable for conditional management by evaluating the potential sources of pollution in terms of their effect on water quality. Information must be gathered to support the supposition that the growing area will be in the open status of its conditional classification for a reasonable period of time; that the pollution events which determine this period of time are known, predictable and are not so complex that the factors of these events cannot be reasonably managed; and that the bacteriological water quality can be correlated with the factors affecting the distribution of pollutants in the growing area. The investigation may also consider relevant resource management, social, economic, or political factors that may influence the open and closed periods, and the establishment of boundaries, for the conditional classification of a growing area. The management plan for each growing area placed in a conditional classification is based on the information gathered during the investigation. Some potential sources of pollution which could be managed under a conditional classification management plan include: bypasses and overflows within a sewage collection and treatment system, intermittent discharges from boats, seasonally related pollution occurrences, animals, land runoff, and freshwater flows.

The second step in determining the suitability of conditional classifications is to determine whether the Authority has sufficient resources available to survey, manage, monitor, control harvesting, close and

reopen the area as required. Use of these classifications imposes additional manpower and resource burdens on the Authority. For example sources of pollution must be routinely monitored; coordination between state, local and industry officials must be timely; performance standards must be monitored; and closures must be immediate and effective. Any Authority that has elected to use the conditionally approved or conditionally restricted classifications has found the resource investment to be substantial and this investment must be balanced against the benefit of the additional shellfish resource available.

The third step is to evaluate each source of pollution in terms of the pollution load and to determine if performance standards can be formulated for each pollution source having a significant effect on the sanitary quality of the growing area. The conditional classification management plan must establish a strict set of criteria, which must be met for the growing area to remain in the open status. The following are examples of different types of performance standards that could be used:

* Performance standards might stipulate the bacteriological quality of effluent from sewage treatment plants. The microbiological quality can be monitored in terms of disinfection residual or dosage for ultraviolet light disinfection. An example of a performance standard for an effluent discharge is: "The median fecal coliform MPN, in any one month, shall not exceed 200 per 100 ml, based on not less than 16 samples per month, and not more than 10 percent of the samples shall have an MPN in excess of 1,000 per 100 ml. This fecal coliform limit shall be presumed to be met if the chlorine residual in the effluent is at least 1.0 ppm and the chlorine residual in the effluent is continuously recorded on a chart by chlorine residual analyzer or is measured hourly and recorded in the daily monitoring records as required for the plant's NPDES permit."

* For disinfection by ultraviolet (UV) light, the disinfection is based on dosage. An example of a performance standard is, "A minimum UV dose of 37 mW-Sec/cm² is to be maintained. The calculation of intensity of the UV light is to include factors for effluent quality, including turbidity, suspended solids, and transmittance. The effluent factors contributing to the dose, including turbidity, suspended solids, transmittance, and flow will be continuously measured and recorded. An alarm will be activated if any of the factors are above design limits."

* Performance standards might be based upon the amount of vessel traffic in the area and the concomitant amount of sewage that can be expected.

* Performance standards might be based upon the amount of rainfall in the immediate area. An example is: "The growing area will be closed to harvesting for (number of days) when there has been 2 inches or more rainfall registered at a rain gauge at (specified location) within a 24-hour period."

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

The design of a waste treatment plant and the plant effluent specifications are critical to the use of the conditional classifications. Design criteria which may be useful in determining the quality of sewage which can be discharged into an area without exceeding the desired water quality standards include: population equivalent (fecal coliform) of sewage, predicted survival of fecal coliform in seawater, effectiveness of disinfection and the amount of clean dilution water in an area.

The mechanical equipment at critical sewage treatment or plant components should be such that interruptions will be minimized. Requirements, which might be imposed, depend upon the importance of

the unit's relationship to maintenance of water quality in the growing area. Important design features, which should be considered in the design of the sewage collection system, include:

- * Exclusion of storm water runoff from sewer collection systems and use of devices such as flow equalization tanks to control effects of storm water infiltration on treatment plant performance;
- * Provision of stand by power at critical sewage pumping stations through the use of on-site emergency generators, or other alternate power sources;
- * Use of gauges, charts and other recording devices to monitor flows and performance standards; and
- * Use of alarms, telemetering or other devices to report immediately failure of any critical components at the wastewater treatment plant and in the collection system at sewage pumping stations.

A detailed discussion of ways to increase the reliability of sewage treatment plants can be found in *Protection of Shellfish Waters* (USEPA, 1974) and *Design Criteria for Mechanical, Electric and Fluid System Component Reliability* (USEPA, 1974).

The fourth step is to determine the water quality, which will occur in the growing area when the performance standards are not met, and what portion of the growing area will be affected. Once these determinations are made, the Authority can select the appropriate management strategy for the portion of the growing area that will be placed in the closed status when performance standards are not met, and can select the boundaries for the closed status. The boundaries of that portion of the growing area to be placed in the closed status would depend upon such items as the distance and travel time from the pollution source to the area, the concentration of pollutants in the discharge during the breakdown condition, amount of effluent and hydrographic factors including dilution available in the receiving water.

The use of the conditional classification where a sewage treatment plant is the pollution source being managed requires a fifth step. An area in the prohibited classification (closed safety zone) must be established between the sewage treatment plant and the growing area placed in the conditionally approved or conditionally restricted classification. The size of the prohibited area should be based on the level of sewage treatment; the total time it would take for the person responsible for the operation of the sewage treatment facility to detect a failure and notify the Authority; and the time it would take the Authority to issue a notice to stop shellstock harvesting. The size of the area in the prohibited classification should allow for a effluent travel time through the prohibited area that is at least twice that required for the notification process to become effective. Due consideration should be given to the possibility that emergency actions might be necessary on holidays or at night. A minimum effluent dilution is to be determined at the prohibited boundary and can be the controlling factor in situations where there is efficient detection and notification of breakdowns.

The length of time that a growing area should be in the closed status of its conditional classification will depend upon several factors. These factors include the degree of pollution in the growing area and flushing capacity of the estuary, the species of shellfish, water temperature, shellstock activity and cleansing rates, and presence of silt or other chemicals that might interfere with the physiological activity of the shellstock. Additional information on the natural cleansing of shellstock is provided in the NSSP Guidance Document, *Shellstock Relay* (ISSC/FDA, 2002).

Minimum Requirements for a Conditional Area Management Plan

The management plan for a growing area in the conditionally approved or conditionally restricted classification must meet certain minimum requirements to ensure that the safety of the shellfish for

human consumption is maintained. The use and success of the conditional classification depends upon a thorough and accurate management plan. Therefore, it is important that all aspects of the management plan be fully considered and implemented. The minimum requirements to be addressed are:

- A. An understanding of and agreement to the conditions of the management plan by the one or more Authorities involved, other local, state and federal agencies which may be involved, the affected shellfish industry, and the persons responsible for the operation of any treatment plants or other discharges that may be involved;
- B. A written management plan for the growing area being placed in the conditional classification, which includes a general description of the growing area with a map showing the area's boundaries, and which addresses all items in C through H;
- C. A sanitary survey that shows the growing area will be in the open status of its conditional classification for reasonable periods of time. The survey must provide a description of the factors determining the growing area's suitability for being classified conditionally approved or conditionally restricted, and the supporting information and data.
- D. A description of the predictable pollution event or events that are being managed and the performance standards established for each pollution source contributing to the pollution event including:
 - (1) For a wastewater treatment facility, the performance standard should be based on:
 - * Peak effluent flow
 - * Bacteriological quality of the effluent
 - * Physical and chemical quality of the effluent
 - * Bypasses from the treatment plant or its collection system
 - * Design, construction, and maintenance to minimize mechanical failure or overloading (i.e. The reliability of the treatment system and collection system components)
 - * Provisions for verifying and monitoring efficiency of the wastewater treatment plant and the feedback system for addressing inadequate treatment.
 - * Identification of conditions that lead to wastewater treatment plant failure and closure of the conditionally approved area.
 - (2) For meteorological or hydrological events, the performance standard should be based on:
 - * Identification of the specific meteorological and/or hydrologic event that will cause the growing area to be placed in the closed status;
 - * Discussion and data analyses concluding that effects on water quality from these specific meteorological and/or hydrologic events are predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for the growing area placed in the conditional classification; and
 - * The predicted number of times, based on historical findings, that the pollution event will occur within one year.
 - (3) For seasonal events, such as marina operation, seasonal rainfall, and waterfowl migration, the performance standard should be based on:
 - * Identification of the seasonal event that will cause the growing area to be placed in the closed status, including its estimated duration; and
 - * Discussion and data concluding that the seasonal event is predictable, and that the data are sufficient to establish meaningful performance standards or criteria for the establishment and implementation of a management plan for a growing area placed in the conditional classification;
- E. A description of the plan for monitoring water quality including numbers and frequency;

- F. A description of how the closed status for the conditional classification will be implemented, which must include:
- (1) A clear statement that when the performance standards are not met, the growing area will immediately be placed in the closed status;
 - (2) A requirement to notify the Authority or Authorities that the management plan performance standards have not been met, including:
 - * The name of the agency or other party responsible for notifying the Authority;
 - * The anticipated response time between the performance standards not being met and notification of the Authority; and
 - * The procedures for prompt notification including contingencies such as night, weekend and absences of key personnel;
 - (3) A description of the implementation and enforcement, including:
 - * The response time between the notification to the Authority of the failure to meet performance standards and activation of the legal closure of the growing area by the Authority;
 - * The procedures and methods to be used to notify the shellfish industry; and
 - * The procedures and methods to be used to notify the patrol agency (enforcement agency) including:
 - The name of the responsible patrol agency;
 - The anticipated response time between the Authority's legal closure of the growing area and notification of closure to the patrol agency; and
 - A description of the patrol agencies anticipated activities to enforce the closed status.
- G. A description of the criteria that must be met prior to reopening a growing area in the closed status, including the need to determine that:
- (1) The performance standards established in the management plan are again fully met;
 - (2) The flushing time for pollution dissipation is adequate;
 - (3) A time interval has elapsed which is sufficient to permit reduction of human pathogens as measured by the coliform indicator group in the shellstock;
 - (4) Where necessary, the bacteriological quality of the water must be verified; and
 - (5) Shellstock feeding activity is sufficient to achieve reduction of pathogens to levels present prior to the pollution event.
- H. A commitment to a reevaluation of the management plan at least annually using, at a minimum, the reevaluation requirements in the NSSP Model Ordinance.

References

1. Casper, Victor L. 1982. *Memorandum, Quarterly Report - Shellfish, October 1, 1982 Through December 31, 1982; Oyster Related Gastroenteritis Outbreaks*. U.S. Food and Drug Administration, Washington, D.C.
2. Interstate Shellfish Sanitation Conference. 2002. Sanitary Survey and the Classification of Growing Waters. In ISSC (ed.), *NSSP Guide for the Control of Molluscan Shellfish*. Interstate Shellfish Sanitation Conference, Columbia, SC.
3. Interstate Shellfish Sanitation Conference. 2002. Shellstock Relay. In ISSC (ed.), *NSSP Guide for the Control of Molluscan Shellfish*. Interstate Shellfish Sanitation Conference, Columbia, SC.
4. U.S. Environmental Protection Agency. 1974. *Design Criteria for Mechanical, Electric, and Fluid System and Component Reliability*. EPA 430/9-74-001.
5. U.S. Environmental Protection Agency. 1974. *Protection of Shellfish Waters*. Office of Water Program Operations. EPA 430/9-74-010.