

National Shellfish Sanitation Program
Guide for the Control of Molluscan Shellfish
2007

FDA MANUAL OF INTERPRETATIONS
Interpretation Number: 07-IV-@.02-100

[Guide Contents](#)

National Shellfish Sanitation Program
U.S. Food and Drug Administration
Shellfish Safety Team
Division of Cooperative Programs
Office of Compliance

Date: January 4, 1995
Reissued: January 19, 2001
Revised: December 8, 2002

Model Ordinance Chapter IV @.02 D. (3) (a)

Reference: Chapter IV @.02 E. (3) (a)

Key Words: Water Samples; Time Interval; Adverse Pollution Conditions; Remote Areas

Question: What is the acceptable time interval between water quality samples collected from approved growing areas when using adverse pollution condition monitoring (IV @.02 E. (3) (a)), or an approved area designated as remote (IV @.02 D. (3) (a))?

Interpretation:

In accordance with Chapter IV @.02 E. (3) (a) and Chapter IV @.02 F. (6) (a), approved areas monitored under adverse pollution conditions shall have a minimum of five (5) samples collected annually from each station in the growing area. Samples shall be collected at intervals, which distribute them over a twelve (12) month period unless it can be demonstrated through data analysis that adverse pollution conditions are represented by a shorter time period. In this case, sampling may be limited to the reduced time period and shall include a minimum of five (5) samples representative of the adverse pollution condition. Sample collection shall be timed to distribute samples over the entire reduced monitoring period.

In accordance with Chapter IV @.02 D. (3) (a), approved areas designated as remote shall have a minimum of two (2) samples collected annually from each station in the area. Ideally, sample

collection shall be timed to distribute samples over a twelve (12) month period. If the two-sample minimum is incorporated by the SSCA, then sample collection shall occur at a frequency of one (1) sample every six (6) months.

It is always the option of the SSCA to collect more than the minimum number of samples required by the Model Ordinance. When the SSCA elects to collect more than the minimum requirement, it is recommended that additional samples be distributed over a twelve (12) month period.

The Model Ordinance neither intends nor implies that sample collection be performed in a manner which results in multiple samples per sampling station visit or multiple samples over several consecutive days or weeks.

Rationale:

Although the Model Ordinance is not specific concerning the time interval between sample collection for adverse pollution condition monitoring in approved areas, or for approved areas designated as remote, it is a basic premise of the NSSP to coordinate sample collection to provide data representative of water quality over time. Collection of multiple samples on the same day or over brief time intervals negates the intent of the Model Ordinance and the SSCA's ability to evaluate data associated with changing environmental conditions.

Supportive documentation is found in Chapter IV @.03 C. (3) (b) (ii), which states that for conditionally approved areas, "monthly water samples are required when the growing area is in the open status of its conditional classification." Here, emphasis is placed on the need to sample monthly, qualifying the Model Ordinance intent to sample at discrete time intervals necessary to provide representative temporal data. Chapter IV @.02 F. (6) (b) (iii), specifies the requirements for systematic random sampling, stating, "A minimum of six (6) random water samples shall be collected annually from each sample station in the growing area" and Chapter IV @.02 F. (6) (b) (ii) states that "Sample collection shall be scheduled sufficiently far in advance to support random collection with respect to environmental conditions." By design, this strategy provides for the sampling of an area over a twelve (12) month period to ensure collection under varying environmental conditions.

Contact:

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway (HFS-628)
College Park, MD 20740

Distribution:

Shellfish Specialists
Regional Federal State Program Managers
Division of Federal State Relations
Shellfish Sanitation Group/ Office of Seafood
SPIB Northeast Technical Unit
Interstate Shellfish Sanitation Conference