

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

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**FDA MANUAL OF INTERPRETATIONS**  
**Interpretation Number: 07-I-@.02-101**

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

**Date: November 5, 2004**  
**Final: March 25, 2005**

**Interpretation Number: 07-I-@.02-101**

**Model Ordinance Reference: Chapter I@02.F (1)**

**Key Words:** Inspections, unannounced, announced

**Question:** The USFDA did not concur with ISSC adoption of Proposal 03-200. The FDA indicated that states presently have the discretion to schedule inspections when unannounced visits are not successful. The ISSC Executive Board and FDA agreed that resolution of the issue of unannounced inspections could be accomplished by the development of an NSSP interpretation acknowledging state discretion.

**Interpretation:** The Authority shall make unannounced inspections of the dealer's facilities unless extenuating circumstances exist that would preclude this. Such extenuating circumstances are to be determined by the Authority, at their discretion, as long as documentation detailing the extenuating circumstances is maintained and the minimum inspection frequencies stipulated in §(1)(b) are met.

**Rationale:** Unannounced inspections for HACCP and/or sanitation based food processing inspection programs always offer the best evaluation of a firm's compliance with the rules and regulations that apply to a process. For dealers regulated by the NSSP, the same reason for unannounced inspections applies to shellfish facilities. The Authority should make every effort to conduct unannounced inspections at shellfish facilities. It is

recognized, however, that there are times when unannounced inspections may not be feasible, or may create undo hardship on the Authority's shellfish inspection program. In all cases, professional judgment should be used in determining when it is appropriate to announce an inspection, and announced inspections should only be conducted when other options have been exhausted.

Examples of instances where announced inspections should be considered include:

- (A) When inspection staff members repeatedly have been unable to make contact with a facility operator in order to conduct an inspection during operating hours (such as may occur with small staffed operations that open intermittently, operations that open only seasonally, or facilities that are open only during certain occasions);
- (B) A dealer's facility is located a considerable distance from the inspector's office, such that coordination is needed to ensure that the facility will be open and operating during an inspection visit, thereby ensuring that the inspector can manage his/her workload and travel funds without wasting the Authority's personnel time or budget.

**Other References:** None

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