

Interpretation Number: 09-I-@.02-100

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

Date: July 15, 1994
Revised: December 8, 2002

Model Ordinance

Reference: Chapter I @.02 A. (1)
NSSP Guidance Document -
Shellfish Plant Inspection Standardization Procedures

Key Words: Standardization, Limited, Officers

Question: What procedures are to be used to standardize a State Shellfish Standardization Officer in jurisdictions which have less than five (5) dealers to certify for the ICSSL?

Interpretation:

**OPTIONS FOR STANDARDIZING STATE SHELLFISH STANDARDIZATION OFFICERS
WITHIN JURISDICTIONS WITH FEWER THAN 5 CERTIFIED DEALERS**

1. Determine the number of intrastate shellfish dealers not listed on the ICSSL and include as many as necessary to obtain the minimum 5 inspections. All certified dealers must be included in the sample.
2. Arrange to conduct standardization inspections in another jurisdiction, using as many certified dealers as necessary to complete the exercise. All certified dealers within the candidate's home state must be included in the sample. This exercise must be conducted with an FDA Standardization Officer.
3. If options 1 or 2 are possible, they must be selected before pursuing option 3. When the Regional Shellfish Specialist agrees that option 1 or 2 cannot be utilized, the FDA Standardization Officer and the State Candidate will inspect all interstate and intrastate dealers within the state. If this number of dealers equals less than 5, the standardization exercise will be based upon the inspection of the number of available plants. However, the Candidate must achieve 80% agreement on EACH inspection. The FDA Standardization Officer shall review annually the number of dealers available within the jurisdiction and standardize the State Shellfish Officer using 5 dealers whenever they become available. The State Shellfish Officer shall make every effort to achieve standardization using 5 dealers. If a State Shellfish Standardization Officer

standardized under this option relocates to another state with five (5) or more dealers, that Officer must be restandardized by the Regional FDA Shellfish Specialist through field standardization using 5 dealers.

IN ALL OF THE ABOVE OPTION CASES, THE STATE SHELLFISH STANDARDIZATION OFFICER CANDIDATE MUST SUCCESSFULLY COMPLETE THE FDA CLASSROOM TRAINING PORTION OF THE STANDARDIZATION PROCESS.

4. A state may choose to contract with another state which has a recognized State Standardization Officer to conduct routine and pre-certification inspections.

Rationale:

NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures, in the Guide for the Control of Molluscan Shellfish, establishes the procedures for measuring the training and performance of an applicant to become a standardized State Shellfish Officer or Plant Inspector. NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures requires that, during the plant inspection phase of standardization, a minimum of 8 plants be jointly inspected by the FDA Standardization Officer and the candidate for State Shellfish Officer. Three of the 8 plant inspections are considered to be a review or warm-up inspections, and 5 inspections are counted as the official number of inspections for the standardization process.

However, several states and foreign countries that participate in the ISSC and want to list firms on the ICSSL have fewer than 5 plants within their jurisdiction. Therefore, they are unable to follow the procedures set forth in NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures to standardize a State official. NSSP Guidance Document - Shellfish Plant Inspection Standardization Procedures addresses this issue vaguely, stating that, "For states that do not have 8 plants, all of the available plants must be inspected with the Standard determining the appropriate review number."

To clarify this issue, FDA offers the above options. Election of any option will:

- Meet the intent of the standardization procedures;
- Maintain uniform requirements for Standardized State Officers; and
- Uphold the criteria for listing dealers on the ICSSL.

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