

National Shellfish Sanitation Program

Guide for the Control of Molluscan Shellfish

2007

Section IV. Guidance Documents

Chapter I. General

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.01 EVALUATION STANDARDS

Background: 1995 Evaluation Standards Committee

As the result of an issue submitted at the 1994 ISSC annual meeting, the 1995 ISSC Evaluation Standards Committee was created. The Committee was charged with reviewing the standards of the Evaluation Research Society and making a recommendation to the ISSC as to whether these standards should be included in the NSSP and the form the inclusion should take. The Committee reviewed these standards as well as the American Evaluation Association's (AEA) *Guiding Principles for Evaluators*. The Committee recommended that the ISSC adopt the five principles of the AEA. The Committee consensus was that these principles should apply to all participants of the ISSC and should be included in the FDA state program evaluation manual currently in development. The Committee also submitted a resolution to the ISSC voting delegates recommending that the principles be adopted by the ISSC and that FDA incorporate these principles into its state program evaluation manual. The ISSC adopted the both the Committee's recommendation and resolution at its 1995 Annual meeting for use in the NSSP.

Evaluation Standards

In 1995, at its Annual Meeting, the ISSC adopted the following principles of the American Evaluation Association and requested that the Food and Drug Administration conduct its evaluations consistent with these principles.

- *Systematic Inquiry*: Evaluators conduct systematic, databased inquiries about whatever is being evaluated.
- *Competence*: Evaluators provide competent performance to stakeholders.
- *Integrity/Honesty*: Evaluators ensure the honesty and integrity of the entire evaluation process.
- *Respect for People*: Evaluators respect the security, dignity and self-worth of the respondents, program participants, clients, and other stakeholders with whom they interact.
- *Responsibilities for General and Public Welfare*: Evaluators articulate and take into account the diversity of interest and values that may be related to the general and public welfare.

.02 PROCEDURES FOR INITIATING A NEW STATE PROGRAM UNDER THE NATIONAL SHELLFISH SANITATION PROGRAM

The requirements of the NSSP are contained in its Model Ordinance. Implementation of the Model Ordinance is a shared responsibility of federal, state, tribal and local governments and the shellfish industry. The Model Ordinance establishes the minimum requirements necessary to effectively manage and enforce an interstate program, and is written for ease of legal adoption at all levels of government. It is intended to be adopted by state and tribal regulators to address the interstate movement of shellfish. The Model Ordinance provides a uniform legal instrument for enforcement, better nationwide public health protection, and facilitates the shipment of high quality shellfish in interstate commerce.

The ISSC provides the formal structure wherein state regulatory authorities, with FDA concurrence, can change the Model Ordinance and establish other guidelines and procedures for the sanitary control of the shellfish industry. For additional Information concerning the origin of the Model Ordinance and the ISSC, see the historical overview by Clem (1994) and the NSSP Guide for the Control of Molluscan Shellfish (ISSC/FDA, 2002).

To ensure uniformity in the administration and implementation of the requirements of the NSSP Model Ordinance at the state and tribal regulatory agency level, the FDA reviews their programs on an annual basis. New state or tribal regulatory programs under the NSSP are required to have their proposed program reviewed prior to its initiation to assure that any shellstock produced under the state or tribal program for movement in interstate commerce meets the requirements of the Model Ordinance.

New State or Tribal Program

The Authority must apply to the FDA for evaluation and be found in conformity with the NSSP before initiating a state or tribal shellfish sanitation program or a new program element within an existing state or tribal program. The FDA will act on any application submitted by the Authority within 30 days. If the FDA has not acted within 30 days, the Authority may proceed with the new shellfish sanitation program.

When two or more State or tribal agencies will be involved in the sanitary control of the shellfish industry, a clear statement of each agency's responsibilities should be developed in the form of a memorandum of understanding. This administrative practice eliminates misunderstandings concerning agency responsibility and ensures that all aspects of shared program responsibility are addressed.

States and tribes are responsible for maintaining shellfish programs that conform to the requirements contained in the Model Ordinance. These requirements should be mandatory within each State program.

.03 PATROL EVALUATION GUIDANCE

A. Patrol Evaluation Criteria

(1) Legal Penalties – Chapter VIII. @.01 A. (2) (c)

Are there penalties in place to address illegal harvest?

Compliance Criteria:

The patrol element will be deemed in compliance if laws and regulations exist that provide penalties for controlling harvest from harvest restricted areas. **[Critical]**

- (2) Notification of Harvest Restricted Areas – Chapter VIII. @.01 A. (2) (d)
Is the industry notified of the boundaries of Harvest Restricted Areas? – Chapter VIII. @.01 E. (2)
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the appropriate State Authority demonstrates that the industry has been notified of the boundaries. **[Critical]**
- (3) Comprehensive Listing of Harvest Restricted Areas – Chapter VIII. @ .01
Does the Patrol Agency have a comprehensive listing of Harvest Restricted areas?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the State Authority has a comprehensive listing of all Harvest Restricted areas. **[Critical]**
- (4) Patrol Policy Document – Chapter VIII. @.01 B. (7)
- (a) Does the Patrol Agency have a patrol policy document?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority provides a patrol policy document. **[Key]**
- (b) Is the patrol policy document complete?
Compliance Criteria: The patrol element will be deemed in compliance with this requirement when it is determined that the patrol policy document includes all items in Chapter VIII. @.01 B. (7) listed below. **[Key]**
- (i) Citation of the law providing the legal basis for enforcement authority
 - (ii) Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;
 - (iii) The organizational structure of the unit responsible for patrol activities, including;
 - a. Patrol unit(s) name, address, and phone number;
 - b. The roster and chain of command;
 - c. Area assignments that support the frequencies of patrol delineated in B.(2); and
 - d. A listing of specific vessels, vehicles, and equipment that support the frequencies of patrol delineated in B.(2);
 - (iv) Summaries of training in shellfish patrol techniques;
 - (v) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;
 - (vi) A listing of growing areas where patrol is required;
 - (vii) An identification of any patrol problems;

- (viii) The type and frequency of reporting by patrol personnel;
- (ix) Copy of agreements with other agencies responsible for shellfish control activities; and
- (x) Citations/summons for the past year. If available, this information may include:
 - a. The number of convictions or dismissals;
 - b. Fines in dollar amount;
 - c. Equipment or property confiscations and forfeitures;
 - d. License suspensions or revocations; and
 - e. Jail sentences; and
 - f. Written warnings.

(c) Is the patrol policy document updated annually?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority can determine that the patrol policy document is updated every calendar year. **[Key]**

(5) Officer Training – Chapter VIII. @.01 B. (6)

Has the Patrol Agency met the NSSP patrol training requirements?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Agency can demonstrate that all officers have met or are scheduled for the training requirements of Chapter VIII. @.01 B. (6) before assuming their patrol duties **[Key]**

- (a) Basic law enforcement training, before assuming their patrol duties;
- (b) Training on shellfish control regulations within the jurisdiction of the patrol agency, before assuming independent patrol duties;
- (c) In-service training on the shellfish control regulations within the jurisdiction of the patrol agency, when the regulations change

(6) Patrol Frequency – Chapter VIII. @.01 B. (2)

(a) Has the agency determined risk categories for all harvest restricted areas? – Chapter VIII. @.01 B. (4)?

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the State Authority assigns risk categories for each harvest restricted area and provides a listing of those categories. **[Critical]**

(b) Does a risk management plan exist if required? – Chapter VIII. @.01. B. (3)
(c) and (d)

Compliance Criteria: The patrol element will be deemed in compliance with this requirement when the Patrol Authority has conducted a Risk Management Plan for all areas that are not patrolled at the frequency required in Chapter VIII. @.01 B. (2). **[Critical]**

(c) Has the patrol frequency requirement been met in all areas? – Chapter VIII. @.01 B. (3) (b), (c), and (d)

Compliance Criteria: The patrol element will be deemed in compliance as follows:

(i) When the State Authority achieved 95-100 percent of required patrols in all harvest restricted areas the program is considered to be in conformance with NSSP patrol frequency requirements.

(ii) When the State Authority achieved 80 – 94 percent of required patrols in all harvest restricted areas the program is considered to be in non-conformance with NSSP patrol frequency requirements. **[Key]**

(iii) When the State Authority achieved <80 percent of required patrols in all harvest restricted areas the program is considered to be in major non-conformance with NSSP patrol frequency requirements. **[Critical]**

(7) Memorandum of Understanding/Agreements – Chapter VIII. @.01 B. (5)

If enforcement of shellfish regulations is shared with another agency(s), is there a formalized MOA/MOU with the other agency(s)?

Compliance Criteria: The patrol element will be deemed in compliance when the authority has developed a Memorandum of Understanding/Agreement with all Authorities which have delegated patrol responsibilities. **[Key]**

B. The following procedures will be implemented when an FDA evaluation identifies deficiencies with the above patrol evaluation criteria.

(1) The overall Patrol Program element will be assigned one of the following designations:

(a) **Conformance:** The program is in compliance with all of the criteria listed above.

(b) **Conformance with Deficiencies:** The program only has minor deficiencies associated with a key compliance item.

(c) **Non-Conformance:** The program has:

(i) at least one (1) critical deficiency;

(ii) two (2) or more key deficiencies; or

(iii) a repeat **[Key]** deficiency from the previous evaluation.

(d) **Major Non-Conformance:** The program has multiple deficiencies, key or critical, that suggests the program has become ineffective to control harvest

in harvest restricted waters.

- (2) During the closeout meeting for patrol evaluation, the Shellfish Specialists shall identify any patrol deficiency to the state patrol agency;
- (3) Within 30 days of the closeout meeting, the Shellfish Specialist shall provide a written Program Element Evaluation Report (PEER), including supporting documentation, to the State patrol agency;
- (4) Within 30 days of receiving the PEER, the State patrol agency shall provide a written response that indicates:
 - The item(s) was corrected;
 - A correction plan has been developed with a completion date; or,
 - The reasons why the State disagrees with FDA's finding(s).
- (5) Within 15 days of receipt FDA shall review the State response, and respond to the State;
- (6) Any CRITICAL item deficiency shall be corrected within 30 days of acceptance by FDA of the correction plan;
- (7) Any KEY item deficiency shall be corrected within one year of acceptance by FDA of the correction plan.
- (8) FDA shellfish specialists shall be responsible for monitoring the progress of state action plans.
- (9) Patrol Program recommendations addressing improvements not associated with the criteria included in Section I or recommendations addressing improvements beyond the requirements of the Model Ordinance should be submitted to the State Authority in correspondence separate from the Patrol Element Evaluation Report.

References

Clem, David. 1994. Historical Overview. In: *Environmental Indicators and Shellfish Safety*. Eds. C.R. Hackney and M.D. Pierson. Chapman and Hall, New York. pp. 1-29

Interstate Shellfish Sanitation Conference. 2002. NSSP Guide for the Control of Molluscan Shellfish. Interstate Shellfish Sanitation Conference, 209 Dawson Road, Suite 2, Columbia, South Carolina, 29223.