

<b>Proposal Subject</b>	Inconsistent FDA “PEER” on Producing States
<b>Specific NSSP Guide Reference</b>	Model Ordinance IV, Chapter 1.01
<b>Text of Proposal/ Requested Action</b>	Call upon the ISSC to request the FDA to provide the Patrol Committee with the individual PEER for all producing states. Charge the Patrol Committee with making further recommendations to the FDA for standardization of Specialist training and PEER review.
<b>Public Health Significance</b>	N/A
<b>Cost Information (if available)</b>	None
<b>Action by 2005 Task Force I</b>	Proposal 05-102 was referred to Task Force III.
<b>Action by 2005 Task Force III</b>	Recommended referral of Proposal 05-102 to the NSSP Evaluation Criteria Committee to review and develop recommendations to improve consistency in evaluation of the patrol element. It is also recommended that the committee membership include members with patrol expertise.
<b>Action by 2005 General Assembly</b>	Adopted recommendation of 2005 Task Force III.
<b>Action by USFDA</b>	<p>While FDA agrees with Conference action to refer Proposal 05-102 to the NSSP Evaluation Criteria Committee for review and development of recommendations to improve consistency in evaluation of the patrol element, we request that the ISSC Executive Board consider the following alternative approach by FDA.</p> <p>At the 2005 Biennial Meeting FDA committed to work internally to address state program evaluation and reporting inconsistencies brought to our attention through Proposal 05-102. Shortly after the ISSC meeting we established an internal work group to develop an evaluation and reporting guidance document. This approach, which has been used successfully by FDA under the National Conference on Interstate Milk Shipments (NCIMS), will specifically outline Agency expectations relative to state evaluations, reporting, and follow-up activities. FDA Shellfish Specialists and states will use the guidance document to ensure a more standardized evaluation process. In addition to ISSC concerns relative to the patrol element, the FDA work group will develop guidance for the plant sanitation and growing area elements as well. Once FDA has completed its drafting of the guidance document it will be shared with the ISSC for review and comment prior to finalization and implementation. FDA is confident that this approach will be most effective for addressing evaluation inconsistencies.</p>
<b>Action by 2007 NSSP Evaluation Criteria Committee</b>	The NSSP Evaluation Criteria Committee recommended that the following criteria be used by the USFDA in evaluating the State Patrol Element. FDA should provide a report to the ISSC regarding the effectiveness of the criteria.

**ISSC Patrol Evaluation Guidance**

I. 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]**
    - (1) Citation of the law providing the legal basis for enforcement authority
    - (2) Citation of the laws and regulations, including penalties, which are directly related to effective control of illegal harvest activities;
    - (3) 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);
    - (4) Summaries of training in shellfish patrol techniques;
    - (5) The methods used to inform officers of growing area classifications and status, and of any special activities licensed in the area;
    - (6) A listing of growing areas where patrol is required;
    - (7) An identification of any patrol problems;
    - (8) The type and frequency of reporting by patrol personnel;
    - (9) Copy of agreements with other agencies responsible for shellfish control activities; and
    - (10) 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]**
  
- II. 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:
    - (1) at least one (1) critical deficiency;
    - (2) two (2) or more key deficiencies; or
    - (3) 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.

The NSSP Evaluation Criteria Committee will address the items listed below as they continue to develop evaluation criteria for all program elements.

**Other Chapter VIII. Requirements for Evaluation**

- (1) Licensing of Harvesters
- (2) Vessels – Chapter VIII. .02 B.
  - a. Are vessels inspected?
  - b. Do boats have approved means of human sewage disposal?
- (3) Shellstock Washing – Chapter VIII. .02 D.
- (4) Shellstock Identification – Chapter VIII. .02 E.
- (5) Temperature Control – Chapter VIII.03
- (6) Harvester Education Materials

**Action by 2007 Task Force I**

Recommended adoption of the Evaluation Criteria developed by the NSSP Evaluation Criteria Committee on Proposal 05-102 with an effective date of October 1, 2007.

**Action by 2007 General Assembly**

Adopted recommendation of 2007 Task Force III.

**Action by USFDA**

December 20, 2007  
Concurred with Conference action.