@.03 Evaluation of Shellfish Sanitation Program Elements

B. Criteria for evaluation of shellfish sanitation program elements shall be as follows:

1. Laboratory
   a. Requirements for evaluation of shellfish laboratories shall include at a minimum:
      i. Records audit of laboratory operations both Quality Systems and Technical methods;
      ii. Direct observation of current laboratory operating conditions; and
      iii. Information collection from the Authority and other pertinent sources concerning laboratory operations.
   b. Laboratory status is determined by the number and types of nonconformities found in the evaluation using NSSP standardized criteria contained in the FDA Shellfish Laboratory Evaluation Checklists found in Section IV Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
      i. Quality System Evaluation.
         (a) This checklist includes a conforming and nonconforming status only. All nonconformities must be reconciled prior to scheduling an onsite evaluation of technical methods in NSSP laboratories. As this part of the evaluation specifically refers to the Quality manual and SOPs and other documentation considered the basis for data defensibility, this documentation must be in order prior to further Laboratory Evaluation Officer (LEO) scheduling. The Quality Systems evaluation is performed as a desk audit and is in accordance with the checklist found in Section IV Chapter II.
      ii. Technical Evaluation: Conforms. In order to achieve or maintain conforming status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:
         (a) No critical nonconformities in the microbiological or marine biotoxin component under evaluation have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and
         (b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin components have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and
         (c) Not more than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, twelve (12) critical, key and other nonconformities in total for the paralytic shellfish poisoning (PSP) and amnesic shellfish poisoning (ASP) components, or ten (10) critical, key and other nonconformities in total for the neurotoxic shellfish poisoning (NSP) component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and
         (d) No repeat key nonconformities have been identified in the microbiological or marine biotoxin component under evaluation in consecutive evaluations using the appropriate NSSP Shellfish Laboratory Evaluation Checklist.

iii. Technical Evaluation: Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria:

(a) Not more than three (3) critical nonconformities in the microbiological component, four (4) in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and

(b) Not more than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and

(c) Not more than eighteen (18) critical, key and other nonconformities in total in the microbiological component, or twelve (12) critical, key and other nonconformities in total in the PSP and ASP components or ten (10) critical, key and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and

(d) Not more than one (1) repeat key nonconformity has been identified in the microbiological or marine biotoxin component under evaluation in consecutive evaluations using the appropriate NSSP Shellfish Laboratory Checklist.

iv. Technical Evaluation: Nonconformance. When a laboratory exceeds the following criteria, it will be determined to be in nonconformance:

(a) More than three (3) critical nonconformities in the microbiological component or four (4) in the PSP and ASP components, or three (3) in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Checklist; or

(b) More than thirteen (13) key nonconformities in the microbiological component or six (6) in the marine biotoxin component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist;

(c) More than eighteen (18) critical, key, and other nonconformities in total in the microbiological component, or more than twelve (12) critical, key and other nonconformities in total in the PSP and ASP components, or more than ten (10) critical, key, and other nonconformities in total in the NSP component have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; or

(d) One (1) or more repeat critical or two (2) or more repeat key nonconformities have been identified in consecutive evaluations in either the microbiological or marine biotoxin components using the appropriate NSSP Shellfish Laboratory Evaluation Checklist.

c. Corrective Actions for Conforming Status. A laboratory found to be in conforming status for technical checklists, other than the Quality Systems checklist, has up to ninety (90) days to successfully correct all nonconformities noted in each component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory's status will be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component

in question.

d. Corrective Actions for Provisionally Conforming Status. A laboratory found to be in provisionally conforming status for technical methods checklists has up to sixty (60) days to successfully correct all nonconformities found in each provisionally conforming component evaluated or has an approved action plan in place to deal with the nonconformities noted. After this period, the laboratory will be assigned the following status for the laboratory component(s) in question:

   i. Conforms if all the critical and key nonconformities have been successfully corrected in each provisionally conforming component evaluated; or

   ii. Nonconforming if any critical or key nonconformities remain to be successfully corrected in each provisionally conforming component evaluated or if the lab is not able to be evaluated because of a nonconforming Quality System. As a result, data being generated by the laboratory will no longer be acceptable for use in support of the NSSP for the laboratory component in question.