Section II. Model Ordinance
Chapter III. Laboratory

Requirements for the Authority.

Additional Guidance - Section IV Guidance Documents
Chapter II. 11. Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

[Note: The Authority must meet the requirements of this section even if the Authority does not formally adopt this section in regulation.]

@.01 Quality Assurance.

A. NSSP Conformance Required. All laboratory analyses shall be performed by a laboratory found to conform or provisionally conform by the FDA or FDA certified State Shellfish Laboratory Evaluation Officer (LEO) in accordance with the requirements established under the NSSP.
B. State Program Requirements. The Authority shall assure that all samples are collected, maintained, transported, and analyzed in a manner that assures the validity of the analytical results. The Authority shall:
    (1) Require laboratories to develop a written quality assurance plan that:
        (a) Describes the organization and management structure of the laboratory;
        (b) Describes the laboratory staff training program ensuring that all laboratory personnel are qualified, properly trained, and supervised;
        (c) Describes all procedures and methods used to collect, maintain, transport and analyze samples;
        (d) Describes quality control measures, their frequency and tolerance limits, for determining equipment performance;
        (e) Requires maintenance of records of analytical performance, quality control results, and equipment maintenance and calibration; and
        (f) Provides a quality assessment program to demonstrate laboratory and analyst competence. At a minimum this program must include triennial onsite laboratory evaluations conducted by either FDA laboratory evaluation officers or FDA certified state laboratory evaluation officers, and annual internal laboratory audits. For microbiological laboratories, participation in the annual FDA sponsored proficiency test programs is also required; and
        (g) Requires corrective action for any deficiencies found in the laboratory quality assurance program.
    (2) Require laboratories to implement their quality assurance plan;
    (3) Ensure that the laboratory has appropriate facilities and resources to effectively manage the workload;
    (4) Require triennial or more frequent evaluations of all laboratories which conduct both microbial and marine biotoxin and analyses used to officially support the state shellfish program; and
    (5) Require a laboratory to be re-evaluated when any major changes in personnel, workload, or facilities occur and when a laboratory is found in nonconformance.

C. An FDA certified State Shellfish Laboratory Officer may evaluate laboratories in a different State under a memorandum of understanding agreement between the States and FDA. The agreement shall be consistent with NSSP requirements.

D. Laboratory Evaluation.

(1) 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, Guidance Documents Chapter II Growing Areas 11. Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.

(a) Conforms. In order to achieve or maintain its conforms status, a laboratory shall meet the following requirements under the NSSP standardized laboratory evaluation criteria:

(i) No critical nonconformities have been identified;

(ii) Not more than 12 key nonconformities for microbiological or 5 for paralytic shellfish poisoning component have been identified;

(iii) Not more than 17 critical, key, and other nonconformities in total or 9 for paralytic shellfish poisoning component have been identified (not to exceed the critical and key criteria); and

(iv) No repeat key nonconformities have been identified in consecutive evaluations.

(b) Provisionally Conforms. In order to achieve provisionally conforming status, a laboratory shall meet the following requirements under the NSSP standardized microbiological laboratory evaluation criteria:

(i) Not more than 3 critical nonconformities for the microbiological or 2 for paralytic shellfish poisoning component have been identified;

(ii) Not more than 12 key nonconformities for the microbiological or 5 for paralytic shellfish poisoning component have been identified; and

(iii) Not more than one repeat Key nonconformity has been identified in consecutive evaluations.

(c) Nonconformance. When a laboratory exceeds the following criteria, the laboratory shall be determined to be in nonconformance:

(i) More than 3 critical nonconformities for the microbiological or 2 for paralytic shellfish poisoning component have been identified;

(ii) More than 12 key nonconformities for the microbiological or 5 for paralytic shellfish poisoning component have been identified;

(iii) More than 17 critical, key, and other nonconformities for microbiological or 9 for paralytic shellfish poisoning component have been identified; or

(iv) One or more repeat critical or two or more key nonconformities have been identified in consecutive evaluations.

E. Time Limit on Laboratory Status.

(1) Conforming Status. A laboratory found to be in conforming status has up to ninety (90) days to successfully correct all nonconformities noted in the evaluation or has an approved action plan. After this period, the laboratory's status shall be downgraded to nonconforming if any key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.

(2) Provisionally Conforms Status. A laboratory found to be in the provisionally conforming status has up to sixty (60) days to successfully correct all nonconformities found or has an approved action plan. After this period, the laboratory shall be assigned a status of:

(a) Conforms if all the critical and key nonconformities have been successfully corrected; or

(b) Nonconforming if any critical or key nonconformities remain to be successfully corrected. As a result, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.

(3) Nonconformance.

(a) Upon a determination of nonconforming status, the laboratory has up to thirty (30) days to demonstrate successful correction of all nonconformities found. After this period, if all critical and key nonconformities have been successfully corrected, the status of the laboratory will be upgraded to conforming. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory shall continue to be nonconforming; and as a result, data being generated by the laboratory is no longer acceptable for use in support of the NSSP.

(b) When a laboratory is found to be nonconforming either for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority shall ensure that an action plan is developed to correct the situation in an expeditious manner.

(c) When all critical and key nonconformities have been successfully corrected by a nonconforming laboratory, the laboratory will be reevaluated either on-site or through a careful review of appropriate documentation as determined by the FDA or FDA certified State Shellfish LEO. Only a finding of fully conforming in laboratories whose data has ceased to be acceptable to the NSSP will restore its acceptability for use in the NSSP.

F. Laboratory Services for Depuration Processors. For any laboratory providing services for the quality assurance program (e.g. water quality) including end-product testing of any depuration processor, the Authority shall:

(1) Require the annual inspection of the laboratory in accordance with 01 and 02 of this Chapter; and

(2) Require the laboratory to retain its records for a minimum of the previous two years.

Additional Guidance - Section IV Guidance Documents
Chapter II.10 Approved NSSP Laboratory Tests

@.02 Methods.

A. Microbiological. Methods, practices, and procedures for the analyses of shellfish and shellfish growing or harvest waters shall be the methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

B. Chemical and Physical.

(1) Methods for the analysis of shellfish and shellfish growing or harvest waters shall:

(a) Be the current AOAC or APHA method for all physical and chemical measurements; and

(b) Express results of all chemical and physical measurements in standard units, and not instrument readings.

(2) When an AOAC or APHA method is not available, EPA methods may be used.

(3) If a method is not approved or validated by AOAC, APHA, or EPA then the method shall be validated in accordance with Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC.

C. Biotoxin. Methods for the analyses of shellfish and shellfish harvest waters shall be:

(1) The current AOAC and APHA methods used in the bioassay for paralytic shellfish poisoning toxins : and

(2) The current APHA method used in the bioassay for *Karenia brevis* toxins; or

(3) Methods validated for use in the National Shellfish Sanitation Program under Procedure XVI of the Constitution, Bylaws and Procedures of the ISSC and / or cited in the Guidance

Documents, Chapter II. Growing Areas .10 Approved National Shellfish Sanitation Program Laboratory Tests.

D. Emerging Methods.

(1) When there is an immediate or critical need and no NSSP approved methods exists, and the ISSC Executive Board considers allowing an unapproved or non-validated method to be used for a specific purpose, the minimum requirements as defined in the Lab Method Review Committee Advisory for Emerging Methods will be provided to the Executive Board and shall contain the following criteria:

(a) Name of Method

(b) Date of Submission

(c) Specific purpose or intent of the method for use in the NSSP

(d) Step by step procedure including equipment, reagents and safety requirements necessary to run the method

(e) Data generated in the development and/or trials of the method and/or comparing to approved methods if applicable

(f) Any peer reviewed articles detailing the method

(g) Name of developer(s)/submitters

(h) Developer/submitter contact information

(2) Within two years of the initial allowed use of the method, the entire Single Lab Validation Protocol should be submitted. The Lab Methods Review Committee will report to the Executive Board on the status of the Single Lab Validation data submission.