Proposal No. **17-114**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative

Submitter	U.S. Food and Drug Administration (FDA)
Affiliation	FDA
Address Line 1	5001 Campus Drive
Address Line 2	HFS-325
City, State, Zip	College Park, MD 20740
Phone	240-402-1401
Fax	301-436-2601
Email	Melissa.abbott@fda.hhs.gov
Proposal Subject	National Shellfish Sanitation Program Quality System - Laboratory Evaluation Checklist
Specific NSSP Guide Reference	Section II Model Ordinance - Chapter I Shellfish Sanitation Program @.03 Evaluation of Shellfish Sanitation Program Elements And Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists
Text of Proposal/ Requested Action	**Section II Model Ordinance - Chapter I Shellfish Sanitation Program @.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 the 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 LEO scheduling. The Quality Systems evaluation is performed as a desk audit and is in accordance with checklist found in Chapter II.

	~~i~~. ii. Technical Evaluation: Conforms. In order to achieve or maintain conform~~s~~ing status under the NSSP, a laboratory must meet the following laboratory evaluation criteria: ~~ii~~(a) No critical nonconformities in the microbiological or marine Biotoxin component under evaluation have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and ~~iii~~(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 FDA Shellfish Laboratory Evaluation Checklist; and ~~iv~~(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 PSP component, or ten (10) critical, key and other nonconformities in total for the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and ~~v~~(d) No repeat key nonconformities have been identified in the microbiological or marine Biotoxin component under evaluation in consecutive evaluations using the appropriate FDA Shellfish Laboratory Evaluation Checklist. ~~c.~~iii. Technical Evaluation: Provisionally Conforms. In order to be deemed provisionally conforming under the NSSP, a laboratory must meet the following laboratory evaluation criteria: ~~i.~~(a) Not more than three (3) critical nonconformities in the microbiological component, four (4) in the PSP component, or three (3) in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; and ~~ii~~(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 FDA Shellfish Laboratory Evaluation Checklist; and ~~iii~~(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 component or ten (10) critical, key and other nonconformities in total in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist. This number must not exceed the numerical limits established for either the critical or key criteria; and ~~iv~~(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 FDA Shellfish Laboratory Checklist.

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

~~i.~~(a) More than three (3) critical nonconformities in the microbiological component or four (4) in the PSP component, or three (3) in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Checklist; or

~~ii.~~(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 FDA Shellfish Laboratory Evaluation Checklist;

~~iii.~~(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 component, or more than ten (10) critical, key, and other nonconformities in total in the NSP component have been identified using the appropriate FDA Shellfish Laboratory Evaluation Checklist; or

~~iv.~~(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 FDA Shellfish Laboratory Evaluation Checklist.

~~e.~~c. Corrective Actions for Conforming Status. A laboratory found to be in conforming status for ~~either the microbiological or marine Biotoxin component or for both components~~ 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.

~~f.~~ d. Corrective Actions for Provisionally Conform~~s~~ing Status. A laboratory found to be in provisionally conforming status for ~~either the microbiological or marine Biotoxin component or for both components~~ 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 evaluate, 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. g e. Nonconformance. i. Upon a determination of nonconforming status in any of the either the microbiological or marine Biotoxin component or in both technical method components, 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 for the laboratory component(s) in question. However, if any critical or key nonconformities remain to be successfully corrected, the status of the laboratory for the laboratory component(s) in question will continue to be nonconforming; and as a result, data being generated by the laboratory for this/these laboratory components will continue to be unacceptable for use in support of the NSSP. ii. Upon a determination of nonconformance for the Quality Systems component, the laboratory will have to successfully implement a quality system prior to the onsite technical evaluation. Once all nonconformities are reconciled successfully, a technical evaluation for NSSP methods using the appropriate method specific FDA Shellfish Laboratory Evaluation Checklist will be scheduled with the laboratory. iiiii. When a laboratory is found to be nonconforming in either the microbiological or marine Biotoxin technical or quality component or in both components for failure to successfully implement the required corrective action, or for having repeated critical or key nonconformities in consecutive evaluations, the Authority will ensure that an action plan is developed to correct the situation in an acceptable and expeditious manner or discontinue use of the laboratory to support the NSSP. iii. For each laboratory component evaluated, the laboratory will be reevaluated either on-site or through a thorough desk audit as determined by the FDA Shellfish Laboratory Evaluation Officer and the FDA certified State Shellfish Laboratory Evaluation Officer if one is utilized by the State. 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 for the laboratory components in question. **Section IV Guidance Documents Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists** The requested action is to adopt the text of the attached checklist for the Quality System of NSSP Laboratories and to append the checklist to the list of NSSP Laboratory Evaluation Checklists at the end of .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists.
Public Health Significance	A Quality System is critical to the successful defense of laboratory data. A defensible laboratory quality results in data accuracy, reliability, and minimization of laboratory errors. Laboratory quality assurance operations must be reliable, and

	quality control well documented. The management of the system is critical to its success to ensure it is maintained. Without oversight and documentation of the steps a laboratory takes to ensure the highest level of laboratory quality management, the data generates is indefensible. Whether the data is challenged in a court of law or during an audit for customer or quality, a Quality System provides a level of assurance upon which data can be relied. Additionally, with time and resources for State and Federal Programs at premium, Quality Systems are an element that can successfully be evaluated remotely and ensure laboratories have continued contact with Federal partners. Once quality system essentials are in place, an onsite audit may proceed; thus, resources are conserved and laboratories are fully prepared. NSSP laboratories are producing excellent data and must be as defensible as laboratories held to accreditation standards. Currently, there is no checklist adopted by the ISSC and no standardized evaluation method for the NSSP to determine defensibility of the Quality System adopted by the NSSP. The attached checklist provides the metric by which laboratory evaluation officers will evaluate quality management, quality assurance and quality control elements of NSSP laboratory Quality Systems. The checklist documents whether items are present or not present, noting the labs conformance or nonconformity. If the lab fails to maintain a quality system an onsite evaluation will not be scheduled until such time as the nonconformities are rectified.
Cost Information	There will not be an additional immediate cost as this would be the first step in the routine triennial evaluation cycle.