Proposal No. 19-148

Proposal for Task Force Consideration at the ISSC 2019 Biennial Meeting	1. a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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10. Proposal Subject	Correct language of MO to reflect current checklists
11. Specific NSSP Guide Reference	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.03 Evaluation of Shellfish Sanitation Program Elements B. Criteria for evaluation of shellfish sanitation program elements shall be as follows: 1. Laboratory
12. Text of Proposal/ Requested Action	Section II Model Ordinance – Chapter I. Shellfish Sanitation Program for the Authority @.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: Shellfish Laboratory will be technical.y evaluation and will be assigned the designation of conforms, provisionally conforms or non-confomance. The criteria used in determining the evaluation designations are included in the NSSP Shellfish Laboratory Evaluation Checklist designated for the specific type of laboratory evaluation being performed. (For more information see Section IV. Guidance Documents Chapter II. Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists

~~(b) Conforms. In order to achieve or maintain conforming status under the NSSP, a laboratory must meet the following laboratory evaluation criteria:~~

~~(c) No critical nonconformities in the microbiological or marine biotoxin component under evaluation have been identified using the appropriate NSSP Shellfish Laboratory Evaluation Checklist; and~~

~~(d) (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 identifiedusing 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 umber 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.~~
13. Public Health Significance	The goal of a laboratory evaluation is to monitor implementation of NSSP Quality Systems and Approved methods. Laboratory data is standardized as a result of this process and reciprocity of shellfish in the commercial market is protected and preserved through defensible practices and transparent requirements. As the laboratory program in the NSSP continues to develop and grow it is prudent to keep requirements in accessible documents with few deviations. Checklists are a cornerstone document for laboratories, referring to these documents ensures laboratories have access to requirements at all times. As laboratorians are the target audience, this is the most sensible place for the actual numbers of nonconformities to reside, and the reference to the checklists in the Model Ordinance ensures the checklists are part of the overarching document adopted by reference or into legislation. Multiple locations of numbers of permissible nonconformities only ensures updates will be missed. As existing structure is in place through the Lab Committee to handle checklists and edits therein, this seems the most reasonable solution.
14. Cost Information	No cost incurred by change. Practice is already in place.
15. Research Needs Information (Optional)	

a. Proposed specific research need/ problem to be addressed	none
b. Explain the relationship between proposed research need and program change recommended in the proposal	**There is no research need to implement proposal recommendation. This is a change requested to reflect language that exists in the MO. The language changes proposed have not been changed as new Checklists were introduced and the numbers of Critical key and other nonconformities are not constant. Therefore, it makes sense to refer to the checklist rather than continue to have to occasionally update arbitrary numbers in Chapter 1. This will save time and money in the future as more checklists are introduced. Checklists have a great deal of attention by the Lab Committee, in fact, they have a subcommittee dedicated entirely to their drafting or editing. Any questions would be answered here.**
c. Estimated cost	**none**
d. Proposed sources of funding	**N/A**
e. Time frame anticipated	**N/A**
For Research Guidance Committee Use Only	Relative priority rank in terms of resolving research need ☐ Immediate ☐ Required ☐ Valuable ☐ Important ☐ Other