Proposal No. 19-101

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	Conditionally Conforming Laboratory Status
11. Specific NSSP Guide Reference	Section II. Model Ordinance Chapter I. Shellfish Sanitation Program Requirements for the Authority @.03 B. 1. b. Section II. Model Ordinance Chapter III. Laboratory @.01 Section II. Model Ordinance Chapter XV. Depuration .03 J. (4)
12. Text of Proposal/ Requested Action	The requested action is to create a NSSP laboratory status of conditionally conforming. This status is based on a demonstrated proficiency of laboratory method performance. Laboratories that are found to conditionally conform for a laboratory analysis may support the NSSP. **MO Chapter 1.@.03 B. 1. b.** v. Performance Evaluation: Conditionally Conforms. Tto be deemed conditionally conforming under the NSSP, a laboratory must meet one of the following laboratory performance criteria: (a) Complete an appropriate ISSC Accepted SLV; or (b) Complete a Method Verification Study, Section IV. Chapter II. .20 that successfully transfers; or (c). Successfully complete a proficiency and/or inter-laboratory study approved by the FDA Shellfish LEO or State certified Shellfish LEO. (d) This laboratory status will remain in effect until an technical FDA Shellfish LEO or FDA certified State Shellfish LEO Evaluation occurs as in @.03 B. **MO Chapter III. @.01 Quality Assurance** A. NSSP Conformance Required for all laboratories supporting the NSSP. All laboratory analyses shall be performed by a laboratory found to conform, conditionally conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under the NSSP. **MO Chapter XV. .03 J. (4)** (a) Are analyzed by a laboratory which has been evaluated and found to conform or conditionally conform to the NSSP pursuant to the requirements in Chapter III, using an NSSP-Approved Method;
13. Public Health Significance	A technical Laboratory evaluation, as outlined in MO Chapter 1.@.03B.1.b.ii, is conducted to verify that conditions are present *in the laboratory* which **should**

	result in the accurate outcome of method data. A performance evaluation **verifies** that the method data produced *by the laboratory and for all analysts* is accurate. A technical evaluation does not examine the quality of a laboratory's method data for validity, standardization or for individual analysts. If a laboratory has successfully passed a proficiency study, SLV or MV, and statistically confirmed method data results, the laboratory can be assumed to have technically performed the method correctly. Under current interpretation a laboratory may have completed and had accepted by the conference a method SLV with accompanying checklist yet not be able to support the NSSP with data until a FDA Shellfish LEO or FDA certified State Shellfish LEO conducts a technical inspection at their laboratory using the laboratory's own checklist. If a laboratory has proven its ability to perform a method, then the laboratory should be able to conditionally support the NSSP with data. A cooperative goal of the NSSP, FDA and the SSCA is to assure that a laboratory's data is accurate, verified and standardized. Method based performance evaluations confirm data which results in standardization across laboratories. Method based performance evaluations statistically verify data accuracy. Performance Evaluations therefore support the legal defensibility of the laboratory's Laboratory Quality Management System.
14. Cost Information	Cost of conducting SLV, MV or Proficiency Participation
Action by 2019 Laboratory Committee	Recommended no action on Proposal 19-101. Rationale: This issue is addressed by Proposal 19-301.
Action by 2019 Task Force I	Recommended adoption of Proposal 19-101 as submitted.
Action by 2019 General Assembly	Recommended referral of Proposal 19-101 to an appropriate committee as determined by the Conference Chair.
Action by FDA February 21, 2020	Concurred with Conference action on Proposal 19-101.
Action by 2023 Laboratory Committee	Recommended referral of Proposal 19-101 to an appropriate committee as determined by the Conference Chairperson
Action by 2023 Task Force I	Recommended referral of Proposal 19-101 as amended to the Laboratory Committee with the provision that a recommendation for interim approval be provided at the 2023 Fall Executive Board Meeting. **MO Chapter 1.@.03 B. 1. b.** v. Performance Evaluation: Conditionally Conforms. Tto be deemed conditionally conforming under the NSSP, a laboratory must meet one of the following laboratory performance criteria: (a) Complete an appropriate ISSC Accepted SLV; or (b) Complete a Method Verification Study, Section IV. Chapter II. .20 that successfully transfers; or ~~(c). Successfully complete a proficiency and/or inter-laboratory study approved by the FDA Shellfish LEO or State certified Shellfish LEO.~~ (c~~d~~)

	This laboratory status will remain in effect until an technical FDAShellfish LEO or FDA certified State Shellfish LEO Evaluation occurs as in @.03 B. **MO Chapter III. @.01 Quality Assurance** A. NSSP Conformance Required for all laboratories supporting the NSSP. All laboratory analyses shall be performed by a laboratory found to conform, conditionally conform or provisionally conform by the FDA Shellfish LEO or FDA certified State Shellfish LEO in accordance with the requirements established under the NSSP. **MO Chapter XV. .03 J. (4)** (a) Are analyzed by a laboratory which has been evaluated and found to conform or conditionally conform to the NSSP pursuant to the requirements in Chapter III, using an NSSP-Approved Method;
Action by 2023 General Assembly	Adopted the recommendation of Task Force I on Proposal 19-101.
Action by FDA July 7, 2023	Concurred with Conference action on Proposal 19-101.
Action by 2024 Laboratory Committee	Recommended Proposal 19-101 as substituted and submit to the 2024 Executive Board for interim approval. **Chapter III** **@.01 Quality Assurance** C. FDA Responsibilities. The FDA will ensure that all laboratories generating data in support of the NSSP will be evaluated at a minimum frequency of once every three (3) years. (1) Evaluations will be conducted by either an FDA Shellfish LEO or an FDA certified State Shellfish LEO as appropriate. Normally the initial evaluation of a laboratory will be conducted by FDA. (2) Evaluations are ~~generally~~ conducted onsite; however, evaluations may be conducted ~~but can under certain circumstances be~~ by desk/virtual audit wen scheduling or extenuating circumstances will not permit a timely onsite evaluation. ~~(evaluation follow up, action plan monitoring, nonconformity corrections, major changes in personnel, workload or facilities, etc.).~~ (3) When there is an immediate and critical need, and: (a) no NSSP conforming or provisionally conforming laboratory exists to perform a specific Approved NSSP Method, or (b) no NSSP conforming or provisionally conforming laboratory is accessible (i.e. due to distance, etc.) to perform specific Approved NSSP method, or (c) following a request for emergency consideration as defined in Section II, Ch. 1 @.01 I. The following alternative laboratories may implement that Approved ISSC Method in support of the NSSP:

	(a) A laboratory that has not been evaluated or assigned an NSSP operational status, provided that: i. the ISSC Executive Board is notified within a reasonable period of time regarding the laboratory used; and, ii. the appropriate FDA Office is notified within a reasonable period of time regarding the laboratory used; and, iii. the laboratory meets the following laboratory performance criteria: 1. completed the SLV study which resulted in the Approved NSSP method; or 2. maintains a recognized laboratory accreditation status (e.g., ISO 17025:2017, LAAF, etc.), with documentation of accreditation provided to the FDA prior to method implementation; and 3. successfully completed a Method Verification Study, as outlined in Section IV, Chapter II, .20, and the method verification data package has been approved by an FDA Shellfish LEO. If an FDA Shellfish LEO is unavailable to review the method verification data package in a timely manner, an FDA certified State Shellfish LEO may review and approve the data package instead. State Shellfish LEOs will only review method verification data packages pertaining to methods for which they have documented proficiency and evaluation standardization. (b) An existing NSSP conforming or provisionally conforming laboratory that has not been evaluated for the specific Approved NSSP method to be used, provided that: i. the ISSC Executive Board is notified within a reasonable period of time regarding the laboratory used; and, ii. the appropriate FDA Office is notified within a reasonable period of time regarding the laboratory used; and, iii. the laboratory has successfully completed a Method Verification Study, as outlined in Section IV, Chapter II, .20, and the method verification data package has been approved by an FDA Shellfish LEO. If an FDA Shellfish LEO is unavailable to review the method verification data package in a timely manner, an FDA certified State Shellfish LEO may review and approve the data package instead. State Shellfish LEOs will only review method verification data packages pertaining to methods for which they have documented proficiency and evaluation standardization. If the immediate and critical need for analysis becomes an ongoing or recurring need, the laboratory implementing the method will work with the FDA

	Shellfish LEOs to promptly initiate the evaluation process. D. Wet Storage and Post-Harvest Processors. For any laboratory providing analytical testing services for depuration, wet storage or PHP, initial and subsequent triennial evaluations will be required and conducted in accordance with @.01 and @.02 of this Chapter by an FDA Shellfish LEO or an FDA certified State Shellfish LEO ~~as appropriate~~. It is understood that academic laboratories involved in PHP Validation or Verification have special circumstances such as extended periods of inactivity resulting from university schedules or funding constraints; however, written documentation of Quality Control practices will be required for time periods in which they are preparing for or actively participating in a PHP Validation or Verification. Times in which the lab is inactive can be explained with a not applicable notation.
Action by 2023 Executive Board	Adopted the recommendation of 2024 Laboratory Committee. Interim Approval on October 30, 2024.