Proposal No. **17-112**

Proposal for Task Force Consideration at the ISSC 2017 Biennial Meeting	a. ☒ Growing Area b. ☐ Harvesting/Handling/Distribution c. ☐ Administrative
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Proposal Subject	Requirements for certification of State Shellfish Laboratory Evaluation Officers (LEOs).
Specific NSSP Guide Reference	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 IV Guidance Documents – Chapter II Growing Areas .15 Evaluation of Laboratories by State Shellfish Laboratory Evaluation Officers Including Laboratory Evaluation Checklists amend language. General Provisions 1. If the State Shellfish Control Authority (Authority) uses the analytical services of private/commercial/fee for services laboratories to support the NSSP, then he/she should select a qualified individual to become certified as a State Shellfish Laboratory Evaluation Officer (State Shellfish LEO). 2. If the Authority uses the analytical services of multiple public laboratories (state, county, parish town, etc.) to support the NSSP, then he/she may select a qualified individual to become a State Shellfish LEO. 3. If the Authority chooses not to participate in the certification process, FDA can evaluate the state's public laboratories. FDA, however, does not normally evaluate private/commercial/fee for services laboratories. FDA may, under certain circumstances as resources permit, evaluate these laboratories on a case-by-case basis at the request of the Authority. This request must be in writing and made through the FDA ~~Regional~~ Shellfish Specialist. 4. State Shellfish LEOs will perform official NSSP evaluations of laboratories which have been previously evaluated by FDA and been found to fully conform to NSSP laboratory requirements. 5. State Shellfish LEOs may evaluate laboratories in a different state under a memorandum of understanding between the states involved and FDA, consistent with NSSP requirements. 6. State Shellfish LEOs may not evaluate laboratories in which they are employed or which they supervise or laboratories within the same supervisory chain of command to ensure complete objectivity in the evaluation process and avoid the appearance of a conflict of interest. 7. To qualify for certification, the prospective State Shellfish LEO ~~should~~ must ~~be~~: a. ~~A~~ Be a state employee; b. Have a minimum of two years of shellfish laboratory experience or

a laboratory background~~;~~ with three to five years of bench level experience with the specific methods that will be evaluated;

c. ~~Preferably h~~ Have ~~laboratory evaluation~~ experience performing laboratory evaluations or supervising a laboratory; and,

d. Be free from any commercial, financial or other pressures or conflicts of interest that might cause or appear to cause the prospective State Shellfish LEO to act in other than an impartial or non-discriminatory manner.

8. If the prospective or current State Shellfish LEO is employed by the laboratory supporting the NSSP, that laboratory must be fully conforming to NSSP requirements or the individual will not be certified and if currently certified, certification will be revoked.

Responsibilities of the FDA National Laboratory Standard

1. The FDA National Laboratory Standard/s will be responsible for standardizing all LEOs.
2. The FDA National Laboratory Standard will conduct certifications/recertifications. The Standardization evaluation process will consist of a minimum of two (2) practice evaluations in areas under consideration for certification and one (1) formal standardization evaluation. The evaluation will be checklist specific and the State Shellfish LEO will be standardized to evaluate the methods only for which they have been certified.
3. FDA Standard Operating Procedure for Laboratory Evaluations will be provided to every LEO candidate for the purpose of evaluation standardization.

Responsibilities of the State Shellfish Control Authority

1. The Authority must ensure that appropriate written documentation is provided to FDA to demonstrate that a prospective State Shellfish LEO is adequately qualified to assume the responsibilities of a State Shellfish LEO as described above.
2. The Authority must provide or ensure that adequate time, resources and support are made available to the State Shellfish LEO to fully participate in the certification process and to fulfill his/her obligation as a State Shellfish LEO.
3. The Authority will provide, or ensure adequate opportunity for, State Shellfish LEOs to maintain communication with FDA LEOs, as needed, to provide guidance and updates relevant to the NSSP laboratory evaluation program and any changes to their State programs.

FDA's Responsibilities

1. FDA is responsible for the certification/recertification of State Shellfish LEOs.
2. As a result FDA must:

a. Select qualified individuals to receive training based upon the documentation supplied by the Authority;

b. Develop and provide training that will enable prospective and current State Shellfish LEOs to consistently and uniformly apply evaluation criteria in determining the competence of laboratories to support or continue to support the NSSP;

c. Certify prospective State Shellfish LEOs that successfully complete the

certification process;
d. Maintain communication with State Shellfish LEOs as needed to provide guidance and updates relevant to the NSSP laboratory evaluation program;
e. Recertify current State Shellfish LEOs pursuant to the criteria established for satisfactory performance below;
f. Monitor the performance of State Shellfish LEOs to ensure that the evaluation process is being performed consistent with NSSP requirements as described in the current NSSP Guide for the Control of Molluscan Shellfish and this guidance;
g. Maintain communication as needed with the Authority and other pertinent state officials, prospective and current State Shellfish LEOs and FDA Shellfish Specialists relevant to the certification/recertification process;
h. Revoke certification of State Shellfish LEOs for cause; and,
i. Void certification when the need for a State Shellfish LEO no longer exists within the state shellfish sanitation program or when the State Shellfish LEO is no longer employed by the state.

State Shellfish Laboratory Evaluation Officer's Responsibilities

1. Conduct on-site laboratory evaluations at least every three (3) years. However, more frequent evaluations are strongly encouraged and may be necessary with marginally performing laboratories, or when major changes in workloads or priorities have occurred or when there has been a substantial turnover of personnel, or, at the specific request of the Authority.
2. Provide appropriate post-evaluation follow-up for each laboratory evaluated, (i.e., monitoring corrective actions and resolutions of all nonconformities).
3. Prepare ~~timely~~ narrative evaluation reports within 30 days for all laboratories evaluated. The report should consist of the completed FDA Shellfish Laboratory Evaluation Checklist for the component(s) evaluated and a narrative discussion that accurately and concisely describes the overall operation of the laboratory. All nonconformities noted should be described in this narrative~~;~~, and, where relevant, an explanation provided relating the potential impact of the deficiency to ~~on~~ the analytical results. Completed corrective actions should be included in the narrative report only if they were completed on-site. Recommendations for corrective action or, if applicable, suggestions to enhance laboratory operations should also be included in the narrative report.
4. Distribute completed evaluation reports with checklists to FDA LEOs and to the appropriate FDA ~~Regional~~ Shellfish Specialist.
5. Inform FDA Shellfish ~~Laboratory Evaluation Officers~~LEOs when a laboratory has been found to be in nonconforming status immediately upon closeout. A letter informing FDA National Laboratory Standard of upgraded status by way of a separate Completed Corrective Action Memo will be sent, should one be necessary.
6. Coordinate proficiency testing at least yearly for all laboratories in the State supporting the microbiology component of the NSSP.
7. Prepare annually (in December) a summary list of all laboratories, ~~and~~ qualified analysts, and methods performed in each NSSP laboratory and transmit it to the FDA Shellfish LEOs.

Certification Process

Certification is designed to be accomplished through individualized training and field standardization. Individuals are certified for evaluating either the microbiological and/or ~~post harvest processing (PHP)~~ vibrio detection and/or marine ~~B~~biotoxin components of the NSSP depending on their qualifications and the needs of the state shellfish sanitation program. ~~and at the discretion of FDA.~~ Certification is dependent upon the perspective State Shellfish LEO satisfying all the following performance criteria.

a. Demonstration of good familiarity with evaluation requirements.
b. Demonstration of a thorough knowledge of the evaluation methods and documents.
c. Demonstration of the technical knowledge/familiarity with the analytical procedures being used.
d. Ability to communicate effectively both orally and in writing.
e. Successful completion of both training course and field standardization.

Field Standardization

1. Field Standardization is designed to evaluate the prospective State Shellfish LEO's ability to determine the competence of the laboratory to meet NSSP laboratory requirements,~~;~~ recognize laboratory practices inconsistent with NSSP requirements when they occur,~~;~~ make appropriate recommendations for corrective action,~~;~~ and~~,~~ provide the necessary follow-up activity to bring the laboratory into conformity with the NSSP.

2. Field standardization consists of ~~one or several joint but independent~~ a minimum of two practice and one ~~final~~ onsite evaluations ~~with~~ ~~an~~ the FDA National Laboratory Standard. ~~Shellfish Laboratory Evaluation Officer and preparation of the corresponding narrative evaluation reports.~~ For the final standardization assessment, the onsite evaluation, all "Critical" nonconformities cited, or lack thereof, must be in agreement between the FDA National Laboratory Standard and the State LEO candidate. Additionally, for "Key" and "Other" nonconformities, the evaluation checklists completed by the prospective State Shellfish LEO candidate and the FDA National Laboratory Standard should be in 90% agreement.

~~2.~~3. During all joint field evaluations the State Shellfish LEO Candidate will be the lead evaluator. He or she will be responsible for requesting documents, assessing records, and conducting the evaluation. FDA Standard Operating Procedure for inspection will be followed regarding assessment requests. The Candidate shall also conduct the "exit" interview and discuss all significant findings with management.

~~3.~~4. The narrative evaluation report must be prepared by the State Shellfish LEO candidate for each joint but independent evaluation conducted. The report(s) should consist of the completed FDA Shellfish Laboratory Evaluation Checklist(s) and a narrative discussion that accurately and concisely describes the overall operation of the laboratory. All nonconformities noted should be described in the narrative, and where relevant, an explanation provided relating the potential impact of the deficiency ~~on~~ to the analytical results. Recommendations for corrective action, or if applicable, suggestions to enhance laboratory operations should be included in this narrative report(s).

~~4.~~5. Final ~~F~~field standardization should be performed in NSSP laboratories within the prospective State Shellfish LEO's home state to provide realistic

evaluation scenarios. ~~The narrative evaluation report detailing the evaluation findings must be prepared.~~ The draft narrative report(s) with accompanying checklist(s) must be submitted to the certifying FDA Shellfish Laboratory Evaluation Officer within 30 ~~60~~ days of the evaluation(s). All documents submitted will be reviewed for appropriate content, accuracy, and uniformity of approach by the certifying FDA ~~Shellfish Laboratory Evaluation Officer~~ National Laboratory Standard.

~~5.~~6. Field standardization is ~~based on a~~ pass/fail ~~system~~.

~~6.~~7. After successfully completing the Field Standardization Exercise, the State Shellfish LEO Candidate will be granted the title of Laboratory Evaluation Officer. A certificate recognizing that accomplishment will be forwarded to the State Shellfish LEO Candidate, along with formal notification to the State Shellfish LEO Candidate's supervisor, within thirty (30) days.

~~Certification~~

~~1. Certification is dependent upon the perspective State Shellfish LEO satisfying all the following performance criteria.~~

~~a. Demonstration of good familiarity with evaluation requirements.~~

~~b. Demonstration of a thorough knowledge of the evaluation methods and documents.~~

~~c. Demonstration of the technical knowledge/familiarity with the analytical procedures being used.~~

~~d. Ability to communicate effectively both orally and in writing.~~

~~e. Successful completion of both training and field standardization.~~

~~2. Upon successful completion of the certification process, a letter of certification will be issued by the FDA Shellfish Laboratory Evaluation Officer and a copy will be sent to both the requesting Authority and the FDA Regional Shellfish Specialist.~~

~~3. Certification is normally valid for up to five (5) years unless revoked or voided.~~

Failure to be Certified

1. If a prospective State Shellfish LEO fails to satisfy any of the performance criteria listed above, he/she will not be certified.
2. As resources permit ~~and at the discretion of FDA~~, the prospective State Shellfish LEO may receive additional training to better prepare him/her to be certified; including attending the Shellfish Program Laboratory Methods and Evaluation Procedures Course. If the LEO candidate is unsuccessful in his/ her final standardization attempt he/ she must repeat the two (2) practice evaluations and one (1) final standardization evaluation. If failure continues after the second attempt, the candidate will not be eligible for a third attempt at standardization without the expressed permission of the National Laboratory Standard.
3. The requesting Authority may withdraw the prospective State Shellfish LEO from consideration.

Recertification

1. Recertification normally occurs every ~~five (5)~~ six (6) years and is contingent upon the continuing need in the state shellfish sanitation program for the services of a State Shellfish LEO.

	2. Recertification is based on the State Shellfish LEO satisfactorily meeting the following employment and performance criteria. a. The individual must continue to be employed by the state and be free of any commercial, financial or other pressures or conflicts of interest real or perceived that may cause the State Shellfish LEO to act in other than an impartial and non-discriminatory manner. b. The individual must demonstrate continued competence in the evaluation of NSSP laboratories by performing ~~one to several joint~~ evaluations with an FDA Shellfish Laboratory Evaluation Officer and providing an appropriate narrative evaluation report to the FDA National Laboratory Standard.~~co-evaluator for review and comment for each of the laboratories jointly evaluated.~~ c. The individual must have performed laboratory evaluations at the minimum frequency prescribed in the current edition of the Guide for the Control of Molluscan Shellfish and have all Narrative evaluation reports up to date. 3. State Shellfish LEOs who successfully complete recertification will be issued a letter of recertification by FDA and be cleared to distribute the completed report(s) to the appropriate ~~Regional~~ Shellfish Specialist. A copy of this letter will be sent to the State Shellfish Control Authority and appropriate ~~Regional~~ Shellfish Specialist. 4. If FDA is unable to conduct a recertification visit by the expiration of the individual's certification, his/her certification may be extended until such time as recertification can be completed. If requested, a letter extending the certification can be provided as appropriate. Standardization Maintenance 1. Maintenance will be provided in the form of updated Laboratory Evaluation Officer courses, updated field standardization guides, and other guidance/technical assistance activities on an as needed basis. 2. State Shellfish LEOs will be required to attend the Shellfish Program Laboratory Methods and Evaluation Procedures Course every three years or when it is offered by FDA Revocation of Certification 1. State Shellfish LEOs who fail to meet any of the certification/recertification, employment, or performance criteria listed above will have their certification revoked. 2. Certification may be voided when state shellfish sanitation programs no longer have a need for the services of a State Shellfish LEO. 3. Voided certifications may be reactivated at the discretion of FDA if the need for the analytical services of additional laboratories by the state shellfish sanitation program recurs. 4. Revoked certifications will not normally be restored. 5. The National Laboratory Standard will document the reason(s) for revocation of the LEO certification. This information shall be forwarded to the Candidate's supervisor and a copy shall be placed in the FDA file. All evidence and conclusions reached by the FDA shall be documented in writing by the Standard and shall be retained for three (3) years in accordance with the Freedom of Information Act.
Public Health	The updated/revised requirements for certifying State Shellfish LEOs will help to

Significance	ensure a more objective, standardized approach to the certification process.
Cost Information	Costs associated with activities for certification of State Shellfish LEOs are the responsibility of the State Shellfish Control Authority. However, it is anticipated that costs specifically associated with attendance at the Shellfish Program Laboratory Methods and Evaluation Procedures Course would be funded by FDA.