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U.S. FOOD AND DRUG ADMINISTRATION
OFFICE OF FOOD SAFETY
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SHELLFISH LABORATORY EVALUATION CHECKLIST

LABORATORY:		
ADDRESS:		
TELEPHONE:	**FAX:**	
EMAIL:		
DATE OF EVALUATION:	**DATE OF REPORT:**	**LAST EVALUATION:**

LABORATORY REPRESENTED BY:	**TITLE:**
LABORATORY EVALUATION OFFICER:	**SHELLFISH SPECIALIST:**
OTHER OFFICIALS PRESENT:	**TITLE:**

Conformity is noted by a (Y), no (N), or not applicable (N/A) for each checklist item. Please note that for all N/A indications, you must document the reason why this requirement is N/A on a separate record. Record comments related to any requirement on the space provided in the summary of nonconformities. All nonconformities must be identified and explained. Quality System must be in place for onsite laboratory evaluation to be scheduled.

Parts of the Quality Checklist	
Part I	Quality Management: Laboratory Operations and Responsibilities for Quality Systems
Part II	Quality Assurance: The Process of Documenting and Maintaining a Quality System
Part III	Quality Control: Documentation for Quality System Defensibility

PART I – Quality Management: Laboratory Operations and Responsibilities for National Shellfish Sanitation Program Laboratory Quality Systems		
	ITEM	
Conformance Comments	**Ref**	
		1.1 Components of the Laboratory Quality System
	1,3,6,9	1.1.1 The laboratory has an overall Quality System supported by quality management structure, quality assurance processes and quality control functions.
	1,3,6,9	1.1.2 Management and technical structure exist to support the Quality System.
	1,3,6,9	1.1.3 Quality documentation is required by the laboratory. These include a Quality Assurance (QA) Manual (or otherwise named) and Standard Operating Procedures (SOPs) to support the quality assurance process of the laboratory.
	1, 9	1.1.4 The documents used to implement the quality assurance process and records used to verify quality control (QC) function of the laboratory are reviewed and controlled.
	9	1.1.5 An established process of Quality System assessment and technical proficiency are documented with results retained until the next review.
	9	1.1.6 Resolution, management review and prevention of nonconformities are a documented component of the Quality System.
		1.2 Laboratory Management Structure and Quality Systems
	1,3,6,9	1.2.1 The laboratory's structure is clearly organized with supervisory chain delineated.
	9	1.2.2 The laboratory has ensured that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work.
	9	1.2.3 The laboratory has documentation of dedicated personnel with the authority and resources required to carry out their duties, including implementing and maintaining the Quality System of the laboratory.
	1, 9	1.2.4 The laboratory's designated quality personnel ensure adherence to the quality system, including SOPs and QC. These staff have clear documented authority to initiate actions to prevent or minimize departures from quality system and monitor the corrective action process.
	9	1.2.5 The laboratory has documentation of a designated quality system manager, responsible for monitoring all aspects of the quality system to assure defensibility. This person shall have unrestricted access to FDA Shellfish Laboratory Evaluation Officers (LEOs) and the highest levels of the laboratories management. In the case of a single person laboratory, FDA LEOs will assist with developing a monitoring plan.
	1, 9	1.2.6 A documented system is in place to ensure that appropriate review of and communication regarding the elements of the quality system are established among the laboratory staff and laboratory management.
		1.3 Laboratory Personnel and Roles in a Quality System
	1,3, 9	1.3.1 The roles and responsibilities of all personnel are defined in the QA manual, read by all staff and the acknowledgments of these

			responsibilities are retained.
	9	1.3.2	The laboratory policy and the training procedures for personnel are documented and relevant to the scope of the current activities in the laboratory. If the laboratory intends to add methods to their scope, training SOPs must also be added with successful completion by the analyst(s) that will perform the method(s). In the case of a single person laboratory, method proficiency verification must be retained during the life of the methods use in the laboratory.
	9	1.3.3	The laboratory shall maintain a personnel file/ record of any relevant authorization(s), qualifications, trainings, and/or proficiencies for each analyst. This information shall be available upon request as verification of staff training and shall be retained for all staff until two years after they are no longer employed by the laboratory.
	1, 3, 9	1.3.4	The laboratory has documented that all personnel involved in testing have read and understand the applicable SOPs and associated quality documentation and implement the policies and procedures required for the performance of their technical function.
PART II – Quality Assurance: The Process of Documenting and Maintaining a Quality System			
		2.1 Quality Assurance Process: QA Manual, SOPs and Document Control	
	1, 9	2.1.1	The QA manual shall include or make reference to all laboratory SOPs and any supporting procedures, including technical procedures.
	1, 9	2.1.2	SOPs are controlled documents and include detailed, written instructions to achieve uniformity of test methods and quality control procedures, such that items that might affect the quality or defensibility of the outcome are mitigated.
	1, 9	2.1.3	SOPs and the QA Manual are controlled documents, such that specific individuals are designated within the laboratory with editorial control. These individuals are identified in the QA Manual.
	1, 9	2.1.4	Each time an SOP or the QA manual has changed, the new version will be marked as such and will be distributed to the laboratory with older versions removed from circulation.
	1, 9	2.1.5	Staff training requirements are documented in the QA manual and the training procedure is included.
		2.2 Quality Manual Items	
	1, 9	2.2.1	Quality Assurance Manual contains: □ Table of Contents; □ Organizational chart; □ A description of the Quality System and procedure for implementation and maintenance; □ Policy and procedure for resource management (human resources, competence and training, work environment and safety), description of responsibilities; □ Policy and procedures for rejection criteria; □ Policy and procedures for calibration of equipment and Equipment file items such as maintenance; □ Policy and procedure for traceability and required documentation, □ Policy and procedure for internal audits; □ Policy and Procedure for data analysis and control of nonconforming work; and □ Policy for corrective actions (CAs) and preventative actions (PAs).
	1,3,6,9	2.2.2	The organizational chart clearly depicts laboratory structure with quality and technical personnel listed.

	1, 9	2.2.3	The policy for human resources provisions includes hiring and assignment of staff, competence and responsibilities for positions, and a procedure of training for each technical competence, including proficiencies required.
	1, 3, 4, 6, 9	2.2.4	Policies for work environment and safety protocols, analytical methods, and quality control performed for the National Shellfish Sanitation Program (NSSP) are included or referenced in the QA Manual and shall be provided upon request.
	1, 9	2.2.5	A policy regarding appropriate equipment file maintenance and retention (e.g., calibration records, maintenance documentation, manuals of operation) is included in the QA Manual.
	1, 9	2.2.6	The SOP for calibration and maintenance of equipment is kept or referenced in the QA Manual and shall be provided upon request.
	1, 9	2.2.7	The SOP for traceability of analytical results is included or referenced in the QA Manual and shall be provided upon request. This traceability procedure includes a documented procedure for the unique identification of samples and the process for chain of custody verification.
	1, 9	2.2.8	The QA Manual has a policy and a procedure for internal quality audits. These audits are planned and scheduled annually or as needed. The policy states auditors do not audit their own work. In the case of a single person laboratory, FDA LEOs will assist with an audit plan.
	1, 9	2.2.9	The QA Manual contains a policy for data analysis to require that all analyses performed have been carried out correctly, documented, controls were used accurately and the results meet specified requirements.
	1, 9	2.2.10	The QA Manual contains a procedure for the control of nonconforming work in the case of: □ identification, documentation, evaluation, segregation (where practical), disposition of nonconforming sample/analyte/result and customer notification; □ assigning responsibility for the review and the authority for disposition of nonconforming sample/analyte/result; □ a nonconforming result correction and the re-verification/calibration of the affected equipment after the correction to demonstrate conformity (if necessary); and □ handling a nonconforming result when it is detected, after delivery to the customer.
	1, 9	2.2.11	The QA manual contains a procedure for preventative actions in which laboratory staff identify potential nonconformities in audit results, quality records, or customer complaints through a review process. Steps are then determined to identify preventive actions to implement. The necessary changes are made to SOPs and this exercise is recorded, and records maintained.
	1, 3, 6, 9	2.2.12	The QA manual has a policy and a procedure for developing corrective action(s) to eliminate the cause of identified nonconformities in order to prevent recurrence. Corrective actions describe the nonconformities, define the process for evaluating the need for actions to ensure that nonconformities do not recur (root cause analysis), explain the process to implement the corrective action(s) needed, and the resultant outcome. There is also a procedure to monitor progress of any ongoing corrective actions and the resolution.

	1, 3, 4, 6, 9	2.2.13	The QA Manual contains a policy stating laboratory management shall ensure and document the competence of staff independently operating equipment resulting in a documented measurement, analysis result, quality control value/result, determination of data value for sample result, and review/closure of corrective action for efficacy.
	1, 9	2.2.14	The policy for sample rejection criteria includes what the laboratory will accept and reject based on NSSP requirements and chain of custody.
	1, 3, 4, 6, 9	2.2.15	The laboratory shall have sample acceptance procedures that include safe handling, transport, and storage to prevent contamination or deterioration and to protect the sample integrity. These procedures are provided to customers.
	1, 3, 4, 6, 9	2.2.16	The laboratory has procedures for handling nonconforming samples and who will be contacted in the case of sample rejection.
PART III- Quality Control: Documentation for Quality System Defensibility			
		3.1 Documentation	
	1, 9	3.1.1	The laboratory investigates proficiency testing (PT) programs for areas of continual improvement and actively addresses problematic results through the prescribed corrective action process.
	1, 9, 10	3.1.2	The laboratory personnel performing sampling and testing participate in PT programs and exercises when available. If no PT exists, participation in interlaboratory comparisons is considered.
	1, 3, 6, 9, 10	3.1.3	Corrections to quality control records, bench sheets and reports follow the requirements below: □ A single line is drawn through the incorrect information; □ The correct information is written next to the incorrect information; □ The person responsible for the correction initialed the information; □ If not obvious, the reason for correction has been included; and □ If corrections are necessary in an electronic document, old information must be retained in some form, the person making the change must be identified, the date of the change noted, and the reason for the change noted.
	1, 3, 6, 9, 10	3.1.4	All records, required to be retained for two years (or length of time as dictated by State law), shall be legible and shall be stored in such a way that they are readily retrievable to prevent damage or loss.
	1	3.1.5	All records and documents must be written in indelible ink.
		3.2 Method Performance Validation	
	1, 3, 6, 9	3.2.1	The laboratory will internally validate new methods to confirm with objective evidence that the intended protocols are demonstrated and outcomes are fulfilled.
	1, 9	3.2.2	Methodologies do not deviate from the validated method and the laboratory's internal validation shall remain on file in the laboratory.
	1, 3, 6, 9, 10	3.2.3	The laboratory shall report the method chosen in writing to the customer.
	1, 4, 9	3.2.4	Methodologies and protocols are selected based on NSSP requirements and samples are processed as per the citation in the current Model Ordinance.
		3.3 Environmental Conditions	
	1, 3, 4, 5, 6, 9, 10	3.3.1	Laboratory facilities for analysis, including lighting and environmental conditions such as temperature and humidity, shall support accurate performance of the tests.
	1, 3, 4, 5, 6, 9,	3.3.2	The laboratory shall monitor, control, and record environmental conditions as required by the relevant specifications, methods and

	10		procedures, or where they influence the outcome of results (e.g., biological sterility, dust, humidity, electrical supply, temperature, vibration).
	1, 3, 4, 6, 9, 10	3.3.3	Laboratory personnel shall stop testing when the environmental conditions jeopardize the results of analyses.
	1, 3, 4, 6, 9, 10	3.3.4	Personnel shall ensure good housekeeping in the laboratory.
		3.4 Equipment	
	1, 3, 4, 6, 9, 10	3.4.1	The laboratory shall have instructions and/ or SOPs on the use and operation of all relevant equipment, and on the handling and preparation of items for testing, where the absence of such could jeopardize the outcome of analysis or influence results.
	1, 9, 10	3.4.2	All equipment in the laboratory is labelled with the manufacturer's name, identification number, and serial number or other unique identification that is traceable.
	1, 9, 10	3.4.3	Equipment files contain reports and certificates of all calibrations, the due date of next calibration, dates and results of any maintenance, adjustments, damage, malfunction, and modification or repair to the equipment.
	1, 2, 9, 10	3.4.4	If equipment (e.g., thermometer, balance) was sent out of the laboratory for service, performance has been verified prior to use again in the laboratory.
		3.5 Temperature Measuring Devices	
	1, 2, 8, 9, 10	3.5.1	Unique identifier, ice point date (if applicable) and any correction factor is recorded on in use temperature measuring device (TMD).
	1, 2, 8, 9, 10	3.5.2	TMDs are calibrated as per the NSSP requirements and ice points/steam points are performed annually on Standards thermometers.
	1, 8	3.5.3	TMDs calibration certificates are retained for three consecutive calibration cycles.
	1, 8, 9, 10	3.5.4	Where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure these records are retained until the next check is performed.
	1, 8, 9, 10	3.5.5	Range and graduations of all TMDs are appropriate for the designated use. Dial thermometers are not used in the laboratory.
	8, 9, 10	3.5.6	For electronic TMDs, probe/sensor is uniquely labeled and placement within unit being monitored follows manufacturer's instructions to ensure accurate readings, as devices vary.
	1, 8, 9, 10	3.5.7	Temperature Monitoring Systems (wired/wireless) must record temperature reading from each sensor/probe in the piece of equipment being monitored at the same or greater frequency and accuracy as stipulated for mercury in glass thermometers, as per manufacturer specifications.
		3.6 Disposables and Pipettors	
	1, 3, 4, 6, 9, 10	3.6.1	Pipettors, accuracy checked, fixed volume or electronic are calibrated according to NSSP requirements.
	1, 3, 10	3.6.2	Pipettors are etched with identification (imprinted serial numbers acceptable) and tagged with last date of accuracy check.
	1, 3, 4, 6, 9, 10	3.6.3	Appropriate pipettor tips are used and sterility checks are performed on an appropriate quantity.
	1, 3, 4, 6, 9, 10	3.6.4	Sterility checks on disposables are performed according to a cited QC practice, within a designated SOP. (e.g., laboratory may cite and implement a recognized standard of sterility testing, they may test 10% of a "lot" or any 3 in a box.)

		3.7 Test Record/Bench Sheet Requirements	
	1, 3, 4, 6, 9, 10	3.7.1	Test records/bench sheets shall contain information to facilitate repeatability under conditions as close as possible to the original including QC information (or reference) for media and supplies used.
	1, 9, 10	3.7.2	Test records/bench sheets must show date, time and temperature of samples at the start of analysis and contain the name or initials of the analyst performing the test for each group of samples.
	1, 4, 9, 10	3.7.3	Test records/bench sheets must include sterility controls or a reference to the document containing sterility controls for disposables and dilution buffer.
	1, 4, 9, 10	3.7.4	Test records/bench sheets must include media productivity (positive and negative) controls or a reference to the document containing media productivity controls.

REFERENCES

1. Title 21, Code of Federal Regulations, Part 58, *Good Laboratory Practice for Nonclinical Laboratory Study*. U.S. Government Printing, Washington, D.C. *Technical Programs – Criteria for Laboratories Performing Food Testing*. AOAC, Arlington, Va.
2. U.S. Department of Commerce. 1976. *NBS Monograph 150*. U.S. Department of Commerce, Washington, D.C.
3. Association of Official Analytical Chemists (AOAC). 1991. Quality Assurance Principles for Analytical Laboratories. AOAC, Arlington, VA.
4. Interstate Shellfish Sanitation Conference (ISSC). National Shellfish Sanitation Program for the Control of Molluscan Shellfish: 2015 Revision http://www.issc.org
5. The NELAC Institute (TNI). 2003 National Environmental Laboratory Accreditation Conference (NELAC) STANDARD QUALITY SYSTEMS. July 2005. Weatherford, TX.
6. U.S. Environmental Protection Agency (EPA). 1975. *Handbook for Evaluating Water Bacteriological Laboratories*. EPA – 670/9-75-006. U.S. EPA, Cincinnati, Ohio.
7. U S. Food and Drug Administration (FDA). 1998. *Bacteriological Analytical Manual*, Association of Analytical Chemists Inc, Arlington, VA. Edition 8A https://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm2006949.htm
8. National Institute of Standards and Technology Special Publication 250-23, 128 pages (Sept. 1988) U.S. Government Printing office, Washington, D.C. Library of Congress Catalog Number: 88-6000580.
9. The International Organization for Standardization and the International Electrotechnical Commission. Online: https://www.iso.org/obp/ui/#iso:std:iso-iec:17025:ed-2:v1:en accessed June 6, 2017.
10. National Conference on Interstate Milk Shipments. Cultural Procedures, 2400 Form. Online: http://ncims.org/programs/ accessed June 6, 2017.

LABORATORY:			**DATE of EVALUATION:**
SHELLFISH LABORATORY EVALUATION CHECKLIST **SUMMARY of NONCONFORMITIES**			
Page	Item	Observation	Documentation Required

LABORATORY STATUS	
LABORATORY	**DATE**
LABORATORY REPRESENTATIVE/POINT OF CONTACT:	

NSSP Quality System Evaluation: (Part I-III)

A. Criteria for Determining Laboratory Status of the Quality System Component:

1. **Laboratory must satisfy all sections of the Quality System prior to onsite evaluation**:

a. The total # of nonconformities in Part I _____

b. The total # of nonconformities in Part II _____

c. The total # of nonconformities in Part III _____

B. Laboratory Status (*circle appropriate*)

Does Not Conform **Conforms**

Acknowledgment by Laboratory Director/Supervisor:

All Corrective Actions will be implemented and verifying substantiating documentation received by the Laboratory Evaluation Officer on or before _____ so onsite evaluation can be scheduled.

Laboratory Signature: _____ Date:_____

LEO Signature: _____ Date:_____

LABORATORY:

Page	Item	Observation