PART 3 – Policies, Procedures, and Requirements for Approved Establishments and Systems *(Rev October 2024)*

Chapter 1 - Authority 2
Chapter 2 – Scope 2
Chapter 3 - Introduction 2
Chapter 4 - Definitions 3
Chapter 5 – Application for Approved Establishment Participation. 5
Chapter 6 – Prior to USDC SIP Assessment and Registration of the System 5
Chapter 7 – Initial Assessment of the System 5
Chapter 8 – Changes to the Approved System 6
Chapter 9 – System Audits - Surveillance 6
Chapter 10 – Establishments that receive an Unreliable rating 7
Chapter 11 – Corrective Action Plans 7
Chapter 12 – Appeal Procedures 8
Chapter 13 – Analytical Testing and Product Verification 8
Chapter 14 – Advertising Participants 8
Chapter 15 – Audit Based Certification and Grading Programs (rev. 7/2024) 8
Chapter 16 – System Compliance Rating Criteria 9

Chapter 1 - Authority

Authority for the United States Department of Commerce Seafood Inspection Program (USDC SIP) to provide services can be found within the Agricultural Marketing Act of 1946, the Fish and Wildlife Act of 1956, and the regulations promulgated under these authorities (i.e., 50 CFR Part 260).

Chapter 2 – Scope

USDC SIP policy is to encourage and assist interested parties in the development and implementation of food safety and quality management systems. Any organization, whether processor, retail operation, or vessel, foreign or domestic, may become part of this program.

This document provides guidance for the development, implementation, and operation of systems, which meet USDC SIP Approved Establishment requirements.

Chapter 3 - Introduction

NOAA Handbook Part 3 provides interested parties with the various policies, procedures, and requirements that shall be met for establishments to participate in the USDC SIP Approved Establishment program.

In July 1992, the USDC published a Federal Register notice announcing the availability of a Seafood Inspection Program (SIP) based on Hazard Analysis Critical Control Point (HACCP) principles. In January 2000, this program was further enhanced to include the ISO 9001 Quality Management Standard. This program is designed to further reduce inspection effort of USDC SIP personnel by partnering with industry participants and their responsibility for food safety, wholesomeness, economic integrity, and quality concerns for the system and products produced at the establishment.

USDC SIP Approved Establishment participants are those that process products under the USDC SIP on a contract basis. Approved Establishments are included on a list published on the USDC SIP's official website. Inclusion on this list is contingent upon the organization's continued ability to maintain USDC SIP Approved Establishment requirements.

Approved Establishments are verified by audit to meet all applicable federal regulations governing the construction and maintenance of facilities and equipment, processing techniques, and employer practices in the production of fishery products for human consumption along with all stated USDC SIP Approved Establishment food safety and quality management system criteria as outlined in Chapter 15. USDC SIP audits ensure that the food safety and quality system in place is adequate to control the critical functions by regular inspection of the system. These audits evaluate the food safety and quality system by examining product, processes, and records.

Approved Establishments shall notify USDC SIP of regulatory visits and findings. Participation as a USDC SIP Approved Establishment does not eliminate the responsibility and obligation to meet all federal and applicable state regulations and requirements.

USDC SIP Approved Establishment participation is consistent with global activities and standards to harmonize inspection protocols. In addition, Approved Establishment participation enhances the safety, wholesomeness, economic integrity, and quality of seafood available to consumers while improving seafood industry quality assurance and regulatory oversight.

Chapter 4 - Definitions

1. **Administrative Audit:** A review of the organization's records and procedures to determine whether they are in compliance with applicable laws, regulations, and USDC SIP program requirements.
2. **Applicant:** Any interested party who requests service under the policies in this part.
3. **Audit:** A systematic documented and independent process for obtaining evidence and evaluating it objectively to determine the extent to which the criteria are fulfilled.
4. **Auditor:** A person qualified to perform audits.
5. **Contamination:** The presence of microbial pathogens, chemicals, foreign material, spoilage, objectionable taints, and unwanted or diseased matter in food or water which may compromise the quality or suitability for consumption.
6. **Control Point:** Any step in a process whereby biological, chemical, or physical factors may be controlled.
7. **Corrective Action:** An action taken to eliminate the cause(s) of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.
8. **Critical Control Point (CCP):** A point, step, or procedure in a food process at which control can be applied, and a food hazard can, as a result, be prevented, eliminated, or reduced to an acceptable level.
9. **Critical Deficiency:** A hazardous deviation from plan requirements such that maintenance of the safety, wholesomeness, and economic integrity is absent and will result in unsafe, unwholesome, or misbranded product.
10. **Critical Limit:** The maximum or minimum value to which a physical, biological, or chemical parameter shall be controlled at a critical control point, or defect action point, to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food hazard.
11. **Decomposition:** A persistent and distinct objectionable odor and/or flavor including texture breakdown caused by the deterioration of the product.
12. **Deviation:** Any specifically defined variation from a particular requirement.
13. **Establishment:** Any premises, buildings, structures, facilities, and equipment (including vehicles) used in the processing, handling, transporting, and storage of fish and fishery products.
14. **Food Safety and Quality Management System**: A set of written procedures which define the range of actions taken by the organization to ensure that the food produce is safe to eat, of the required quality, and legally compliant.
15. **Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
16. **Hazard:** A chance for, or the risk of, a biological, chemical, physical, or economic property in a food product that could violate established program criteria or cause the consumer distress or illness.
17. **Hazard Analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the food safety management plan.
18. **High-Risk Product:** Seafood that may pose a significant danger to the health of the public when prepared for consumption by conventional or traditional means. For example, ready-to-eat; heat and/or brown-and-serve products; products that may contain a microbial pathogen, biotoxin, or physical or chemical contaminant that may pose an unacceptable health risk at the time of consumption.
19. **Hybrid Audit**: A combination of administrative and in-person review of the organization's records and procedures to determine whether they are in compliance with applicable laws, regulations, and USDC SIP program requirements.

20. **Interested Party:** Any individual possessing a financial stake in the relevant commodity, organization, or who can influence, be influenced by, or perceive themselves as influenced by a decision or action. This encompasses, without limitation, the United States and any of its agencies or instruments, any State, county, municipality, or public carrier, as well as any duly authorized representative acting on behalf of these entities.
21. **Live Processor:** An establishment that produces/services live products only.
22. **Lot:** A production unit as defined by mutual agreement between the processor and the USDC SIP consisting of processed product of the same type, style, and size which has been produced under conditions as nearly uniform as possible. The quantity of product in a "lot" should not exceed that quantity which is produced during a specific production shift.
23. **Low-Risk Product:** Seafood that poses no significant risk to the health of the public when prepared for consumption by conventional or traditional means.
24. **Monitoring Procedures:** Scheduled evaluations recorded to report the findings.
25. **Objective Evidence:** Information, which can be proved true, based on facts, obtained through observation, measurement, test, or other means.
26. **Prerequisite Program:** Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the food safety and quality management system.
27. **Process:** One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.
28. **Processed Product:** Any fishery product or other food product covered under the policies in this part that has been preserved by any recognized commercial process, including, but not limited to, canning, freezing, dehydrating, drying, the addition of chemical substances, or fermentation.
29. **Product Form:** Products that are similar in appearance, species, and/or processing method. For example, raw shrimp, cooked shrimp, breaded shrimp, etc.
30. **Quality:** Totality of features and characteristics of a product or service that bear on its ability to satisfy given needs. The inherent properties of any processed product which determine the relative degree of excellence of such product, and includes the effects of preparation and processing, and may or may not include the effects of packing media, or added ingredients.
31. **Quality Objective:** Criteria established that is measurable, consistent with the quality policy, and relevant to product and service conformity.
32. **Record:** A document that furnishes objective evidence of activities performed or results achieved.
33. **Risk:** The probability that exposure to a hazard will lead to negative consequences.
34. **Serious Deficiency:** A severe deviation from plan requirements such that maintenance of safety, wholesomeness, and economic integrity is prevented; and, if the situation is allowed to continue, may result in unsafe, unwholesome, or misbranded product.
35. **Severity:** The seriousness of the effect(s) of a hazard or defect.
36. **Specification:** A detailed document describing the materials, dimensions, and workmanship requirements of a product.
37. **Systems Audit:** USDC SIP evaluation of the effectiveness of following the food safety and quality plan after the initial assessment has been completed.
38. **Validation:** The collection and evaluation of scientific and technical information to determine if the system, when properly implemented, will effectively control the hazards and defects.
39. **Verification:** Those activities performed, other than monitoring that determine the system continues to be reliable and is operating according to the plan.
40. **Wholesome:** The minimum basis of acceptability for human food purposes, of any fish or fishery product.

Chapter 5 – Application for Approved Establishment Participation.

Organizations wishing to participate as a USDC SIP Approved Establishment should contact the appropriate USDC SIP regional inspection branch.

USDC SIP may reject an application due to nonpayment for previous services rendered or if it appears that performing the service would not be in the best interest of the U.S. Government. If the application is rejected, the applicant will be notified promptly of the reason(s) in writing. An application may be withdrawn by the applicant at any time provided that the applicant shall pay for any reimbursable time spent as well as for any expenses incurred.

The USDC SIP regional inspection branch will provide the applicant with all necessary materials to inform them of the program, its requirements, and policies.

Chapter 6 – Prior to USDC SIP Assessment and Registration of the System

The establishment shall begin implementing the food safety and quality management plan provisions while maintaining all associated records. The establishment shall contact the USDC SIP regional inspection branch when they believe the plan is functioning successfully. The USDC SIP regional inspection branch will schedule a site visit. The establishment shall verify through end-product examination that implementation of the food safety and quality management system results in product that complies with all regulations, program requirements, and applicable quality standards or specifications. The organization must document validation of the food safety and quality management system

Chapter 7 – Initial Assessment of the System

Once the establishment submits an application for Approved Establishment participation, the USDC SIP regional inspection branch will schedule an audit with the establishment. USDC SIP personnel will evaluate the buildings, premises, facilities, and food safety and quality management system and shall determine compliance with these requirements and any corrections that may be required. A full report will be provided detailing these findings.

The audit performed on-site will determine whether the objectives have been identified, the food safety and quality management plan is being followed, and the identified product objectives and processes are being effectively controlled. The audit will be conducted on a fee basis by USDC SIP personnel assigned based on the demands of the audit. The number and structure of the team are determined by the size and complexity of the establishment's process and the nature of the hazards associated with the product and processes to be evaluated. All audits (registration and surveillance) will include document and record reviews, sanitation and in-process observations, photographic evidence, and end-product verification. All reviews will be performed using accepted auditing practices based on internationally recognized audit standards.

Establishments will be evaluated using the System Compliance Rating Criteria (Ch. 16) and other requirements as applicable. Establishments deemed acceptable may finalize a contract with the Program. If during the audit, deficiencies are noted that prevent an acceptable rating, the establishment may correct these deficiencies and request the audit team review these corrections prior to departing to determine system acceptability. Otherwise, a successful audit, either with significant deficiencies corrected or on a corrective action plan, will be necessary prior to completing a contract with the Program.

Note for Vessels: The CSO will accompany the vessel, if determined necessary, for an appropriate time period, performing checks of critical control points and auditing the plan at the same time. Once the work is performed, the officer is taken off the vessel as soon as is practicable. Further, it is expected that such a visit will only be necessary for high-risk products, such as cooked crab.

Chapter 8 – Changes to the Approved System

After the system has been approved, modifications may be made. The establishment shall notify the servicing USDC SIP regional inspection branch of any modifications to the food safety and quality management system. However, any urgent changes to address a health or safety issue may be made without prior approval and shall be documented in a corrective action plan.

Chapter 9 – System Audits - Surveillance

With a valid contract and continued demonstrated compliance with all applicable laws, regulations, and policies, the establishment will remain listed as a USDC SIP Approved Establishment. After approval of the establishment's system, USDC SIP will conduct audits at a minimum frequency—illustrated in the table below—to determine continued adherence to federal regulations and USDC SIP Approved Establishment requirements. More frequent audits may be necessary for cause as determined by the Regional Inspection Branch.

Systems Audit Target Frequencies		
Processors	**Live Processors**	**Freezer/Catcher Vessels**
Once per 12-week period	Twice per 12-month period	On-site, at minimum 1 time per 12-month period. Additional audits augmented by virtual technique may be scheduled.

In addition, the policies and procedures for each class of operation described below will be followed.

Seasonal Processors

'Seasonal" suspension eligibility is determined by the processing status of an organization. If the organization is processing, the contract cannot be suspended. Processing includes handling, storing, preparing, freezing, manufacturing, packing, or labeling.

If export certification is requested outside the contract dates, the destination of the product will determine if an export health certificate can be issued. Non-contract rates apply.

Audit frequency for organizations operating on a seasonal basis will be determined on a case-by-case basis. With regard to seasonal contracts, a written request to the servicing USDC SIP regional inspection branch shall be submitted to both suspend and reactivate the contract.

Vessels

Vessels shall provide the appropriate USDC SIP regional inspection branch with their tentative season schedules and off-loading schedules and sites as soon as they are known. Vessels shall give the Regional Inspection Branch Office notice prior to each port arrival, providing sufficient time for a USDC SIP Officer

to audit the vessel when required. Failure to do so could result in the removal of the vessel from the Program.

An on-site visit of the vessel will be conducted at minimum once per 12 month period. The visit may not require the auditor to be on board during fishing, but may require the auditor to be present during off-loading. Additional audits may be performed either by desk audit or during evaluation of stored product in the off season as applicable.

Chapter 10 – Establishments that receive an Unreliable rating

As a result of an audit, USDC SIP may rate an establishment that has demonstrated difficulties in administering the food safety and quality management plan as unreliable. Five (5) serious deficiencies or one (1) critical deficiency at the conclusion of an audit are generally deemed unreliable. An establishment, that is deemed unreliable, may continue to use official marks or other applicable advertising privileges **if** consent is given by USDC SIP. Consent will be on a case-by-case basis and granted only if USDC SIP believes the nature of the condition which caused the establishment to become unreliable can be adequately addressed through other means until the reliability of system control has been re-established.

Actions that may be taken include:

Establishments that are rated unreliable have a period of thirty days to take the necessary corrective actions to have the unreliable status removed. Failure to do so may result in the establishment's removal from the USDC SIP Approved Establishment list.

- Products may be certified during daily auditing. However, if any condition(s) exist(s) that is considered critical, no product certification will occur until the condition is corrected to the satisfaction of the USDC SIP.
- At the USDC SIP's discretion, product compliance may be verified by end-item evaluation.
- Firms participating in the Approved Establishment program deemed unreliable twice in a twelve-month period may be removed from the program. Firms who have been removed may submit a request for reapplication. Applications will be accepted by USDC SIP only if evidence of a change in management philosophy can be provided. Firms which have been removed from the program may still be eligible to enter into full-time auditing of the facility, system, and product.

Chapter 11 – Corrective Action Plans

When applicable, the establishment shall submit a corrective action plan to the USDC SIP auditor detailing how they will correct the problem. The corrective action plan shall include, at a minimum, detailed descriptions of the following:

- A statement of the problem;
- Identification of the person or persons responsible for addressing the situation;
- The methods to be used to correct the problem;
- A schedule which details the time frame to correct the problem; and
- A statement with signatures of top management attesting to their commitment to correct the deficiency, the corrective action plan shall be written in sufficient detail to provide USDC SIP with all necessary information for its approval or disapproval.

Chapter 12 – Appeal Procedures

An application for an appeal may be made by any interested party who has cause to disagree with the results of a product inspection or audit finding. Interested parties can request an appeal by completing a submission form at Sip Appeal Inquiry . Additional documentation supporting the appeal can be emailed to SIP.Appeals@noaa.gov.

Please refer to NOAA Handbook Part 1 Chapter 14 for details of the Appeals process.

Chapter 13 – Analytical Testing and Product Verification

The establishment shall perform periodic end-item verification of product compliance with the plan requirements. Samples for analytical testing shall be collected at a frequency sufficient to ensure the system is producing compliant product. The level of analytical sampling per lot shall be statistically sufficient to draw a proper conclusion. Records of all analytical findings will be made available to USDC SIP personnel during audits and at other times as necessary.

To determine whether the product produced at the establishment meets requirements and/or a specification, USDC SIP will routinely perform a product audit on up to three (3) lots produced since the last audit. This information will be used to guide the auditor in their audit of the system. Product audits will be completed by conducting records reviews and finished product inspections. Additional lots may be sampled if the situation warrants.

Chapter 14 – Advertising Participants

Establishments successfully participating in the Approved Establishment program will be listed in the USDC SIP Approved Establishments List. The list will include the establishment's name, all pertinent locations, and approved processes. This list is updated regularly on the Program's website. Establishments may advertise their participation in the Program as long as all advertisement claims are truthful and not misleading. Advertisement forms may include flyers, banners, print media, other media, and statements on product. To make certain advertisements meet all regulations and Program requirements, it is strongly advised that participant claims be approved by the USDC SIP prior to use.

Chapter 15 – Audit Based Certification and Grading Programs (rev. 7/2024)

SIP offers audit based programs that allow NOAA SIP Approved Establishments to receive Grade A and PUFI grading or export certification without lot inspection.

To display the NOAA SIP Official Insignia (Grade A, PUFI) on product labels, an Approved Establishment must engage in either onsite finished product inspection or an audit based Product Management Plan (PMP). *NOAA Handbook Part 4, Chapter 9 – Eligibility Requirements for Use of NOAA SIP Official Insignia* contains guidance for audit based PMP.

In addition, SIP offers an audit based export certification program, where NOAA SIP Approved Establishments can become eligible for export certification without lot inspection with an accepted

Export Management Plan (EMP). *NOAA Handbook Part 7, Chapter 2- Audit Based Export Certification Export Management Plan* contains guidance for audit based EMP**.**

Chapter 16 – System Compliance Rating Criteria

1.0 Management Controls and Responsibilities

1.1.0 Management Responsibilities

1.1.1 Management shall demonstrate leadership and commitment with respect to the food safety and quality management system

Top management shall provide evidence of its commitment to the development and implementation of the food safety and quality management system and to continually improving its effectiveness by: a) showing food safety and quality is supported by the business objectives of the organization, b) communicating to the organization the importance of meeting food safety and quality standards, statutory and regulatory requirements, as well as customer requirements relating to food safety and quality, c) establishing a food safety and quality policy with clear food safety and quality objectives, d) conducting management reviews of the system, and e) ensuring the availability of resources.
Deficiency: Critical

1.1.2 Food safety and quality policy is established, implemented, and maintained.
Top management shall define, document and communicate its food safety and quality policy with the aim of enhancing customer satisfaction. Top management shall ensure that the food safety and quality policy a) defines the scope of the system and is appropriate to the role of the organization in the food chain, b) conforms with both statutory and regulatory requirements and with mutually agreed food safety and quality requirements of customers, c) is communicated, implemented, and maintained at all levels of the organization, d) is reviewed for continued suitability which includes a commitment to comply with requirements and continual improvement, e) is supported by measurable objectives while providing a framework for establishing and reviewing food safety and quality objectives, and f) the integrity of the food safety and quality management system is maintained when changes to the system are planned and implemented.

Reassessment of the food safety and quality management system's adequacy shall occur at least annually or and whenever any changes occur that could affect or alter the plan in any way. A qualified individual shall perform the reassessment. The system shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements.
Deficiency: Serious

1.1.3 Food safety and quality management system planning conforms to all applicable statutory and regulatory requirements.
Top management shall ensure that planning of the food safety and quality management system is properly carried out to meet all applicable statutory and regulatory requirements including, but not limited to, label control system and net weights and measurements systems.
Deficiency: Serious

1.1.4 Responsibility and authority properly defined and communicated.
Top management shall ensure that responsibilities and authorities are defined and communicated within the organization to ensure the effective operation and maintenance of the food safety and quality management system. All personnel shall have responsibility to report problems with the food safety and quality management system to identified person(s). Designated personnel shall have defined

responsibility and authority to initiate and record actions
Deficiency: Serious

1.2.0 Food Safety and Quality Team

1.2.1 Food safety and quality team leader appointed.

Top management shall appoint a food safety and quality team leader who, irrespective of other duties, shall have the responsibility and authority to: a) manage a food safety and quality team and organize its work, b) report to top management on the performance of the system and any need for improvement, c) ensure relative training and education of the team members, and d) ensure that the food safety and quality management system is implemented, maintained, and updated.
Deficiency: Serious

1.3.0 Communication

1.3.1 Effective external communication established, implemented, and maintained.

To ensure that sufficient information on issues concerning food safety and quality is available throughout the food chain, the organization shall establish, implement, and maintain effective arrangements for communicating with: a) suppliers and contractors, b) customers or consumers, c) statutory and regulatory authorities, and d) other organizations that have an impact on or will be affected by the effectiveness or updating of the food safety and quality system.

The communication shall provide information on food safety and quality aspects of the organization's products that may be relevant to other organizations in the food chain. This applies especially to known food safety hazards that need to be controlled by other organizations in the food chain. Records of communications shall be maintained. Food safety and quality requirements from statutory and regulatory authorities and customers shall be available. Designated personnel shall have defined responsibility and authority to communicate information concerning food safety and quality externally. Information obtained through external communication shall be included as input to all system updating and management reviews.
Deficiency: Serious

1.3.2 Effective internal communication established, implemented, and maintained.

The organization shall establish, implement, and maintain effective arrangements for communicating with personnel on issues having an impact on food safety and quality. In order to maintain the effectiveness of the food safety and quality management system, the organization shall ensure that the food safety and quality team is informed in a timely manner of changes, including but not limited to the following: a) products or new products, b) raw materials, ingredients and services, c) production systems and equipment, d) production premises, location of equipment, and surrounding environment, e) cleaning and sanitation programs, f) packaging, storage, and distribution systems, g) personnel qualification level and/or allocation of responsibilities and authorizations, h) statutory and regulatory requirements, i) knowledge regarding food safety hazards and control measures, j) customer, sector, and other quality requirements which the organization observes, k) relevant enquiries from external interested parties, l) complaints indicating food safety hazards associated with the product, and m) other conditions which have an impact on food safety or quality.

The food safety and quality team shall ensure that this information is included in the updating of the food safety and quality management system. Top management shall ensure that relevant information is included as input to management review.
Deficiency: Serious

1.4.0 Emergency Preparedness and Response

1.4.1 Emergency response procedures established, implemented and maintained.

Top management shall establish, implement and maintain procedures to manage potential emergency

situations and accidents that can impact food safety and quality relevant to the role of the organization in the food chain.
Deficiency: Serious/Critical

1.5.0 Management Review

1.5.1 Management review performed and documented.

Top management shall review the organization's food safety and quality management system at planned intervals to ensure its continuing suitability, adequacy, and effectiveness. This review shall include assessing opportunities for improvement and the need for change to the system, including the food safety and quality policy and objectives. Records from management reviews shall be maintained.

The input to management review shall include information on: a) follow-up actions from previous management reviews, b) analysis of results of verification activities, c) changing circumstances that can affect food safety or quality, d) emergency situations, accidents, and withdrawals, e) results of system updating activities, f) communication activities including customer feed-back, g) results of external and internal audits or inspections, h) process conformance and product conformity, i) status of preventative or corrective actions, and j) recommendations for improvement. The data shall be presented in a manner that enables top management to relate the information to stated objectives of the food safety and quality management system.

The output from the management review shall include decisions and actions related to: a) assurance of food safety and quality, b) improvement of the effectiveness of the food safety and quality management system and its processes, c) resource needs, and d) revisions of the organization's food safety and quality policy and objectives.
Deficiency: Serious

1.6.0 Resource Management

The organization shall provide adequate resources for the establishment, implementation, maintenance and updating of the food safety and quality management system to ensure continual improvement and enhance customer satisfaction.

1.6.1 Necessary human resource competencies identified.

The food safety and quality team and the other personnel carrying out activities having an impact on food safety and quality shall be competent and shall have appropriate education, training skills and experience. Where the assistance of external experts is required for the development, implementation, operation, or assessment of the food safety and quality management system, records of agreement or contracts defining the responsibility and authority of external experts shall be available.
Deficiency: Serious

1.6.2 Personnel have received documented training necessary for the function of the food safety and quality system.

The organization shall: a) provide training or take other action to ensure personnel have the necessary competencies, b) ensure that personnel responsible for monitoring, corrections, and corrective actions of the management system are trained, c) evaluate the implementation and the effectiveness of a) and b), d) ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety and quality, and e) maintain appropriate records of training and actions described above.

At a minimum, the following functions shall be performed by an individual who has successfully completed training in the application of HACCP principles to fish and fishery product processing at least equivalent to that received under standardized curriculum recognized as adequate by the U.S. Food and Drug Administration or who is otherwise qualified through job experience to perform these

functions. Job experience will qualify an individual to perform these functions if it has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

- Developing a food safety management plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor
- Reassessing and modifying the management plan in accordance with the corrective action procedures and verification procedures, and the hazard analysis in accordance with the verification activities
- Performing food safety and quality management system record review and verification.

In addition, copies of all trained personnel's certificates and/or training records shall remain on file with the establishment. If failure of this element will not likely cause an immediate hazard it is rated as a Serious deficiency.

Deficiency: Serious/Critical

1.6.3 Sufficient infrastructure to implement and maintain the food safety and quality system.
The organization shall provide the resources for the establishment and maintenance of the infrastructure including personnel needed to implement a reliable food safety and quality system.
Deficiency: Serious

1.6.4 Work environment is properly established, managed, and maintained relative to food safety and quality.
The organization shall provide the resources for the establishment, management, and maintenance of the work environment needed to implement a reliable food safety and quality management system.
Deficiency: Serious

1.7.0 Measurement, Analysis, and Improvement
1.7.1 Customer satisfaction/dissatisfaction data maintained and monitored.
The establishment shall monitor information and data on customer satisfaction or dissatisfaction. The methods and measures for obtaining this information and data including the nature and frequency of reviews shall be defined and documented.
Deficiency: Serious

1.7.2 Internal audits established and performed.
The organization shall conduct internal audits at planned intervals to determine whether the food safety and quality management system a) conforms to the management system requirements established by the organization and to the applicable regulatory requirements, and b) is effectively implemented and updated.

An audit program shall be planned, taking into consideration the importance of the processes and areas to be audited, as well as any updating actions resulting from previous audits. The audit criteria, scope, frequency, and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure.
Deficiency: Serious

1.7.3 Continuous improvement activities performed including analysis of data with regard to the system.
Top management shall ensure that the organization continually improves the effectiveness of the food

safety and quality management system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis and results of verification activities, validation of control measure combinations, and corrective actions.
The organization shall collect data generated by measuring and monitoring activities and other relevant sources as a means of determining the effectiveness of the management system and for identifying where improvements can be made. The organization shall analyze applicable data to provide information on: a) the suitability, effectiveness, and adequacy of the system, b) process operation trends, c) customer satisfaction and dissatisfaction, d) conformance to customer requirements, e) characteristics of processes and products and their trends, and f) suppliers.
Deficiency: Serious

2.0 System Management
The elements of this section apply to all participants in the USDC SIP in the evaluation of facilities, processes and systems. The organization shall plan and develop the processes needed for the realization of safe wholesome products. The organization shall implement, operate, and ensure the effectiveness of the planned activities and any changes to those activities. This includes the food safety and quality plan.

2.1.0 Hazard Analysis and Quality Objective Assessment
2.1.1 Description of products, processes and control measures performed.
All relevant information needed to conduct the hazard analysis and quality objective assessment shall be collected, maintained, updated and documented. Records shall be maintained.

All raw materials, ingredients and product-contact materials shall be described in the food safety and quality management plan to the extent needed to conduct the hazard analysis and quality objective assessment, including the following, as appropriate: a) biological, chemical, and physical characteristics, b) composition of formulated ingredients, including additives and processing aids, c) origin, d) method of production, e) packaging and delivery methods, f) storage conditions and shelf life, g) preparation and/or handling before use or processing, and h) food safety and quality related acceptance criteria or specifications of purchased materials and ingredients appropriate to their intended uses. The organization shall identify statutory and regulatory food safety requirements related to the above.

The characteristics of end products shall be described in the food safety and quality management plan to the extent needed to conduct the hazard analysis and quality objective assessment, including information on the following, as appropriate: a) product name or similar identification, b) composition, c) biological, chemical and physical characteristics relevant for food safety and quality, d) intended shelf life and storage conditions, e) packaging, f) labeling relating to food safety and quality including instructions for handling, preparation and usage, and g) method of distribution. The organization shall identify statutory and regulatory food safety requirements related to the above.

The intended use, the reasonably expected handling of the end product, and any unintended but reasonably expected mishandling and misuse of the end product shall be considered and shall be described in documents to the extent needed to conduct the hazard analysis and quality objective assessment. Groups of users and, where appropriate, groups of consumers shall be identified for each product, and consumer groups known to be especially vulnerable to specific food safety hazards shall be considered.

Flow diagrams shall be prepared for the products or process categories covered by the food safety and quality management system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase, or introduction of food safety hazards or quality objective nonconformance. Flow diagrams shall be clear, accurate and sufficiently detailed. Flow diagrams shall, as appropriate, include the following: a) the sequence and interaction of all steps in the operation, b) any outsourced processes and subcontracted work, c) where raw materials, ingredients and intermediate products enter the flow, d)

where reworking and recycling take place, e) CCPs, and f) where end products, intermediate products, by-products and waste are released or removed. The food safety and quality team shall verify the accuracy of the flow diagrams by on-site checking. Verified flow diagrams shall be maintained as records.

All information described above shall be updated as necessary.
Deficiency: Serious

2.1.2 Hazard analysis and quality objective assessment performed.
The food safety and quality team shall conduct a hazard analysis and quality objective assessment to determine which hazards and objectives need to be controlled, the degree of control required to ensure food safety and quality, and which combination of control measures is required. All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process, and actual processing location shall be identified and recorded. All identified quality objectives that are to be met in relation to the type of product and process shall be identified and recorded.

Control measure categorized as belonging to the food safety management plan shall be implemented as such. Quality control measures categorized as belonging in the quality plan shall be implemented as such. The methodology and parameters used for this categorization shall be described in documents, and the results of the assessment shall be recorded.
Deficiency: Serious/Critical

2.1.3 Hazard analysis and quality objective assessment are available.
The hazard analysis and quality objective assessment are the foundation of the food safety and quality plan. If the analysis and assessments are not performed, the entire plan and its efficacy is suspect. Establishments shall provide this analysis to the requesting Consumer Safety Officer in writing. If it is not provided and evidence suggests that it was performed but a written document is not available, a Serious deficiency will be assessed. Otherwise, a Critical deficiency will be assessed.
Deficiency: Serious/Critical

2.1.4 All applicable statutory, regulatory, and program requirements are met.
System shall ensure that the food safety and quality management system is designed to meet all applicable statutory, regulatory, and program requirements. Procedures for label reviews, net weight determination and verification, and where applicable review and understanding of export requirements by country shall be defined and documented.

Quality objectives for quantity, including for weight/count shall be established, and implemented, to ensure products meet the applicable customer and legal requirements. This shall include a program for calibration and verification of equipment used for quantity control.

All products must be labelled in accordance with applicable statutory and regulatory requirements in the country of intended use, including allergen and customer specific requirements. Where a claim is made on the product label, the organization shall ensure there are quality objectives in place to support the claim including but not limited to traceability.

Deficiency: Serious

2.2.0 Product and service criteria

2.2.1 Traceability system adequate.
The organization shall establish and apply a traceability system that enables the unique identification of incoming material from suppliers and the initial distribution routes of the end product. When establishing and implementing the traceability system, the following shall be considered as a minimum a) relation of lots of received materials, ingredients, packaging, and intermediate products to the end

products, b) reworking or materials/products, c) distribution of the end product. Traceability records shall be maintained for a defined period for system assessment to enable the handling of potentially unsafe products and in the event of product withdrawal. Records shall be in accordance with statutory and regulatory requirements (including those for registration and traceability relative to the Bioterrorism Act) and customer requirements and may, for example, be based on the end product lot identification.
Deficiency: Serious

2.2.2 Evaluation and selection criteria for products and services established.
The establishment shall develop and maintain data that clearly describe or reference the specified requirements, including food safety and quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, an agreement that the suppliers, contractors, and consultants agree to notify the establishment of changes in the product or service so that establishments may determine whether the changes may affect the safety or quality of a finished product

The establishment shall establish and maintain the requirements (including safety, wholesomeness, proper labeling, and quality requirements) that shall be met by suppliers, contractors, and consultants. The establishment shall:

- Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements.
- Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
- Establish and maintain records of acceptable suppliers, contractors, and consultants.

The establishment shall develop and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements including any arrangements by the customer. Verification by the customer shall not absolve the supplier of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.
Deficiency: Serious

2.3.0 Verification and Validation

2.3.1 Verification procedures are adequate and established
The food safety and quality management plan shall list the verification procedures, and frequency thereof, that the processor will use. Every processor shall verify that the food safety and quality management plan is adequate and effectively implemented to control food safety hazards and quality objectives.

- Ongoing verification activities including:
    - A review of any consumer complaints that have been received by the processor to determine whether they relate to the performance of critical control points or reveal the existence of unidentified critical control points;
    - The calibration of process-monitoring instruments; and,
    - Periodic end-product or in-process testing

- Records review. A review, including signing and dating, by a qualified individual.

- The monitoring of critical control points. This verification review shall occur within 1 week of the day that the records are made.
- The taking of corrective actions. This verification review shall occur within 1 week of the day that the records are made.
- The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product or in-process testing that is part of the processor's verification activities. These verification review shall occur within 1 week of the day that the records are made.

Verification results shall be recorded and shall be communicated to the food safety and quality team. If system verification is based on testing of end product samples, and where such test samples show nonconformity with the acceptable level of the food safety hazard or quality objective, the affected lots of product shall be handled as potentially unsafe or nonconforming.
Deficiency: Serious

2.3.2 Verification procedures followed.
Verification procedures are those that provide for management to determine the overall effectiveness of the plan. Not following these procedures could ultimately cause the plan to fail or misidentify a hazard, defect, or control procedure. Since failure of these procedures will likely not immediately cause the plan to fail, it is rated at a Serious level. This item should be checked on a trend basis, not based on isolated incidences unless they are of such severity to warrant action.

Deficiency: Serious

2.3.3 Validation activities performed
The food safety and quality team shall plan and implement the processes needed to validate control measures and/or control measure combinations. Prior to implementation of control measures to be included in operational prerequisite programs and food safety and quality management plans and after any change therein, the organization shall validate that a) the selected control measures are capable of achieving the intended control of the food safety hazard and quality objectives for which they are designated, and b) the control measures are effective and capable of, in combination, ensuring control of the identified food safety hazard and quality objective resulting in end products that meet the defined acceptable levels.

If the result of the validation shows that one or both of the above elements cannot be confirmed, the control measure and/or combinations thereof shall be modified and re-assessed. Modifications may include changes in control measures (i.e. process parameters, rigorousness and/or their combination) and/or change(s) in the raw materials, manufacturing technologies, end-product characteristics, methods of distribution and/or intended use of the end product.
Deficiency: Serious

2.4.0 Records
2.4.1 Adequate information included in records (Name and location, etc.)
All records required by this part shall include:

1. The name and location of the processor or importer;
2. The date and time of the activity that the record reflects;
3. The signature or initials of the person performing the operation; and
4. Where appropriate, the identity of the product and the production code, if any.

Deficiency: Report Remark

2.4.2 Record is accurate.
All entries shall be accurate or the record is meaningless. All records shall be kept up-to-date. Entries shall be made as they are measured. The records shall contain the actual values and observations obtained during monitoring or measurement. Further, as the use of correction fluid and obliterating a record entry are not proper in the keeping of records, their routine use should be considered an inaccurate reading.

The maintenance of records on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.
Deficiency: Serious

2.4.3 Records are available for inspection.
If the organization is unable to supply the requested record in a reasonable amount of time for inspector review, they are not in compliance with this item. All required records shall be retained at the processing location or importer's place of business in the United States for at least 1 year after the date they were prepared in the case of refrigerated products and for at least 2 years after the date they were prepared in the case of frozen, preserved, or shelf-stable products.

Records that relate to the general adequacy of equipment or processes being used by a processor, including the results of scientific studies and evaluations, shall be retained at the processing location or the importer's place of business in the United States for at least 2 years after their applicability to the product being produced.

If the processing location is closed for a prolonged period between seasonal packs, or if record storage capacity is limited on a processing vessel or at a remote processing site, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned for official review upon demand.
Deficiency: Critical

2.4.4 Documents or records are not falsified.
This item is self-explanatory. However, intent on the part of the organization or its representatives shall be shown. For example, if an item on a record was shown to be corrected with correction fluid or other means of obliteration, the inspector shall show that someone with, full knowledge, changed the entry to reflect a value that was not the value measured or observed. Otherwise, this will be considered an inaccurate entry.
Deficiency: Critical

2.5.0 Corrective action

2.5.1 Corrective action taken
An organization is provided room for error in their plan through a system of corrective actions. If an error or problem arises in the implementation of the food safety and quality management plan, documented corrective action shall be taken. This includes but is not limited to a deviation from a critical limit, sanitation, monitoring or verification procedures.

In addition, the organization shall assess the validity of the previous measurement results when the equipment or process is found not to conform to requirements. If the measuring equipment is nonconforming, the organization shall take action appropriate for the equipment and any product affected. Records of such assessment and resulting action shall be maintained.

Failure to file a corrective action report will be considered a failure to take a corrective.
Deficiency: Critical

2.6.0 Control of Nonconformity

2.6.1 Nonconforming product is controlled.

The controls and related responses and authorization for dealing with potentially unsafe products shall be documented. The establishment shall establish and maintain procedures to control product that does not conform to specified requirements. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. The evaluation and any investigation shall be documented.

The establishment shall develop and maintain procedures for the disposition of nonconforming products by taking action to prevent the nonconforming product from entering the food chain unless it is possible to ensure that a) the food safety hazard of concern has been reduced to the defined acceptable levels, b) the food safety hazard of concern will be reduced to identified acceptable levels prior to entering the food chain, or c) the product still meets the defined acceptable level of the food safety hazard of concern despite the nonconformity. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.

All lots of product that may be affected by a nonconforming situation shall be held under control of the organization until they have been evaluated. If products that have left the control of the organization are subsequently determined to be unsafe, the organization shall notify relevant interested parties and initiate a withdrawal or recall. The controls and related responses and authorization for dealing with potentially unsafe products shall be documented.

The establishment shall develop and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented.

Each lot of product affected by the nonconformity shall only be released as conforming when any of the following conditions apply: a) evidence other than the monitoring system demonstrates that the control measure have been effective, b) evidence shows that the combined effect of the control measures for that particular product complies with the performance intended, c) the results of sampling, analysis and/or other verification activities demonstrate that the affected lot of product complies with the identified acceptable levels for the food safety hazard or quality objective.

Following evaluation, if the lot of product is not acceptable for release it shall be handled by one of the following activities: a) reprocessing or further processing within or outside the organization to ensure that the food safety hazard or quality nonconformance is eliminated or reduced to acceptable levels; b) destruction and/or disposal as waste.

Deficiency: Serious/Critical

2.6.2 Withdrawal and recall procedures designed and implemented.

To enable and facilitate the complete and timely withdrawal of lots of end products which have been identified as unsafe a) top management shall appoint personnel having the authority to initiate a withdrawal and personnel responsible for executing the withdrawal, and b) the organization shall establish and maintain a documented procedure for

- notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
- handling of withdrawn products as well as affected lots of the products still in stock, and
- the sequence of actions to be taken.

Withdrawn products shall be secured or held under supervision until they are destroyed, used for purposes other than originally intended, determined to be safe for the same (or other) intended use, or reprocessed in a manner to ensure they become safe. The cause, extent and result of a withdrawal shall be recorded and reported to top management as input to the management review. The organization shall verify and record the effectiveness of the withdrawal program through the use of appropriate techniques (e.g. mock or practice withdrawal).
Deficiency: Serious

3.0 Plans, Operating Procedures, and Prerequisite Programs
3.1.0 Food Safety Management Plan
3.1.1 Written food safety management plan available and implemented.
Every processor shall have and implement a written food safety management plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. The organization shall provide this plan to the requesting Consumer Safety Officer.
Deficiency: Serious

3.1.2 Hazard is listed in the plan.
The food safety management plan shall, at a minimum list the food safety hazards that are reasonably likely to occur and that thus shall be controlled for each fish and fishery product.

In the event that one or more hazards are not identified, a deficiency will be assessed.
Deficiency: Serious

3.1.3 Hazard is controlled.
Measures shall be in place to control food safety hazards that are reasonably likely to occur for each fish and fishery product.
Deficiency: Critical

3.1.4 CCPs are properly identified in the plan.
The food safety management plan shall, at a minimum list the critical control points for each of the identified food safety hazards, including as appropriate:

- Critical control points designed to control food safety hazards that could be introduced in the processing environment; and
- Critical control points designed to control food safety hazards introduced outside the processing environment, including food safety hazards that occur before, during, and after harvest.

Deficiency: Serious

3.1.5 Appropriate critical limit is listed in the plan.
Critical limits shall be determined for the monitoring established for each critical control point. Critical limits shall be established to ensure that the identified acceptable level of the food safety hazard in the end product is not exceeded. Critical limits shall be measurable. The rationale for the chosen critical limits shall be documented. Critical limits that are evaluated by observation (e.g., visually or by sensory evaluation) shall be supported by instructions or specifications and/or education and training.
Deficiency: Serious

3.1.6 Critical limit are followed.
Self-explanatory.
Deficiency: Critical

3.1.7 Monitoring procedure stated in the plan is adequate.
Monitoring procedures shall be established for each critical limit. The results of monitoring will indicate whether the CCP is in or out of control. The system shall include all scheduled measurements or observations relative to the critical limit. The monitoring system shall consist of relevant procedures, instructions and records that cover the following: a) measurements or observations that provide results within an adequate time frame; b) monitoring devices used; c) applicable calibration methods; d) monitoring frequency; e) responsibility and authority related to monitoring and evaluation of monitoring results; f) record requirements and methods. The monitoring methods and frequency shall be capable of determining when the critical limits have been exceeded in time for the product to be isolated before it is used or consumed. Where allergen controls are not sufficient or identified allergens are not declared on product labels where appropriate, a critical deficiency will be assessed.
Deficiency: Serious/Critical

3.1.8 Monitoring procedures followed:
Monitoring procedures shall be followed to maintain control of the process.

Deficiency: Serious

3.1.9 Corrective action listed in plan is appropriate and adequate.
Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the food safety management plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter controlled at the CCP is brought back under control, and that recurrence is prevented.

A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

- No product enters commerce that is either injurious to health, is otherwise adulterated as a result of the deviation, or does not meet Program requirements; and
- The cause of the deviation is corrected.

Deficiency: Serious

Plan is location and/or fish species specific.
A food safety management plan shall be specific to:

- Each location where fish and fishery products are processed by that processor; and
- Each kind of fish and fishery product processed by the processor. The plan may group kinds of fish and fishery products together, or group kinds of production methods together, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed are identical for all fish and fishery products so grouped or for all production methods so grouped.

Report Remarks

3.2.0 Quality Management Plan

3.2.1 Written quality management plan available and implemented.

Every establishment shall have and implement a written quality plan which covers each of the elements delineated in the quality assessment. The organization shall provide this plan to the requesting Consumer Safety Officer.

The organization shall establish and maintain a quality plan that includes the scope of the quality management system and the documented procedures established for the quality management system.
Deficiency: Serious

3.2.2 Product characteristics described including raw materials, ingredients, and end product.
The organization shall implement effective liaison with its customers, with the aim of meeting customer requirements. The organization shall define communication requirements relating to product information and order handling, including amendments. Such communication shall be recorded and shall include customer agreement to the terms.

The customer requirements, including any requested changes, are to be reviewed before a commitment to supply a product is provided to the customer to ensure that: a) identified customer requirements are clearly defined for the product, b) where the customer provides no written statement of requirement, the order requirements are confirmed before acceptance, c) contract or order requirements differing from those previously expressed are resolved, and d) the establishment has the ability to meet the customer requirements for the product.

The organization shall identify quality requirements to the above and these descriptions are to be kept properly updated.
Deficiency: Serious

3.2.3 Quality plan followed
The organization shall follow the policies outlined in their quality management plan. This deficiency will be assessed whether or not it was determined that product was affected.
Deficiency: Critical

3.3.0 Operational Prerequisite Programs
3.3.1 Operational prerequisite programs present and effective.
Each processor shall have and implement a written operational prerequisite procedures or similar document that is specific to each location where fish and fishery products are produced. The operational prerequisite programs shall be documented and shall include the following information for each program: a) food safety hazard or quality objective to be controlled by the program, b) control measure, c) monitoring procedures that demonstrate that the prerequisite programs are implemented, d) corrections and corrective actions to be taken if monitoring shows that the operational prerequisite programs are not in control, e) responsibilities and authorities, and f) records of monitoring.
Deficiency: Serious

3.3.2 Operational prerequisite procedures followed.
This deficiency will be assessed if it is determined that the organization did not follow their written procedures, whether or not specific deficiencies were observed.
Deficiency: Serious

3.4.0 Sanitation Standard Operating Procedures
3.4.1 Sanitation standard operating procedures present and effective.
Each processor shall have and implement a written sanitation standard operating procedure (SSOP) or similar document that is specific to each location where fish and fishery products are produced. The SSOP shall specify how the processor would meet those sanitation conditions and practices that are to be monitored.
Deficiency: Serious

3.4.2 Sanitation standard operating procedures followed.
This deficiency will be assessed if it is determined that the organization did not follow their written SSOPs, whether or not specific sanitation deficiencies were observed.
Deficiency: Serious

3.4.3 Sanitation monitored.
Each processor shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices appropriate to location and the food being processed and relate to the following:

1. Safety of the water that comes into contact with food or food contact surfaces, or is used in the manufacture of ice;
2. Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments;
3. Prevention of cross-contamination from unsanitary objects to food, food packaging material, and other food contact surfaces, including utensils, gloves, and outer garments, and from raw product to cooked product;
4. Maintenance of hand washing, hand sanitizing, and toilets;
5. Protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants;
6. Proper labeling, storage, and use of toxic compounds;
7. Control of employee health conditions that could result in the microbiological contamination of food, food packaging materials, and food contact surfaces; and
8. Exclusion of pests.

The organization shall define the applicable frequencies of monitoring in their sanitation standard operating procedures and shall adhere to these frequencies.
Deficiency: Serious

3.4.4 Safety of Process Water
Process water shall be of suitable quality as it directly interfaces or becomes part of the product being manufactured. Therefore, no filth, deleterious chemicals, bacteria, or other contaminants may be present in solution as it will directly affect the safety or wholesomeness of the product. Available water shall pass potability standards established by federal, state, and local authorities. Water that is supplied shall meet certain minimum standards. However, processing water shall also be reasonably protected. Conditions that allow contamination to occur cannot be allowed. These may include cross-connection of plumbing, back-siphonage, or back flow from a contaminated source to the supply system or open vessels of water.

3.4.4.1 Safe and sanitary water supply.
The water supply, including seawater, will be in compliance when by certification or direct testing the supply is found to meet the federal standards set forth by the Environmental Protection Agency or the World Health Organization as applicable. Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.
Deficiency: Serious/Critical

3.4.4.2 Water potability certificate current
Private supplies shall have testing performed at a minimum of every six (6) months. Certification of municipal or community systems should be secured at a minimum of once per year. Where used, seawater shall meet processing use requirements and potability shall be tested at a frequency sufficient

to ensure the acceptability of the water source from that geographic area.
Deficiency: Serious

3.4.4.3 Self water treatment performed properly.
Where water supply is treated (such as chlorinated, ozone, UV) on premises, equipment shall be properly maintained and/or residual shall be within acceptable limits based upon statutory, regulatory, and requirements of the end-user.
Deficiency: Serious

3.4.4.4 Protection against backflow, back-siphonage, and other sources of contamination.
A cross-connections are eliminated and backflow prevention devices are installed wherever backflow or siphonage may occur, or where other possible forms of contamination may be present. A diagram or chart of all such devices will be on file for review.
Deficiency: Serious

3.4.4.5 Ice manufactured, handled, and used in a sanitary manner.
Potable water is used for manufacturing ice, when the manufacturing equipment is clean, and the ice only contacts impervious surfaces; the ice holding containers are clean and made of appropriate impervious material; handling equipment is clean and appropriate for food contact; and ice is properly used. For locations receiving ice from an outside supply, a certificate of conformance will be necessary to ensure that the ice being received meets the standards set forth in this document. In addition, potability checks shall be made at a minimum of every six (6) months on ice received.
Deficiency: Serious/Critical

Adequate supply of water and hot water.
The water supply shall be sufficient for the operation intended. Plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations. Water shall be sufficient to properly convey sewage and liquid disposable waste. Running water at a suitable temperature and under pressure as needed, shall be provided in all areas where required for processing of food, for the cleaning of equipment, utensils and food packaging, or for employee sanitary facilities.

Hot water is necessary for many cleaning techniques. In addition, a hot water supply is necessary to provide a comfortable means for employees to wash their hands. The tap shall produce at minimum a luke-warm supply of water in sufficient quantities for the task. The supply shall also be easily accessible for its proper use.
Report Remark

3.4.5 Food Contact Surfaces

3.4.5.1 Equipment and utensils' design, construction, location, and materials can be readily cleaned or sanitized; does not preclude product adulteration or contamination.
Any equipment used in the manufacturing or handling of the food product shall be designed or constructed so that it can be properly cleaned and inspected. Seams on product-contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.

All equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. All equipment should be so installed and maintained as to facilitate the cleaning of the equipment and of all adjacent spaces. Product-contact surfaces shall be corrosion-resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food and, if applicable, cleaning compounds and sanitizing agents. Food containers and food-packaging materials that are safe and suitable are to be used. Product-contact surfaces shall be maintained to protect food

from being contaminated by any source, including unlawful indirect food additives.
Deficiency: Serious/Critical

3.4.5.2 Equipment and utensils maintained in proper repair and removed when necessary. (Food contact surfaces)
All food contact surfaces shall be kept in good repair. If the contact surface cannot be repaired, then the piece of equipment or utensil should be removed so as not to allow for its use. Assessment of this deficiency will be made relative to the risk of the product at that stage of production.
Deficiency: Serious (finding for products at a high risk stage of processing)

3.4.5.3 Food contact surfaces cleaned and sanitized before use, after interruptions, and as necessary.
Food contact surfaces and food containers shall be adequately cleaned using proper techniques to remove dirt and debris and shall be adequately sanitized. Sanitizers shall be used before product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered non-compliance. Risk should be considered when assessing this deficiency. Product leaving a cooker to be packaged and frozen will have a higher level of risk than a raw fish at receiving.
Deficiency: Serious/Critical

Concentrations of cleaners and sanitizers are effective, safe, and routinely checked.
All sanitizing agents (e.g., hand sanitizers, equipment sanitizers, etc) shall be used in the proper concentration and in the manner prescribed in the usage instructions to be effective.
Report Remark

3.4.6 Prevention of Cross Contamination

3.4.6.1 Sufficient separation by space or other means to prevent adulteration or contamination.
There shall be sufficient separation between different activities in the processing, packaging and handling of food products such as a) separation between activities, b) layout (employee traffic), c) product sequencing, and d) product display. This includes the complete separation of living/sleeping quarters or heavy maintenance areas from food-handling areas. The food product should flow easily from one stage to another and not be allowed to come into contact with non-food contact surfaces if exposed. In addition, the layout should not be such that product contamination/adulteration is likely due to issues such as heavy employee traffic through work areas. Production is organized and scheduled in a manner which prevents cross-contamination or cross-contact of product by allergens. Adequate separation can be by physical barrier, time, space, etc. Sanitary handling procedures and processing methods during operations are to be in place to protect food against contamination to include physical protection from airborne contamination.

Retail product displays should be arranged so that there is sufficient separation to assure that no cross-contamination can occur between raw, cooked, and live product.

Food manufacturing areas and equipment used for manufacturing human food should not be used to manufacture nonhuman food grade animal feed or inedible products unless there is no reasonable possibility for the contamination of human food.
Deficiency: Serious/Critical

3.4.6.2 Condition of roof, ceilings, walls, floors, and lighting in areas directly affecting product or packaging material maintained; lights protected.
For those areas that will directly affect product or primary packaging materials (packaging immediately surrounding product), the roof, ceiling, walls, floors, the storage of ingredients or materials that permits cross-contamination or cross-contact by allergens or ingredients, and lighting fixtures shall be maintained as designed and lights shall be protected.
Deficiency: Serious

3.4.6.3 Cleaning methods prevent adulteration or contamination.
Employees shall take care to use methods that will not adulterate or contaminate the product. Any cleaning or sanitizing procedures or techniques that may cause the product to become adulterated or contaminated will be deemed non-compliant. Examples of non-compliance include but are not limited to inadvertent touching of product or product surfaces with wash water, detergent, sanitizers, etc., during production.
Deficiency: Serious (Critical for products at a high risk stage of production)

3.4.6.4 Finished product/primary packaging material properly covered and protected.
Finished product shall be packaged, covered or protected to prevent contamination or adulteration prior to shipment and during transportation. Primary packaging materials should be adequately covered when stored or not in use.

Deficiency: Serious

3.4.6.5 Processing or food handling personnel take necessary precautions to prevent adulteration and contamination of food.

All persons, while in food preparation or handling areas, shall wear clean outer garments and conform to hygienic practices while on duty to the extent necessary to prevent contamination or adulteration of food. This includes occasional workers or visitors to the area.
All persons, while in a food preparation or handling area, shall:

- Wash their hands thoroughly to prevent contamination by undesirable microorganisms before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated. After washing, the hands shall be sanitized
- Remove all insecure jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized or properly covered.
- If gloves are used in food handling, maintain them in an intact, clean, and sanitary condition. Such gloves shall be of an impermeable material except where their usage would be inappropriate or incompatible with the work involved. If gloves are used they will be washed and sanitized at the same frequency as employees' hands as described in number one of this list.
- Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall comply with this requirement.
- Not expectorate; nor store clothing or other personal belongings; not eat food or drink beverages; nor use tobacco in any form in areas where food or food ingredients are exposed, or in areas used for food processing, storage of food ingredients and/or packaging materials, washing of equipment and utensils, or in production areas.
- Take other necessary precautions to prevent contamination of foods with microorganisms or foreign substances including, but not limited to perspiration, hair, cosmetics, tobacco, chemicals, and medicants.
- Using sanitary handling procedures during operations to protect food against contamination, e.g., picking up dropped food from the floor.

Deficiency: Serious/Critical

3.4.6.6 Management implements measures to restrict people with known disease from contaminating the product.
No person affected by disease in a communicable form, or while a carrier of such disease, or while affected with boils, sores, infected wounds, or other abnormal sources of microbiological

contamination, shall work in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Management shall require employees to report illness or injury to supervisors.
Deficiency: Serious

Design, layout of materials used can be readily cleaned and sanitized; does not preclude product contamination. Sufficient lighting for the applicable operation.
Design and structure should provide easy access to all areas. This is necessary for proper cleaning and sanitizing of floors, walls and ceilings, as well as for visual inspections. This would include insufficient lighting, improper materials for walls, ceilings, etc., as well as hard-to-reach rooms or corners even when the equipment is removed from the room.
Report Remark

Grounds condition prevent contaminants from entering.
There shall be no conditions on the grounds such as dusty roads or parking lots, standing or ponding water, chemical spills, etc., that can cause contamination to enter through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc.
Report Remark

Non-food contact surfaces, equipment, and areas cleaned before use.
Non-food contact areas shall also be cleaned prior to use. Areas such as walls, ceilings, floors, as well as equipment shall also be cleaned prior to use. However, sanitizing is not required.
Report Remark

3.4.7 Handwashing, Hand Sanitizing, and Toilet Facilities

3.4.7.1 Hand washing and hand sanitizing stations present and conveniently located.
Hand washing and hand sanitizing stations shall be present and located properly and in sufficient numbers to provide employees ease of their use. Devices or fixtures, such as water control valves, shall be so designed and constructed to protect against recontamination of clean, sanitized hands.
Deficiency: Serious/Critical (Critical for products at a high risk stage of production)

3.4.7.2 Proper disposal of toilet waste or sewage.
Sewage systems shall drain properly, vent to the outside, and connect to an approved private septic system or a public septic and/or sewage system.
Deficiency: Critical

3.4.7.3 Adequate supplies/signs for employees.
The restrooms and hand-washing stations shall provide supplies such as toilet paper, soap, waste containers, running water, sanitary towel service or suitable drying devices, etc., sufficient to meet employees' needs. Readily understandable signs directing employees handling unprotected food, food packaging materials, or food contact surfaces to wash and sanitize their hands at the proper frequency. Refuse receptacles shall be constructed and maintained in a manner that protects against contamination of food.
Deficiency: Serious

3.4.7.4 Sufficient number of functional toilets.
One operable, clean, in good repair, and conveniently accessible toilet per fifteen (15) employees is required. Toilet facilities shall be maintained in a sanitary condition with self-closing doors that do not open directly into areas where food is exposed to airborne contamination, except where alternate means of protection have been implemented.
Deficiency: Serious

3.4.8 Protection from Adulteration

3.4.8.1 Condensation and other deleterious sources are not present.

Adequate physical protection of food from adulterants that may drip, drain, or be drawn into the food shall be in place. Provide adequate physical protection or separation of food during processing (filling, packaging, assembling, etc.) to protect from contamination. Condensation, overhead leaks, water splash or other conditions that may result in the adulteration of product or primary packaging material results in non-compliance for this item.

Deficiency: Critical

Adequate air exchange exists.

Adequate air exchange shall exist to preclude the development of foul odors or contamination of product. This is assessed only for products at a high risk stage of production.

Report Remark

3.4.9 Proper Labeling, Use, and Storage of Toxic Compounds

Chemicals are cleaners, sanitizers, rodenticides, insecticides, food grade machine lubricants, etc. They shall be used according to manufacturer's instructions, have proper labeling, and be stored in a safe manner or they may pose a risk of contaminating the food product that the establishment is handling or manufacturing.

Chemical shall be used according to manufacturer's instructions and recommendations and stored in an area of limited access away from food handling or manufacturing. All chemicals shall be labeled to show the name of the manufacturer, instructions for use, and the appropriate EPA approval.

Only the following toxic materials may be used or stored where food is processed or exposed: a) those required to maintain clean and sanitary equipment and surfaces, b) those necessary for use in laboratory testing procedures, c) those necessary for equipment maintenance and operation, and d) those necessary for use in operations.

3.4.9.1 Chemical properly used or handled.

Deficiency: Critical

3.4.9.2 Chemical properly stored.

Deficiency: Serious

3.4.9.3 Material Safety Data Sheets (MSDS) available for all chemicals in use.

Deficiency: Serious

Chemical properly labeled.

Report Remark

3.4.10 Exclusion of Pests

The presence of rodents, insects, and other animals shall not be allowed because they are sources for the contamination of food with foreign material, filth, and bacteria, etc.

3.4.10.1 Extermination

Birds--Nesting areas shall be eliminated.

Insects--There should not be a significant number of insects present. Insect electrocution devices, when used, shall be located near the entranceway. Approved insecticides should be used whenever insect populations become noticeable.

Rodents--There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal droppings present; urine stains on bags or walls; slide marks along rodent runways; or

feeding areas around stored dry goods bags that may be excessive.
Deficiency: Serious

3.4.10.2 Proper disposal of processing waste.
Processing wastes shall be placed in proper containers, in appropriate locations, and removed frequently.
Deficiency: Serious

3.4.10.3 Written pest control program.
Self-explanatory. Diagrams of bait station locations shall be maintained and kept available for review.
Deficiency: Serious

3.4.10.4 Pesticides applied by a licensed individual.
Self-explanatory. However, in some locations, particularly outside the United States, licensing is not performed. In such instances the application shall be performed by a trained individual.
Deficiency: Serious

Exclusion
Openings to the outside or within may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise sealed. Screens shall be of a mesh not larger than 1/16th of an inch in order to exclude insects. Cracks or holes should be sealed and doors and windows should close tightly (no opening larger than 1/4 ") to exclude rodents or other animals. Air curtains and strip curtains shall be effective. Air curtains shall comply with National Sanitation Standard Number 37 for Air Curtains for entranceways in food establishments. Strip curtains shall run the entire opening with sufficient overlap between flaps (1/2 inch). In addition, every effort should be made to keep birds from areas where food is transferred or processed.
Report Remark

Harborage and attractant areas not present.
The location and grounds are free of harborage areas. These include but are not limited to: uncut weeds, brush or tall grass; improper storage of unused equipment or materials; presence of litter, waste and refuse; or standing or stagnant water. All garbage and refuse containers are rodent/insect-resistant and outside storage areas are to be properly constructed. If the grounds are bordered by grounds not under the operator's control and these grounds are not maintained in a proper manner with regard to this element, care shall be exercised to exclude pests that may be a source of contamination by the means outlined in the other areas of this element.
Report Remark

Adequate housekeeping.
Any excess clutter in production areas, employee areas, or other areas will result in non-compliance. This does not include those areas designated as office areas.
Report Remark