PART 9 – Policies, Procedures and Requirements for the approval of Freezer/Catcher Vessels

Chapter 1 - Authority

Authority for the Seafood Inspection Program to provide these 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 - Introduction

NOAA Handbook Part 9 is intended to refer specifically to vessel participants that freeze at sea. Freezer/Catcher vessels under the USDC Seafood Inspection Program on a contract basis must receive approval for the applicable processes prior to the inauguration of such service. A freezer/catcher vessel is a vessel on which the fishery products are frozen whole or after a preparation such as bleeding, heading, or evisceration.

Processing vessels wishing to participate in the program should refer to NOAA Handbook Part 3 for NOAA SIP Approved Establishment requirements.

Approved establishments are verified by on-site audits to meet U.S. Department of Commerce and U.S. Food and Drug Administration regulations governing the construction and maintenance of vessels and equipment, and employer practices in the production of fishery products for human consumption. USDC approved establishments shall notify USDC of regulatory visits and findings. Participation in the USDC Seafood Inspection Program does not eliminate the responsibility and obligation of the industry participant to meet all federal and applicable state regulations and requirements.

This Part has been developed to provide interested parties with the various policies, procedures, and requirements, which must be met in order for freezer/catcher vessels to be approved by USDC. In summary, these services are consistent with global activities to harmonize inspection protocols. In addition, USDC believes that the services will enhance the safety, wholesomeness, economic integrity of seafood available to consumers, as well as improve seafood industry quality assurance and regulatory oversight.

Chapter 3 – Scope

Program policy is to encourage and assist interested parties in the development and implementation of management systems. The purpose of this policy is to facilitate the production and distribution of fishery products that are safe, wholesome, and properly labeled.

Chapter 4 - Definitions

1. **Applicant:** Any interested party who requests inspection service under the regulations in this part.
2. **Audit:** A systematic and independent examination to determine whether activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
3. **Auditor:** A person qualified to perform audits.

4. **Contamination:** The presence of microbial pathogens, chemicals, foreign material, spoilage, objectionable taints, unwanted or diseased matter in food or water which may compromise the quality or suitability for consumption.
5. **Control Point:** Any step in a process whereby biological, chemical, or physical factors may be controlled.
6. **Corrective Action:** An action taken to eliminate the cause(s) of an existing nonconformity, defect, or other undesirable situation in order to prevent recurrence.
7. **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 acceptable levels.
8. **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.
9. **Critical Limit:** The maximum or minimum value to which a physical, biological, or chemical parameter must 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.
10. **Decomposition:** A persistent and distinct objectionable odor and/or flavor including texture breakdown caused by the deterioration of the product.
11. **Deviation:** Any specifically defined variation from a particular requirement.
12. **Establishment:** Any vessel used in the processing, handling, transporting, and storage of fish and fishery products.
13. **Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
14. **Freezer/Catcher Vessel:** A vessel on which the fishery products are frozen whole or after a preparation such as bleeding, heading, or evisceration.
15. **HACCP Plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety and control of defects which are significant for essential quality, composition, and/or labeling provisions in the segment of the food chain under consideration.
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 HACCP plan.
18. **High risk products:** 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 which may contain a microbial pathogen, biotoxin, or physical or chemical contaminant which may pose an unacceptable health risk at the time of consumption.
19. **Interested party:** Any person who has a financial interest in the applicable vessel. This includes, but is not limited to, the United States and any instrument or agency thereof, any State, county, municipality, or common carrier, and any authorized agent on behalf of the foregoing.
20. **Lot:** A production unit as defined by mutual agreement between the processor and the USDC Seafood Inspection Program 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" may not exceed that quantity which is produced during a specific production shift.
21. **Low risk products:** Seafood that poses no significant risk to the health of the public when prepared for consumption by conventional or traditional means.

22. **Monitoring Procedures:** Scheduled testing and/or observations recorded by the vessel to report the findings at each CCP
23. **Objective Evidence:** Information, which can be proved true, based on facts, obtained through observation, measurement, test, or other means.
24. **Official Establishment:** Any establishment which has been approved by the Program and utilizes inspection service on a contract basis.
25. **Prerequisite Program:** Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.
26. **Preventive Measure(s) (control measure(s)):** Physical, chemical, or other factors that can be used to control an identified food safety hazard.
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 regulations in this part which has been preserved by any recognized commercial process, including, but not limited to, canning, freezing, dehydrating, drying, the addition of chemical substances, or by fermentation.
29. **Processing/Factory Vessel:** vessel on which fishery products are subjected to one or more of the following operations, followed by conditioning or packaging and, if necessary, refrigeration or freezing: filleting, cutting, skinning, peeling, chipping or processing.
30. **Product Form:** Products which are similar in appearance, species, and/or processing method. For example, raw shrimp, cooked shrimp, breaded shrimp, etc.
31. **Record:** A document that furnishes objective evidence of activities performed or results achieved.
32. **Risk:** The probability that exposure to a hazard will lead to negative consequences.
33. **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.
34. **Severity:** The seriousness of the effect(s) of a hazard or defect.
35. **Specification:** A document stating requirements. A detailed document describing the materials, dimensions, and workmanship requirements of a product.
36. **Systems Audit:** On-site USDC SIP evaluation of the vessel's effectiveness in following the plan after validation.
37. **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.
38. **Verification:** Those activities performed by the vessel, other than monitoring that determine the system continues to be valid and is operating according to the plan.
39. **Wholesome:** The minimum basis of acceptability for human food purposes, of any fish or fishery product as defined in section 402 of the Federal Food, Drug, and Cosmetic Act, as amended.

Chapter 5 – Application for Services

Freezer/Catcher vessels wishing to receive vessel inspection and certification services may apply orally or in writing to any inspector or officer of the Program at or nearest the place where service is desired or the appropriate Regional Inspection Branch. If application is made orally, it must be confirmed promptly in writing in the English language. As part of the application, the requesting party must provide the necessary information to perform the service, including, but not limited to: the name and address of the vessel, the interest of the applicant, the purpose for which the service is desired, and whether the facility was inspected or certified by any other official party.

Failure to comply with these procedures may cause the application to be rejected. In addition, the Program may reject an application due to nonpayment for previous services rendered or if it appears that to perform 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 reasons in writing. An application for such services may be withdrawn by the applicant at any time before the service is performed, provided that the applicant shall pay for any reimbursable time spent on the servicing of the application, as well as for any expenses incurred.

The Regional Inspection Branch will provide the applicant with all necessary materials to inform them of the program, its requirements, and policies.

> **NOTE**: Firms wishing to have a more in-depth presentation of the Program and its requirements may request a meeting of all interested parties. This may incur a cost and should be discussed with the Regional Inspection Branch.

Chapter 6 – Prior to USDC Validation of the System

The freezer/catcher vessel should begin following their plan as soon as possible. The vessel must adhere to the plan's provisions and keep all records associated with the tentatively-approved plan. The vessel will contact the Regional Inspection Branch as soon as they believe the plan is functioning successfully and when they have records to support validation of the system. The Regional Inspection Branch will schedule a site visit with the vessel. The vessel must verify through end-product examination that the process controls result in product which complies with all regulations and applicable quality standards or specifications. If documentation has not been previously provided, the vessel must collect data prior to the site visit which will be sufficient to demonstrate this relationship. The inspection records must be available to USDC personnel upon request.

> **NOTE:** Vessels may request the USDC to perform the end item evaluation described above, which can be done immediately prior to or during the validation of the system.

Chapter 7 – Initial Assessment and Validation

Once an application has been filed for this service, the Regional Inspection Branch will schedule a site visit with the vessel. Program personnel will evaluate the vessel, and food safety management system according to the requirements of the USDC Seafood Inspection Program and shall determine compliance to these requirements and any corrections that may be required. A full report will be provided detailing these findings.

The vessel must verify through end-product examination that the process controls result in product which complies with all federal regulations and applicable Program requirements. If documentation has not been previously provided, the vessel must collect data prior to the site visit which will be sufficient to demonstrate this relationship. This verification may be accomplished utilizing the product inspection services of the USDC Seafood Inspection Program.

The audit performed on site will determine whether all of the hazards and CCPs have been identified, the food safety management plan is being followed and monitored by the vessel, and the identified product hazards and processes are being effectively controlled. The site visit will be conducted on a fee basis by personnel assigned based upon the demands of the audit. The number and structure of the team will be

determined by the size and complexity of the vessel's process and nature of the hazards associated with the product and processes to be evaluated. All audits (initial and surveillance) will include conducting document and record reviews, evaluating sanitation and in-process observations, photographic evidence, and end-product verification. All reviews will be performed using accepted auditing practices based on international recognized audit standards. Conducting a combination of statistical reviews of records and finished product sample inspections will complete product verifications.

At least one lot for each product form under requested contract will be evaluated by USDC by inspecting samples of finished product. USDC inspection personnel may sample and audit product in excess of this guideline if necessary. Vessels will be evaluated using the System Compliance Rating Criteria and other requirements as applicable. Vessels deemed acceptable may finalize a contract with the Program. If during the audit deficiencies are noted that prevent an acceptable rating, the vessel 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:** The CSO will accompany the vessel, if determined necessary, for an appropriate time period, performing the background checks of critical control points and auditing the plan at the same time. The officer may assist the quality assurance/management group on board the vessel in any alterations to bring the system toward approval and a successful audit. Once the work is performed, the officer is taken off the vessel as soon as is practicable. These procedural accommodations are made in recognition of possible space restrictions and to reduce the numbers of transfers at sea.

Chapter 8 – Changes to the Approved System

After the system has been approved, modifications may be made. The vessel must notify the servicing Regional Inspection Branch, in writing (including faxes or e-mail), of any modifications in their food safety system before implementing the changes. However, any changes to address a health or safety issue may be made without prior approval, but must be documented in a corrective action plan. The Regional Inspection Branch must be notified of these immediate changes within one working day.

As the food safety or outlines the basic foundation and policies of the vessel's program, changes to the plan must be approved in advance with Program management. However, the specific work procedures may change as necessary without prior approval, as long as they meet the Program's criteria. Prior to signing the contract, it will be determined which of the vessel's documentation requires pre-approval.

Chapter 9 – System Audits - Surveillance

With a valid contract and continued demonstrated compliance with all applicable laws, regulations, and policies, the vessel may collect data to be used by USDC personnel towards issuing applicable official certification of the vessel's products or facility compliance. After the vessel's system is approved, USDC will conduct audits at a minimum frequency—illustrated in the table below—to determine the vessel's continued adherence to federal regulations and Program requirements. More frequent audits may be necessary for cause as determined by the Regional Inspection Branch.

Freezer/Catcher Vessels
On site, at minimum 1 time per 12-month period. Additional

audits augmented by virtual
technique may be scheduled.

Note: Audit frequency for vessels operating on a seasonal basis will be determined on a case-by-case basis. With regard to seasonal contracts, the vessel must request in advance, in writing, to the servicing Regional Inspection Branch, to both suspend and reactivate the contract.

Vessels that receive five (5) serious deficiencies or one (1) critical deficiency at the conclusion of an audit are deemed unreliable and may be removed from the Program.

In addition, the policies and procedures described below will be followed.

Vessels must provide the appropriate Regional Inspection Branch with their tentative season schedules and off-loading schedules and sites as soon as they are known. In order to request an audit onboard a vessel, NOAA SIP must be notified in writing within 30 days. Destination approval requires, at a minimum, IATC Headquarters and State Department clearances. Failure to do so could result in the removal of the vessel from the Program.

Site visits may not require the auditor to be on board during fishing, but may require the auditor to be present during off-loading.

Chapter 10 – Corrective Action Plans

When applicable, the vessel must submit a corrective action plan to the Consumer Safety Officer detailing how they will correct the problem. The corrective action plan must include, at a minimum, detailed descriptions of the following:

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

Chapter 11 – 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 13 for details of the Appeals process.

Chapter 12 – Analytical Testing and Product Verification

The vessel must perform periodic end-item verification of product compliance to program requirements. Both the vessel and USDC must agree upon the vessel's frequencies and end-item requirements; however samples for analytical testing must be collected and tested at least once per year as part of their verification procedures. The level of analytical sampling per lot must be statistically sufficient to draw a proper conclusion and agreed upon by the USDC Seafood Inspection Program. Records of all analytical findings will be made available to USDC personnel during Systems Audits and at other times as necessary. As part of the system evaluation, USDC may have product tested analytically to verify the validity of the system. .

To determine whether the product produced at the vessel meets specification and/or requirements, USDC will routinely perform a product audit on up to three (3) lots produced by the vessel since the last Systems Audit. This information will be used to guide the auditor in his/her audit of the system. Product audits will be completed by conducting records reviews and finished product sample inspections. Additional lots may be sampled if the situation warrants. Lots must be defined by the vessel and the definition agreed upon by the USDC Seafood Inspection Program.

Chapter 13 – Advertising Participants

Vessels who are successfully participating in the Approved Establishment Program will be listed in the USDC Participants List as an approved establishment. The list will include the Vessel's name, all pertinent locations, and approved processes. This list is updated regularly on the Program's website. These vessels may advertise their participation in the Program as long as all advertisement claims are truthful and not misleading as to product certification. 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 Seafood Inspection Program prior to use.

Chapter 14 – System Compliance Rating Criteria

a. 1.0 Management Controls and Responsibilities

The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of freezer/catcher vessels.

1.1.0 Management Responsibilities

1.1.1 Management commitment not properly implemented or communicated.

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

Deficiency: Critical

1.1.2 Food safety policy not prepared or properly implemented.

Top management shall define, document and communicate its food safety policy. Top management shall ensure that the food safety policy a) 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

requirements of customers, c) is communicated, implemented, and maintained at all levels of the organization, d) is reviewed for continued suitability, e) adequately addresses communication, and f) is supported by measurable objectives.
Deficiency: Serious

1.1.3 Food safety management system planning not properly performed.
Top management shall ensure that a) planning of the food safety management system is properly carried out to meet all applicable requirements, and b) the integrity of the food safety management system is maintained when changes to the food safety management system are planned and implemented.
Deficiency: Serious

1.1.4 Responsibility and authority not properly defined or 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 management system. All personnel shall have responsibility to report problems with the food safety 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 Team
1.2.1 Food safety team leader not appointed.
Top management shall appoint a food safety team leader who, irrespective of other duties, shall have the responsibility and authority to: a) manage a food safety team and organize its work, b) ensure relative training and education of the team members, and c) ensure that the food safety management system is established, implemented, maintained and updated.
Deficiency: Serious

1.3.0 Communication
1.3.1 Effective external communication not established, implemented, or maintained.
To ensure that sufficient information on issues concerning food safety 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, in particular in relation to product information (including instructions regarding intended use, specific storage requirements, and as appropriate, shelf life), enquiries, contracts or order handling including amendments, and customer feedback including customer complaints, 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 system.

The communication shall provide information on food safety 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 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 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 not established, implemented, or maintained.
The organization shall establish, implement, and maintain effective arrangements for communicating with personnel on issues having an impact on food safety. In order to maintain the effectiveness of the food safety management system, the organization shall ensure that the food safety 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, 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 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.

The food safety team shall ensure that this information is included in the updating of the food safety 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 not established, implemented or maintained.

Top management shall establish, implement and maintain procedures to manage potential emergency situations and accidents that can impact food safety relevant to the role of the organization in the food chain.
Deficiency: Critical

1.5.0 Management Review

1.5.1 Management review not properly performed or documented.

Top management shall review the organization's food safety 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. Records from management reviews shall be maintained.

The input to management review shall include, but is not limited to 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) reviewing results of system updating activities, f) review of communication activities including customer feed-back, and g) external audits or inspections. 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, b) improvement of the effectiveness of the food safety management system, c) resource needs, and d) revisions of the organization's food safety 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 management system.

1.6.1 Necessary human resource competencies not identified.

The food safety team and the other personnel carrying out activities having an impact on food safety 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 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 not received documented training necessary for the proper function of the food system.
The organization shall: a) identify the necessary competencies for personnel whose activities have an impact on food safety, b) provide training or take other action to ensure personnel have the necessary competencies, c) ensure that personnel responsible for monitoring, corrections, and corrective actions of the management system are trained, d) evaluate the implementation and the effectiveness of a), b), and c), e) ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to food safety, f) ensure that the requirement for effective communication is understood by all personnel whose activities have an impact on food safety, and g) maintain appropriate records of training and actions described above.

Training must include the areas of HACCP, good manufacturing practices, and allergens to appropriate personnel. Per 21 CFR part 123, these duties are assigned only to properly trained personnel. However, failure of this element will not likely cause an immediate hazard or defect. Therefore it is rated as a Serious deficiency. Per 21 CFR part 123, these duties are assigned only to properly trained personnel. Failure of this element could lead to an immediate hazard or defect.

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.

- Developing a HACCP plan, which could include adapting a model or generic-type HACCP plan, that is appropriate for a specific processor, in order to meet the requirements of Sec. 123.6(b);
- Reassessing and modifying the HACCP plan in accordance with the corrective action procedures specified in Sec. 123.7(c)(5), the HACCP plan in accordance with the verification activities specified in Sec. 123.8(a)(1), and the hazard analysis in accordance with the verification activities specified in Sec. 123.8(c); and
- Performing the record review required by Sec. 123.8(a) (3). The trained individual need not be an employee of the processor.

Deficiency: Serious/Critical

1.6.3 Insufficient infrastructure to implement and maintain the food safety system.
The organization shall provide the resources for the establishment and maintenance of the infrastructure needed to implement a proper food safety system.
Deficiency: Serious

1.6.4 Work environment is not properly established, managed, or maintained relative to food safety.
The organization shall provide the resources for the establishment, management, and maintenance of the work environment needed to implement a proper food safety management system.
Deficiency: Serious

1.7.0 Continual Improvement
1.7.1 Continuous improvement activities not performed.
Top management shall ensure that the organization continually improves the effectiveness of the food safety management system through the use of communication, management review, internal audit, evaluation of individual verification results, analysis of results of verification activities, validation of

control measure combinations, and corrective actions.
Deficiency: Serious

b. 2.0 Food Safety
The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of facilities, processes and systems.

The organization shall plan and develop the processes needed for the realization of safe products. The organization shall implement, operate, and ensure the effectiveness of the planned activities and any changes to those activities. This includes pre-requisite programs as well as the HACCP plan.

2.1.0 Operational Prerequisite Programs
2.1.1 Operational prerequisite programs not present or not effective.
Each vessel 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(s) to be controlled by the program, b) control measure(s), 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; f) record(s) of monitoring.
Deficiency: Serious

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

2.2.0 Hazard Analysis
2.2.1 Hazard analysis not properly performed.
The food safety team shall conduct a hazard analysis to determine which hazards need to be controlled, the degree of control required to ensure food safety, and which combination of control measures is required. A food safety hazard that is reasonably likely to occur is one for which a prudent processor would establish controls because experience, illness data, scientific reports, or other information provide a basis to conclude that there is a reasonable possibility that it will occur in the particular type of fish or fishery product being processed in the absence of those controls.

All food safety hazards that are reasonably expected to occur in relation to the type of product, type of process and actual processing facilities shall be identified and recorded.

The identification shall be based on a) the preliminary information and data collected according to the previous section, b) experience, c) external information including, to the extent possible, epidemiological and other historical data, and d) information from the food chain on food safety hazards that may be of relevance for the safety of the end products, intermediate products and the food at consumption. The step(s) (from raw materials, processing and distribution) at which each food safety hazard may be introduced shall be indicated.

When identifying the hazards, consideration shall be given to a) the steps preceding and following the specified operation, b) the process equipment, utilities/services and surroundings, and c) the preceding and following links in the food chain.

For each of the food safety hazards identified, the acceptable level of the food safety hazard in the end product shall be determined whenever possible. The determined level shall take into account established statutory and regulatory requirements, customer food safety requirements, the intended

use by the customer and other relevant data. The justification for, and the result of, the determination shall be recorded.

A hazard assessment shall be conducted to determine, for each food safety hazard identified, whether its elimination or reduction to acceptable levels is essential to the production of a safe food, and whether its control is needed to enable the defined acceptable levels to be met. Each food safety hazard shall be evaluated according to the possible severity of adverse health effects and the likelihood of their occurrence. The methodology used shall be described, and the results of the food safety hazard assessment shall be recorded.

Based on the hazard assessment, an appropriate combination of control measures shall be selected which is capable of preventing, eliminating or reducing these food safety hazards to defined acceptable levels. In this selection, each of the control measures as determined shall be reviewed with respect to its effectiveness against the identified food safety hazards. The control measures selected shall be categorized as to whether they need to be managed through operational prerequisite programs or by the HACCP plan.

The existing control measures and the rigorousness with which they are applied, or procedures that may influence food safety, shall be described to the extent needed to conduct the hazard analysis. External requirements (e.g., from regulatory authorities or customers) that may impact the choice and the rigorousness of the control measures shall also be described.

The selection and categorization shall be carried out using a logical approach that includes assessments with regard to the following: a) its effect on identified food safety hazards relative to the strictness applied; b) its feasibility for monitoring (e.g., ability to be monitored in a timely manner to enable immediate corrections); c) its place within the system relative to other control measures; d) the likelihood of failure in the functioning of a control measure or significant processing variability; e) the severity of the consequence(s) in the case of failure in its functioning; f) whether the control measure is specifically established and applied to eliminate or significantly reduce the level of hazard(s); g) synergistic effects (i.e., interaction that occurs between two or more measures resulting in their combined effect being higher than the sum of their individual effects).

Control measures categorized as belonging to the HACCP 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

2.2.3 Hazard analysis not available.
The hazard analysis is the foundation of the HACCP plan. If the analysis is not performed, the entire plan and its efficacy is suspect. Vessels must 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

2.3.0 HACCP Plan

2.3.1 No written HACCP plan when one is required.
Every processor shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. (21CFR123.6b) Vessels must provide this plan to the requesting Consumer Safety Officer.
Deficiency: Serious

2.3.2 Hazard(s) is not listed in the plan.
The HACCP plan shall, at a minimum list the food safety hazards that are reasonably likely to occur and

that thus must be controlled for each fish and fishery product. Consideration should be given to whether any food safety hazards are reasonably likely to occur as a result of the following:

1. Natural toxins;
2. Microbiological contamination;
3. Chemical contamination;
4. Pesticides;
5. Drug residues;
6. Decomposition in scombroid toxin-forming species or in any other species where a food safety hazard has been associated with decomposition;
7. Parasites, where the processor has knowledge or has reason to know that the parasite-containing fish or fishery product will be consumed without a process sufficient to kill the parasites, or where the processor represents, labels, or intends for the product to be so consumed;
8. Unapproved use of direct or indirect food or color additives or allergens; and
9. Physical hazards

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

2.3.3 Hazard(s) is not controlled.
Vessels may not have met the requirements of performing the hazard analysis or writing a required HACCP plan. However, controls may still be in place for the hazards identified by the Consumer Safety Officer. If it is determined that the controls are not in place, a Critical deficiency will be assessed.
Deficiency: Critical

2.3.4 CCPs are not properly identified in the plan.
The HACCP plan shall, at a minimum list the critical control points for each of the identified food safety hazards, including as appropriate:

1. Critical control points designed to control food safety hazards that could be introduced in the vessel environment; and
2. Critical control points designed to control food safety hazards introduced outside the vessel environment, including food safety hazards that occur before, during, and after harvest. (21CFR123.6c.2)

Deficiency: Serious

2.3.5 Appropriate critical limit(s) is not 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. If evidence is present that the critical limits were improperly identified but those identified were followed, the deficiency will be assessed here. (21CFR123.6c.3)
Deficiency: Serious

2.3.6 Critical limits not followed.
Self-explanatory.
Deficiency: Critical

2.3.7 Monitoring procedure stated in the plan is inadequate.
Monitoring procedures shall be established for each critical limit. (21CFR123.6c.4) 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(s). 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. **Deficiency: Serious/Critical**

2.3.8 Monitoring procedures not followed:
Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed the vessel is not in compliance with this item
Deficiency: Serious

2.3.9 Corrective action listed in plan is not appropriate or adequate.
Planned corrections and corrective actions to be taken when critical limits are exceeded shall be specified in the HACCP plan. The actions shall ensure that the cause of nonconformity is identified, that the parameter(s) controlled at the CCP is (are) brought back under control, and that recurrence is prevented. Documented procedures shall be established and maintained for the appropriate handling of potentially unsafe products to ensure that they are not released until they have been evaluated and the cause of the deviation is corrected (e.g., not injurious to health or adulterated).

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:

1. 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
2. The cause of the deviation is corrected. (21CFR123.7)

Deficiency: Serious

2.3.10 Corrective action not taken
Whenever a deviation from a critical limit, sanitation, monitoring or verification procedures occurs, a vessel shall take corrective action. Vessels shall develop written corrective action plans, which become part of their plans by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit.

A vessel is provided room for error in their plan through a system of corrective actions. If an error or problem arises in the conduct of the food safety management plan, the vessel must file a corrective action report. All other deficiencies may possibly be averted in this checklist if corrective action reports are filed for each problem or situation. Failure to file a corrective action report will be considered a failure to take a corrective action and the vessel will then not be in compliance with this item.

When a deviation from the plan occurs and the vessel does not have a corrective action plan that is appropriate for that deviation, the vessel shall:

1. Segregate and hold the affected product.
2. Perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals who have adequate training or experience to perform such a review.

3. Take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation or does not meet other program requirements;
4. Take corrective action, when necessary, to correct the cause of the deviation;
5. Perform or obtain timely reassessment of the system by an individual or individuals who have been properly trained to do so, to determine whether the plan needs to be modified to reduce the risk of recurrence of the deviation, and modify the plan as necessary.

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.
Deficiency: Critical

2.3.11 Verification procedure stated in plan is inadequate.
The HACCP plan shall list the verification procedures, and frequency thereof, that the vessel will use. Every vessel shall verify that the HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, and that the plan is being effectively implemented.

Verification shall include, at a minimum:

1. Reassessment of the food safety management system. A reassessment of the adequacy of the plan whenever any changes occur that could affect the hazard analysis or alter the plan in any way or at least annually. (21CFR123.8a.1) Such changes may include changes in the following: Raw materials or source of raw materials, product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been trained in accordance with Sec. 123.10 of 21 CFR Part 123.

The system shall be modified immediately whenever a reassessment reveals that the plan is no longer adequate to fully meet the requirements.

2. Ongoing verification activities. Ongoing verification activities including:
    - A review of any customer complaints that have been received by the vessel 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,
    - At the option of the vessel, the performing of periodic end-product testing. (See Program requirements.) (21CFR123.8a.2)
3. Records review. (21CFR123.8a.3) A review, including signing and dating, by an individual who has been trained in accordance with Sec. 123.10, of the records that document:
    - The monitoring of critical control points. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that they document values that are within the critical limits. This review shall occur within 1 week of the day that the records are made;
    - The taking of corrective actions. The purpose of this review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with Sec. 123.7. This review shall occur within 1 week of the day that the records are made; and

- The calibrating of any process control instruments used at critical control points and the performing of any periodic end-product testing that is part of the vessel's verification activities. The purpose of these reviews shall be, at a minimum, to ensure that the records are complete, and that these activities occurred in accordance with the vessel's written procedures. These reviews shall occur within 1 week of the day that the records are made.

4. Vessels shall immediately follow corrective action procedures whenever any verification procedure, including the review of a customer complaint, reveals the need to take a corrective action. (21CFR123.8b)(See Corrective Action sections listed above.)
5. Reassessment of the hazard analysis. (21CFR123.8c) Whenever a vessel does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the vessel shall reassess the adequacy of that hazard analysis whenever there are any changes that could reasonably affect whether a food safety hazard now exists. Such changes may include, but are not limited to changes in: Raw materials or source of raw materials, product formulation, product distribution systems, or the intended use or consumers of the finished product. The reassessment shall be performed by an individual or individuals who have been properly trained in accordance with 21 CFR 123.10. (See 1.6.2)
6. Recordkeeping. (21CFR123.8d) All verification activities, including the calibration of process-monitoring instruments and the performing of any periodic end-product testing, shall be documented and recorded and is subject to the recordkeeping requirements listed below. The organization shall provide evidence that the specified monitoring and measuring methods and equipment are adequate to ensure the performance of the monitoring and measuring procedures. Where necessary to ensure valid results, the measuring equipment and methods used a) shall be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards, where no such standards exist, the basis used for calibration or verification shall be recorded, b) shall be adjusted or re-adjusted as necessary, c) shall be identified to enable the calibration status to be determined, d) shall be safeguarded from adjustments that would invalidate the measurements results, and e) shall be protected from damage and deterioration. When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and shall be reconfirmed as necessary.

The output of this activity shall be in a form suitable for the organization's method of operations. Verification results shall be recorded and shall be communicated to the food safety team. Verification results shall be provided to enable the analysis of the results of the verification activities. 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, the affected lots of product shall be handled as potentially unsafe.

The food safety team shall systematically evaluate the individual results of planned verification. If verification does not demonstrate conformity with the planned arrangements, the organization shall take action to achieve the required conformity. The food safety team shall analyze the results of verification activities, including the results of the internal and external audits. The results of the analyses and the resulting activities shall be recorded and shall be reported, in an appropriate manner, to top management as input to the management review.

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.
Deficiency: Serious

2.3.12 Verification procedures not 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. Vessels must reassess their hazard analyses when information or other evidence indicates the need and at least yearly. The plan must be signed and dated by a management official responsible for the operation of the vessel. The plan must be signed upon implementation and at least once each year.
Deficiency: Serious

2.4.0 Control of Nonconformity
2.4.1 Traceability system inadequate.
The organization shall establish and apply a traceability system that enables the identification of product lots and their relation to batches of raw materials delivery records. 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 vessel 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

2.4.2 Improper handling of potentially unsafe products
The organization shall handle nonconforming products by taking action(s) to prevent the nonconforming product from entering the food chain unless it is possible to ensure that a) the food safety hazard(s) of concern has(ve) been reduced to the defined acceptable levels, b) the food safety hazard(s) 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(s) of the food safety hazard(s) of concern despite the nonconformity.

All lots of product that may have been 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.

Each lot of product affected by the nonconformity shall only be released as safe 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(s) concerned.

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 is eliminated or reduced to acceptable levels; b) destruction and/or disposal

as waste.
Deficiency: Serious

2.4.3 Withdrawals and recalls not designed or implemented properly.
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

1. notification to relevant interested parties (e.g. statutory and regulatory authorities, customers and/or consumers),
2. handling of withdrawn products as well as affected lots of the products still in stock, and
3. 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

2.5.0 Validation
2.5.1 Validation activities improperly performed
The food safety 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 the HACCP plan 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(s) 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(s) to obtain 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

2.6.0 Records
2.6.1 Record data is missing.
All records must be kept up-to-date. Entries must be made as they are measured. The records shall contain the actual values and observations obtained during monitoring or measurement Examples of non-compliance include: measurement observed to be taken but not entered on record; partial entry of information from monitoring procedures; initials for QA verification not recorded in a timely manner; etc.

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 for Labels

2.6.2 Records are inaccurate.
All entries must be accurate or the record is meaningless. If calculations, time test measured, etc., are not correct, the box for this deficiency should be checked. 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 and the serious deficiency assigned. This deficiency will also be used for the compliance of product leaving the vessel.
Deficiency: Serious/Critical

2.6.3 Records are not available for inspection.
If the vessel is unable to supply the requested record(s) in a reasonable amount of time for inspector review, they are not in compliance with this item. If portions of a record are not available, the vessel is not in compliance with this item. All required records shall be retained at vessel or importer's place of business in the United States for at least 1 year after the date they were for at least 2 years after the date they were prepared in the case of frozen products.

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

If the vessel is not fishing for a prolonged period between seasonal packs, or if record storage capacity is limited on a vessel, 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

2.6.4 Documents or records are falsified.
This item is self-explanatory. However, intent on the part of the vessel or its representatives must 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 must 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

c. 3.0 Sanitation and Prerequisite Programs
The elements of this section apply to all participants in the USDC Seafood Inspection Program in the evaluation of vessel's systems.

References: 21 CFR Part 110; 21 CFR Part 123.11(b); 50 CFR Parts 260.96-260.104

3.1.0 Sanitation Standard Operating Procedures and Prerequisite Programs
3.1.1 Sanitation standard operating procedures or prerequisite programs not present or not effective.
Each vessel 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 vessel will meet those sanitation conditions and practices that are to be monitored.
Deficiency: Serious

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

3.1.3 Sanitation not monitored.

Each vessel shall monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in 21 CFR Part 110 and 123 that are both appropriate to the vessel 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 toilet facilities;
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 from the vessel.

The vessel shall define the applicable frequencies of monitoring in their sanitation standard operating procedures and must adhere to these frequencies.

Deficiency: Serious

3.2.0 Safety of Process Water (if applicable)

Process water must be of suitable quality if 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 must pass potability standards established by federal, state, and local authorities. Water that is supplied to the vessel must meet certain minimum standards. However, if water is processed onboard, it must also be reasonably protected in the vessel. 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.

3.2.1 Unsafe or unsanitary 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

3.2.2 Water potability certificate not 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 must meet processing use requirements and potability must be tested at a frequency sufficient to ensure the acceptability of the water source from that geographic area.

Deficiency: Serious

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

3.2.4 No protection against backflow, back-siphonage, or other sources of contamination.
A vessel will be in compliance when all cross-connections are eliminated, 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

3.2.6 Ice not manufactured, handled, or used in a sanitary manner.
A vessel will be in compliance when 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 vessels 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 must be made at a minimum of every six (6) months on ice received.
Deficiency: Critical

3.3.0 Food Contact Surfaces
3.3.1 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned or sanitized; does not preclude product adulteration or contamination.
Any equipment used in the manufacturing or handling of the food product must be designed or constructed so that it can be properly cleaned and inspected. Failure to do so will cause the facility to be out of compliance. In addition, if the materials used are not of a material suitable for its intended purpose or there is reuse of single-service items, then the vessel is also out of compliance.

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 vessel 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

3.3.3 Food contact surfaces not cleaned or sanitized before use, after interruptions, or as necessary.
Food contact surfaces and food containers must be adequately cleaned using proper techniques to remove dirt and debris and must be adequately sanitized. Sanitizers must 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.
Deficiency: Serious/Critical

3.4.0 Prevention of Cross Contamination
3.4.2 Vessel

3.4.2.1 Insufficient separation by space or other means allows product to be adulterated or contaminated.
There must be sufficient separation between different activities s such as 1) separation between activities, 2) layout of vessel (employee traffic) 3) product sequencing. 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 of the vessel should not be such that product contamination/adulteration is likely due to issues such as heavy employee traffic through work areas. 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.

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

3.4.3 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.
3.4.3.1 Areas directly affecting product or packaging material.
For those areas that will directly affect product, the roof, ceiling, walls, floors, the storage of fish that permits cross-contamination and lighting fixtures, must be maintained as designed and lights must be protected. Failure to do so causes the vessel to be out of compliance.
Deficiency: Serious

3.4.4 Cleaning methods permit adulteration or contamination.
Employees must 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 cause the vessel to be in non-compliance. 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)

3.4.5 Finished product/primary packaging material not properly covered or protected.
Fish must be protected so as to not permit contamination or adulteration prior to offloading. Failure to provide these conditions will result in non-compliance.
Deficiency: Serious

3.4.8 Processing or food handling personnel do not maintain a high degree of personal cleanliness.
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.
Deficiency: Serious

3.4.9 Processing or food handling personnel do not take necessary precautions to prevent adulteration or contamination of food.
All persons, while in a food preparation or handling area, shall:

1. 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.
2. 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.

3. 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.
4. Not expectorate; nor store clothing or other personal belongings; not eat food or drink beverages; nor use tobacco in any form in areas where fish are exposed, or in areas used for fish storage, washing of equipment and utensils
5. 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.
6. Using sanitary handling procedures during operations to protect food against contamination.

Deficiency: Serious/Critical

3.5.0 Handwashing, Hand Sanitizing, and Toilet Facilities

3.5.1 Hand washing and hand sanitizing stations not present or conveniently located.

Hand washing and hand sanitizing stations must 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:

3.5.2 Improper disposal of toilet waste or sewage.

A vessel is in compliance when sewage systems drain properly, are vented to the outside.
Deficiency: Critical

3.5.3 Inadequate supplies/signs for employees.

The restrooms and hand-washing stations must provide supplies such as toilet paper, soap, waste containers, running water (see 3.2.5), sanitary towel service or suitable drying devices, etc., sufficient to meet employees' needs. Refuse receptacles shall be constructed and maintained in a manner that protects against contamination of fish.
Deficiency: Serious

3.5.4 Insufficient number of functional toilets.

The vessel must have one operable, clean, in good repair, conveniently accessible toilet per fifteen (15) employees, per gender. For men, urinals may be substituted for toilet bowls, but only to the extent of one-third (1/3) of the total number of bowls required. Facilities shall be maintained in a sanitary condition with self-closing doors that do not open directly into areas where fish is exposed to airborne contamination, except where alternate means of protection have been implemented.
Deficiency: Serious

3.6.0 Protection From Adulteration

3.6.1 Condensation or other deleterious sources present.

Adequate physical protection of fish from adulterants that may drip, drain, or be drawn into the fish must be in place. **Deficiency: Critical**

3.7.0 Proper Labeling, Use, and Storage of Toxic Compounds

Vessel chemicals are cleaners, sanitizers, rodenticides, insecticides, food grade machine lubricants, etc. They must 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 fish.

A vessel will be in compliance when the chemicals are used according to manufacturer's instructions and recommendations and stored in an area of limited access away from fish. All chemicals must 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 in a vessel where fish 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 vessel and equipment maintenance and operation, and d) those necessary for use in the plant's operations.

3.7.1 Chemical(s) improperly used or handled.
Deficiency: Critical
3.7.2 Chemical(s) improperly stored.
Deficiency: Serious
3.7.3 Chemical(s) improperly labeled.
Deficiency: Serious

3.8.0 Control of Employee Health Conditions
3.8.1 Vessel management does not have in effect 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 on a vessel in any capacity in which there is a reasonable possibility of fish becoming contaminated by such person. Vessel management shall require employees to report illness or injury to supervisors.
Deficiency: Serious

3.9.0 Exclusion of Pests
The presence of rodents, insects, and other animals in the vessel must not be allowed because they are sources for the contamination of food with foreign material, filth, and bacteria, etc.

3.9.1 Extermination
Insects--There should not be a significant number of insects present in the vessel. Insect electrocution devices, when used, must 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. The vessel should have appropriate rodent control measures in place. If not, the vessel is not in compliance.
Deficiency: Serious

3.9.2 Improper disposal of processing waste.
A vessel is in compliance with regard to processing wastes when they are placed in proper containers, placed at appropriate locations and removed frequently.
Deficiency: Serious

3.9.3 No written pest control program.
Self-explanatory. Diagrams of bait station locations in the vessel shall be maintained and kept available for review.
Deficiency: Serious

3.9.6 Pesticides not 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

Example Audit Report: Vessel

REPORT

INFORMATION

Applicant Name:	
Est. (FEI) Number:	
Physical Address:	
Mailing Address:	
Contact & Title:	
E-mail Address:	
Phone Number:	
Auditor(s):	
Audit Date(s):	
Corrective Action Required:	
Audit Type:	
Audit Objective:	To determine if the firm has implemented a program that adequately addresses the applicable requirements of the USDC Seafood Inspection Program which include all applicable U.S. regulatory requirements.
Audit Criteria:	• 21 CFR part 123 Fish and Fishery Products • 21 CFR part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food • Fish and Fisheries Product Hazards and Controls Guidance 4th Edition, June 2022 • NOAA Manual 25 Seafood Inspection
Audit Scope:	Program requirements, documentation, records, work procedures, and facility operations under the firm's financial and operational control and as referenced in their HACCP plan for the applicable fishery products.

The auditor, an employee of the Seafood Inspection Program of the United States Department of Commerce, was requested to verify the accuracy, validity, and the implementation of the food

safety plan at the *[VESSEL]* facility in *[STATE of COUNTRY]*. The request was made and the audit performed on behalf of the Seafood Inspection Program.

Upon arrival at the firm, the opening meeting was performed by procedure and was attended by the auditor and *[LIST ATTENDEES]*. The firm's food safety plan was received and reviewed. The audit plan included evaluation of the firm's hazard analysis, critical control points (implementation, accuracy, and efficacy), sanitation standard operating procedures, verification procedures, and record keeping. The audit included an evaluation of plant and food hygiene, and final product evaluation. Where possible, observations were verified by interviews, records, photographs, or testing. After gaining all necessary objective evidence, findings were developed and are listed below. A closing meeting was conducted and the audit findings discussed. The meeting was attended by *[LIST ATTENDEES]*.

Corrective action is necessary to improve the process or to bring the system back into control. Please provide a written corrective action to the findings listed above. Be certain to include both short-term solutions as well as long term more permanent solutions to each issue. *[AUDITOR DISCRETION TO ADD TIME LINE EXPECTATIONS]*

As no findings exist, no corrective action is necessary.

(Keep which corrective action statement above is applicable)

The USDC Seafood Inspection Program conducted an audit on *[VESSEL]* located in *[CITY, PROVINCE, COUNTRY] on [DATE(S) OF AUDIT]*. This audit included an examination of the company's food safety plan for the receipt, processing, and packaging of [PRODUCTS and product forms] and the operation of the plan, including sanitation standard operating procedures, for compliance. Based on this audit we have concluded that the firm is in compliance with NOAA Seafood Inspection Program requirements and applicable U.S. requirements and regulations.

The USDC Seafood Inspection Program can only provide such attestations on an audit-by-audit basis, as an audit is a picture in time. This report, or any statements therein, is not a certification or approval of a specific lot of product. It is only a report on the viability of the system and the processes in place.

FINDINGS *(LISTED IN ORDER OF SIGNIFICANCE)*

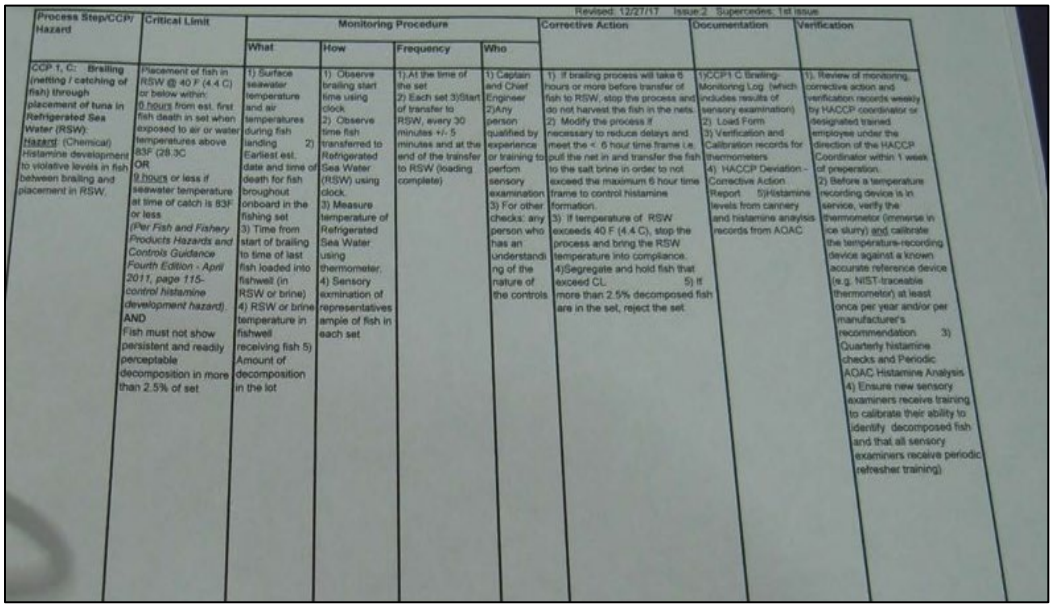
(In this section list out the findings providing sufficient information in which to lead a reader to understand the scope of the issue, the evidence found, and the conclusions of the auditor, including why the decision was made to assess a deficiency or not. An example of a write up is found below. Photographs can be placed in a way to illustrate and define the issue. Be sure to

caption the photograph and keep the statements to fact. Justify paragraph margins for the entire report to both sides and keep margins to a minimum of 1 inch.)

Verification procedures not followed

Verification procedures of the vessel's HACCP records are those that provide for management to determine the overall effectiveness of the plan. Not following these verification procedures could ultimately cause the plan to fail or misidentify a defect or hazard. Since failure of these procedures will likely not immediately cause the plan to fail, it is rated at a serious level. During the record review the auditor requested the Thermometer Calibration Log of the firm's fish well temperature recording devices. The vessel did not have the documentation available. The USFDA recommends at a minimum, a yearly calibration of temperature recording devices. This is also stated in the vessel's HACCP Plan. The fish well thermometers on the vessel will be in compliance when the vessel properly documents the calibration of each fish well temperature recording device. **2.3.13 – SERIOUS**

Fish well monitoring probes are located in all fish wells



Revised: 12/27/17 Issue:2 Supercedes: 1st issue

Process Step/CCP/ Hazard	Critical Limit	Monitoring Procedure				Corrective Action	Documentation	Verification
		What	How	Frequency	Who			
CCP 1, C: Brailing (netting / catching of fish) through placement of tuna in Refrigerated Sea Water (RSW): Hazard: (Chemical) Histamine development to violative levels in fish between brailing and placement in RSW.	Placement of fish in RSW @ 40 F (4.4 C) or below within: 6 hours from est. first fish death in set when exposed to air or water temperatures above 83F (28.3C OR 9 hours or less if seawater temperature at time of catch is 83F or less (Per Fish and Fishery Products Hazards and Controls Guidance Fourth Edition - April 2011, page 115-control histamine development hazard). AND Fish must not show persistent and readily perceptable decomposition in more than 2.5% of set	1) Surface seawater temperature and air temperatures during fish landing 2) Earliest est. date and time of death for fish broughout onboard in the fishing set 3) Time from start of brailing to time of last fish loaded into fishwell (in RSW or brine) 4) RSW or brine temperature in fishwell receiving fish 5) Amount of decomposition in the lot	1) Observe brailing start time using clock 2) Observe time fish transferred to Refrigerated Sea Water (RSW) using clock. 3) Measure temperature of Refrigerated Sea Water using thermometer. 4) Sensory exmination of representatives ample of fish in each set	1) At the time of the set 2) Each set 3) Start of transfer to RSW, every 30 minutes +/- 5 minutes and at the end of the transfer to RSW (loading complete)	1) Captain and Chief Engineer 2) Any person qualified by experience or training to perform sensory examination 3) For other checks: any person who has an understanding of the nature of the controls	1) If brailing process will take 6 hours or more before transfer of fish to RSW, stop the process and do not harvest the fish in the nets. 2) Modify the process if necessary to reduce delays and meet the < 6 hour time frame i.e. pull the net in and transfer the fish to the salt brine in order to not exceed the maximum 6 hour time frame to control histamine formation. 3) If temperature of RSW exceeds 40 F (4.4 C), stop the process and bring the RSW temperature into compliance. 4) Segregate and hold fish that exceed CL. 5) If more than 2.5% decomposed fish are in the set, reject the set.	1) CCP1 C Brailing-Monitoring Log (which includes results of sensory examination) 2) Load Form 3) Verification and Calibration records for thermometers 4) HACCP Deviation – Corrective Action Report 5) Histamine levels from cannery and histamine anaylsis records from AOAC	1). Review of monitoring, corrective action and verification records weekly by HACCP coordinator or designated trained employee under the direction of the HACCP Coordinator within 1 week of preperation. 2) Before a temperature recording device is in service, verify the thermometer (immerse in ice slurry) and calibrate the temperature-recording device against a known accurate reference device (e.g. NIST-traceable thermometer) at least once per year and/or per manufacturer's recommendation 3) Quarterly histamine checks and Periodic AOAC Histamine Analysis 4) Ensure new sensory examiners receive training to calibrate their ability to identify decomposed fish and that all sensory examiners receive periodic refresher training)

Verification procedures state yearly frequency of all thermometers used on the vessel

Remarks: *(include this section if applicable)*

(This section is for those observations that are not significant but should be noted. They do not need to be as prominent as findings, therefore using tables in the document to place text next to any photographs is more appropriate.)