PART 3 – Policies, Procedures and Requirements for the approval of Facilities and Systems

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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

Participants that process products under the USDC Seafood Inspection Program on a contract basis must receive approval of buildings, facilities, and the applicable processes prior to the inauguration of such service.

These establishments or vessels must be certified to meet U.S. Department of Commerce regulations governing the construction and maintenance of facilities and equipment, processing techniques, and employee practices in the production of fishery products for human consumption. Approved establishments are eligible to produce fishery products bearing an official inspection mark. (Facilities outside the United States currently are not eligible to have their products bear inspection marks, although the master cases may bear statements applicable to their status per Program policy.) Approved facilities are included on a list published on the Program's official website and periodically in hard copy. Inclusion on this list is contingent upon the firm's continued ability to maintain USDC requirements.

Approved establishments are verified by on-site audits to meet U.S. Food and Drug Administration and U.S. Department of Commerce regulations governing the construction and maintenance of facilities and equipment, processing techniques, 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.

There are three systems of participation as an approved facility, each of which offers differing methods of product inspection service by USDC personnel. One system requires the system to be audited on a regular basis and, while product bearing a USDC Inspection Mark is being produced, a USDC inspector is present ascertaining the quality level of the product per applicable regulations and Program requirements. This method is referred to as Resident Inspection.

The second system which reduces the product inspection effort is called the Integrated Quality Assurance (IQA) Program and was established in the Federal Register, Volume 37, Number 161 on August 18, 1972. Audits of the system are also performed regularly. However the firm's quality assurance personnel provide assistance to the USDC inspector by inspecting all lots to the applicable US Grade or specification requirements. The USDC inspector then evaluates the system through a product verification system. This system does not necessarily require the USDC inspector to be present for all product inspection activity. However, it does require a USDC approved quality assurance system. All products inspected or verified through this system are eligible to bear a mark.

In July 1992, the USDC published a Federal Register notice announcing the availability of a new seafood inspection program 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 further reduces the inspection effort of the USDC personnel by partnering with industry participants and their responsibility for all food safety, wholesomeness, economic integrity, and quality

concerns for the system and products produced at the firm. The firm is audited on varying levels based upon its compliance to the Program requirements.

This chapter has been developed to provide interested parties with the various policies, procedures, and requirements which must be met in order for facilities and systems to be approved by USDC. Participants may elect to contract in any these of three programs. Under the IQA and the HACCP QMP, the company takes on the responsibility of documenting and implementing a quality system. USDC will then ensure that the quality system in place is adequate to control the critical functions by regular inspections of the system, known as audits. These audits will evaluate the quality system by examining product, processes, and records.

This chapter includes sections which explain the requirements of the Resident Inspection, IQA and HACCP QMP programs for documenting a system that will meet USDC requirements. The document is also a guide manual for use by interested parties in developing their own food safety and/or quality manual. The IQA and HACCP QMP will allow participants an opportunity to apply their existing quality systems more efficiently, receive the management benefits of producing safe, wholesome, and properly labeled products more consistently and obtain the marketing benefits of using marks associated with the Program.

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, and quality of seafood available to consumers, as well as improve seafood industry quality assurance and regulatory oversight.

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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, properly labeled, and of desired uniform quality. Any facility, whether processing plant, retail operation, or vessel, foreign or domestic, may become part of this program.

The development and implementation of Integrated Quality Assurance or HACCP Quality Management systems is optional. However, their use should result in more efficient use of industry and USDC resources to inspect, grade, and certify fishery products. This document also provides guidance for the development, implementation, and operation of these systems, which will meet USDC approval.

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. **Decision Tree:** A sequence of questions applied to each process step with an identified hazard to identify which process steps are CCPs. For the purpose of this Program, this also applies to a DAP (Defect Action Point.)
11. **Decomposition:** A persistent and distinct objectionable odor and/or flavor including texture breakdown caused by the deterioration of the product.
12. **Defect:** A condition found in a product which fails to meet essential quality, composition and/or labeling provisions of the appropriate product standards or specifications.
13. **Defect Action Point (DAP):** A point, step or procedure at which control can be applied and a defect can be prevented, eliminated or reduced to acceptable level, or a fraud risk eliminated.
14. **Deviation:** Any specifically defined variation from a particular requirement.
15. **Establishment:** Any premises, buildings, structures, facilities, and equipment (including vehicles) used in the processing, handling, transporting, and storage of fish and fishery products.
16. **Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
17. **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.
18. **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.
19. **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.
20. **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.
21. **Interested party:** Any person who has a financial interest in the applicable commodity, facility, or firm. 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.
22. **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.

23. **Low risk products:** Seafood that poses no significant risk to the health of the public when prepared for consumption by conventional or traditional means.
24. **Major Deficiency:** A significant deviation from plan requirements, such that maintenance of safety, wholesomeness, or economic integrity is inhibited.
25. **Minor Deficiency:** A failure of the part of the HACCP-based system relative to facility sanitation which is not likely to reduce materially the facility’s ability to meet acceptable sanitation requirements.
26. **Monitoring Procedures:** Scheduled testing and/or observations recorded by the firm to report the findings at each CCP or DAP.
27. **Objective Evidence:** Information, which can be proved true, based on facts, obtained through observation, measurement, test, or other means.
28. **Official Establishment:** Any establishment which has been approved by the Program and utilizes inspection service on a contract basis.
29. **Plant:** The premises, buildings, structures, and equipment (including, but not limited to, machines, utensils, and fixtures) employed or used with respect to the manufacture or production of processed products.
30. **Prerequisite Program:** Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.
31. **Preventive Measure(s) (control measure(s)):** Physical, chemical, or other factors that can be used to control an identified food safety hazard. For the purposes of this program, this also applies to a DAP.
32. **Process:** One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.
33. **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.
34. **Product Form:** Products which are similar in appearance, species, and/or processing method. For example, raw shrimp, cooked shrimp, breaded shrimp, etc.
35. **Quality:** Totality of characteristics of an entity that bear on its ability to satisfy stated and implied 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.
36. **Record:** A document that furnishes objective evidence of activities performed or results achieved.
37. **Risk:** The probability that exposure to a hazard will lead to negative consequences.
38. **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.
39. **Severity:** The seriousness of the effect(s) of a hazard or defect.
40. **Specification:** A document stating requirements. A detailed document describing the materials, dimensions, and workmanship requirements of a product.
41. **Systems Audit:** On-site USDC SIP evaluation of the firm’s effectiveness in following the plan after validation.
42. **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.
43. **Verification:** Those activities performed by the firm, other than monitoring that determine the system continues to be valid and is operating according to the plan.

44. **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.

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Chapter 5 – Application for Services

Firms wishing to receive facility 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 facility, 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 firm should begin following their plan as soon as possible. The firm must adhere to the plan's provisions and keep all records associated with the tentatively-approved plan for at least five (5), and not more than thirty (30), consecutive production days. The firm will contact the Regional Inspection Branch as soon as they believe the plan is functioning successfully and when they have records covering the minimum number of production days. The Regional Inspection Branch will schedule a site visit with the firm. The firm 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 firm must collect data prior to the site visit which will be sufficient to demonstrate this relationship. Firms attempting to document this relationship must collect data on not less than 20 percent of their lots using sampling plans comparable in statistical confidence to those in 50 CFR Part 260, with at least one lot representing each product form. The inspection records must be available to USDC personnel upon request. Although not required, USDC recommends that the firm submit end-item verification records with their QMP Plan. This will allow the firm to test their controls, provide plan reviewers more information, and possibly reduce the time and cost of the site visit.

NOTE: Firms 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 – Additional Requirements for IQA and HACCP Quality Management Program Plan Review and Desk Audit

In addition to the requirements and procedures described thus far, each applicant entering the IQA or HACCP QMP programs must submit a quality management plan which describes the policies and procedures the firm will use to ensure product and process quality. Model system templates are available through the USDC Seafood Inspection Program. At the request of the firm, USDC will provide consultation toward the development of the IQA or HACCP Quality Management Program plan on a fee basis.

Plans are submitted to the servicing Regional Inspection Branch for desk review. Reviews of the plan may require requests for changes, clarifications, deletions, etc., from the firm. The servicing region will work with the firm to finalize the development of the QMP Plan. A written review is sent to the firm indicating what changes, if any, are necessary prior to scheduling the site visit. After any identified changes have been made by the firm the Regional Inspection Branch will issue tentative approval of the plan and work with the firm to schedule a date to conduct the validation audit. All work of the assigned CSO and the Regional Inspection Branch is performed on a fee basis at established rates.

Chapter 8 – Initial Assessment and Validation

Once an application has been filed for this service, the Regional Inspection Branch will schedule a site visit with the firm. Program personnel will evaluate the buildings, premises, facilities, 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 firm 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 firm 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 (and defects/DAPs for the IQA and HACCP QMP Program) have been identified, the food safety management and/or quality management plan is being followed and monitored by the firm, and the identified product hazards and/or defects 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. Firms applying for inclusion in either the IQA or HACCP QMP Programs must have records available covering not less than 5 production days for all processes and products requested for inclusion. The number and structure of the team will be determined by the size and complexity of the firm'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. Firms will be evaluated using the System Compliance Rating Criteria and other requirements as applicable. Firms deemed acceptable may finalize a contract with the Program. If during this audit deficiencies are noted that prevent an acceptable rating, the firm may correct these deficiencies and request the audit team review these corrections prior to departing to determine system acceptability. For those participating in the IQA or HACCP QMP Programs, a favorable audit will make all products under review during the audit, including the previous five (5) to thirty (30) days of production evaluated during the audit, eligible to bear the appropriate official marks or advertising claim. 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 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. Further, it is expected that such a visit will only be necessary for high risk products, such as cooked crab product.

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Chapter 9 – Label Review Procedures

All labels bearing an inspection mark or statement must be approved prior to use, in accordance with requirements and procedures of the USDC Seafood Inspection Program.

Chapter 10 – Changes to the Approved System

After the system has been approved, modifications may be made. The firm must notify the servicing Regional Inspection Branch, in writing (including faxes or e-mail), of any modifications in their food safety and/or quality 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 quality system outlines the basic foundation and policies of the firm'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 firm's documentation requires pre-approval.

Chapter 11 – System Audits - Surveillance

Only with a valid contract and continued demonstrated compliance with all applicable laws, regulations, and policies may 1) the firm be eligible to use official marks or other related statements and 2) firm-collected data be used by USDC personnel towards issuing applicable official certification of the firm's products or facility compliance. After the firm's system is approved, USDC will conduct audits at a minimum frequency—illustrated in the table below—to determine the firm's continued adherence to federal regulations and Program requirements. More frequent audits may be necessary for cause as determined by the Regional Inspection Branch.

Resident and IQA Systems Audit Target Frequencies

Processors	Retail	Vessels
Once every calendar quarter	Once every six months	Once every calendar quarter

IQA firms will have their systems audited at the above frequency as well, but will have their product quality audited at least once per week, as the workload demands. Firms in the HACCP QMP Program will be audited at the frequencies illustrated in the tables found in Appendix 1.

> Note: Audit frequency for firms operating on a seasonal basis will be determined on a case-by-case basis using the guidance of the frequency listed in the chart above and the tables in Appendix 1. With regard to seasonal contracts, the firm must request in writing, to the servicing Regional Inspection Branch, to both suspend and reactivate the contract.

Firms that receive five (5) serious deficiencies or one (1) critical deficiency at the conclusion of an audit are deemed unreliable and will be addressed using the tightened audit procedures described below.

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

a. ***Vessels***
   Firms must provide the appropriate Regional Inspection Branch with their tentative season schedules and off-loading schedules and sites as soon as they are known. Firms must give the Regional Inspection Branch Office or the designated USDC Consumer Safety Officer notice prior to each port arrival, providing sufficient time for the Officer to audit the vessel when required. Failure to do so could result in the removal of the vessel from the Program.

A site visit of the vessel will be conducted at least once per year. The visit may not require the auditor to be on board during fishing, but may require the auditor to be present during off-loading. The other audits may be performed either by desk audit or during evaluation of stored product in the off season as applicable. If the vessel receives an unreliable rating, it will be audited on a tightened level (as necessary) until the firm is back under compliance.

b. ***Processing Establishments***
   USDC personnel will conduct unannounced Systems Audits to determine the firm's continued adherence to their plan. International facilities will be scheduled for site visits at a minimum of twice during the year. The remaining audits may be performed by desk audit review of documentation and records.

Processors which desire product certification for lots produced under their operation must either have an approved IQA or HACCP QMP system, have the lots inspected by USDC for conformance during production, or USDC will inspect the product after it is produced using lot inspection services.

c. ***Retail and Food Service Establishments***
USDC personnel will conduct unannounced Systems Audits to determine the firm's continued adherence to their plan.

Chapter 12 – Tightened Audit Procedures

A firm at the tightened audit frequency has demonstrated difficulties in administering their food safety and/or quality management plan and was therefore rated by the USDC Seafood Inspection Program as unreliable. If a Consumer Safety Officer rates a facility unreliable, he/she will rate the facility and immediately contact his/her Supervisor. The decision to rate a facility unreliable will be made prior to the Consumer Safety Officer performing the exit interview. Facilities which 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 will result in the facility's removal from the approved list or the IQA or HACCP QMP Program. A firm in the IQA or HACCP QMP Program which is deemed unreliable may continue to use the mark or other applicable advertising privileges if consent is given by USDC for daily auditing of the firm. Consent will be on a case by case basis and granted only if USDC believes the nature of the condition which caused the firm to become unreliable can be adequately addressed through daily auditing. Daily auditing will be acceptable to the Program under the following conditions:

a. The firm must submit a corrective action plan to the Consumer Safety Officer (auditor) detailing how they will correct the problem.
b. The Consumer Safety Officer will review the corrective actions identified by the firm and will approve or disapprove them and notify his/her Supervisor. Daily auditing will continue until the issue is corrected, or up to a maximum of thirty calendar days.
c. 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.
d. At the auditor's discretion, product compliance will be verified by end-item evaluation. No products covered by the contract will leave the firm without USDC approval.
e. Firms participating in the IQA or HACCP QMP programs deemed unreliable twice in a twelve month period will be removed from the respective program. Firms who have been removed may submit a request for reapplication after a period of three calendar months. Application will be accepted by USDC only if evidence of a change in management philosophy can be provided. Firms which have been removed from such programs may still be eligible to enter into full-time auditing of the facility, system, and product.

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Chapter 13 – Corrective Action Plans

When applicable, the firm 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 14 – Appeal Procedures

If a firm wishes to appeal an unreliable rating, they are to contact, in writing, the servicing Region Inspection Branch Chief. The facility must provide, in writing, 1) all pertinent information as to why it is believed the rating was determined in error and 2) the actions the firm has taken at that facility to address the perceived deficiency(ies) and ensure that the facility, processes, and products will meet applicable requirements. Once the Region Chief receives all information, he/she will investigate the matter and consult with, and gain approval of, the Chief Quality Officer at headquarters. The final determination will be communicated to the facility as soon as possible, followed by a written report.

Chapter 15 – Analytical Testing and Product Verificaiton

The firm must perform periodic end-item verification of product compliance to program requirements. Both the firm and USDC must agree upon the firm'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 will have product tested analytically throughout the year as described in the Surveillance Sampling Program.

To determine whether the product produced at the firm meets specification and/or requirements, USDC will routinely perform a product audit on up to three (3) lots produced by the firm 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 firm and the definition agreed upon by the USDC Seafood Inspection Program.

Chapter 16 – Use of Marks

Participating firms are responsible for using the marks in accordance with the regulations set forth in 50 CFR Part 260 and the Policy and Guidelines for Advertising and Marking Products Inspected by the U.S. Department of Commerce. Firms may be issued official stamping devices to aid in affixing marks on cases or product if they meet program requirements. Facilities who have received official stamping devices must have written procedures in place to ensure security of the devices and protection from misuse.

Chapter 17 – Advertising Participants

Firms who are successfully participating in the Approved Facility Program will be listed in the USDC Participants List for Firms, Facilities, and Products as an approved facility. The list will include the firm's

name, all pertinent locations, and approved processes. This list is updated regularly on the Program's website and printed in hard copy twice per year. These firms 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 18 – 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 facilities, processes and systems.

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

1.2.2 Food safety team leader does not report to top management.
The food safety team leader must report to the organization's top management and will inform them on the effectiveness and suitability of the food safety management system.
Deficiency: Major

1.2.3 Food safety team is not interdisciplinary as applicable.
The food safety team shall have a combination of multi-disciplinary knowledge and experience in developing and implementing the food safety management system. This includes, but need not be limited to, the organization's products, processes, equipment and food safety hazards within the scope of the food safety management system. Records shall be maintained that demonstrate that the food safety team has the required knowledge and experience.
Deficiency: Major

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 action s described above.

Training must include the areas of HACCP, good manufacturing practices, and allergens to appropriate personnel. Each firm must have available a person who has met the training requirement by NOAA for this program. The training requirement 1) fulfills the 21 CFR part 123.10 training requirement and, 2) personnel must pass the NOAA HACCP Exam with an 80% or better. In addition, copies of all trained personnel's certificates must on file with the firm. 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 to only 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 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(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 firm did not follow their written procedures, whether or not specific s deficiencies were observed.

Deficiency: Serious

2.2.0 Hazard Analysis

2.2.1 Description of products, processes or control measures not properly performed.

All relevant information needed to conduct the hazard analysis shall be collected, maintained, updated and documented. Records shall be maintained.

All raw materials, ingredients and product-contact materials shall be described in documents to the extent needed to conduct the hazard analysis, 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; h) food safety-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 documents to the extent needed to conduct the hazard analysis, 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; d) intended shelf life and storage conditions; e) packaging; f) labeling relating to food safety and/or instructions for handling, preparation and usage; g) method(s) 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. 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 management system. Flow diagrams shall provide a basis for evaluating the possible occurrence, increase or introduction of food safety hazards. 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)

where end products, intermediate products, by-products and waste are released or removed. The food safety 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: Major

2.2.2 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. Such hazard analysis must also consider any products, including ingredients or additives, that may contain allergens as a significant hazard. Allergen assessment must also consider unintentional inclusion of an allergenic ingredient or additive. (21CFR123.6a)

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.

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The existing control measures, process parameters and/or 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 measure 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 and defect analysis is the foundation of the HACCP plan. If the analysis is not performed, the entire plan and its efficacy is suspect. Firms 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)Firms must provide this plan to the requesting Consumer Safety Officer.
Deficiency: Serious

2.3.2 Plan is not location and/or fish species specific.
A HACCP plan shall be specific to:

1. Each location where fish and fishery products are processed by that processor; and
2. 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.

Deficiency: Major

2.3.3 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

2.3.4 Hazard(s) is not controlled.
Firms 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

2.3.5 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 processing plant environment; and
2. Critical control points designed to control food safety hazards introduced outside the processing plant environment, including food safety hazards that occur before, during, and after harvest. (21CFR123.6c.2)

Deficiency: Serious

2.3.6 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

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

2.3.8 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. Where allergen controls are not sufficient or proper or identified allergens are not declared on product labels where appropriate, a critical deficiency will be assessed.

Deficiency: Serious/Critical

2.3.9 Monitoring procedures not followed:

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

Deficiency: Serious

2.3.10 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)

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Deficiency: Serious

2.3.11 Corrective action not taken

Whenever a deviation from a critical limit, sanitation, monitoring or verification procedures occurs, a processor shall take corrective action. Processors 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 firm 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 firm 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 firm will then not be in compliance with this item.

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

2.3.12 Verification procedure stated in plan is inadequate.
The HACCP plan shall list the verification procedures, and frequency thereof, that the processor will use. Every processor 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 formulation, processing methods or systems, finished 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 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,
    - At the option of the processor, the performing of periodic end-product or in-process testing. (Note: Some end item testing is required as part of the HACCP QMP system. 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 or in-process testing that is part of the processor'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 processor's written procedures. These reviews shall occur within 1 week of the day that the records are made.

4. Processors shall immediately follow corrective action procedures whenever any verification procedure, including the review of a consumer 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 processor does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur, the processor 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, processing methods or systems, finished 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 and in-process 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 organization shall conduct internal audits at planned intervals to determine whether the food safety management system a) conforms to the planned arrangements, to the food safety management system

requirements established by the organization, 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 actions resulting from previous audits. The audit criteria, scope, frequency and methods shall be defined and documented. Selection of auditors and the conduct of audits shall ensure the objectivity and impartiality of the audit process. Auditors shall not audit their own work. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate nonconformities and their causes.

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

2.3.13 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. Firms 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 facility. 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, processing and delivery records. The traceability system shall be able to identify incoming material from the immediate suppliers and the initial distribution route 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 firm 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.

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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 Inadequate information on records (Facility name and location, etc.)
Based on the required information stated in 21 CFR Part 123.9a.
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: Major

2.6.2 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. All time schedules outlined in the QMP plan must be maintained. 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. If record data is missing, a Major deficiency will be assessed.

All labels must be up-to-date. All labels must be kept on file by the firm. If labels are not up-to-date, a Serious deficiency will be assessed.

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: Major (Serious for Labels)

2.6.3 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 firm.
Deficiency: Serious/Critical

2.6.4 Records are not available for inspection.
If the firm 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 firm is not in compliance with this item. All required records shall be retained at the processing facility 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 facility 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 processing facility 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

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2.6.5 Documents or records are falsified.
This item is self-explanatory. However, intent on the part of the firm 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 facilities, processes and 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 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

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

3.1.3 Sanitation not 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 specified in 21 CFR Part 110 and 123 that are both appropriate to the plant 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 food plant.

The firm 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
Process water must 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 must pass potability standards established by federal, state, and local authorities. Water that is supplied to the plant must meet certain minimum standards. However, processing water must also be reasonably protected in the facility. 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 facility 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

3.2.5 Inadequate 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 throughout the plant. Water shall be sufficient to properly convey sewage and liquid disposable waste from the plant. 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. If the tap is on and a luke-warm supply of water is present in sufficient quantities for the tasks it will perform in the facility, the plant is in compliance. The supply must also be easily accessible for its proper use.
Deficiency: Minor (Lack of hot water)/Major (Lack of sufficient water supply)

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3.2.6 Ice not manufactured, handled, or used in a sanitary manner.
A facility 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 facilities 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: Major/Critical

3.2.7 Other areas covered by the CGMPs.
Deficiency: Minor

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 facility 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 plant 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

3.3.2 Equipment and utensils not maintained in proper repair or removed when necessary. (Food contact surfaces)
All food contact surfaces must 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. Failure to provide these conditions will result in non-compliance. Assessment of this deficiency will be made relative to the risk

of the product at that stage of production. For example, if the equipment under consideration is being used for handling product after a kill step in the process, this product is higher risk and therefore the deviation is more significant.
Deficiency: Major (Serious for products at a high risk stage of processing)

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. 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

3.3.4 Concentrations of cleaners and sanitizers are not effective, safe, or routinely checked.
All sanitizing agents (e.g., hand sanitizers, equipment sanitizers, etc) must be used in the proper concentration and in the manner prescribed in the usage instructions to be effective.
Deficiency: Major

3.3.5 Other areas covered by the CGMPs.
Deficiency: Minor

3.4.0 Prevention of Cross Contamination
3.4.1 Grounds condition can permit contaminants to enter the facility.
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 be carried into the plant through such means as wind drafts, personnel foot traffic, adherence to personnel clothing, flooding, etc.
Deficiency: Minor/Major

3.4.2 Facility
3.4.2.1 Design, layout of materials used cannot be readily cleaned and sanitized; does not preclude product contamination. Insufficient lighting for the applicable operation.
Design of the facility structure should be such that access is easily obtained to all areas. This is necessary for proper cleaning and sanitizing of floors, walls and ceilings, as well as for visual inspections. If the rooms (including restrooms and employee break rooms) in the facility are laid out or designed in such a way that they cannot be readily cleaned or sanitized, then the facility is not in compliance. 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.
Deficiency: Major

3.4.2.2 Insufficient separation by space or other means allows product to be adulterated or contaminated.
There must be sufficient separation between different activities in the processing, packaging and handling of food products such as 1) separation between activities, 2) layout of facility (employee traffic) 3) product sequencing and 4) 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 of the facility should not be such that product contamination/adulteration is likely due to issues such as heavy employee traffic through work areas. Production is not organized and scheduled in a manner which precludes 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

3.4.3 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 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 must be maintained as designed and lights must be protected. Failure to do so causes the facility to be out of compliance.
Deficiency: Serious

3.4.3.2 Other.
For areas in the facility other than in 3.4.3.1 above, the roof, ceilings, walls, floors, or lighting fixtures must also be maintained as designed. This does not include those areas designated as offices and in which food products or primary packaging materials in any stage of production will not be handled or stored.
Deficiency: Major

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 facility 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.
Finished product must be packaged, covered or protected so as to not permit contamination or adulteration prior to shipment and during transportation. Primary packaging materials should be adequately covered when stored or not in use. Failure to provide these conditions will result in non-compliance.
Deficiency: Major/Serious

3.4.6 Equipment and utensils not maintained in proper repair or removed when necessary. (Non-food contact surfaces)
All non-food contact surfaces should also be maintained in good repair. The facility is in non-compliance when the maintenance of all additional equipment or areas of equipment and utensils not referred to in item 3.4.3.1 above is insufficient and may allow indirect product contamination.
Deficiency: Minor (Major for products at a high risk stage of production)

3.4.7 Non-food contact surfaces, equipment, or areas not cleaned before use.
Non-food contact areas must also be cleaned prior to use. Areas such as walls, ceilings, floors, as well as equipment must also be cleaned prior to use. However, sanitizing is not required.
Deficiency: Major

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: Major/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. After washing, the hands must be sanitized
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. Wear hair nets, caps, masks, or other effective hair restraint. Other persons that may incidentally enter the processing areas shall comply with this requirement.
5. 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.
6. 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.
7. Using sanitary handling procedures during operations to protect food against contamination, e.g., picking up dropped food from the floor.

Deficiency: Serious/Critical

3.4.10 Other areas covered by the CGMPs.
Deficiency: Minor

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: Serious (Critical for products at a high risk stage of production)

3.5.2 Improper disposal of toilet waste or sewage.
A facility is in compliance when sewage systems drain properly, are vented to the outside, and are connected to an approved private septic system or a public septic and/or sewage system.
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. 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: Major/Serious

3.5.4 Insufficient number of functional toilets.
The facility 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 food is exposed to airborne contamination, except where alternate means of protection have been implemented.
Deficiency: Major/Serious

3.5.5 Other areas covered by the CGMPs.
Deficiency: Minor

3.6.0 Protection From Adulteration
3.6.1 Condensation or other deleterious sources present.
Adequate physical protection of food from adulterants that may drip, drain, or be drawn into the food must be in place. Provide adequate physical protection or separation of food during processing (filling, packaging, assembling, etc.) to protect from contamination. If any condensation, overhead leaks, water splash or other conditions occur that may result in the adulteration of product or primary packaging material, the facility is in non-compliance for this item.
Deficiency: Critical

3.6.2 Adequate air exchange does not exist.
A facility is in compliance when adequate air exchange exists to preclude the development of foul odors or contamination of product.
Deficiency: Minor (Only for products at a high risk stage of production)

3.6.3 Other areas covered by the CGMPs.
Deficiency: Minor

3.7.0 Proper Labeling, Use, and Storage of Toxic Compounds
Plant 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 food product that the establishment is handling or manufacturing.

A facility 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 food handling or manufacturing. 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 plant 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 plant 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: Major
3.7.4 Material Safety Data Sheets (MSDS) not available for all chemicals in use at the facility.
Deficiency: Serious
3.7.5 Other areas covered by the CGMPs.
Deficiency: Minor

3.8.0 Control of Employee Health Conditions
3.8.1 Facility 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 in a food plant in any capacity in which there is a reasonable possibility of food or food ingredients becoming contaminated by such person. Plant management shall require employees to report illness or injury to supervisors.
Deficiency: Serious

3.8.2 Other areas covered by the CGMPs.
Deficiency: Minor

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

3.9.1 Harborage and attractant areas present.
The facility 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 plant 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 in the facility to exclude pests that may be a source of contamination by the means outlined in the other areas of this element.
Deficiency: Major

3.9.2 Pest control measures not effective.
3.9.2.1 Exclusion
Openings to the outside of or within the facility may allow vermin or other pests to enter. Openings and cracks should be screened or otherwise sealed. Screens must 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 must be effective. Air curtains shall comply with National Sanitation Standard Number 37 for Air Curtains for entranceways in food establishments. Strip curtains must run the entire opening with sufficient overlap between flaps (1/2 inch). In addition, every effort should be made to keep birds from areas of the plant where food is transferred or processed.
Deficiency: Major

3.9.2.2 Extermination
<u>Birds</u>--Nesting areas must be eliminated.
<u>Insects</u>--There should not be a significant number of insects present in the facility. Insect electrocution devices, when used, must be located near the entranceway. Approved insecticides should be used whenever insect populations become noticeable.
<u>Rodents</u>--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 facility should have appropriate rodent control measures in place. If not, the facility is not in compliance.
Deficiency: Major/Serious

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

3.9.4 Inadequate housekeeping.
Any excess clutter in production areas, employee areas, or other areas of the facility will cause the facility to be in non-compliance. This does not include those areas designated as office areas.
Deficiency: Minor

3.9.5 No written pest control program.
Self-explanatory. Diagrams of bait station locations at the facility 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

3.9.7 Other areas covered by the CGMPs.
Deficiency: Minor

d. 4.0 Quality System

The elements of this section apply to participants in the Integrated Quality Assurance Program and the HACCP Quality Management Program in the evaluation of facilities, processes and systems. This section may also apply if requested specifically.

4.1.0 Management Responsibilities
4.1.1 Management commitment not properly implemented or communicated.
Top management shall provide evidence of its commitment to the development and implementation of the quality management system and to continually improving its effectiveness by: a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements, b) establishing a quality policy, c) ensuring that quality objectives are established, d) conducting management reviews, and e) ensuring the availability of resources.
Deficiency: Critical

4.1.2 Food quality policy not prepared or properly implemented.
Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction. Top management shall ensure that the quality policy a) is appropriate to the role of the organization, b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system, c) provides a framework for establishing and reviewing quality objectives, d) is communicated and understood within the organization, and e) is reviewed for continuing suitability.
Deficiency: Serious

4.1.3 Quality system planning not properly performed.
Top management shall ensure that quality objectives, including those needed to meet requirements for

product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy. Top management shall ensure that a) the planning of the quality management system is carried out as well as the quality objectives, and b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.
Deficiency: Serious

4.1.4 Responsibility and authority not properly defined or communicated.
Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.
Deficiency: Serious

4.2.0 Quality Team
4.2.1 Quality team leader not appointed.
Top management shall appoint a quality team leader who, irrespective of other responsibilities, shall have the responsibility and authority to: a) ensure that processes needed for the quality management system are established, implemented and maintained, b) report to top management on the performance of the quality management system and any need for improvement, and c) ensure the promotion of awareness of customer requirements throughout the organization.
Deficiency: Serious

4.3.0 Internal Communication
4.3.1 Effective internal communication not established, implemented, or maintained.
Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.
Deficiency: Serious

4.4.0 Management Review
4.4.1 Management review not properly performed or documented.
Top management shall review the organization's 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 quality policy and objectives. Records from management reviews shall be maintained.

The input to management review shall include information on: a) results of audits, b) customer feedback, c) process performance and product conformity, d) status of preventive and corrective actions, e) follow-up actions from previous management reviews, f) changes that could affect the quality management system, and g) recommendations for improvement.

The output from the management review shall include decisions and actions related to: a) improvement of the effectiveness of the quality management system and its processes, b) improvement of product related to customer requirements, and c) resource needs.
Deficiency: Serious

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4.5.0 Resource Management
The organization shall determine and provide the resources needed a) to implement and maintain the quality management system and continually improve its effectiveness, and b) to enhance customer satisfaction by meeting customer requirements.

4.5.1 Necessary human resource competencies not identified.
Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.
Deficiency: Serious

4.5.2 Personnel have not received documented training necessary for the proper function of the quality system.
The organization shall: a) identify the necessary competencies for personnel performing work affecting product quality, b) provide training or take other action to satisfy these needs, c) evaluate the effectiveness of the actions taken, d) ensure that the personnel are aware of the relevance and importance of their individual activities in contributing to the quality objectives, f) maintain appropriate records of training and action s described above.
Deficiency: Critical

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

4.5.4 Work environment is not properly established, managed, or maintained relative to food quality.
The organization shall provide the resources for the establishment, management, and maintenance of the work environment needed to achieve conformity to product requirements.
Deficiency: Serious

4.6.0 Quality Manual
4.6.1 Quality manual is inadequate.
Every IQA or HACCP QMP processor, as applicable, shall have and implement a written quality manual which covers each of the elements delineated in the Quality System Requirements. Firms must provide this plan to the requesting Consumer Safety Officer.

The organization shall establish and maintain a quality manual that includes a) the scope of the quality management system, b) the documented procedures established for the quality management system, or reference to them, and c) a description of the interaction between the processes of the quality management system.
Deficiency: Serious

4.6.2 Defect action plan is not adequate to control product quality characteristics.
Every processor, as applicable, shall have and implement a written Defect Action Plan and a quality defect analysis for products that will either bear an inspection mark or will be advertised as under the NOAA Seafood Inspection Program. Firms must provide this plan to the requesting Consumer Safety Officer.
Deficiency: Serious

4.6.3 Defect action plan/quality manual not followed.
This deficiency will be assessed if the firm did not follow the policies outlined in their Quality manual or did not follow the procedures listed in their defect action plan. This deficiency will be assessed whether or not it was determined that product was affected.
Deficiency: Critical

4.7.0 Product requirements and specifications.
4.7.1 Product characteristics not properly described including raw materials, ingredients, and end product.
All raw materials, ingredients and food contact materials shall be described in documents to the extent

needed to conduct the hazard and defect analysis, including the following: 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 characteristics of end products shall be described in documents to the extent needed to conduct the hazard and defect analysis, including information as appropriate on the following: a)product name or similar identification, b)composition, c)biological, chemical, and physical characteristics relevant to food safety and quality, d)intended shelf life and storage conditions, e)packaging, f)labeling relating to food safety and quality, and/or instructions for handling, preparation, and usage, and g)methods of distribution.

The customer requirements, including any requested changes, are to be reviewed before a commitment to supply a product is provided to the customer (e.g. submission of a tender, acceptance of a contract or order) 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 organization has the ability to meet the customer requirements for the product. The results of reviews and subsequent follow-up are to be recorded.

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

4.7.2 Intended use and reasonably expected handling of the product not properly considered.
The intended use, the reasonably expected handling of the end product, and unintended but reasonably expected mishandling and misuse of the end product shall be considered and be described in documents to the extent needed to conduct the hazard and defect analysis. 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, or product defects, shall be considered. The descriptions shall be kept updated.
Deficiency: Major

4.7.3 Product requirements not discussed and agreed with the customer.
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 must include customer agreement to the terms.
Deficiency: Serious

4.7.4 Labels and/or specifications are inadequate.
Title 50 of the Code of Federal Regulations (CFR) requires that establishments contracting for fishery product inspection service obtain NOAA approval of labels prior to use on products packed under Federal inspection, regardless of whether or not they bear official inspection or grade marks. Additionally, the "Policy for Advertising Services and Marks" identifies additional labeling and advertising of marks and services that must be approved prior to use. The Regulations Governing Processed Fishery Products require that specifications for all products for which U.S. Standards for Grades are not available be approved by the Secretary of Commerce and that end-product samples, when requested, be evaluated to determine their compliance with approved specifications prior to

NOAA inspection and certification of such products.
Deficiency: Serious

4.7.5 Nonconforming product is improperly controlled.
The manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. 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.

The manufacturer shall establish 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.

The manufacturer 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.
Deficiency: Critical

4.8.0 Purchasing
4.8.1 Evaluation, re-evaluation, and selection criteria for suppliers are not established.
The manufacturer shall establish and maintain the requirements (including safety, wholesomeness, proper labeling, and quality requirements) that must be met by suppliers, contractors, and consultants. The manufacturer shall:

a. Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
b. Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results. This shall be dependent upon the type of product, the impact of subcontracted product on the quality of final product, and, where applicable, on the quality audit reports and/or quality records of the previously demonstrated capability and performance of subcontractors.
c. Establish and maintain quality records of acceptable suppliers, contractors, and consultants.

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Deficiency: Major

4.8.2 Purchasing documents are not clear, reviewed, approved, or adequate.
The manufacturer shall establish 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 manufacturer of changes in the product or service so that manufacturers may determine whether the changes may affect the safety or quality of a finished product. The manufacturer shall review and approve purchasing documents for adequacy of the

specified requirements prior to release.
Deficiency: Serious

4.8.3 Verification of purchased product not properly performed or documented.
The manufacturer shall establish 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

4.8.4 Customer property not properly maintained or controlled.
The manufacturer shall establish and maintain documented procedures for the control of verification, storage, and maintenance of customer-supplied product provided for incorporation into the supplies or for related activities. Any such product that is lost, damaged, or is otherwise unsuitable for use shall be recorded and reported to the customer.

Verification by the manufacturer does not absolve the customer of the responsibility to provide acceptable product.
Deficiency: Serious

4.9.0 Measurement, Analysis, and Improvement
4.9.1 Customer satisfaction/dissatisfaction data not maintained or monitored.
The organization 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

4.9.2 Internal audits not established or properly performed.
The organization shall conduct internal audits at planned intervals to determine whether the food safety and quality management system a) conforms to the planned arrangements, 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. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of the verification audits.
Deficiency: Serious

4.9.4 Analysis of data and continuous improvement not properly performed with regard to the system.
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

e. 5.0 Food Security

This section outlines the elements found in federal guidance on food security systems and as such only applies if requested.

5.1.0 Management

5.1.1 A comprehensive food security plan has not been written, implemented, and periodically reviewed by the processor.

A comprehensive food security plan must be written, implemented and periodically reviewed. Such a plan should consider:

1. Preparing for the possibility of tampering or other malicious, criminal, or terrorist actions
    - assigning responsibility for security to knowledgeable individual(s)
    - conducting an initial assessment of food security procedures and operations, which we recommend be kept confidential
    - having a security management strategy to prepare for and respond to tampering and other malicious, criminal, or terrorist actions, both threats and actual events, including identifying, segregating and securing affected product
    - planning for emergency evacuation, including preventing security breaches during evacuation
    - maintaining any floor or flow plan in a secure, off-site location
    - becoming familiar with the emergency response system in the community
    - making management aware of 24-hour contact information for local, state, and federal police/fire/rescue/health/homeland security agencies
    - making staff aware of who in management they should alert about potential security problems (24-hour contacts)
    - promoting food security awareness to encourage all staff to be alert to any signs of tampering or other malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions, and reporting any findings to identified management (for example, providing training, instituting a system of rewards, building security into job performance standards)
    - having an internal communication system to inform and update staff about relevant security issues
    - having a strategy for communicating with the public (for example, identifying a media spokesperson, preparing generic press statements and background information, and coordinating press statements with appropriate authorities)
2. Supervision
    - providing an appropriate level of supervision to all staff, including cleaning and maintenance staff, contract workers, data entry and computer support staff, and especially, new staff
    - conducting routine security checks of the premises, including automated manufacturing lines, utilities and critical computer data systems (at a frequency appropriate to the operation) for signs of tampering or malicious, criminal, or terrorist actions or areas that may be vulnerable to such actions
3. Recall strategy
    - identifying the person responsible, and a backup person
    - providing for proper handling and disposition of recalled product
    - identifying customer contacts, addresses and phone numbers
4. Investigation of suspicious activity

- investigating threats or information about signs of tampering or other malicious, criminal, or terrorist actions
- alerting appropriate law enforcement and public health authorities about any threats of or suspected tampering or other malicious, criminal, or terrorist actions

5. Evaluation program
    - evaluating the lessons learned from past tampering or other malicious, criminal, or terrorist actions and threats
    - reviewing and verifying, at least annually, the effectiveness of the security management program (for example, using knowledgeable in-house or third party staff to conduct tampering or other malicious, criminal, or terrorist action exercises and mock recalls and to challenge computer security systems), revising the program accordingly, and keeping this information confidential
    - performing random food security inspections of all appropriate areas of the facility (including receiving and warehousing, where applicable) using knowledgeable in-house or third party staff, and keeping this information confidential
    - verifying that security contractors are doing an appropriate job, when applicable

Deficiency: Critical

5.2.0 Human Element

5.2.1 Access to plant or sensitive areas of the facility (by employees or visitors) is not sufficiently restricted to authorized personnel. **Deficiency: Serious**

*5.2.2 Appropriate controls are not required of employees for gaining access to the facility.***Deficiency: Serious**

5.2.3 Hiring practices do not include a screening process.
Self-explanatory. **Deficiency: Serious**

5.3.0 Facility

5.3.1 Facility, including outside premises, grounds, and perimeter, are not properly secure.
Self-explanatory. **Deficiency: Critical**

5.4.0 Operations

*5.4.1 Raw material suppliers are not subject to a documented approval/screening process.***Deficiency: Critical**

5.4.2 Supplier COCs or invoices do not address the subject of product origin and food security. **Deficiency: Serious**

5.4.3 Product integrity is not assured from time of shipping raw materials to processor through delivery of finished product to end-user.
Self-explanatory. **Deficiency: Serious/Critical**

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Appendix 1

a. HACCP Quality Management Program Audit Frequency

	Systems Audit Target Frequencies	Deficiencies

Facility Rating	Processors	Retail	Vessels	Minor	Major	Serious	Critical
Reduced	Once every calendar quarter	Once every six months	N/A	**0-6**	**0-5**	**1**	**0**
Normal	Once every month	Once every calendar quarter	Once every calendar quarter	**≥7**	**6-10**	**2-4**	**0**
Tightened	Daily until corrected	Daily until corrected	As necessary until corrected	**NA**	**≥11**	**≥5**	**≥1**
Requirements to be Audited at a Reduced Frequency	Three consecutive audits at Reduced Rating	Three consecutive audits at Reduced Rating	N/A				

Audit frequency for firms operating on a seasonal basis will be determined on a case-by-case basis using the guidance of the frequency listed in the chart above. With regard to seasonal contracts, the firm must request in writing, to the servicing Regional Inspection Branch, to both suspend and reactivate the contract.

b. Chain Retail Store Audit Frequency

Firms which operate a chain of stores may have the stores under the program sampled as outlined in the chart below, provided they have an established approved Quality Assurance System.

Table 3	**Stores to Sample Per Calendar Quarter**		
Number of Facilities	**Reduced**	**Normal**	**Tightened**
2 - 4	1	2	ALL
5 - 8	3	4	5
9 - 12	4	6	8
13 - 16	6	8	10
17 - 20	8	10	13
21-30	9	13	18
31-40	10	15	21
41-70	10	18	25
71-100	10	19	30

101 or more	10	20	35

In addition, the following criteria apply:

1. All firms will begin at Tightened Sampling. After two successive calendar quarters the firm will move to Normal sampling. After two successive calendar quarters at Normal sampling, the firm will move to reduced sampling.
2. No stores in the sample may be considered unreliable. If a store in the sample is deemed unreliable (Five Serious deficiencies or One Critical deficiency), the Firm's Quality Assurance System is suspect. USDC will perform an audit on the total Quality Assurance System for the next thirty days. This audit will include the sampling of additional stores.
3. If, after the audit, the Quality Assurance System is deemed under control, the firm will be sampled at the Tightened level and the system begins again.
4. If the Quality Assurance System is deemed to not be performing as designed, Regional Management will evaluate the company's entire program and suggest the necessary changes to continue in the Program. This evaluation may result in a permanent or temporary removal from the program.
5. During this thirty day period, the stores may continue to use all advertisement claims.
6. If the sample of stores does not meet the above requirements, then each store in the chain must be audited on its own until such time as the Quality Assurance System has been re-approved

Appendix 2

a. Product Verification for IQA Facilities

To assess the plant QA's ability to evaluate accurately a product's degree of compliance with its applicable standard, specification, or other approved document, the USDC inspector must sample and inspect the product(s) produced for USDC certification. The inspector's results are then compared to the results obtained and reported by the plant's QA department to determine whether any significant differences exist. The plant is required to sample, inspect, and record the findings of each lot produced. The USDC inspector is required to sample and inspect (verify) a certain percentage of the lots produced. It is extremely important that the verification samples and inspections be conducted on an unscheduled, random basis, and independently from the plant's own sampling and inspection. This independence of sampling and inspection, and recording of inspection findings, is necessary to satisfy the verification objectives under the IQA system.

> **Note**: The independent sampling and inspection for product verification does not mean that the USDC inspector takes no action if his/her inspection results indicate a potential or actual rejection of a production lot currently being processed.

There are three instances where the inspector will notify the plant QA department of potential or actual product rejections when verifying a product being processed.

Absolute Factors: For factors such as flavor and odor, health hazard situations, scores below 81 in the case of a US Grade A product, or for any reason that the product cannot pass inspection, the plant QA will be notified immediately. If the plant QA has found similar results and is taking appropriate action,

no penalty, i.e., a major or minor deviation, will be assessed. However, if the plant QA is unaware of the problem, a major deviation will be assessed and the lot placed on "hold" for proper disposition, i.e., reworking, destruction, appeal, etc.

Acceptance/Rejection Levels for Scores: When the acceptance number for scores has been reached, for example, 1 for a sample size of 6, 2 for a sample size of 13, etc., the plant QA will be notified of a potential rejection. The inspector will review the plant QA records to determine whether similar results have been found and corrective action taken. If so, the inspector will take no action. If the plant QA does not have similar findings, it will be advised of a potential rejection and a minor deviation will be assessed. It should be noted that if a sample size of 3 is used, there is no mechanism for alerting the plant QA since the acceptance number is 0. Some plants may wish to increase the sample size to 6 in this instance, **prior** to the start of production.

Averages: For factors in which acceptance is based on an overall average, a running computation will be kept. When the "W" number is exceeded, the inspector will notify the QA department of a potential rejection. The inspector will review the plant QA records to determine whether similar results have been found and corrective action taken. If so, the inspector will take no action. If the plant QA does not have similar findings, it will be advised of a potential rejection and a minor deviation will be assessed.

In the above situations the inspector must keep in mind that this does not mean that he/she is to work so closely with QA as to diminish the independent nature of USDC and plant QA activities. The inspector must remember that USDC is verifying what the plant QA is doing – not working so closely with it as to influence QA results to agree with those found by USDC.

i. Product Group:

For verification purposes, products which are similar in appearance and scoring factors (or other inspection criteria) may be combined to represent one product group. Products grouped in this manner will be identified in the QA plan on a plant-by-plant basis as approved by USDC. A product group is considered to be but one product when determining the product verification rate.

ii. Product Verification Rate:

The minimum number of products to be verified by the inspector will depend upon the total number of products produced since the last Group 1 verification. (The time period between successive product verifications will not exceed one production week.) The following product rate table is used to determine the minimum number of products that require verification.

Total Number of Products Processed since the Last Group 1 Verification	Minimum Number of Products to Verify
1	1
2-4	2
5-8	3
9-13	4
14-19	5
20 or more	6

Based on the product rate table, the particular products to be verified will be randomly selected from the total number of products produced since the last product verification; except in those cases where all products must be verified or as noted below.

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After a particular product has been verified and found to be acceptable, it may be excluded from further applications of product verification until all other products produced have been verified; except when an audit indicates potential noncompliance.

When there is reason to suspect that a particular product is not in compliance and QA has not taken appropriate action, that product will be verified.

iii. Selection of Lots from each Product: Following the random selection of products to be verified, the number of lots of each product must be selected. This may be accomplished in either of two ways.

1. Random Selection from All Lots: For each product to be verified, randomly select 25 percent of all lots produced since the last Group 1 verification. More than 25 percent of the lots may be selected and verified if results indicate the need. If less than 4 lots are available, select 1 lot at random to verify. Otherwise, use the following rule: When the percentage calculation yields a decimal part of 0.25, round down; if the decimal part is 0.50 or 0.75, then round up. For example, if 9 lots are available, then 2 lots would be verified; whereas, if 10 or 11 lots are available, then 3 lots would be verified.
2. Random Selection of Lots from each of Five Possible Lot Size Classes: To use this method, all lots of a product produced since the last Group 1 verification are assigned to a lot size class depending on the sample size each lot would require using the single sampling plans contained in 50 CFR 260.61 as follows:

Lot Size Class	Sample Size Required for Inspection
1	**3**
2	**6**
3	**13**
4	**21**
5	**29**

Note: Lot size class 5 includes all lot sizes requiring (per 50 CFR 260.61) sample sizes of 29 or more. For lots in this class a sample size of 29 will be drawn.

For example, those lots of a product to be verified that would require a sample of 3 units make up lot size class 1. Then from each lot size class, randomly select 25 percent of the applicable lots. More than 25 percent of the lots may be selected and verified if results indicate the need. If less than 4 lots are available, select 1 lot at random to verify. Otherwise, use the following rule: When the percentage calculation yields a decimal part of 0.25, round down; if the decimal part is 0.50 or 0.75, then round up. For example, if 9 lots are available, then 2 lots would be verified; whereas, if 10 or 11 lots are available, then 3 lots would be verified.

The inspector has the option of using either of the above two methods. In some cases the lot size class method may reduce the total number of sample units needed to perform product verification. The product(s)/lot(s) rates specified above serve only as minimum requirements. The inspector may increase these rates provided that the total number of products, lot, and sample units are within the inspector's capability to verify.

iv. Selection of Sample Units:
Only single sampling plans as specified by lot size in 50 CFR 260.61 will be used by the inspector when verifying each selected lot. A maximum of 29 sample units per lot will be used.

v. Product Examination and Quality Assurance Records Review:
Product verification consists of examining the product sample units and reviewing and evaluating all plant QA records covering the particular product(s)/lot(s) selected for verification.

Verification Factors: For each product, the verification factors (as applicable) are:

1. Net Weight
2. Pressed Weight
3. Count
4. Scored Grade Factors (Items rated by score points will be evaluated individually. However, for purposes of determining verification acceptance, not more than one deviation may be counted for all scored grade factors.)
5. Total Score
6. Percent Fish Flesh
7. Flavor and Odor
8. Container Integrity
9. Other product characteristics per approved specifications, standards, standards of identity, etc.

Once a product is selected for product verification, a complete examination is made for all factors which can be determined on the product. Some factors such as net weight, flesh content, pressed weight, and total score point will be verified by statistical means. The deviations noted between USDC verification and plant-generated results will be the primary basis for determining continued reliability of a processor's QA program. Consideration by the inspector and his/her supervisor will be given to the type of deviation, the severity, and the frequency of their occurrence when making decisions about the processor's continued reliability.

vi. Classifying Deviations:
The plant data and information needed for comparison with USDC examination results shall be obtained from product score sheets, certificates, laboratory test reports, and other documents pertinent to product evaluation. Deviations are classified into two categories: Minor and Major.

Minor Deviation: A minor deviation is a failure of a part of a quality assurance system, or a difference between USDC and plant quality assurance product evaluation results which, in itself, is not likely to reduce materially the effectiveness or reliability of the quality assurance system, or result in the uncertainty of a product's disposition.

Major Deviation: A major deviation is a failure of one or more parts of a quality assurance system, or a difference between USDC and plant quality assurance product evaluation results which will reduce materially the effectiveness or reliability of a quality assurance system, or results in the uncertainty of a product's disposition.

Following are some common deviations with their classifications:

Significant deviations are defined as: 1) USDC results statistically indicate that a product standard is not satisfied, or 2) USDC/Plant results are not in statistical agreement.

vii. Verification Acceptance Plan for Group 1 Deviations:

Minors

Number of Verifications	Acceptance Number
1 – 2	1
3 – 4	2
5 – 7	3
8 – 10	4
11 – 14	5
15 – 17	6
18 – 20	7
21 – 25	8
26 – 29	9
30 or more	10

Majors

Number of Verifications	Acceptance Number
1-7	1
8-16	2
17-28	3
29 or more	4

viii. Unreliable Status:

The plant's QA program under product verification(s) will be considered to be unreliable when one or more of the following occur:

1. No corrective action is initiated on program deviations.
2. Minor deviations exceed acceptance numbers during 3 out of any 5 consecutive product verification periods of evaluation.
3. Major deviations exceed acceptance numbers during 2 out of 5 consecutive product verification periods of evaluation.

Deviation	Minor	Major
Plant QA evaluation indicates product is one or more grade level(s) above USDC verification.		X
Plant QA evaluation indicates product is one or more grade level(s) below USDC verification.	X	

QA evaluation results for individual factor(s) or groups of factors which are not statistically reviewed deviate from USDC verification results by a substantial margin as adjudged by the USDC inspector	X	
Inaccurate, incomplete or missing records.		X
Verification(s) indicate QA evaluation or records inaccurate as to meeting requirements or specifications.		X
Verification(s) indicate statistical significant deviation from QA evaluation for measurable factors (averages only).	Attachment 7	
Verification(s) of quality assurance records show incorrect procedure(s).		X
Verification results indicate incorrect assessment of acceptability and/or disposition of lot(s).		X

Reporting Unreliability: Findings of unreliability will be reported by the Regional Inspection Office to the Headquarters Office and the National Seafood Inspection Laboratory so that a determination can be made as to an establishment's continued participation in the IQA program. If a determination of unreliability is made, certification will no longer be based on contractor QA results, and products will be certified only when a USDC inspector is present during processing. This may require USDC to increase inspection manpower during the unreliable period. The firm will be notified of this action in writing. To regain IQA Program approval, reliability must be re-established. This will be determined by a system audit and satisfactory review.

Appendix 3

a. Codex Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1) **(Click here)**
b. Approved Facilities Sanitation Inspection (coming soon)
    i. Processing Room
    ii. Vessels
    iii. Freezer/Cold Storage
    iv. Dry Storage
    v. Transportation
    vi. Exterior Surroundings
    vii. Hazardous Material Storage
    viii. Labeling
c. Instructions for Inspection of Fish Meal Establishments found in NOAA Handbook Part 6 Fishmeal and Fishery By-products.

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ATTACHMENT – Sample of Audit Report Template

Seafood Inspection Program
U.S. Department of Commerce
1315 East-West Highway
Silver Spring, Maryland 20910-3282
USA

Audit Report
(Template and Instructions)

Facility

(Place the full legal business name of the firm here.)

Site Visit Dates

(List the range of the actual dates of the site visit portion of the audit.)

Lead Auditor

(Place the name of the lead auditor, their title, phone number and e-mail as contact information.)

(In this box of the template, you may place a picture of the front of the business or a picture of the firm's logo. Do not include any photos with personnel, yourself, team members, or product in this area. If no appropriate photo exists, leave the box blank.)

Purpose

- To determine if the firm has implemented a program that will adequately address the applicable requirements for exporting products to the U.S. market and to identified buyers**.**
- To determine if the submitted HACCP plan meets U.S. Food and Drug Administration (FDA) requirements (CFR Title 21, Part 123) and if the system meets USDC Seafood Inspection requirements (e.g., the quality plan is being followed by the facility as written).

(These two statements are template language to provide an example in the case of overseas audits. Keep the purpose statements simple, broad, and factual.)

Scope

Full Systems Audit--All 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.

(This is template language and again should be left alone without a compelling reason.)

References

Applicable FDA regulations, including but not limited to:

- CFR Title 21, Part 123
- CFR Title 21, Part 110

Fish and Fisheries Product Hazards and Controls Guide

(List the main reference materials for this section.)

Introduction

The audit team, consisting of employees 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 and quality management plan at the [FACILITY NAME] facility in [STATE of COUNTRY]. The request was made and the audit performed on behalf of the U.S. importing firm that purchases product from the facility.
(Example language. However keep the introduction simple. It is not necessary here to add operations information on the facility.)

Methodology

Upon arrival at the firm, the opening meeting was performed by procedure and was attended by the audit team and [LIST ATTENDEES]. The firm's food safety and quality management plan was received at the start of the site visit and a desk audit was performed. The audit plan included evaluation of the firm's hazard analysis, critical control points (implementation, accuracy, efficacy), sanitation standard operating procedures, verification procedures, and record keeping. The audit included an evaluation of plant and food hygiene, final product, and analysis of the gas used in the treated product. Biotrace Pro-Tect protein swabs and Millipore HPC Total Count Swab Kits were employed to assist in determining cleanliness of selected equipment and utensils. Histamine analysis was performed on product during processing using the Biomedix IDR HistaQuant analysis. Where possible, observations were verified by interviews, records, photographs, or testing. Otherwise, observations were verified through both members of the team. After gaining all necessary objective evidence findings were developed and are listed below.

(This is template language and should be adapted to fit the audit. It is designed for a general description of the methods of obtaining evidence of the audit only. In addition only include those tests and evaluations actually performed.)

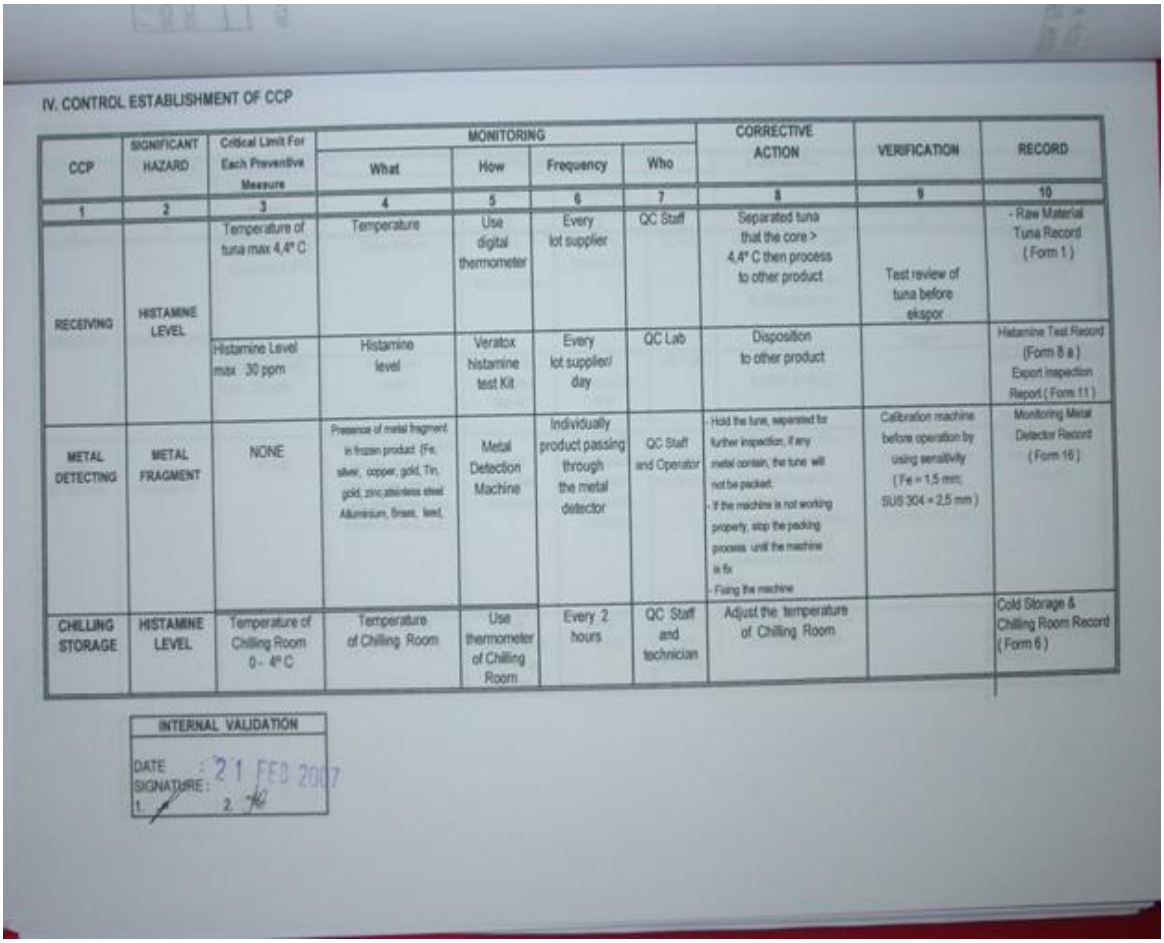
Findings
(listed in order of significance)

(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 paragraphs for the entire report to both sides and keep margins to a minimum of 1 inch.)

Finding 1: No written HACCP Plan when one is required.
Chapter 6 of the U.S. Food and Drug Administration's *Fish and Fisheries Products Hazards and Controls Guidance: Third Edition* states "Ciguatera toxin is carried to humans by contaminated fin fish for the extreme southeastern U.S., Hawaii, and subtropical and tropical areas worldwide." It further states "In Hawaii and throughout the central Pacific, barracuda, amberjack, and snapper are frequently ciguatoxic, and many other species both large and small are suspect." In reviewing the firms species produced it was found that Red Snapper is often produced and sent to the United States but no HACCP plan was in place for the product. Further investigation revealed that the country of Indonesia has not issued an alert for any ciguatoxic species. As the control for this hazard is to not accept fish from known toxic areas it was determined the hazard was still under control despite no written HACCP plan. However, now that the hazard is well known by the firm, a HACCP plan for this hazard and product must be developed. The USDC Seafood Inspection Program will provide templates and correction will be monitored for the next visit.**2.3.1 – SERIOUS**

Finding 2: Monitoring procedure stated in the HACCP plan is inadequate.
Chapter 7 of the U.S. Food and Drug Administration's *Fish and Fisheries Products Hazards and Controls Guidance: Third Edition* provides for two control mechanisms for histamine producing species. One control method relies upon records and data from the harvest vessel and does not require product evaluation or testing. The other method requires histamine analysis on each lot received per supplier. Further, only the primary processor is required to use one of these methods. Those who are secondary processors may assume the firm providing them product has met the USFDA requirements and are only required to ascertain the product was properly maintained during shipment and up to receipt.

When evaluating the firm's HACCP plan for the hazard of histamine, it was found they relied upon the method of histamine analysis to accept product. However, insufficient samples were being taken and improper compositing occurred. Further, the firm is still required to perform sensory analysis on selected product and no sensory analysis elements are found at the receiving critical control point. Records reviews indicate histamine analysis was performed and results indicated the hazard was under control. Therefore, only a tightening of the monitoring procedure is necessary. **2.3.8 – SERIOUS**



IV. CONTROL ESTABLISHMENT OF CCP

CCP	SIGNIFICANT HAZARD	Critical Limit For Each Preventive Measure	MONITORING				CORRECTIVE ACTION	VERIFICATION	RECORD
			What	How	Frequency	Who			
1	2	3	4	5	6	7	8	9	10
RECEIVING	HISTAMINE LEVEL	Temperature of tuna max 4,4° C	Temperature	Use digital thermometer	Every lot supplier	QC Staff	Separated tuna that the core > 4,4° C then process to other product	Test review of tuna before ekspor	- Raw Material Tuna Record (Form 1)
		Histamine Level max 30 ppm	Histamine level	Veratox histamine test Kit	Every lot supplier/ day	QC Lab	Disposition to other product		Histamine Test Record (Form 8 a) Export Inspection Report (Form 11)
METAL DETECTING	METAL FRAGMENT	NONE	Presence of metal fragment in frozen product (Fe, silver, copper, gold, Tin, gold, zinc,stainless steel Alluminium, Brass, lead,	Metal Detection Machine	Individually product passing through the metal detector	QC Staff and Operator	- Hold the tuna, separated for further inspection, if any metal contain, the tuna will not be packed. - If the machine is not working properly, stop the packing process until the machine is fix - Fixing the machine	Calibration machine before operation by using sensitivity (Fe = 1,5 mm; SUS 304 = 2,5 mm)	Monitoring Metal Detector Record (Form 16)
CHILLING STORAGE	HISTAMINE LEVEL	Temperature of Chilling Room 0 - 4° C	Temperature of Chilling Room	Use thermometer of Chilling Room	Every 2 hours	QC Staff and technician	Adjust the temperature of Chilling Room		Cold Storage & Chilling Room Record (Form 6)

INTERNAL VALIDATION

DATE : 21 FEB 2007

SIGNATURE : 1. 2.

HACCP plan illustrating the receiving critical control point.

Observations

(This section is for those observations (usually minor and major deficiencies) 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.)

3.9.1 – Harborage and attractant areas present. Dry storage had all materials pushed up against the wall. This not only prohibits effective sanitation control, but pests can find harborage in the tight areas. **MAJOR**

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Summary and Conclusions

(Again, this is template language and should not be changed.)

The USDC Seafood Inspection Program conducted an audit on [FACILITY] located in [CITY, PROVINCE, COUNTRY] from [DATES OF AUDIT]. This audit included an examination of the company's food safety and quality management plan for the receipt, processing, and packaging of [PRODUCTS] and the operation of the plan, including sanitation standard operating procedures, for compliance with the applicable sections of the U.S. Food and Drug Administration (USFDA) regulations addressing "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products (21 CFR Parts 123 and 1240). Based on this audit we have concluded that:

- The firm has implemented the seven principles of HACCP as delineated within the guidelines of National Advisory Committee for Microbiological Criteria for Foods, Codex Alimentarius, the European Union, and complies with the applicable requirements of the USFDA,
- The firm was in conformance to ISO 22000:2005-Requirements for Food Safety Management Systems, and
- The firm produced product that meets the specifications of [FIRM NAME] as identified on [DATE].

The USDC Seafood Inspection Program can only provide such attestations on an audit-by-audit basis, as an audit is a picture in time. It is believed that if the firm follows the HACCP plan as written, there is a reasonable expectation that the products described above and produced by this firm will be acceptable for import into the United States. 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.

Corrective Action Request

Corrective action is necessary to improve the process or to bring the system back into control. Even if the firm does not desire to proceed with another audit or continue with the Program, it is still highly recommended that the management provide a written corrective action plan to this agency for inclusion in the report. In this way, the firm's commitment to quality and its due diligence in correcting deficiencies could be documented. As no findings exist, no corrective action is necessary. *(This last sentence is added only if true.)*

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.

With respect to continued improvement, we have also enclosed the Systems Compliance Rating to this report, which contains information and photographs of observed sanitation deficiencies noted during the course of this audit.

Analytical Test Results

(Place results of tests in this section.)

Location	Protein Swabs	HPC Total Counts

Swabs were taken at locations where product would come into direct contact with product in various forms. The results above indicate that the conditions are generally acceptable.

Histamine Analysis

Sample	USDC	Facility

Chiller Temperatures

(Insert Chart Here)

A Cox Datasource/Marathon Temperature recorder was used to evaluate the cooling capabilities of chilled storage of the final product. No deficiencies were noted.
(Note: the spike in temperature at the end of the graph indicates when the device was removed from the cooler and the delay in downloading the data.)

Supplemental Report

(In this section you are to give a general idea of the controls evaluated and found. The narrative below is an example of the level of detail expected. Attempt to give statements of fact but you may also indicate other issues, positive and negative, found during your audit.)

Management Controls and Responsibilities
The element of management controls and responsibilities was evaluated through interview, documentation review, and records assessment. The firm takes reasonable care to place necessary procedures in writing for consistency. Management commitment to food safety and quality is implemented or communicated through posted memos and staff meetings. Food safety policy has been prepared and implementation was demonstrated. The food safety management system planning was not fully performed in that the hazard of ciguatoxin was not identified. Responsibility or authority for food safety is clearly defined and communicated, and a food safety team leader is in place which reports to top management. Effective external and internal communication is established, implemented, and maintained. Emergency response procedures have not yet been established. Management review is properly performed and documented through memos to staff and meeting notes. The necessary human resource competencies have been minimally identified. Personnel have received training necessary for the proper function of the food system and the training is documented. The infrastructure to implement and maintain the food safety system is sufficient. The work environment is properly established, managed, and maintained with regard to food safety. Continuous improvement activities are minimally performed.

Food Safety Management
The firm's food safety management plan was reviewed at the start of the site visit by the audit team. Evaluation of the hazards through a properly developed hazard analysis was complete for all products except those of ciguatoxic concern. Care was taken to review the controls and monitoring of the firm's histamine products relative to the USFDA requirements. The firm is controlling this hazard with a receiving strategy and laboratory analysis. All elements of the HACCP Plan were developed correctly and implemented properly and the firm's plan was signed and dated within the last year. Traceability is maintained sufficient to perform a mock recall. The firm maintains comprehensive records and reports that control the hazards for histamine and non-histamine products. The firm's record keeping system is fully acceptable with the quality assurance staff competent in their abilities and responsibilities.

Sanitation and Prerequisite Programs
Sanitation standard operating procedures (covering the eight areas of sanitation listed in 21CFR Part 123 and 21CFR Part 110) and acceptable prerequisite programs are in place and sanitation is properly monitored. The water used for processing in the facility is frequently tested and no deficiencies were noted in its use and that of the making of ice. The risk of cross contamination between the fresh and frozen processing areas is minimal, since all of the product is raw and frozen in the final state. Personnel are well maintained and practice good hygiene within the operational facility. Pest control measures are in place and no evidence of rodents was noted. Facility and food hygiene were both well maintained.

Quality Management
The element of quality management was evaluated through interview, documentation review, and records assessment. The firm takes reasonable care to place necessary procedures in writing for

consistency. Quality management procedures are well defined and implemented, with the quality assurance staff adequately performing control measures within their quality management. Management commitment to quality is implemented or communicated through posted memos and staff meetings. A quality policy has been prepared and implementation was demonstrated. Quality planning was fully performed and well implemented. Responsibility or authority for food quality is clearly defined and communicated, and a quality team leader is in place which reports to top management. Effective communication is established, implemented, and maintained. Management review is properly performed and documented through memos to staff and meeting notes. The quality manual is adequate for the current needs. Customer needs are considered and implemented where possible. The infrastructure to implement and maintain the food safety system is sufficient. Non-conforming product is properly controlled. Equipment calibration and laboratory testing is conducted by the firm's personnel with private firms and governmental agencies conducting periodic audits. Continuous improvement activities are minimally performed.

Food Security

Authorized personnel enter the facility through one guarded gated, that maintains security personnel. All visitors are escorted at all times while on the grounds of the facility. Product is segregated and secured to limit tampering, and all suppliers are approved prior to purchase. Chemicals are properly stored, controlled and supervised during use. Raw materials, packaging and labels are stored with-in the facility grounds, with access limited to authorized personnel. Product integrity is assured through delivery of finished product to end-user. However, a comprehensive food security plan was not written, an issue that is under correction.

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