PART 2 – Policies and Procedures for System Audits

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Chapter 1 - Purpose

These procedures describe how audits of quality systems for the USDC Seafood Inspection Program shall be scheduled, planned, conducted, and documented.

Chapter 2 - Scope

All audits of food safety and quality management systems of the USDC Seafood Inspection Program come under the scope of these procedures.

Chapter 3 – Definitions

1. Advisory finding: Advice which, in the opinion of the audit team, would improve the effectiveness of a quality system or minimize a potential hazard.
2. Auditee: The organization being audited.
3. Auditor: A person qualified to perform audits.
4. Audit Team: One or more persons conducting an audit, supported if needed by technical expert/subject matter expert (SME)
5. Corrective Action: An action taken to eliminate the causes of an existing deviation, defect, or other undesirable situation in order to prevent recurrence.
6. Critical Deficiency: A hazardous deviation from plan requirements such that maintenance of the safety, wholesomeness, and economic integrity is absent; and, if the situation is allowed to continue, will result in unsafe, unwholesome, or misbranded product.
7. Lead auditor: A person representing NOAA Fisheries SIP with audit management experience who is in charge of the audit team.
8. Major Deficiency: A significant deviation from plan requirements, such that maintenance of safety, wholesomeness, or economic integrity is inhibited.
9. 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.
10. Objective Evidence: Information which can be proved true based on facts obtained through observation, measurement, test, or other means.
11. Process: One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.
12. Quality: Totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs.
13. Quality Audit: A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.
14. Record: A document which furnishes objective evidence of activities performed or results achieved.
15. 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.
16. Specification: A document stating requirements.
17. Technical Expert/Subject Matter Expert (SME): person who provides specific knowledge or expertise regarding a product or process to the audit team

Chapter 4 - Introduction

Audits are normally designed for one or more of the following purposes:

a. to determine the conformity or non-conformity of the food safety and quality management system elements with specified requirements;
b. to determine the effectiveness of the implemented food safety and quality management system in meeting specified quality objectives;
c. to provide the auditee with an opportunity to improve the food safety and quality management system;
d. to meet regulatory requirements; and
e. to verify compliance and adherence to all Program requirements to permit the listing of the audited organization as an approved establishment.

These audits may be routine, or may be prompted by significant changes in the organization's system, process, product, or service quality, or by a need to follow up on corrective action.

Notes

- Audits shall not result in a transfer of the responsibility to achieve food safety or quality from an operating staff to the auditing organization.
- Audits shall not lead to an increase in the scope of food safety and quality functions over and above those necessary to meet food safety and quality objectives.

Chapter 5 – Audit Scheduling

Program management shall determine the frequency of the auditing of quality systems, reflecting the perceived risks involved. Details can be found in the requirements for the specified program.

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Chapter 6 – Audit Team

Whether an audit is carried out by a team or an individual, a lead auditor shall be placed in overall charge. Depending upon the circumstances, the audit team may include experts with specialized background, auditor trainees or observers who are acceptable to the program management and the lead auditor. Where a joint audit is conducted, agreement must be reached among the auditing organizations before the audit commences on the specific responsibilities of each organization, particularly with regard to the authority of the team leader appointed for the audit.

Chapter 7 – Auditor's Responsibilities

Auditors are responsible for:

1. determining compliance with the applicable audit requirements;
2. communicating and clarifying audit requirements;

3. remaining within the audit scope;
4. planning and carrying out assigned responsibilities effectively and efficiently;
5. documenting the observations;
6. exercising objectivity;
7. documenting, identifying, collecting and analyzing evidence that is relevant and sufficient to permit the drawing of conclusions regarding the audited quality system;
8. being receptive to any indications of evidence that can influence the audit results and possibly require more extensive auditing;
9. reporting the audit results;
10. evaluating, providing constructive feedback, and verifying the effectiveness of corrective actions taken as a result of the audit;
11. retaining and safeguarding documents pertaining to the audit, submitting such documents as required, and ensuring such documents remain confidential where applicable;
12. treating privileged information with discretion;
13. cooperating with and supporting the lead auditor; and
14. acting in a professional and ethical manner at all times.

Auditors should be able to answer such questions as: 1) are the procedures, documents and other information describing or supporting the required elements of the food safety and quality management system known, available, understood and used by the auditee's personnel, and 2) are all the documents and other information used to describe the system adequate to achieve the required objectives.

Chapter 8 – Lead Auditor's Responsibilities

The lead auditor is ultimately responsible for all phases of the audit. The lead auditor shall have management capabilities and experience and shall be given authority to make final decisions regarding the conduct of the audit and any audit observations.

The lead auditor's responsibilities include:

- is ultimately responsible for each phase of the audit
- is responsible for coordinating with NOAA Fisheries SIP management regarding the composition of the audit team and shall assign audit tasks according to the specific competence of individual audit team member(s)
- shall ensure compliance with auditing requirements and directives, and have the authority to make decisions regarding the direction of the audit.
- shall make contact with the auditee to discuss date(s) for the audit and provide the name(s) of personnel who will conduct the audit.
- shall plan the audit including defining the scope, objectives, and parameters of the audit. As part of the audit plan, the lead auditor shall review & follow up on previous audit report(s) and pending FDA actions, as well as coordinate travel logistics and other audit details.
- shall represent the audit team in communications with the auditee throughout the audit process including conducting the opening & closing meetings
- shall develop and maintain a collaborative working relationship among the audit team members and manage the schedule during the audit.
- shall report any critical nonconformities or major obstacles encountered in performing the audit to firm Management and NOAA Fisheries SIP Supervisor.

- shall organize any findings and/or observations after a caucus of the audit team members or a review by the individual auditor prior to the closing meeting.
- shall provide the firm with the Preliminary Audit Findings Report during the closing meeting.
- shall prepare and complete the report.

Chapter 9 – Independence of the Auditor

Auditors must be free from bias and influences which could affect objectivity. All persons and organizations involved with an audit shall respect and support the independence and integrity of the auditors.

Chapter 10 - Client

The client:

- determines the need for and the purpose of the audit and initiates the process;
- determines the auditing organization;
- determines the general scope of the audit, such as what quality system standard or document it is to be conducted against;
- receives the audit report;
- determines what follow-up action, if any, is to be taken, and informs the auditee of it.

In most cases, the client will be the USDC Seafood Inspection Program management.

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Chapter 11 - Auditee

The auditee's management shall:

- inform relevant employees about the objectives and scope of the audit;
- appoint responsible members of staff to accompany members of the audit team;
- provide all resources needed for the audit team in order to ensure an effective and efficient audit process;
- provide access to the facilities and evidential material as requested by the auditors; cooperate with the auditors to permit the audit objectives to be achieved; and
- determine and initiate corrective actions based on the audit report.

Chapter 12 – Audit Objectives, Scope and Criteria

Within the overall objectives of an audit program, an individual audit shall be based on documented objectives, scope, and criteria. The audit objectives define what is to be accomplished by the audit and may include the following:

- determination of the extent of conformity of the auditee's management system, or parts of it, with audit criteria;
- evaluation of the capability of the management system to ensure compliance with statutory, regulatory, and contractual agreements;
- evaluation of the effectiveness of the management system in meeting its specified objectives; and
- identification of areas for potential improvement of the management system.

The audit scope describes the extent and boundaries of the audit, such as physical locations, organizational units, activities, and processes to be audited, as well as the time period covered by the audit. The audit criteria are used as a reference against which conformity is determined and may include applicable policies, procedures, standards, laws and regulations, management system requirements, contractual requirements or industry/business sector codes of conduct. The audit objectives will be defined by the audit client or applicable program requirements. The audit scope and criteria shall be defined between the audit client and the audit team leader in accordance with audit program procedures. Any changes to the audit objectives, scope or criteria must be agreed to by the same parties. Where a joint audit is to be conducted, it is important that the audit team leader ensures that the audit objectives, scope, and criteria are appropriate to the nature of the combined audit.

Chapter 13 – Audit Feasibility

The feasibility of the audit should be determined, taking into consideration such factors as the availability of sufficient and appropriate information for planning the audit, adequate cooperation from the auditee, and adequate time and resources. Where the audit is not feasible, an alternative will be proposed to the audit client, in consultation with the auditee.

Chapter 14 – Audit Frequency

The need to perform an audit shall be determined by USDC Seafood Inspection Program management, taking into account specified or regulatory requirements, program audit instructions, and any other pertinent factors. Significant changes in management, organization, policy, techniques, or technologies that could affect the food safety and quality system, or changes to the system itself and the results of recent previous audits, are typical of the circumstances to be considered when deciding audit frequency.

Chapter 15 – Selecting the Audit Team

When the audit has been declared feasible, an audit team shall be selected, taking into account the competence needed to achieve the objectives of the audit. If there is only one auditor, the auditor will perform all applicable duties of an audit team leader. In deciding the size and composition of the audit team, consideration should be given to the following:

- audit objectives, scope, criteria, and estimated duration of the audit;
- whether the audit is a combined or joint audit;
- the overall competence of the audit team needed to achieve the objectives of the audit;
- statutory, regulatory, contractual, and accreditation/certification requirements, as applicable;

- the need to ensure the independence of the audit team from the activities to be audited and to avoid conflict of interest;
- the ability of the audit team members to interact effectively with the auditee and to work together; and
- the language of the audit, and an understanding of the auditee's particular social and cultural characteristics; these issues may be addressed either by the auditor's own skills or through the support of a technical expert.

The client makes the final decisions on which system elements, physical locations, and organizational activities are to be audited within a specified time frame. This should be done with the assistance of the lead auditor.

The scope and depth of the audit shall be designed to meet the client's specific information needs.

The standards or documents with which the auditee's quality system is required to comply shall be specified by the client or found in the detailed program's audit instructions.

Sufficient objective evidence shall be available to demonstrate the operation and effectiveness of the auditee's food safety and quality system.

The resources committed to the audit shall be sufficient to meet its intended scope and depth.

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Chapter 16 – Audit Plan

The audit plan should be designed to be flexible in order to permit changes in emphasis based on information gathered during the audit, and to permit effective use of resources. The plan should include:

- the audit objective(s) and scope;
- identification of the individual(s) having significant direct responsibilities regarding the objectives and scope;
- identification of reference documents (such as the applicable quality system standard and the auditee's quality manual);
- identification of audit team members;
- the language of the audit;
- the date and place where the audit is to be conducted;
- identification of the organizational units to be audited;
- the expected time and duration for each major audit activity;
- the schedule of meetings to be held with auditee management;
- confidentiality requirements; and
- audit report distribution and the expected date of issue.

If the auditee objects to any provisions in the audit plan, such objections should immediately be made known to the lead auditor. They should be resolved between the lead auditor and the auditee and, if necessary, applicable Program supervision or management before executing the audit.

Specific details of the audit plan may be withheld from the auditee if it is considered by the lead auditor that premature release may compromise the collection of objective evidence.

The audit plan shall be approved by the Program Manager or Supervisor assigning the audit and kept on file by the auditor for a period of one year.

Chapter 17 – Audit Team Assignments

Each auditor shall be assigned specific system elements or functional departments to audit. Such assignments shall be made by the lead auditor in consultation with the auditors concerned.

Chapter 18 – Working Documents

The documents required to facilitate the auditor's investigations, and to document and report results, must include:

- checklists used for evaluating quality system elements (normally prepared by the auditor assigned to audit that specific element);
- forms for reporting audit observations; and
- forms for documenting supporting evidence for conclusions reached by the auditors.

Working documents should be designed so that they do not restrict additional audit activities or investigations which may become necessary as a result of information gathered during the audit.

Working documents involving confidential or proprietary information shall be suitably safeguarded by the auditing organization. Working documents should also include: relevant departmental files; relevant legislation and regulations; and previous audit reports and findings, if any, on the auditee. It is suggested that checklists are prepared with spaces between questions to make room for answers and supplementary questions. Auditors should not give copies of the completed, expanded checklist to the auditee, as it may contain confidential information and must be suitably safeguarded.

Chapter 19 – System Documentation Review

The auditor shall review for adequacy the auditee’s recorded description of the methods for meeting the food safety and quality system requirements (such as the food safety and quality manual or equivalent).

Chapter 20 – Opening Meeting

The lead auditor must ensure that the following aims and objectives are achieved at the opening meeting:

- Introduce the audit team to the auditee;
- Discuss the audit agenda and itinerary;
- Record start and finish times of the meeting;
- Ensure that the names and titles of those present are accurately recorded on the attendance sheet;
- Explain to the auditee the methods and procedures to be used to conduct the audit;

- Confirm the status of the quality manual, plans or other documentation provided by the auditee;
- Establish the official communication links between the audit team and the auditee and arrange for necessary escorts for the audit team;
- Explain any administrative and billing arrangements;
- Arrange a private venue for the audit team caucus;
- Agree on a tentative time for the exit meeting and invite the auditee's senior management to attend; and
- Arrange a familiarization walk-through of the establishment if appropriate.

Chapter 21 – Collecting Objective Evidence

Evidence shall be collected through interviews, examination of documents, photographs, and observation of activities and conditions in the areas of concern. Observations suggesting deviations are to be noted when they seem significant or reflect a pattern of deviations, even though not covered by checklists, and should be investigated. Information gathered through interviews should be tested by acquiring the same information from other independent sources, such as physical observation, measurements, and records.

During the audit, the lead auditor may make changes to the auditors' work assignments, and to the audit plan with Program management's approval and the auditee's agreement, if this is necessary to ensure the optimal achievement of the audit objectives.

If the audit objectives appear to become unattainable, the lead auditor shall report the reasons to Program management and the auditee.

Auditors must record all observations and other relevant evidence at the time of discovery, although this information may be transferred to other recording means later.

Auditors must record the names of persons interviewed, reference numbers or dates of documents checked, and the serial numbers or other identification of cartons or containers of product checked.

Auditors must:

- Collect and analyze evidence that is relevant and sufficient to draw conclusions about the audited quality system;
- Remain alert for any indications of evidence that can impact on the audit results and possibly require more extensive auditing; and
- Be able to answer such questions as:

Are the procedures and the documents describing or supporting the required elements of the quality system known, available, understood, and used by the auditee?;
Are all the documents used to describe the quality system adequate to achieve the required quality objectives?

Reference Chapter 33 Appendix A Memorandum

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Chapter 22 – Caucus

At the completion of the audit, and as necessary throughout the audit, the audit team must meet privately to review their observations, and determine which are to be reported as findings. If there is disagreement, the lead auditor must decide.

Any findings deemed to be nonconformities must be supported by objective evidence such as a confirmed departure from approved procedures, documented quality system requirement, and/or other approved documented requirements. In all cases, the lead auditor must be satisfied a deviation exists.

Care should be taken by the auditors to document positive audit findings (e.g., where elements of the quality system are working well to achieve planned arrangements) for presentation to the auditee at the exit meeting, and inclusion in the audit report under the heading "General Observations".

Chapter 23 – Audit Observations

All audit observations shall be documented at the time of discovery, although this information may be transferred to more permanent (electronic) recording at a later time. If the auditor considers the issue to be critical, he or she must immediately consult the lead auditor. After all activities have been audited, the audit team should review all of their observations to determine which are to be reported as nonconformities. The audit team shall then ensure that these are documented in a clear, concise manner and are supported by evidence. Nonconformities shall be identified in terms of the specific requirements of the standard or other related documents against which the audit has been conducted. Observations shall be reviewed by the lead auditor with the responsible auditee manager. All observations of nonconformities should be acknowledged by the auditee management.

On identifying an apparent deviation, the auditor must document the evidence.

Chapter 24 – Record Review Procedures

It is vitally important that the audit team have flexibility in determining the compliance of the recordkeeping system. However, it is important for the success of the Program to provide consistent results between audits and auditors wherever possible. Therefore, prescribed procedures must be implemented to maintain as even an audit function as possible.

For the most part, the System Audit Checklist covers the assessment of various deficiencies relating to records. However, the area of the accuracy of the records does require more specifics. It is here where a review of the record keeping system provides the audit team with confidence that product leaving the firm is in compliance with all Program requirements. But evaluation criteria are necessary to successfully couple review records.

The sample size is twelve days of records, randomly chosen. Look at all records in the sample.

Significant deficiencies include:

- missing entries for measurements or readings;
- calculation errors that indicate safety or quality levels are compromised;
- values changed without justification or initials;
- values on record do not agree with auditor's evidence from other sources; and

- any deviation that would have a significant effect on the safety, wholesomeness, labeling, or quality of the final product.

Minor deviations include:

- dates, addresses, or missing signatures;
- missing calculations, such as averages, that in themselves do not affect the acceptance of the product; and
- any deviation that, although listed as required on the record, does not have a significant effect on the safety, wholesomeness, labeling, or quality of the final product.

Reject system if:
Two (2) significant deviations are found, or
Minor deviations are over 8 in number.

Consider a "Serious" deviation for "Records are inaccurate" if no other evidence exists. If it can be shown that the specific system failure did result in at least one lot of non-complying product (through end item examination or product outside the firm), and significant deviations were found, consider a "Critical" deviation for "Records are inaccurate." If there are less than twelve days of production, sample all days.

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Chapter 25 – End Product Evaluation

During the system audit, the auditor may elect to evaluate end product. If so, no more than three lots of product, based on the definition of lot listed in the firm's plan, are to be evaluated during the routine or surveillance audit. Initial audits may require more end-product evaluation.

The method of discovery sampling will be used, where the sample purpose is to locate one adverse factor or deviation. If any deviation is found, minor or significant, the auditor is to investigate the deviation found until it can be determined its significance and scope. (Note: This may require evaluation of additional product. However, care should be taken to investigate only the adverse factor to limit product destruction.) Once the root cause is found, the auditor will make an assessment of its significance or severity and assess it on the Systems Compliance Rating form as appropriate. If it is found that two of the lots do not meet compliance requirements, this would be considered a "Serious" under "Records are inaccurate." If all three lots show non-compliance, this would be considered a "Critical" under "Records are inaccurate."

If three lots are not available, including lots under production, and the lots show non-compliance, only consider the "Serious" deviation.

Chapter 26 – Closing Meeting with Auditee

At the end of the audit, prior to preparing the audit report, the audit team shall hold a meeting with the auditee's senior management and those responsible for the functions concerned. The main purpose of this meeting is to present audit observations to the senior management in such a manner so as to ensure that they clearly understand the results of the audit.

The lead auditor shall present findings, taking into account their significance. The lead auditor shall also present the audit team's conclusions regarding the system's effectiveness in ensuring that food safety and quality objectives will be met. The lead auditor must also advise the auditee of their Program status as a result of the audit.

A record of the closing meeting shall be kept. The Preliminary Audit Summary (Attachment 1) shall be provided to the auditee's senior management during the closing meeting. The lead auditor must ensure that the names and titles of those present are accurately recorded. In addition, a brief description of any deficiencies observed along with their severity shall be documented. The document is not intended to be in lieu of an audit report. The auditor should take care not to include statements that are likely to be contradicted in the report.

If requested, the auditor may also make recommendations to the auditee for improvements to the quality system. Recommendations are not binding on the auditee. It is up to the auditee to determine the extent, the way and means of actions to improve the quality system.

At the exit, or closing, meeting, after the findings have been explained to the auditee, the lead auditor must ensure that a representative of the auditee's senior management understands the findings, the responsibilities of the firm, and their appeal rights and procedures.

Attachment #1

Seafood Inspection Program
U.S. Department of Commerce
National Oceanic & Atmospheric Administration
1315 East West Highway
Silver Spring, MD 20910

Preliminary Audit Summary

Date of Audit:
Facility:
Lead Auditor/Team member:
Contact info:
Closing Meeting attendees:

Deficiencies: (severity, and brief description)

Lead Auditor:

_____
Consumer Safety Officer
USDC, Seafood Inspection Program

Note: This is a preliminary list of deficiencies noted during the audit and is not intended to be your final report. The official report will be forwarded to your firm with final findings and observations. The above-mentioned findings and observations are provided as an official summary of the audit and, in lieu of additional information, will be included in the final report.

Chapter 27 – Audit Report and Completion

The audit report is prepared under the direction of the lead auditor, who is responsible for its accuracy and completeness. Audit team members are to assist the lead auditor in the completion of the report. The audit is not complete until all corrective actions have been received, evaluated, and accepted, and the final report has been reviewed and filed.

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Chapter 28 – Report Content

The audit report should reflect both the tone and content of the audit. It shall be dated and signed by the lead auditor. It shall contain the following items:

- the scope and objectives of the audit;
- details of the audit plan, the identification of audit team members and auditee's representative, audit dates, and identification of the specific organization audited;
- identification of the reference documents against which the audit was conducted (quality system standard, auditee's quality manual, etc.);
- observations of nonconformities;
- audit team's judgment of the extent of the auditee's compliance with the applicable quality system standard and related documentation; and
- the system's ability to achieve defined quality objectives.

Any communications made between the time of the closing meeting and the issue of the report shall be by the lead auditor.

Chapter 29 – Report Distribution

Once the site visit is completed the lead auditor will leave a completed Systems Compliance Rating form with the auditee with a listing of observations. This can be done in hard copy or by e-mail. The draft audit report shall be sent to the assigning supervisor or manager by the lead auditor for review. Once reviewed and all corrections are made, the final report will be appropriately filed. It is the responsibility of the assigning supervisor or manager to provide the auditee's senior management with a copy of the final audit report. Any additional distribution should be determined in consultation with the auditee (e.g., copies to buyers). Audit reports containing confidential or proprietary information shall be suitably safeguarded.

The audit report should be issued as soon as possible. If it cannot be issued within an agreed upon time period, the reasons for the delay should be given to both the Program management and the auditee and a revised issue date established.

Chapter 30 – Report Retention

Audit documents shall be retained as per Program policy and regulation.

Chapter 31 – Audit Completion

The audit is completed upon submission of the audit report to Program management.

Chapter 32 – Corrective Action and Follow-up

The auditee is responsible for determining and initiating corrective action needed to correct a deviation. The auditor is only responsible for identifying the deviation.

If the finding has already been corrected by the time the exit meeting is held, the correction is to be noted in the report with the finding. If the auditee can demonstrate that the deviation or finding did not exist (as distinct from having been rectified during the audit), the lead auditor may remove the finding from the report or make note of the information in the report as part of the finding.

Corrective action and subsequent follow-up audits shall be completed within a time period agreed to by Program management and the auditee. More detail may be found in the audit instructions for the program in question.

The lead auditor must determine deadlines for rectification of the findings. The lead auditor must be prepared to negotiate these deadlines with the auditee, if necessary, at the exit meeting, prior to confirming a corrective action request. Rectification dates for nonconformities should reflect the severity of the deviation.

If a follow-up visit or audit is necessary, the scope must be only that necessary to determine corrective action of the specified finding unless it is performed jointly during the next scheduled audit. If the follow-up audit or visit indicates that the auditee has not satisfactorily rectified the finding, it is now a critical deficiency noted as “Corrective Action Not Taken.” Action to be taken by the Program in relation to suspension or revocation of contracts shall be in accordance with procedures.

The lead auditor shall keep the Program management informed of the status of corrective action activities and follow-up audits. After verification of corrective action implementation, the lead auditor must prepare a follow-up report and distribute it in a manner similar to the original audit report, or make an addendum to the original audit report.

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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.)

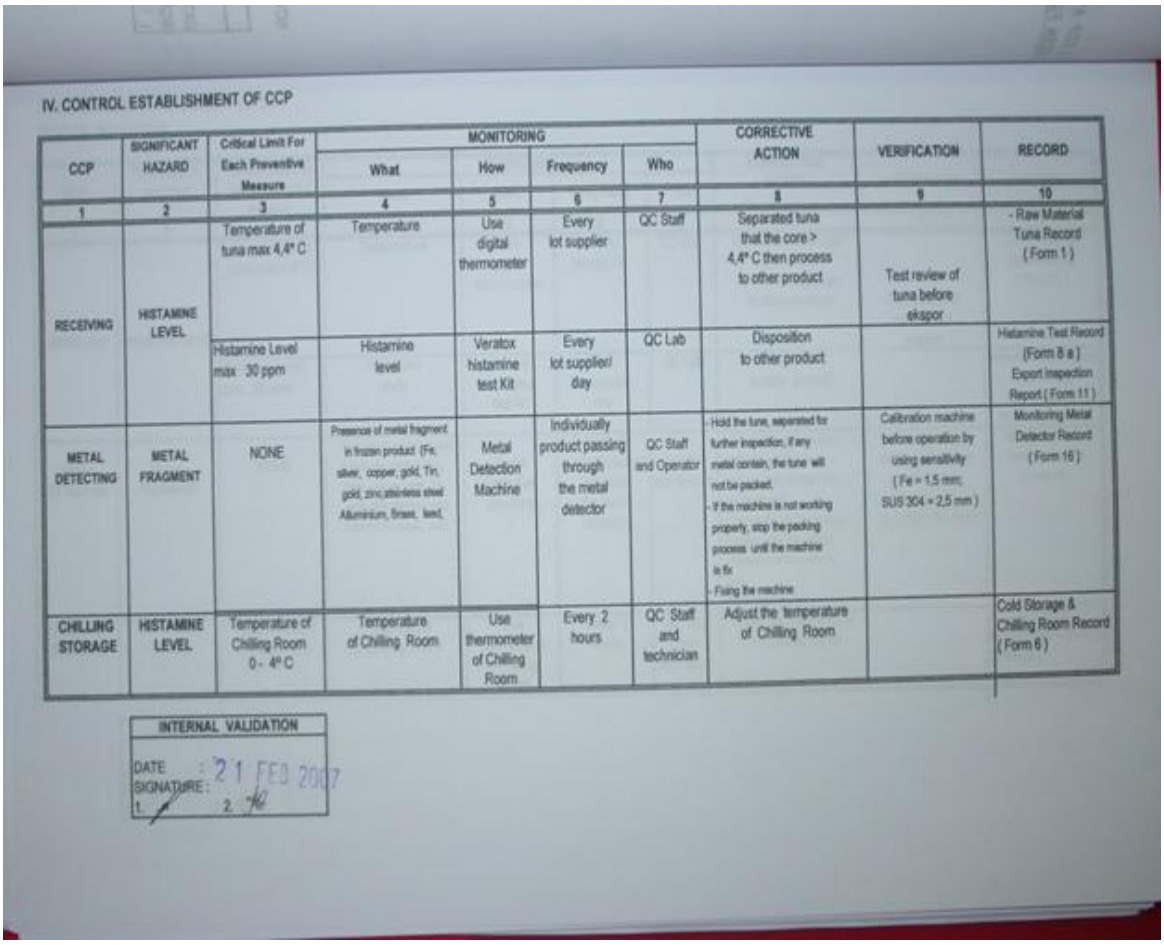
Findings
(listed in order of significance)

(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.)

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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**

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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Chapter 33 – Appendix

Appendix A: Memorandum: Documentation of Information Collected During Audits and Inspections

Seafood Inspection Program
U.S. Department of Commerce
National Oceanic & Atmospheric Administration
1315 East West Highway
Silver Spring, MD 20910

September 11, 2019

MEMORANDUM FOR: Seafood Inspection Program Staff and Program Participants

FROM: Steven Wilson
Director of Seafood Commerce and Certification

SUBJECT: Documentation of Information Collected During Audits and Inspections

This memo provides confirmation and clarification of the Seafood Inspection Program's (SIP) policy regarding the collection of records from users of SIP services and the use of photography and photocopying by SIP personnel during facility audits, sanitation reviews, and product inspection.

Under existing SIP policy, (NOAA Handbook 25) USDC Approved Establishments are required to allow SIP auditors to collect copies of records and take photos during facility audits, sanitation evaluation and product inspection. This policy extends as well to any necessary photographs or copies of records necessary to finalize product inspection and certification for U.S. Grade or Acceptance to Approved Specifications.

SIP program participants that process products under the USDC Seafood Inspection Program on a contract basis (Approved establishments) must receive approval of buildings, facilities, and the applicable processes prior to the inauguration of such service. Approved establishments and vessels are verified by on-site audits by SIP personnel 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 employee practices in the production of fishery products for human consumption. Approved establishments are included on a list published on the SIP's official website. Inclusion on this list is contingent upon the firm's continued ability to maintain USDC SIP requirements.

When SIP audits an Approved Establishment, the SIP personnel conducts document and record reviews, evaluates sanitation, observes processing operations, documents conditions via observation, interview and photographic evidence. This language for procedures has been in the program manual (NOAA Handbook 25) since 2001.

The collection of information, by copy or photograph, of firm records during an audit allows the SIP auditor to obtain evidence of both compliance and non-compliance observed during the process. The collection of evidence also allows for supporting evidence of the system design and implementation along with the ability to document conditions before and after corrective action is taken. SIP auditors will collect copies of records as necessary during all audits of USDC Approved Establishments. SIP auditors shall keep confidential all information obtained or created during the performance of the audit activities and shall not release or disclose that information except as required by law.