

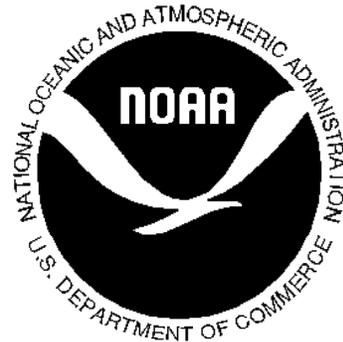
NOAA HACCP
Quality Management Program
(HACCP QMP)

Program Requirements
(Rev-January 1, 2000)



National Marine Fisheries Service

Seafood Inspection Program
1315 East-West Highway
Silver Spring, Maryland 20910



NOAA HACCP Quality Management Program

Authority

Authority for the Seafood Inspection Program to provide this HACCP Quality Management Program can be found in 50 CFR 260.103

Introduction

HACCP (Hazard Analysis Critical Control Point) is a non-traditional, non-continuous inspection technique recommended by the National Academy of Sciences as a more scientific, analytical, and economical approach than that provided by traditional inspection and quality control methods. HACCP, which focuses on problem prevention and problem solving, relies heavily on proper monitoring and record keeping by the industry. One of the primary economic benefits of HACCP is that it provides for reduced destructive sampling of the finished product as compared to the end-product sampling required under traditional inspection systems. The application of HACCP principles to seafood inspection has been adopted by several countries, including Canada, Iceland, and the European Union, and is becoming more broadly recognized by the international community as a mechanism to apply uniform inspection procedures.

HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, management must be strongly committed to the HACCP concept. A firm commitment to HACCP by top management provides company employees with a sense of the importance of producing safe food.

In July 1992, NOAA Fisheries (NOAA) published a Federal Register notice announcing the availability of a new seafood inspection program based on Hazard Analysis Critical Control Point (HACCP) principles. This program is in addition to the Integrated Quality

Assurance (IQA) Program that also uses HACCP principles. However, the IQA program, having unique methods for the inspection and grading of products, will continue as an option for applicants to the program.

The guidelines for the HACCP Quality Management Program have been compiled to inform interested parties that the NOAA is offering an alternative inspection program in addition to what is presently available. Participation in one program over the other is a decision, which must be made by the company's management. Under the Quality Management Program, the company takes on the responsibility of documenting and implementing a quality system. NOAA 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 document includes sections, which explain the specifications or requirements of the QMP program for documenting a quality system that will meet NOAA requirements. The document is also a guide manual for use by interested parties in developing their own quality manual. The HACCP Quality Management Program 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, the HACCP-based service is consistent with global activities to harmonize inspection protocols. In addition, NOAA believes that the service 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.

Scope

NOAA policy is to encourage and assist interested parties in the development and implementation of HACCP-based quality management systems to facilitate consistent distribution of safe, wholesome, and properly labeled fishery products of desired uniform quality. The development and implementation of HACCP-quality management systems is optional. However, their use should result in more efficient use of NOAA resources to inspect, grade, and certify fishery products. This document is designed to provide guidance for the development, implementation, and operation of HACCP-quality management systems, which will meet NOAA approval.

Definitions

1. **Auditee:** The organization being audited.
2. **Auditor:** A person qualified to perform audits.
3. **Contamination:** The occurrence of a contaminant in fish due to microbial pathogens, chemicals, foreign bodies, spoilage, objectionable taints, unwanted or diseased matter, which may compromise fish safety or suitability.
4. **Control measure (preventive measure):** Action performed to eliminate a hazard or reduce it to an acceptable level. For the purposes of this guide a control measure is also applied to a defect.
5. **Control Point:** Any step in a process whereby biological, chemical, or physical factors may be controlled.
6. **Corrective Actions:** An action taken to eliminate the causes 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; 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 Defect Action Point.
11. **Decomposition:** A persistent and distinct objectionable odor or flavor including texture breakdown caused by the deterioration of fish.
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. **Food Safety Hazard:** Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.
15. **HACCP Plan:** A document prepared in accordance with the principles of HACCP to ensure control of hazards which are significant for food safety and control of defects which are significant for essential quality, composition, and/or labeling provisions in the segment of the food chain under consideration.
16. **Hazard:** A chance for, or the risk of, a biological, chemical, physical, or economic property in a food product that could violate established program criteria or cause the consumer distress or illness.
17. **Hazard analysis:** The process of collecting and evaluating information on hazards and conditions leading to their presence to decide

- which are significant for food safety and therefore should be addressed in the HACCP plan.
18. **High risk products:** Seafood that may pose a significant danger to the health of the public when prepared for consumption by conventional or traditional means. For example, ready-to-eat; heat and/or brown and serve products; products which may contain a microbial pathogen, biotoxin, or physical or chemical contaminant which may pose an unacceptable health risk at the time of consumption.
 19. **Low risk products:** Seafood that poses no significant risk to the health of the public when prepared for consumption by conventional or traditional means.
 20. **Major Deficiency:** A significant deviation from plan requirements, such that maintenance of safety, wholesomeness, or economic integrity is inhibited.
 21. **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.
 22. **Monitoring Procedures:** Scheduled testing and/or observations recorded by the firm to report the findings at each CCP or DAP.
 23. **NUOCA (Notice of Unusual Occurrence and Corrective Action):** The record that outlines the incident and the corresponding corrective action implemented by the facility.
 24. **Objective Evidence:** Information, which can be proved true, based on facts, obtained through observation, measurement, test, or other means.
 25. **Prerequisite Program:** Procedures, including Good Manufacturing Practices that address operational conditions providing the foundation for the HACCP system.
 26. **Preventive Measure(s) (control measure):** 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.
 27. **Process:** One or more actions or operations to harvest, produce, store, handle, distribute, or sell a product or group of similar products.
 28. **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.
 29. **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.
 30. **Record:** A document that furnishes objective evidence of activities performed or results achieved.
 31. **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.
 32. **Severity:** The seriousness of the effect(s) of a hazard or defect.
 33. **Specification:** A document stating requirements. A detailed document describing the materials, dimensions, and workmanship requirements of a product.
 34. **Systems Audit:** On-site NOAA evaluation of the firm's effectiveness in following the plan after validation.
 35. **Validation:** That element of verification focused on collecting and evaluating scientific and technical information to determine if the Quality Management Plan, when properly implemented, will effectively control the hazards and defects.
 36. **Verification:** Those activities performed by the firm, other than monitoring, that determine the validity of the Quality Management Plan and that the system is operating according to the plan.

Applying to Enter the Program

Firms who wish to participate in the Program may apply orally or in writing to the appropriate Regional Inspection Branch. If application is made orally, it must be confirmed promptly in writing. The Regional Inspection Branch will provide the applicant with all necessary materials to inform them of the program and its requirements. This material will also include the requirements and any policies necessary for development and submission of a Quality Management Plan. The firm develops its Quality Management Plan and submits it for review according to the plan review procedures described further in this document.

NOTE: Firms who wish 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.

Education and Training

The success of a HACCP system depends on educating and training management and employees in the importance of their role in producing safe foods. This should also include information concerning the control of food borne hazards related to all stages of the food chain. It is important to recognize that employees must first understand what HACCP and quality management is and then learn the skills necessary to make it function properly. Specific training activities should include working instructions and procedures that outline the tasks of employees monitoring each CCP or DAP.

Management must provide adequate time for thorough education and training. Personnel must be given the materials and equipment necessary to perform these tasks. Effective training is an important prerequisite to successful implementation of a HACCP or quality plan. *Each facility must employ a NOAA-certified person knowledgeable in the program's principles to be present during all processing times. The certification must be kept on file and available to NOAA at all times.*

NOTE: Retail establishments of significant size do not require the certification of an individual at each store or facility location. However, they must have demonstrated sufficient control of the training of all pertinent individuals and have a sufficient number of management personnel trained and certified in their system to maintain proper control of the concepts and the HACCP plan.

Plan Review and Desk Audit

Each applicant must submit a QMP plan in accordance with this document. At the request of the firm, NOAA will provide consultation toward the development of the 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. All work of the assigned CSO and the Regional Inspection Branch is performed on a fee basis at established rates.

Label Review Procedures

All applicable labels must be approved prior to use in accordance with Part I, Chapter 3, Section 5 of NOAA Handbook 25, Inspection Manual.

System Assessment, Site Visit, and Plan Approval

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 approved QMP plan for at least five (5) consecutive production days. The firm will contact the Regional Inspection Branch as soon as they believe the approved plan is functioning successfully and when they have records covering the minimum 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 to 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 NOAA personnel upon request. Although not required, NOAA 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.

The audit performed on site will determine whether all of the hazards/defects and CCPs/DAPs have been identified, the quality management plan is being followed and monitored by the firm, and is effectively controlling the identified hazards/defects. The site visit will be conducted on a fee basis by a team of personnel assigned based upon the needs of the audit and the expertise available. The number and structure of the team will be determined by the size and complexity of the firm's process and nature of hazards associated with the products covered under the QMP Plan. The audit will include conducting document and record reviews, evaluating sanitation and in-process observations and product verification. All reviews will be performed using accepted auditing practices based on the current standards of ISO 10011. 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 will be verified by inspecting samples of finished product. NOAA inspection personnel may, for cause, sample and verify product in excess of this guideline. Firms will be evaluated using the QMP System Evaluation Criteria. If the firm is determined to be acceptable it will

qualify as a participant in the program and may finalize a contract for services with NOAA. If the audit at the firm is favorable, all products under review during the audit, including the previous five (5) production days, are eligible to bear the appropriate official marks or advertising claim.

Note for Vessels: Due to logistical factors, only one NOAA Consumer Safety Officer will perform the site visit. The NOAA Consumer Safety Officer will accompany the vessel, if determined necessary, for an appropriate time period during a fishing season, performing the background checks of critical control points and auditing the plan at one time. The officer may assist the quality assurance/management group on board the vessel in any alterations to make to their QMP Plan to work toward plan approval and a successful audit. Once the QMP plan is approved, 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.

QMP Plan Changes

After the QMP plan has been approved, modifications may be made under the following conditions. The firm must notify the servicing Regional Inspection Branch, in writing (Faxes are acceptable), of any modifications in their QMP plan 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 QMP Plan outlines the basic foundation and policies of the firm's quality 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 NOAA Program Quality System Standard found at the end of this document. Prior to signing the contract, it will be determined

what of the firm's document requires pre-approval.

Systems Audits

Only with a valid contract and continued demonstrated compliance with all applicable laws and 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 NOAA towards issuing official certification of the firm's products or facility compliance. After the firm's QMP Plan is approved, NOAA will conduct Systems Audits at a frequency listed below to determine the firm's continued adherence to their QMP Plan.

Table 1

Facility Rating	Systems Audit Target Frequencies			Deficiencies			
	Processors	Retail	Vessels	Minor	Major	Serious	Critical
Reduced	Once every calendar quarter	Once every six months	Once every fourth trip	0-6	0-5	1	0
Normal	Once every month	Once every calendar quarter	Once every other trip*	≥7	6-10	2-4	0
Tightened	Daily Until Corrected	Daily Until Corrected	Daily Until Corrected	NA	≥11	≥5	≥1
Requirements to be Audited at a Reduced Frequency	Three consecutive audits at Reduced Deficiency criteria	Three consecutive audits at Reduced Deficiency criteria	Two consecutive audits at Reduced Deficiency criteria				

* An audit of a trip will consist of ten percent of the total trip days. If for example the trip is 30 days, the audit will consist of three days during the trip.

Vessels

Firms must provide the appropriate NOAA Regional Inspection Branch with their tentative season schedules and off-loading schedules and sites as soon as they are known. Firms must give the servicing Regional Inspection Branch notice prior to each port arrival, providing sufficient time for auditors to verify and audit the vessel when required. Failure to do so could result in the removal of the vessel from the Program. Vessels will be visited once every other trip, with at least one visit per year.

A visit will be composed of a maximum of ten (10) percent of the scheduled fishing days for the trip in question. For example, if a trip is scheduled to last 30 days, the Systems Audit will be performed over approximately three days. Additional days may be necessary if the Consumer Safety Officer has encountered a problem during the audit. Audits may not require the auditor to be on board during fishing, but will require the auditor to be present during off-loading.

NOTE: Samples of finished product may

be pulled while the NOAA Consumer Safety Officer is on board or at dockside. If samples are pulled while on board, they will be evaluated immediately for compliance.

Processing Establishments

NOAA will conduct unannounced Systems Audits to determine the firm's continued adherence to their plan. Facilities will be visited at least once every month.

Retail and Food Service Establishments

NOAA will conduct unannounced Systems Audits at the frequencies outlined in Table 1 to determine the firm's continued adherence to their plan. Facilities will be visited at least once every three months.

NOTE: NOAA is interested in providing this program with a minimum possible burden to retail participants. Record keeping should not be so grand as to cause undue hardship on the retailer. Records should be of a precision only to show what products were received by what supplier on a particular day.

Procedures for Retail and Food Service Operations with Multiple Outlets and with an Established Quality Assurance Program
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 2

Stores to Sample Quarterly			
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 enter the Program at the Tightened level of sampling. After two successive audits at this level, the firm will move to the Normal level of sampling. After two successive audits at the Normal level, the firm will move to the Reduced level of 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. NOAA will then perform an audit on the Quality Assurance System of the firm for the next thirty days. This audit will include the sampling of additional stores. During this 30 day period, the stores may continue to use all advertisement claims.
3. If after this audit the Quality Assurance System is deemed to be under control, the firm will be sampled at the Tightened level and the system begins again as described above.
4. If the Quality Assurance System is deemed to not be performing as designed, Regional management and the Quality Team will evaluate the firm's entire program and suggest the necessary changes to continue in

the Program. This evaluation could include each store being audited and/or removed from the Program or may result in a permanent or temporary removal of the firm 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.

Tightened Frequency Audit Procedures

A firm at the tightened frequency has demonstrated difficulties in administering their QMP Plan and has rated the facility 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. Once the rating is confirmed, the Chief Quality Officer of the Seafood Inspection Program is to be informed and provided with all documentation, including but not limited to: Final Audit Report, scoresheets, supporting documentation, etc. Facilities who are rated unreliable have a period of thirty days

to remove the unreliable status. Failure to do so will result in the facility's removal from the NOAA HACCP Quality Management Program, or the EU HACCP Program. A firm who is deemed unreliable may continue to use the mark or other applicable advertising privileges if consent by NOAA is given for daily auditing of the firm. Consent will be on a case by case basis and granted only if NOAA believes the nature of the condition which caused the firm to become unreliable warrants daily auditing. Daily auditing will be acceptable to NOAA under the following conditions:

a. The firm must submit a corrective action plan to the NOAA Consumer Safety Officer detailing how they will correct the problem (Faxes are acceptable). 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 handling the situation
3. The methods to be used to correct the problem
4. A schedule which details the time frame to correct the problem
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 NOAA with all necessary information for its approval or disapproval.

- b. The NOAA Consumer Safety Officer will review the corrective actions identified by the firm and will approve or disapprove the corrective actions and notify his/her Supervisor. Daily auditing will continue until the issue is corrected for a maximum of thirty calendar days.
- c. Products may be certified during daily auditing. However, if any condition(s) exists that is considered critical, no product certification will occur until the condition is corrected to the satisfaction of NOAA.

d. At the inspector's discretion, product compliance will be verified by end-item inspection. No products covered by the QMP plan will leave the firm without NOAA approval.

e. Firms deemed unreliable twice in a twelve month period will be removed from the HACCP Quality Management Program or the EU HACCP Program.

f. Firms who have been removed from the HACCP Quality Management Program or the EU HACCP Program may submit a request for reapplication into the program after a period of three calendar months. Application will be accepted by NOAA only if evidence of a change in management philosophy can be provided.

g. Firms who have been removed from the NOAA HACCP Quality Management Program or EU HACCP Program may still be eligible to enter into the traditional Inspection Program.

Appeal Procedures

If a facility wishes to appeal this decision, they are to contact, in writing, the Chief Quality Officer in NOAA Seafood Inspection Program headquarters. The facility must provide, in writing, all pertinent information as to why it is believed the rating was determined in error and what the facility expects to be a proper correction. Once the Chief Quality Officer receives all information, he/she will investigate the matter and make a determination. The decision will be communicated to the Regional Inspection Branch and the facility as soon as it is made. A written report will follow.

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. Facilities who have received official stamping devices must have written procedures in place securing the device and protecting from its abuse.

Analytical Testing and Product Verification

The firm must perform periodic end-item verification of product compliance to program requirements. Both the firm and NOAA must agree upon the firm's frequencies of testing and end-item product requirements, however, product samples for analytical testing must be collected and analyzed at least once per year as part of the firm's verification procedures. The level of analytical sampling per lot must also be comparable to that found in the Hazards and Controls Guide of the Food and Drug Administration. Records of all analytical findings will be made available to NOAA inspectors during Systems Audits and at other times as necessary. As part of the product verification discussed below, NOAA will have product tested analytically throughout the year. Six lots will be tested based upon the information found in the FDA Hazards and Controls Guide. Three lots will be tested for any criteria that is

considered quality or economic integrity in nature, such as moisture content of scallops. Variation in the described sampling frequency may occur if evidence warrants. However, any changes to the frequency (and their effects) will be discussed with the applicable parties prior to their implementation.

To determine whether the product produced at the firm meets specification and/or U.S. grade standard requirements, NOAA 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 in their QMP plan and approved by NOAA.

QMP System Evaluation Criteria

1.0 General Requirements

1.1 21 CFR Part 123

1.1.1 Hazard analysis not performed.

Every processor shall conduct, or have conducted for it, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product processed by that processor and to identify the preventive measures that the processor can apply to control those hazards. Such food safety hazards can be introduced both within and outside the processing plant environment, including food safety hazards that can occur before, during, and after harvest. 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.

The hazard and defect analysis is the foundation of the quality 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 only be assessed. Otherwise, a Critical deficiency will be assessed.

Deficiency: Serious/Critical

1.1.2 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. Firms must provide this plan to the requesting Consumer Safety Officer.

Deficiency: Serious

1.1.3 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 in paragraph are identical for all fish and fishery products so grouped or for all production methods so grouped.

Deficiency: Major

1.1.4 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; and
9. Physical hazards

Deficiency: Serious

1.1.5 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

1.1.6 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.

Deficiency: Serious

1.1.7 Appropriate critical limit(s) is not listed in the plan.

The HACCP plan shall, at a minimum list the critical limits that must be met at each of the critical control points. If evidence is present that the critical limits were improperly identified but those identified were followed, the deficiency will be assessed here.

Deficiency: Serious

1.1.8 Monitoring procedure(s) in the plan is inadequate.

The HACCP plan shall, at a minimum, list the procedures, and frequency thereof, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

Deficiency: Serious

1.1.9 Corrective action listed in plan is not appropriate.

Whenever a deviation from a critical limit occurs, a processor shall take corrective action by

following a corrective action plan that is appropriate for the particular deviation.

Deficiency: Serious

1.1.10 Verification procedure(s) 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 HACCP plan. A reassessment of the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. 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 HACCP plan 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.

3. Records review. 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 a reasonable time after 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. (See Corrective Action sections listed below.)

5. Reassessment of the hazard analysis. 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 2.3.1)

6. Recordkeeping. The calibration of process-monitoring instruments, and the performing of any periodic end-product and in-process testing shall be documented in records that are subject to recordkeeping requirements listed below.

Deficiency: Serious

1.1.11 Sanitation standard operating procedures not present.

Each processor should 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 should specify how the processor would meet those sanitation conditions and practices that are to be monitored.

Deficiency: Serious

1.1.12 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 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.

Deficiency: Serious

1.2 Program Requirements

1.2.1 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: Critical

1.2.2 Quality Manual is inadequate.

Every 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.

Deficiency: Serious

1.2.3 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

2.0 Adherence to HACCP-based Plan

2.1 Procedures

The procedures outlined in a firm's QMP plan must be followed as written. The plan was approved by NOAA as a whole, not procedure-by-procedure. Not following a procedure could affect the entire critical control point.

2.1.1 Monitoring procedures not followed:

Monitoring procedures must be followed to maintain control of the process. If any monitoring procedure has not been followed and a corrective action report is not filed, the firm is not in compliance with this item.

Deficiency: Serious

2.1.2 Critical limits not followed.

Self Explanatory.

Deficiency: Critical

2.1.3 Corrective action not taken

Whenever a deviation from a critical limit, sanitation, verification, or quality plan occurs, a processor shall take corrective action. Processors may develop written corrective action plans, which become part of their QMP plans by which they predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. 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.

A firm is provided room for error in their plan through a system of corrective actions. If an error or problem arises in the conducting of the QMP plan, the firm must file a corrective action report (Notice of Unusual Occurrence and Corrective Action--NUOCA). 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 QMP 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 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.

Deficiency: Critical

2.1.4 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 and defect 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

2.1.5 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

2.1.6 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: Serious

2.2 Records

2.2.1 Inadequate information on records (Facility name and location, etc.)

Self Explanatory. Based on the required information stated in 21 CFR Part 123.

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. Processing and other information shall be entered on records at the time that it is observed.

Deficiency: Major

2.2.2 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)

2.2.3 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. This deficiency will also be used for the compliance of product leaving the firm.

Deficiency: Serious/Critical

2.2.4 Records are not available for inspection.

If the firm for any unreasonable amount of time does not surrender the applicable record 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

2.2.5 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

2.3 Other Requirements

2.3.1 Program trained personnel not available. Hazard analysis, reassessment or modification of HACCP plan, or records review performed by untrained personnel.

Each firm must employ a person who has been certified by NOAA for this program. At least one NOAA HACCP-certified person is required to be present during production. In addition, copies of all certified personnel's certificates must on file with the firm. Per 21 CFR part 123, these duties are assigned only to properly trained personnel. For the QMP Program, properly trained will be any person who has passed the NOAA Certification Exam. 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

2.3.2 Modification to QMP plan without approval.

Any change in procedures whether they are written or not will be considered non-compliance by the firm for this item. This includes all procedures at critical control points, sanitation procedures, recall procedures verification procedures, and consumer complaint procedures. Exceptions will be allowed for those procedures the firm can justify that were necessary to avert or control a public safety or health situation provided a corrective action report is on file for the incident and a request for plan modification is

filed with the servicing NOAA Regional Inspection Branch within a 24-hour period.

Deficiency: Serious

3.0 Facility Sanitation

References: 21 CFR Part 110; 21 CFR Part 123.11(b)

3.1 Safety of Process Water

Process water must be of very high 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 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.

3.1.1 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. 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.

Deficiency: Critical

3.1.2 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.

Deficiency: Serious

3.1.3 Inadequate supply of hot water.

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

3.1.4 Ice not manufactured, handled, or used in a sanitary manner.

A facility will be in compliance when potable water is used for manufacturing, when the manufacturing equipment is clean, and the ice only touches 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 not reused on ready-to-eat product. 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: Critical

3.2. Food Contact Surfaces

3.2.1 Equipment and utensils' design, construction, location, or materials cannot be readily cleaned and 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 easily taken apart for regular cleaning and inspection. 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.

Deficiency: Major

3.2.2 Equipment, primary packaging materials, and utensils not maintained in proper repair or removed when necessary. (Product-contact surfaces)

All product 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. 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 for products at a high risk stage of processing)

3.2.3 Product contact surfaces not cleaned or sanitized before use, after interruptions, or as necessary.

Product contact surfaces must be cleaned using proper techniques to remove dirt and debris. Sanitizers must be used before product contacts the surface. Sanitizing without cleaning is insufficient. Any violation will be considered non-compliance.

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

3.2.4 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, use clean cloths, 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

3.2.5 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 using the company-provided hand dip stations.

2. Remove all insecure jewelry, and when food is being manipulated by hand, remove from hands any jewelry that cannot be adequately sanitized.
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.

Deficiency: Serious/Critical

3.3. Prevention of Cross Contamination

3.3.1 Grounds condition can permit contamination to enter the facility.

There shall be no conditions on the grounds such as dusty roads or parking lots, mud puddles, 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. 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.

Deficiency: Minor

3.3.2 Facility

3.3.2.1 Design, layout of materials used cannot be readily cleaned and sanitized; does not preclude product adulteration or contamination.

If the rooms (including restrooms and employee breakrooms) 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 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

3.3.2.2 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. 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 surfaces if exposed. In addition, the layout of the facility should not be such that product contamination is likely due to heavy employee traffic through work areas.

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.

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

3.3.3 Condition of roof, ceilings, walls, floors, or lighting not maintained; lights not protected.

3.3.3.1 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, 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: Critical

3.3.3.2 Other.

For areas in the facility other than in 3.3.3.1 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: Minor (Major for products at a high risk stage of production)

3.3.4 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)

3.3.5 Finished product not properly covered or protected.

Finished product must be either packaged, covered or protected so as to not permit contamination or adulteration prior to shipment.

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

3.3.6 Equipment and utensils not maintained in proper repair or removed when necessary. (Non-product 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 3.2.1 above is insufficient and may allow indirect product contamination or adulteration.

Deficiency: Minor (Major for products at a high risk stage of production)

3.3.7 Non-product contact surfaces not cleaned before use.

Non-product contact areas must also be cleaned prior to use. However, sanitizing is not required. This includes wall, ceilings, floors, and other room areas as well as equipment.

Deficiency: Major

3.4. Handwashing, Hand Sanitizing, and Toilet Facilities

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

Hand washing and hand sanitizing stations must be present and located conveniently and in sufficient numbers to provide employees ease of their use.

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

3.4.2 Improper disposal of 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 sewerage system.

Deficiency: Critical

3.4.3 Inadequate supplies.

The restrooms must provide supplies such as toilet paper, soap, etc., sufficient enough to meet employees' needs.

Deficiency: Major

3.4.4 Insufficient number of functional toilets.

The facility must have one operable, 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.

Deficiency: Minor

3.5. Protection From Adulteration

3.5.1 Condensation.

3.5.1.1 Areas directly affecting product or primary packaging material.

If any condensation, overhead leaks, or water splash is found in areas in the facility where the condensation has the potential to come in contact with product or primary packaging material, the facility is in non-compliance.

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

3.5.1.2 Other

Any areas other than those noted above where food is stored, handled, processed, packaged, or displayed shall be condensation-free. If condensation is noted in these areas, the facility shall be in non-compliance.

Deficiency: Major

3.5.2 Adequate air exchange does not exist.

A facility is in compliance when adequate air exchange exists to preclude the development of foul odors.

Deficiency: Minor (Only for products at a high risk stage of production)

3.6. Proper Labeling, Use, and Storage of Toxic Compounds

Plant chemicals are cleaners, sanitizers, rodenticides, insecticides, 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 or USDA approval.

3.6.1 Chemical(s) improperly used or handled.

Deficiency: Critical

3.6.2 Chemical(s) improperly stored.

Deficiency: Serious

3.6.3 Chemical(s) improperly labeled.

Deficiency: Major

3.7. Control of Employee Health Conditions

3.7.1 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. 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.

3.8.1 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 properly constructed.

Deficiency: Major

3.8.2 Pest control measures not effective.

3.8.2.1 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 width of the 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

3.8.2.2 Extermination

Birds--Nesting areas must be eliminated.

Insects--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.

Rodents--There should not be evidence of rodent activity. Evidence of rodents includes, but is not limited to: fecal droppings present; urine stains on bags or walls; slide marks along rodent runways; or feeding areas around stored dry goods bags that may be excessive. The facility should have appropriate rodent control measures in place. If not, the facility is not in compliance.

Deficiency: Serious

3.8.3 Inadequate 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

3.8.4 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

NOAA Seafood Inspection Program Quality System Standard

1.0 MANAGEMENT RESPONSIBILITY

1.1 Quality Policy

Management with executive responsibility in the firm must endorse a policy statement that fully reflects company policy and objectives relating to quality (including the control of the safety, wholesomeness and integrity of the product), and its commitment to quality assurance. The policy must consider the expectations and needs of the customer. There must be a procedure to ensure the quality policy is known, understood, implemented, and maintained at all levels of the company.

1.2 Organization

The company shall establish and maintain an adequate organizational structure to ensure that the applicable fish and fishery products are designed and produced in accordance with the requirements of this standard.

1.2.1 Responsibility and Authority

The manufacturer shall establish and document the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and verify work affecting quality, and provide the independence and authority necessary to perform tasks including but not limited to:

- a) Initiate action to prevent the occurrence of any nonconformities relating to the product, process, and quality system;
- b) Identify and record any problems relating to the product, process, and quality system;
- c) Initiate, recommend, or provide solutions through designated channels;
- d) Verify the implementation of solutions;
- e) Control further processing or delivery of nonconforming product until the deficiency or deficiencies have been corrected.

1.2.2 Resources

Each manufacturer shall provide adequate resources, including the assignment of trained

personnel, for management, performance of work, and verification activities, including internal quality audits, to meet the requirements of this standard.

1.2.3 Management Representative

Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority and responsibility for:

- a) Ensuring that quality system requirements are effectively established, implemented, and effectively maintained in accordance with this standard; and
- b) Reporting on the performance of the quality system to management with executive responsibility for review and as a basis for improvement of the quality system.
- c) liaison with external parties on matters relating to the quality system.

1.3 Management Review

Management with executive responsibility shall review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of this standard and the manufacturer's established quality policy and objectives. The dates and results of quality system reviews shall be documented.

2.0 QUALITY SYSTEM

2.1 General

The manufacturer shall establish, document, and maintain a quality system that ensures all applicable fish and fishery products conform to specified product standards and requirements and this standard. The manufacturer shall prepare a quality manual covering the requirements of this standard. The quality manual shall make reference to the quality system procedures and outline the structure of the documentation used in the quality system.

2.2 Quality System Procedures

The manufacturer shall:

- a) prepare documented procedures consistent with the requirements of this standard and the manufacturer's stated quality policy, and
- b) effectively implement the quality system and its documented procedures.

The range and detail of the procedures will depend on the complexity of the work, the methods used, and the skills and training needed by the personnel involved in carrying out the referenced activity. Documented procedures may make reference to work instructions that define how an activity is performed.

2.3 Quality Planning

The manufacturer shall establish how the requirements for quality will be met. Quality planning shall be consistent with all other requirements of the quality system and shall be documented in a format to suit the method of operation. The manufacturer shall give consideration to the following activities, as appropriate, in meeting the specified standards and requirements for fish and fishery products:

- a) the quality and safety objectives to be attained;
- b) the specific allocation of responsibilities and authority during the development, implementation, and maintenance of the system;
- c) the specific procedures, methods and work instructions to be applied;
- d) the specific tasks required for application of a HACCP system;
- e) suitable testing, inspection, examination and audit programs at appropriate stages;
- f) a method for making changes and modifications in a HACCP or quality plan as they are developed and implemented;
- g) other measures to meet necessary objectives such as methods for meeting requirements of Good Manufacturing Practices (GMPs).

3.0 CONTRACT REVIEW

3.1 General

The manufacturer shall establish and maintain documented procedures for contract review and for the coordination of these activities.

3.2 Review

Before submission or the acceptance of a contract or order (statement of requirement), the contract or order shall be reviewed by the manufacturer to ensure that:

- a) the requirements are adequately defined and documented; where no written statement of requirement is available for an order received by verbal means, the manufacturer shall ensure that the order requirements are agreed before their acceptance;
- b) any differences of understanding of the contract or accepted order requirements are resolved;
- c) the manufacturer has the capability to meet the contract or accepted order requirements.

3.3 Amendment to Contract

The manufacturer shall identify how an amendment to a contract is made and correctly transferred to the functions concerned within the organization.

3.4 Records

Records of contract reviews shall be maintained.

4.0 DESIGN CONTROL

4.1 General

The manufacturer shall establish and maintain documented procedures for translating the customer's specifications and requirements into technical specifications for raw materials, processing, packaging, storage, etc., and their verification. The specifications must also cover buildings, equipment and facilities (internal and external) where relevant. Responsibility for developing these specifications must be assigned to specific people and there must be a planned approach to each activity.

4.2 Design and Development Planning

The manufacturer shall establish and maintain plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall be reviewed, updated, and approved as design and development evolves. These activities shall be assigned to qualified personnel equipped with adequate resources. The plans shall be updated as necessary.

4.3 Organizational and Technical Interfaces

The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process.

4.4 Design Input

The manufacturer shall establish and maintain procedures to ensure that the design requirements relating to the applicable fish and fishery product are appropriate and address the intended use by the purchaser or consumer. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be documented and shall be reviewed and approved by a designated individual(s). The approval, including the date and signature of the individual(s) approving the requirements, shall be documented.

4.5 Design Output

The manufacturer shall establish and maintain procedures for defining and documenting design output in terms that can be verified. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the safety, wholesomeness, economic integrity, and quality of the fish or fishery product are identified. Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

4.6 Design Review

The manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the product's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. Records of such reviews shall be maintained.

4.7 Design Verification

The manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the verification shall be recorded.

4.8 Design Validation

Design validation shall be performed to ensure that product conforms to defined user needs, requirements, and intended use. Design validation shall include risk analysis where appropriate. Validation is normally performed on the final product, but may be performed in earlier stages prior to product completion. Multiple validations may be necessary if there are different intended end uses.

4.9 Design Changes

All design changes and modifications shall be identified, documented, reviewed, and approved by authorized personnel before their implementation.

5.0 DOCUMENT AND DATA CONTROL

5.1 General

The manufacturer shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this standard including, to the extent applicable, documents of external origin such as standards and customer specifications. Documents and data can be in the form of any type of media, such as hard copy or electronic media.

5.2 Document and Data Approval and Issue

The documents and data shall be reviewed and approved for adequacy by authorized personnel prior to issue. A master list or equivalent document-control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

- a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;
- b) invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;
- c) any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

5.3 Document and Data Changes

Changes to documents and data shall be reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their review and approval. Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

6.0 PURCHASING

6.1 General

The manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.

6.2 Evaluation of Suppliers, Contractors, and Consultants

The manufacturer shall establish and maintain the requirements (including safety, wholesomeness, economic integrity, 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.

6.3 Purchasing Data

The manufacturer shall establish and maintain data that clearly describe or reference the specified requirements, including quality requirements, for purchased or otherwise received product and services. Purchasing documents shall include, where possible, 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 quality of a finished product. The manufacturer shall review and approve purchasing documents for adequacy of the specified requirements prior to release.

6.3 Verification of Purchased Product

6.3.1 Supplier Verification at Subcontractor's Premises

Where the manufacturer proposes to verify purchased product at the subcontractor's

premises, the manufacturer shall specify verification arrangements and the method of product release in the purchasing documents.

6.3.2 Customer Verification of Subcontracted Product

Where specified in the contract, the manufacturer's customer or the customer's representative shall be afforded the right to verify at the subcontractor's premises, and the manufacturer's premises that subcontracted product conforms to specified requirements. Such verification shall not be used by the manufacturer as evidence of effective control of quality by the subcontractor.

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.

7.0 CONTROL OF CUSTOMER-SUPPLIED PRODUCT

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.

8.0 PRODUCT IDENTIFICATION AND TRACEABILITY

8.1 Identification

The manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation.

8.2 Traceability

The manufacturer shall establish and maintain documented procedures for unique identification of individual product, batches, or lots. This identification shall be recorded.

9.0 PROCESS CONTROL

The manufacturer shall identify and plan the production of processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

- a) documented procedures defining the manner of production where the absence of such procedures could adversely affect quality;
- b) use of suitable equipment, and a suitable working environment;
- c) compliance with reference standards/codes, quality plans, and/or documented procedures;
- d) monitoring and control of suitable process parameters and product characteristics;
- e) the approval of processes and equipment, as appropriate;
- f) criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples, or illustrations);
- g) suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, the processes shall be carried out by qualified operators and/or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel, shall be specified.

Records shall be maintained for qualified processes, equipment, and personnel, as appropriate.

10.0 INSPECTION AND TESTING

10.1 General

The manufacturer shall establish and maintain documented procedures for inspection and testing activities in order to verify that the

specified requirements for the product are met. The required inspection and testing, and the records to be established, shall be detailed in the quality plan or documented procedures.

10.2 Receiving Inspection and Testing

10.2.1 The manufacturer shall ensure that incoming product is not used or processed (except in the circumstances described in 4.10.2.3) until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the quality plan and/or documented procedures.

10.2.2 In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided.

10.2.3 Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.

10.3 In-process Inspection and Testing

The manufacturer shall:

- a) inspect and test the product as required by the quality plan and/or documented procedures;
- b) hold product until the required inspection and tests have been completed or necessary reports have been received and verified, except when product is released under positive-recall procedures (see 10.2.3). Release under positive-recall procedures shall not preclude the activities outlined in 10.3a.

10.4 Final inspection and testing

The manufacturer shall carry out all final inspection and testing in accordance with the quality plan and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

The quality plan and/or documented procedures for final inspection and testing shall require that all specified inspection and tests, including those specified either on receipt of product or in-process, have been carried out and that the results meet specified requirements.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

10.5 Inspection and Test Records

The manufacturer shall establish and maintain records which provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply (see 4.13).

Records shall identify the inspection authority responsible for the release of product (see 4.16).

11.0 CONTROL OF INSPECTION, MEASURING, AND TEST EQUIPMENT

The manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. The manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained. The procedures shall include provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained. These activities shall be documented.

Calibration procedures shall include specific directions and limits for accuracy and precision. When accuracy and precision limits are not met, there shall be provisions for remedial action to reestablish the limits and to evaluate whether

there was any adverse effect on the device's quality. These activities shall be documented.

Calibration standards used for inspection, measuring, and test equipment shall be traceable to national or international standards. If national or international standards are not practical or available, the manufacturer shall use an independent reproducible standard. If no applicable standard exists, the manufacturer shall establish and maintain an in-house standard.

The equipment identification, calibration dates, the individual performing each calibration, and the next calibration date shall be documented. These records shall be displayed on or near each piece of equipment or shall be readily available to the personnel using such equipment and to the individuals responsible for calibrating the equipment.

12.0 INSPECTION AND TEST STATUS

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed. The identification of inspection and test status shall be maintained, as defined in the quality plan and/or documented procedures, throughout production, installation, and servicing of the product to ensure that only product that has passed the required inspections and tests [or released under an authorized concession (see 13.2)] is dispatched, used, or installed.

13.0 CONTROL OF NONCONFORMING PRODUCT

13.1 General

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.

13.2 Review and Disposition of Nonconforming Product

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.

14.0 CORRECTIVE AND PREVENTIVE ACTION

14.1 General

The manufacturer shall establish and maintain documented procedures for implementing corrective and preventive action.

Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.

The manufacturer shall implement and record any changes to the documented procedures resulting from corrective and preventive action.

14.2 Corrective Action

The procedures for corrective action shall include:

- a) the effective handling of customer complaints and reports of product nonconformities;

- b) investigation of the cause of nonconformities relating to product, process, and quality System, and recording the results of the investigation (see 16);
- c) determination of the corrective action needed to eliminate the cause of nonconformities;
- d) application of controls to ensure that corrective action is taken and that it is effective.

14.3 Preventive Action

The procedures for preventive action shall include:

- a) the use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities;
- b) determination of the steps needed to deal with any problems requiring preventive action;
- c) initiation of preventive action and application of controls to ensure that it is effective;
- d) confirmation that relevant information on actions taken is submitted for management review (see 1.3).

15.0 HANDLING, STORAGE, PACKAGING, PRESERVATION, AND DELIVERY

15.1 General

The manufacturer shall establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.

15.2 Handling

The manufacturer shall provide methods of handling product that prevent damage or deterioration.

15.3 Storage

The manufacturer shall use designated storage areas or stock rooms to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated.

In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.

15.4 Packaging

The manufacturer shall control packing, packaging, and marking processes (including materials used) to the extent necessary to ensure conformance to specified requirements.

15.5 Preservation

The manufacturer shall apply appropriate methods for preservation and segregation of product when the product is under the supplier's control.

15.6 Delivery

The manufacturer shall arrange for the protection of the quality of product after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

16.0 CONTROL OF QUALITY RECORDS

The manufacturer shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of quality records.

Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Pertinent quality records from the subcontractor shall be an element of these data.

All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of quality records shall be established and recorded. Where agreed contractually, quality records shall be made available for evaluation by the customer or the customer's representative for an agreed period.

Records may be in the form of any type of media, such as hard copy or electronic media.

17.0 INTERNAL QUALITY AUDITS

The manufacturer shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Internal quality audits shall be scheduled on the basis of the status and importance of the activity to be audited and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.

The results of the audits shall be recorded (see 16) and brought to the attention of the personnel having responsibility in the area audited. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken (see 16).

18.0 TRAINING

The manufacturer shall establish and maintain documented procedures for identifying training needs and provide for the training of all personnel performing activities affecting quality. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required. Appropriate records of training shall be maintained (see 16).

19.0 SERVICING

Where servicing is a specified requirement, the manufacturer shall establish and maintain documented procedures for performing, verifying, and reporting that the servicing meets the specified requirements.

20.0 STATISTICAL TECHNIQUES

20.1 Identification of Need

The manufacturer shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.

20.2 Procedures

The manufacturer shall establish and maintain documented procedures to implement and control the application of the statistical techniques identified in 20.1.