

# **NSF International**

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## **Supplier Assurance Audit**

### **Food Safety, Quality and Food Defense Expectations and Criteria For**

### **- Food Warehouse and Distribution Facilities -**

**December 17<sup>th</sup>, 2014**

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Version #: 5.1	Version Date: December 17, 2014
Document Title: <b>NSF International Supplier Assurance Food Safety, Quality and Food Defense Expectations and Criteria for Food Warehouse &amp; Distribution Facilities</b>	
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## BACKGROUND

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NSF International SUPPLIER ASSURANCE audits focus on the development, implementation and control of systems that impact Food Safety, Food Quality and Food Defense.

The audit evaluates the adequacy of documentation, compliance to documented procedures, effectiveness of procedures to control the process within defined limits and the ability to implement corrective and preventive action plans.

Specifically, this audit evaluates:

- Compliance to Regulatory Standards.
  - The Expectations Manual regards regulatory standards as minimum requirements.
- Adherence to client specifications.
- Adherence to client policies and procedures.
- The ability to successfully trace product movement and execute a product recall.

This manual provides criteria and expectations that the facility will be audited against and is generic for all types of food storage establishments. The criteria and expectations documented in this manual **Must** be rigorously applied when there is direct food contact by handling or processing in any way. In all cases, Section B HACCP applies.

Some specific criteria may not be applicable. It is the responsibility of the manufacturer to justify that a specific criterion is not applicable. Likewise, additional criteria may be applied based on changing regulatory requirements, specific client needs or the ever-changing food safety and food defense environment. Food defense is the terminology used to describe the actions that need to be implemented to prevent the intentional tampering with product to cause harm to the consuming public.

Food storage facilities located outside the U.S. **Must** meet customer expectations and U.S. (FDA, USDA) regulatory requirements.

The following criteria and expectations are based on:

- Customer specifications and requirements
- Food, Drug and Cosmetic Act (21 CFR) and appropriate amendments
- Food Code, 2005 edition (FDA/USPHS) and appropriate supplements
- Federal Meat Inspection Act (9 CFR) and amendments
- Poultry Products Inspection Act (9 CFR) and amendments
- Egg and Egg Products Inspection Act (EPIA) and amendments

Links to these documents and other reference sources are available at our web site: [www.nsf.org](http://www.nsf.org)

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### DEFINITIONS

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## SCORING GUIDELINES

### Scoring.

A non-scored version of the audit report is available. The non-scored format focuses the outcome on identification of items needing improvement and corrective action. The scoring system for a scored audit is detailed below.

### Explanation of Section Scorings

Section scorings in the below table are provided as a reference and are calculated on the following formula:

<b>Non-Conformance</b>	Deduction of 5% per finding
<b>Major Non-Conformance</b>	Deduction of 25% per finding
<b>Critical</b>	0%

<b>Summary By Section</b>				
	<u>Non-Conformance</u>	<u>Major Non-Conformance</u>	<u>Critical</u>	<u>Section Score (%)</u>
Section A - ADMINISTRATION & REGULATORY COMPLIANCE	0	0	0	100
Section B – HACCP MANAGEMENT	0	0	0	100
Section C - FACILITIES & EQUIPMENT	0	0	0	100
Section D - SANITATION, HOUSEKEEPING & HYGIENE	0	0	0	100
Section E - RODENT & PEST CONTROL MANAGEMENT	0	0	0	100
Section F - APPROVED SUPPLIERS, RECEIVING & INVENTORY CONTROL	0	0	0	100
Section G - PROCESS & PRODUCT EVALUATION	0	0	0	100
Section H – PACKAGING & LABELING	0	0	0	100
Section I – STORAGE & SHIPPING	0	0	0	100
Section J - TRAINING REQUIREMENTS	0	0	0	100
Section K – FOOD DEFENSE	0	0	0	100

### Explanation of Overall Audit Result

The overall score result is based on the total number and level of non-conformances. The overall audit is allocated 100% and deductions made as follows:

<b>Non-Conformance</b>	= 1% deduction per finding off the total score
<b>Major Non-conformance</b>	= 10% deduction per finding off the total score
<b>Critical Non-conformance</b>	= 25% deduction per finding off the total score

FINAL AUDIT RATING	BASED ON SCORE
<b>Meets Expectations</b>	100-95%
<b>Needs Improvement</b>	94-85%
<b>Significant Improvement Needed</b>	84-76%
<b>Fail</b>	≤ 75%

While a score is provided for this report, NSF strongly recommends moving away from a scoring system and put the emphasis on identification and correction of non-conformances, so as to drive continuous improvements in food safety. NSF also offers an un-scored version of the Supplier Assurance Audit.

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## Scoring Examples

### **Example 1**

Section A contains 2 “nonconformance” ratings and Section B contains 1 “major nonconformance” rating, giving Section Scores for Section A = 90% and Section B = 75%. If there are no further non-conformances then the overall audit score is 88% (-2% for the 2 nonconformances and -10% for the major nonconformance) and the overall audit rating is "Needs Improvement"

### **Example 2**

The audit identifies one Major non- conformance in Section C (75% Section Score) and one Major non-conformance in Section D (75% Section Score) and 2 Non-conformances in Section K (90% Section Score). If there are no further non-conformances then the overall audit score is 78% (-2% for the 2 nonconformances and -20% for the 2 major nonconformances) and the overall audit rating is "Significant Improvement Needed"

**Corrective Action and improvement.** Improvements and Corrective actions for any finding noted in this audit must be implemented and documented. The findings noted in the audit should be evaluated and reviewed regardless of the numerical score. Corrective action is defined as the correction of the immediate problem as well as prevention of re-occurrence of the problem.

### **Examples of Critical deficiencies are defined as:**

- Direct observation of product contamination and/or adulteration.
- Significant deviation from identified CCP in the HACCP plan.
- Mislabeled or misbranded product.
- Record falsification.
- Facility is not operating in compliance with applicable regulatory requirements.

### **Repeat Deficiencies**

Repeat assessments of less than "Acceptable", where the facility has not taken corrective action to effectively address previously cited deficiencies in the most recent NSF International Supplier Assurance audit, will be noted by the auditor in the report. Repeat Non-conformance ratings may cause a downgrade of the current audit rating depending on the nature of the deficiency.

Within the Expectation Manual, the following terms have these meanings:

**Must** – An absolute requirement of this expectation document.

**Should** – A strong suggestion for a component of a Food Safety/Quality System.

Annually - a 12 month period.

### **Alternative Procedures**

At times it may be acceptable to have an alternative procedure or practice to those defined in the criteria. If this occurs, the alternative procedure **Must** accomplish the same degree of control as indicated in the criteria. The sub-section **Should** be considered applicable and rated based on the level of compliance to the intention of the criteria and the alternative procedure **Must** be noted in the comments.

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## DEFICIENCY CLASSIFICATION AND GUIDELINES

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Within the Expectation Manual, the following terms have these meanings:

**Shall or Must** – An absolute requirement of this expectation document.

**Should** – A strong suggestion for a component of a Food Safety/Quality System.

**Annually** - a 12 month period.

The audit report will not contain recommendations or suggestions for enhancement for improvement. The audit is intended as an objective assessment of the food safety management programs in a food facility.

### **Audit Question/Statement Answers Options:**

**"Acceptable"** ratings are awarded when the element being audited meets or exceeds the applicable expectation.

**"Non-conformance"** is the assessment made when:

- The element being audited does not fully meet expectations of an element.
- Improvements are required to meet the expectation.

**"Major Non-conformance"**. An assessment of Major non-conformance may be made when:

- Deficiencies of an element present a high probability of food safety or regulatory failure.
- Significant improvement is needed to meet the expectations.
- HACCP requirements have not been fully documented or implemented
- An element of the standard has not been documented (if required) or implemented
- A situation is observed where, based on objective evidence, there is significant doubt as to the conformity of product being supplied.
- There are numerous findings of Non-conformance that indicate a lack or failure in a required section and a potential risk to product safety, quality or regulatory non-compliance exists.

**"Critical Non-conformance"**. An assessment of Critical Non-conformance may be made when:

- There is objective evidence or direct observation that product is unsafe, could potentially cause serious illness, death or is a risk to health and is subject to a Class I or Class II recall.
- The product or process does not meet regulatory requirements.

Note: Any Critical Non-conformance will result in a failure of the audit.

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## EXPECTATIONS AND CRITERIA FOR FOOD WAREHOUSE AND DISTRIBUTION FACILITIES

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The following requirements outline the management programs and performance criteria expected of a modern food warehouse or distribution facility to meet the food safety, food quality and food defense requirements of the public, regulatory agencies and customers. The marketing and delivery of safe, wholesome and high quality foods requires a dedicated effort of knowledgeable food handling professionals from product receipt through handling, storage, and distribution. While food safety programs are the hallmark of modern food storage facilities, high quality is an essential ingredient to assure success with the consumer. Reliable food storage systems with a disciplined and knowledgeable work force that fully understand both food safety and consistent quality are necessary to compete in today's market.

The following criteria are considered essential to meeting these goals on a consistent basis. Of course, the intensity of food safety, food quality, and food defense is being increased as leading companies work to improve their level of performance to provide reliably safe and high quality products. Demonstrating consistent conformance with these criteria is the expectation of our clients.

If a client agrees with a facility's deviation from an expectation or specification, the facility **Must** obtain written approval for the variance/deviation prior to the audit process. This approval **Must** be available to the auditor during the audit process. Variances are in effect for one calendar year from the date of issuance or as specified by the client.

The auditor will evaluate documented policies and procedures, past and present monitoring records and facility conditions as they exist at the time of the observation. Ratings and scoring will be based on these observations. Corrective actions taken during the audit will not eliminate the observation nor change the scoring but will be documented in the audit report. Existing documentation provided to the auditor after the conclusion of the exit meeting will not change scoring.

Some warehouses and distribution centers may come under USDA-FSIS or FDA inspection because they conduct food handling, repacking or transportation services. The additional criteria that apply to those types of facilities and all facilities that directly handle or process food products may be specifically identified within sub-sections. Sub-sections may be divided into requirements 1) specific to all food storage facilities and 2) specific to food storage facility food contact areas. These will be noted under the headings, "All Storage Facility Requirements" and " Food Contact Handling/Processing Area Requirements", respectively.

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## A. ADMINISTRATION & REGULATORY COMPLIANCE

### 1) Organization and Responsibilities

There **Must** be a facility management organization chart indicating the reporting structure of the facility operating departments. Consideration **Should** be given to responsible parties for food safety, food quality, and food defense. The structure **Must** clearly show the reporting relationship of the Quality Manager both internally and to a corporate or head office, if applicable. The document **Must** be current, dated and signed by the appropriate responsible executive.

- a) The Quality Manager **Must** be responsible to the local facility manager or to a designated corporate official to assure that food safety and quality decisions can be made independently. Consideration will be given for smaller plants where individuals have numerous organizational responsibilities.
- b) There **Must** be a clear documentation of the responsibilities and authorities of the Quality department signed by management.
- c) The control and release of withheld and retained product **Must** also be clearly designated as the responsibility of the Quality department.

### 2) Policies and Procedures Manual

- a) The facility **Must** have documented policies and procedures relevant to the receiving, handling, storage, shipping, control and evaluation of food products to assure that they meet appropriate food safety, food quality and food defense requirements. The documentation **Should** clearly define expectations through detailed product and process specifications, testing procedures, sampling programs and accept/reject criteria.
- b) These policies and procedures **Must** be well organized, available, current, dated and signed by management.
- c) Policies and procedures **Must** be reviewed for effectiveness annually. Specific policies and procedures will be addressed in detail in later sections.

### 3) Management Awareness and Commitment

Management commitment and active support is the foundation of an effective Food Safety and Quality Management System. Support can be demonstrated by providing adequate financial and staffing resources for food safety, product quality, and training programs. It can also be reflected by the general condition of the facilities, equipment and employee support facilities.

- a) Management participation in the audit process and an awareness of corrective action programs to outside audits, regulatory inspections and internal audits is expected.
- b) A senior member of management **Must** at least be in attendance during the opening and closing meetings during the audit.

### 4) Product Identification, Traceability and Recall Plans and Procedures

The facility **Must** have comprehensive written procedure for product identification, traceability and a recall plan specifically for that plant location.

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- a) Product identification codes and lot definition **Must** be documented. Identification systems **Must** include:
- i. Incoming food items and food contact packaging materials.
  - ii. Rework or returned food items and food contact packaging materials.
  - iii. Shippable food items and food contact packaging materials.
- b) There **Must** be evidence of traceability for all food items and food contact packaging materials as well as rework, carryover, work in process, and food contact packaging materials used in making finished shippable food items, as applicable. Shipping records **Must** also be available for all food items and food contact packaging materials shipped from the facility. Each facility **Must** have procedures specific to that location to effectively trace lots from the time of receipt to the first level of distribution. Traceability procedures **Must** include:
- i. Documentation of rework or carryover usage **Must** provide traceability into specific finished product lots. Finished product documentation **Must** be capable of tracing backwards rework or carryover usage.
  - ii. Lot numbers of shipped food items and food contact packaging materials **Must** be accurately shown on shipping documents and indicate quantities on “split” pallets, if applicable.
  - iii. Incoming food items and food contact packaging materials **Must** have traceable lot codes upon receipt. These lot codes **Must** follow the item throughout storage and usage.
  - iv. An incoming material tracking program **Must** be in place to trace food items and food contact packaging materials from receipt through use into finished product.
- c) Traceability Exercises (Mock Recalls) **Must** be conducted on shipped product at least twice annually (about every 6 months) to the first level of distribution. In the absence of a recall plan, or if no trace exercises are conducted at all, the rating and score for this item **Must** be no higher than a “Major Nonconformance”.
- i. A management assessment of each traceability exercise, after the exercise is completed, **Must** be conducted and documented to include a material balance sheet of total quantity of identified product received and/or produced vs. product shipped, product on hand and product otherwise documented (damaged, lost, samples, etc.), product unaccounted for, a calculated percent recovery, start and end times for the exercise, and any corrective actions identified.
  - ii. An effective traceability exercise is one where a shipped product exercise (4.c.i) or an exercise where identified lots of incoming food items or food contact packaging materials are traced to lots of shipped product and to the first level of distribution achieving 99.5% - 105% recovery, taking into account normal waste and shrinkage, within four hours. Failure to meet these requirements necessitates a repeat traceability exercise until the criteria are met.
- d) The Recall Plan procedures **Must** be clear and concise and the plan **Must** be reassessed for effectiveness and signed annually.
- i. The recall plan **Must** include at a minimum the following:

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1. Recall Team.
    - Names of members.
    - Responsibilities of team members.
    - A Recall coordinator **Must** be clearly identified.
    - 24/7 contact information **Must** be included.
  2. Contact numbers for appropriate regulatory contacts **Must** be included.
  3. Contact numbers for clients and customers **Must** be available.
  4. A public relations spokesperson **Must** be clearly identified.
  5. Designation of appropriate records and documents that **Must** be available for recall actions.
- ii. Recall procedures **Must** include a plan to conduct a traceability exercise at least twice annually.
  - iii. The plan **Must** include an investigation that is conducted while the recall is underway, to determine the root cause of the problem, initiate corrective actions, and to ensure there are no other lots of product affected.

## 5) Regulatory Compliance

It is essential that food storage facilities operate in total compliance to regulatory requirements and that a positive working relationship be evident with the assigned regulators. Regulatory requirements typically establish a minimum baseline for food safety performance. The NSF International SUPPLIER ASSURANCE Expectations Manual holds the facility accountable to identified Best Industry Practices in addition to minimum regulatory requirements. An evaluation of the facility's performance in complying with appropriate regulatory agency requirements (i.e. USDA, FDA, CFIA, USDC, State or Local) involves an assessment of documents, "letters" of action, inspection reports and documented responses and corrective actions to issues reported by any regulatory agency. Each written inspection or notice from a regulatory agency **Must** have a documented response and corrective action.

An evaluation **Must** be made of the number and nature of Noncompliance Report's (NRs) issued for USDA facilities. An evaluation **Must** be made of recent (within one year) FDA 483 Forms or similar documents. They **Should** be evaluated for the nature of deficiencies, repeat deficiencies and effectiveness of corrective actions. "Corrective Actions" **Should** be clearly distinct from responses to fix the immediate problem. They **Should** address long term plans to prevent a recurrence of the issue.

**Note:** Refusal by facility to show any requested regulatory report, including USDA NR's, FDA Form 483, CFIA notifications, HACCP reviews, State Inspections and the like, is a "Major Nonconformance" since regulatory compliance cannot be verified.

- a) The facility **Must** maintain a file of all regulatory actions, visits, reports or other notifications received from any regulatory agency.
- b) If a USDA facility, NR's **Must** indicate a prompt response with an immediate corrective action to address the existing situation and **Must** also include a specific preventive action plan to prevent a recurrence of the problem. There **Should** not be a pattern of repeat NR's for the same or similar issue.

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- c) A log of samples submitted for pathogen, antibiotic or environmental testing **Must** be maintained with records of results available for review.
- d) Written responses **Must** be documented for any audit or inspection by customers, third party auditors or internal company audits. Failure to provide such audit reports is a "Major Nonconformance" since effective corrective action responses cannot be verified.

## 6) Document & Record Management

A policy **Must** be available that specifies document control, procedures for preparing operational documents, identification of areas for control, collecting data, indexing completed forms, controlling distribution of documents, document filing and file storage. The policy **Must** identify a specific time limit for holding files and the proper disposition of outdated documents and records. Locations for the storage of documents and records **Must** be designated. Documents and records maintained "off site" **Must** be retrievable within a reasonable time.

If documents are managed electronically, this criteria applies to electronic and intranet documentation. Applicable authority for change and change dates **Must** be a part of the documentation process. Electronic signatures are desirable, however not necessary if the system clearly identifies the individual with the authority to approve changes.

- a) A document control policy **Must** be available that identifies the current revision status of all documents to avoid use of invalid or obsolete documents.
- b) Obsolete documents **Must** be clearly identified and retained for historical purposes.
- c) Records relevant to the control of the operation or evaluation of food safety, food quality and food defense **Must** be:
  - i. Complete with no missing data or blank blocks without an explanation for lack of data.
  - ii. Initialed by operator and signed by supervisor to verify accuracy.
  - iii. Recorded on a timely basis with accurate date and time.
  - iv. Recorded in ink, not pencil (Error single-lined through and initialed).
  - v. Marked to record or chart out-of-control or out-of-specification conditions. Records **Must** indicate disposition of product and corrective actions taken. Records **Must** be indexed and easily retrievable.
  - vi. Evidence of intentional record falsification is a "Critical Nonconformance" for this subsection.
- Changes to documents and specifications **Should** be assessed by and approved by the designated individuals. Where practicable, the nature of the change **Should** be indicated on the document or appropriate attachments.

## 7) Change Management

The facility **Must** have a documented policy to manage change. The policy **Must** describe how to effectively communicate changes in personnel and changes in specifications, policies and procedures.

- a) There **Must** be a documented procedure to assure that new management and supervisory personnel are aware of all facility policies and procedures impacting food safety, food quality, and food defense.

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- b) There **Must** be a written procedure for ensuring that all changes to policies, procedures, product formulations, processing equipment, HACCP plan monitoring forms or product specifications are adequately communicated to the appropriate management and operational personnel.

## 8) Documentation to Track Effectiveness of Policies

- a) There **Must** be documented management reviews or monitoring programs (Internal Audits) to assess the level of conformance to operational policies.
- b) Management reviews of internal audits **Must** be conducted at least annually.

## 9) Crisis and Natural Disaster Management

A crisis management team **Must** be assembled. The team **Must** include a sufficient number of members representing the necessary departments to handle and resolve any critical situations that may occur, i.e. natural disasters, catastrophic events and other emergency situations (power outage, tampering, etc.).

- a) The team **Must** have responsibility for managing all aspects of a crisis situation, including contacting of regulatory officials, law enforcement, or media, as necessary.
- b) A current list of responsible team members that are available 24 hours a day and 7 days a week, as well as regulatory contacts, corporate contacts, client contacts, outside support (trade associations) contacts, supplier contacts and other key contacts for use by the Crisis Team **Must** be maintained. The list **Must** contain both office and after hours telephone numbers.
- c) Team members **Must** receive specific training in the crisis management procedures and responses.
- d) The crisis team **Must** meet at least annually to evaluate the status of the program. All meetings and actions **Must** be documented.
- e) Detailed plans for handling critical situations **Must** assure that food items and food contact packaging materials are protected and, in case of prolonged interruptions, that there are plans for alternate product supply to the customer.

Policy **Must** designate Quality Management as responsible for determining the status of food items and food contact packaging materials involved in a critical event situation. Quality Management **Must** make sure that all food items and food contact packaging materials are suitable for use prior to shipping.

## 10) Customer/Consumer Complaint Management

- a) The facility **Must** have a written program for handling customer or consumer complaints. The policy **Must** address responsibilities, response time and corrective actions based on an investigation of the complaint.

**Note:** if customer/consumer complaints are handled by a corporate entity, the plant **Must** have a copy of the corporate customer/consumer complaint policy/procedure. In addition, the plant **Must** have a procedure for how it receives complaint inquiries from corporate, investigates, and determines and implements corrective actions.

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- b) A complaint log **Must** track complaints by product identification, production dates, cause and origin of complaint.

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## B. HACCP MANAGEMENT (The HACCP / Food Safety System)

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Codex Alimentarius Commission (CODEX) provide internationally recognized resources for understanding the principles of Hazard Analysis and Critical Control Point (HACCP).

The HACCP system is science based and provides a systematic approach to identify specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess potential hazards and establish control systems that focus on prevention rather than relying on finished product testing.

A HACCP system **Must** be developed by each food establishment and tailored to its individual products, process and distribution conditions. The HACCP plan **Must** analyze and identify control measures for the potential biological, chemical and physical hazards from procurement, receipt, and storage of food items and food contact packaging materials through the handling, storage and distribution of those items. It is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan.

Approval of the HACCP plan **Must** be documented with a written signature by top management. The plan **Must** be kept current with regular performance reviews by the HACCP management team. Experts who are knowledgeable in the food process **Must** either participate in or verify the completeness of the hazard analysis and the HACCP plan.

Food warehouses and distribution centers that receive, handle, store, and distribute seafood products are required by FDA 21 CFR Part 123 to develop and implement a HACCP plan.

### 123.3 Definitions.

(d) *Fish* means fresh or saltwater finfish, crustaceans, other forms of aquatic animal life (including, but not limited to, alligator, frog, aquatic turtle, jellyfish, sea cucumber, and sea urchin and the roe of such animals) other than birds or mammals, and all mollusks, where such animal life is intended for human consumption.

k)(1) *Processing* means, with respect to fish or fishery products: Handling, storing, preparing, heading, eviscerating, shucking, freezing, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, or holding.

(l) *Processor* means any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country.

### 123.6 Hazard Analysis and Hazard Analysis Critical Control Point (HACCP) plan.

(a) *Hazard analysis*. 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.

**Note:** If the product is amenable to a mandatory HACCP plan requirement, the plan **Must** be in compliance with the regulatory requirements. If a mandatory HACCP plan is not required, the facility **Must** still comply with prerequisite programs (found in subsequent sections of this document) and all HACCP requirements through the determination and documentation of whether any hazards and CCPs exist. If it is determined that CCPs do exist, a complete HACCP program is required whether mandated or not.

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In all cases, a formal assessment and sign-off of the program by the HACCP team, including top management, is required at least annually. The assessment is to document performance and/or to determine if any changes are needed in the plan. If at any time a process, food item or food contact packaging material change is made, the team **Must** immediately and formally evaluate the change to determine if the HACCP plan is impacted, making all necessary changes to the plan documents.

## 1) Preliminary HACCP Tasks

There are five preliminary tasks that **Must** be accomplished before the application of the HACCP principles.

- a) A HACCP team **Must** be assembled with individuals having the appropriate product specific knowledge and expertise necessary for the development of an effective HACCP plan. Where such expertise is not available on site, expert advice **Should** be obtained from other sources.
  - i. Team members and their responsibilities **Must** be clearly identified as part of the HACCP plan. The entire team **Must** be involved in the development, final approval, and subsequent reviews of the plan.
  - ii. Documented team meetings **Must** occur at least annually to assess HACCP records and issues. The team **Must** assess all deviations, documentation errors, corrective actions, and assure that corrective actions are monitored for effectiveness.
- b) The intended use of the product **Must** be determined and **Should** be based on the expected uses of the product by the end user or consumer.
- c) The HACCP Team **Must** construct a clear and easy to understand process flow diagram for each HACCP plan.
  - i. The process flow diagram **Must** outline each step involved in the process that is directly under the control of the establishment. The diagram **Must** indicate the receiving of food items and food contact packaging materials, their storage, handling, and shipment and, if applicable, all preparation steps, equipment used, processing steps, rework and returned products, packaging materials, packaging equipment and the steps preceding and following the handling and/or processing of a food item for shipment . The same flow diagram may be used for a number of products that are manufactured using similar processing steps.
  - ii. The process flow diagram **Must** remain current.
  - iii. Once CCPs (Critical Control Points) have been determined, they **Must** be clearly identified on the flow diagram and numbered to correspond with the Hazard Analysis and CCP records and documentation.
- d) On-site Confirmation of Flow Diagram - The HACCP team **Must** perform and document an on-site review of the operation to verify the accuracy and completeness of the process flow diagram during all stages and hours of operation. Modifications **Must** be documented on the flow diagram, as necessary.

## 2) Hazard Analysis (HACCP Principle 1)

There **Must** be a detailed Hazard Analysis document for each type of product or product line. Failure to have a complete, accurate hazard analysis **Must** be rated as a Major Nonconformance.

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- a) The HACCP team **Must** prepare a list of all of the hazards (chemical, physical, biological or other) that may be reasonably expected to occur at each step, from receipt, processing, if applicable, storage, and distribution until the point of consumption. Evaluation **Must** include all food items and food contact packaging materials and, if applicable equipment, processing steps, and packaging materials.
- b) The HACCP team **Must** conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. The hazard analysis **Must** include:
  - i. The likely occurrence of hazards and severity of their adverse health effects.
  - ii. The qualitative and/or quantitative evaluation of the presence of hazards.
  - iii. Survival or multiplication of microorganisms of concern.
  - iv. Production or persistence in foods of hazardous toxins, chemicals or physical agents.
  - v. Conditions leading to the above.

**Note:** Consideration **Should** be given to what identified prerequisite control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specific control measure.

### 3) Critical Control Points (HACCP Principle 2)

- a) A logical, reasoned, documented approach **Must** be used to determine Critical Control Points (CCPs) for potential hazards. If a formal hazard analysis is not used to determine the need for CCP's, there **Must** be a documented risk assessment for that purpose.
- b) Documentation for determining whether a step or process is a CCP or not **Must** be clear and thoroughly explained, defining the hazard and the specific controls that eliminate or reduce the hazard.

**Note:** If it has been determined that there are no hazards or CCPs, no further HACCP plan development is necessary. However, the HACCP Team **Must** continue to conduct regular meetings to review any changes in the process or procedures that could affect the hazard or CCP determination. The requirements of sub-sections "Verification and Validation" (HACCP Principle 6) and "Documentation and Record Keeping" (HACCP Principle 7) below **Must** also be satisfied to verify the HACCP conclusions and to document all HACCP decisions and conclusions.

### 4) Critical Limits (HACCP Principle 3)

Once a control measure has been established for a CCP, operating and critical limits **Must** also be established.

- a) Critical limits **Must** be specified and validated for each CCP. Failure to demonstrate that CCP critical limits are scientifically and/or technologically sound for controlling each hazard **Must** be rated as a Major Nonconformance.
- b) Critical limits **Must** be measurable. Variable or attribute measures are acceptable.
- c) There **Must** be a scientific or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. (Validation) Proprietary data may

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be acceptable, providing there are sufficient data approved by an appropriate, qualified authority.

- d) Documented process capability studies or CCP monitoring records **Must** be available to demonstrate that established CCP limits are compatible with the plant process and capable of being met.

## 5) CCP Monitoring (HACCP Principle 4)

Monitoring procedures **Must** be able to detect loss of control at the CCP.

- a) If monitoring is not continuous, then the type and frequency of monitoring **Must** be sufficient to guarantee the CCP is in control.
- b) Monitoring data **Must** be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.
- c) Documentation of the measured variable **Must** be on clearly identified HACCP records. Records **Must** have CCPs identified by name and number, the item to be measured, the frequency of the measurement, the CCP limit, the responsible monitor and the corrective action required in the event that a measurement is not in compliance.
- d) A deviation log **Must** be maintained and available for review.
- e) All records and documents associated with monitoring CCPs **Must** be signed by the person(s) doing the monitoring.

## 6) Corrective Actions (HACCP Principle 5)

Specific corrective actions **Must** be developed for each CCP in the HACCP system to deal with deviations when they occur.

- a) Corrective actions **Must** include instructions of necessary actions to take to secure and manage affected product.
- b) Corrective actions **Must** ensure that the CCP has been brought under control and require that an assessment be conducted to prevent a recurrence of the situation.
- c) Documented product disposition procedures that would become effective if a deviation were to occur **Must** be developed.

## 7) Verification and Validation (HACCP Principle 6)

Verification documentation is required, confirming that the products are achieving the level of safety required and that the HACCP plan is operating effectively.

- a) Examples of verification activities include:
  - i. Review of the HACCP system and plan and its records.
  - ii. Review of deviations and product dispositions.
  - iii. Confirmation that CCPs are properly monitored and kept under control.
- b) Validation of the HACCP plan **Must** be available through documentation or supporting data that confirms the Plan is scientifically and technically sound, that all hazards have been

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- identified, that CCPs are effective and valid and that if the HACCP plan is properly implemented, these hazards will be effectively controlled.
- c) Subsequent validation of the plan **Must** be performed and documented on an ongoing basis as needed based on corrective and preventive actions and **Must** be performed at least annually.

## 8) Documentation and Record Keeping (HACCP Principle 7)

HACCP procedures **Must** be documented.

- a) Documentation and record keeping **Must** be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.
- i. Examples of documentation include: hazard analysis, CCP determination, risk analysis, and critical limit determination.
  - ii. Examples of record keeping include: CCP monitoring activities, deviations and associated corrective actions, verification procedures performed, modifications to the HACCP plan.
  - iii. Records may be electronic, but if so, **Must** be effectively access-controlled. (See section A.6)
- b) Deviations from the HACCP plan **Must** be thoroughly documented with detailed corrective actions and product dispositions.
- c) The documents and their data **Must** be self-explanatory and complete. The records **Must** be in ink (not pencil) and signed by the operator. There **Must** be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation **Must** be provided.
- d) The final record **Must** be signed by the operator, and by the designated HACCP records reviewer.
- e) Records **Must** be easily retrievable and secured in a safe storage area.

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## PREREQUISITE PROGRAMS

### C. FACILITIES & EQUIPMENT (The Manufacturing Environmental Controls Prerequisite System)

The following guidelines are provided as minimum requirements for food item and food contact packaging material storage and handling facilities. They are general in nature and may not be appropriate for all operations, but the intent of the requirements, as stated, **Must** be achieved.

#### 1) Potable Water, Ice, Backflow Prevention, Steam & Waste Water Management

##### All Storage Facility Requirements

- a) Waste disposal **Must** be such that it does not compromise food safety or employee health.
- b) Wastewater and sewer drains **Must** not be vented inside the facility.

##### Food Contact Handling/Processing Area Requirements

Where a facility's activities actually involve the physical handling of food (not just pass-through), in those food handling/processing areas the facility **Must** demonstrate that the food contact water supply is potable and that potability is maintained at all times. Potability **Must** meet local requirements at a minimum.

- a) A certified laboratory **Must** document potability testing at least annually. Potability certificates available from municipal water suppliers are acceptable. If the facility is using water from a private well, there **Must** be a credible potability test at least every 6 months.
- b) Facilities using their own private wells **Must** be able to demonstrate water potability on a continuing basis. If chlorination is applied, the system **Must** have automated controls that prevent inadvertent use of the water or an alarming mechanism to immediately notify facility management if the chlorination system fails.
- c) Facility **Must** have an identification system for potable and non-potable water lines and current schematics. Dead ends on potable water lines **Must** be eliminated. Hose drops **Must** not be submerged.
- d) Facility **Must** have an adequate supply of both hot and cold water for handling/processing and sanitation. Hand wash facilities **Must** deliver tempered water (90-105°F within 10 seconds).
- e) Purchased ice **Must** have annual certificates of potability or documented satisfactory microbiological testing results.
- f) Hose drops **Must** have back flow prevention devices installed. (High pressure lines (>80 psi) do not need backflow protection.) These devices **Must** have annual, documented inspections to demonstrate effectiveness. Hose nozzles do not provide effective backflow prevention. Hoses and hose nozzles **Must** not be left on the floor or in tanks.
- g) Facility **Must** have a documented procedure for handling backed-up drains in the food handling/processing areas. Drain cleaning equipment **Must** enter and exit the food handling/processing area in such a way that it does not cause further contamination.

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- h) Steam used for product processing and that touches food product surfaces, including food contact packaging materials, **Must** be from “edible” sources. Documentation **Must** be available that indicates all boiler water components meet approved boiler additive standards. A listing of registered Nonfood Compounds is available at [http://www.nsf.org/business/nonfood\\_compounds/index.asp?program=NonFoodComReg](http://www.nsf.org/business/nonfood_compounds/index.asp?program=NonFoodComReg)

## 2) Facility Construction and Design

The construction of the facility **Must** be such that it facilitates the storage and handling of wholesome product and that it at least meets the customer and regulatory food safety and quality requirements.

### All Storage Facility Requirements

- a) Exterior of facility and grounds **Must** be constructed to minimize dust and be free of standing water.
- b) With the exception for facilities storing product in glass or brittle plastic, glass and/or brittle plastic **Must** not be used in, above or near food handling/processing or storage areas unless absolutely necessary (This includes glass thermometers).
- c) Facilities storing product in glass containers **Must** be constructed and equipped to properly protect product in the event of glass breakage.
- d) Facilities **Must** be designed so that food items and food contact packaging materials do not come into contact with non-product zones (i.e. floor, walls, etc.).
- e) Facility construction and layout **Must** be such that exposed food items and food contact packaging materials are adequately separated and protected from any operations that could cause contamination.
- f) Floors **Must** be well drained, smooth, easy to clean.
- g) Floors **Must** be maintained in clean and dry (if possible) condition.
- h) Standing water **Must** not be evident in food handling/processing or storage areas.
- i) Drains **Must** have traps and drain covers **Must** be maintained in place. Drains **Must** be free from off-odors.
- j) Ceilings **Must** be constructed of a smooth, non-porous, non-absorbent and easily cleanable material.
- k) Adequate heating, ventilation or refrigeration **Must** be provided in all areas to maintain proper environmental and sanitary conditions for food items and food contact packaging materials. All systems **Must** be clean, properly functioning and designed in such a manner to prevent product contamination from condensation, mold, bacteria, insects, dust or odors. Heating and ventilation **Must** be balanced to prevent condensation on walls or ceilings in product areas.
- l) Objectionable odors, fumes or vapors **Must** not be present.
- m) The facility roof **Must** be uncluttered, free draining and free of standing water, bird or pest harborages.

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### Food Contact Handling/Processing Area Requirements

- a) All essential glass or brittle plastic that exists in any equipment including but not limited to cameras, emergency lighting, dial and gauge covers etc. **Must** be documented to indicate location, condition, maintenance and monitoring on at least a monthly basis.
- b) Catwalks and other walkways over or adjacent to exposed food items **Must** be designed and constructed to prevent product contamination. A standard OSHA 4-inch kickplate is insufficient for this purpose. An 18 inch food safety shield is recommended.
- c) Bearings and bearing blocks **Must** be properly protected, or designed, so that no lubricant can leak or be forced into food item zones. Catch pans for bearing blocks **Must** be properly drained. **Note:** this applies whether or not food grade lubricants are in use.
- d) Hand wash and food item wash sinks **Must** be properly plumbed to drain lines. Discharge water from sinks **Must** not run directly onto the floor.
- e) Concrete floors **Must** have no exposed aggregate and no cracks, holes or broken areas. Epoxy-coated floors **Must** be free of cracks, broken surface areas, and air/water bubbles under the surface.
- f) All fans, fan guards, ductwork, louvers, and heating and air conditioning registers **Must** be clean and in good repair.
- g) All ceiling and wall ventilation fans venting to the outside **Must** have properly functioning, self-closing louvers and **Must** be screened to prevent insect entry. Self-closing louvers that sufficiently seal the opening and are maintained operational with appropriate inspection and preventive maintenance plans will suffice in lieu of insect screening.
- h) Facilities that utilize compressed air that makes direct contact with food, food contact surfaces or food contact packaging materials **Must** develop a program to assure the compressed air does not introduce any contaminants (including microorganisms) into the product. The necessary requirements for maintaining sanitary air **Must** be monitored and documented.

### 3) Facility Condition (Walls, Ceilings, Floors, etc.)

#### All Storage Facility Requirements

- a) Facilities **Must** be well maintained in an orderly, clean condition with floors, walls, ceilings and equipment maintained so as not to provide undue obstacles to sanitation and pest management or present opportunities for foreign material contamination.
- b) Ceiling surfaces, as well as other overhead equipment, **Must** be clean, in good repair, free of flaking paint, loose caulking, rust, holes or unsealed openings, or other conditions that could result in product contamination.
- c) Overhead structures such as ventilation units, light fixtures, electrical raceways, piping, conveyors, etc., **Must** be clean and free of product buildup, dust, mold, rust, peeling paint and condensation.

#### Food Contact Handling/Processing Area Requirements

- a) Ceiling panels, framework and supports **Must** be properly secured with no missing or damaged parts.

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- b) Ceiling penetrations for pipes, conveyors, wiring, etc., **Must** be sealed to prevent harborage, ceiling leaks and contamination.
- c) There **Must** be no evidence of water leaks on ceilings.
- d) Insulation materials **Must** be in good repair, smooth, non-absorbent and easily cleanable. Joint areas **Must** be sealed.
- e) Nails, staples or screws **Must** not be used to secure ceiling material.
- f) All skylights, transoms, windows or similar openings **Must** be free of damage, tight fitting and properly screened when opened.
- g) All ceiling and wall junctures **Must** be cleanable and on the Master Sanitation Schedule to preclude pest harborage or access.
- h) String, rope, wire or tape **Must** not to be used as pipe, line or equipment supports.
- i) Pipes or other overhead equipment above food item zones **Must** be adequately protected to eliminate potential product contamination.
- j) Temporary or unused hangers or other equipment support in food handling/processing areas **Must** be removed when no longer in use.
- k) Walls **Must** be of a smooth, non-toxic material with easily cleanable construction. They **Must** be free from cracks, holes and crevices that would inhibit cleaning or provide harborage for microorganisms, soil or pests. They **Must** be free of dust, dirt, product, or moisture accumulation and flaking paint.
- l) Walls **Must** be sealed and the wall/floor juncture **Must** be cleanable and on the Master Sanitation Schedule.
- m) Wall coverings **Must** not be attached with exposed nails, staples or screws.
- n) Openings in walls where pipes, equipment or conveyors pass **Must** be sealed.
- o) Windows **Must** be closed if outside conditions exist that may expose the plant to airborne contamination.
- p) All windows **Must** be maintained in a clean and sound condition, with no broken panes and **Must** be screened when open.

#### 4) Employee Facilities

Cafeteria, locker rooms/areas and toilet facilities **Must** be adequate in size for the maximum number of employees, convenient and physically separated from food handling/processing areas. They **Must** be maintained to set an example of clean and orderly food sanitation and housekeeping requirements.

- a) Cafeterias and break areas **Must** be adequately sized, well lit, clean and effectively ventilated. Adequate storage for employee food items, in easily cleanable areas, **Must** be available. Food preparation areas **Must** meet restaurant standards for sanitation and cleanliness. Vending machines **Must** be maintained in a sanitary condition with easy access for cleaning underneath and behind.
- b) Locker rooms/areas **Must** be adequately sized, well lit and clean and orderly. Lockers **Must** be available for storing personal items. There **Must** be a policy in place prohibiting food

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- storage anywhere in locker rooms/areas. There **Must** also be a documented program in place to verify compliance with the policy.
- c) Toilet facilities **Must** be available and convenient to operational areas. They **Must** be well ventilated, well lit, clean and orderly.
  - d) Doors to toilet facilities **Must** be self-closing and **Must** not open directly into food handling/processing areas.
  - e) All toilet facilities **Must** be under negative pressure and mechanically ventilated to the outside.
  - f) A procedure for immediately cleaning and re-opening clogged toilet facility drains **Must** be in place.
  - g) A plan **Must** be available that specifies appropriate sanitation procedures to restore sanitary conditions following repair of overflowed drains or toilets.

## 5) Handwashing Facilities

### All Storage Facility Requirements

- a) Handwashing facilities **Must** be convenient and adequate in number to accommodate the maximum number of employees in the area to prevent delays that may discourage proper handwashing procedures.
- b) Handwashing facilities minimally **Must** be in toilet facilities.
- c) The handwashing stations **Must** deliver tempered water (90-105°F) within 10 seconds. Additionally there **Must** be an adequate supply of hand sanitizing soap and/or sanitizing agent. Single service towels **Must** be available with convenient disposal at each station.
- d) Required signage, in appropriate languages and/or graphics, **Must** be clearly posted at the locations and contain instructions as provided below.
  - i. Signs at locker room and toilet facility exits **Must** instruct employees to wash their hands prior to returning to work. **Note:** Washing hands prior to exiting the locker room and toilet facilities does not substitute for washing hands just prior to or immediately upon entrance to food handling and food processing areas.
  - ii. Signs at hand wash stations **Must** instruct employees on the proper procedures for washing their hands.

### Food Contact Handling/Processing Area Requirements

- a) Handwashing facilities minimally **Must** be adjacent to entrances to food handling/processing areas.
- b) In areas where food is exposed and/or handled by employees, handwash and/or sanitizing stations **Must** be convenient to the employee workstations. Sanitizing stations are not a replacement for handwashing.
- c) Handwashing stations in or adjacent to food handling/processing areas **Must** be 'hands-free' activated so that hand contact is not required to turn water 'On' or 'Off'.
- d) Required signage, in appropriate languages and/or graphics, **Must** be clearly posted at the locations and contain instructions as provided below.

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- i. Signs at entrances to food handling/processing areas **Must** instruct employees to wash and sanitize their hands prior to returning to work.
- ii. Signs at hand wash stations **Must** instruct employees on the proper procedures for washing their hands.

## 6) Equipment Layout, Design and Condition

### All Storage Facility Requirements

- a) All food item and food contact packaging material storage equipment **Must** meet food sanitary design requirements and be installed in such a manner as to permit proper operation and access for cleaning and inspection.
- b) Refrigeration unit drip pans **Must** be adequately sized to be effective and properly drained to prevent accumulation of standing water. Refrigeration drip pan overflow **Must** not flow onto the floor. Drain lines into sewer or vent lines **Must** be “trapped” (e.g., P-trap), or if drained into floor drains, **Must** have an “air gap”.

### Food Contact Handling/Processing Area Requirements

- a) Food handling/processing, packaging and storage equipment **Must** meet sanitary design requirements and be designed, installed and maintained in such a manner as to produce a safe, wholesome and quality product.
- b) Equipment **Must** be designed and maintained to provide easy access, disassembly and reassembly for thorough cleaning, sanitizing and inspection.
- c) Equipment **Must** be of smooth, impervious, non-toxic, non-absorbent and corrosion-resistant material where it has direct food contact.
- d) Conveyor belts for food contact **Must** be of impervious, non-absorbent material. Fiber-backed or sandwiched belts **Must** not be used for food contact conveyors. Belts **Must** be maintained in good condition with no holes, cuts, frayed edges or damage that renders the belt difficult to clean or present a foreign material hazard.
- e) Food contact surfaces, such as conveyor belts **Must** not be closer than 18” to the floor or **Must** be effectively protected from contamination during operations.
- f) Equipment **Must** be free of cracks and non-continuous or rough welds where food may become embedded and make cleaning difficult.
- g) Equipment with sides or shields or scrapers or other items that are attached to food contact areas **Must** have sufficient clearance between the pieces to permit cleaning and prevent food accumulation (approximately ¼” is generally sufficient).
- h) Equipment **Must** be free of oil leaks and excessive grease build-up on bearings and motor housings where they may contaminate food. Bearings and motors near and above exposed food areas **Must** have catch pans to protect food below. The pans **Must** be drained in a sanitary manner.
- i) Equipment **Must** be constructed in such a manner to preclude metal-to-metal contact between moving parts.
- j) Hollow drums or rollers **Must** not be used for food handling/processing equipment. Open rollers that can be effectively cleaned or solid rollers or drums are required. If hollow

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drums/rollers are used, they **Must** be completely sealed and the maintenance department **Must** have a record of inspection and corrective actions instituted.

- k) Appropriate covers/lids **Must** be provided to protect food from contamination. Tanks or vessels containing food products **Must** be covered when they are not actually being filled, used or involved in other activities requiring access.
- l) Equipment **Must** be free of flaking paint, rust or other contaminants that could become detached.
- m) Equipment **Must** be designed to preclude or divert condensate away from food and food contact surfaces.
- n) Food and clean food containers **Must** be adequately protected to preclude contamination.
- o) Gasket material **Must** be non-toxic, non-absorbent and in good condition.
- p) Small support utensils and equipment **Must** have specific, convenient and sanitary storage hangers or shelves.

## 7) Facility Lighting and Protection

Facility lighting **Must** be of such design and construction to provide adequate illumination in food handling/processing, support, and storage areas. The lighting fixtures **Must** provide adequate protection from breakage and possible contamination.

- a) Facility lighting **Must** be adequate and appropriate for the tasks being performed.
- b) All glass lighting **Must** be completely enclosed in shatter-resistant protective shields or manufactured with shatter-resistant materials to prevent glass contamination of product. This includes all operating areas, warehouses, packaging areas, receiving and shipping docks, storage areas, maintenance, toilet areas, break rooms, and welfare areas. All lights **Must** be protected, including but not limited to, emergency lights, forklift lights, and adjustable trailer lights on the dock.
- c) Light fixtures **Must** be maintained clean and free of cracks, dust or other materials that could cause contamination. Protective covers in food handling/processing areas **Must** be kept free of any evidence of moisture accumulation inside the covers.
- d) A periodic assessment of this program **Must** be undertaken to ensure the glass and brittle plastic program is current and up to date.

## 8) Maintenance Standard (Support of GMPs, Housekeeping, Lubricants)

### All Storage Facility Requirements

- a) Engineering and maintenance support **Must** be managed to provide a well-maintained, clean and orderly facility that presents a good image of sanitary food handling and storage for employees and visitors. Equipment **Must** be maintained in sound working order as originally designed or with modifications meeting food sanitation (sanitary design) requirements. Repairs to facilities and equipment **Must** be addressed in a timely manner and consistent with good food manufacturing practices.
- b) Facility **Must** have regularly scheduled internal audits of the facility that identify and correct potential contamination or sanitation hazards.

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### Food Contact Handling/Processing Area Requirements

- a) Food handling/processing areas **Must** have a documented preventive maintenance program that covers all equipment and facilities.
- b) The food handling/processing areas **Must** have regularly scheduled internal audits that identify and correct the following conditions before they become contamination or sanitation hazards: flaking/peeling paint or rust or grease buildup on equipment; condensation on equipment or ceilings; holes, cracks or loose ceiling or wall panels or supports; repair of fixed and wheeled equipment to prevent contamination or cleaning problems such as: cracks or rolled edges on totes, shovels, buckets or other utensils; frayed or damaged conveyor belt; cutting board conditions.
- c) Temporary repairs **Must** be consistent with GMPs and do not permit the use of inappropriate materials. Permanent repairs **Must** be made promptly. Nonfood grade materials such as wire, tape, string, plastic or cardboard **Must** not be used for temporary repair.
- d) Food grade lubricants **Must** be stored separately from non-food grade lubricants. Non-food grade lubricants **Must** be clearly identified as not for use in food contact areas.
- e) To avoid food contamination, shop scrap **Must** be controlled.

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## D. SANITATION, HOUSEKEEPING & HYGIENE (The Sanitation Prerequisite System)

The effective management of sanitation, housekeeping and hygiene is a critical prerequisite requiring the involvement and cooperation of all operating departments and support groups. It requires specific policies covering requirements and expectations, training to communicate those requirements and management support and follow-up to assure that the requirements are properly met and that all sanitary standards are fully enforced.

### 1) Master Sanitation Schedule and Monitoring

- a) The facility **Must** have a documented cleaning schedule (Master Sanitation Schedule) not only for food handling/processing areas, if applicable, but also for the warehouse, storage, maintenance, employee facilities (locker rooms/areas, cafeteria, break areas and toilet facilities) and other facility areas including the building, grounds and roof areas.
- b) The scheduled tasks **Must** be monitored for completion and documented with sign off on a regular basis.
- c) It is highly recommended that an environmental pathogen testing program be developed and implemented for the facility and equipment in:
  - i. All food handling and processing areas.
  - ii. Exposed food product, food contact packaging material and dry ingredient storage areas.
  - iii. Storage areas where roof leaks may contaminate raw materials or finished product.
  - iv. Coolers and freezers **Should** be included, as appropriate.
- d) Where environmental pathogen testing is performed, the results of that testing **Must** be provided to the auditor for review during the audit process. The auditor will not disclose any pathogen testing results in the audit report. The purpose of the review is to evaluate whether corrective actions are taken when appropriate. Failure to provide these results will result in a Major Nonconformance for this sub-section since the auditor will not be able to confirm that appropriate corrective actions are taken commensurate to test results.

### 2) Standard Sanitation Operating Procedures (SSOPs) and Monitoring

#### All Storage Facility Requirements

- a) The facility **Must** have documented Standard Sanitation Operation Procedures (SSOP) for facility areas and structures, which specifies and defines:
  - (i) Standard cleaning methods including the level of disassembly required for cleaning and assigned responsibility for each task.
  - (ii) Frequency of cleaning.
- b) The facility and equipment **Must** have detailed SSOP Monitoring Procedures with records of monitoring activity. Records **Must** clearly show equipment and facility condition and list all deficiencies found. When deficiencies are found there **Must** be a clear explanation of the activities performed to bring the equipment into a sanitary condition and a detailed corrective action plan to prevent a recurrence. **Note:** performed activities (fixes) and corrective actions are not the same.

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### Food Contact Handling/Processing Area Requirements

- a) The food handling/processing areas **Must** have a documented Standard Sanitation Operation Procedure (SSOP) for individual pieces of food handling/processing equipment, as well as facility areas and structures, which specifies and defines:
  - (i) Standard cleaning methods including the level of disassembly required for cleaning and assigned responsibility for each task.
  - (ii) Frequency of cleaning.
- b) Unless purchased as ready-to-use, there **Must** be specific preparation procedures regarding dilution factors for the specific chemicals or sanitizers being used and, where appropriate, verification testing and documentation.
- c) Water temperature requirements for washing (>140°F for cleaning unless otherwise recommended in writing by chemical supplier).
- d) Food handling/processing equipment **Must** have detailed SSOP Monitoring Procedures with records of monitoring activity. Records **Must** clearly show equipment and facility condition and list all deficiencies found. When deficiencies are found there **Must** be a clear explanation of the activities performed to bring the equipment into a sanitary condition and a detailed corrective action plan to prevent a recurrence. **Note:** performed activities (fixes) and corrective actions are not the same.
- e) Written procedures and schedules for daily cleaning and sanitizing of food handling/processing equipment and facilities **Must** be current and available. A Master Sanitation Schedule **Must** be developed and implemented for routine, non-daily cleaning tasks within the areas.
- f) If food handling/processing operators are responsible for general maintenance and equipment cleaning, procedures **Must** be available describing steps for cleaning and sanitizing and the cleaning **Must** be documented in the Master Sanitation Program or on the Master Sanitation Schedule, as appropriate.
- g) Written procedures **Must** be available for cleaning and sanitizing food handling/processing equipment after maintenance is performed and prior to returning equipment into service. Records of such maintenance and documentation of sanitation is required.
- h) All food handling/processing equipment taken out of service for maintenance **Must** be properly cleaned and sanitized before being put back into service. These activities **Must** be appropriately documented.

### 3) Cleaning Chemical and Sanitizer Control

- a) Cleaning and sanitizing chemical control **Must** be a part of an effective sanitation program.
- b) Cleaning chemicals **Must** be purchased from approved suppliers and be approved for their intended use.
- c) All containers for cleaning chemicals and sanitizers **Must** be properly labeled.
- d) All containers for cleaning chemicals and sanitizers **Must** be used for their intended purpose only.
- e) Chemicals used for cleaning and sanitizing **Must** be securely stored during periods of non-use.

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- f) Chemical storage areas **Must** be restricted to authorized personnel and **Must** have applicable signage.
- g) Empty containers **Must** be stored in a manner that does not compromise food safety.
- h) Facility **Must** have MSDS sheets for all cleaning and sanitizing chemicals readily available.

#### 4) Pre-Operational Monitoring and Corrective Action

##### Food Contact Handling/Processing Area Requirements

- a) A pre-operational checklist **Must** be used to verify that the area (containers, utensils, walls, floors, ceilings, light fixtures, miscellaneous overhead structures, etc.) and food handling/processing equipment are clean and sanitary prior to start-up.
- b) A documented inspection program **Must** be in place to assess sanitation effectiveness and area and equipment conditions prior to startup.
- c) Deficiencies **Must** be documented.
- d) Corrective actions and preventive measures **Must** be documented to prevent recurrence.

#### 5) Verification of Cleaning Effectiveness

##### Food Contact Handling/Processing Area Requirements

- a) Sanitation effectiveness of food handling/processing equipment and facilities **Must** be monitored visually prior to production.
- b) Visual monitoring **Must** be supplemented with an objective measurement such as bioluminescence or microbiological surveys that **Must** be performed at a sufficient frequency to demonstrate the effectiveness of the sanitation procedures. Results **Must** be documented.
- c) Cleaning procedures for food handling/processing equipment to remove allergenic residues **Must** be validated as effective. This validation **Must** be done utilizing FAARP (or equivalent) approved, specific allergen protein test methods for identified target allergens. A general bioluminescence test is not acceptable.

#### 6) Operational Housekeeping

##### All Storage Facility Requirements

- a) All areas of the facility **Must** be kept clean, orderly and free from accumulation of debris, unused equipment parts, etc.
- b) All containers **Must** be properly labeled (i.e. edible, inedible, trash, etc).
- c) Mold, mildew or slime on walls, floors, ceilings or equipment **Must** be prevented.

##### Food Contact Handling/Processing Area Requirements

- a) Garbage, trash and waste materials **Must** be removed from the food handling/processing areas in a timely manner so as not to cause a food safety risk.

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- b) Accumulation of garbage, trash and waste materials **Must** be done in a manner that does not create any food safety risk.
- c) All blowers, fans, vents and grids **Must** be kept free of dirt and/or grease build-up.
- d) Conduits, pipe runs and other electrical fixtures **Must** be sealed and free of dust and debris. This is particularly important in wet operations where water may enter pipes and conduits and become a microbiological harborage area creating a serious food safety risk.
- e) Rolling stock, totes, hand tools, utensils, etc. **Must** be cleaned and stored in designated areas. If color-coding is used for small tools or containers, the color code scheme **Must** be prominently displayed in the areas where the items are used or stored.
- f) Mops, brooms, squeegees, etc. **Must** be stored on hanging storage fixtures and not on the floors or in buckets. Squeegees used for condensate control **Must** be stored in sanitizer solutions specific for that task.
- g) No wooden handled utensils may be used in food handling/processing areas.
- h) High-pressure hoses **Must** not be used in food handling/processing areas after sanitation is complete.
- i) Stored food contact equipment **Must** be re-sanitized prior to use.
- j) Floor drains **Must** be kept clean, odor free, covered and trapped.
- k) Equipment and floors **Must** be cleaned, as necessary, during operations to provide a hygienic environment.
- l) All re-usable food contact containers **Must** be effectively cleaned, sanitized and inspected before reuse.
- m) If packaging supplies are not removed from the food handling/processing area during cleanup, they **Must** be covered to prevent contamination. There **Must** be an effective procedure in place to avoid packaging materials from becoming contaminated by the cleaning process.
- n) Tools **Must** be stored in clean toolboxes or in affixed positions. Tools and materials **Must** not be stored on top of equipment, electrical boxes or window ledges.
- o) All tool pouches **Must** be made of cleanable materials and used in a manner to avoid cross contamination.

## 7) Personal Hygiene and Good Manufacturing Practices

### All Storage Facility Requirements

- a) The following constitutes minimum guidelines for Personal Hygiene Practices:
  - (i) Eating, drinking, spitting, chewing or using tobacco products **Must** not be permitted except in designated areas.

### Food Contact Handling/Processing Area Requirements

- a) Food handling/processing area employees **Must** observe the strictest of personal hygiene practices as outlined in the Code of Federal Regulations, Section 21, Part 110, "Current Good Manufacturing Practices" for food plants.
- b) The following constitutes minimum guidelines for Personal Hygiene Practices:

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- (i) Fine mesh net hair restraints for head and facial hair **Must** be required in all food contact/handling areas of the facility by all employees. If mustaches, without hair restraint, are allowed by management, they **Must** be well groomed and not extend below the corners of the mouth. These hair restraint requirements do not apply to pass through warehouses or distribution facilities or to general storage areas of such facilities that do not have direct employee handling of food products.
- (ii) A written dress code **Must** be clearly and prominently available for all employees. It **Must** be uniformly enforced for all employees (including new and part-time) visitors, vendors and contractors.
- (iii) Employees **Must** wear clean clothing and shoes appropriate for the working conditions.
- (iv) Employees **Must** not wear false fingernails, fingernail polish, jewelry, rings, exposed body piercings, or watches, etc.
- (v) Employees **Must** not work in food handling/processing areas if they have an infectious or communicable illness, or have open sores on hands, faces or arms, etc. Employees **Must** notify management if they are diagnosed with a communicable disease transmitted through food or are experiencing symptoms of diarrhea, vomiting, fever or jaundice.
- (vi) Employees in food handling/processing areas **Must** wash and sanitize their hands before starting to work, after each absence from the work station and any time their hands may have become contaminated (touching equipment or other items that are unclean). If gloves are worn, they **Must** be intact, with no holes, and kept clean. They **Must** also be washed and sanitized, or replaced, if at any time unclean items are touched.
- (vii) If dedicated aprons, lab coats, smocks, etc. are utilized, the facility **Must** provide, and food handling/processing employees **Must** use a means to avoid contamination of their dedicated outer clothing when using the toilet facilities. Coat hooks **Must** be made available for employees to hang their outer garments outside the toilet facilities.
- (viii) Pens, combs, pencils, thermometers, etc. **Must** not be carried above the waist at any time while in the food handling/processing areas.

## 8) GMP Self-Inspections and Corrective Actions (Internal Audits and Corrective Actions)

- a) A key management responsibility is to verify that the policies and programs essential in the management of wholesome food products are routinely and effectively implemented. It is necessary that routine internal audits (self-assessments) of policies and procedures be conducted to assure management that they are being effectively implemented and that the facilities and equipment are maintained to meet sanitary and operational needs.
- b) Facilities **Must** have documented procedures for planning and implementing internal audits to verify compliance to policies and to evaluate the effectiveness of the policies.
- c) The internal audits **Must** assess facility, maintenance, pest control, food handling/process, sanitation, and housekeeping conditions and personnel hygienic practices for systematic effectiveness and to initiate corrective actions for deficiencies.
- d) Internal audits **Must** be scheduled routinely and be performed by responsible, trained individuals. If the internal audits are not conducted by a management person, there **Must** be

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- periodic verification by management. These inspections **Must** be documented along with corrective actions and follow-up.
- e) Follow-up inspection activities for deficiencies and repeat items **Must** record the effectiveness of the corrective actions taken. Repeat issues **Must** receive top management priority to effect a timely corrective action.
  - f) All internal audit reports showing deficiencies **Must** include corrective actions.

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## E. RODENT & PEST CONTROL MANAGEMENT (The Pest Management Prerequisite System)

All food storage and distribution facilities, including those that may handle/process food items, **Must** operate under the authority of a licensed pest control operator or contractor. PCOs **Must** have a proper license (or recognition), certification and insurance. They **Must** provide aggressive support to the facility's pest control, housekeeping and sanitation programs. Since they are trained experts in recognizing and evaluating conditions that contribute to potential pest activity such as sanitation, housekeeping, properly sealed doors and windows, perimeter accessibility and outside grounds conditions, they **Must** include observation comments on these situations in their service or activity reports with appropriate recommendations. Any comments on the service or activity reports **Must** have a documented response and corrective action, if appropriate.

If pest management is conducted internally without the services of a licensed pest control contractor, the same level of expertise **Must** be provided. Likewise, the same aggressive approach to the above areas of concern **Must** be required with documented activity reports and responses.

The following criteria are in part based on the NPMA (National Pest Management Association) – Pest Management Standards for Food Plants.

<http://www.npmapestworld.org/TechSupport/documents/FoodStandards60506.pdf>

### 1) Documented and Specific Pest Control Program

A written, detailed pest management policy and program **Must** be available. The policy **Should** outline and describe all procedures required to ensure that activities conducted by the Pest Control Operator (PCO) and trained employees are carried out in accordance with prescribed policy. A current Pest Management Manual or file **Must** be available for review. The information contained **Must** include:

- a) PCO **Must** submit an activity or service report for each inspection (see sub-section 6).
- b) Activity or service reports or a Pesticide Usage Log **Must** document what pesticide chemicals are used, if any, where, why, how much, target pests, method of application, and EPA registration number.
- c) Training of company employees can be by the PCO or other qualified experts. Forms used by the PCO and the company personnel **Should** be the same for uniformity.
- d) A current PCO applicator's license and letter of liability insurance **Must** be on file along with appropriate Material Safety Data Sheet (MSDS) forms for all chemicals used. MSDS forms **Must** be retained for a year after the chemical becomes inactive.
- e) Company employees engaged as PCOs **Must** have proof of appropriate training and licensing as required by state or local regulations.
- f) PCO service **Must** be in compliance with the contract and pest management policy.
- g) Per the device service schedule, all traps, bait stations, and vector devices **Must** be opened and inspected. Trained employees or the PCO **Must** conduct effective inspections at the following frequencies.
  - i. Outside bait stations at least monthly (weather permitting).
  - ii. Interior rodent glue boards and traps at least weekly.

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iii. Vector devices (insect light traps, pheromone traps, and the like) at least weekly.

**Note:** High pest activity may dictate more frequent servicing and extremely low pest activity may, with a documented risk assessment based on activity trend data, allow for a reduction in frequency.

- h) The record of service verification tag or bar code label **Must** be on the inside of the traps, bait stations or other devices.
- i) Site maps for traps, glue boards, bait stations and vector devices **Must** be reviewed regularly and dated and signed or initialed by the person having responsibility for the program.

## 2) Outside Premises Management (Grounds, Waste Disposal Areas)

Buildings and grounds **Must** be well maintained. Bait stations placed outside **Must** be placed based on habitat and potential access. They **Must** be positioned to prevent intrusion of casual water and rain and firmly secured to prevent removal from the assigned position or opened by unauthorized personnel. **Note:** "firmly secured" could be the bait station is fixed to a not easily removed concrete block or pad.

- a) Outside premises **Must** be free of discarded equipment or equipment stored on the ground, litter, pallets, weeds and other clutter that may provide harborage or breeding places or attractants for insects, birds, rodents or other pests or that may inhibit evaluation of premises for pest activity.
- b) Adequate trash and waste disposal facilities **Must** be available.
- c) There **Must** be no standing water on the premises that could attract pests.

## 3) Inside Premises Management

Interior conditions **Must** reflect orderly and clean conditions throughout the facility, allowing easy access for evaluation along the wall in all areas. Pest control devices **Must** be used inside the facility as a preventive measure in areas where pest activity is likely to occur.

- a) Inside walls (perimeter and interior) **Must** be maintained in a clear and clean manner to allow for full inspection.
- b) All spilled or damaged product or ingredients **Must** be cleaned up or disposed of immediately to prevent pest attraction.
- c) Insect light traps (ILT) that electrocute attracted insects, if used, in food handling/processing areas **Must** be used at least 8 feet from food or food contact surfaces to avoid any potential for contamination.
- d) Only mechanical traps or glue boards **Must** be used inside the facility (interior baiting is allowed in some countries outside of the US). All trapping devices **Must** be in proper working condition. No rodent bait stations are permitted inside the plant or warehouse.
- e) Trap locations **Should** be recommended by the PCO based on potential access and knowledge of pest habits. Exterior opening doorways **Must** have traps on both sides of the interior side of the doorway.

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#### 4) Pest Tight Doors & Entrance Closures

- a) All doors, including overhead doors, **Must** be tight closing with no visible light observed between the floor and doorjambs.
- b) Exterior holes/cracks in walls, pipe chases, vent openings, windows, etc., **Must** be filled or screened to prevent entry of pests.
- c) Building structure **Must** be sound with no holes, unscreened exterior openings, broken windows, etc. that may allow pest entry into the facility.

#### 5) Secure Storage and Documentation of Pest Related Chemicals

Pest management chemicals **Should** not be stored in the facility. It is preferred that these materials be stored with the PCO contractor and brought to the location when needed and removed at the time the PCO leaves the facility. If it is necessary to maintain pest management chemicals at the facility, they **Must** be stored in a secured location with limited access and:

- a) A detailed inventory log of chemicals received, quantities used, lot codes, the date used and for what purpose **Must** be maintained. Containers **Must** be destroyed once empty.
- b) This inventory **Must** be evaluated regularly to verify that the quantities received, the amount used and the amount currently on hand balance. Any discrepancies **Must** be evaluated and explained.
- c) Safety precautions for storage of pest related chemicals **Must** be available, including spill control kits, power ventilation, respirator, fire extinguisher, eyewash and first aid supplies.

#### 6) Detailed Activity Reports and Corrective Actions

Activity reports by the PCO and/or facility personnel **Must** be available for each inspection and whenever activity is observed. Consideration **Must** be given to pests indigenous to the area.

- a) PCO activity or service reports **Must** document the evidence of pests or pest activity such as gnawing, digging, droppings or stains from the outside bait stations, inside traps or glue boards and vector units.
- b) PCO activity or service reports **Must** document conditions outside or inside that would compromise the pest management program or make it difficult to evaluate.
- c) PCO activity or service reports **Must** document specific sites of activity, type of activity, and recommended corrective action.
- d) The PCO activity or service reports or a Pesticide Usage Log **Must** document the specific chemicals used, quantities used, lot codes, EPA registration number, locations where used, the date used and for what purpose.
- e) Activity or service reports **Must** be signed by the PCO.
- f) Each deficiency noted in the PCO activity or service reports **Must** be addressed by the PCO or management with corrective action documentation. This may be on the activity report itself or attached to the report.

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## F. APPROVED SUPPLIERS, RECEIVING & INVENTORY CONTROL (The Incoming Materials Prerequisite System)

The facility is expected to have detailed, written policies describing how suppliers are approved, receiving criteria for carrier and food item and food contact packaging material acceptance, and handling and storage criteria for food items and food contact packaging materials.

### 1) Supplier Approval Policies and Procedures

There **Must** be a documented Supplier Approval Program that identifies criteria for approving suppliers. The Approved Supplier Program **Must** contain as a minimum:

- a) Continuing Letters of Pure Food Guarantee **Must** be current and available for all food items and food contact packaging materials for which there are no lot specific Certificates of Analysis (COA).
- b) Specifications for food items and food contact packaging materials.
- c) Supplier approval criteria and approval process.
- d) Allowable circumstances to deviate from an Approved Supplier.
- e) Monitoring of Approved Suppliers.

### 2) Incoming Vehicle Inspection and Documentation

There **Must** be a documented program to ensure that transportation of food items and food contact packaging materials into the facility does not place the food safety of the materials received at risk.

- a) Facility **Must** have a written inspection program for all inbound carriers that fully describes acceptable and/or unacceptable conditions.
- b) All food items and food contact packaging materials **Must** be received from Approved Suppliers.
- c) All railcars, trucks, etc., **Must** be inspected at time of receiving to assure condition, cleanliness, and that they are free of moisture and offensive odors. Carriers **Must** be in good repair, with no evidence of pest activity and free of foreign substances such as glass, chemicals or odors.
- d) Interior of trailers, trucks or cars **Must** be free of loose or broken boards, nails, and holes in sidewalls that could cause contamination or pest harborage.
- e) Incoming food items and food contact packaging materials **Must** be inspected for damage, potential contamination, etc. The inspection program **Must** include:
  - i. Specific damage evaluation procedures with acceptance criteria.
  - ii. Foreign material contamination checks.
  - iii. Microbiological evaluation, if required.
- f) Trailer or railcar security seals **Must** be verified as the original seal number applied at the original shipping point.
- g) For temperature sensitive ingredients, receiving vehicle temperature and product temperature **Must** be documented on receiving documents.

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- h) Documentation of condition of each inbound shipment **Must** be shown on receiving documents.
- i) Records **Must** be maintained to match supplier codes to the materials received.

**Note:** During the audit process, all food items and food contact packaging materials within the facility will be subject to sampling by the auditor for evidence of compliance to the criteria detailed in this sub-section.

### 3) Release Criteria for Ingredients

- a) All food items and food contact packaging materials **Must** be maintained in a secure fashion (reference Food Defense Section L).
- b) An inventory management system **Must** document that food items and food contact packaging materials are used in proper rotation.
- c) Control procedures **Must** be in place to prevent use of non-conforming materials.

### 4) Storage and Handling Policies and Practices

Procedures **Must** be established to assure that food items and food contact packaging materials are not subject to sources of contamination.

- a) Receiving docks and areas around and under docks **Must** be clean and free from litter, spilled material, food residues, standing water, etc. The docks and receiving areas **Must** be maintained orderly, clean, and free of equipment or pallet accumulation that interferes with daily cleaning.
  - i. Dock levelers and dock plates **Must** be included on the Master Sanitation Schedule.
- b) All facility areas **Must** be clean and orderly, with no spilled, damaged or exposed product. Opened product containers **Must** not be stored in the receiving storage areas.
- c) Refrigerated and frozen storage rooms **Must** have their temperature controlled and monitored at least daily to the appropriate temperature requirements for their contents (typically <42° F for refrigerated and < -10° F for frozen).
- d) Slip-sheets **Must** be used when double stacking palletized food items and food contact packaging materials for protection from dirty or damaged pallets.
- e) Temperature sensitive areas **Must** be properly monitored with daily logs to verify that appropriate storage temperatures are maintained.
- f) Food items or food contact packaging materials **Must** not be stored directly on the floor.

### 5) Bulk Receiving Systems-Sanitation and Monitoring

- a) If applicable, bulk food item hoses, piping, and storage tanks **Must** be capped, locked and maintained in a sanitary manner, with a documented cleaning procedure.
- b) If applicable, bulk dry food item storage units **Must** be cleaned at least annually or more frequently as evidence dictates.

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## 6) Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds

All restricted or sensitive ingredients and potentially toxic chemicals **Must** be maintained under strict control and stored separately to minimize the potential for accidental product contamination.

- a) Toxic and sanitation chemicals and flammable solvents **Must** be stored in areas away from the food item and food contact packaging material storage areas. The storage area **Must** be secured with access restricted to properly authorized personnel.
- b) Sensitive ingredients **Must** be identified upon receipt and placed in designated areas with clearly visible marking identifying them as ingredients needing special control.
- c) Material Data Safety Sheet (MSDS) information **Must** be readily available for all chemical compounds in the facility.

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## G. PROCESS & PRODUCT EVALUATION (THE PROCESS AND PRODUCT CONTROL PREREQUISITE SYSTEM)

The facility **Must** have written policies and procedures specifying the operational control practices required to assure that food handling/processing operations are in control on a continuing basis. Operating records **Must** be available to verify conformance to these policies.

### 1) Process Control and Documentation Procedures

#### Food Contact Handling/Processing Area Requirements

Food **Must** be handled/processed under documented control procedures. The procedures **Must** take into consideration all food safety aspects.

- a) Effective application of the HACCP plan **Must** be clearly evident by the presence of identified CCP and other control measure monitoring points with appropriate and complete documentation.
- b) HACCP CCP monitoring documents **Must** clearly identify the CCP being monitored, the responsible operator, the critical limit, monitoring frequency, the action to be taken when limits are exceeded, the corrective actions required, and the signatures required by operational and supervisory personnel.
- c) In-process food items and food contact packaging materials **Must** be adequately protected and properly labeled with date and lot number.
- d) There **Must** be a pallet management program in place to assure that pallets do not present microbiological or foreign material risks.
- e) If the facility utilizes a laboratory in its process controls, the laboratory **Must** operate utilizing documented test methods based on recognized standards, and **Must** utilize appropriate equipment routinely calibrated to maintain accuracy. If the facility utilizes an outside laboratory, it **Must** meet industry certification requirements.

### 2) Specification and Formulation Control and Accuracy

#### Food Contact Handling/Processing Area Requirements

- a) Documented finished product specifications **Must** be developed by the customer and/or facility that define acceptable product attributes.
- b) Records **Must** be available demonstrating compliance to all finished product specifications including customer specifications, if applicable.
- c) Blending and mixing records **Must** show times, quantities and lot identification of food items used.
- d) Food handling/processing records **Must** be maintained for twelve months beyond product ship date. This is to assure continual compliance to customer, plant and regulatory requirements.
- e) Test protocols and frequencies **Must** be followed as identified in the specification.
- f) Issues, concerns or requests for changes regarding the accuracy, completeness, or frequency of testing **Must** be addressed with the customer, if applicable, with changes only permitted with written authorization.

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### 3) Routine Calibration of Operational Equipment and Measuring Devices

It is essential that all measuring, counting or protective devices (such as thermometers, scales, metal detectors, etc.) used in food handling/processing and temperature controlled storage areas be properly calibrated to assure the accuracy of these activities and the effectiveness of their performance. Accurate measurements are critical for monitoring HACCP CCPs.

- a) Key process control devices such as thermometers, scales, recording devices, etc., require routine calibration or certification by a credible authority at least annually. There **Must** also be a program to verify the performance of measuring devices to assure accuracy on a day-to-day basis.
- b) There **Must** be procedures in place to verify, on a daily basis, the accuracy of thermometers used for food item evaluations. The thermometers **Must** be identifiable (i.e. individual ID numbers or letters) and verification results **Must** be documented. Thermometers **Must** be verified at or near the temperature range at which they are used.
  - i. It is recommended that accurate intermediate thermometers be used to verify the daily calibrations of thermometers where the intermediate thermometers are checked against a NIST (National Institute of Standards Testing) traceable unit at least weekly. This prevents excessive use and handling of the NIST traceable thermometer. Full documentation of the calibration of the intermediate thermometers **Must** be available. If applicable, the use of ice baths is allowable.
- c) Electronic measuring devices (i.e. temperature, pressure, conductivity) utilizing remote transmitting devices (RTDs) **Must** be calibrated at least annually by comparison with an NIST standard instrument (i.e. thermometer, pressure gauge, conductivity meter). The calibration **Must** be performed with the measuring system (RTD, electrical connections, and recorder/display) intact. The data **Must** be obtained and recorded in the appropriate units of measurement for the system. This process and the results **Must** be documented
- d) Assigned personnel **Must** check scales used for weighing production components and finished product preparation daily. Standard weights in the range of the weights being produced **Must** be used for these verification checks. Daily verification checks **Must** be documented.
- e) Calibration procedures **Must** describe the frequency of testing, the testing method and the acceptable range of variation.
- f) There **Must** be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used. All product produced since the last acceptable check **Must** be assessed to determine if it **Must** be held for further evaluation.

### 4) Foreign Material Control

#### Food Contact Handling/Processing Area Requirements

Measures designed to prevent physical contamination **Must** be employed in food handling/processing areas. Examples of such measures would include metal detectors or x-ray units, the use of fine mesh screens, rare earth magnets, or specific visual inspection. These measures **Must** be calibrated, if appropriate, monitored and documented. The plant **Must** have a documented procedure for monitoring their process and finished product for the presence of foreign material.

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- a) Electronic Foreign Material Detectors, if used **Must** have a written procedure describing the maintenance, set-up and verification tests of detector systems. The procedure **Must** describe the initial set-up procedures and frequency of verification checks with actual product at start-up, during the shift and at the end of production. Test units to check equipment performance **Must** be used and appropriate for the nature of the product and the size of the package. Detectors **Must** be set-up at the beginning by qualified personnel and calibrated for the particular product being run. Documentation of calibration and set-up **Must** be part of daily production records along with initial, operational and final verification checks.
- i. Detectors **Must** have calibration and set-up verified by placing the test units or cards containing them along with the first product or package through the detector. Calibration **Must** include the use of ferrous, non-ferrous and stainless steel test samples. Customer specifications **Must** be used, if available. At the start of the production run, the first product through **Must** be tested to verify performance and ability to detect and reject the specified test units. Test units **Must** be placed along with the product in a sanitary manner so as to avoid product contamination. Special care **Must** be given to make sure that test units are promptly recovered from the test packages.
  - ii. A successful verification check **Must** detect and reject three successive challenges for each test unit. For those situations where three successive challenges may be difficult to accomplish, one challenge for each test unit is acceptable during the production run; however, three successive challenges are still required at start up and at finish. An example of this might be a system where detection is conducted just prior to packaging of a bulk ground meat product that is conveyed in line and insertion of the test unit is quite complicated.
  - iii. If product used in the verification checks is not discarded, it **Must** be re-run through the detector after the test units have been removed from the package.
  - iv. Frequency of verification checks during production and test metal samples used **Must** be sufficient to assure continued accurate performance. Some customers may require specified verification frequencies and test metal samples used.
  - v. A verification check of the detector performance **Must** be made on the last product run during the shift or lot. This will provide documentation that the detector was functioning properly from beginning to the end of production.
  - vi. Rejected units from the detector **Must** be retested and pass 3 successive times before accepted as a false positive. The detector **Must** be properly calibrated at the time the rejected product is retested. Reject units **Must** be opened promptly and examined to determine the source of the problem.
  - vii. A record of detector rejects and the cause for rejection **Must** be recorded on the verification/test log.
  - viii. In the event the detector fails a verification check, all product produced since the last documented successful verification check **Must** successfully pass through a properly functioning detector device.
- b) When magnets are used for the detection and removal of potential metal contaminants, the method of calibration **Must** be the manufacturer's recommended pull strength test.

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- c) A program **Must** be in place to minimize foreign material contamination from the outside of bagged ingredients when being added in open mixing units.
- d) There **Must** be an accountability program in place for knives and similar hand tools.

## 5) Application of Statistical Control

- a) Process critical limits for CCPs **Must** be attainable on the equipment that is utilized. This can be determined based on a sound process capability study of the equipment or by process monitoring records that demonstrate ongoing achievement of control.
- b) Management of the CCP critical limits **Must** be based on individual data points and not on averaged data.

## 6) Allergen and Sensitive Ingredient Controls

In facilities where allergens or sensitive ingredients are used or stored and there is a potential for cross-contamination, there **Must** be detailed procedures to prevent the contamination of other products.

### All Storage Facility Requirements

- a) There **Must** be a documented training program for employees on the proper handling of allergen sensitive ingredients and products.

### Food Contact Handling/Processing Area Requirements

- a) Food items containing allergens **Must** be clearly identified as such and properly controlled or isolated in the production to prevent cross-contamination.
- b) If food handling/processing of products containing allergens is not performed on dedicated lines or equipment, the following practices **Must** be in place:
  - i. Equipment used for allergen products **Must** be disassembled and chemically cleaned prior to use for non-allergen products.
  - ii. Verification of the cleaning processes' performance **Must** be documented.
  - iii. A validation program confirming the effectiveness of the cleaning processes used to eliminate specific allergens **Must** be implemented and documented (see C.5.c).
- c) Utensils used for these food items **Must** be dedicated and not used for other food items unless there is a thorough cleaning and sanitizing procedure applied between uses.
- d) Employees handling food items that are, or contain, allergens **Must** not handle non-allergen or different allergen ingredients or products without a complete change of outer garments, hair restraints, sanitary gloves and protective sleeve guards.
- e) Labeling for allergen containing products **Must** indicate the presence of the allergen or sensitizing agent, as required by regulations.
- f) Labeling operations **Must** have a documented line clearance procedure to ensure labels and products are cleared from the line and labeling equipment during product changeovers.

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## 7) Specification Compliance Documentation

### Food Contact Handling/Processing Area Requirements

Quality programs rely on documentation to confirm that the desired quality parameters were achieved. Records **Must** be maintained to assure that for food items handled/processed by the facility the appropriate product attributes were evaluated and that the results were consistent over time.

- a) Finished product **Must** have documentation verifying that the product meets specifications. Specification compliance documentation **Must** be available for review.
- b) A finished product evaluation procedure **Must** include frequency of testing, documentation of results and availability of records for 12 months beyond the product ship date.
- c) If the product fails to pass any inspection and/or test, the procedures for control of nonconforming product **Must** apply.

## 8) Rework and Carryover Products

### Food Contact Handling/Processing Area Requirements

The facility **Must** have a documented procedure for managing rework. Production dates and original lot numbers, as appropriate, **Must** be carried forward into the production documents when the material is ultimately used.

- a) The facility **Must** be able to trace the usage of all rework products into finished product. Rework is defined as product not meeting initial specifications and requiring reprocessing or product carry-over from one lot to a subsequent production lot thus commingling lots.
- b) The responsibility for assessment and release of rework product **Must** be specified.
- c) Rework **Must** be clearly identified with the date of production and original lot number, as appropriate. There **Must** be adequate documentation to assure that product tracking records are complete and can easily identify the lots where the product was used.
- d) Rework **Must** be handled in accordance with documented procedures. Product waiting reworking **Must** be stored in a dedicated place or exhibit an obvious physical indication of its status (i.e. on hold or rework).
- e) All rework **Must** be kept to a minimum and used promptly at the first opportunity. There **Must** be a routine and documented "clean break" in the rework cycle.

## 9) Analytical Records Management

An integral part of the food safety function centers on accurate, available product information used for decision making.

- a) Quality systems **Must** be established to properly store and retrieve analytical information, documents, reports, records, etc.
- b) Records and reports of analytical information gathered by organizations (internal and external) **Must** be cataloged and maintained in a fashion that provides feedback for operational control.
- c) When an outside laboratory is used, documented procedures **Must** be available to properly interpret and manage the information provided.

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## H. PACKAGING & LABELING

### Food Contact Handling/Processing Area Requirements

Procedures and policies **Must** be in place to assure proper labeling of food items handled/processed by the facility. Labels used **Must** accurately represent the product in the packages. Product coding systems **Must** provide adequate information for recall purposes.

#### 1) Label Accuracy and Regulatory Compliance

The facility **Must** have a program to assure that labels in use and product being produced are matched. Facilities with variable or optional product formulations **Must** be able to demonstrate that the proper label is always used.

- a) Labels **Must** satisfy regulatory requirements and **Must** include: accurate product name, Ingredients, in descending order of predominance, handling statement (Keep Frozen or Keep Refrigerated, if required), Appropriate “Manufactured by” or “Manufactured or Distributed for” signature line, nutritional labeling and safe handling information, if appropriate, for meat or poultry products.
- b) Sensitizing agents or allergenic ingredients **Must** be included on the label of products containing allergenic or sensitizing ingredients.
- c) There **Must** be some documented method of matching the proper label with the product or production schedule or formulation. The method chosen **Must** compare printed label codes and product container codes.
- d) Country of Origin Labeling **Must** be followed for covered commodities per the Department of Agriculture guidelines (7 CFR, Part 65).

#### 2) Net Weight or Count Compliance Policy & Performance

Facilities performing food handling/processing activities **Must** have a documented policy for net weight, liquid contents or product count to verify compliance to label requirements and/or specifications.

- a) Scales used to determine final product weight **Must** be verified for accuracy by designated individuals. Standard weights in the range of the products being labeled **Must** be used. Verification checks **Must** be documented on the production records. These verification checks **Must** take place at the beginning of the production day to assure all products are properly weighed. More frequent checks are recommended. Scale failure of a verification check **Must** result in an investigation of product produced since the last good check.
- b) Net weight, volume, or count control checks **Must** be performed and documented at an appropriate frequency to assure ongoing label declaration compliance. Hourly intervals are recommended.
- c) Product counters **Must** be verified per manufacturer instructions or documented using data-based performance studies.
- d) Records **Must** be available showing status of conformance and verification checks.

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### 3) Clear Manufacturing Codes on Individual and Cased Product

Clear coding of processed foods is essential for proper management of production lots and traceability and **Must** meet customer specifications.

- a) All product coding and label information **Must** be of such size, color and contrast to afford easy legibility at a reasonable distance.
- b) Code may be “open code”, sell-by, use-by, or cryptic code, such as the Julian system, that is clearly understood by both the customer and facility operation.
- c) Each individual sell unit **Must** have a production or lot code. Packages within the sell unit **Must** have a lot code, except for single use consumer units like condiments. The individual package code date and the case code date **Must** indicate the same date.
- d) The product information on the shipping case **Must** agree with the product information on the individual packages in the shipping case. Each package in the case **Must** bear the same information.

### 4) Package Integrity and Function for Distribution

For facilities with food handling/processing operations, both the sell unit package and the shipping unit **Must** be designed and assembled to provide the necessary protection for the product from environmental and shipping conditions.

- a) Plant **Must** have an effective program to assure that the product cases, if used, are properly closed and sealed. Shipping units **Must** be properly constructed and secure.
- b) Finished product cases, if used, **Must** be appropriately sized to provide adequate protection to the internal product.
- c) Finished product cases, if used, **Must** be intact and adequately sealed to prevent contamination.

### 5) Label Security and Obsolete Label Controls

There **Must** be a written plan describing the security measures for labeling materials to prevent unauthorized or accidental use and to prevent the use of obsolete labels.

- a) There **Must** be a documented procedure detailing how labels are controlled so that they are not used out of sequence or co-mingled in storage or at the point of use.
- b) There **Must** be a procedure for immediate isolation and securing or destroying obsolete labels.

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## I. STORAGE & SHIPPING

Food items and food contact packaging materials **Must** be stored under controlled conditions. Products handled/processed by the facility **Must** not be released for shipment without assuring that all food safety and quality evaluations have been completed. All product shipped **Must** be able to be tracked in case of a product recall.

### 1) Warehouse and Finished Product Management

Storage conditions **Must** be maintained and controlled in a manner to assure product integrity.

- a) Finished product, packaging materials, equipment or ingredients **Must** not be stored in close proximity to any chemical, cleaning product, pesticide or other nonfood materials. Such nonfood items **Must** be stored in separate areas that can be closed and secured, away from any food materials or ingredients.
- b) Only properly packaged product in undamaged containers may be stored in and shipped from the finished warehouse. Product not "cleared" for shipment, or held for any other purpose, **Must** be clearly identified and not stored in a location in the warehouse where it is likely that it may be shipped in error.
- c) Damaged, leaking or unsound product **Must** be immediately isolated and placed on hold for evaluation by designated personnel. Product disposition **Should** be timely.
- d) Partially used or previously opened food containers **Must** not be stored with finished product. Such product may be stored in a designated separate storage area, if it is properly identified and sealed to prevent contamination.
- e) Allergen containing foods **Must** be stored separately from non-allergen containing foods and different allergen containing foods. Separation **Must** take place both horizontally and vertically in storage locations.

### 2) Retained and Returned Products

The facility **Must** establish and maintain documented procedures to ensure that product that does not conform to specified requirements is not shipped. This control **Must** provide for identification, secured segregation, documentation, evaluation, disposition and reconciliation of product that is placed on hold.

- a) Policies and Practices for Retained and Returned Products.
  - i. The facility **Must** have a written policy for retained and returned products that describe individuals responsible for evaluating product and making decisions regarding disposition of it. The policy **Must** be understood by all authorized personnel.
  - ii. A Hold Tag procedure **Must** include a permanent written log of each product or item placed on hold.
  - iii. The facility **Must** have a policy and procedure for handling returned products.
  - iv. Returned products **Must** be identified and placed on hold immediately.
- b) Designated Areas for Retained and Returned Products.
  - i. Products retained or returned to a processing plant **Must** be handled securely.

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- ii. There **Must** be a designated, clearly identified area for returned or retained products or product **Must** exhibit an obvious physical indication of its status (i.e. on hold or returned). A computer block alone is not acceptable. There **Must** be some type of records indicating the product is returned or retained.
  - iii. Returned or retained products **Must** be clearly identified as such.
- c) Hold and Test Procedures.
- If any ingredient, material or finished product is tested for pathogens or other food safety concerns, the entire production lot of the item being tested **Must** be placed on hold pending test results. While product being tested is on hold, effective measures **Must** be taken to ensure that the item is not used in production or shipped.
- d) Verification and Release Documentation.
- i. Documents **Must** be available to show the current location of products not cleared for shipment as well as those that are authorized for shipment.
  - ii. Disposition or corrective actions **Must** be commensurate with the seriousness of risk identified. Disposition **Must** be dated and signed.
  - iii. All non-conforming products **Must** be handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.
  - iv. Product destined for destruction **Must** be adequately secured and disposed of promptly.
  - v. Disposition of non-conforming material **Must** be tracked to ensure that inventories are adjusted accordingly to facilitate recall.
  - vi. Damaged, sampled or destroyed finished product **Must** be recorded and proper adjustments to the product inventory records **Must** be made to accurately account for the inventory loss.
  - vii. An inventory log **Must** be maintained showing current product on hold and list the disposition of all released product with proper authorization.
  - viii. At least weekly there **Must** be a physical accounting of the product on hold to verify that actual product quantities match records. Discrepancies **Should** be treated as a serious food safety failure.

### 3) Storage Facility and Dock Maintenance

Storage areas **Must** be clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Racks and pallets will be used as necessary.

- a) Product **Must** not be stacked so that it blocks blowers or vents preventing the circulation of air.
- b) Items stored in all warehouses **Must** be a minimum of 6" off the floor (standard pallet heights are acceptable). Units of finished product may be stored on slip sheets or unit wrapping on the floor if the finished product is packaged in sealed, rigid containers and there is evidence of effective sanitation and pest management programs.
- c) Wall perimeters **Must** be maintained in a clear and clean manner and allow for pest management inspections and sanitation/housekeeping requirements.

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- d) Refrigerated and frozen storage rooms **Must** have their temperature controlled and monitored at least daily to the appropriate temperature requirements for their contents (typically <42° F for refrigerated and < -10° F for frozen).
- e) Pallets, racks and shelving **Must** be clean and in good repair.
- f) Floors and walls **Must** be in good condition and free from holes or damage.
- g) Floors under pallets, racks and in aisle-ways **Must** be clean and free from dirt, accumulated debris, spilled product or broken pallets.
- h) Shipping docks, dock plates, dock levelers and areas around and under the docks **Must** be clean and free from accumulated debris, food materials, water, etc. These areas **Must** be on the Master Sanitation Schedule.
- i) Slip-sheets **Must** be used when double stacking palletized finished product to prevent potential contamination from dirty or damaged pallets.

#### 4) Transport Condition

Transportation of food products **Must** only occur on acceptable carriers. Procedures **Must** be established to minimize concerns that could occur with improper product handling after the finished products leave the facility.

- a) Written procedures describing acceptable and/or unacceptable carrier conditions **Must** be available to shipping personnel.
- b) All outbound trailers **Must** be inspected for condition, odors, sanitation, and potential contamination sources. Inspection results **Must** be documented on shipping documents.
- c) All outbound refrigerated trailers **Must** be inspected for the proper operation and temperature setting of the refrigeration units, that the units are running during the loading of the trailer, and the trailer has been pre-cooled prior to the loading of product.
- d) Product **Must** not be loaded into unacceptable carriers. Trailers **Must** be cleaned, if necessary.
- e) Trailers and railcars **Must** not be cleaned at the dock, as this creates a warehouse sanitation problem and a potential for pest harborage.
- f) Slip-sheets **Must** be used when double stacking palletized finished products to prevent potential contamination from dirty or damaged pallets.

#### 5) Release Authorization to Ship Product

##### Food Contact Handling/Processing Area Requirements

Product can be shipped only with proper authorization.

- a) Processed product **Must** not be shipped until all the activities specified in the food safety and quality plan have been made available to and approved by management. Records **Must** be signed and dated by the person responsible for the release of product.
- b) Products produced under mandatory regulatory HACCP programs **Must** have an authorized signed release verifying that all HACCP records are complete, properly signed and that there are no CCP deficiencies prior to shipment.

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## J. TRAINING REQUIREMENTS (THE EMPLOYEE TRAINING PREREQUISITE SYSTEM)

To assure the effective implementation of the facility's food safety, food quality, and food defense programs there **Must** be a documented training program for both management and operational personnel. The facility **Must** have specific training requirements for all personnel relative to their job function and responsibilities. These training requirements **Should** be specific to each job classification. The following are minimum training requirements:

### 1) New Hire Training

- a) Training **Must** be provided to new hire operating and management personnel for at least the topics below. This training **Must** be completed within a predefined, reasonable period of time.
  - i. Food safety (including HACCP overview).
  - ii. Food defense.
  - iii. Personal hygiene and GMP's.
  - iv. Basic safe food handling.
  - v. Allergens, if applicable.
  - vi. Plant process and product specific training, as appropriate.
- b) Specific training for identified critical food safety jobs or HACCP Critical Control Point monitoring responsibilities **Must** be provided prior to the individual being assigned sole responsibility for such activities.
- c) Training to new managers, supervisors, and quality technicians **Must** include those food safety, food quality, and food defense policies and procedures for which they will have implementation and oversight responsibilities.

### 2) Training Language

- a) Training **Must** be provided in the language and presentation format that can be easily and clearly understood by the trainee.

### 3) Prerequisite Program Training

- a) The facility **Must** have a documented training policy describing the training program for food handling/processing sanitation employees (including new sanitation employees, applicable operators, temporary sanitation employees, and contract sanitation employees).
- b) This sanitation training **Must** include: Master Sanitation Schedule, Standard Sanitation Operating Procedures (SSOP), food handling sanitation, and sanitation chemical safety.

### 4) Refresher Training

- a) Refresher training in the topics identified in 1.a, b, and 3. above **Must** be provided and documented at least annually.
- b) Documented training covering updates/topical agendas on the above topics **Must** also take place at least quarterly. Regardless of the frequency at which updates/topical training is

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delivered, it **Must** be documented with at least the training topic, trainer, and attendees identified.

## 5) Proof of Knowledge

- a) A method to document individual understanding, such as testing at the conclusion of the training or documented performance evaluations by supervision, conducted within a reasonably short period of time (14 to 30 days), **Must** be an integral part of the training program.

## 6) Training Records

- a) Employee training records **Must** be maintained and include the information below for all staff levels:
  - i. Employee name.
  - ii. Training date.
  - iii. Employee position/title.
  - iv. Trainer name.
  - v. Training agenda and/or training content.
  - vi. Proof of knowledge.

## 7) Training Program Review

- a) The training program **Must** be reviewed and updated at least annually and take into consideration new regulatory, media, or customer issues, scientific and technological advances, or new or revised food safety, food quality, or food defense programs.

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## K. Food Defense (The Food Defense Prerequisite System)

In the United States, the National Infrastructure Protection Center has identified the food system as one of the eight critical infrastructures that could be negatively impacted by malicious attacks. This program is focused on malicious and intentional tampering and is called “Food Defense” by the U.S. Regulatory agencies. The following Food Defense section is in part based on the FDA/CFSAN — Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance. Key elements of this guidance have been included in this audit. For a full understanding of this guidance go to <http://www.cfsan.fda.gov/~dms/secguid6.html>

FSIS has also created a self-assessment guideline for food processors titled “Food Security Guidelines for Food Processors”. These guidelines are available at the following link: <http://www.fsis.usda.gov/oa/topics/SecurityGuide.pdf>. The associated self-assessment checklist is available at: [http://www.fsis.usda.gov/PDF/Self\\_Assessment\\_Checklist\\_Food\\_Security.pdf](http://www.fsis.usda.gov/PDF/Self_Assessment_Checklist_Food_Security.pdf)

The checklist is a very useful tool that helps drive the process of evaluating a facility’s Food Defense status. It addresses all aspects of Food Defense including plan management; interior to exterior physical security; receiving, storage and shipping; utilities and personnel. In part, it has been used along with the guidelines listed above to establish the Food Defense criteria that follow.

In addition, the following criteria are based on meeting expectations already covered in this audit (receiving & shipping, allergens, labels, etc.) that would otherwise be listed as Food Defense concerns.

Additional food defense guidance, for program development purposes, can be found in the Product Security - Expectations and Criteria Manual available at [www.nsf.org](http://www.nsf.org)

The specifics of a Food Defense program **Must** be considered confidential. Only the essential details **Should** be made available to employees.

- The FDA 24-hour Emergency Contact Number is 301-443-1240.
- USDA Food Safety and Inspection Service, Emergency Response Division, 24-7 Emergency Operations Center number is 202-720-5711.
- CFIA (Canadian Food Inspection Agency) Media Relations number is 613-228-6682 or <http://www.inspection.gc.ca/english/corpaffr/relations/contacte.shtml>
- Access to the FDA Bioterrorism website by going to: <http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html>

### 1) Management

Management **Must** develop and implement a comprehensive Food Defense program with specific emphasis on identifying those policies and procedures necessary for a comprehensive food supply protection program. Management may utilize both internal and external resources to identify, organize, communicate and implement a documented Food Defense program that is fully understood, as applicable, by facility employees, suppliers, customers, and regulatory agencies.

- a) A Food Defense team **Must** be established that will evaluate the vulnerabilities and risks that exist from food sourcing, storage, handling/processing, shipping of finished goods, and personnel.

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- b) Each facility **Must** conduct and document a Food Defense Risk Evaluation utilizing an Operational Risk Management (ORM), CARVER + Shock (program used by U.S. regulatory agencies) or similar valid process. This process will help prioritize the preventive measures that are most likely to have the greatest impact on reducing the risk of tampering or other malicious, criminal, or terrorist actions against food.
- c) Based on the Food Defense Risk Evaluation and the priorities established by the Food Defense team, the facility **Must** identify and implement control measures that will eliminate or significantly reduce the risk of external and internal intentional adulteration of food. (No details of food defense control measures will be identified in the audit report unless requested by the plant).
- d) Product and facility security roles and responsibilities **Must** be documented and defined regarding the development and maintenance of guidelines, training and enforcement of requirements and procedures.
- e) The Food Defense program **Must** be reviewed at least annually to verify and validate that the implemented food defense control measures are effective and no new food defense risks are present.
- f) Required Food Defense Program Control Measures.
  - i. Food Item Isolation — It is essential to isolate and remove any potentially compromised food item or material. As dictated by the circumstances, a comprehensive assessment by food safety personnel, general management and the applicable regulatory agency **Must** be performed to determine the suitability of ingredients and plant security prior to resuming any production operations.
  - ii. Computers — A procedure to back-up computer systems and documentation critical to food safety **Must** be developed and implemented. Access to computer systems for the purpose of document changes **Must** be limited to identified, authorized personnel.
  - iii. Off site warehousing — All off-site warehousing, manufacturing, and distribution locations that are in the facility’s control **Must** be included in the facility’s Food Defense programs, unless it is documented that these locations have an independent Food Defense program.
  - iv. Facility Registration — The warehouse or distribution center **Must** demonstrate proof of having registered their facility with the FDA under the PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002 or the USDA, as applicable. Failure to register or show proof or "certification" of registration is a “Major Nonconformance”.
  - v. Unusual Occurrences — Employees **Must** be trained to report unusual food defense occurrences. There **Must** be a procedure in place that makes it easy to do so quickly and in an appropriate manner. Reported occurrences **Must** be documented and assessed by management and corrective actions taken, as necessary. An unusual occurrence could be an employee who acts unusual (i.e. unhappy, despondent, antagonistic or without an identifiable purpose), stays unusually late or arrives unusually early, accesses unauthorized files, information or areas of the facility outside of their areas responsibility or asks unusual questions.

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## 2) Human Element

An effective system **Must** be in place to assure that only authorized personnel have access to the facility and that their entrances and exits are monitored and recorded. Internal risk.

### a) Internal risk

- i. Screening: A written screening program **Must** be in place for all employees, including management, seasonal and temporary employees and contracted services (e.g., pest control, cleaning services, maintenance contractors, etc). Any persons not included in this pre-hiring screening program **Should** be covered by the facility visitor policy.
- ii. Positive Employee Identification: There **Must** be a documented and implemented system for the positive identification and recognition of all employees entering the facility.
- iii. Training: A written program **Must** be developed and implemented to train employees in the food defense rules of the facility. This program **Must** explain the severe criminal nature of tampering with or deliberate contamination of food products and **Should** include: plant specific rules, how to recognize and address signs of and evidence of tampering, reporting instructions in the event of a food defense issue (threats, chemical spills, wrong doing, etc.).
- iv. Employees: The facility **Must** maintain a current and accurate roster of employees and work assignments. Employees **Must** be prohibited from bringing personal items such as purses, cases, containers, lunch boxes, etc. into processing areas. Temporary employees **Must** be fully supervised at all times.

### b) External Risk.

- i. Contractors: The facility **Must** have documented policies and procedures that define food safety and food defense requirements for on-site contractor employees. There **Must** be a contractor employee sign-in and sign-out log that also verifies they have received a copy of the facility's GMP, food safety hygiene, and food defense rules. Contractor personnel **Must** be restricted to defined work areas and not allowed into other areas of the facility.
- ii. Visitors: Facility **Must** have documented visitor policies and procedures. There **Must** be a visitor sign-in and sign-out log that also verifies they have received a copy of the facility's GMP, food safety personal hygiene, and food defense rules. Visitor authenticity **Must** be verified by photo identification. Visitors **Must** always be accompanied by a designated, responsible employee when in the facility.

## 3) Facility

### a) External Risk.

- i. Policies and procedures **Must** address how access to and from the facility grounds and the manufacturing and storage areas are restricted to non-employees.
- ii. A schematic of the facility and outside grounds **Must** be available that identifies all entrances into the building, accesses to the roof and accesses to external sensitive areas (bulk storage tanks, bulk loading/unloading areas, etc.).

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- iii. Access to external sensitive areas **Must** be restricted and secured. All employee entrances **Must** be locked or manned to ensure unauthorized persons are not permitted access. Water supply, utilities, gas, bulk ingredient unloading and storage and chemical storage are some areas that **Must** be restricted. Local regulations may have limitations on restricting access.
  - iv. During off hours or times of shutdown; (i.e., evenings, weekends, holidays or vacations), all external ingredient, water, and bulk storage tanks **Must** be effectively secured.
  - v. At all times, the following **Must** be secured when not in use: non-traffic doors (e.g. emergency exits), dock doors, railcar unloading areas, unloading pits, pneumatic pipes and hoses used for receiving bulk ingredients. Emergency doors **Must** be alarmed.
- b) Internal Risk.
- i. The facility **Must** have a documented process for issuing, tracking and retrieving keys, identification badges, electronic access devices, and passes for the buildings and for secure areas.
  - ii. The food defense team **Must** identify potential sensitive areas within the facility's manufacturing and storage areas. Policies and procedures **Must** address how access to and from identified sensitive areas is restricted.

#### 4) Operations

- a) All aspects of facility operations **Must** be evaluated for vulnerability to tampering and sabotage.
- b) Identified sensitive production and storage areas/conditions **Must** have documented policies and procedures developed and implemented to provide control measures addressing each potential risk.

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## DEFINITIONS

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**ALLERGEN:** Food compounds can cause an allergic or food intolerance response in sensitive individuals. Food allergens elicit serious adverse reactions in some individuals. Allergic individuals can tolerate very little of the offending food.

### United States

In the United States, allergens of concern include:

- Milk,
- Egg
- Fish
- Crustacean Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soybeans

The US-FDA Food Allergen Labeling Act that goes into effect January 1, 2006 defines allergens as follows:

The term 'major food allergen' means any of the following:

- 1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
- 2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:
  - a) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
  - b) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w)."

(The exemptions would include those ingredients that are submitted for exemption and granted by the Secretary, those ingredients where scientific evidence is presented that demonstrates the allergen is not present or those where the allergen does not present an allergenic response that poses a risk to human health)

### Canada

Canadian definition of allergens is as follows:

\* Peanut or its derivatives, e.g., Peanut - pieces, protein, oil, butter, flour, and mandelona nuts (an almond flavored peanut product) etc. Peanut may also be known as ground nut.

\* Tree Nuts (almonds, Brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts (pinyon, pinon), pistachios and walnuts or their derivatives, e.g., nut butters and oils etc.

- Sesame or its derivatives, e.g., paste and oil etc.
- Milk or its derivatives, e.g., milk caseinate, whey and yogurt powder etc.
- Eggs or its derivatives, e.g., frozen yolk, egg white powder and egg protein isolates etc.
- Fish or its derivatives, e.g., fish protein and extracts etc.
- Shellfish (including crab, crayfish, lobster, prawn and shrimp)
- Mollusks (including snails, clams, mussels, oysters, cockle and scallops) or their derivative, e.g., extracts etc.

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- Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates etc.
- Wheat or its derivatives, e.g., flour, starches and grains etc.
- Sulphites, e.g., sulphur dioxide and sodium metabisulphites etc.
- Others (as considered necessary)
- (See Sensitive Ingredients)

**CALIBRATION OF INSPECTION, MEASURING AND TEST EQUIPMENT:** Calibration of measuring equipment against an accepted industry standard **Must** be conducted at a frequency sufficient to confirm accuracy and precision.

**CERTIFICATES OF ANALYSIS:** Written documentation of specific microbiological, chemical or functional analysis based on customer specifications that are required on lots of product or ingredients prior to customer acceptance.

**CERTIFIED LABORATORY:** A laboratory that is able to calibrate its performance standards by performing crosscheck sample analysis with an accredited lab on a quarterly basis.

**CONTINUING LETTER OF GUARANTEE:** Document provided by supplier indicating that all food, food contact packaging materials, inks, coatings, etc. comply with all provision of the Food, Drug and Cosmetic Act and Amendments.

**CORRECTIVE ACTION:** Action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.

**FOOD CODE:** Reference Guide published by U.S. Dept. of Health and Human Services, Public Health Service and Food and Drug Administration, 2005 and appropriate supplements.

**GOOD MANUFACTURING PRACTICES (GMPs):** Manufacturing Guidelines as cited in the Code of Federal Regulation 21, Part 110.

#### HACCP DEFINITIONS

**CCP Decision Tree** – A sequence of questions to assist in determining whether a control point is a critical control point (CCP).

**Control** – Managing conditions of an operation to maintain compliance with established criteria.

**Control Measure** – Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

**Control Point** – Any step in the process at which biological, chemical or physical hazard can be controlled, reduced or eliminated.

**Corrective Action** – Documented procedures followed when a process or product deviation occurs.

**Criterion** – A requirement on which a judgment or decision can be based.

**Critical Control Point** – A step at which control can be applied and is essential to prevent or eliminate a food safety hazard likely to occur or reduce it to an acceptable level.

**Critical Limit** – A maximum and/or minimum value to which a biological, chemical or physical parameter **Must** be controlled at a CCP to prevent, eliminate or reduce the occurrence of a food safety hazard to an acceptable level.

**Deviation** – Failure to meet a critical limit.

**HACCP** – (Hazard Analysis and Critical Control Point) A systematic approach to the identification, evaluation and control of food safety hazards reasonably likely to occur.

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**HACCP Plan** – The written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

**HACCP System** – The result of the implementation of the HACCP plan.

**HACCP Team** – The group of people who are responsible for developing, implementing and maintaining the HACCP system.

**Hazard** – A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

**Hazard Analysis** – The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and **Must** be addressed in the HACCP plan.

**Monitor** – To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.

**Prerequisite Programs** – All procedures used in the facility, which address operational conditions providing the foundation for the HACCP system.

**Severity** – The seriousness of the consequences of exposure to the hazard.

**Step** – A point, procedure, operation or stage in the food system from primary production to final consumption.

**Validation** – That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented is effectively controlling the hazards that are reasonably likely to occur.

**Verification** – The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

**INTERNAL G.M.P. AUDITS:** Audits conducted by the company by the company or for the company that assess the company's compliance to GMPs (Good Manufacturing Practices).

**MUST:** A mandatory requirement of the standard.

**POTABLE WATER:** Water that is safe for human consumption.

**PRE-REQUISITE PROGRAMS:** Required programs that **Must** be implemented by a plant in order to produce a safe and quality product and support a HACCP program. Examples would be Sanitation Programs, Good Manufacturing Programs, Pest Management Programs, etc.

**PREVENTIVE ACTION:** Action taken to eliminate the causes of a potential nonconformity, defect or other undesirable situation in order to prevent occurrence.

**PROCESS CAPABILITY:** The statistical determination of the capability of a process to produce a product within specified limits.

**REPACKAGING:** Activities whereby previously packaged product is opened to the environment and placed in new packages. This activity requires elements such as labels, net or random weight, and coding.

**REPEAT FINDING** : A previously cited deficiency, which has not been effectively addressed with corrective action.

**RETAINED:** Product that is being held from further distribution pending information necessary to determine the proper disposition of the product.

**RETURNED:** Returned products are products that have left the control of the facility being audited.

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**REWORK:** Product which has the physical identity altered and is reincorporated into another product.

**RISK:** This is the likelihood that a food safety hazard will happen.

**SENSITIVE AREAS:** Sensitive areas are those areas that provide a greater likelihood or severity for contamination to occur. In the case of Food Defense, a sensitive area is one that poses a greater likelihood of deliberate contamination if left unattended.

**SENSITIVE INGREDIENTS:** Food intolerances (other than allergens) which affect a limited number of individuals and which do not involve immunologic mechanisms.

**SHOULD:** **Should** is used to express what is highly recommended, probable or expected in most situations.

**STATISTICAL CONTROL:** The control of a process to meet a predetermined outcome through the gathering of data related to the process and the mathematical evaluation of the data to predict and set limits for conformance to the predetermined outcome.

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