# SUPPLIER ASSURANCE

## FOOD WAREHOUSE AND DISTRIBUTION AUDIT STANDARD

PROGRAM REQUIREMENTS MANUAL

APRIL 1, 2020

| | |
|---|---|
| **Version – Revision:** | 6.0 |
| **Authorized By:** | NSF Supplier Assurance |
| **Date:** | April 1, 2020 |
| **Created By:** | Supplier Assurance Technical Management |
| **Scheme/Customer:** | NSF Supplier Assurance Proprietary |

# REVISION HISTORY

| Version | Date | Manager | Description |
|---|---|---|---|
| 6.0 | April 1, 2020 | SA Technical Management | • Updated formatting, layout, sentence structure and grammar<br>• Change in title<br>• Inclusion reference to customer, industry best practices and global regulatory requirements<br>• Section B. HACCP incorporation of Food Safety Plan language<br>• Combine previous section into one: Approved Supplier, Receiving, Storage & Shipping/Inventory Control<br>• Additional Criteria for facilities that repack or resize product (thus exposed product criteria)<br>• Incorporation of ESSENTIAL elements (Required Compliance)<br>• Removal or change of all SHOULD requirements to SHALL.<br>• Removed allergen list and replaced with link to the FARRP international allergen list |

# 1 TABLE OF CONTENTS



 

# 2 INTRODUCTION

NSF International's Supplier Assurance audit focuses on the development, implementation and control of systems that impact Food Safety, Food Quality and Food Defense for food holding facilities, including warehouses and distribution centers. The expectations outline the management programs and performance criteria required for a modern food holding facility to meet the basic food safety, quality, and defense requirements of the public, regulatory agencies and customers.

The expectations are considered essential to keeping safe, wholesome and quality products on a consistent basis. Demonstrating consistent conformance with this standard is the expectation of our clients.

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

This manual provides criteria and requirements that the facility will be audited against and is generic for all types of food holding establishments. Standards shall be rigorously applied when there is direct food contact by handling in any way. In all cases, Section B HACCP/Food Safety Plan applies.

Some specific criteria may not be applicable. It is the responsibility of the facility to provide proper justification in such cases. Likewise, additional criteria may be applied based on changing regulatory requirements, specific client needs or the ever-changing food safety and food defense environment.

Note: 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 holding facilities located within the U.S.A., as well as those that are located in countries outside the U.S.A. but export to the U.S.A., domestically, shall meet customer expectations and FDA/USDA regulatory requirements. Where this Standard is applied in food holding facilities in jurisdictions outside of the U.S.A. for food not intended for export to the U.S.A., the regulations and customer expectations in those jurisdictions shall apply.

The following expectations and supporting documentation are based on customer specifications, industry best practices and regulatory Acts, Amendments and Regulations, including, but not limited to, those enforced by agencies globally.

**NOTE:** Some warehouses and distribution centers may engage in food processing activities as defined by the FDA or USDA. In those instances, the NSF Manufacturing audit will be the basis for assessment.

 

# 3 DOCUMENTATION

## DOCUMENTS REVIEWED DURING THE AUDIT

This list is to provide guidance to the type of documents and procedures the auditor may ask to review during the audit. A document and records review will be conducted during the audit. There may be additional documents, policies and procedures requested that are not included in this list. Some of these documents may not apply to every type of facility. When policies are stored electronically and/or managed at a corporate location, it is the facility's responsibility to provide access to this information during the audit. Documents and records that cannot be produced on the request of the auditor during the duration of the audit shall be considered as not conforming to this Standard.

### EXAMPLE DOCUMENTS AND RECORDS THAT COULD BE REVIEWED DURING THE AUDIT

- Facility management organization chart and QA responsibilities
- Food Safety and Quality Policies and Procedures Manual
- Product list or proposed product list for client
- Product specifications for client or facility product specifications
- Policy and documentation of management and employee training
- Detailed Product Recall Manual, including records of mock recalls
- Regulatory compliance policies and documents of regulatory visits or comments
- Document management and record keeping policies and procedures
- Change management policies to address changes in management, policies or procedures
- Emergency or catastrophic event product management program
- Policy compliance and effectiveness review program
- Consumer complaint policy & procedures and records
- Current, signed HACCP/Food Safety Plan with team members designated
- HACCP/Food Safety Team member credentials
- Documented records of HACCP team program oversight
- Plans are available for auditor review
- Flow Chart of process (this would include the repack and resizing steps)
- Hazard analysis and documentation
- Critical Control Point (CCP) validation, including application of relevant process capability evaluations (clarify this point)
- Monitoring and Corrective Action policies and documentation
- Repacking/Resizing policies and procedures in HACCP plan and Flow Chart
- Records Management & Security policies
- Verification and Validation procedures and documentation
- Prerequisite program documentation and performance records

 

**NOTE:** HACCP/Food Safety Plan shall include the following:

- Identification of HACCP team
- Description of the food and its distribution
- Description of customer and intended use
- Documented detailed hazard analysis
- Detailed process flow charts, showing all inputs, outputs, and recycle pathways
- Annual review (at minimum) by HACCP team and signed by the most senior on-site executive responsible for the facility and its operation

## ALTERNATE PROCEDURES/PROCESSES - DEVATION FROM THE STANDARD

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 shall accomplish the same degree of control as indicated in the criteria. The sub-section shall be considered applicable and rated based on the level of compliance to the intention of the criteria and the alternative procedure shall be noted in the comments.

It is the responsibility of the site to produce documented evidence in the form of a risk assessment, scientific data, regulatory guidance, data trending, etc. to support the alternate procedure/practice that varies from that of the expectation. The site shall present all evidence at the time of the audit to the auditor.

If a specific client allows a facility's deviation from an expectation or specification of this document, the facility shall obtain written approval from the client for the variance/deviation prior to the audit process. This approval shall be made 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.

 

# 4 TERMS AND DEFICIENCY CLASSIFICATIONS

Within the expectations of this Standard, the following terms have these meanings:

- **Shall –** An absolute requirement.
- **Annually** - a 12 month period.

The audit report will not contain recommendations or suggestions for enhancement for improvement, nor will non conformances be cited for situations where best practices are not implemented in a facility (provided that the expectations of this Standard are being met). Conversely, no additional points are awarded for best practices. The audit is intended as an objective assessment of the food safety management programs in a food facility.

The auditor will evaluate documented policies and procedures, past and present monitoring records and facility conditions and personnel practices as they exist at the time of the visit. Ratings and scoring will be based on these observations. Corrective actions taken during the audit will not remove any non-conformance observations nor change the scoring, but the auditor will document those immediate corrective actions in the audit report. In addition, any documentation provided to the auditor after the conclusion of the exit meeting will not change scoring.

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

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

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

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

a. Deficiencies of an element present a high probability of food safety or regulatory failure.
b. Significant improvement is needed to meet the expectations.
c. HACCP/Food Safety Plan requirements have not been fully documented or implemented
d. An element of the standard has not been documented (if required) or implemented
e. A situation is observed where, based on objective evidence, there is significant doubt as to the conformity of product being supplied.
f. 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"** is the assessment made when:

a. There is clear objective evidence of or direct observation that product is unsafe, could potentially cause serious illness or death or is a risk to health and is subject to a Class I or Class II recall.
b. There is a complete failure to meet an **ESSENTIAL** element of the expectations as listed in the **ESSENTIAL** Elements Chart in this section.

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

Some expectations of this Standard are identified as **ESSENTIAL**. A complete failure to meet the intent of these expectations shall be assessed as a critical non-conformance and cause audit failure.

The following are **ESSENTIAL** elements in the Supplier Assurance Expectations:

| | |
|---|---|
| A3.5 Traceability. | The lack of any system to trace product as per regulatory requirements and customer expectations shall be assessed as a Critical Non-conformance. |
| A 4.2 Records. | Evidence of intentional record falsification shall be assessed as a Critical Non-conformance. |
| B 6.1 Specific correction actions to deal with deviations shall be in place for each CCP. | Failure to take corrective action for a critical limit deviation shall be assessed as a Critical Non-conformance. |
| C 1.1. Potability of water, ice and steam supply. | Use of non-potable water as part of or in contact with food, food contact equipment or other inappropriate use shall be assessed as a Critical Non-conformance. |
| C2.2 Facility construction and layout is not a source of contamination | Any condition in the facility that, on the basis of objective evidence or observation, results in product contamination and adulteration shall be assessed as a Critical Non-conformance. |
| C6.1 Equipment is not a source of contamination. | Finding through observation or on the basis of objective evidence that equipment or food contact materials are unsuitable for use with food or that equipment condition is a cause of product contamination shall be assessed as a Critical Non-conformance |
| C 9.2 Equipment affecting food safety is effectively calibrated. | Equipment found to be out of calibration leading to potential for illegal or unsafe food shall be assessed as a Critical Non-conformance. |
| E1.3 Pests are not a source of contamination. | Observation of pests on or in food or food contact packaging, shall be assessed as a Critical Non-conformance. |
| F4.1 Allergen Management is effective. | Evidence of cross-contact with allergens that will result in a threat to health and would result in a Class I or Class II recall shall be assessed as a Critical Non-conformance. |

 

# 5 SCORING GUIDELINES

## EXPLANATION OF SECTION SCORINGS:

Section scorings is calculated using the following formula. Note the calculation of a section score is different than the calculation of the overall audit score.

- **Non-Conformance** = deduction of 5% per finding
- **Major Non-Conformance** = deduction of 25% per finding
- **Critical** = deduction of 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 are made as follows:

- **Non-Conformance** = 1% deduction per finding off the total score
- **Major Non-conformance** = 10% deduction per finding off the total score
- **Critical Non-conformance** = 25% deduction per finding off the total score

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

While a score is provided for this report, NSF strongly recommends putting 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 this Supplier Assurance Audit

**Scoring Example 1**

Section A contains 2 nonconformance ratings and Section B contains 1 major non-conformance, 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 non-conformances and -10% for the major nonconformance) and the overall audit rating is "Needs Improvement"

**Scoring 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 N (90% Section Score). If there are no further non-conformances then the overall audit score is 78% (-2% for the 2 non-conformances and -20% for the 2 major non-conformances) and the overall audit rating is "Significant Improvement Needed"

## CORRECTIVE ACTION AND IMPROVEMENT

Improvements and Corrective actions for any finding noted in this audit should be implemented and documented. The findings noted in the audit should be evaluated and reviewed regardless of the numerical score.

Note: Corrective action is defined as the correction of the immediate problem as well as prevention of reoccurrence of the problem.

## REPEAT DEFICIENCIES

Repeat assessments of non-conformance, 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 an additional downgrade of the audit question's rating, depending on nature of the deficiency and its impact on food safety at the facility. In addition, repeat non-conformances without effective correction actions taken shall be reflected as a non-conformance against management commitment (A.1.3)

# 6 EXPECTATIONS OF THIS STANDARD

## A: ADMINISTRATION & REGULATORY COMPLIANCE

### A1. ADMINISTRATION, MANAGEMENT AND ORGANIZATION

#### 1.1. THERE SHALL BE A FACILITY MANAGEMENT ORGANIZATION CHART INDICATING THE REPORTING STRUCTURE OF THE FACILITY OPERATING DEPARTMENTS.

a. There shall be an up to date organizational chart outlining the organizational structure of all positions.
b. The facility shall document job descriptions and competencies for job duties for the roles included in the organization structure.
c. There shall be a suitably trained member of the facility's management team available at all times during operating hours.

#### 1.2. THERE SHALL BE IMPLEMENTED AND DOCUMENTED POLICIES AND PROCEDURES THAT ADDRESS RELEVANT FOOD SAFETY, QUALITY AND SECURITY REQUIREMENTS FOR THE RECEIVING, HANDLING, STORAGE AND SHIPPING OF PRODUCT.

a. A quality assurance program shall be fully described and include a food safety, quality and security policy and key quality measurables (such as key performance indicators) that drive continuous improvement at the facility.
b. The facility shall have documented policies and procedures covering all aspects of product receipt, storage and shipping. These policies and procedures shall be well organized, available, current, dated and approved by an authorized person.
c. Policies and procedures shall be reviewed for effectiveness annually with reporting on this review to the facility's senior management.
d. The facility shall have a documented policy to manage change. The policy shall describe how to effectively communicate changes in personnel and changes in documents (such as specifications, policies, and procedures) and records to all levels of the facility's organization.

#### 1.3. THERE SHALL BE MANAGEMENT COMMITMENT AND ACTIVE SUPPORT OF THE FACILITY'S FOOD SAFETY, QUALITY AND SECURITY SYSTEMS.

a. Adequate financial and staffing resources shall be provided for food safety, product quality, and security programs, as well as for overall facility and equipment upkeep.
b. There shall be management participation in the audit process and a commitment to the completion of corrective actions resulting from both outside and internal audits and inspections.
c. There shall be documented management reviews (internal audits) to assess the level of conformance to operational policies. Management reviews of internal audits shall be conducted at least annually.

 

## A2. REGULATORY COMPLIANCE

### 2.1. A FILE OF REGULATORY AUDIT VISITS AND REPORTS SHALL BE MAINTAINED.

a. The facility shall maintain a file of regulatory actions, visits, reports or other notifications received from any regulatory agency.
b. Written responses with appropriate corrective actions shall be documented.
c. The facility shall provide copies of the above reports to the auditor for evaluation of corrective and preventive actions.

### 2.2. THE FACILITY SHALL HAVE A DOCUMENTED PROCESS FOR THE IDENTIFICATION OF REGULATIONS THAT ARE APPLICABLE TO THEIR SPECIFIC ACTIVITIES. THIS PROCESS SHALL INCLUDE IDENTIFICATION OF REGULATIONS FOR PRODUCTS IN COUNTRIES IN WHICH THE FACILITY'S PRODUCTS ARE EXPORTED.

a. The facility shall have a documented procedure outlining how they ensure that all regulatory requirements are met for all applicable activities. The procedure shall also include how the facility ensures regulatory requirements are met when products are exported to other countries. The facility shall be able to show that they are properly licensed to operate.

## A3. PRODUCT IDENTIFICATION AND TRACEABILITY

### 3.1. THERE SHALL BE A DOCUMENTED, CURRENT AND IMPLEMENTED FACILITY SPECIFIC RECALL PLAN.

a. The recall manual shall be current and include a detailed process of how complaints, information or crises leading to withdrawal, recalls or potential recalls are processed.
b. Recall procedures shall include investigation, analysis and corrective and preventive action where appropriate.
c. Decision making protocol, risk assessment guidelines, documents and individuals responsible for the recall execution shall be clearly stated.
d. The recall program shall identify how all materials/products are identified/labeled to ensure traceability from receipt through shipment.
e. The recall plan shall be reassessed for effectiveness at least annually and as changes are made.

### 3.2. RECALL MANAGEMENT RESPONSIBILITY SHALL BE ASSIGNED.

a. There shall be a designated recall team.
b. The recall team roster shall include the responsibilities for all team members including alternates.
c. There shall be back up personnel assigned for each team role.
d. There shall be a designated team leader or coordinator.

 

e. There shall be a contact list of all personnel within the company who would be involved in a recall. The list shall include 24 hour contact numbers. The list shall be up to date and current. Additionally, a contact list shall be present for all customers, legal representation and regulatory entities who would need to be contacted in the event of a recall.

### 3.3. TRACEABILITY EXERCISES SHALL BE CONDUCTED AT A MINIMUM OF TWICE ANNUALLY.

a. Trace exercises shall be conducted at a minimum of twice annually, with at least one of these exercises completed outside of normal business hours. If the facility operates 24/7, the site shall perform at least on exercise outside the standard operating hours of 8:00-17:00 or perform the trace exercise on a weekend day (Saturday or Sunday) or on a recognized holiday.
b. Trace exercises shall be conducted on both finished product and raw materials, including food contact packaging.
c. Traceability exercises shall demonstrate a 99.5% to 105% accounting within 4 hours, taking into account normal loss, waste or shrinkage.

**NOTE:** An effective traceability exercise is one where a shipped product exercise or an exercise where identified incoming food items or food contact packaging materials are traced to 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.

### 3.4. A DOCUMENTED MANAGEMENT ASSESSMENT SHALL BE COMPLETED AFTER EACH TRACEABILITY EXERCISE TO EVALUATE THE EXERCISE FOR NEEDED IMPROVEMENTS AND ANY CORRECTIVE ACTIONS TAKEN.

a. Records from the exercise shall include a material (mass) balance sheet taking into account:
   - Total product shipped and destination.
   - Affected product on hand.
   - Product otherwise categorized (e.g., damaged, lost, samples).
   - Product unaccounted for.
   - A calculated percent recovery.
   - Start and end times for the exercise.

b. All corrective actions resulting from trace exercises are documented and implemented prior to a subsequent trace exercise.

### 3.5. **ESSENTIAL** THERE SHALL BE EVIDENCE OF TRACEABILITY FOR ALL FOOD, AND FOOD CONTACT PACKAGING MATERIALS. SHIPPING RECORDS SHALL BE AVAILABLE.

a. Materials shall be traceable including:
   - Food.
   - Food contact packaging materials (and/or food contact utensils, cups, bowls, dishware, etc.).
   - Food contact materials (e.g., utensils, cups, bowls/containers, dishware, etc.).

- Samples (e.g., reference, retention).

b. The program shall identify how all materials are identified/labeled to ensure traceability from receipt through shipment.

***ESSENTIAL ELEMENT: THE COMPLETE LACK OF A SYSTEM TO TRACE INGREDIENTS AND FINISHED PRODUCT AS PER REGULATORY REQUIREMENTS AND CUSTOMER EXPECTATIONS SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

### 3.6 THE FACILITY SHALL BE ABLE TO SUCCESSFULLY DEMONSTRATE THE TRACEABILITY SYSTEM DURING THE AUDIT.

a. The facility shall be able to demonstrate that they are able to effectively trace product during the audit. The auditor will select a product and the facility shall demonstrate how they are able to locate how the product will be tracked to the supplier and the first customer (one step up and one step back). Successful demonstration will be accounting for 99.5% to 105% within a four hour time frame.

## A4. RECORDKEEPING AND RETENTION

### 4.1. THE FACILITY SHALL HAVE A RECORD RETENTION AND STORAGE POLICY.

a. The facility shall have procedures for the retention and storage of records relevant to food safety controls or evaluation of food safety, food quality and food defense.

b. The time period for retention of records shall be documented by the site and shall be as per customer requirements, and/or self-life of the product while under control of the facility. Obsolete documents shall be clearly identified and retained for historical purposes.

### 4.2. **ESSENTIAL** RECORDS RELEVANT TO FOOD SAFETY CONTROLS OR EVALUATION OF FOOD SAFETY, FOOD QUALITY AND FOOD DEFENSE SHALL BE PROPERLY COMPLETED.

a. All records shall be:
- Genuine and legible.
- Initialed by operator and independently verified for accuracy.
- Records shall be self-explanatory and complete.
- They shall be completed in ink on a timely basis with an accurate date and time. There shall be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation shall be provided.
- Errors shall be marked with single line-out and initialed and/or marked to record or chart out-of-control or out-of-specification conditions.
- Records shall be easily retrievable and secured. Quality systems shall be established to properly store and retrieve analytical information, documents, reports, records, etc. Records and reports of analytical information gathered by organizations (internal and external) shall be cataloged and maintained in a fashion that provides feedback for operational control.

 

- If documents and/or records are managed electronically, applicable authority for change and change dates shall 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. Electronic records shall be effectively access controlled.
- Records shall indicate disposition of product and corrective actions taken.

*** ESSENTIAL ELEMENT: EVIDENCE OF INTENTIONAL RECORD FALSIFICATION SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

## A5. CRISIS AND NATURAL DISASTER MANAGEMENT

### 5.1. CRISIS MANAGEMENT POLICIES AND PROCEDURES SHALL BE DEVELOPED TO ADDRESS ANY CRITICAL SITUATIONS THAT MAY OCCUR (E.G., PRODUCT RECALLS AND BUSINESS CONTINUITY INTERRUPTIONS, SUCH AS NATURAL DISASTERS, CATASTROPHIC EVENTS AND OTHER EMERGENCY SITUATIONS INCLUDING, BUT NOT LIMITED TO, POWER OUTAGE, TAMPERING).

a. The policy shall assign management responsibility for the following activities in the event of crisis:
   - Determine the status of food or food contact packaging materials involved in a crisis event situation.
   - Ensure there is a documented evaluation of all product involved in a crisis event.
   - Ensure there is a documented release of any affected product prior to shipping.

b. Records of the activities are maintained.

### 5.2. MANAGEMENT RESPONSIBLE FOR CRISIS MANAGEMENT SHALL CONDUCT MOCK CRISIS EXERCISES AT MINIMUM ANNUALLY.

a. These exercises shall include all of the activities outlined in 5.1.

## A6. CUSTOMER/CONSUMER COMPLAINT MANAGEMENT

### 6.1. THE FACILITY SHALL MANAGE CUSTOMER AND/OR CONSUMER COMPLAINTS.

a. There shall be a written procedure for handling and documenting customer and/or consumer complaints that addresses responsibilities, response time, root cause investigation and, where appropriate, corrective action.

b. Records of complaints received and actions taken shall be made available to the auditor.

## B: HACCP/FOOD SAFETY PLAN

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-based system shall be developed by each establishment and tailored to its individual products, storage and distribution conditions. The HACCP plan shall analyze and identify appropriate Preventive Control measures for any biological, chemical and physical hazards deemed significant from procurement, receipt, handling storage and distribution of food items and food contact packaging. It is essential that the unique conditions within each facility be considered during the development of all components of the Food Safety Plan.
Approval of the Food Safety Plan shall be documented with a written signature by top management. The plan shall be kept current with regular effectiveness reviews by the Food Safety management team. Individuals knowledgeable of HACCP and Food Safety concepts and their execution shall either participate in or verify the completeness of the hazard analysis and the Food Safety Plan.

**Note:** If the product is subject to a mandatory HACCP plan requirement, the plan shall be in compliance with the regulatory requirements. For example, facilities that receive, handle, store, and distribute seafood products are required by FDA 21 CFR Part 123 to develop and implement a Seafood HACCP plan. If a mandatory HACCP plan is not required, the facility shall 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.

**Compliance with US FDA Requirements:** US warehouse and distribution centers are subject to the requirements of 21 CFR 117.

- At minimum, Current Good Distribution Practices must be followed
- If a facility that is solely engaged in the storage of unexposed* packaged food stores any such refrigerated packaged food that requires time/temperature control for safety, the facility must conduct the following activities as appropriate to ensure the effectiveness of the temperature controls:
    - Establish and implement temperature controls adequate to significantly minimize or prevent the growth of, or toxin production by, pathogens;
    - Monitor the temperature controls with adequate frequency to provide assurance that the temperature controls are consistently performed;
    - If there is a loss of temperature control that may impact the safety of such refrigerated packaged food, take appropriate corrective actions to:

      (i) Correct the problem and reduce the likelihood that the problem will recur;

      (ii) Evaluate all affected food for safety; and

      (iii) Prevent the food from entering commerce, if you cannot ensure the affected food is not adulterated
    - Verify that temperature controls are consistently implemented by:

(i) Calibrating temperature monitoring and recording devices (or checking them for accuracy);

(ii) Reviewing records of calibration within a reasonable time after the records are created; and

(iii) Reviewing records of monitoring and corrective actions taken to correct a problem with the control of temperature within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days;

- Establish and maintain the following records:

(i) Records (whether affirmative records demonstrating temperature is controlled or exception records demonstrating loss of temperature control) documenting the monitoring of temperature controls for any such refrigerated packaged food;

(ii) Records of corrective actions taken when there is a loss of temperature control that may impact the safety of any such refrigerated packaged food; and

(iii) Records documenting verification activities.

***Note:** Produce stored in open top bins or vented crates is not "unexposed packaged food". A facility that stores produce packed in vented crates or inspects/repacks produce must conduct a hazard analysis and evaluate whether there are any hazards requiring a preventive control. A facility that appropriately determines through its hazard analysis that there are no hazards requiring a preventive control associated with its food products would document that determination in its written hazard analysis but would not need to establish preventive controls and associated preventive control management components for its products.

***Note: Terms in Section B are based on HACCP terminology, however the terms should be considered interchangeable to meet the regulatory food safety plan requirements of the governing region**. **For example, where it refers to a CCP (Critical Control Point) that shall be equivalent to the regulatory language with which the facility falls under.**

## B1. PRELIMINARY TASKS

### 1.1. A HACCP/FOOD SAFETY TEAM SHALL BE ASSEMBLED WITH INDIVIDUALS HAVING THE APPROPRIATE PRODUCT, PROCESS, AND SANITATION SPECIFIC KNOWLEDGE AND EXPERTISE NECESSARY FOR THE DEVELOPMENT OF AN EFFECTIVE HACCP PLAN.

The HACCP/Food Safety team shall:

a. Have a team leader who has successfully completed formal training (in-classroom or on-line) of at least 1.5 to 2 days duration on the principles of HACCP as defined by Codex and the development of product safety plans based on hazard analysis and risk assessment. The leader of the HACCP/food safety team shall also be able to demonstrate in-depth knowledge of the principles of HACCP during the audit.
b. Have the appropriate product, process, and sanitation-specific knowledge. Where such expertise is not available on site, expert advice shall be obtained from other sources, but the site shall still retain ownership and understanding of the Plan even if external expertise is used.
c. Be clearly identified with their responsibilities as part of the HACCP/Food Safety plan.
d. Be representative of major functions within the organization that have an impact of food safety.

 

### 1.2. THERE SHALL BE A WRITTEN HACCP/FOOD SAFETY PLAN. THE HACCP/FOOD SAFETY TEAM SHALL PARTICIPATE IN HACCP/FOOD SAFETY PLAN DEVELOPMENT AND MAINTENANCE.

The HACCP/Food Safety Team shall:

a. Be involved in the development, final approval, and subsequent reviews of the plan.
b. Develop a description of the product (composition, ingredients, physical/chemical properties, processing details, packaging, shelf life and storage) and determine the intended use of the product based on the expected uses of the product by the end user or consumer.
c. Conduct reviews and approvals of changes and revisions. Hold documented review team meetings at minimum annually to assess HACCP records and issues.
d. Assess all deviations, documentation errors, corrective actions, and assure that corrective actions are monitored for effectiveness.
e. Ensure that all products stored or repacked at the facility, including processed products, repackaged product or reworked product shall be listed and assigned to a designated HACCP plan.

### 1.3. THE HACCP TEAM SHALL CONSTRUCT A CLEAR AND EASY TO UNDERSTAND PROCESS FLOW DIAGRAM FOR EACH HACCP PLAN.

The Process Flow Diagram shall:

a. Outline each step involved in the process that is directly under the control of the establishment. The same flow diagram may be used for products that are repacked and broken down to smaller cases.
b. Indicate the different steps that would be used for inspecting produce, repacking produce and re-sizing cases.
c. Include introduction returned products, and packaging materials.
d. Include the steps preceding and following the process.

### 1.4. THE PROCESS FLOW SHALL INCLUDE PREVENTIVE CONTROLS AND CCPS IF APPROPRIATE, SHALL BE CURRENT AND SHALL BE VERIFIED.

a. The HACCP team shall 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 shall be documented on the flow diagram, as necessary.
b. The process flow diagram shall remain current.
c. Once Preventive Controls and CCPs have been determined, they shall be clearly identified on the flow diagram and numbered to correspond with the Hazard Analysis, monitoring records and documentation.

 

## B2. HAZARD ANALYSIS (HACCP PRINCIPLE 1)

### 2.1. THE HACCP TEAM SHALL PREPARE A LIST OF ALL OF THE HAZARDS (CHEMICAL, PHYSICAL, BIOLOGICAL, RADIOLOGICAL OR OTHER) FOR EACH TYPE OF PRODUCT OR PRODUCT LINE THAT MAY BE REASONABLY EXPECTED TO OCCUR AT EACH STEP, FROM RECEIPT, STORAGE, HANDLING AND DISTRIBUTION UNTIL THE POINT OF CONSUMPTION. EVALUATION SHALL INCLUDE ALL FOODS, FOOD CONTACT PACKAGING MATERIALS, EQUIPMENT AND HANDLING STEPS.

a. The HACCP team shall conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to maintaining safe food. 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.
b. The hazard analysis shall include:
   - The likelihood of hazards and the severity of their adverse health effects.
   - The qualitative and/or quantitative evaluation of the presence of hazards.
   - Survival or multiplication of microorganisms of concern.
   - Production or persistence in foods of hazardous toxins, chemicals or physical agents.
   - Conditions leading to the above.
   - All raw materials and process steps.
c. A preventive control measure shall be identified for every significant hazard determined.

## B3. CRITICAL CONTROL POINTS (PRINCIPLE 2)

### 3.1. THE HACCP TEAM SHALL DETERMINE THE CRITICAL CONTROL POINTS.

a. Critical Control Points shall be determined using a logical, reasoned, documented approach, such as a decision tree and/or defined regulatory requirements (for example, thermal processing defined by a Process Authority). If a formal hazard analysis is not used to determine the need for CCPs, there shall be a documented risk assessment for that purpose.
b. Documentation for determining whether a step or process is a CCP shall 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 no CCPs, no further plan development is necessary. However, the HACCP Team shall continue to conduct regular meetings to review any changes in the process or procedures that could affect the hazard or CCP determination.

**NOTE:** Regardless of whether there are no hazards or no CCP's, the requirements of sub-sections "Verification and Validation" (HACCP Principle 6) and "Documentation and Record Keeping" (HACCP Principle 7) below shall always be satisfied to verify HACCP conclusions and to document all HACCP decisions and conclusions.

 

## B4. CRITICAL LIMITS (PRINCIPAL 3)

### 4.1. CRITICAL LIMITS SHALL BE SPECIFIED AND VALIDATED FOR EACH CCP.

a. Critical limits shall be measurable. Variable or attribute measures are acceptable.
b. There shall be a scientific or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. Proprietary data may be acceptable, providing there are sufficient data approved by an appropriate, qualified process authority.
c. Documented process capability studies or CCP monitoring records shall be available to demonstrate that established CCP limits are compatible with the facility process and capable of being met.

***FAILURE TO DEMONSTRATE THAT CCP CRITICAL LIMITS ARE SCIENTIFICALLY AND/OR TECHNOLOGICALLY SOUND FOR CONTROLLING EACH HAZARD SHALL BE RATED AS A MAJOR NON- CONFORMANCE.**

## B5. CCP MONITORING (HACCP PRINCIPLE 4)

### 5.1. CCPS SHALL BE MONITORED.

a. Monitoring procedures shall be able to detect loss of control at the CCP.
b. All CCP's shall have a documented and fully implemented and executed procedure that describes how the CCP is to be monitored, who is responsible for performing it, how often it is completed and where the activity is to be documented. The type and frequency of monitoring shall be sufficient to guarantee the CCP is in control.
c. Monitoring data shall be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

### 5.2. CCP MONITORING RECORDS SHALL BE MAINTAINED.

a. Documentation of the measured attribute shall be clearly identified in HACCP records.
b. Records shall 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. All corrective action procedures shall clearly indicate where deviations are recorded and who is responsible for actions taken.
c. A deviation log shall be maintained and available for review.
d. All records and documents associated with monitoring CCPs shall be signed by the person(s) doing the monitoring.

## B6. CORRECTIVE ACTIONS (HACCP PRINCIPLE 5)

### 6.1. **ESSENTIAL** SPECIFIC CORRECTIVE ACTIONS TO DEAL WITH DEVIATIONS FROM ESTABLISHED CRITICAL LIMITS SHALL BE IN PLACE FOR EACH CCP.

a. Corrective actions shall include instructions of necessary actions to take to secure and manage affected product, including who needs to be informed in the event that a critical limit is exceeded.

 

b. Corrective actions shall ensure that the CCP has been brought under control and require that an assessment be conducted to prevent a recurrence of the situation.
c. There shall be documented product disposition procedures in the event of a CCP deviation.

***ESSENTIAL ELEMENT--FAILURE TO TAKE CORRECTIVE ACTION FOR A CRITICAL LIMIT DEVIATION SHALL BE ASSESSED AS A CRITICAL NONCONFORMANCE.**

## B7. VERIFICATION AND VALIDATION (HACCP PRINCIPLE 6)

### 7.1. THERE SHALL BE WRITTEN VERIFICATION ACTIVITIES THAT CONFIRM THAT THE PLAN IS BEING IMPLEMENTED AS INTENDED.

a. Verification activities shall include where appropriate:
- Review of the HACCP system and Plan and its records.
- Review of deviations and product dispositions.
- Confirmation that CCPs are properly monitored and kept under control.
- Management sign-off that no deviations took place or that all deviations resulted in the prescribed corrective action.

### 7.2. THERE SHALL BE DOCUMENTED VALIDATION OF THE EFFECTIVENESS OF THE HACCP PROGRAM.

a. Validation of the HACCP plan shall be available through documentation or supporting data that confirms:
- The Plan is scientifically and technically sound.
- All hazards have been identified.
- CCPs are effective and valid and that if the HACCP plan is properly implemented, these hazards will be effectively controlled.

b. The HACCP plan shall be reviewed and validated by the HACCP team at minimum annually, or as needed based on changes to raw materials/processes/product change, and/or corrective and preventive actions. At the time of the HACCP plan review, the HACCP team shall also include a review of the training needs and competency of its members, to ensure that the expertise of the team remains current. This validation of the plan and review of the team shall be documented.

## B8. DOCUMENTATION AND RECORD KEEPING (HACCP PRINCIPLE 7)

### 8.1. THERE SHALL BE DOCUMENTATION AND RECORD KEEPING THAT IS APPROPRIATE TO THE NATURE AND SIZE OF THE OPERATION.

a. Documentation and record keeping shall be sufficient to assist the business to verify that the HACCP controls are in place and being maintained.
b. Documentation shall include:
- Hazard analysis.
- CCP determination.

- Risk analysis (likelihood and severity).
- Critical limit determination.

c. Records shall include:
   - CCP monitoring activities.
   - Deviations and associated corrective actions.
   - Verification procedures performed.
   - Modifications to the HACCP plan.
   - Effective access control, in the event that the records are electronic.
   - Appropriate signing and initialing to verify compliance and completeness.

d. Deviations from the HACCP plan shall be thoroughly documented with detailed corrective actions and product dispositions.

e. The documents and their data shall be self-explanatory and complete. The records shall be in ink (not pencil) and signed by the operator. There shall be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation shall be provided.

f. All records and documents associated with HACCP plan monitoring shall be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company. Signatures of the operator, supervisor and designated record reviewer are required in some regulated situations.

g. Records shall be easily retrievable and secured in a safe storage area.

## C. FACILITIES & EQUIPMENT

The following guidelines are provided as minimum requirements for food holding facilities. They are general in nature and may not be appropriate for all operations, but the intent of the requirements, as stated, shall be achieved. Some products or materials may require more stringent elements.

### C1. WATER, STEAM AND ICE

#### 1.1. **ESSENTIAL** THE FACILITY SHALL DEMONSTRATE THAT THE WATER, ICE AND STEAM SUPPLY IS POTABLE AND THAT POTABILITY IS MAINTAINED AT ALL TIMES. POTABILITY CRITERIA FOR MICROBIOLOGICAL, CHEMICAL AND PHYSICAL PARAMETERS SHALL BE USED.

a. There must be an adequate supply of water for proper holding and sanitation. Ice produced in the facility from the facility's own water supply shall follow the potability requirements as per this section (1.1) subparts b-d.
b. Potability testing of municipal water supplies shall be conducted by a certified laboratory at minimum annually. Potability certificates available from municipal water suppliers are acceptable.
c. Facilities operating their own private well or water systems shall be able to demonstrate, through credible testing at minimum on a continuous basis or at least every 6 months, that facility water meets applicable regulatory standards for drinking water.
d. Potability shall meet local regulatory requirements at a minimum.

FOR PRODUCE REPACKING AND/OR RESIZING AREAS:

e. Water treatment program shall be documented along with training or qualification of personnel involved in the process.
   - All chemicals used shall have food grade approval and be documented as such.
   - Treatment records shall include testing results, amounts used and when used.
   - Water treatment shall be verified by 3rd party vendors.
f. Purchased ice (manufactured ice brought into the facility from an outside vendor) shall have annual certificates of potability or documented satisfactory microbiological testing results.
g. Potable water distribution systems shall be segregated or adequately protected from cross contamination.
   - There shall be no cross connections between potable and non-potable water supplies.
   - All hoses, taps or other similar sources of possible contamination shall be designed with properly maintained back flow preventers. These devices shall have annual, documented inspections to demonstrate effectiveness.
   - Water filters shall be kept effective as per the manufacturers' recommendations and maintained in a sanitary manner.
   - Volume, temperature and pressure of water shall be adequate to meet operational and sanitation needs.
   - Water storage, if necessary, shall be in adequately designed, maintained and identified storage facilities.

 

- Recirculated water shall be treated, monitored and maintained for its intended use. It shall be clearly identified.

***ESSENTIAL ELEMENT—THE USE OF NON-POTABLE WATER, STEAM OR ICE IN CONTACT WITH FOOD, FOOD CONTACT EQUIPMENT OR OTHER INAPPROPRIATE USE SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

## C2. FACILITY CONSTRUCTION, DESIGN AND CONDITION

### 2.1. THE EXTERIOR OF THE FACILITY IS CONSTRUCTED AND MAINTAINED TO FACILITATE THE HOLDING OF WHOLESOME PRODUCT AND THAT IT AT MINIMUM MEETS THE CUSTOMER AND REGULATORY FOOD SAFETY AND QUALITY REQUIREMENTS.

a. The facility exterior (yards, grounds, parking lots and roads) is maintained free of debris, refuse and adequately drained.
b. Building exteriors are designed and maintained to prevent contamination or entry of pests, contaminants (such as, but not limited to, dust and chemicals) or unauthorized personnel.
c. Procedures and records shall be in place to support building maintenance.

### 2.2. **ESSENTIAL** FACILITY CONSTRUCTION AND LAYOUT SHALL BE SUCH THAT PRODUCT IS ADEQUATELY STORED, SEPARATED AND PROTECTED FROM ANY OPERATIONS THAT COULD CAUSE CONTAMINATION.

a. There shall be no evidence of potential for cross-contamination, including allergen cross-contamination, due to facility layout or construction.
b. There shall be no cross connection between sewage and other waste effluent systems and effluent shall not present a hazard due to contact or odor. Sewage must be disposed of using adequate means.
c. Objectionable odors, fumes or vapors shall not be present.
d. Adequate heating, ventilation or refrigeration shall be provided in all areas to maintain proper environmental and sanitary conditions for products, equipment, and packaging materials. This maintenance of proper conditions includes, but is not limited to, minimizing risk of allergen cross-contamination and condensate/frost/ice buildup.

*** ESSENTIAL ELEMENT--ANY CONDITION IN THE FACILITY WHICH, BASED ON OBJECTIVE EVIDENCE OR OBSERVATION, RESULTS IN PRODUCT OR RAW MATERIAL CONTAMINATION AND/OR ADULTERATION SHALL BE ASSESSED AS A CRITICAL NONCONFORMANCE.**

## C3. FACILITY CONDITION (STATE OF REPAIR, CLEANABILITY)

### 3.1. FACILITIES SHALL BE DESIGNED AND MAINTAINED IN A SUITABLE CONDITION SO AS NOT TO IMPEDE THE ABILITY TO THOROUGHLY CLEAN ALL SURFACES, PROVIDE PEST HARBORAGE, OR PRESENT OPPORTUNITIES FOR FOREIGN MATERIAL CONTAMINATION.

a. Materials used to construct walls, floors, overhead structures and ceilings shall be smooth and easily cleanable. Joints or cracks in walls, floors and ceilings shall be properly sealed.
b. Walls, ceilings, overhead structures and floors are maintained in good repair.
c. Floors are sufficiently sloped, as needed, to provide drainage and to prevent the accumulation of liquid.
d. Drainage is designed away from higher risk areas and to minimize product contamination.
e. Wet holding areas shall have floor drains with grates that are easily removed for cleaning and inspection.
f. Windows in holding areas shall be shatter proof or properly sealed to prevent glass contamination.
g. No unprotected glass shall be allowed in close proximity to storage or handling areas.
h. Doors and windows shall be in suitable condition (see Pest Control section for additional requirements regarding doors and windows).

## C4. EMPLOYEE FACILITIES

### 4.1. EMPLOYEE FACILITIES SHALL BE ADEQUATE IN SIZE, READILY ACCESSIBLE, SEPARATE FROM FOOD HOLDING AREAS, AND PROPERLY MAINTAINED.

a. Cafeteria, Locker Rooms and Toilet facilities shall be:
    - Adequate in size for the maximum number of employees.
    - Readily accessible by employees.
    - Physically separated from food holding and handling areas.
b. They shall be maintained in a clean and sanitary condition.

## C5. HAND WASHING FACILITIES

### 5.1. HAND WASH REQUIREMENT SIGNS, IN APPROPRIATE LANGUAGES AND/OR GRAPHICS, SHALL BE CLEARLY POSTED AT REQUIRED LOCATIONS AND CONTAIN INSTRUCTIONS AS PROVIDED BELOW.

a. Signs shall instruct employees to wash their hands prior to returning to work. Signs shall be located at
    - Locker room and toilet facility exits.
    - Entrances to food storage areas.
b. Signs at hand wash stations shall instruct employees on the proper procedure for washing their hands and be in appropriate languages for the facility.

### 5.2. HAND WASHING STATIONS SHALL BE ADEQUATE IN LOCATION, SUITABLY DESIGNED, OPERATIONAL AND PROPERLY STOCKED.

a. Hand wash stations shall be strategically located and have adequate room to accommodate the number of personnel in the area and prevent delays that may discourage proper hand washing procedures.

 

b. The hand washing stations shall deliver water at a suitably warm temperature within an appropriate time period. There shall be an adequate supply of hand sanitizing soap. Single service towels shall be available and protected with an appropriate dispenser with convenient disposal at each station. Where specific customer requirements or country regulations apply to hand-washing, these shall take precedence.

### FOR PRODUCE REPACKING AND/OR RESIZING AREAS:

c. Handwash sinks shall be available and located appropriately in areas where produce/exposed product is handled or inspected.
d. Hand washing stations in or adjacent to food handling areas shall be 'hands-free' activated so that hand contact is not required to turn water 'On' or 'Off'.

## C6. EQUIPMENT LAYOUT, DESIGN AND CONDITION

### 6.1. **ESSENTIAL** ALL EQUIPMENT SHALL MEET SANITARY DESIGN REQUIREMENTS AND BE MAINTAINED IN SUCH A MANNER AS TO PERMIT PROPER OPERATION AND ACCESS FOR CLEANING AND INSPECTION.

a. All equipment is in good repair and does not pose a product contamination issue.
b. Facility has a procedure in place for qualification of new equipment prior to use in order to ensure safety and quality of product is not compromised.
c. Equipment shall be designed and maintained to provide easy access, disassembly and reassembly for thorough cleaning, sanitizing and inspection.

### FOR PRODUCE REPACKING AND/OR RESIZING AREAS:

d. Equipment in direct contact with food shall be of smooth, impervious, non-toxic, nonabsorbent and corrosion-resistant material.

***ESSENTIAL ELEMENT--FINDING THROUGH OBSERVATION OR ON THE BASIS OF OBJECTIVE EVIDENCE THAT EQUIPMENT OR FOOD CONTACT MATERIALS ARE UNSUITABLE FOR USE WITH FOOD OR THAT EQUIPMENT CONDITION IS A CAUSE OF PRODUCT CONTAMINATION MAY BE ASSESSED AS A CRITICAL NON-CONFORMANCE**

## C7. UTENSILS/TOOLS

### 7.1. UTENSILS, TOOLS AND CONTAINERS ARE CLEARLY IDENTIFIED AND MAINTAINED IN SUITABLE CONDITION.

a. Utensils, tools and containers shall be properly identified for their intended use by labels and/or color coding.

 

### FOR PRODUCE REPACKING AND/OR RESIZING AREAS:

b. Utensils, tools and containers used to handle edible material shall not be used to handle inedible material and are clearly identified and maintained.
c. Utensils, tools and containers shall be maintained, cleaned and stored in order to prevent cross contamination of products. An example of proper storage includes, but is not limited to, making provision for appropriate drying of utensils, tools and containers, as needed.
d. Single use containers used for microbiologically sensitive or allergenic products shall not be reused.
e. Facilities that utilize compressed air and/or other gasses that make direct contact with product, product contact surfaces or product contact packaging materials shall develop a program to assure the compressed gaseous material does not introduce any contaminants (including microorganisms) into the product. The necessary requirements for maintaining sanitary air shall be monitored and documented.

## C8. FACILITY LIGHTING

### 8.1. FACILITY LIGHTING SHALL BE SUITABLE.

a. Facility lighting shall be adequate and appropriate for sanitation, inspection and handling tasks being performed.
b. Light bulbs and fixtures in areas where food products and packaging material are exposed are shielded or protected against breakage.

## C9. MAINTENANCE STANDARDS

### 9.1. MAINTENANCE PROGRAM AND STANDARDS SHALL BE IN PLACE.

a. Facility shall have a documented preventive maintenance program that covers all equipment and facilities.
b. Appropriate materials shall be used for temporary repairs in areas where food/product is not exposed. For equipment or areas where exposed food is present non-food grade materials or otherwise inappropriate materials including, but not restricted to, wire, tape, string, plastic or cardboard shall not be used for repairs.
c. Temporary repairs shall have specific time line for permanent repair.
d. Repair parts and replacement equipment shall be stored in properly maintained storage areas.
e. There shall be a procedure to ensure that cleaning and sanitation is done following maintenance as needed. This shall include a reconciliation of all tools and spare parts used during the maintenance work to ensure that the work site has been returned to conditions for safe holding or handling of food.
f. Records of all maintenance activity shall be maintained.

 

### 9.2. **ESSENTIAL** EQUIPMENT OR CONTROL DEVICES THAT IMPACT ON FOOD SAFETY AND/OR PRODUCT COMPLIANCE TO QUALITY AND REGULATORY REQUIREMENTS ARE EFFECTIVELY CALIBRATED.

a. There shall be written procedures implemented to verify, on a daily basis, the accuracy of thermometers used for measuring product and refrigerated/frozen storage area temperatures. The thermometers shall be identifiable (i.e. individual ID numbers or letters) and verification results shall be documented. Thermometers shall be verified at or near the temperature range at which they are used.
    - If intermediate thermometers are used to verify the daily calibrations of monitoring thermometers, the intermediate thermometers must be checked against a NIST (National Institute of Standards Testing) or equivalent traceable unit at least weekly, or otherwise verified as accurate. If applicable, the use of ice baths is allowable. Full documentation of the intermediate thermometer calibration checks shall be available.
    - Calibration procedures shall describe the frequency of testing, the testing method and the acceptable range of variation.

b. Electronic measuring devices utilizing remote transmitting devices (RTDs) shall be calibrated at least annually by comparison with an NIST standard instrument. The calibration shall be performed with the measuring system (RTD, electrical connections, and recorder/display) intact. The data shall be obtained and recorded in the appropriate units of measurement for the system. This process and the results shall be documented.

#### FOR PRODUCE REPACKING AND/OR RESIZING AREAS:

c. Assigned personnel shall check scales used for weighing products and materials daily. Standard weights in the range of the weights being routinely measured shall be used for these verification checks. Daily verification checks shall be documented.

d. There shall be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used. This shall include steps in place to assess and ensure that product is still acceptable to ship.

***ESSENTIAL ELEMENT--EQUIPMENT FOUND TO BE OUT OF CALIBRATION LEADING TO POTENTIAL FOR ILLEGAL OR UNSAFE FOOD SHALL BE A CRITICAL NON-CONFORMANCE.**

## C10. WOOD CONTROL POLICY

### 1.1 WOOD, WHERE USED, SHALL BE CONTROLLED AND INSPECTED.

a. Wooden pallets and other tools that contain wood used in the facility shall be dedicated for that purpose, clean, maintained in good order and inspected as needed based on risk assessment, and their condition documented.

## C11. GLASS & BRITTLE PLASTICS CONTROL POLICY

### 1.1. THERE SHALL BE A PROGRAM TO MANAGE GLASS AND BRITTLE PLASTIC.

a. There shall be a procedure to segregate and clean areas after glass breakage occurs.
b. All essential glass or brittle plastic that exists in any area of the plant including, but not limited to, cameras, emergency lighting, dial and gauge covers shall be documented to indicate location and condition.
c. Monitoring of the condition of glass and brittle plastic shall be completed and documented at a specified and documented frequency based on a valid risk assessment.

 

# D. CLEANING, SANITATION, HOUSEKEEPING, HYGIENE

## D1. CLEANING AND SANITATION

### 1.1. THERE SHALL BE A MASTER CLEANING AND/OR SANITATION SCHEDULE AND MONITORING AND RECORDING OF CLEANING.

a. This schedule shall include:
   - Storage/Warehouse areas (floors, walls, drains, overheads).
   - Equipment (including portable and temporary equipment).
   - Maintenance areas.
   - Employee facilities (locker rooms, cafeteria, break areas and toilet facilities).
   - Other facility areas including the building, grounds and roof areas.

b. The scheduled tasks shall be monitored for completion and documented with sign off on a consistent basis.

### 1.2. THERE SHALL BE STANDARDIZED CLEANING PROCEDURES (E.G., STANDARD SANITATION OPERATING PROCEDURES OR SSOPS).

a. The facility shall have documented cleaning procedures, including level of disassembly required, frequency of cleaning, preparation of cleaning chemicals and assigned responsibility for each task as per D1.1.

#### FOR PRODUCE REPACKING AND/OR RESIZING AREAS:

b. The facility shall have documented cleaning procedures for individual pieces of direct contact equipment (e.g. utensils, tables, scales, etc.) that specifies and defines:
   - Unless purchased as ready-to-use, there shall be specific preparation procedures regarding dilution factors for the specific chemicals or sanitizers being used and, where appropriate, verification testing and documentation.
   - Water temperature requirements for washing >140°F for cleaning unless otherwise recommended in writing by chemical supplier.

c. Plant shall have detailed SSOP Monitoring Procedures with records of monitoring activity. Records shall clearly show equipment condition and list all deficiencies found. When deficiencies are found there shall 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.

d. Written procedures and schedules for routine cycle cleaning and sanitizing of equipment shall be current and available.

e. If machine operators are responsible for general maintenance and equipment cleaning, procedures shall be available describing steps for cleaning and sanitizing and the cleaning shall be documented.

f. Written procedures shall be available for cleaning and sanitizing equipment after maintenance is performed and prior to returning equipment into service.

### 1.3. THERE SHALL BE A DOCUMENTED PRE-OPERATIONAL INSPECTION.

 

a. A pre-operational inspection, including both visual and document review, shall occur prior to regular activities and after the completion of the following activities:
   - Routine clean-ups.
   - Allergen clean-ups.
   - Maintenance activities due to breakdowns or preventive maintenance after planned sanitation activities.

b. Corrective action procedures are established and documented for incomplete or inadequate sanitation practices. Records of corrective actions completed shall be maintained.

### 1.4. OPERATIONAL HOUSEKEEPING SHALL BE EFFECTIVE.

a. Accumulation of garbage, trash and waste materials shall be kept at a minimum and removed in a manner that does not create any food safety risks.
b. All equipment, utensils, containers shall be cleaned as necessary during and post operations and stored off the floor as applicable when not in use. This also includes cleaning and sanitizing equipment, which must be stored properly when not in use (for example, hoses used for cleaning hung up after use so that nozzle ends are not left directly on the floor).
c. All containers shall be appropriately designated.
d. Floors, walls, ceilings and overhead structures shall be cleaned as necessary to provide a hygienic environment.

## D2. PERSONAL HYGIENE AND GOOD DISTRIBUTION PRACTICES

### 2.1. THE FACILITY HAS A DOCUMENTED PROGRAM FOR GDP AND PERSONAL HYGIENE PRACTICES TO WHICH COMPLIANCE IS MONITORED AND RECORDED.

a. Facility employees shall observe personal hygiene practices as outlined in the relevant regulations.
b. Personal hygiene practices shall include:
   - A written dress code for all employees (including new and part-time), visitors, vendors and contractors. Employees shall wear clean clothing and shoes appropriate for the working conditions.
   - No working in food storage or handling areas for employees that have an infectious or communicable illness, or have open sores on hands, face, arms or other exposed skin areas.
   - Employees shall notify management if they are diagnosed with a communicable disease that may be transmitted through food or are experiencing symptoms of diarrhea, vomiting, fever or jaundice.
   - Employees shall wash their hands before starting to work, after each absence from the work station and any time their hands may have become contaminated.
   - Eating, drinking, spitting, chewing or using tobacco products shall only be permitted in designated areas.

#### FOR PRODUCE REPACKING AND/OR RESIZING AREAS:

c. The use of fine mesh net hair restraints for head and beard guards for facial hair in warehouse areas by all employees and persons entering these areas.
d. Pens, combs, pencils, thermometers, tools and similar loose objects shall not be carried above the waist at any time while in food handling areas.

e. No false fingernails, fingernail polish, jewelry (rings, exposed body piercings, bracelets), or watches.
f. If gloves are worn, they shall be intact, with no holes, and kept clean. Non disposable gloves shall be washed and sanitized if they become contaminated. Disposable gloves shall be replaced if they become contaminated.
g. If dedicated uniforms, aprons, lab coats, gloves, or smocks are utilized, the facility shall provide these. Employees shall use a means to avoid contamination of their dedicated outer clothing when using the toilet facilities. For example, coat hooks or other means can be made available for employees to store their outer protective garments before entering toilet facilities.
h. Plasters (bandages) shall be available and shall be a contrasting color from the product that is exposed.

## D3. SELF INSPECTION

### 3.1. GDP SELF INSPECTIONS SHALL BE COMPLETED.

a. There shall be routine facility inspections (can be completed by a cross functional team or by a designated individual at the facility) performed to assure management that GDP policies have been
   - Effectively implemented.
   - Facilities and equipment are maintained to meet sanitary and operational needs.
b. Inspections shall be documented to show non-conformances identified and corrective actions taken. If corrective actions are still to be completed, a timeframe for that completion shall be included in the documentation.

## D4. CHEMICAL CONTROL

### 1.4. ALL CHEMICALS (INCLUDING, BUT NOT LIMITED TO, THOSE USED FOR SANITATION, MAINTENANCE, AND PEST CONTROL) SHALL BE APPROVED FOR USE, SECURELY STORED, CLEARLY IDENTIFIED AND USED ONLY BY TRAINED PERSONS.

a. Non-food chemicals shall be stored when not in use in areas away from finished products, product packaging materials, processing equipment, and ingredients. The chemical storage area(s) shall be properly vented, provide for adequate spill control and be secured with access restricted to properly authorized personnel.
b. Safety Data Sheet (SDS), letters of guarantee or similar information shall be readily available for all chemical compounds in the facility.
c. All personnel handling chemicals shall be trained in chemical control measures and safety.
d. All chemical containers, whether original or secondary, shall be properly identified with the contents.
e. If it is necessary to maintain pest management chemicals at the plant, they shall be stored in a secured location with limited access.
f. Chemicals used for cleaning and sanitizing shall be securely stored when not in use.
g. There shall be a list of all approved chemicals used at the facility.

 

# E. RODENT & PEST CONTROL MANAGEMENT

## E1. PEST CONTROL

### 1.4. THERE SHALL BE A DOCUMENTED AND SPECIFIC PEST CONTROL PROGRAM.

a. There shall be a current Pest Management manual, program or file available for review.
b. A current Pest Control Operator (PCO) applicator's license and letter of liability insurance shall be on file, along with Safety Data Sheet (SDS) for all chemicals used.
c. There shall be written procedures to direct the activities conducted by the PCO and trained employees. They shall include:
   - Types of pests being controlled.
   - Frequency of monitoring/inspection.
   - Method of labeling, inspecting and recording of inspections.
   - The record of service verification tag or bar code label shall be on the inside of the traps, bait stations or other devices.
d. Company employees engaged as PCOs shall have proof of appropriate training and licensing as required by local regulations.
e. An up-to-date site map of all pest control devices shall be maintained.

### 1.2. OUTSIDE PREMISES MANAGEMENT SHALL MINIMIZE OPPORTUNITY FOR PESTS.

a. Outside premises shall be free of conditions (including, but not limited to, stored equipment, litter, waste, weeds, tall grass) that may provide harborage or attractants for insects, birds, rodents or other pests. There shall be at minimum an 18 inch (46 cm) vegetation free perimeter around exterior of facility.
b. Outside bait stations shall be place around the exterior perimeter of the building at intervals as directed by the Pest Control Company (PCO). If the PCO has not provided this direction, the outside bait stations shall be placed at 50 foot (15.25 meter) intervals.
c. Exterior pest control devices shall be tamper resistant, locked, labeled and secured.

### 1.3 **ESSENTIAL** THERE SHALL BE NO EVIDENCE OF INFESTATION.

a. There shall be no evidence of pest infestation inside the facility.
b. There shall be no observation of pests on food or food contact packaging.

*** OBSERVATION OF A PEST INFESTATION INSIDE THE FACILITY IS A MAJOR NON-CONFORMANCE**

***ESSENTIAL ELEMENT—OBSERVATION OF PESTS, PEST EXCRETA OR INFESTATION IN OR ON FOOD OR FOOD CONTACT PACKAGING SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE (DIRECT CONTAMINATION)**

 

### 1.4. PEST CONTROL DEVICES SHALL BE PROPERLY MANAGED.

a. All devices shall be identified and placed to correspond to the map location.
b. Devices shall be in proper working order.
c. Exterior pest control devices shall be inspected and documented at minimum once/month in winter and twice per month in summer months, unless a documented and validated risk assessment with supporting current trend data supports a different frequency.
d. Insect light traps shall be suitably located and not located over, adjacent to or within 8 feet (2.44 meters) of product or packaging.
e. Labelled mechanical rodent traps shall be placed based on recommendations of the Pest Control Service provider and, at a minimum, inside and on either side of doors that exit to the exterior, including all dock doors with wall signage indicating location.
f. Interior pest devices shall be inspected at minimum weekly, unless a documented and validated risk assessment with supporting current trend data supports a different frequency.
g. There shall be no bait used inside the facility. Only glue boards or pheromone traps shall be used inside the facility as required.

### 1.5. DOORS AND WINDOWS SHALL BE TIGHT FITTING AND CLOSED WITH OPENINGS SEALED TO PREVENT PEST ENTRY INTO THE BUILDING.

a. Doors, windows and docks (including doors and dock plates) shall be adequately sealed to prevent pest entry.
b. Doors, windows and dock doors shall remain closed when not in use for product and material transfer or be suitably screened.

### 1.6. PEST CONTROL REPORTS SHALL BE MAINTAINED.

Pest Control records shall:

a. Record all pest control activities.
b. Record all pest activity, findings, investigations and corrective actions.
c. Record observations and findings of conditions that compromise pest management including recommendations and corrective actions.
d. An adequately trained facility or facility employee shall be responsible to ensure that all corrective actions resulting from pest control inspections are completed and documented. Corrective actions shall be completed as required as a result of the pest control inspections.
e. Record on a pesticide usage log the usage of chemicals and pest control agents, including name, amount, lot codes, relevant regulatory registration or approval information, location(s) where applied, the date, and purpose for use.

 

# F. APPROVED SUPPLIERS, RECEIVING, STORAGE & SHIPPING AND INVENTORY CONTROL

The facility is expected to have detailed, written policies describing how suppliers are approved, receiving criteria for carrier and product acceptance, and handling and storage criteria for products.

## F1. APPROVED SUPPLIER PROGRAM

### 1.1. THERE SHALL BE A DOCUMENTED APPROVED SUPPLIER PROGRAM. THE PROGRAM SHALL BE BASED ON RISK ASSESSMENT OF THE SUPPLIERS.

a. The program shall require written criteria for approving suppliers based on risk assessment.
b. The program shall indicate how suppliers are evaluated and/or approved for use and well as continually monitored for compliance.
c. The program shall detail the allowable circumstances to deviate from an approved supplier.

### 1.2. SUPPLIERS SHALL BE REQUIRED TO PROVIDE RELEVANT DOCUMENTATION TO SUPPORT THEIR STATUS AS AN APPROVED SUPPLIER.

a. Documentation shall be maintained and reviewed annually or as suppliers are added or removed from the approved list.

## F2. VEHICLE AND MATERIALS INSPECTION

### 2.1. THERE SHALL BE A WRITTEN PROCEDURE FOR THE INSPECTION OF DELIVERY VEHICLES. THIS SHALL APPLY TO RECEIVING AND SHIPPING. PROCEDURES SHALL DEFINE WHEN CARRIERS ARE TO BE REJECTED.

a. The carrier inspection (including bulk carrier) procedure shall describe acceptable and unacceptable conditions including, but not limited to, clean and intact, free of moisture and offensive odors, pests, chemicals, and glass.
b. All receiving and shipping equipment (including loading and unloading equipment, hoses and ports, pumps, screens, and filters for bulk deliveries) shall be secure, clean and stored in sanitary manner.
c. Cleaning procedures shall be in place where required for equipment and carriers.
d. Products requiring temperature control shall be shipped in vehicles capable of ensuring proper temperatures through all phases of transportation.
e. The temperature setting and operation of all outbound refrigerated trailers shall be verified.
f. Vehicles shall be pre-cooled prior to loading and shipping of finished product.
g. Records of carrier inspection and acceptance or rejection shall be maintained.

 

### 2.2. THERE SHALL BE A WRITTEN PROCEDURE FOR THE INSPECTION AND RECEIPT OF INCOMING MATERIALS.

a. The procedures shall:
   - Confirm all receipts are from approved suppliers.
   - Verify that delivery requirements have been met and materials are in good condition, free from contamination and damage.
   - Include the recording of results for any testing required at receipt.
   - Include temperature verification at receipt and confirmation of receipt of Certificates of Analyses or similar documentation as per F1.2 where specified.

b. Records of carrier inspection and acceptance or rejection shall be maintained.
c. Receiving areas shall be adequately separated from food holding areas such that product contamination is prevented.

## F3. STORAGE, TEMPERATURE AND INVENTORY CONTROL

### 3.1. PRODUCTS SHALL BE SECURE AND PROTECTED IN STORAGE.

a. Storage areas and material in storage shall be clean, orderly and free from spilled, damaged or exposed product.
b. Racks shall be clean.
c. Product shall be stored six inches (15 cm) off the floor or on pallets.
d. An effective inspection perimeter (at minimum 18 inches/46 cm) shall be maintained between walls and ceilings and product.
e. Chemical storage shall be segregated from food and food contact packaging and secured with restricted access.

### 3.2. STORAGE TEMPERATURES SHALL BE CONTROLLED AND MONITORED.

a. Refrigerated, frozen, and other controlled temperature storage rooms shall be monitored at minimum daily, or through continuous recording and alarming devices, to ensure that appropriate temperatures are maintained for their contents (typically less than or equal to 40°F/4°C for refrigerated and equal to or less than 0°F/-18°C for frozen).
b. Temperature logs shall be maintained.

### 3.3. INVENTORY CONTROL SHALL BE IN PLACE.

a. There shall be an inventory management process that ensures that products are shipped in rotation.
b. No expired or obsolete materials shall be shipped.
c. Electronic inventory systems, if properly executed, may preclude the need for a paper-based system (such as the use of paper hold tags or similar).

 

## F4. ALLERGEN AND SENSITIVE INGREDIENT CONTROL

### 4.1. **ESSENTIAL** ALL RESTRICTED OR SENSITIVE INGREDIENTS AND POTENTIALLY TOXIC CHEMICALS SHALL BE MAINTAINED UNDER STRICT CONTROL AND STORED SEPARATELY FROM FOOD AND FOOD CONTACT PACKAGING TO MINIMIZE THE POTENTIAL FOR ACCIDENTAL PRODUCT CONTAMINATION.

a. In facilities where allergens or sensitive ingredients are stored and there is a potential for cross-contamination, there shall be detailed procedures to prevent the contamination of other products.
b. There shall be a documented training program for employees on the proper handling of allergen sensitive ingredients and products.
c. Toxic and sanitation chemicals and flammable solvents shall be stored in areas away from the food item and food contact packaging material storage areas. The storage area shall be secured with access restricted to properly authorized personnel.
d. Safety Data Sheet (SDS) information shall be readily available for all chemical compounds in the facility.

***ESSENTIAL ELEMENT--EVIDENCE OF CROSS-CONTAMINATION WITH ALLERGENS THAT WILL RESULT IN A THREAT TO HEALTH SHALL BE ASSESSED AS CRITICAL NON-CONFORMANCE.**

## F5. RETAINED PRODUCT AND RETURNS

### 5.1. THERE SHALL BE POLICIES AND PRACTICES FOR THE CONTROL OF RETAINED AND RETURNED PRODUCTS.

The facility shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is not shipped. This control shall 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:
   - The facility shall 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 shall be understood by all authorized personnel.
   - A Hold Tag procedure shall include a permanent written log of each product or item placed on hold.
   - The facility shall have a policy and procedure for handling returned products.
   - Returned products shall be identified and placed on hold immediately.
b. Designated Areas for Retained and Returned Products:
   - There shall be a designated, clearly identified area for returned or retained products or product shall exhibit an obvious physical indication of its status (i.e. on hold or returned). A computer block alone is not acceptable. There shall be some type of records indicating the product is returned or retained.
   - Returned or retained products shall be clearly identified as such.
c. Verification and Release Documentation:
   - Documents shall be available to show the current location of products not cleared for shipment as well as those that are authorized for shipment.

 

- Disposition or corrective actions shall be commensurate with the seriousness of risk identified. Disposition shall be dated and signed.
- All non-conforming products shall be handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.
- Product destined for destruction shall be adequately secured and disposed of promptly.
- Disposition of non-conforming material shall be tracked to ensure that inventories are adjusted accordingly to facilitate recall.
- Damaged, sampled or destroyed finished product shall be recorded and proper adjustments to the product inventory records shall be made to accurately account for the inventory loss.
- An inventory log shall be maintained showing current product on hold and list the disposition of all released product with proper authorization.

d. At least weekly there shall be a physical accounting of the product on hold to verify that actual product quantities match records. Discrepancies shall be treated as a serious food safety failure.

# G. TRAINING REQUIREMENTS

## G1. TRAINING

### 1.1. NEW EMPLOYEE AND TEMPORARY EMPLOYEES SHALL BE TRAINED IN APPROPRIATE POLICIES AND PROCEDURES.

a. Training shall be provided to new hires (operating and management personnel) for the topics below, at a minimum:
   - Product safety (including HACCP/product safety plan overview).
   - Product defense.
   - Personal hygiene and GMP's (training delivered before starting work).
   - Allergens, including the handling of allergens and sensitive materials.
   - Plant process and product specific training, as appropriate.

b. There shall be specific training for identified critical product/food safety jobs. This shall include:
   - HACCP Critical Control Point monitoring, corrective action and verification responsibilities prior to the individual being assigned sole responsibility for such activities.
   - Sanitation employees (including new sanitation employees, applicable operators, temporary sanitation employees, and contract sanitation employees). Training shall include master Sanitation Schedule, Standard Sanitation Operating Procedures (SSOPs), food handling sanitation, and sanitation chemical safety.

### 1.2. TRAINING SHALL BE CONDUCTED IN THE APPROPRIATE LANGUAGE(S).

a. Training shall be provided in the language and presentation format that can be easily and clearly understood by the trainee.

### 1.3. REFRESHER TRAINING SHALL BE CONDUCTED.

a. The training programs shall be reviewed and content updated at least annually to take into consideration new regulatory, media, or customer issues, scientific and technological advances, or new or revised product safety, quality, or product defense programs.

### 1.4. THERE SHALL BE A METHOD OF ASSESSMENT TO DETERMINE PROOF OF LEARNING FOLLOWING TRAINING.

a. There shall be a method to document individual understanding at the conclusion of training. Methods may include written, “hands-on” demonstrations, and/or oral testing or documented performance evaluations by supervisors.
b. Assessments shall be conducted within a reasonably short period of time after training (14 to 30 days).
c. Assessments shall be an integral part of the training program.

 

## 1.5. TRAINING RECORDS SHALL BE MAINTAINED.

a. Employee training records shall be maintained and include the information below for all staff levels:
   - Employee name.
   - Training date.
   - Employee position/title.
   - Trainer name.
   - Training agenda and/or training content.
   - Proof of knowledge verification.

# H. FOOD/PRODUCT DEFENSE

## H1. FOOD/PRODUCT DEFENSE

### 1.1. THERE SHALL BE A WRITTEN PROGRAM WHICH DESCRIBES ASSIGNED RESPONSIBILITY FOR FOOD/PRODUCT SECURITY AND HOW IT IS MAINTAINED.

a. A Food Defense team shall be established that will evaluate the vulnerabilities and risks that exist from personnel, product sourcing, storage and shipping of products.
b. This team shall meet to review the food defense plan at a minimum annually, as well as whenever changes are planned or made and after any incident.

### 1.2. EACH FACILITY SHALL CONDUCT AND DOCUMENT A FOOD/PRODUCT DEFENSE RISK EVALUATION TO ELIMINATE OR SIGNIFICANTLY REDUCE THE RISK OF EXTERNAL AND INTERNAL INTENTIONAL ADULTERATION OF FOOD/PRODUCT (INCLUDING FOOD FRAUD).

a. The facility shall have conducted a documented Food Defense Evaluation that takes into account all aspects of the physical facility and activities. The potential of food fraud shall also be considered in this evaluation.
b. Food Security inspections shall be conducted to measure effectiveness of the program and ensure buildings and grounds are secure.

### 1.3. A COMPREHENSIVE FOOD/PRODUCT DEFENSE PLAN SHALL BE IMPLEMENTED TO MANAGE THE RISKS IDENTIFIED IN THE EVALUATION.

The implemented Food Defense Plan shall include:

a. Security assessment of off -site storage.
b. Protection of air, gas and water supplies.
c. Protection of control systems.
d. Protection of environmental control systems.
e. Protection of sensitive data systems and the data (e.g., formulations, specifications, business information).
f. Identification and management of unusual occurrences.

### 1.4. EMPLOYEES SHALL BE SCREENED, TRAINED IN FOOD/PRODUCT DEFENSE AWARENESS AND ACCESS TO THE FACILITY SHALL BE CONTROLLED.

a. New and existing employees shall be screened to ensure they are appropriate for employment in a food/product warehouse/distribution center facility.
b. Employee training programs are established to address food/product security issues. This includes:
    - Awareness for possible tampering occurrences in mail and products held and handled on-site.
    - Reporting requirements for unusual occurrences, observed behavior or unrecognized people in the facility.
c. Visitor and contractor access to the facility shall be controlled.

 

d. Employee identification methods shall be used to ensure that only authorized personnel are allowed in the facility or in restricted areas.
e. Temporary (unscreened) employees shall only work in areas with pre-packed, coded and labeled product and do not have direct access to unprotected product.
f. Temporary workers shall be adequately supervised at all times when on site.

### 1.5. INCOMING AND OUTGOING MATERIALS SHALL BE PROTECTED AND INSPECTED.

a. The site shall assess the vulnerability of incoming shipments and shall take appropriate actions such as:
   - Inspect vehicles and incoming product for evidence of tampering.
   - Require incoming vehicles to be locked or sealed.
   - Match seal numbers to shipping documents at receiving.
b. The transportation systems being used to deliver products shall be reviewed to ensure food security is maintained from pick-up to delivery, including locking or sealing outgoing vehicles.

### 1.6. FACILITYS SHALL BE REGISTERED WITH THE APPROPRIATE REGULATORY AUTHORITY.

a. There shall be proof that the facility is registered with the relevant authorities.

***FAILURE TO REGISTER OR SHOW PROOF OR "CERTIFICATION" OF REGISTRATION IS A "MAJOR NONCONFORMANCE".**

# 7 DEFINITIONS

**ALLERGEN:** Product compounds can cause an allergic or product intolerance response in sensitive individuals. Product allergens elicit serious adverse reactions in some individuals. Allergic individuals can tolerate very little of the offending product. Contamination with allergens shall be considered a potential risk and requiring consideration even in packaging manufacturing facilities. Globally, priority allergens requiring labelling vary. International regulatory information regarding allergens can be accessed through the University of Nebraska's Product Allergy Research and Resource Program. As of October 1 2019, the international regulatory chart for priority allergens is provided below, and can be accessed through the following link:

https://farrp.unl.edu/IRChart

**CALIBRATION OF INSPECTION, MEASURING AND TEST EQUIPMENT:** Calibration of measuring equipment against an accepted industry standard shall 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.

**LETTER OF GUARANTEE:** Document provided by supplier indicating that product provided by supplier (including, but not limited to food, food contact packaging materials, inks, and coatings) comply with all regulatory requirements.

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

**FOOD DEFENCE:** The policies and procedures implemented to prevent intentional product or raw material contamination by biological, physical, chemical or radiological hazards that are not reasonably likely to occur in the food supply. Including product safety prevention from malicious contamination or theft.

**GOOD MANUFACTURING PRACTICES (GMPs):** Manufacturing Guidelines as cited in the Code of Federal Regulation 21, Part 110, (USA FDA) or similar regulatory bodies.

## HACCP/FOOD SAFETY 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 shall 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.

**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 shall 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.

**Ready-to-eat food (RTE food)** -- any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

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

**INTERNAL G.D.P. AUDITS (self-inspections):** Audits conducted of the company by the company or for the company that assess the company's compliance to GDPs (Good Distribution Practices).

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

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

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

**RESIZING –** activities whereby product in large packages is broken down and divided into smaller packages for specific customer requirements.

**REPEAT FINDING:** Ann exact deficiency cited at the most recent NSF International Supplier Assurance audit, 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.

**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.

**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.

 