

GDP Food Safety Expectations

Good Distribution Practices (GDP)/Food Safety
Expectations Manual for Food Distribution Centers,
version 4.0

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The following requirements outline the management programs and performance criteria expected of a modern food distribution facility to meet the food safety needs expected by the consuming public, the majority of retail and foodservice buyers, and regulatory agencies. The repackaging (if applicable), storage, and delivery of safe, wholesome, and high-quality foods requires a dedicated effort of knowledgeable food professionals, from product sources through the repackaging, distribution, and sale of the food products. While food safety programs are the hallmark of modern food distributors, high quality is the essential ingredient to ensure success with the consumer. Reliable food distribution systems with disciplined and knowledgeable workforce that fully understand both food safety and consistent quality are necessary to compete in today's market.

There have been a number of changes to the GDP expectations manual and audit form from the previous 2017 GDP expectations manual and audit form.

Throughout the audit, changes have been made to incorporate the widespread changes to the requirements for the storage and distribution of safe food, including those prescribed by the Food Safety Modernization Act (FSMA). While this expectations manual and associated audit asks questions related to preventive control requirements under the FSMA Act, successful completion of the audit may not be considered by the FDA as compliance to FSMA.

The criteria contained within this document are considered essential to meeting these goals on a consistent basis. Of course, the bar is continually being raised as leading companies, not just big companies, work to improve their level of performance to provide reliably safe and high-quality products. Demonstrating consistent achievement of these criteria is the expectation of SAI Global Limited (SAI Global).

This criteria document describes the content of SAI Global's GDP for Distribution Centers/Food Safety Audit. This audit evaluates the adequacy of documentation, compliance to documented procedures, effectiveness of these procedures to control the process within defined limits, and the ability to implement corrective and preventive action plans.

Specifically, this audit evaluates:

- Compliance to United States (U.S.) and/or local regulatory standards
- Compliance to regulations imposed by foreign governments for product exportation, where applicable
- Adherence to specific client and/or internal specifications
- Adherence to specific and/or internal policies and procedures
- The ability to successfully execute a product recall

All information obtained by SAI Global prior to, during, or after the audit will be treated as confidential between SAI Global and the client. Except as required by law, SAI Global will not release any information or report of the audit to a third party without written authorization by the client.

This manual clarifies many audit criteria and expectations that help to ensure product safety and quality.

This manual is generic for all types of food distribution establishments. Some criteria may not be applicable to all facilities. It is the judgment of the auditor or responsibility of the distributor to justify that a specific criteria is not applicable. Likewise, some criteria may be added based on shifting regulatory requirements, specific client requirements, or the ever-changing food safety environment. The criteria are designed for wholesale product and produce distribution.

Distributors located outside the U.S. shall meet SAI Global's expectations, local regulatory requirements, and regulatory requirements for all countries to which products are exported. Specific customer requirements or expectations not captured within this document may be included within an audit addendum, completed in conjunction with the SAI Global audit as applicable.

The stated criteria and expectations are based on:

- Food, Drug and Cosmetic Act (21 CFR) and appropriate amendments
- Food Safety Modernization Act, 2011
- Food Code, 2009 edition (U.S. Food and Drug Administration [FDA]/U.S. Public Health Service [USPHS])
- Canadian Food Inspection Act (Canadian Food Inspection Agency [CFIA]) Safe Foods for Canadians Act
- Federal Meat Inspection Act (9 CFR) and amendments
- Poultry Products Inspection Act (9 CFR) and amendments
- Egg and Egg Products Inspection Act (EPIA) and amendments
- Seafood-US FDA Seafood HACCP (21 CFR Regulation 123)
- Molluscan Shellfish-National Shellfish Sanitation Program (NSSP) Model Ordinance for Molluscan Shellfish
- U.S. Bioterrorism Act of 2002
- Food Safety Modernization Act (FSMA)
- Sanitary Transportation Act.
- Specific client requirements and/or specifications

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DEFINITIONS

Acceptable Laboratory

A laboratory that is able to calibrate its performance standards. This shall be accomplished by performing crosscheck sample analysis with an accredited lab (accreditation shall be achieved through a national accreditation service, e.g., ISO 17025) on a quarterly basis.

Allergen

Food compounds that can cause an allergic or food intolerance response in sensitive individuals. Food allergens elicit serious adverse reactions in some individuals. Allergic individuals can tolerate very little of the offending food. Allergens of regulatory significance in the U.S. include peanuts, tree nuts, eggs and egg products, milk and milk products, soy and soy products, wheat and wheat products, fish, and shellfish (i.e., crustacean). In Canada, oysters, clams and mussels, sulfites over 10ppm, sesame seeds and mustard are also considered allergens. The distribution center shall identify all allergens present in the facility and shall have a written program that will prevent cross-contamination of undeclared allergens (see Sensitive Ingredients).

Calibration of Inspection, Measuring and Test Equipment

The facility shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring, and test equipment (including test software) used by the facility to demonstrate the conformance of product to specified requirements. Inspection, measuring, and test equipment shall be used in a manner to ensure that the measurement uncertainty is known and is consistent with the required measurement capability. Calibration against an accepted industry standard or certified standard shall be conducted at a frequency sufficient to confirm acceptability based on manufacturers' recommendations.

Carrier

A carrier is the person who owns, leases, or is ultimately responsible for the food transport vehicle and its driver.

Certified Laboratory

A laboratory that has met specific certification standards as defined by a laboratory accreditation body to the standard of ISO 17025 (see Acceptable Laboratory).

Client

The manufacturing, distribution or production facility in which the audit will be conducted and whose systems and programs are evaluated. This is generally the entity responsible for payment of the audit service.

Correction

Actions, adjustments, or modifications taken by the client during the audit as a result of an audit finding by the auditor. This correction is generally in response to a finding of a non-conformance, but can be taken at the finding of an opportunity for improvement as well. These actions, when observed by the auditor, will be included within the audit report.

Corrective Action

Corrective action shall be documented for any negative finding reported on a regulatory review, internal assessment, customer complaint or third-party audit finding. The procedures for corrective action shall include:

- Investigation of the cause of the negative finding or complaint. It is important that the root cause of the issue is identified so that adequate improvements can be identified and implemented. Some examples of causes may be lack of training, equipment failure, failure to follow procedure, etc.
- Determination of the corrective action needed to eliminate the cause of non-conformities and the prevention of its reoccurrence.
- Application of controls to ensure that corrective action is taken and that the corrective action is effective to prevent reoccurrence of similar problems.
- Determination of appropriate disposition of non-conforming or affected product.

Cross Contact

The actual or potential contamination of non- allergen-containing product or ingredients with allergen-containing product or ingredients. Cross contact can also occur with the contamination of non-like allergens as well, such as peanut contamination of a milk-based product.

Cross Contamination

The actual or potential contamination of a product or ingredient that has undergone an intervention step (e.g., cooking or washing) to reduce the microbiological level of the product or ingredient with a raw product or ingredient that has not undergone the intervention step. The presence of foreign material or non-potable water in finished or Ready-To-Eat (RTE) product.

Customer

The retail, food service, distribution or manufacturing buyer that is a user of the information obtained during the audit for the purpose of supply chain management. Generally, the customer is not the responsible party for payment of the audit, thus the customer must be given access to the audit information by the authorization of the client.

Document and Data Control

The system for the management, development, revision, correction and storage of all documents, programs, specifications, procedures, forms and records that are used by the facility to manage its food safety and quality management systems.

This system would include an identification system, an approval system and accessibility requirements for records. This system may be electronically managed or completed manually.

Food Code

Reference guide published by U.S. Dept. of Health and Human Services, Public Health Service and Food and Drug Administration, 2017 (<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodCode/FoodCode2017/>).

Food Safety Plan.

Food Safety Modernization Act (FSMA) requires food distributors to have a Food Safety Plan when handling temperature sensitive products and Produce.

Good Manufacturing Practices (GMPs) Guidelines as cited in Code of Federal Regulation 21, Part 117 <https://www.fda.gov/media/94731/download>

Hazard Analysis Critical Control Point (HACCP) Definitions

Applies only to Meat and Poultry Products, Seafood products, Juice Products and Low Acid Canned Foods. For all other products FDA requires a Food Safety Plan.

DCs handling only shelf stable fully enclosed products are exempt from requiring a FSP.

CCP Decision Tree - A sequence of questions to assist in determining whether a control point is a Critical Control Point (CCP).

Control - (a) To manage the conditions of an operation to maintain compliance with established criteria. (b) The process that states where correct procedures are being followed and criteria are being met.

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 to an acceptable level the occurrence of a food safety hazard reasonably likely to occur.

Deviation - Failure to meet a critical limit.

HACCP - Hazard Analysis 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 that is based upon the principles of HACCP and that delineates the procedures to be followed.

HACCP System - The result of the implementation of the HACCP plan.

HACCP Team - The group of people representing the DC management, technical and food safety experts, manufacturing, maintenance, engineering and others 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.

Pre-requisite Programs - All procedures used in the facility that address operational conditions providing the foundation for the HACCP/FSP system.

Severity - The seriousness of the effect(s) of a hazard.

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

Validation - That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP/FSP plan, when properly implemented, will effectively control the hazards that are reasonably likely to occur.

Verification - The application of methods, procedures, tests and audits, in addition to monitoring, to determine compliance with the HACCP plan.

High Risk Vendor

One who is actively supplying product of increased foodborne illness risk to the end consumer. Broad categories include: RTE items, cheese, cooked or fermented meats, leafy greens and ground beef.

Hold

Product that has been identified as non-conforming or awaiting disposition and has been placed in a do not use status.

Internal Good Distribution Practices (GDP) Audits

An effort to evaluate the performance of a facility in regards to good distribution practices and other established company protocols by internal staff. These audits assess internal and external facilities and the results are utilized to drive continuous improvement.

Mock Recall

An evaluation of the company's product recall system that tests the effectiveness of the identification of affected product and the communication tools with key stakeholders.

Pre-Requisite Programs

Supplemental programs to the HACCP/Food Safety Plan, required for the total food safety management by the facility of its product and distribution. Examples include pest management, training, maintenance, allergen management, food defense, etc. Further examples are described later in this manual.

Preventive Maintenance

A series of routines, procedures and steps taken in order to identify and resolve potential problems before they happen.

Primary Packaging

The packaging material that comes into direct contact with the food product.

Process Capability

The ability of a process to distribute a defect-free product (within specification 100% of the time) or service in a controlled manner of production or service environment.

Process Control

The features or mechanisms that control the execution of a process. These control mechanisms ensure a process is conducted to maximum cost effectiveness through effective set-ups and ongoing measures.

Processing

If the character, or nature of the product is changed this will be considered processing and will be judged under Good Manufacturing Practices (GMPs). Examples include cutting, dicing, slicing, washing, rinsing, cooking and cooling.

Ripening of fruit is not considered processing.

Product Traceability

The linking of all identified raw materials, primary packaging, inbound product, repacked and recouped product, rework and selected outbound product through a coding, identification or tracking system from the first level of supplier for inbound product to the first customer product distributed for outbound product.

Product Withdrawal

An activity that recovers all shipped suspect product that has only reached distribution (first customer) and has not yet entered the retail market.

Program

Documented policies, procedures, tasks or activities that describe specific functions within the facility.

Receiver

The receiver is the person who receives product at its final destination.

Recoup

The reclaiming of product and subsequent review to determine the usability of that product. This could be included as returns, rework, or salvage.

Repack

Moving a unit of unexposed product from one outer case to another outer case that requires labeling linked to the original product lot code.

Repackaging.

Working with an exposed product where caution must be taken to avoid contamination of the products.

Risk

The likelihood that a food safety hazard will happen.

Sensitive Ingredients

Food intolerances affecting a limited number of individuals that do not involve immunologic mechanisms (e.g., sulfites, MSG, FDC Yellow #5 and #6).

For the most part, sensitive ingredients involve less severe manifestation and sensitive individuals can tolerate limited quantities of the offending food (see Allergens).

Shipper

The shipper is the person who initiates the shipment of food.

Standard Operating Procedure (SOP)

A series of signed, detailed documents that specifically define how an individual job function or activity will be performed.

Transport Vehicle

Any vehicle that is used to carry food products from one area of the distribution facility to an off- site location or customer. The off-site location may be under the control of the food production or distribution facility.

NON-CONFORMANCE CLASSIFICATION GUIDE AND SCORING GUIDELINES

Rating Criteria	Points
All bold items listed in questions are considered Critical if found and would constitute an automatic failure.	50 points lost in the question; automatic failure of the audit
Major non-conformance would result in a systemic failure of the question: no program in place, employees unaware of non-compliance, more than 3 observations of the audit violation, or the potential for a food safety incident based on the observation.	All points lost in the question
Minor non-conformance would be an isolated occurrence of the observation (1 or 2 instances), elements missing from records or programs, some inconsistency with document vs. actual practice.	Half of points lost for the question
Compliant would be facility fully meets the established SAI Global criteria, facility is able to demonstrate full implementation of the criteria, employees are aware and in compliance.	0 points deducted per question
Not Applicable (N/A) would be used by the auditor for any question the auditor determines is not applicable for the facility being audited.	Points from question removed from total audit score, no points deducted

Automatic ratings are linked to a score. The SAI audit rating system is as follows:

- 97.0-100 Superior
- 93.0-96.99 Excellent
- 87.0-92.99 Compliant
- ≤86.99 Fail

Critical issues that require a rating of FAIL on the audit include:

- Actual adulteration of the stored ingredients, materials, food contact packaging, and product from any cause (e.g., rodents, insects, dripping condensate, dripping oil).
- Failure to have a HACCP program, including a Food Safety Plan (FSP), as applicable.
- Failure to have documented allergen program (repackaging areas only).
- Lack of policy to prevent cross contact that includes segregation during storage.
- Failure to have a documented product recovery program.
- Employees observed not following documented hygiene program causing direct contamination of product (repackaging areas only).
- Observation of significant evidence of pest activity on the interior of the facility.
- A numerical grade of 86.99% or less.

The rating will automatically print next to the score on the final audit report and the auditor is not required to do anything to cause this to happen.

Note: This score and rating may be independent to any addendum or requirements of customers requiring an audit.

REQUIRED DOCUMENTATION

A number of critical documents will be reviewed during the audit process that will assist in evaluating HACCP/Food Safety Plan, Sanitation, GDP, and Management system compliance. **The auditor will randomly select records supporting the implementation and maintenance of each program over a period of six months or, in the case of a re-audit, back to the previous audit. In addition, the implementation of each program may also be verified via interview of employees (where and when applicable).** To facilitate a smooth, organized audit, SAI Global requests that the following documents and records be readily available at the beginning of the audit (note: the bolded documents are required for re-pack facilities only).

A. FOOD SAFETY

- Instrument calibration procedures and records.
- Validated HACCP/Food Safety plan and worksheets; hazard analysis must address how identified hazards are to be prevented or inhibited from growth

NOTE: HACCP/FSP must include the following:

- Identification of HACCP/Food Safety team
- Description of the food and its distribution
- Description of customer and intended use
- Documented detailed hazard analysis based on hazardous conditions for all products
- Documented detailed hazard analysis showing consideration of likelihood of hazardous condition occurrence and severity if it did occur to determine where controls are required.
- Detailed flow chart, showing receiving, storage and shipping and where applicable repackaging of exposed products.
- Document identifying where food safety hazardous conditions are reasonably likely to occur (Temperature abuse, raw over ready to eat, allergens over non-allergens, exposed products, i.e. produce and re-packaging).
- Documents showing compliance to HACCP/Food Safety Plan
 - Monitoring records of Critical Control Points (CCPs/PPCs).
 - Deviation records and corrective action plans.
- Policy and compliance procedure for the allergen program, including all storage requirements demonstrating compliance.
- Label reconciliation program demonstrating compliance to the allergen program, if applicable due to re-packaging exposed products.
- Policy and compliance procedure for foreign material management, including glass and brittle plastic.

Preventive Control aspects as applicable per regulation

- Document identifying any hazards that require a preventive control.
- Associated monitoring, corrective action procedures and records for each preventive control identified.
- Associated evidence that preventive controls, when implemented, will control the identified hazards. Documents for this section include those that document verification of the food safety plan including records related to:
 - Validation
 - Verification of monitoring
 - Verification of corrective actions
 - Calibration of process monitoring and verification instruments
 - Product testing

- Environmental monitoring
- Reanalysis
- Records that document the supply chain program
- Documentation related to the Preventive Controls Qualified Individual, including defined role, responsibilities related to the Food Safety Plan; training documentation; understanding of plan oversight including adherence to all required timelines identified with the Food Safety Plan.

B. PRE-REQUISITE PROGRAMS

- Documented preventive maintenance program and corrective action plan
- Detailed product recall manual, including records of mock recalls (with product coding policy)
- Quality policies and procedures manual
- **Document management and record keeping policies and procedures including record retention policies**
- GDP audit records and corrective action plan
- Policy and procedures for handling returned and retained product
- Customer/consumer complaint procedures manual and appropriate corrective action plan
- Detailed policy and procedure for calibration of in-house measuring devices (e.g., cooler temperature probes, Relative Humidity [R.H.], receiving thermometers)
- Potable water and ice testing records. Potability should be tested at least annually; if the facility is using water from a private well, there must be an acceptable potability test every six months; all samples for potability must be taken from the facility, not just reported from the municipality.
- Calibration monitoring records including testing standards and certification
 - Policy and procedures outlining product coding, if applicable.
- Policy and procedures for handling of any repack or repackaged products (control and traceability), if applicable
- Policy and compliance records relevant to quality attributes
- Standard Sanitation Operating Plan (SSOP)
- Master sanitation schedule
- Sanitation monitoring records with corrective actions and preventive measures
- **Sanitation verification program (including environmental monitoring when applicable), records, and corrective actions**
- Approved supplier program and related records
- Documentation of food safety pre-requisite programs
- Documents of management and employee training
- Documents of training for contracted employees
- Good Distribution Program and employee hygiene policy manual
- Policy and compliance records relevant to GDP/HACCP/Food Safety training

C. RECEIVING AND SHIPPING

- Policy and procedures for receipt of dry, refrigerated and frozen product, including those transported in bulk.
- Product specifications (where applicable)
- Copies of Pure Food Guarantees and continuing Letters of Guarantee for food packaging materials (where applicable)
- Incoming and outgoing trailer inspections
- Policy and procedures for the rotation of stored product

- Policy and procedures for the storage (including temperature monitoring when applicable) of all product

D. GROUNDS AND EQUIPMENT

- Schematic of DC showing water and sewer lines, location of backflow prevention devices, separation of ready-to-eat areas and DC traffic flow patterns
- If high intensity halogen lamps are used, a letter from the supplier indicating that they are shatterproof
- Policy and compliance records related to temporary repairs.

E. PEST MANAGEMENT PROGRAM

- Rodent and pest management procedures manual
- Rodent and pest management activity records
- Current pest control business license, insurance, and pesticide application license

EMPLOYEE HYGIENE PRACTICES

- Good Distribution Program and employee hygiene policy manual
- GDP audit records and corrective action plan

G. FOOD DEFENSE

- Policy and procedures outlining the defense program for the facility
- Policy and procedures outlining the protection of product from intentional contamination

A. FOOD SAFETY (100 SERIES)

A.1 HACCP/FSP

The HACCP/FSP process is the primary food safety management program. HACCP/FSP combines the energies and resources of management with the scientific knowledge of the product and process. Under HACCP/FSP, the operational and quality management groups provide a comprehensive food safety management process, involving all departments in the effective management of food safety. HACCP/FSP is truly a team effort requiring the continuing involvement and commitment of top management, operational management, employee supervision and all operating personnel. Specific, documented training is essential for both management and operating personnel. The HACCP/FSP plan is facility-specific and requires the input of all operating and technical departments with signed approval of top management. The plan must be kept current with annual reviews of operating performance by the management team. Records and documentation of the HACCP/FSP program must be strictly controlled, monitored and signed by appointed management personnel. Any deviations from the HACCP/FSP plan must be thoroughly documented with detailed corrective actions and product dispositions.

The HACCP/FSP team is required to conduct a formal review and sign-off of the program at least annually. The review should document performance and determine if any changes are needed in the plan. The program must be reviewed at least annually, but other potential triggers may also prompt a review. Other prompts outside of the formal schedule include (but are not limited to): any change in raw materials or suppliers (including packaging), changes to formulation, changes to any part of the process, failures in the system such as recalls or product withdrawals. If at any time a new product category is added, the team must immediately formally evaluate the change to determine if the HACCP/FSP plan is impacted, then make any necessary changes to the plan documents. All operating department managers and top management must be continually involved, committed and supportive of the HACCP process to ensure successful management of food safety.

The detailed HACCP program shall include:

Team Involvement and Activity: Team members and their responsibilities are clearly identified as part of the HACCP/FSP plan and include top management, operating department heads, quality management and appropriate operating personnel. The entire team is involved in the development and final approval of the plan. There is documented evidence of team meetings, on a regular basis, to review HACCP/FSP records and issues. The team reviews actual deviations and/or documentation errors as well as trends in the data, with corrective actions monitored for effectiveness.

- **HACCP/FSP Plan Thoroughness:** The plan is specific for distribution center and is current. All appropriate CCPs/PCPs have been identified with appropriate control limits, based on scientific data. Corrective actions for each CCP/PCP have been identified as appropriate. Corrective actions must include instructions on actions to take to secure involved product, bring the distribution process back into compliance and a review to prevent a reoccurrence of the situation. There must be a plan for each type of product or product line (product and lines with the same hazards and CCPs/PCPs may be included in a single plan). Documentation for managing the essential prerequisite programs that support the HACCP/PCP plan shall readily available.
- **Flow Charting Documentation:** There must be an easy-to-understand flow chart for each plan, taking into consideration individual product types, all receiving and storage requirements, all equipment used, repackaging steps, where applicable, and returned products and packaging equipment, as applicable. The flow chart must identify CCPs/PPCs as identified in the Hazard Analysis. CCPs/PPCs must be clearly identified and numbered to correspond with the Hazard Analysis and CCP/PCP records and documentation. The flow chart shall be signed by knowledgeable operations management and dated. The chart must remain current.
- **Hazard Analysis:** There must be a detailed Hazard Analysis document for each group of products distributed. The Hazard Analysis must evaluate all hazards likely to occur. The Hazard Analysis must evaluate the severity of the illness or injury and the probability that the hazard will occur in the absence of controls to determine if a control measure is necessary. Control points must be evaluated to determine those that are critical to the continual storage and distribution of safe food. The Hazard Analysis must be updated, with full documentation, when a change is made to types of products or repackaging or otherwise deemed necessary by the HACCP team.
- **Hazard analysis requirements:** The Hazard Analysis must identify known or reasonably likely hazardous conditions. Known hazards must consider those that Such as temperature abuse, contamination of exposed products and Produce, where applicable.
- **Monitoring Procedures:** Monitoring procedures for CCPs/PPCs must be based on the variability of the activity to be controlled. The frequency shall be sufficient to ensure that all product distributed is within the established limit. Documentation of the measured variable shall be on clearly identified HACCP/PPC records, with the CCP/PPC identified by name and number, the item to be measured, the frequency of the measurement, the CCP/PPC limit, the responsible monitor and the corrective action required, in the event that a measurement is not in compliance. A method to track deviations shall be maintained and available for review.
- **Records Management, Review and Retention:** Documents for monitoring the elements of the Food Safety Plan, including HACCP are extremely important and must be strictly controlled. They may be the basis for determining whether the monitoring was properly managed in the event of a recall or alleged foodborne illness situation. The documents and their data must be self-explanatory and complete. The records must be in ink (not pencil) and signed by the monitor. There must be no blanks or missing data. In the event of down time, or no distribution during a specified monitoring time, an explanation must be provided. The final record must be signed by the monitor and by the designated HACCP/PPC records reviewer. The records must be easily retrievable and secured in a safe storage area. The Food Safety Plan must not be stored off site.
- It is not essential to keep HACCP/PPC documents separate from regular distribution records, if they are secure, but it is recommended. Records related to the Food Safety Plan must be retained for a period defined by the company, taking into consideration the shelf life of the product and any

regulatory or customer requirements. Records should be retained for a period of at least the shelf life of the product plus 12 months, or 2 years: whichever is **longer by FDA requirement**.

- **Validation and Verification Procedures:** Documentation must be available that confirms that there is a scientific basis confirming the effectiveness of the CCPs/PPCs, or other supporting data that demonstrates the validity of the CCPs/PPCs. In addition, the calibration of all related equipment used in the monitoring process must be included in the verification procedures. Lastly, the facility must also meet any specific regulatory requirements related to verification of the plan.

A.2 ALLERGEN CONTROL

In facilities where allergens or sensitive ingredients are stored and there is a potential for cross contact, there must be detailed procedures to prevent the contamination of other products. In the U.S., the eight allergens recognized are milk, peanut, soy, tree nuts, wheat, eggs, fish, and shellfish (i.e., crustacean). Sulfites of over 10ppm, oysters, clams and mussels, sesame seeds and mustard are also considered allergens by the Canadian Food Inspection Agency (CFIA). Any additional allergens may need to be considered depending on the area to which the facility exports product.

The following should be included in the allergen management program:

Dry storage

- **High Risk Product Identification:** Any allergenic products at risk of cross contact, soft-pack or other fragile packaged allergens, must be identified. The facility must develop procedures and controls to protect products during storage and handling. At a minimum, allergenic products identified as high risk due to packaging type or volume, etc. shall be physically controlled with a space or physical barrier.

Applicable in Centers that Repackage exposed Product

- **Allergen Identification:** The facility must review all products being repackaged, stored and shipped to identify all allergens that were used in the manufacturing of the product. The facility must then identify all ingredients from receipt and through product repackaging (if applicable), storage, and shipping, ensuring they are clearly identifiable to all employees who may handle them. The facility must ensure there is proper communication of all allergen-containing product (repackaging included) and how it is identified to ensure traceability and prevent cross contact.
- **Prevention of Cross Contact:** The facility must have a program identifying how allergens are handled from receipt, storage and throughout every step of shipping process (including repackaging, if applicable) such that the risk of cross contact is controlled. Employees handling products that are, or contain, allergens must not handle non- allergenic products without steps to protect against cross contact. Utensils used for these allergenic products must be dedicated and not used for other ingredients unless there is a thorough cleaning and sanitizing procedure applied between uses. Repackaging of products containing allergens should be in dedicated areas where possible. If the use of dedicated areas or equipment is not possible, allergen-containing products shall be scheduled sequentially. For example, scheduling non- allergen containing products first. Soft-packed finished product containing allergens shall be properly segregated from unlike allergen- containing and/or non-allergen-containing finished product. Initial validation and subsequent verification of the cleaning process must be documented.
- **Label Reconciliation:** Labeling for allergen- containing products must indicate the presence of the allergen or sensitizing agent, as required by regulations. The label must include the common name for each allergen.

A.3 REGULATORY COMPLIANCE

It is essential that centers operate in total compliance with regulatory requirements wherever products are shipped and that a positive working relationship is evident with the assigned regulators. The implementation of the program will be verified via review of records and interview of employees.

In order to demonstrate compliance, a facility must include the following as part of its program:

- **FDA Registration Requirement:** Facilities that hold food for human or animal consumption in the U.S. must register with FDA per the Bioterrorism regulation. Foreign facilities that manufacture/process, pack, or hold food that is exported for consumption in the U.S. are required to register with FDA as a part of the Foreign Supplier Verification Program (FSVP) unless the food undergoes further processing

or packaging at another facility outside the U.S. Establishments excluded from the registration requirement are farms, restaurants and other retail food establishments, non-profit food establishments, fishing vessels (except those engaged in processing as defined in Sec. 123.3[k], 21 CFR 123.3[k]) and meat, pork and poultry facilities that are inspected by the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS).

- **Compliance with Regulation:** The facility must demonstrate that there is a system in place to ensure that it is aware and in compliance with food regulation that applies to the products that are repackaged and stored within the facility. Examples of regulatory compliance requirements include weight claims, ingredient labeling, ingredient statements, allergen labeling, and product and process verification.
- **Country of Origin Tracking:** The facility must have a documented SOP defining how COOL is evaluated and managed throughout the receiving, storage, picking and shipping processes. Elements of the SOP must include definition of the regulated products, labeling requirements, maintenance of records and methods for ensuring compliance. The SOP must also include instructions on how to amend receiving, storage and shipping documentation if there are errors or if changes need to be made. For distribution facilities, COOL regulations allow labeling to be provided on the product case, shipping container or on shipping documents for inbound and outbound product. Regulated foods include wild and farmed raised fish and shellfish, fresh or frozen fruits and vegetables, macadamia nuts, pecans, ginseng and peanuts.

A.4 PREVENTIVE CONTROLS

Distribution Centers that are required to comply with the provisions of the Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) (i.e. DCs carrying temperature sensitive products and/or Produce) must have a Food Safety Plan (FSP) that includes the identification of Preventive controls. The Food Safety Plan encompasses any hazardous condition at a DC that could cause a food product to become unsafe (Raw animal products stored over RTE; allergens stored over non-allergens, chemicals stored over food products, temperature abuse of temperature sensitive products during in-bound transportation, in cooler storage, and/or during out-bound transportation and the possible contamination of exposed products during re-packaging). For any preventive controls that are identified, it is the responsibility of the center to ensure these controls are properly implemented. The following must be included for any preventive controls that are identified by the distribution center.

- Preventive controls must be written, and where applicable to a facility, must include process controls, food allergen controls, sanitation controls, a recall plan, and any other procedures necessary to prevent a hazardous condition, temperature abuse or contamination of an exposed product or Produce.
- For all hazardous conditions that are determined to be reasonably likely to occur and require a preventive control, the facility must be able to demonstrate that, when properly implemented, the controls will eliminate prevent the hazardous condition. Verification, including validation of preventive controls, must show that the preventive controls are implemented consistently and effectively.
- Validation of preventive controls must be based on scientific and technical evidence to determine that the food will remain safe.
- Verification activities include calibration, environmental monitoring, if re-packaging exposed RTE products. Records review must be part of verification procedures and have specified timeframes, such that any monitoring records must be reviewed within 7 working days of the activity being monitored.
- When preventive controls are not effectively implemented, there must be defined corrective action procedures. The procedures must address how to immediately control the hazardous condition (corrective action) as well actions that will be taken to reduce the likelihood the problem will occur again (preventive action).
- If a hazardous condition or temperature abused product is found corrective actions must be taken. Similarly, other triggers for corrective action include: identification that a preventive control has not been properly implemented and a corrective action has not been established, if the food safety plan is found to be ineffective, or if a records review identifies records are not complete and/or procedures were not carried out as defined.

PREVENTIVE CONTROLS QUALIFIED INDIVIDUAL

- The food safety plan must be overseen by a Preventive Controls Qualified Individual (PCQI). This individual must have successfully completed training in the development and application of risk-based preventive controls or be otherwise qualified through job experience to develop and apply a food safety system.
- The roles and responsibilities of the PCQI must be clearly defined, including the oversight of: preparation of the food safety plan, validation of the preventive controls, review of records, and reanalysis of the food safety plan. The PCQI is also responsible to provide written justification where timeframes for validation, review, and/or reanalysis exceed the limits set out. The PCQI must be able to demonstrate, through interview or other means, that they clearly understand the requirements of their role.

REANALYZE

- The reanalysis of the food safety plan must occur at least once every 3 years, but it is recommended that it be reviewed as part of the (at least) annual review of the HACCP system. The events that would trigger a review of the HACCP system (section A.1) must also trigger a review of the food safety plan.

B. PRE-REQUISITE PROGRAMS (200 SERIES)

B.1 TRAINING

Documents must be available to demonstrate management's commitment to a planned training program for both management and food distribution personnel. The implementation of the training program will be verified via the review of the training records, interview of employees to ensure knowledge of various topics, and observation during the physical audit.

The following must be included in the pre-requisite training management program:

- The formalized program must include introductory training programs for new management and as new operating personnel. The training policy must address the communication of basic food handling, sanitation, food defense, refresher training for experienced employees, and specific training for identified jobs such as receivers, HACCP Critical Control Point monitoring, or Food Safety Plan, PCP monitoring responsibilities. This program must be reviewed and revised annually, if necessary, to ensure that management and supervision are aware of new food safety issues and control programs. Training programs shall be given to all employees, including new employees, temporary employees and contract employees in the appropriate languages reflecting the workforce population. A method to document understanding, typically testing or performance evaluation shall be an integral part of the training program.
- The facility must require those specifically involved in the monitoring and/or verification of HACCP- and Food Safety Plan (FSP) -related activities to undergo job-specific training ensuring that they understand the importance of food safety as it relates to HACCP/FSP, and specifically the facility's critical control points and preventive controls. The training shall include the same facets as the general training program; it should confirm competence and reassess training as needed, or at least annually. All records related to the training must be maintained. At least one employee must have received formal HACCP training (with certificate) and where applicable PCQI training.
- Distribution Center personnel must be given GDP and personnel hygiene training at minimum on an annual basis to review and update their understanding of food handling requirements to ensure product safety and quality. This training may also be broken down into a quarterly basis. Examples of quarterly training activities could include lunch and learn presentations, departmental meetings, or in-house seminars/workshops covering appropriate food safety and sanitation topics. Training programs shall be given to all employees, including new employees, temporary employees and contract employees in the appropriate languages reflecting the work force population (note: this training can be included along with other training provided by the facility).
- The facility must ensure that those persons responsible specifically for sanitation duties receive all applicable training related to chemical handling. This training must be documented and all records maintained as part of the overall training program.
- The facility must develop a complete list of all training activities related to food safety, quality, sanitation, and food defense, as well as other job specific duties. Requirements of the record are participants' names, description of training provided, who provided the training, verification that the training was completed, verification of competency, and the skill gained by the participant.
- During the audit, compliance may be evaluated by direct questions to employees to determine their knowledge level (e.g., How should refrigerated products be handled during receiving to prevent increase in temperature and possible bacterial growth?).

B.2 MAINTENANCE

The facility must ensure that equipment and materials used for palletizing, repackaging, storage, and transport are suitable for the purpose intended and in good repair. The facility shall have a written program for preventive and corrective maintenance that is up to date and in use. Review of related records and observation during physical audit will serve as verification of the implemented program.

The following must be included in the maintenance management program:

- The documented program must include a list of food handling (if repackaging occurs) and transport equipment. Procedures detailing the maintenance required for each piece of equipment, including requirements for release back into distribution and frequency of maintenance. Preventive Maintenance (PM) frequency shall be adjusted in accordance with equipment history and the outcome of the last service. The facility must address repairs conducted both by internal personnel as well as contractors as they relate to part reconciliation, personal hygiene, product and facility security, and potential product contamination.
- The facility must have scheduled PM activities for all listed equipment. The program shall be tailored to the specific product stored or facilities. Priority shall be given to maintenance of pieces of equipment that may affect food safety, quality, or employees safety.
- The facility must ensure that all records related to the PM activities are maintained. These records may be electronic or paper (note: document control requirements apply) and should be maintained for a period of time to ensure regulatory and/or client requirements are met (note: maintenance of at least six months' records is required for any SAI Global audit).
- Equipment repairs are intended to be permanent and must be performed using proper materials; therefore, the facility must have a program prohibiting the unnecessary use of temporary repairs. The program should include a complete list of materials that are prohibited for use in repairs in the facility.

B.3 PRODUCT RECOVERY AND TRACEABILITY

The facility must have procedures to effectively trace products through the shipping and distribution channels from the first supplier to the first outside customer (note: if the facility does re- pack any incoming products, and/or re-package exposed products these must be included in the program).

The following must be included in the product recovery and traceability management program:

- The product recovery procedure must describe how the suspect product will be identified during receiving, storage and distribution within the facility. The procedure must also describe how recovered products will be disposed of (if applicable).
- The facility's program must identify the recall team members and describe their responsibilities. Current office and after-hour telephone contact numbers and email addresses of all recall team members, both at the DC and head office, if appropriate, must be available to all team members. The facility must also include notification procedures, including contact lists and customer contacts, including back-ups.
- The facility's program must include conducting mock recalls on an annual basis. The program must include the criteria of at least recovery of 100 +/- 2 % of suspect product within four hours. Involvement of the entire team in mock recalls is expected. A management review must be conducted after the exercise is completed and should include documented results of level of success and recommendations for any necessary improvements.

B.4 QUALITY ASSURANCE/QUALITY CONTROL The facility must have detailed policies and procedures ensuring the quality of the product from receiving, handling, repack/repackaging (when applicable), shipping, control and evaluation of food products to ensure that they meet internal and external client specification requirements. These policies must be well organized, available, current, dated and signed by management. The program must be communicated to the organization relative to specific job descriptions. The program must be validated and subsequently verified. The implemented program will be verified via the review of the written program, related records, and interview of facility personnel identified in the roles and responsibilities of the program, and observation during the physical audit. Changes shall be clearly identified and appropriately signed and dated.

The following must be included in the quality assurance/quality control management program:

Document Control: The facility must have a policy with specific procedures for document control, including preparing the distribution documents, identifying areas for control, collecting data, indexing completed forms,

controlling distribution of documents, document filing, and file storage. The policy must identify a specific time limit for holding files and the proper disposition of outdated records. Locations for document storage must be designated. Records maintained off-site must be retrievable within a reasonable time frame. The Food Safety Plan and its records must not be stored off-site. Access to records shall be limited to designated individuals. The documents and data shall be reviewed at least annually and approved for adequacy by responsible personnel prior to use. An updated list of responsible personnel shall be on file. A master list, or equivalent document control procedure identifying the current revision status of documents, shall be established and be readily available to preclude the use of invalid and/or obsolete documents. Invalid and/or obsolete documents must be promptly removed from all points of issue or use, or otherwise ensured against unintended use.

- **Internal Self-Audits:** A key management responsibility is to verify that policies and programs essential in the management of wholesome food products are routinely and effectively implemented. It is necessary to conduct routine self-inspections of policies and procedures to assure management that the proper actions are being taken and that the facilities and equipment are maintained to meet sanitary and operational needs. To that end, the facility must have documented procedures for planning and implementing internal self-inspections to verify compliance to policies and evaluate the effectiveness of the policies. A monthly frequency, at a minimum, is recommended.
- **Corrective Action Program:** The facility must ensure that audit results and subsequent corrective actions are reviewed and signed by management to ensure timely responses to deficiencies and needed corrective actions. Follow-up audit activities for deficiencies and repeat items must record the effectiveness of the corrective actions taken. Repeat issues must receive top management priority to ensure a timely corrective action.
- **Product Holds:** The facility must establish and maintain documented procedures to ensure that product not conforming to specified requirements is not shipped. This control must provide for identification, secured segregation, documentation, evaluation, disposition and reconciliation of product that is placed on hold. A hold tag policy must include a permanent written log of each product or item placed on hold. The log shall list the date, the product, the quantity, the reason for the hold, the results of the evaluation and the disposition. Disposition must be dated and signed of all on-hold products. The facility must have a policy for handling returned products. Returned products must be identified and placed on hold immediately. There must be a designated, clearly identified area or management system to ensure a location is maintained for returned or retained products. The facility must outline roles and responsibility relative to the disposition of all food products. The auditor will test the implementation of the program during the audit; the auditor will randomly select a product on the hold log and verify its location within the facility.
- **Customer Complaints:** The facility must have a written program for handling customer or consumer complaints. The policy must address responsibilities, response time and corrective actions based on an investigation of the complaint. A log is essential to track complaints by product identification, shipping dates, cause and origin of complaint. Customer information can be a valuable resource for validating HACCP/FSP criteria and, to that end, should be used as part of the continuous improvement program.

Equipment Calibration: It is essential that all measuring devices (e.g., thermometers, scales, cooler probes) be properly calibrated to ensure the accuracy of these activities and the effectiveness of their performance. Routine annual calibration (i.e., certification) of scales by an outside contractor is required. The thermometers must be identifiable, and calibration of results must be documented.

Calibration of thermometers shall be based on certified standard thermometers or a recognized standard (e.g., ice water).

Calibration procedures shall describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions shall be specified and noted when exercised. There shall be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used.

B.5 SANITATION

The effective management of sanitation, housekeeping and hygiene is a critical element requiring the commitment and cooperation of all operating departments and support groups. It requires specific policies covering requirements and expectations, training to communicate those requirements with management follow-up to ensure that the requirements are properly met and that all sanitary standards are fully enforced. Review of related records and observation during physical audit will serve as verification of the implemented program. The SSOP is the instructions for how a cleaning activity is to be completed. The SSOP would include who will perform the cleaning, what equipment and chemicals are needed, how the cleaning is completed, how often the cleaning is required, and what records need to be completed.

The following must be included in the sanitation management program:

- The facility must have a documented SSOP for any product spill in any area of the facility. This would include poultry, beef or pork spillage or drippings. Allergens dripping (Milk, eggs, etc.) and bags of allergens getting damaged (i.e. flour). This SSOP should describe the specific equipment to be used for the clean-up and the method of sanitizing the area (e.g., chlorine or quaternary ammonia).
- The facility must also have documented SSOPs for receiving, storage, shipping, salvage, trash storage, recoup and any repack/repackaging areas. In addition, external areas of the facility (e.g., docks, dock levelers, dumpsters) must have a SSOP covering their sanitation.
- If the facility does any re-packaging they must develop a verification procedure for the sanitation program that is relevant to the risk of the process. At minimum, management must use a pre-operational checklist to verify the area and equipment are clean and sanitary. All equipment, containers, utensils, walls, floors, ceilings, light fixtures, miscellaneous overhead structures, etc., shall be evaluated for visual cleanliness. Deficiencies noted and corrective actions taken must be documented. In addition to the pre-operational inspection, Adenosine triphosphate (ATP) measurements are based on the detection of ATP by bioluminescence and can be the initial method of choice in monitoring cleaning efficiency. It is a rapid measurement of the actual hygiene status of a sampled surface, allowing fast initiation of corrective actions in the case of inadequate cleaning. ATP measurement, however, should not completely replace traditional techniques (swabbing), and should be integrated with traditional cultural techniques as part of a coherent surface cleanliness monitoring system. Although manufacturers of ATP measuring devices give general guidance on acceptable ranges for routine hygiene controls, internal standards have to be set for the given processing environments. If the facility is re-packaging an exposed RTE product, the verification program must include food contact swabbing for protein residues and environmental swabbing for *Listeria monocytogenes* or species. The facility must retain all records related to the verification of the sanitation program.

B.6 SUPPLIER MANAGEMENT

The facility must ensure that each product supplier is capable of providing product(s) as specified. Specifically, for the suppliers of products in which the distribution center takes ownership, including product in a facility-branded package of which the supplier is chosen by the distributor (private label), an approved supplier program is required to be documented. It is important that the detailed program be developed outlining how each potential supplier will meet agreed specifications for those products of which the distributor has taken ownership. Criteria to be included within the program would include the level of risk the potential supplier's finished product poses, the requirement of GMPs and SSOPs at the potential supplier's facility, the fact that product/raw materials will be received from approved suppliers only, and the overall methods for granting supplier approval. Interview of responsible personnel and review of related records pertaining to the program will serve as verification of proper implementation during the audit process.

The following must be included in this supplier management program:

- Where required by the above description, the facility must have an approved supplier program outlining requirements for its specific facility (note: this includes facilities where the corporate office develops the supplier program). The facility should outline how it will implement and facilitate the requirements.
- The facility must include ongoing monitoring and assessment of all approved suppliers. The facility must outline which method is used to monitor/assess the suppliers. The assessment process must be documented and include feedback between the supplier and the facility. Records related to the approval program must be maintained.

C. RECEIVING, STORAGE AND SHIPPING (300 SERIES)

C.1 RECEIVING AND SHIPPING

The facility is expected to have detailed, written policies describing how the receiving, acceptance, handling, and shipping of dry, refrigerated (temperature sensitive) and frozen products are performed and documented. The following must be included in the receiving and shipping management program:

- The facility must have a written inspection program for all inbound and outbound carriers that fully describe acceptable and/or unacceptable conditions. For contracted carriers in which each vehicle is not inspected, there must be written specifications to that contracted carrier, including any specific sanitary requirements for the vehicle and transportation equipment, as well as any cleaning procedures. The specifications must also include temperature requirements for the food being received/shipped including pre-cooling phase, where applicable. All railcars, trucks, etc., must be inspected at time of receiving or loading to ensure condition, cleanliness, and that they are free of moisture and offensive odors. Materials within vehicles must be appropriately separated to prevent contamination from raw to ready to eat food and/or from incompatible materials (e.g. chemicals) or odors. Carriers must be in good repair, with no evidence of pest activity, and free of foreign substances such as glass, chemicals or odors. Interior of trailers, trucks or cars must be free of loose or broken boards, nails, and holes in sheet metal sides that could cause contamination or serve as pest harborage. Trailer or railcar security seals must be verified as the original seal number applied at the original shipping point when product is being received. The distribution center must also ensure that all carriers are appropriately secured (e.g., seals or locks) prior to their departure from the secured shipping area except for Less Than Full Loads (LTL). For temperature sensitive products, receiving and shipping vehicle and product temperatures must be documented on receiving/shipping documents.
- Documentation of condition of each inbound/outbound shipment and seal number (or evidence that trailer was otherwise secured) must be shown on receiving/shipping documents or their equivalent. The implementation of the program will be verified during the audit by interview with responsible employees during the physical audit of the receiving and shipping activities and review of documented receiving/shipping inspection records.
- If the distribution center uses a third-party carrier, it is the responsibility of the distribution center to ensure all shipping employees have received appropriate training to ensure the safety of the food being transported.
- The facility must ensure that all perishable products are handled during receipt in such a way that potential contamination and/or temperature abuse does not occur. The receiving and shipping areas shall be maintained in a sanitary manner without debris build-up. The facility must also outline procedures as part of the receiving program to ensure that temperature sensitive items are not held outside of the appropriate temperature storage areas for a prolonged period of time, generally no more than one hour. In addition, the facility shall ensure that dock shelters, dock doors, and levelers are maintained in good condition to prevent potential pest entry. The distribution center shall ensure that any third-party carrier complies with defined specifications to ensure the safe transport of food, including any temperature requirements, or specifications related to incompatible materials or commingling of raw and ready to eat foods.
- The distribution center shall ensure that incoming products are not stored or repackaged until they have been inspected or otherwise verified as conforming to internal requirements. Verification of the specified requirements shall be in accordance with the product safety and quality plan and/or documented procedures.
- Systems shall be established to handle product that is in non-compliance along with documented verification as to the disposition of that product.

C.2 STORAGE

The facility must have policies and procedures outlining how they protect product during repackaging of exposed products (if applicable) and while being stored.

The following must be included in the storage management program:

- The facility must have a detailed procedure outlining how incoming products are rotated to ensure food safety and/or quality is not compromised. At a minimum, the facility must be using a rotation program based upon first in first out (FIFO). The facility may use other types of rotation based upon client specification. When such systems are used, the facility must have documentation of the procedure.

The distribution center must ensure that product is not subjected to potential contamination during storage and product shall be stored at least six inches from the floor and 18 inches from exterior walls. This is to ensure proper sanitation and to facilitate the implementation of the pest management program. The center will also ensure that the product is stored dry, intact, and in good condition. The center must have a process for inspecting and removing product that becomes damaged during storage. There should be an identified area in each separate storage area of the facility. The center must also ensure that products are not subjected to potential contamination due to dripping, condensation, or improper storage practices (e.g., raw over RTE or chemicals over food product or water dripping from ceilings, pipes, or refrigeration units). The implementation of the program will be verified during the record review and the physical tour of the center.

- Appropriate allergen storage practices must be adhered to according to the documented allergen management program.
- Products are to be stored in racks or on pallets and not stored or located on the floor (note: incidental product that was observed to have fallen on the floor will not be considered a non-conformance).
- Dripping from ice must be controlled, so as not to pose a risk to any non-ice packed product.
- Warehouse storage areas (e.g., floors, walls, and ceiling) must be clean and orderly, with no long-standing spills, debris/dust build-up, and be free of any mold growth. All racking, ceilings, and other overhead structures must be in good repair with no chipping or flaking paint and are maintained in a sanitary manner (e.g., dust build-up or leakage of any kind) so as not to cause contamination.
- Temperature sensitive areas (when applicable) must be properly monitored with daily logs to verify that appropriate temperatures are maintained. The probes in these areas should be properly located in the warmest area of the storage cooler/freezer. The facility must ensure that these areas are monitored at least twice daily. The implementation will be verified via review of random records from the past six months or in the time period since the previous audit, as well as a verification of the accuracy of room thermometers during the physical audit of the facility.
- Temperature sensitive areas should be free of condensate and ice build-up that may lead to contamination.
- If product or ingredients are stored in transportation vehicles, the distribution center must ensure the vehicles are regularly inspected to ensure product integrity. The distribution center must be able to demonstrate compliance to any temperature requirements of stored products. The monitoring must occur at a documented frequency and the site shall be able to demonstrate compliance at all times. Transportation vehicles shall remain locked and all product and/or ingredients stored shall be inspected prior to use or being transported.

C.3 PRODUCT RECLAIM

The facility must have a procedure outlining how to handle reclaimed/returned product to ensure that it does not pose a contamination risk to stored product and that reshipped product does not possibly pose any hazard to the consumer (note: facilities that do not re-pack are only required to implement the segments of the program relative to the handling of returned product).

The following must be included in the product reclaim management program:

- The center must have a documented program (including roles and responsibilities) outlining how reclaimed/returned product is received, repackaged (if applicable), and staged for further disposition. The facility must include specific procedures at each step of the process that include roles and responsibilities, where product is staged during each step of the reclaim/return process to prevent

possible contamination, and policy/procedures used to determine final disposition of product. The verification will include the review of the written program, interview of identified employees to ensure that they are knowledgeable of the procedures, and inspection of the reclaim/returned areas to ensure that the program is being followed as written.

- As part of the documented program, the center must include specific policies on how reclaimed/returned product is received (including roles and responsibilities). The outlined policy must include procedures used to determine product status. Examples will include coding, relabeling, repack, reprocess, product destruction and storage of returned product.
- The facility must ensure that the all personnel involved in the reclaim/returned product process receive documented training to ensure knowledge of the program as well as methods of implementation. Training will be verified via interview of personnel and handling of product during the audit process.
- The facility's documented reclaim/return policy must address the repackaging of any reclaimed/returned product (if applicable) and how the center manages the labeling of product for traceability. The implementation will be verified via the direct observation of these tasks during the audit, interview of responsible personnel, as well as review of random records in the past six months or in the time period since the previous audit).

D. GROUNDS, FACILITY AND EQUIPMENT (400SERIES)

The construction of the grounds, facility, and equipment must be such that it facilitates the repackaging (if applicable) and storage of wholesome product and that it meets the standard and regulatory food safety and quality requirements. The following must be included in the grounds, facility and equipment management program:

D.1 DISTRIBUTION CENTER GROUNDS

- Exterior of the distribution center and grounds must be constructed to minimize dust and be free of standing water. The area must be included on the master cleaning schedule to ensure that there is/are not any debris build-up, overflowing trash cans, and/or improperly maintained employee lunch areas present. The auditor will inspect the following areas during the audit to verify the implementation of the program: all dock areas, exterior dock plates stations, employee smoke and lunch areas, and changing facilities if appropriate
- The facility must ensure that all on-site trash disposal areas are maintained so as not to become a source of pest harborage or potential contamination. Doors and lids to all disposal units must be kept closed between uses. The facility must ensure that the removal of all waste is adequate to prevent unnecessary build-up that may lead to pest harborage, odor, and potential contamination. The facility must ensure that all disposal units and areas are included on the master cleaning schedule.
- The facility must ensure that any and all equipment stored on the exterior of the facility is done so in a manner whereby it does not become a potential source of pest harborage and/or contamination to the finished product. It is recommended that equipment be stored at least 20 feet away from the building.

D.2 FACILITY

- Ceiling surfaces, as well as other overhead equipment, must be clean, in good repair, free of flaking paint, rust, holes or unsealed openings, or free of other conditions that could result in product contamination. Ceiling panels, framework and supports must be properly secured with no missing or damaged parts. Ceiling penetrations for pipes, conveyors, wiring, etc., must be sealed to prevent harborage, ceiling leaks and contamination. There shall be no evidence of water leaks on ceilings. Ceilings shall be constructed of a smooth, non-porous, non-absorbent and easily cleanable material. Insulation materials used overhead shall be in good repair, smooth, non-absorbent and easily cleanable. Joint areas must be sealed.
- Distribution Center Storage: All lighting shall be completely enclosed in protective shields or manufactured with shatterproof materials to prevent glass contamination of any exposed product. This includes all repackaging (if applicable) areas, produce areas, and general storage areas. In addition, enclosed, shatterproof lighting is highly recommended for all storage areas (e.g., coolers, freezers, dry), receiving and shipping docks, maintenance, toilet areas, break rooms, and welfare areas.
- All lights must be protected, including emergency lights, forklift lights, and adjustable trailer lights on the dock. Light fixtures shall be maintained clean and free of cracks, dust or other materials that could cause contamination. General distribution center lighting shall be a minimum of 20-foot candles (100 lux and 200 lux in those areas used for inspection).
- Equipment shall be designed to preclude or divert condensate away from product. Adequate heating, ventilation or refrigeration shall be provided in all areas to maintain proper environmental and sanitary conditions for ingredients, finished product, and packaging materials. All systems must be clean, properly functioning and designed in such a manner to prevent product contamination from condensation, mold, bacteria, insects, dust or odors. Heating and ventilation must be balanced to prevent condensation on walls or ceilings in product areas.
- Locker rooms shall be adequately sized (where applicable), well lit, clean and orderly. It is recommended that lockers be available for storing personal clothing items. Food and equipment or utensils shall not be stored in locker rooms. A routine locker-cleaning schedule shall be maintained. Locker tops shall be sloped to prevent accumulation of dust and debris, as well as to facilitate cleaning. Adequate and convenient hand washing facilities must be provided in or adjacent to locker rooms, in toilet facilities, and at entrances to

repackaging areas. Signs in appropriate languages, or graphics, shall be clearly posted in locker rooms.

- Toilet facilities must be available in locker rooms or convenient to operational areas if located distant from the locker rooms. They shall be well ventilated, well lit, clean and orderly. Covered receptacles must be present in female facilities. Doors to toilet facilities shall be self-closing and must not open directly into repackaging or storage areas.
- Hand washing stations must be available in bulk receiving and/or where raw material is received to minimize the risk of cross contamination. Personnel must be able to demonstrate through observation or interview the proper procedures for hand washing.
- The hand washing stations must deliver tempered water (90 - 105° F (32-41° C)) within 20 seconds. Additionally, there must be an adequate supply of hand soap and/or sanitizing agent (if applicable). Single service towels shall be available with convenient disposal at each station. Additional sanitizing stations may be required near workstations in repackaging areas.
- Lunch/break rooms should be properly equipped with storage, heating, and cooling to ensure food is not stored in personal locker areas.
- Trash cans or waste receptacles need to be covered.
- Floors must be well drained, smooth, easy to clean with no aggregate exposed and no cracks, holes or broken areas. Drains must have traps and drain covers must be maintained in place. Drains must be free from odors. Standing water must not be evident in repackaging or warehouse areas.
- The facility must ensure that battery-charging areas used for transport vehicles do not pose a potential threat to stored product. The facility must ensure that procedures are in place to address any emergency that may arise, and any potentially affected product is held for further disposition.

D.3 EQUIPMENT

- Storage equipment shall be designed, installed and maintained in such a manner as to produce a safe, wholesome and quality product. Equipment (if used) must be designed and maintained to provide easy access, disassembly and reassembly for thorough cleaning, sanitizing and inspection. Equipment must be of smooth, impervious, non-toxic, non-absorbent and corrosion-resistant material where it has direct product contact. Conveyor belts for product contact shall be of impervious, non-absorbent material. Fiber-backed or sandwiched belts shall not be used for product contact conveyors. Belts shall be maintained in good condition with no holes, cuts, frayed edges or damage that renders the belt difficult to clean or presents a foreign material hazard.
Product contact surfaces, such as conveyor belts, shall not be closer than 18 inches to the floor or shall be effectively protected from contamination during operations. Equipment must be free of cracks and non-continuous or rough welds where product may become embedded and make cleaning difficult.
- The facility must ensure that all equipment and containers used in the repackaging process (when applicable) are suitable for the identified purpose. All equipment must meet requirements for use in a food establishment. Containers previously used for chemicals or other product that may pose cross contact or contamination potential must not be reused anywhere in the center.
- Non-food grade materials such as wire, tape, string, plastic or cardboard shall not be used for temporary repairs.
- The facility must ensure that all transport equipment is in good repair such that it does not pose potential contamination to the product due to dripping fluids, damaged lights and/or brittle plastic, rough welds on trolleys, over lubrication, foreign material due to torn seats, etc.

E. PEST MANAGEMENT (500 SERIES)

It is recommended that all food storage and distribution facilities operate under the authority of a licensed Pest Management Provider (PMP). Typically, these are individuals from outside the company. They must have a proper license, certification and insurance. They shall be expected to provide aggressive support to the distribution center pest management, housekeeping and sanitation programs especially as they relate to potential pest harborages and conditions that compromise the evaluation of pest management. Since they are trained experts in recognizing and evaluating conditions that contribute to potential pest development such as sanitation, housekeeping, properly sealed doors and windows, perimeter accessibility and outside grounds conditions, it is expected that they will include observation comments on these situations in their activity reports with appropriate recommendations for corrective action, including issues pertaining to storage, sanitation and structural repair. Any comments on the activity reports must have a documented response and corrective action, if appropriate. If pest management is internal, the same level of expertise must be provided. Likewise, the same aggressive approach to the above areas of concern must be required with documented activity reports and responses.

E.1 THE PEST MANAGEMENT PROGRAM

The following must be included in the management program:

- A written, detailed pest management policy and program must be available. The policy shall outline and describe all procedures required to ensure that activities conducted by the PMP and trained employees are carried out in accordance with the prescribed policy. A distribution center-specific pest management manual shall be current and updated at least annually (program must outline who conducts the services, the frequency of service, the pesticides that are used or could be used at the facility, and a schematic map that lists the location of all pest management devices that are in place). Oversight of the pest management program shall be assigned to a qualified and trained company employee. The policy shall identify forms used by the PMP. The activity/action reports shall document what chemicals are used, if any, where, why, and with relevant observations of activity. Schematic site maps for traps, glue boards and bait stations shall be reviewed regularly, dated and initialed by the person who has responsibility for the program. The development (roles and responsibility) and implementation of the program will be verified via review of the documents developed by the center or provided by the contracted service provider. All records related to the program will be randomly reviewed (five random records over the past six months or in the time period since the previous SAI Global audit).

Interview of responsible personnel related to the program and its individual parts also will be conducted to verify appropriate implementation.

- The PMP must have a current business license and operating insurance. In addition, a PMP applicator's license and letter of insurance must be on file along with appropriate Safety Data Sheet (MSDS) forms for all chemicals and pesticides used and product data sheets describing how and where the product can be used and against what target pest. Company employees engaged as PMPs must have proof of appropriate training and licensing as required by state or local regulations. Training of company employees can be by the PMP or other qualified experts. Forms used by the PMP and the company personnel shall be the same for uniformity.
- The PMP shall conduct inspections, as needed, based on history of pest activity. PMP activity reports must indicate specific sites of activity, type of activity and recommended corrective action. Interior rodent traps must be monitored on a weekly basis and exterior stations monitored monthly at a minimum. Subsequent reports shall indicate effectiveness of actions. If electronic scanners are used to check bait stations or traps, the tag or barcode must be inside the station or trap.

- The PMP must ensure that equipment used in servicing the facility does not pose a threat to the food safety of the product. Only mechanical traps or glue boards may be used inside the facility. No bait stations are permitted inside the distribution center. Rodents shall be disposed of immediately upon discovery. If zapping or electrocution- type Insect Light Traps (ILTs) are in use, they must be placed so that they do not become a possible contamination hazard to product (especially where exposed product is stored and/or repackaging occurs). If used in the aforementioned areas, these ILTs must be a minimum of 15 feet away from exposed product areas and/or equipment.
- Trap locations shall be recommended by the PMP based on potential access points and knowledge of pest habits. Exterior opening doorways must have traps on both the left and right sides of the opening inside the doorway. Bait stations used outside shall be placed based on habitat and potential access. They shall be positioned to prevent the intrusion of casual water and rain and firmly secured to prevent removal from the assigned position or opened by unauthorized personnel. Bait shall be secured within the bait station and secured to prevent removal from the station. Bagged or other unsecured baits shall not be used.
- The facility must ensure that interior traps are properly maintained in sanitary condition, good repair and in the appropriate position per the schematic site map. All rodent devices must be placed directly against the wall to ensure that they work properly. ILTs must be plugged in and bulbs must be operational. ILT bulbs must be shatterproof and replaced on an annual basis, at a minimum (documentation must be present). Exterior stations must be kept clean, stocked with fresh bait, anchored to the ground, free of damage, and tamperproof (i.e., locked).
- As a demonstration of the successful implementation of the program, the facility must be free of pest activity to prevent possible product contamination. If live activity associated with pathogen-carrying pests (e.g., rodents, birds, cockroaches) is observed, it is a critical violation and will result in failure of the audit. The facility must be free of any evidence that suggests that there are pest issues present (e.g., rodent droppings, insect carcasses). Any sign of decomposed rodents in the facility (be it in a trap or in the facility) is not permitted and shows a major deficiency in the pest management program.
- PMP activity reports must indicate specific sites of activity, type of activity and recommended corrective action. Subsequent reports shall indicate effectiveness of said actions. Responsible distribution center personnel, noting PMP observations and comments, shall sign activity reports. There shall be a documented management response to all recommendations on the activity report.
- The building structure must be sound with no holes, unscreened exterior openings, broken windows, etc. that may allow pest entry into the facility. All entrances including employee doors, shipping and receiving dock areas shall have appropriate protection to prevent the entrance of flying, crawling or running pests. Specifically, receiving and loading doors and shelters must be in good repair and not have any openings that could allow for entry. There should be no gaps greater than one- fourth inch (1/4") around dock doors or dock levelers that could allow for pest entry. Finally, dock levelers must function properly to allow for easy closing of dock doors after the loading or unloading of trailers is completed. When verifying gaps at dock doors, check the gap with a pen to ensure that it is no greater than one-fourth inch.
- The facility must ensure that any pesticides housed on the premises are stored appropriately. All pesticides must be stored segregated and secured from all other chemicals. These pesticides must be properly labeled and used in such a way that they do not pose a threat to food or food packaging.

F. EMPLOYEE HYGIENE PRACTICES (600 SERIES)

Facility employees must observe the strictest of personal hygiene practices as outlined in the Code of Federal Regulations, Section 21, Part 117, and current GDP for food distribution centers. This regulation establishes the minimum requirements for basic food handling. The goal of high quality and long shelf life products also dictates adherence to a stricter standard. Consequently, a specific documented, detailed and closely monitored management program is expected to cover this vital area of wholesome food production. The following must be included in the employee hygiene practices management program:

F.1 THE EMPLOYEE GMP PROGRAM

- The facility must have a distribution center- specific documented GDP training program for all employees. All new employees (e.g., seasonal, part time, contract) must be provided initial training covering basic GDPs and specific distribution center policies regarding sanitation, housekeeping and personal hygiene. The program should specifically cover: Good distribution requirements and regulatory basics, personal dress, hand sanitation and grooming requirements, distribution center sanitation policies and procedures, food safety (HACCP/FSP) and quality control policies, and product tampering awareness and consequences. Follow-up, continuing refresher training shall be provided at least annually. Special training to address operational deficiencies must be provided as required. The implementation of the program will be verified via the review of the written document(s) and accompanying record(s) that evidence training of all employees involved in repackaging and /or distribution activities. The implementation will also be verified during the physical audit whereby the auditor will observe any repackaging as well as applicable areas in the distribution center for compliance to the documented program.
- The facility must encourage adherence to GDPs via the posting of appropriate GDPs in those areas where compliance is required. In distribution centers this would include any and all applicable repackaging areas as well as receiving of bulk and raw meat ingredients.
- Exceptions to the written GMP program must be clearly identified and included on the posted signage in any excluded areas.
- GDP self-inspections shall be scheduled routinely by responsible first line supervision and verified on a random basis by management. These audits shall be documented with corrective actions attached. Frequency and verification shall be based on need to ensure effective control. At least a monthly frequency is recommended. Audit results and corrective actions shall be reviewed and signed by management to ensure timely responses to deficiencies and needed corrective actions. Follow-up audit activities for deficiencies and repeat items shall record the effectiveness of the corrective actions taken. Repeat issues must receive top management priority to affect a timely corrective action. The implementation of the program will be verified via the review of records related to the self-inspection program and subsequent corrective actions (i.e., random records will be reviewed from the past six months or the time period since the previous SAI Global audit).
- The center must have a documented GDP program for visitors, contractors, and tours. The program must list all GDPs that must be followed by visitors, contractors, and tours (including when and where they must be followed). The center must require written acknowledgement of the GDPs by all visitors, contractors, and tours.

F.2 EMPLOYEE HYGIENE PROGRAM IMPLEMENTATION

- The facility must ensure that employees are in compliance with the written GDP program.
- Employees working in repackaging areas, where product is exposed, must not wear fake fingernails, fingernail polish, jewelry, rings (with the exception of plain wedding band), watches, or visible piercings, etc. Outside pockets above the waist on smocks, shirts or coats shall be sewn shut.
No pens, combs, pencils, thermometers, etc. may be carried in these pockets at any time while in the repackaging area.
- Fine mesh nets or other effective hair restraints for head and facial hair must be worn in all repackaging by all employees (e.g., visitors, contractors, tours, management not involved in the process).

- The DC must provide and the employees must use means to avoid contamination of their outer clothing when using the toilet facilities when working in any repackaging areas. Coat hooks are generally made available for employees to hang their outer garments outside the toilet facilities.
 - Eating, drinking or using tobacco products is not permitted except in designated areas. This must be enforced by the facility. Any exception to drinking in repackaging or work areas must be clearly outlined and monitored by the facility.
 - Locker rooms shall be adequately sized, well lit, clean and orderly. It is recommended that lockers be available for storing personal clothing items.
 - Hand wash stations must have adequate room to accommodate the number of personnel in the repackaging area to prevent delays that may discourage proper hand washing procedures. The facility must have a process in place to verify compliance to this standard upon entry into repackaging areas and after breaks. The hand washing stations must deliver tempered water (90 - 105° F (32- 41° C)) within 20 seconds. Additionally, there must be an adequate supply of hand sanitizing soap and/or sanitizing agent.
- Single service towels shall be available with convenient disposal at each station.

G. FOOD DEFENSE (700 SERIES)

Food distribution facilities must develop specific procedures to secure their product, to deter and to prevent intentional contamination, and have protocols in place to quickly and accurately identify, respond to and contain threats or acts of intentional contamination. The implementation of each area of the program (outlined below) will be verified via the following methods (when and where applicable): review of the written program, related records, and interview of facility personnel identified in the roles and responsibilities of the program, and observation during the physical audit. The following must be included in the food defense management program:

G.1 THE FOOD DEFENSE PROGRAM

- The facility must develop a food defense program outlining the site's food defense procedures and strategies. The program must include clearly defined roles and responsibilities of those individuals responsible for maintaining the program and addressing access to the facility, visitors, incoming product, security inspections, employee identification and other appropriate food defense requirements per local regulation. The program must be communicated to all employees throughout the organization and reviewed on an annual basis.
- The facility must ensure that background screening checks on employee candidates are performed. This requirement will include all levels of employees.
- The facility must ensure that there is a system in place to record, track and provide identification and appropriate restricted access of all people, including employees, visitors and contractors, 24 hours per day seven days per week.
- The facility's program must include the requirement to provide identification and require sign-in of all contractors and visitors prior to entering the facility. The program must also include that the visitor and/or contractor remain escorted at all times while on the premises. In the event that a visitor and/or contractor are allowed to enter and work on the premises unescorted, a documented screening procedure must be in place.
- The facility must have a documented procedure in place that addresses the protection and monitoring of incoming products as well as product during repackaging (if applicable) and storage. The procedure must ensure that all incoming goods are inspected to ensure packaging integrity. The facility must have a documented procedure that addresses the security of transportation vehicles for customer delivery or inter-company transfers. This could include the sealing or locking of trailers or the use of tamper-evident packaging on products.

G.2 FOOD DEFENSE IMPLEMENTATION

- The facility must implement a routine assessment (a minimum of monthly) of the food defense program. This will include all physical areas such as verification of restricted areas, possible evidence of tampering at any point in the process (tamper-evident packaging), etc.
- The facility must demonstrate that the restricted access policy is properly implemented, thus doors entering the facility that should be secured must be verified as such. If doors are not secured into the facility, staff, such as a receptionist, must continually monitor them. In the event that closed-circuit cameras, security guards and/or gates are used, the correct use must be verified and documented. The facility must also have a designated visitors' entrance with appropriate signage indicating it as such.
- In the event that the facility uses water treatment, and/or water storage systems, these must be verified as secure between uses. In addition, the facility must properly protect any equipment stored for future use as well as ensure that this equipment will not be subject to contamination. In the event the facility does not fence the perimeter of the grounds, the facility must ensure all equipment is protected via alternative methods (e.g., the use of caps and/or locks).
- As part of the receiving and food defense programs, documentation that incoming products are received in a secure manner (via seal and/or lock) is required. Documentation of proper implementation (including signature verifying the use of a seal and/or lock) must be maintained. All outbound products must be secured as well.

- The facility must be able to demonstrate that all loading and unloading of product is properly supervised to ensure security. If after hours deliveries are accepted, this process to ensure proper supervision and security must be outlined and implemented.