Expectations Manual

GMP Food Safety Expectations

Good Manufacturing Practices (GMP)/Food Safety Expectations Manual for Food and Food Packaging Manufacturing Facilities, version 5.2

SAI GLOBAL

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The following requirements outline the management programs and performance criteria expected of a modern food or food packaging processing facility to meet the food safety needs expected by the consuming public, the majority of retail and foodservice buyers, and regulatory agencies. The manufacture and delivery of safe, wholesome, and high-quality foods, food products and food contact food packaging materials requires a dedicated effort of knowledgeable food professionals who understand processes from ingredient sources through the manufacturing, distribution, and sale of the food and food packaging products. While food safety programs are the hallmark of modern food and food packaging manufacturers, high quality is the essential ingredient to ensure success with the consumer. Reliable food manufacturing systems with a disciplined and knowledgeable work force that fully understand both food safety and consistent quality are necessary to compete in today's market.

There have been a number of key changes to the Good Manufacturing Practices (GMP) Food Safety Expectations Manual for Food Manufacturing Facilities and audit form to bring it into compliance with the Food Safety Modernization Act (FSMA) and 21 CFR Part 117. Throughout the audit, changes have been made to incorporate the widespread changes to the requirements for the production of safe food, including those prescribed by the Food Safety Modernization Act (FSMA) relative to subpart C -- Hazard Analysis and Risk Based Preventive Controls. 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 being totally in compliance with FSMA.

The following criteria are considered essential to meeting these goals on a consistent basis. Of course, the bar is continually being raised as leading companies, not just large companies, work to improve their level of performance to provide reliable, 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 and requirements of SAI Global's GMP/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 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
- Ability to successfully execute a product recall

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All information obtained by SAI Global during the collection of information 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 processing establishments. Some specific criteria may not be applicable to all facilities. It is the judgment of the auditor or responsibility of the manufacturer to justify that a specific criterion is not applicable. Likewise, some criteria may be added based on changing regulatory requirements, specific client requirements or the ever-changing food safety environment.

Manufacturing plants located outside the U.S. shall meet SAI Global expectations, local regulatory requirements, and regulatory requirements for all countries to which product are exported.

Specific customer requirements or expectations not captured within this document may be included within a customer audit addendum, completed in conjunction with the SAI Global audit as applicable.

Foreign food suppliers who export to the US for consumption by people living in the US must be registered with the FDA and follow FSMA.

Foreign food packaging manufacturers must be in compliance with FSMA whereas domestic suppliers are exempt.

The stated criteria and expectations are based on all or parts of the following based on applicability:

- Food, Drug and Cosmetic Act (21 CFR Part 117) and appropriate amendments.
- Food Safety Modernization Act 2011.
- Intentional Adulteration Act.
- Sanitary Transportation Act.
- Produce Food Safety Regulations.
- Model Food Code, 2017 edition (FDA/USPHS).
- Safe Food for Canadians (CFIA).
- Federal Meat Inspection Act (USDA) (9 CFR) and amendments.
- Poultry Products Inspection Act (USDA) (9 CFR) and amendments.
- Egg and Egg Products Inspection Act (EPIA) and amendments
- Seafood-US FDA Seafood HACCP (FDA) (21 CFR Regulation 123)
- Molluscan Shellfish-National Shellfish Sanitation Program (NSSP) Model Ordinance for Molluscan Shellfish. (FDA).
- U.S. Bioterrorism Act of 2002.
- Specific client requirements and/or specifications.

A remote audit appendix has been added to the Good Manufacturing Practices manual as of October 2020.

Doc ID: 9858 / Issue date: February 2021

TABLE OF CONTENTS

Section **Page**

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., crustaceans -shrimp, lobster and crabs). In Canada, sulphites of over ten ppm, shellfish- oysters, clams and mussels, sesame seeds and mustard are also considered allergens. The plant 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 the 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.

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).

Certificates of Analysis (COA)

Specific microbiological, chemical or physical analysis of key ingredients or products, generally against a documented specification, prior to acceptance into inventory or receipt. COA must be lot or product code specific and should include the product identification, the description of the type of analysis, the method utilized, the sample size, and the result of the analysis. Verification of COA accuracy and product process shall be established by product testing of samples for conformance.

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.

Continuing Letter of Guarantee

Document provided by supplier indicating that all food ingredients and food contact packaging materials (e.g., inks, coatings) comply with all provisions of the Food, Drug and Cosmetic Act and Amendments or local regulatory requirements.

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 pathogenic contamination of a product or ingredient that has undergone an intervention step (e.g., cooking or washing) to reduce the microbiological level (bacteria, viruses and/or parasites) 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, foodservice, 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 for those customers they must only 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, if password protected, or completed manually.

Food Safety Plan

The FDA requires Food Safety Plans for all FDA regulated products sold for consumption in the US except for Seafood products, Juice products and Low Acid Canned Foods where a HACCP Plan is required.

A Food Safety Plan requires a written Hazard Analysis and then Preventive Controls to prevent, eliminate or reduce to a safe level all hazards where the probability of occurrence and the severity if they did occur warrant a preventive action. The Preventive Controls that may need to be applied are Process Preventive Controls, Allergen Preventive Controls, Sanitation Preventive Controls, when making an RTE product, and Supplier Preventive Controls, when the manufacturer cannot control the hazard themselves.

Finished Product Inspection

The analysis, inspection or review of the finished product prior to release of that product into commerce. The supplier must define what final inspection and review must be completed on each lot or batch of finished product. The requirements for the finished product inspection could include visual observation, physical inspection, microbiological or chemical analysis or record review, as required by FDA FSMA for Food Safety Plans and HACCP Plans, USDA for HACCP Plans and CFIA for FSEP Plans. The supplier should evaluate the product specification, customer requirements or local regulatory requirements when defining its finished product inspection requirements.

Food Code

Reference Guide published by U.S. Dept. of Health and Human Services, Public Health Service and Food and Drug Administration, 2017.

Good Manufacturing Practices (GMPs)

Guidelines as cited in Code of Federal Regulation FDA 21 Part 117 and USDA 21 CFR 9 and CFIA.

Good Laboratory Practices (GLPs)

Guidelines that are established to ensure the accuracy and precision of results from described evaluations.

Hazard Analysis Critical Control Point (HACCP) Definitions.

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 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 plant 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, which address operational conditions providing the foundation for the HACCP 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 plan, when properly implemented, will effectively control the hazards 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, 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 GMP Audit

An effort to evaluate the performance of the facility in regards to good manufacturing 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 program required for the total food safety management by the facility of its product and production.
Examples include pest management, training, maintenance, allergen management, food defence, etc. Further examples are described later in this manual.

Preventive Maintenance

A series of routines, procedures and maintenance 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 produce 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.

Product Traceability

The linking of all identified raw materials, primary packaging, processing aids, rework and work in progress to a finished product through a coding, identification or tracking system.

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.

Ready-To-Eat (RTE) Products

All foods that, when purchased by the consumer, do not require any further preparation i.e. pathogen elimination step prior to consumption (i.e. cooking).

Products that are required to be cooked prior to consumption shall have detailed cooking instructions on the outer case for foodservice products, or on the individual inner packages for retail packaging, to heat product to a minimum internal temperature per regulation (review Model Food Code, 2017 edition, Chapters 3-4).

Repack

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

Rework

Product that has been recovered or rejected from normal production and has been reprocessed, re-blended, or reformatted into the finished product.

Risk

The likelihood that a food safety hazard will happen and the severity if it did.

Sensitive Ingredients

Food intolerances affecting a limited number of individuals that do not involve immunologic mechanisms (e.g., sulphites (allergen considers these an allergen), MSG, FDC colors Yellow #5 and #6).

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

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 food production or distribution facility to an off-site location. 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-compliances, more than 3 observations of the same audit line item violation, or the potential for a direct 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. SAI Global 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/FSP/FSEP program.
- Failure to have a documented allergen control program.
- Lack of policy to prevent cross contact that includes segregation during storage.
- Failure to have a documented product recovery (Recall) program.
- Building/roof in unsuitable conditions and/or leaking.
- Employees observed not following the documented hygiene program causing direct contamination of product.
- Observation of evidence of rodent or bird 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 (FSP)/FSEP, Sanitation, GMPs, Product Specification 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 will be verified via interview of employees (where and when applicable). To facilitate a smooth, organized audit, we request that the following documents and records be readily available at the beginning of the audit.

A. FOOD SAFETY

- Validated HACCP/FSP/FSEP plan and worksheets; hazard analysis must address how identified hazards are to be reduced or eliminated

  NOTE: HACCP/FSP/FSEP Plan 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 for all ingredients, process steps and products
  - Documented detailed hazard analysis showing consideration of likelihood of hazard occurrence and severity if hazard did occur to determine which hazards require control.
  - Detailed process flow charts, showing all inputs, outputs, and product rework or recycle pathways
- Document identifying food safety hazards reasonably likely to occur in finished product, process, raw materials or ingredients
- Documents showing compliance to HACCP/FSP/FSEP plan:
  - Monitoring records of HACCP Critical Control Points (CCPs), FSP/FSEP - Preventive Control Points
  - Policy and compliance procedure for the HACCP/FSP/FSEP Allergen Program, including all process records

Deviation records and corrective action plans demonstrating compliance

- Monitoring Food Safety Plan records for Process Preventive Controls, Allergen Preventive Controls, Sanitation
- Deviation records and corrective action plans.
- Label reconciliation program demonstrating compliance to the Allergen Program, if applicable
- Policy and compliance procedure for Foreign Material management, including glass and brittle plastic, metal detection (when used), as well as additional foreign material detectors (e.g., x-ray)
- Policy and compliance records relevant to regulatory compliance (e.g., Bioterrorism, Country of Origin Labelling [COOL]).

<u>Preventive Control aspects as applicable per regulation</u>

- 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
  - Re-analyse
  - 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. PREREQUISITE PROGRAMS

- Laboratory policies and procedures manual (laboratory methods, sampling plan), if applicable
- Laboratory instrument calibration programs, if applicable
- Records of laboratory cross-check program, if applicable
- Documented preventive maintenance program and corrective action plan
- Detailed product recall manual, including records of mock recalls (including product coding policy)
- Quality policies and procedures manual
- Document management and record keeping policies and procedures
- GMP 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-plant measuring devices (e.g., metal detectors, flow meters, temperature recorders, Relative Humidity [R.H.], pressure)
- 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
- Calibration monitoring records including testing standards and certification
- Policy and procedures outlining product coding, if applicable
- Policy and procedures for handling of rework product (control and traceability), if applicable
- Policy and compliance records relevant to quality attributes
- Standard Sanitation Operating Plan (SSOP)
- Approved supplier program and related records
- Documentation of food safety pre-requisite programs
- Documents of management and employee training
- Good Manufacturing Program and employee hygiene policy manual
- Policy and compliance records relevant to GMP/HACCP/Food Safety training

C. RECEIVING AND SHIPPING

- Policy and procedures for receipt of raw materials, ingredients, packaging materials, and processing aids
- Raw materials and ingredient specifications
- Copies of Pure Food Guarantees and Continuing Letters of Guarantee for food packaging materials
- Incoming and outgoing trailer inspections
- Policy and procedures for the rotation of raw materials, ingredients, packaging materials and finished products
- Policy and procedures for the storage (including temperature monitoring, when applicable) of all raw materials, ingredients, packaging materials, processing aids, and finished product(s)

D. PROCESSING

- Analytical and microbiological test results
- Policy and procedures for thawing of raw materials and ingredients, if applicable
- Raw materials and ingredient specifications
- Records verifying compliance to product specifications
- Finished product inspection policy and procedures and monitoring records
- Policy and procedures outlining product coding
- Policy and procedures for handling of rework product (control and traceability)
- Policy and compliance records relevant to quality attributes Policy and records verifying compliance to product specifications for customers

E. GROUNDS AND EQUIPMENT

- Blueprint of plant showing water and sewer lines, location of backflow prevention devices, separation of ready-to-eat areas and plant traffic flow patterns
- If high intensity halogen lamps are used, a letter from the supplier indicating that they are shatterproof

F. PEST MANAGEMENT PROGRAMS

- Rodent and pest management procedures manual
- Rodent and pest management activity records

G. EMPLOYEE HYGIENE PRACTICES

- Good Manufacturing Program and employee hygiene policy manual
- GMP audit records and corrective action plan

H. FOOD DEFENSE and SITE SECURITY

- Policy and procedures outlining the security program for the facility. The program shall restrict site access to authorized personnel only.
- Policy and procedures outlining the protection of product from intentional contamination
- Crisis Management

I. SANITATION

- 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

A: FOOD SAFETY (100 SERIES)

A.1 HACCP/FSP/FSEP PREVENTIVE CONTROLS

The HACCP process is a primary food safety management program. HACCP combines the energies and resources of management with the scientific knowledge of the product and process. Under HACCP, the operational and quality management groups provide a comprehensive food safety management process, involving all departments in the effective management of food safety. HACCP 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 plan is plant and process 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 process must be strictly controlled, monitored and signed by appointed management personnel. Any deviations from the HACCP plan must be thoroughly documented with detailed corrective actions and product dispositions.

If the product is required to meet HACCP requirements, then the plan must be in compliance with the regulatory requirements. Examples of industries where HACCP is mandated are seafood, meats, juice and low acid canned foods (LACF).

The HACCP 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 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 defined as part of the HACCP 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, and there is documented evidence of team meetings held on a regular basis to review HACCP 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 Plan Thoroughness:** The plan is specific for plant and product and is current. All appropriate Critical Control Points (CCPs) have been identified with appropriate control limits, based on scientific data. Corrective actions for each CCP have been predetermined. Corrective actions must include instructions on actions to take to secure involved product, bring the manufacturing 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 may be included in a single plan). Documentation for managing the essential pre-requisite programs that support the HACCP plan shall be readily available.
- **Flow Charting Documentation:** There must be an easy-to-understand flow chart for each plan, taking into consideration individual ingredients, all preparation steps, all equipment used, blending steps, processing steps, rework and returned products and packaging equipment. The flow chart must identify CCPs as identified in the Hazard Analysis. CCPs must be clearly identified and numbered to correspond with the Hazard Analysis and CCP 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 type of product or product line. The Hazard Analysis must evaluate all ingredients, equipment, processing steps, and packaging for 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 production of safe food. The Hazard Analysis must be updated, with full documentation, when a change is made to ingredients, processes or packaging or otherwise deemed necessary by the HACCP Team.

- **Hazard analysis requirements:** The hazard analysis must identify known or reasonably likely hazards, including biological, chemical (including radiological), and physical hazards. Known hazards must consider those that can occur naturally, as well as those that can be intentionally and unintentionally introduced. **CCP Decisions Clear and Appropriate:** The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), Decision Tree (http://www.fsis.usda.gov/about/NACMCF/index.asp) or other logical reasoning tool shall be applied in determination of CCPs. Documentation for determining whether a step or process is a CCP or not must be clear and thoroughly explained, defining the hazard and the specific controls that eliminates or reduce the hazard. There must be a scientific or regulatory basis, with appropriate documentation or regulatory references, to both the hazard and the control required. Proprietary data may be acceptable, providing there is sufficient data that is approved by an appropriate, qualified process authority.

- **Monitoring Procedures:** Monitoring procedures for CCPs must be based on the variability of the process to be controlled. The frequency shall be sufficient to ensure that all product produced is within the established limit. Documentation of the measured variable shall be on clearly identified HACCP records, with the CCP identified by name and number, the item to be measured, the frequency of the measurement, the CCP limit, the responsible monitor and the corrective action required, in the event that a measurement is not in compliance. 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 documents and must be strictly controlled. They may be the basis for determining whether the process 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 operator. There must be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation must be provided. The final record must be signed by the monitor and by the designated HACCP records reviewer. The records must be easily retrievable and secured in a safe storage area. It is not essential to keep HACCP documents separate from regular process control 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***.
- **Validation and Verification Procedures:** Documentation must be available that confirms there is a scientific basis confirming the effectiveness of the CCPs, or other supporting data demonstrating the validity of the CCPs. Verification documentation, such as analysis to confirm that the products are achieving the level of safety required and that the HACCP plan is operating effectively, is required. In addition, 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 used or 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 crustacean (lobster, crab and shrimp). Sulphites of over ten ppm, shell fish

(oysters, clams and mussels), sesame seeds and mustard are also considered allergens by the Canadian Food Inspection Agency (CFIA) in Canada. 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:

- **Allergen Identification:** The facility must review all product formulations to identify all allergens that are used in the manufacturing of the product. This should include a risk assessment of all allergen-containing ingredients used in its products (may be completed as part of the hazard analysis). The facility must then identify all ingredients from receipt and through every step of the process ensuring they are clearly identified to all employees who may handle them. The facility must ensure there is proper communication of all allergen containing ingredients and product, Work-In-Process (WIP) included and how the allergen 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 the manufacturing process such that the risk of cross contact is controlled.
Employees handling ingredients and products that are or contain allergens must not handle non-allergenic products without steps to protect against cross contact. This could include change of aprons, sleeve guards, frocks, and hand washing etc.
Clothing used in allergen sensitive products shall not be co-mingled with clothing from non-allergenic production.
Utensils used for these allergenic ingredients must be dedicated and not used for other ingredients unless there is a thorough cleaning and sanitizing procedure applied between uses. The allergen program should also consider allergens permitted in employee break rooms and cafeterias and appropriate controls to prevent cross-contact from these areas to production areas.
Production of products containing allergens should be on dedicated lines or equipment where possible. If the use of dedicated line or equipment is not possible, allergen-containing products shall be scheduled sequentially. For example, scheduling non-allergen containing products first. Initial validation and subsequent verification of the cleaning process must be documented.

- **Use of a Changeover Process to Prevent Cross Contact:** When cleaning or flushing is implemented with the purpose of eliminating the risk of allergen contact, the facility must develop a product sequencing/cleaning matrix. Compliance with the product sequencing/ cleaning matrix and completion of cleaning shall be recorded. Following each event to remove allergenic residue (change-over), the facility must ensure that the equipment cleaning process was followed and the results documented. The equipment cleaning process must remove visible product/residue from all product contact surfaces. The efficacy of the equipment cleaning process shall be validated and subsequently verified to demonstrate that it removes visible residues from all product contact surfaces. This validation must be an allergen specific assessment of the allergenic residue removal process and must be documented.
- **Label Reconciliation:** Labelling 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. Old or obsolete labels must be properly identified and controlled to prevent their inadvertent use within the facility.

A.3 FOREIGN MATERIAL

A foreign material control program must be in place. Such a program could include the use of magnets, sieves, screens, bone detection devices, and metal detectors as necessary, based on the process and the manufacturing environment. The program must include barriers to all potential physical hazards relevant to the identified process and how those hazards will be addressed. The program shall be properly communicated throughout the organization, identifying specific roles and responsibilities.

The following must be included in the foreign material management program:

- **Glass and Brittle Plastics Management:** The facility must outline how the potential hazards associated with glass and/or brittle plastics will be managed throughout the process. The program must include communication of such hazards to all within the

organization (including a policy of items prohibited from the production facility). The program must also identify all glass and brittle plastic that is present in the facility and the frequency with which it is inspected. The inspection frequency should be based on risk such that

disposition of any affected product, how the area will be secured, cleaned, and inspected prior to resuming production and include inspection and potential disposal of any affected PPE

- **Metal Detection Use:** There must be a written policy describing the maintenance, set-up, validation and verification tests of the metal detectors if used. The policy must describe the initial set-up procedures, the frequency of verification checks with actual product at start- up, during the shift and at the end of production. Test units to check equipment performance must be appropriate for the nature of the product and the size of the package. Metal detectors must be set-up prior to start-up by qualified personnel and calibrated for the particular product being run. Documentation of calibration and set-up must be part of daily production records along with initial, operational and final verification checks. All records related to the use of the metal detection system, including rejected product logs, must be maintained.
- **Verification of other types of foreign material detection devices used (e.g., x-ray machines).** The policy must describe the initial set-up procedures, the frequency of verification checks with actual product at start-up, during the shift and at the end of production. Test units to check equipment performance must be appropriate for the nature of the product and the size of the package. The equipment must be set up prior to start-up by qualified personnel and calibrated for the particular product being run. Documentation of calibration and set- up must be part of daily production records along with initial, operational and final verification checks. All records related to the use of the foreign material detection system including rejected product logs must be maintained.

materials that may directly affect product are inspected more frequently than materials that are outside of the production areas. The program must outline how the facility will address incidental breakage of glass and/or brittle plastics, including

A.4 REGULATORY COMPLIANCE

It is essential that food plants operate in total compliance with regulatory requirements specific to where products are shipped and that a positive working relationship is evident with the assigned regulators.

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

- **FDA Registration Requirement:** Facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. must register with the 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 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 produced within the facility. Examples of regulatory compliance requirement include weight claims, ingredient labelling, ingredient statements, allergen labelling, and product and process verification.
- **Country of Origin Tracking:** The facility must have a documented SOP defining how COOL is evaluated and managed throughout receiving, storage, picking and shipping processes. Elements of the SOP must include definition of the regulated products, labelling 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 labelling to be provided on the product case, shipping container or on shipping documents for inbound and outbound product. Regulated foods include but are not limited to farmed raised fish and shellfish, fresh or frozen fruits and vegetables, macadamia nuts, pecans, ginseng and peanuts.

A.5 PREVENTIVE CONTROLS

Manufacturing facilities that are required to comply with the provisions of the Food and Drug Administration's (FDA) Food Safety Modernization Act (FSMA) or the Safe Food for Canadians Act must have a Food Safety Plan that includes the identification of Preventive controls. HACCP Plans are required by the FDA for Seafood processing, Juice Processing and Low Acid Canned Foods (LACF) and by the USDA for Meat, Poultry and Catfish processing.

- Preventive controls must be written, and where appropriate by the facility, must include process controls, food allergen controls, sanitation controls, supply chain controls, a recall plan, and any other procedures necessary to reduce or eliminate the identified hazard.
- For all hazards 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 the hazard or reduce it to an acceptable level. 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 hazards will be controlled.

- Verification activities include calibration, product testing, and environmental monitoring all using scientifically valid and detailed procedures. 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 hazard (corrective action) as well actions that will be taken to reduce the likelihood the problem will occur again (preventive action). If a pathogen or indicator organism is detected in a ready to eat product or the environment, 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.
- 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 GOOD LABORATORY PRACTICES (GLPs)

An integral part of the food safety function canters on accurate, available product information used for decision-making. Quality systems must be established to properly store and retrieve analytical information, documents, reports, records, etc. When conditions warrant, laboratory support functions (both internal and external) provide very valuable information to ensure process control, food safety and product quality.

The following must be included in the GLP management program:

- Laboratory procedures shall be documented. Testing procedures shall be based on recognized and approved procedures. Documentation of all testing shall be available, including records of Certificates of Analysis (COA) where in-house testing is not performed. The plant laboratory for chemical, physical and microbiological evaluation of ingredients, in-process components and finished product must be adequately equipped and staffed to provide the essential technical support to the plant. The laboratory shall comply with the procedures outlined in the GLP policy (reference 21CFR, Part 58). Records and reports of analytical information gathered by organizations (internal and external) must be catalogued and maintained in a fashion that can provide feedback for operational control. When an outside laboratory is used, documented procedures must be available to properly interpret and manage the information provided. Any laboratory waste outlets should be downstream of the process, at a minimum.
- It is essential that every laboratory have a detailed and documented calibration program for instruments and measuring devices. Balances and laboratory test equipment shall be calibrated (certified) by a competent certifying company at a prescribed frequency as defined by the manufacturer. Records of this certification shall be maintained. Additionally, there shall be an in-house policy for frequent calibration of test equipment, including scales and thermometers. This shall include daily checks of scales and thermometers with appropriate test weights and standardized thermometers. The thermometers must be calibrated against a certified thermometer or a recognized standard (e.g., ice water bath). Documentation logs of all calibrations must be complete showing date, instrument identification and person performing checks. Finally, all thermometers and scales or balances shall be checked at the beginning of the shift with adequate and complete documentation. Documentation may be on routine data sheets.
- There must be documented evidence that the results of the laboratory are accurate and reliable. Quality manual test procedures, work instructions, training records and record keeping must be established to verify that monitoring is occurring, and the results meet specifications and finished product requirements. The laboratory shall participate in a check sample program with an accredited laboratory to verify reliability and accuracy. The plant must have documented detailed procedures for all microbiological, physical and chemical tests performed. Microbiological tests procedures must meet accepted standards (Bacteriological Analytical Manual, U.S. Department of Agriculture or recognized authority) and include appropriate corrective action and root cause analysis when inaccuracies are found. Any chemical test procedures must meet accepted standards (Association of Analytical Chemists or recognized authority).
- The laboratory shall be isolated from the production area so that it does not contribute to potential contamination. The laboratory shall be vented directly to the outside and under negative pressure. Pathogen analyses shall not be performed at a plant laboratory unless there is competent professional supervision and there is an effective program to secure pathogen organisms from misuse (e.g., locked, secured and restricted storage, documented inventory control and formal procedures to address any potential breach of security). Microbiological testing areas shall be isolated and only designated personnel permitted access.
- When the facility is participating in pathogen testing, documents must be available to show the current location of products not cleared for

shipment, as well as those that are authorized for sale. An inventory log shall be maintained showing current product on hold and list the disposition of all released product with proper authorization. Product destined for destruction must be adequately secured and disposed of promptly.

B.2 MAINTENANCE

The facility must ensure that equipment and materials used for production are suitable for the purpose intended and in good repair. The facility shall have in place and in use a written program for preventive and corrective maintenance that is up to date.

The following must be included in the management program:

- The documented program must include a list of food handling equipment, as well as procedures detailing the maintenance required for each piece of equipment, including requirements for release back into production 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 maintenance program must include the evaluation of equipment based on sanitary design principles to ensure equipment can be easily cleaned and maintained. Equipment must be designed so as to minimize accumulation of food particles, dirt and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact. If there are issues found with existing equipment, the facility must ensure corrective action procedures are in place to ensure any hazards are controlled (e.g. extra cleaning procedures, disassembly, etc.). The program must include documented procedures for the inspection of newly commissioned equipment and/or equipment that is repaired outside of the production areas prior to being put into service. The procedure must identify the acceptance criteria for placing the equipment into service, including verification of allergen cleaning if applicable.
- The facility must have PM activities for all listed equipment. The program shall be tailored to the specific products or facilities. Priority shall be given to maintenance of pieces of equipment that may affect food safety, quality, or employee safety.
- The facility must ensure that there is a system in place to properly communicate all scheduled and unscheduled repairs. The tracking program must be used to verify the completion of projects as well as feed into the continuous improvement and/or long-term project program for the facility's PM program. The program should include some type of alarming system to prevent critical repairs from being missed.
- The facility must have measures to ensure the equipment and facilities are clean, sanitized, and in good repair prior to release for production after maintenance activities (e.g., drilling, cutting, polishing, welding) have occurred. The outlined program must include roles and responsibilities related to who is to be contacted.
- The facility must ensure that all records related to the maintenance activities (including PMs and emergency repairs) are maintained and adequately reviewed. 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. There must be a documented temporary/emergency repair policy which outlines the proper protection of product in the event emergency repairs must be made to keep production running. The policy must identify the requirement to make any temporary repairs permanent within a reasonable time frame and clearly identify those materials that are prohibited to be used for any repair (e.g. wood, string, clear tape, cardboard, etc.).

B.3 PRODUCT RECOVERY AND TRACEABILITY

The facility must have procedures in place to effectively trace specific lots of ingredients, packaging, processing aids, and finished products through the shipping and distribution channels.
The implementation of the program will be tested during the audit process.

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

- The facility must have ability to trace ingredient or component product-in-process, carryover product and rework. Production records must identify rework or carryover usage in specific lots as well as specific lots being capable of showing presence of specific rework. The facility must be able to trace ingredient lots to finished product. This includes bulk ingredients that may be used from bulk silos. The program must include lot coding information for finished product(s) and definitions for all codes. The program must also address how finished product labels are reconciled and that all ingredients are properly included on the label. This traceability shall extend to the first customer (i.e., distribution center, restaurant or secondary processor) and back to their supplier (one up and one back). The program must also include how customers are instructed to return/dispose of affected product.

  The facility's program must identify the recall team members and describe each team member's responsibilities. Current office and after-hour telephone contact numbers and email addresses of all recall team members, both at the plant and head office, if appropriate, must be available to all team members. The facility must also include notification procedures, including contact lists and customer and regulatory contacts.
- The facility's program must include conducting mock recalls on an annual basis. The program must include performance standards set (note: industry best practice has been set at recovery of 100+/-2 % of suspected product within four hours). Involvement of 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, manufacturing, shipping, control and evaluation of food products to ensure that the products 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 their specific job description. The program must be validated and subsequently verified. Changes shall be clearly identified and appropriately signed and dated.

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

- **Document Control:** The facility must have a policy with specific procedures for document control, including preparing the process 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 the storage of documents must be designated. Records maintained off-site must be retrievable within a reasonable time. The Food Safety Plan 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 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 protected against unintended use.
- **Internal Self-Audits:** A key management responsibility is to verify that the policies and programs essential in the management of wholesome food products are routinely and effectively implemented. It is necessary that routine self-inspections of policies and procedures be conducted to assure management the proper actions are being taken and 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 to evaluate the effectiveness of the policies. A monthly frequency, at a minimum, is recommended.
- **Corrective Action Program:** The facility must ensure that from audits as well as other implemented programs (e.g., complaint management, pest management) results and 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 affect a timely corrective action.

Product Holds: The facility must establish and maintain documented procedures to ensure that product that does not conform to specified requirements is not shipped. This control must provide for identification, secured segregation, documentation, evaluation, disposition and reconciliation of product that is placed on hold. A 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. 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 for returned or retained products. There shall be a physical accounting of the product on hold at least weekly to verify that that actual product quantities match records. Discrepancies shall be treated as a serious food safety failure.
Returned or retained products must be clearly identified as such. The facility must outline roles and responsibility relative to the disposition of all food products.

- **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, production dates, cause and origin of complaint. Customer information can be a valuable resource for validating HACCP criteria and, to that end, should be used as part of the continuous improvement program as well.
- **Equipment Calibration:** It is essential that all measuring, metering or protective devices (e.g., thermometers, scales, flow meters, metal detectors) be properly calibrated to ensure the accuracy of these activities and the effectiveness of their performance. Routine annual calibration (i.e., certification) of thermometers and scales by an outside contractor is required. There must also be a program to evaluate the performance of measuring devices on a regular basis to ensure accuracy on a day-to-day basis. There must be procedures in place to verify, on a daily basis, the accuracy of thermometers used for product evaluations. The thermometers must be identifiable with documentation of calibration results. Thermometers shall be calibrated at the temperature range at which they are used. Calibration of thermometers shall be based on certified standard thermometers. It is recommended that accurate intermediate thermometers be used to verify the daily calibrations where the intermediate thermometers are checked against the certified National Institute of Standards Testing (NIST) unit weekly to prevent excess use and handling of the certified thermometer. Full documentation of the calibration of the intermediate thermometers must be available. Assigned personnel shall check receiving and distribution scales daily to verify that they are accurate. Documentation of these checks must be available and can be part of the routine daily records for the activity being measured. Test weights in the range of the measurements shall be used. Assigned personnel shall check scales used for weighing ingredients, filling, and finished product preparation daily. Standard weights in the range of the weights being produced shall be used for these verification checks. Daily calibration checks must be documented. 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 (e.g., thermometer, scale, flow meter, counting device, metal detector, coder). All products produced since the last acceptable check must be reviewed to determine if they must be held for further evaluation.
- The facility must ensure that all chemicals used in the cleaning process are approved for use in a food establishment. The facility must ensure that only trained individuals are allowed access and handle chemicals. These individuals must have required Material Safety Data Sheets (MSDS) statements and Personal Protection Equipment (PPE) present for use with all chemicals.

B.5 SUPPLIER MANAGEMENT

The facility must ensure that each raw material supplier is capable of providing product as specified. To that end, it is essential that a detailed program be developed outlining how each potential supplier will meet agreed specifications, the level of risk the potential

supplier's raw material poses to the finished product, the requirement of GMPs and SSOPs at the potential supplier's facility, the fact that raw materials will be received from approved suppliers only, and the overall methods for granting supplier approval.

The following must be included in the supplier management program:

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 program must include all raw material, ingredients, processing aids, and packaging materials.

- The facility must include ongoing monitoring and assessment of all suppliers. The facility must outline which method is used to monitor/assess the suppliers. Assessment and monitoring may include the completion of surveys, questionnaires, second- or third-party audits, or on-site audits. The type of assessment and the frequency of review must be based on risk. Suppliers of raw materials identified as "high risk" (for example those known to be susceptible to food fraud or those with allergen-free claims) should not be approved based on a supplier questionnaire only. The assessment process must be documented and include feedback between the supplier and the facility. Records related to the approval program must be maintained (note: in cases where a corporate program has been developed, the facility must include in its program how ongoing feedback is collected and given to corporate to facilitate overall monitoring of suppliers).

B.6 TRAINING

Documents must be available to demonstrate management's commitment to a planned training program for both management and food production personnel.

The following must be included in the management program:

- The formalized program must include introductory training programs for new management and new operating personnel. The training policy must address the communication of basic food handling, sanitation, food defence, refresher training for experienced employees, and specific training for identified jobs, such as oven operators, HACCP Critical Control Point monitoring, or Food Safety Plan monitoring responsibilities. This program must be reviewed and revised annually, 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 work force population. A method to document understanding, typically testing or performance evaluations 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. The person developing a HACCP Plan must have had the respective HACCP training and for developing a FSP be a Preventive Controls Qualified Individual either by training or experience. The other members of the HACCP/FSP team be trained in HACCP/FSP.
- Operating personnel must be given GMP and personnel hygiene training on hire and on an at least 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 and the proper breakdown of equipment to ensure employee and product safety. This training must be documented and all record maintained as part of the overall training program.
- The facility must develop a complete list of all training activities related to food safety, quality, process control (as applicable), sanitation, food defence, as well as other job specific duties.

Requirements of the training record are: participants' names, description of training provided, who provided the training, verification that the training was completed, verification of competency, and the skill that was gained by the participants.
During the audit, compliance may be evaluated by direct questions to employees to determine their knowledge level (e.g., How is the cleaning or sanitizing compound used?).

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 and handling of ingredients and materials are performed and documented.

The following must be included in the receiving, storage and shipping management program:

- The facility must have a written inspection program for all inbound 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 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 be 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 harbourage. Trailer, railcar or tanker security seals must be verified as the original seal number applied at the original shipping point. For temperature sensitive ingredients, receiving vehicle temperature and product temperature must be documented on receiving documents. Documentation of condition of each inbound shipment and seal number (or evidence that trailer was otherwise secured) must be shown on receiving documents or equivalent.
- When identified by the facility's approved supplier program, Continuing Letters of Guarantee must be current and maintained for all ingredient and packaging materials. The facility must ensure that these documents are present prior to the receipt into the facility or implement other suitable corrective action, (e.g., analysis by the facility).
- The facility must identify as part of its overall receiving program methods by which the traceability process is facilitated during receipt. The facility may use the lot number provided by the approved supplier or apply a unique number and/or date; however, the facility must detail how the information provides traceability back to the original supplier.
- The facility must ensure that all perishable materials are handled during receipt in such a way that potential contamination and/or temperature abuse does not occur. To this end, the facility must 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 more than one hour.
- The facility must ensure those raw materials received via bulk methods do not become potentially contaminated. Depending on the delivery method used, the facility must ensure that the equipment is properly cleaned and maintained in a sanitary manner between uses. In addition, those personnel involved in the receiving process may be involved in additional training to prevent contamination of product being received or to take samples of raw material during the receiving process. To ensure the security of the process, the delivery system must be maintained secured between uses.
- The plant shall ensure that incoming raw materials are not used or processed 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.
  - If the plant uses a third-party carrier, it is the responsibility of facility to ensure all shippers have received appropriate training to ensure the safety of the food being transported in compliance with the FSMA Sanitary Transportation Act and have proof of temperature control during transit for in-bound and out bound loads over 4 hours. The facility 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.

C.2 STORAGE

- The facility must have policies and procedures outlining how they protect product throughout the process while being stored.
- The following must be included in the storage management program:
- The facility must have a detailed procedure outlining how raw materials, packaging material, as well as finished product, are rotated to ensure food safety and/or quality are not compromised. At a minimum, the facility must use a rotation program based upon first in first out (FIFO) (or if using manufacturer's dates FEFO (First Expire/First Out)) unless customers specify otherwise. 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 system must ensure no expired or obsolete materials are appropriately managed to prevent accidental use. There shall be a process for managing obsolete packaging/labels, to ensure accidental use, appropriate disposal and records are maintained *see Allergen Labelling*.
- Warehouse storage areas must be clean and orderly, with no long-standing spills, damaged or exposed product, debris/dust build-up, and be free of any mold growth. An 18-inch perimeter along exterior walls should also be maintained. Opened product containers shall not be stored in receiving storage areas. All racking must be in good repair and maintained in a sanitary manner so as not to cause contamination.
- Curing agents for meat products must be properly secured and placed in locked storage, with documentation of use. Sensitive ingredients and/or ingredients associated with allergic reactions shall be identified upon receipt and placed in designated areas with clearly visible marking identifying them as ingredients needing special control.
- Temperature sensitive areas 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 of the program 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 facility must ensure the vehicles are regularly inspected to ensure product integrity. The facility 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 transport.

D. PROCESSING (400 SERIES)

D.1 PROCESSING AIDS AND INGREDIENTS

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

The following must be included in the production management program:

- Potable water, ice, backflow, steam and wastewater management plant must demonstrate that the water supply is potable and that potability is maintained at all times. Potability must meet local requirements at a minimum (in the U.S., the test for potability is <1 coliform / 100 ml). Potability must be tested on an annual basis, at a minimum. 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. A documented check of the backflow preventers must be completed at least annually.
- The facility must ensure that thawing of

product, when necessary, is performed in such a way that the conditions are controlled to prevent bacterial growth. The facility must have a documented process that is followed to ensure control and that the process is monitored. Records related to the thawing process must be maintained.

- As part of the overall receiving and storage programs, the facility must ensure that ingredients and raw materials are stored in such a manner that contamination does not occur.
- Control procedures must be in place to prevent use of ingredients before approval and to ensure that non-conforming materials are not used. COAs must be reviewed and accepted, with signature, by a quality representative as part of the raw material positive release protocol.

D.2 SPECIFICATIONS

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

- The facility must ensure that product specifications are implemented at the

production location. The program must include all chemical, physical and microbiological parameters present in the facility's product specifications. The program must include the method of analysis, criteria, and corrective actions to be taken when criteria are not met. The program may also tie into the hold and release program, where applicable. The facility must ensure appropriate plant personnel have access to the latest specifications.

- Where COAs are part of the specification requirements as part of the overall

includes bulk ingredients that may be used from bulk silos. The facility must be able to demonstrate the implementation of its program from any point in the process.

- The facility must develop and implement a lot coding procedure outlining how all production runs shall be identified with lot numbers that enable complete linkage from raw material receipt through final packaging. Traceability must be maintained to enable linkage back to the date of manufacture and location for all finished packages, regardless of whether product is involved in rework or later returned into stock after shipment. The facility must identify what constitutes a lot

supplier approval process, the facility must have a documented process and schedule to ensure raw materials and ingredients meet specifications prior to receipt.

- As part of an overall food safety and quality program, the facility must develop finished product specifications for all products being manufactured. These specifications must comply with local regulation at a minimum, as well as those specifications developed by the facility and customers. Finished product specification may include physical attributes (e.g., size/grade, color, net weight); microbiological attributes; chemical attributes; etc. The facility must ensure compliance with the program as well as trending related to non-conformance. Up-to-date documents must be made available to all relevant staff.

D.3 PRODUCT SAFETY

The facility must have procedures to effectively ensure product safety throughout the process. This includes the ability to trace specific lots of ingredients, packaging and finished products through the shipping and distribution channels. The facility must also prevent potential contamination and bacterial growth due to mishandling during processing.

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

- The facility must have ability to trace ingredient or component product-in-process, carryover product and rework. Production records must identify rework or carryover usage in specific lots as well as specific lots capable of showing presence of specific rework. Plant must be able to trace ingredient lots to finished product. This

for its process.

- The facility must ensure the safety of the product throughout the manufacturing process from any potential contaminant due to incidental drips, use of non-food grade lubricants or chemicals, or foreign material (possibly due to improperly filtered air and/or steam). Any such incidental contaminants could lead to direct product contamination by dripping directly into product or onto food contact services. The facility must ensure that RTE operational areas are maintained separate and effectively isolated from other operations and traffic flows that could compromise the high level of sanitation and hygiene essential to RTE product integrity. Personnel access to High risk/RTE areas shall

include facilities for personnel to make appropriate outer garment changes and either change footwear or put on appropriate footwear coverings prior to entering the RTE area. Access routes for personnel and materials shall be free from exposure to raw processing areas or routes exposed to raw products. The facility must provide captive foot wear, use either, boot scrubbers, footbaths or floor foamers for the entrances into high risk/high care/RTE processing areas (i.e. processes that require a kill step, processes that handle high risk items, etc.). The facility must have a documented program that lists the sanitizer used and the strength of the sanitizer used, and a verification of effectiveness of the program.

- The facility must ensure that all perishable processing areas are equipped with a calibrated thermometer to facilitate temperature monitoring. The thermometer must be placed in the warmest area of the room and monitored often enough to maintain control (at least two times per day or during processing). The facility must have a procedure in place to ensure that temperature abuse will be prevented during processing.
- The facility must be able to show how by-product intended for use in animal food is controlled to prevent contamination. The food must be held under suitable conditions so that it does not become contaminated (e.g. at appropriate temperatures to prevent microbial growth if applicable). Procedures must be in place to ensure containers and equipment dedicated to this process are suitable, cleaned and properly maintained, as well as be protected from contamination from trash. Finally, animal feed must be properly identified and labelled, and shipping containers are subject to the same provisions as food intended for humans.

- The facility must develop a quality program addressing the specific points during the process that are critical to the quality of the finished product as identified by the facility itself or its clients. Where the program addresses the process points specifically critical to the client, the facility must ensure that it is in compliance and implementing and documenting corrective action when non- compliance occurs. All records related to the quality of the finished product specific to the facility's clients must be maintained and available for review.

D.4 PROCESS CONTROL

The facility must have written policies and procedures specifying the operational control practices required to ensure that the manufacturing process operates in control on a continuing basis. A formal program is essential to ensuring that the products are produced in accordance with specifications, that they meet quality requirements of the customer, and that they are produced under conditions that promote safe food products. Operating records must be available to verify conformance to these policies.

The following must be included in the process control management program:

- Manufacturing processes that have measurable elements that are important to the quality or consistent production of food or packaging must have documented process targets. Such programs could include Statistical Process Control (SPC) or similar programs that provide operators and management with records of performance (e.g., dwell time, temperature, line or belt speed, pressure, count, weight). It is essential for the client and/or facility to develop specifications that define acceptable product attributes. Each specification must be maintained and tracked under a defined quality assurance program.
- In addition to specification compliance, there must be procedures for assuring control of product formulations. Records must be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications. Corrective actions, as well as input into the facility's continuous improvement program, must be performed relative to the specification compliance.

E. GROUNDS, FACILITY AND EQUIPMENT (500 SERIES)

The construction of the grounds, facility, and equipment must be such that it facilitates the production 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:

E.1 PLANT GROUNDS

- Exterior of plant and grounds must be constructed to minimize dust and be free of standing water.
- The facility must ensure that all on-site trash disposals areas are maintained so as not to become a source of pest harbourage 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 harbourage, 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 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 harbourage and/or contamination to the finished product. This would include capped hose ends and storage away from plant buildings.

E.2 FACILITY

- **High Risk/RTE.** The air with in the high risk/RTE room must not pose a contamination risk, positive pressure should be maintained relative to surrounding areas and the testing frequency established.
- **High Risk/RTE** Air used for direct processing and or comes in to contact with product or food contact surfaces shall not be a source of contamination as confirmed by testing air for contaminants, filters shall be changed at a describe frequency.
- **High Risk/RTE** There shall be a process in place to control condensation during processing and after sanitation activities are completed.
- Ceiling surfaces, as well as other overhead equipment, must be clean, in good repair, free of flaking paint, rust, holes or unsealed openings, or 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 harbourage, 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.
- Walls shall be of a smooth, non-toxic and easily cleanable construction. They shall be free from cracks, holes and crevices that would inhibit cleaning or provide harbourage for soils and pests. They shall be free of dust, dirt, product accumulation and flaking paint. Walls shall be sealed and covered at wall/floor juncture. Wall coverings must not be attached with exposed nails, staples or screws. Openings in walls where pipes, equipment or conveyors pass must be sealed. Windows must be closed if outside conditions exist that may expose the plant to airborne contamination. Ledges shall be sloped to avoid storage and prevent accumulation of debris. All windows shall be maintained in a clean and sound condition, with no broken panes, and must be screened when open.
- Catwalks and other walkways over or adjacent to product zones must be designed to prevent product contamination. "Toe boards or rails" are not acceptable as solid side plates (at least four inches/100 mm in height must be in place). Processing line protection shields shall be knee high.
- All lighting shall be completely enclosed in protective shields or manufactured with shatterproof materials to prevent glass contamination of product. This applies to all operating areas, warehouses, and packaging, receiving and shipping docks, and storage 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. Protective covers in processing areas shall be kept free of any evidence of moisture accumulation inside the covers. General plant lighting shall be a minimum of 30-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 and product contact surfaces. Adequate heating, ventilation or refrigeration shall be provided in all areas to maintain proper environmental and sanitary conditions for ingredients, finished product, and equipment 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 odours. Heating and ventilation must be balanced to prevent condensation on walls or ceilings in product areas.

- Locker rooms shall be adequately sized, well lit, clean and orderly. Lockers shall 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 trash and 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 work areas. In RTE areas and in areas where product is exposed or handled by employees, hand wash and/or sanitizing stations must be convenient to the employee workstations. 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 the female facilities. Doors to toilet facilities shall be self-closing and must not open directly into processing, ingredient or packaging areas. Adequate and convenient hand washing facilities must be provided in locker rooms and toilet facilities.
- The hand washing stations must deliver tempered water (90 - 105° F or 32 - 41° C) within 20 seconds. Additionally there must be an adequate supply of hand soap and/or sanitizing agent. Single service towels shall be available with convenient disposal at each station. Additional sanitizing stations may be required near workstations in RTE areas.
- The facility must have an identification system for potable and non-potable water lines and current schematics. Dead ends on potable water lines must be eliminated. Hose drops must not be submerged in water reservoirs. If there is a chance that back siphoning could occur, hose drops must have back flow prevention devices installed (high pressure lines [>80 psi] do not need backflow protection).
  Back flow prevention devices must be checked annually.
  Hoses must not be left on the floor or in tanks. Hose nozzles must not be allowed to come in contact with the facility floor.
- Floors must be well drained, smooth, and 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 odours. Standing water must not be evident in processing or warehouse areas.
- The facility must ensure that battery charging areas used for transport vehicles do not pose a potential threat to stored raw material, packaging material, or finished product. The facility must ensure that procedures are in place to address any emergency that may arise and that any potentially affected product is held for further disposition.

E.3 EQUIPMENT

- Processing, packaging and storage equipment shall be designed, installed and maintained in such a manner as to produce a safe, wholesome and quality product. Equipment 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. Fibre-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 render the belt difficult to clean or present 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.

- All utensils, tools and food containers must be designed for that purpose and constructed of food grade materials. The facility must not reuse containers previously used to hold raw materials, ingredients, or other food products. Equipment previously used for any type of chemical or other non-food ingredient must not be reused during the process. Equipment previously used for food products can be used as long as they are adequately cleaned, sanitized, and they do not pose a risk to products.
  - Non-foods-grade materials such as wire, tape, and string, plastic or cardboard shall not be used for temporary repair.
  - 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.

F. PEST MANAGEMENT (600 SERIES)

It is required that all food processing, storage and distribution facilities operate under the authority of a licensed pest management contractor. Typically they 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 plant pest management, housekeeping and sanitation programs especially as they relate to potential pest harbourages and conditions that compromise the evaluation of pest control. 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**.** 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.

F. 1 THE PEST MANAGEMENT PROGRAM

The following must be included in the pest 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 Pest Management Provider (PMP) and trained employees are carried out in accordance with the prescribed policy. A plant-specific pest management manual shall be current and updated at least annually. Management 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. Site maps for traps, glue boards and bait stations shall be reviewed regularly, dated and initialled by the person having responsibility for the program.
- The pest management provider 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 SDS/MSDS for all chemicals used and copies of product labels describing how and where the pesticide can be used and against what pest target. 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. Subsequent reports shall indicate the efficacy of those actions. If electronic scanners are used to check bait stations or traps, the tag or barcode must be inside the station or trap. Interior rodent traps must be monitored on a weekly basis and exterior stations monitored monthly at a minimum.
- 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 plant or warehouse. 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 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 those actions. Responsible plant personnel, noting PMP observations and comments, shall sign activity reports. There shall be a documented management response to all recommendations included on the activity report.
- 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.

- 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 labelled and used in such a way that they do not pose a threat to food or food packaging.

G. EMPLOYEE HYGIENE PRACTICES (700 SERIES)

Facility employees must observe the strictest of personal hygiene practices as outlined in the Code of Federal Regulations, Section 21, Part 117, Current Good Manufacturing Practices for food plants. This regulation establishes the minimum requirements for basic food handling, but many food products, such as RTE products, require more stringent practices. 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 management program:

G.1 THE EMPLOYEE GMP PROGRAM

- The facility must have a plant-specific, documented GMP training program for all employees. All new employees (e.g., seasonal, part-time, contract) must be provided initial training covering basic GMPs and specific plant policies regarding sanitation, housekeeping and personal hygiene. The program should specifically cover: good manufacturing requirements and regulatory basics, personal dress, hand sanitation and grooming requirements, plant sanitation policies and procedures, food safety (HACCP/FSP) and quality control policies, and product tampering awareness and consequences. Training shall be conducted in an effective manner and be in the appropriate language. Follow-up, continuing refresher training shall be provided annually, at a minimum. Special training to address operational deficiencies must be provided as required.
- The facility must encourage adherence to GMPs via the posting of appropriate signage in those areas where compliance is required.
- GMP 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 the need to ensure effective control; a monthly frequency is recommended, at a minimum. Audits 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 ensure a timely corrective action.

G.2 EMPLOYEE HYGIENE PROGRAM IMPLEMENTATION

- The facility must ensure that employees are in compliance with the written GMP program.
- Employees working in production areas must not wear fake fingernails, fingernail polish, jewellery, rings (with the exception of a plain wedding band where permitted by the facility), watches, or visible piercings, etc. Outside pockets above the waist on smocks, shirts or coats shall not carry any items (pens, combs, pencils, thermometers, etc.) while in the operations areas. Alternatively, these pockets should be sewn shut.
- Fine mesh nets or other effective hair restraints for head and facial hair must be required in all production, processing and warehouse areas by all employees (e.g., visitors, contractors, tours, management not involved in the process).
- The plant must provide, and the employees must use means to avoid contamination of their outer clothing when using the toilet facilities. Coat hooks are generally made available for employees to hang their outer garments outside the toilet facilities. The plant must provide, and the employees must use means to avoid contamination of their outer clothing when using the toilet facilities. Coat hooks are generally made available for employees to hang their outer garments outside the toilet facilities. The facility must ensure that dedicated distinctively colored outer clothing, must be provided for individuals entering or working in the high risk/RTE area. The facility must ensure that all employees adhere to the use of separate outer clothing in these cases and the results should be documented.
- 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 production areas must be clearly outlined and monitored by the facility.

- Locker rooms shall be adequately sized, well lit, clean and orderly. Lockers shall be available for storing personal clothing items. Food and equipment or utensils shall not be stored in locker rooms. A monthly routine locker-cleaning schedule shall be maintained.
- Cafeterias should have available appropriate heating, cooling, and storage facilities such that employees can properly store food away from locker rooms.
- Entrances to high-risk RTE areas shall include a means to sanitize footwear including: boot scrubbers foamers, footbaths, powdered sanitizer, etc. Hand washing facilities must be "hands-free" activated so that hand contact is not required to turn water on or off in high-risk RTE areas.
- Hand wash stations must have adequate room to accommodate the number of personnel in the 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 processing areas and after breaks. The hand washing stations must deliver tempered water (90-105°F or 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.

H. FOOD DEFENSE (800 SERIES)

Food processing facilities must develop specific procedures to secure their product, to deter and to prevent intentional contamination, and will have protocols in place to quickly and accurately identify, respond to and contain threats or acts of intentional contamination.

The following must be included in the food defence management program:

H.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, raw materials, security inspections, employee identification and other appropriate food defence requirements per local regulation. The program must be communicated throughout the organization and reviewed on an annual basis, and or when an incident occurs or when changes are required.
- 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. There must be a program in place to reclaim access cards/keys/computers/etc. from terminated employees, or otherwise be able to demonstrate how access to the facility is revoked.
- The facility's program must include the requirement to provide identification and require sign-in by all contractors and visitors prior to entering the facility. The program must also include that the visitor and/or contractor be 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, monitoring, of raw material ingredients and products during receiving, bulk storage, blending, processing and packaging. The procedure must ensure that all incoming goods are inspected to ensure packaging integrity. This should also include bulk delivery systems. Once product is finished, this will also include outbound security.

H.2 FOOD DEFENSE IMPLEMENTATION

- The Food Défense Team shall conduct a documented threat assessment and shall include interior and exterior threats, and to identify vulnerabilities for potential risks to products, from a deliberate source to cause product contamination. Mitigation strategies must be developed for each vulnerability identified to prevent or mitigate the risk.
- The facility must implement routine assessment of the food defence 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 (e.g., receptionist) should monitor them continuously. In the event that closed circuit cameras and security guards and/or gates are used, the correct use must be verified and documented.
- In the event that the facility uses water treatment, bulk delivery and/or 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 defence programs, documentation that incoming raw materials are received in a secure manner (via seal and/or lock) is necessary. Documentation of proper implementation must be maintained. In addition, all outbound product must be secured.
- The facility must be able to demonstrate that all loading and unloading of product is properly supervised to ensure security. All bulk hoses and ports to the facility must be secured when not in use.

- The facility must be able to demonstrate a lot number or use-by date is documented on the bill of

H.3 Crisis Management

- The Management team shall ensure a detailed Crisis Management program is in place to effectively manage the impact in the event of a crisis such as natural disaster, emergency situations, civil unrest, including disruption of services or resources to ensure product safety, quality and legality. There shall be a documented inspection/verification of the equipment, materials and finished products, that may have been affected, including authorization for release. The facility must develop and implement a business continuity plan in the event of an interruption, and where possible have approved sub-contractors and back-up suppliers.
- The effectiveness of the crisis management Program shall be conducted at least annually, using the worst-case scenarios, and corrective actions are to be implemented based on the outcome of the mock crisis management exercise.

I. SANITATION (900 SERIES)

Food processing facilities must develop specific procedures to maintain sanitation. The effective management of sanitation, housekeeping and hygiene is a critical element requiring the involvement and cooperation of all operating departments and support groups. A comprehensive sanitation program requires specific policies covering requirements and expectations, training to communicate those requirements with management, support, and follow-up to ensure that the requirements are properly met and that all sanitary standards are fully enforced.

The following must be included in the sanitation management program:

I.1 THE SANITATION PROGRAM

- The facility must have a documented SSOP for food processing equipment that specifies and defines a detailed schedule (including frequency) for all areas of the facility (both interior and exterior).
- The facility's standard cleaning methods for individual pieces of equipment and facility structures must include the level of disassembly required for cleaning and responsibility for each task, chemicals, cleaners and sanitizers used in cleaning with verification of chemical strengths and water temperature (water temperature requirement is >140°F (60°C) for cleaning unless otherwise recommended in writing by chemical supplier).
- The facility 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 plant 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 (e.g., 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 producing RTE product, the verification program must include food contact swabbing. The development of the program must include a baseline study and validation. The facility must retain all records related to the verification of the sanitation program.
- Facilities that manufacture or handle microbiologically sensitive product must have implemented a program for Pathogen Environmental Monitoring (PEM). This program shall enable the detection of pathogens, harbourage areas, and organisms that indicate potential presence of pathogens in the processing environment. It should also verify the effectiveness of controls for preventing cross-contamination, including sanitation, GMPs, preventive maintenance, and plant traffic controls. The program will outline the location of sampling activities as well as frequency of sampling. The facility must identify pass/fail criteria as part of the program that ties into the facility's corrective action program. In addition, if food contact surfaces and/or finished products are tested, the program must describe how the product is controlled during the test and its disposition in the event of a failure. All records related to the program will be retained.

Packaging Appendix

This appendix is to be used by those facilities that solely produce packaging materials and food is not on site in the production or storage areas. It should be pointed out that all reference to food and ingredients is to be understood as food products which would include packaging materials as finished products and ingredients used for packaging materials.

This audit has the ability for items to be scored as "Not Applicable" in the event that the process is not present on site or not required for the process that is present. In many cases this will be assessed by the auditor as being required or not, but below is a list of items in the audit that are generally considered as Not Applicable for packaging facilities:

Item(s)	Department	Category	Reasoning
128	Food Safety	Allergen Control	Allergens are not typically a concern in packaging facilities as they are generally not involved in the manufacture of packaging materials. There are some instances where sulphites and other allergenic materials could be used in the production of packaging materials and in the printing inks. In those cases, these questions would be applicable.
141	Food Safety	Regulatory Compliance	Country of Origin tracking would not be applicable for packaging materials as these products are not covered in the COOL requirements at this time.
204, 205	Pre-requisite Programs	Good Laboratory Practice	Pathogenic testing is rarely conducted on packaging materials and rarely held for this testing.
303	Receiving, Storage, and Shipping	Receiving and Shipping	Temperature control is rarely required for packaging material products. There are some cases where this could be applicable, but typically this is not a concern in a packaging manufacturing facility.
314	Receiving, Storage, and Shipping	Storage	See above
401	Processing	Processing Aids and Ingredients	Frozen goods are not used in packaging facilities and a thawing program is not required. This question deals with microbial concerns during thawing and would not be a concern for packaging facilities.
408, 409	Processing	Product Safety	Packaging material plants are not considered high risk and would not be required to have distinctive product flow to avoid cross contamination or use foot foamers/foot bathes. Item 408 could be considered applicable if the flow of products does pose a risk to products, but this is not typically an issue for packaging plants.
410	Processing	Product Safety	As with 303 and 314; packaging materials are typically exempt for temperature control requirements.

Additionally, there will be some items in the audit that will be evaluated only partially as all of the requirements listed for these items would not be applicable. Below is an example of the items that may be partially audited.

Item(s)	Department	Category	Reasoning
101-104	Food Safety	HACCP	Typically at packaging facilities there are no CCPs within the facility's HACCP system. The requirement for the HACCP preliminary steps and the completion of a hazard analysis would still be required.
230	Pre-requisite Programs	Supplier Management	Biological requirements would not be expected to be present for packaging raw materials unless required by a customer for mold and yeast spores. Chemical and physical requirements would still be expected to be present and specified as to allergens in printing inks or heavy metals.
305	Receiving, Storage, and Shipping	Receiving and Shipping	The temperature requirement for shipping products would not be expected to be present as the majority of packaging materials are shipped in ambient conditions. In the event temperature control is required; this would be considered applicable.
401	Processing	Processing Aids and Ingredients	Water testing would be expected to be present if it is used for cleaning purposes. If cleaning is strictly done with the use of chemicals or dry cleaning this would not be applicable.
502	Grounds, Facility and Equipment	Plant Grounds	Although the question pertains to food waste, it is still expected that waste containers for personnel food wastes are maintained in appropriate condition and do not pose a pest harbourage or attraction risk.
508	Grounds, Facility and Equipment	Facility	Although this question pertains to cooking operations, there are packaging facilities that generate a lot of heat and steam. It is still expected that this is properly removed and condensation is not a risk to the facility.
511	Grounds, Facility and Equipment	Facility	The high-risk requirements of hands-free equipment would not be considered to be required for packaging material facilities.
516	Grounds, Facility and Equipment	Equipment	This question would also pertain to the use of finished packaging materials for unintended uses in the production facility (i.e. using manufactured cups to hold pens at desks).
805	Food Defense	Food Defense Observations	Depending on the type of packaging materials that are produced, it may not be necessary or practical for tamper evident packaging to be used. The auditor will have to determine if this would be necessary depending on the next customer and the end use of the product.

Again, this appendix is a guideline as what would be required during the audit and cannot be considered a "one size fits all" solution for all food contact packaging manufacturing facilities. The ultimate decision if an item is applicable to the facility being audited is on the auditor who will use information gathered during the audit to determine if it is applicable or not.

FSMA does not apply to Domestic packaging manufacturers but does to foreign facilities supplying to the US market.

It is strongly encouraged, but not required, that a facility conduct a risk analysis for all those items that they feel are not applicable and this is presented to an auditor in the event they are questioned why a particular requirement was not implemented.

Remote Audit Appendix

SAI Global now offers a remote option for sites who are unable to have an onsite audit due to extraordinary events that have resulted in travel or site policy restrictions in some regions.

By utilizing protocols defined in the International Accreditation Forum (IAF) Mandatory Document: Use of Information and Communication Technology (ICT) for Auditing and Assessment Purposes[1], SAI Global has developed a procedure for conducting remote GMP audits.

IAF defines the use of ICT as the use of technology for gathering, storing, retrieving, processing, analysing, and transmitting information. ICT includes software and hardware such as smartphones, handheld devices, laptop computers, desktop computers, drones, video cameras, wearable technology, and others for auditing remotely.

By completing a brief feasibility checklist and verifying ICT capabilities, a site may be approved for an audit to be conducted remotely.

SAI Global has developed a checklist that would enable an auditor to work with the site to verify portions of the audit that consist of document review and visual observation of processes using ICT. It is important to identify these questions on the checklist and confirm the site's feasibility of satisfying the audit question by these methods. In the event where limitations are found using ICT to observe a process within the facility, an onsite audit may be warranted.

The scope of the audit does require live video feed to observe multiple areas. Other forms of visual observation may be used as well to demonstrate compliance. If the ICT in use for the audit is not adequate to complete the requirements of the checklist then the audit may pause and restart to correct. Without adequate ICT the audit may not be a remote audit.

If a site is interested and does have the ICT capabilities to participate in a remote audit, the organization has developed helpful tools to effectively, and efficiently support the remote audit process.

Confidentiality	***Confidentiality, Security & Data Protection (CSDP):*** As written in part 8 of SAI's Terms and Conditions for Certification, Assessment Services and TradeMark Licence, 'SAI Global must ensure that its employees, agents and contractors treat as confidential, and do not disclose to any other third person without the prior written consent of the Client, any proprietary or confidential information belonging to the Client with which SAI Global becomes acquainted during the term of the Contract except that, where SAI Global considers it appropriate, SAI Global may disclose the Client's identity and the nature, status, scope or effect of the

	Client's Certification'
Feasibility	The remote audit depends on the feasibility of functioning ICT (Team, Webex, Google, etc.) The remote audit should be conducted in a quiet environment to avoid background noise and interference. A representative from SAI Global will verify the feasibility and methodology of the use of ICT platform(s) that will be used during the remote audit. The site should confirm with the auditor a contingency plan in the event that the agreed ICT platform is not functional the day of the audit.
Duration	The audit day will follow the similar structure to an on-site audit; however, there may be times where the site and the auditor agree to take increased breaks to review documentation, and collectively decide a time to continue with the audit throughout the audit day.
Scope	The Scope for the Remote audit will be the same as an on-site audit: auditing documents, policies, procedures, and records of the audit requirements. The remote audit will also include conducting a trace activity (traceability exercise) and a live video walk through the facility, including both internal and external perimeter (premises). The live video walk will consist of but is not limited to, looking at the product being made (product manufacturing), process forms, facilities lunchroom, restrooms, locker rooms, ingredient/packaging/finished goods storage, incoming goods, outgoing goods (shipping/receiving of goods), chemical storage, maintenance workshop, external perimeter, site security and inspecting inside bait stations.
Pre-Audit	The site and the auditor will complete an ICT Feasibility Checklist. This establishes the method of ICT Communication that will be used for the remote audit. The auditor and the site will 'test' the ICT method prior to the audit to ensure proper functionality.
Document Preparation	The documents and records required by the audit will be requested by the auditor. Records will be sampled specifically at the auditor's request. Organizing a method of display for all materials to be electronic upon request is essential and critical for audit success. Work with the assigned auditor on how to accomplish this critical task. Documents can be sent prior to the audit or displayed during the audit.
Essential Staff Availability	Ensure that essential team members and their schedules are accounted for when working with the auditor during the feasibility and audit planning process. The auditor may want to interview relevant team members as it relates to the audit category or question.
Opening Meeting	In addition to the expected opening meeting content (confirmation of scope, clarification of activities in the plant, review of audit plan, etc), the auditor and site will organize interviews for the key personnel. The auditor and the site may plan check in times during the course of the day to ensure proper audit progress is being made in accordance with the audit duration.
Closing Meeting	Attendees at the closing meeting have an opportunity to ask questions or seek further clarification. Once the audit has been closed, no additional documents or evidence will be accepted or reviewed. If documents, procedures, policies, or records were not available during the pre-allocated audit duration, any potential gaps raised would result in remarks of non-conformances.
Post Audit	Any post audit processes are not affected by the audit being remote, and the site should anticipate report and certificate in the same manner as the audit being performed onsite.

Change log

1/24/2021 (all January changes effective March 1, 2021	A4 (100 series questions)	Updated to include Allergen Control - Label reconciliation
1/24/21	E2 (600 series questions)	All utensils, tools and food containers must be designed for that purpose and constructed of food grade materials.
1/24/21	E2 6100 series questions)	1. Facility to include positive air pressure is present in high risk/high care/RTE areas including frequency of testing. 2. added testing and filtration of air coming into contact with food or food contact surfaces. 3 added condensation control for sanitation activities within high risk/high care/RTE areas
1/24/21	G1 & G2 (700 series questions)	Updated to include training in appropriate language
1/24/21	G2 (700 series questions)	Updated to include high risk/high care/RTE dedicated clothing requirements
1/24/21	H1 & H2 (900 series questions)	The Food Defense team shall conduct a vulnerability assessment. The FD program is reviewed annually
1/24/21	H3 (800 series questions)	Crisis Management Policy had been developed, a team is in place, there is a documents incident report, including product/material and equipment disposition & authorization
1/24/21	H3 (800 series questions)	Added the effectiveness of the Crisis Management is to be tested at least annually