



NSF International

Supplier Assurance Audit

Product Safety, Quality and Defense Expectations and Criteria for Manufacturing Facilities of - Food Contact Packaging Materials, Food-Related Items, and Personal Care (Contact) Products –

December 17th, 2014

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BACKGROUND

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

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

Specifically, this audit evaluates:

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

This manual provides criteria and expectations that the facility will be audited against and is generic for all types of food contact packaging materials, food-related items, and personal care items (direct contact) manufacturing establishments.

- **Food contact packaging materials** includes: primary food packaging materials (cans, bottles, flexible materials, paperboard packages, etc.).
- **Food-related items** includes: secondary packaging materials and other food-related items that do not contact food (shipping containers, fatigue mats, waste containers, storage racks, etc.) as well as food-related items that do contact food (cutting boards, knives, paddles, disposable gloves, etc.).
- **Personal care items** includes: shampoo, skin lotion, combs, tooth brushes, etc. This does not include cosmetics.

The criteria and expectations documented in this manual **Must** be rigorously applied when the item(s) being manufactured are intended for food contact. In all cases, Section B HACCP applies.

This manual provides criteria and expectations that the facility will be audited against and is generic for a variety of food processing and personal care item manufacturing establishments. Some specific criteria may not be applicable. It is the responsibility of the manufacturer to justify that a specific criterion is not applicable. Likewise, additional criteria may be applied based on changing regulatory requirements, specific client needs or the ever-changing product safety and product defense environment. Product defense is the terminology used to describe the actions that need to be implemented to prevent the intentional tampering with product to cause harm to the consuming public.

Manufacturing plants located outside the U.S. **Must** meet customer expectations and U.S. (FDA, USDA) regulatory requirements.

The following criteria and expectations are based on:

Customer specifications and requirements

- Food, Drug and Cosmetic Act (21 CFR) and appropriate amendments
- Food Code, 2005 edition (FDA/USPHS) and appropriate supplements

Links to these documents and other reference sources are available at our web site: www.nsf.org

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DEFINITIONS



SCORING GUIDELINES

Scoring.

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

Explanation of Section Scorings

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

Non-Conformance	Deduction of 5% per finding
Major Non-Conformance	Deduction of 25% per finding
Critical	0%

Summary By Section

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

Explanation of Overall Audit Result

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

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

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

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



Scoring Examples

Example 1

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

Example 2

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

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

Examples of Critical deficiencies are defined as:

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

Repeat Deficiencies

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

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

- Must** – An absolute requirement of this expectation document.
- Should** – A strong suggestion for a component of a Food Safety/Quality System.
Annually - a 12 month period.

Alternative Procedures

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

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DEFICIENCY CLASSIFICATION AND GUIDELINES

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

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

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

Annually - a 12 month period.

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

Audit Question/Statement Answers Options:

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

"Non-conformance" is the assessment made when:

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

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

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

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

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

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

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EXPECTATIONS AND CRITERIA FOR MANUFACTURING FACILITIES OF FOOD CONTACT PACKAGING MATERIALS, FOOD-RELATED AND PERSONAL CARE (CONTACT) ITEMS

The following requirements outline the management programs and performance criteria expected of a modern manufacturing facility to meet the product safety, quality and defense requirements of the public, regulatory agencies and customers. The marketing and delivery of safe, wholesome and high quality products requires a dedicated effort of knowledgeable professionals from raw material sources through manufacture, storage, distribution and sale. While product safety programs are the hallmark of modern food contact packaging material and food-related and personal care (contact) item manufacturers, high quality is an essential ingredient to assure success with the consumer. Reliable product manufacturing systems with a disciplined and knowledgeable work force that fully understand both product safety and consistent quality are necessary to compete in today's market.

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

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

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

Sub-sections may be divided into requirements 1) specific to all food contact packaging material, food-related and personal care (contact) item manufacturing **facilities** and 2) specific to food contact packaging material and food-related food contact item **production areas**. These will be noted under the headings, "All Manufacturing Facility Requirements" and " Food Contact Production Area Requirements", respectively.

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A. ADMINISTRATION & REGULATORY COMPLIANCE

1) Organization and Responsibilities

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

- a) The Quality Manager **Must** be responsible to the local Plant Manager (not Production Manager) or to a designated corporate official to assure that quality and safety decisions can be made independently. Consideration will be given for smaller plants where individuals have numerous organizational responsibilities.
- b) There **Must** be clear documentation of the responsibilities and authorities of the quality department signed by management.
- c) The control and release of withheld and retained product **Must** be clearly designated as the responsibility of the quality department.

2) Policies and Procedures Manual

- a) The plant **Must** have documented policies and procedures covering all aspects of raw material receipt, manufacturing, storage and transport. The documentation **Should** clearly define expectations through detailed product and process specifications, testing procedures, sampling programs and accept/reject criteria.
- b) These policies and procedures **Must** be well organized, available, current, dated and signed by management.
- c) Policies and procedures **Must** be reviewed for effectiveness annually. Specific policies and procedures will be addressed in detail in later sections.

3) Management Awareness and Commitment

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

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

4) Product Identification, Traceability and Recall Plans and Procedures

The plant **Must** have comprehensive written procedures for product identification, traceability and a recall plan specific to that plant location.

- a) Product identification codes and lot definition **Must** be documented. Identification systems **Must** include:
 - i. Incoming raw materials and food contact packaging materials.
 - ii. Rework or returned materials.
 - iii. In-process and carryover materials.

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- iv. Finished products.
- b) There **Must** be evidence of traceability for all raw materials, rework, carryover, and work-in-process into finished product. Finished product shipping records **Must** also be available. Each plant **Must** have procedures specific to that location to effectively trace lots from the time of receipt to the first level of finished product distribution. Traceability procedures **Must** include:
 - i. Documentation of rework or carryover usage **Must** provide traceability into specific finished product lots. Finished product documentation **Must** be capable of tracing backwards rework or carryover usage.
 - ii. Lot numbers of finished products **Must** be accurately shown on shipping documents and indicate quantities on “split” pallets, if applicable.
 - iii. Incoming raw materials **Must** have traceable lot codes upon receipt. Lot codes **Must** follow the item throughout storage and usage.
 - iv. An incoming material tracking program **Must** be in place to trace raw materials from receipt through use into finished product.
 - v. Bulk raw materials when used **Must** maintain the same ability to be traced as other ingredients. If absolute traceability is not possible because of commingling, validated procedures **Must** be documented to ensure that full traceability of bulk raw materials is possible.
- c) Traceability Exercises (Mock Recalls) on finished product **Must** be conducted at least twice annually (about every 6 months) to the first level of distribution. In the absence of a recall plan, or if no trace exercises are conducted at all, the rating and score for this item **Must** be no higher than a “Major Nonconformance”.
 - i. A management assessment after each traceability exercise is completed **Must** be conducted and documented to include a material balance sheet of total quantity of identified finished product produced vs. finished product shipped, finished product on hand and finished product otherwise documented (damaged, lost, samples, etc.), finished product unaccounted for, a calculated percent recovery, start and end times for the exercise, and any corrective actions identified.
 - ii. An effective traceability exercise is one where a finished product exercise (4.c.i) or an exercise where identified lots of raw materials are traced to lots of finished product and to the first level of distribution achieving a 99.5-105% recovery, taking into account normal waste and shrinkage, within four hours. Failure to meet these requirements necessitates a repeat traceability exercise until the criteria are met.
- d) The Recall Plan procedures **Must** be clear and concise and the plan **Must** be reassessed for effectiveness and signed annually.
 - i. The recall plan **Must** include at a minimum the following:
 1. Recall Team.
 - o Names of members.
 - o Responsibilities of team members.
 - o A Recall coordinator **Must** be clearly identified.
 - o 24/7 contact information **Must** be included.
 2. Contact numbers for appropriate regulatory contacts **Must** be included.
 3. Contact numbers for clients and customers **Must** be available.
 4. A public relations spokesperson **Must** be clearly identified.
 5. Designation of appropriate records and documents that **Must** be available for recall actions.

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- ii. Recall procedures **Must** include a plan to conduct a traceability exercise at least twice annually.
- iii. The plan **Must** include an investigation that is conducted while the recall is underway, to determine the root cause of the problem, initiate corrective actions, and to ensure there are no other lots of product affected.

5) Regulatory Compliance

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

Note: Refusal by facility to show any requested regulatory report is a “Major Nonconformance” deficiency, since an evaluation of regulatory compliance cannot be completed. Regulatory compliance requirements may be FDA, USDA, USDC or state and/or local agencies.

- a. The plant **Must** maintain a file of all regulatory actions, visits, reports or other notifications received from any regulatory agency.
- b. Written responses **Must** be documented for any audit or inspection by customers, third party auditors or internal company auditors. Failure to provide such audit reports is a "Major Nonconformance" since effective corrective action responses cannot be verified.

6) Document and Record Management

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

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

- a) A document control policy **Must** be available that identifies the current revision status of all documents to avoid use of invalid or obsolete documents.
- b) Obsolete documents **Must** be clearly identified and retained for historical purposes.
- c) Records relevant to the control of the process or evaluation of product safety, product quality and product defense **Must** be:
 - i. Complete with no missing data or blank blocks without an explanation for lack of data.
 - ii. Initialed by operator and signed by supervisor to verify accuracy.
 - iii. Recorded on a timely basis with accurate date and time.
 - iv. Recorded in ink, not pencil (Error single-lined through and initialed).

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- v. Marked to record or chart out-of-control or out-of-specification conditions. Records **Must** indicate disposition of product and corrective actions taken. Records **Must** be indexed and easily retrievable.
- vi. Evidence of intentional record falsification is a “Critical Nonconformance” for this subsection.

7) Change Management

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

- a. There **Must** be a documented procedure to assure that new management and supervisory personnel are aware of all plant policies and procedures impacting product safety, product quality, and product defense.
- b. There **Must** be a written procedure for ensuring that all changes to policies, procedures, product formulations, processing equipment, HACCP plan monitoring forms or product specifications are adequately communicated to the appropriate management and operational personnel.

8) Documentation to Track Effectiveness of Policies

- a. There **Must** be documented management reviews or monitoring programs (Internal Audits) to assess the level of conformance to operational policies (See D.8).
- b. Management reviews of internal audits **Must** be conducted at least annually.

9) Crisis and Natural Disaster Management

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

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

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production. Finished product involved in an emergency situation **Must** have a documented evaluation and be released by quality management prior to shipping.

10) Customer/Consumer Complaint Management

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

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

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

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

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

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

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

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

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

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

1) Preliminary HACCP Tasks

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

- a) A HACCP team **Must** be assembled with individuals having the appropriate product, process, and sanitation specific knowledge and expertise necessary for the development of an effective HACCP plan. Where such expertise is not available on site, expert advice **Should** be obtained from other sources.
 - i. Team members and their responsibilities **Must** be clearly identified as part of the HACCP plan. The entire team **Must** be involved in the development, final approval, and subsequent reviews of the plan.
 - ii. Documented team meetings **Must** occur at least annually to assess HACCP records and issues. The team **Must** assess all deviations, documentation errors, corrective actions, and assure that corrective actions are monitored for effectiveness.



- b) The intended use of the product **Must** be determined and **Should** be based on the expected uses of the product by the end user or consumer.
- c) The HACCP Team **Must** constructs a clear and easy to understand process flow diagram for each HACCP plan.
 - i. The process flow diagram **Must** outline each step involved in the process that is directly under the control of the establishment. The diagram **Must** indicate the raw material and other material categories used in all preparation steps, all equipment used, blending steps, processing steps, rework and returned products, packaging materials, packaging equipment and the steps preceding and following the process. The same flow diagram may be used for a number of products that are manufactured using similar processing steps.
 - ii. The process flow diagram **Must** remain current.
 - iii. Once CCPs (Critical Control Points) have been determined, they **Must** be clearly identified on the flow diagram and numbered to correspond with the Hazard Analysis and CCP records and documentation.
- d) The HACCP team **Must** perform and document an on-site review of the operation to verify the accuracy and completeness of the process flow diagram during all stages and hours of operation. Modifications **Must** be documented on the flow diagram, as necessary.

2) Hazard Analysis (HACCP Principle 1)

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

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

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

3) Critical Control Points (HACCP Principle 2)

- a) A logical, reasoned, documented approach **Must** be used to determine Critical Control Points (CCPs) for hazards. If a formal hazard analysis is not used to determine the need for CCP's, there **Must** be a documented risk assessment for that purpose.

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- b) Documentation for determining whether a step or process is a CCP or not **Must** be clear and thoroughly explained, defining the hazard and the specific controls that eliminate or reduce the hazard.

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

4) Critical Limits (HACCP Principle 3)

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

- Critical limits **Must** be specified and validated for each CCP. Failure to demonstrate that CCP critical limits are scientifically and/or technologically sound for controlling each hazard **Must** be rated as a Major Nonconformance.
- Critical limits **Must** be measurable. Variable or attribute measures are acceptable.
- There **Must** be a scientific, customer or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. (Validation) Proprietary data may be acceptable, providing there are sufficient data approved by an appropriate, qualified authority.
- Documented process capability studies or CCP monitoring records **Must** be available to demonstrate that established CCP limits are compatible with the plant process and capable of being met.

5) CCP Monitoring (HACCP Principle 4)

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

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

6) Corrective Actions (HACCP Principle 5)

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

- Corrective actions **Must** include instructions of necessary actions to take to secure and manage affected product.

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

7) Verification & Validation (HACCP Principle 6)

- a) Verification documentation is required, confirming that the products are achieving the level of safety required and that the HACCP plan is operating effectively.
 - i. Examples of verification activities include:
 1. Review of the HACCP system and plan and its records.
 2. Review of deviations and product dispositions.
 3. Confirmation that CCPs are properly monitored and kept under control.
 - b) Validation of the HACCP plan **Must** be available through documentation or supporting data that confirms the plan is scientifically and technically sound, that all hazards have been identified, that CCPs are effective and valid and that if the HACCP plan is properly implemented, these hazards will be effectively controlled.
 - i. Subsequent validation of the plan **Must** be performed and documented on an ongoing basis, as needed, based on corrective and preventive actions and **Must** be performed at least annually.

8) Documentation and Record Keeping (HACCP Principle 7)

HACCP procedures **Must** be documented.

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

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

The following guidelines are provided as minimum requirements for all food contact packaging materials, food-related items, and personal care (contact) products manufacturing facilities. They are general in nature and may not be appropriate for all operations, but the intent of the requirements, as stated, **Must** be achieved.

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

All Manufacturing Facility Requirements

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

Food Contact Production Area Requirements

- a) The plant **Must** demonstrate that the product contact water supply is potable and that potability is maintained at all times. Potability **Must** meet local requirements at a minimum.
- b) A certified laboratory **Must** document potability testing at least annually. Potability certificates available from municipal water suppliers are acceptable. If the facility is using water from a private well, there **Must** be a credible potability test at least every 6 months.
- c) Plant water **Must** be chlorinated or otherwise treated to assure potability.
- d) Plants using their own private wells **Must** be able to demonstrate water potability on a continuing basis. If chlorination is applied, the system **Must** have automated controls that prevent inadvertent use of the water or an alarming mechanism to immediately notify facility management if the chlorination system fails.
- e) Plant **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.
- f) Purchased ice **Must** have annual certificates of potability or documented, satisfactory microbiological testing results.
- g) Facility **Must** have an adequate supply of both hot and cold water for production and sanitation. Hand wash facilities **Must** deliver tempered water (90-105°F within 10 seconds).
- h) Hose drops **Must** have back flow prevention devices installed. (High pressure lines (>80 psi) do not need backflow protection.) These devices **Must** have annual, documented inspections to demonstrate effectiveness. Hose nozzles do not provide effective backflow prevention. Hoses and hose nozzles **Must** not be left on the floor or in tanks.
- i) Plant **Must** have a documented procedure for handling backed-up drains in the production areas. Drain cleaning equipment **Must** enter and exit the production area in such a way that it does not cause further contamination.
- j) Steam used for product manufacture and that touches product contact surfaces **Must** be from "edible" sources. Documentation **Must** be available that indicates all boiler water components meet approved boiler additive standards. A listing of registered Nonfood Compounds is available at http://www.nsf.org/business/nonfood_compounds/index.asp?program=NonFoodComReg

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2) Plant Construction and Design

All Manufacturing Facility Requirements

- a) The construction of the facility **Must** be such that it facilitates the production of wholesome product and that it at least meets the customer and regulatory product safety and quality requirements.
- b) Exterior of plant and grounds **Must** be constructed to minimize dust and be free of standing water.
- c) Facilities **Must** be designed so that product and raw materials do not come into contact with non-product zones (i.e. floor, walls, etc.).
- d) Plant construction and layout **Must** be such that exposed product is adequately separated and protected from any operations that could cause contamination.
- e) Floors **Must** be well drained, smooth, and easy to clean.
- f) Floors **Must** be maintained in clean and dry (if possible) condition.
- g) Standing water **Must** not be evident in production or warehouse areas.
- h) Ceilings **Must** be constructed of a smooth, non-porous, non-absorbent and easily cleanable material.
- i) Adequate heating, ventilation or refrigeration **Must** be provided in all areas to maintain proper environmental and sanitary conditions for raw materials, finished product, equipment, and the facility. All systems **Must** be clean, properly functioning and designed in such a manner to prevent product contamination from condensate, mold, bacteria, insects, dust or odors. Heating and ventilation **Must** be balanced to prevent condensation on walls or ceilings in product areas.
- j) Objectionable odors, fumes or vapors **Must** not be present.
- l) The facility roof **Must** be uncluttered, free draining and free of standing water, bird or pest harborage.

Food Contact Production Area Requirements

- a) With the exception of plants manufacturing glass or brittle plastic, glass and/or brittle plastic **Must** not be used in, above or near production or storage areas unless absolutely necessary (This includes glass thermometers).
- b) Plants manufacturing product in glass containers **Must** be constructed and equipped to properly protect the finished product and provide shielding to protect product and raw materials in the event of glass breakage during production.
- c) All essential glass or brittle plastic that exists in the production area including but not limited to cameras, emergency lighting, dial and gauge covers etc. **Must** be documented to indicate location and condition. Monitoring **Must** occur at least monthly.
- d) Concrete floors **Must** have no exposed aggregate and no cracks, holes or broken areas. Epoxy-coated floors **Must** be free of cracks, broken surface areas, and air/water bubbles under the surface.
- e) Catwalks and other walkways over or adjacent to product zones **Must** be designed and constructed to prevent product contamination. A standard OSHA 4-inch kickplate is insufficient for this purpose. An 18 inch safety shield is recommended.
- f) Bearings and bearing blocks **Must** be properly protected, or designed, so that no lubricant can leak or be forced into product zones. Catch pans for bearing blocks **Must** be properly drained. **Note:** this applies whether or not product grade lubricants are in use.

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- g) Hand wash and product wash sinks **Must** be properly plumbed to drain lines. Discharge water from sinks **Must** not run directly onto the floor.
- h) Drains **Must** have traps and drain covers **Must** be maintained in place. Drains **Must** be free from off-odors.
- i) All fans, fan guards, ductwork, louvers, and heating and air conditioning registers **Must** be clean and in good repair.
- j) All ceiling and wall ventilation fans venting to the outside **Must** have properly functioning, self-closing louvers and **Must** be screened to prevent insect entry. Self-closing louvers that sufficiently seal the opening and are maintained operational with appropriate inspection and preventive maintenance plans will suffice in lieu of insect screening.
- k) Facilities that utilize compressed air that makes direct contact with product, product contact surfaces or product contact packaging materials **Must** develop a program to assure the compressed air does not introduce any contaminants (including microorganisms) into the product. The necessary requirements for maintaining sanitary air **Must** be monitored and documented.

3) Plant Condition (Walls, Ceilings, Floors, etc.)

All Manufacturing Facility Requirements

- a) Plant facilities **Must** be well maintained in an orderly, clean condition with repairs to floors, walls, ceilings and equipment maintained so as not to provide undue obstacles to sanitation and pest management or present opportunities for foreign material contamination.
- b) Ceiling surfaces, as well as other overhead equipment, **Must** be clean, in good repair, free of flaking paint, loose caulking, rust, holes or unsealed openings, or other conditions that could result in product contamination.

Food Contact Production Area Requirements

- a) Overhead structures such as ventilation units, light fixtures, electrical raceways, piping, conveyors, etc., **Must** be clean and free of product buildup, dust, mold, rust, peeling paint and condensation.
- b) Ceiling panels, framework and supports **Must** be properly secured with no missing or damaged parts.
- c) Ceiling penetrations for pipes, conveyors, wiring, etc., **Must** be sealed to prevent harborage, ceiling leaks and contamination.
- d) There **Must** be no evidence of water leaks on ceilings.
- e) Insulation materials **Must** be in good repair, smooth, non-absorbent and easily cleanable. Joint areas **Must** be sealed.
- f) Nails, staples or screws **Must** not be used to secure ceiling material.
- g) All skylights, transoms, windows or similar openings **Must** be free of damage, tight fitting and properly screened when opened.
- h) All ceiling and wall junctures **Must** be cleanable and on the Master Sanitation Schedule to preclude pest harborage or access.
- i) String, rope, wire or tape **Must** not to be used as pipe, line or equipment supports.
- j) Pipes or other overhead equipment above product zones **Must** be adequately protected to eliminate potential product contamination.
- k) Temporary or unused hangers or other equipment support in production areas **Must** be removed when no longer in use.

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- l) Walls **Must** be of a smooth, non-toxic material with easily cleanable construction. They **Must** be free from cracks, holes and crevices that would inhibit cleaning or provide harborage for microorganisms, soil or pests. They **Must** be free of dust, dirt, product, or moisture accumulation and flaking paint.
- m) Walls **Must** be sealed and the wall/floor juncture **Must** be cleanable and on the Master Sanitation Schedule.
- n) Wall coverings **Must** not be attached with exposed nails, staples or screws.
- o) Openings in walls where pipes, equipment or conveyors pass **Must** be sealed.
- p) Windows **Must** be closed if outside conditions exist that may expose the plant to airborne contamination.
- q) All windows **Must** be maintained in a clean and sound condition, with no broken panes and **Must** be screened when open.

4) Employee Facilities

- a) Cafeteria, locker rooms/areas and toilet facilities **Must** be adequate in size for the maximum number of employees, convenient and physically separated from production areas. They **Must** be maintained to set an example of clean and orderly sanitation and housekeeping requirements.
- b) Cafeterias and break areas **Must** be adequately sized, well lit, clean and effectively ventilated. Adequate storage for employee food items, in easily cleanable areas, **Must** be available. Product preparation areas **Must** meet restaurant standards for sanitation and cleanliness. Vending machines **Must** be maintained in a sanitary condition with easy access for cleaning underneath and behind.
- c) Locker rooms/areas **Must** be adequately sized, well lit and clean and orderly. Lockers **Must** be available for storing personal items. There **Must** be a policy in place prohibiting food storage anywhere in locker rooms. There **Must** also be a documented program in place to verify compliance with the policy.
- d) Toilet facilities **Must** be available and convenient to operational areas. They **Must** be well ventilated, well lit, clean and orderly.
- e) Doors to toilet facilities **Must** be self-closing and **Must** not open directly into food contact production areas or raw material storage areas.
- f) All toilet facilities and locker rooms **Must** be under negative pressure and mechanically ventilated to the outside.
- g) A procedure for immediately cleaning and re-opening clogged toilet facility drains **Must** be in place.
- h) A plan **Must** be available that specifies appropriate sanitation procedures to restore sanitary conditions following repair of overflowed drains or toilets.

5) Handwashing Facilities

All Manufacturing Facility Requirements

- a) Handwashing facilities **Must** be convenient and adequate in number to accommodate the maximum number of employees. Hand wash stations **Must** minimally be in toilet facilities.
- b) Handwash stations **Must** have adequate room to accommodate the number of personnel in the area to prevent delays that may discourage proper handwashing procedures.

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

Food Contact Production Area Requirements

- a) Handwashing facilities minimally **Must** be adjacent to entrances to food contact production areas.
- b) In areas where product is exposed or handled by employees, handwash and/or sanitizing stations **Must** be convenient and relatively close to the employee workstations. Sanitizing stations are not a replacement for handwashing.
- c) Handwashing stations in or adjacent to production areas **Must** be 'hands-free' activated so that hand contact is not required to turn water 'On' or 'Off'.
- d) Required signage, in appropriate languages and/or graphics, **Must** be clearly posted at the locations and contain instructions as provided below.
 - i. Signs at locker room and toilet facility exits **Must** instruct employees to wash their hands prior to returning to work. **Note:** Washing hands prior to exiting the locker room and toilet facilities does not substitute for washing hands just prior to or immediately upon entrance to food handling and food processing areas.
 - ii. Signs at entrances to product handling and production areas **Must** instruct employees to wash and sanitize their hands prior to returning to work.
 - iii. Signs at hand wash stations **Must** instruct employees on the proper procedures for washing their hands.

6) Equipment Layout, Design and Condition

Food Contact Production Area Requirements

- a) All production and packaging equipment **Must** meet sanitary design requirements and be installed in such a manner as to permit proper operation and access for cleaning and inspection.
- b) Equipment **Must** be designed and maintained to provide easy access, disassembly and reassembly for thorough cleaning, sanitizing and inspection.
- c) Equipment **Must** be of smooth, impervious, non-toxic, non-absorbent and corrosion-resistant material where it has direct product contact.
- d) Conveyor belts for product contact **Must** be of impervious, non-absorbent material. Fiber-backed or sandwiched belts **Must** not be used for product contact conveyors. Belts **Must** be maintained in good condition with no holes, cuts, frayed edges or damage that renders the belt difficult to clean or present a foreign material hazard.
- e) Product contact surfaces, such as conveyor belts **Must** not be closer than 18" to the floor or **Must** be effectively protected from contamination during operations.

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- f) Equipment **Must** be free of cracks and non-continuous or rough welds where product may become embedded and make cleaning difficult.
- g) Equipment with sides or shields or scrapers or other items that are attached to product contact areas **Must** have sufficient clearance between the pieces to permit cleaning and prevent product accumulation (approximately ¼” is generally sufficient).
- h) Equipment **Must** be free of oil leaks and excessive grease build-up on bearings and motor housings where they may contaminate food contact product. Bearings and motors near and above product areas **Must** have catch pans to protect product below. The pans **Must** be drained in a sanitary manner.
- i) Equipment **Must** be constructed in such a manner to preclude metal-to-metal contact between moving parts.
- j) Hollow drums or rollers **Should** not be used for processing equipment. Open rollers that can be effectively cleaned or solid rollers or drums are required. If hollow drums/rollers are used, they **Must** be completely sealed and the maintenance department **Must** have a record of inspection and corrective actions instituted.
- k) Appropriate covers/lids **Must** be provided to protect product from contamination. Tanks or vessels containing raw materials for food contact surfaces **Must** be covered when they are not actually being filled, used or undergoing other activities requiring access.
- l) Food contact product equipment **Must** be free of flaking paint, rust or other contaminants that could become detached.
- m) Equipment **Must** be designed to preclude or divert condensate away from product and product contact surfaces.
- n) Product and clean product containers **Must** be adequately protected to preclude contamination.
- o) Gasket material **Must** be non-toxic, non-absorbent and in good condition.
- p) Small support utensils and equipment **Must** have specific, convenient and sanitary storage hangers or shelves.

7) Plant Lighting and Protection

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

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

All Manufacturing Facility Requirements

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

Food Contact Production Area Requirements

- a) Plant **Must** have a documented preventative maintenance program that covers all food contact production equipment and facilities.
- b) Plant **Must** have regularly scheduled internal audits of the facility that identify and correct potential contamination or sanitation hazards.
- c) Temporary repairs **Must** be consistent with GMPs and do not permit the use of inappropriate materials. Permanent repairs **Must** be made promptly. Non-food grade materials such as wire, tape, string, plastic or cardboard **Must** not be used for temporary repair.
- d) Food grade lubricants **Must** be stored separately from non-food grade lubricants. Non-food grade lubricants **Must** be clearly identified as not for use in food contact production areas.
- e) To avoid product contamination, shop scrap **Must** be controlled.

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

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

1) Master Sanitation Schedule and Monitoring

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

2) Standard Sanitation Operating Procedures (SSOPs) and Monitoring

All Manufacturing Facility Requirements

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

Food Contact Production Area Requirements

- a) The plant **Must** have documented Standard Sanitation Operating Procedures (SSOP) for individual pieces of food contact packaging material production equipment which specifies and defines:

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- I. Standard cleaning methods, including the level of disassembly required for cleaning, and assigned responsibility for each task.
 - II. Unless purchased as ready-to-use, there **Must** be specific preparation procedures regarding dilution factors for the specific chemicals or sanitizers being used and, where appropriate, verification testing and documentation.
 - III. Water temperature requirements for washing (>140°F for cleaning unless otherwise recommended in writing by chemical supplier).
- b) Plant **Must** have detailed SSOP Monitoring Procedures with records of monitoring activity. Records **Must** clearly show food contact packaging material production equipment condition and list all deficiencies found. When deficiencies are found there **Must** be a clear explanation of the activities performed to bring the equipment into a sanitary condition and a detailed corrective action plan to prevent a recurrence. **Note:** performed activities (fixes) and corrective actions are not the same.
 - c) Written procedures and schedules for routine cycle cleaning and sanitizing of food contact packaging material production equipment **Must** be current and available.
 - d) If machine operators are responsible for general maintenance and food contact packaging material production equipment cleaning, procedures **Must** be available describing steps for cleaning and sanitizing and the cleaning **Must** be documented.
 - e) Written procedures **Must** be available for cleaning and sanitizing food contact packaging material production equipment after maintenance is performed and prior to returning equipment into service. Records of such maintenance and documentation of sanitation is required.
 - f) All food contact packaging material production equipment taken out of service for maintenance **Must** be properly cleaned and sanitized before being put back into service. These activities **Must** be appropriately documented.

3) Cleaning Chemical and Sanitizer Control

- a) Cleaning and sanitizing chemical control **Must** be a part of an effective sanitation program.
- b) Cleaning chemicals **Must** be purchased from approved suppliers and be approved for their intended use.
- c) All containers for cleaning chemicals and sanitizers **Must** be properly labeled.
- d) All containers for cleaning chemicals and sanitizers **Must** be used for their intended purpose only.
- e) Chemicals used for cleaning and sanitizing **Must** be securely stored during periods of non-use.
- f) Chemical storage areas **Must** be restricted to authorized personnel and **Must** have applicable signage.
- g) Empty containers **Must** be stored in a manner that does not compromise product safety.
- h) Plant **Must** have MSDS sheets for all cleaning and sanitizing chemicals readily available.

4) Pre-Operational Monitoring and Corrective Action

Food Contact Production Area Requirements

A pre-operational checklist **Must** be used to verify that the production area (containers, utensils, walls, floors, ceilings, light fixtures, miscellaneous overhead structures, etc.) and food contact



packaging material production equipment are clean and sanitary prior to a routine cycle start-up.

- a) A documented inspection program **Must** be in place to assess sanitation effectiveness and line conditions prior to startup.
- b) Deficiencies **Must** be documented.
- c) Corrective actions and preventive measures **Must** be documented to prevent recurrence.

5) Verification of Cleaning Effectiveness

Food Contact Production Area Requirements

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

6) Operational Housekeeping

All Manufacturing Facility Requirements

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

Food Contact Production Area Requirements

- a) Garbage, trash and waste materials **Must** be removed from the food contact packaging material production areas in a timely manner so as not to cause a product safety risk.
- b) Accumulation of garbage, trash and waste materials **Must** be done in a manner that does not create any product safety risk.
- c) All blowers, fans, vents and grids **Must** be kept free of dirt and/or grease build-up.
- d) Conduits, pipe runs and other electrical fixtures **Must** be sealed and free of dust and debris.
- e) Rolling stock, totes, hand tools, utensils, etc. **Must** be cleaned and stored in designated areas.
- f) Mops, brooms, squeegees, etc. **Must** be stored on hanging storage fixtures and not on the floors or in buckets.
- g) High-pressure hoses **Must** not be used in production areas after sanitation is complete.
- h) Stored food contact packaging material processing equipment **Must** be re-cleaned prior to use.
- i) Floor drains **Must** be kept clean, odor free, covered and trapped.
- j) Equipment and floors **Must** be cleaned, as necessary, during operations to provide a hygienic environment.

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- k) All re-usable food contact packaging material production containers **Must** be effectively cleaned, sanitized and inspected before reuse.
- l) If packaging supplies are not removed from the production area during cleanup, they **Must** be covered to prevent contamination. There **Must** be an effective procedure in place to avoid packaging materials from becoming contaminated by the cleaning process.
- m) Tools **Must** be stored in clean toolboxes or in affixed positions. Tools and materials **Must** not be stored on top of equipment, electrical boxes or window ledges.

7) Personal Hygiene and Good Manufacturing Practices

All Manufacturing Facility Requirements

- a) Eating, drinking, spitting, chewing or using tobacco products **Must** not be permitted anywhere in the facility except in designated areas.

Food Contact Production Area Requirements

Production employees **Must** observe strict personal hygiene practices as outlined in the Code of Federal Regulations, Section 21, Part 110, "Current Good Manufacturing Practices".

- a) The following constitutes minimum guidelines for Personal Hygiene Practices:
 - i. A written dress code **Must** be clearly and prominently available for all employees. It **Must** be uniformly enforced for all employees (including new and part-time), visitors, vendors and contractors.
 - ii. Employees **Must** wear clean clothing and shoes appropriate for the working conditions.
 - iii. Fine mesh net hair restraints for head and facial hair **Must** be required in all production areas producing food contact packaging materials by all employees. If mustaches, without hair restraint, are allowed by the plant, they **Must** be well groomed and not extend below the corners of the mouth.
 - iv. Employees **Must** not work in production areas if they have an infectious or communicable illness, or have open sores on hands, faces or arms, etc. Employees **Must** notify management if they are diagnosed with a communicable disease transmitted through food or are experiencing symptoms of diarrhea, vomiting, fever or jaundice.
 - v. Employees handling food contact packaging materials **Must** wash and sanitize their hands before starting to work, after each absence from the work station and any time their hands may have become contaminated (touching equipment or other items that are unclean). If gloves are worn, they **Must** be intact, with no holes, and kept clean. They **Must** also be washed and sanitized, or replaced, if at any time unclean items are touched.
 - vi. If dedicated aprons, lab coats, smocks, etc. are utilized, the plant **Must** provide and the employees **Must** use a means to avoid contamination of their dedicated outer clothing when using the toilet facilities. Coat hooks **Must** be made available for employees to hang their outer garments outside the toilet facilities.

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

A key management responsibility is to verify that the policies and programs essential in the manufacture of wholesome products are routinely and effectively implemented. It is necessary that routine internal audits (self-assessments) of policies and procedures be conducted to assure management that they are being effectively implemented and that the facilities and equipment are maintained to meet sanitary and operational needs.

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- a) Facilities **Must** have documented procedures for planning and implementing internal -audits to verify compliance to policies and to evaluate the effectiveness of the policies.
- b) The internal audits **Must** assess facility, maintenance, pest control, production, sanitation, and housekeeping conditions and personnel hygienic practices for systematic effectiveness and to initiate corrective actions for deficiencies.
- c) Internal audits **Must** be scheduled routinely and be performed by responsible, trained individuals. If the internal audits are not conducted by a management person, there **Must** be periodic verification by management. These inspections **Must** be documented along with corrective actions and follow-up.
- d) Follow-up inspection activities for deficiencies and repeat items **Must** record the effectiveness of the corrective actions taken. Repeat issues **Must** receive top management priority to effect a timely corrective action.
- e) All internal audit reports showing deficiencies **Must** include corrective actions.

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

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

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

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

<http://www.nmapestworld.org/TechSupport/documents/ProductStandards60506.pdf>

1) Documented and Specific Pest Control Program

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

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



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

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

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

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

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

3) Inside Premises Management

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

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

4) Pest Tight Doors and Entrance Closures

- a) All doors, including overhead doors, **Must** be tight closing with no visible light observed between the floor and doorjamb.
- b) Exterior holes/cracks in walls, pipe chases, vent openings, windows, etc., **Must** be filled or screened to prevent entry of pests.

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- c) Building structure **Must** be sound with no holes, unscreened exterior openings, broken windows, etc. that may allow pest entry into the facility.

5) Secure Storage and Documentation of Pest Related Chemicals

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

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

6) Detailed Activity Reports Detailed with Corrective Actions

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

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



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

The plant is expected to have detailed, written policies describing how suppliers are approved, receiving criteria for carrier and raw material acceptance, and handling and storage criteria for raw materials.

1. Supplier Approval Policies and Procedures

There **Must** be a documented Supplier Approval Program for suppliers of food contact packaging raw materials that identifies criteria for approving suppliers. The Approved Supplier Program **Must** contain as a minimum:

- a) The plant **Must** require potential suppliers to complete a pre-qualification questionnaire that at least includes process capabilities, process descriptions, HACCP information, and allergen information. Approved suppliers **Must** complete similar questionnaires (addressing changes from their previous questionnaire) at least annually.
- b) Continuing Letters of Pure Food Guarantee **Must** be current and available for all raw materials for which there are no lot specific Certificates of Analysis (COA).
- c) Specifications for raw materials.
- d) Supplier approval criteria and approval process.
- e) Allowable circumstances to deviate from an approved supplier.
- f) Monitoring of approved suppliers.

2) Incoming Vehicle Inspection and Documentation

There **Must** be a documented program to ensure that transportation of materials to the plant does not place the safety of the materials received at risk.

- a) Plant **Must** have a written inspection program for all inbound carriers that fully describes acceptable and/or unacceptable conditions.
- b) All raw materials **Must** be received from approved suppliers.
- c) All railcars, trucks, etc., **Must** be inspected at time of receiving to assure condition, cleanliness, and that they are free of moisture and offensive odors. Carriers **Must** be in good repair, with no evidence of pest activity and free of foreign substances such as glass, chemicals or odors.
- d) Interior of trailers, trucks or cars **Must** be free of loose or broken boards, nails, and holes in sidewalls that could cause contamination or pest harborage.
- e) Incoming raw materials **Must** be inspected for specification compliance, damage, potential contamination, etc. The inspection program **Must** include:
 - i. Specific damage evaluation procedures with acceptance criteria.
 - ii. Sampling plans describing which raw materials are subject to in-plant testing and which raw materials are accepted based on Certificates of Analysis (COA).
 - iii. Specifications for raw materials and tests to be performed with testing frequencies and accept/reject limits.
 - iv. Foreign material contamination checks.
- f) Trailer, railcar or tanker security seals **Must** be verified as the original seal number applied at the original shipping point.
- g) Documentation of condition of each inbound shipment **Must** be shown on receiving documents.
- h) Records **Must** be maintained to match supplier codes to the materials received.



Note: During the audit process, all raw materials within the plant and its warehouses will be subject to sampling by the auditor for evidence of compliance to the criteria detailed in this sub-section.

3) Release Criteria for Ingredients

All raw materials **Must** be maintained in a secure fashion (reference Product Defense Section L) and released for use against a defined program.

- a) Control procedures **Must** be in place to prevent use of raw materials before approval and to assure that non-conforming materials are not used.

4) Storage and Handling Policies and Practices

Procedures **Must** be established to assure that raw materials and supplies are not subject to sources of contamination.

- a) Receiving docks and areas around and under docks **Must** be clean and free from litter, spilled material, standing water, etc. The docks and receiving areas **Must** be maintained orderly, clean, and free of equipment or pallet accumulation that interferes with daily cleaning.
 - i. Dock levelers and dock plates **Must** be included on the Master Sanitation Schedule.
- b) Warehouse storage areas **Must** be clean and orderly, with no spilled, damaged or exposed raw materials. Opened product containers **Must** not be stored in the receiving storage areas.
- c) Slip-sheets **Must** be used when double stacking palletized raw materials for food contact packaging materials to protect the material from dirty or damaged pallets.
- d) Raw materials for food contact packaging materials **Must** not be stored directly on the floor.

5) Bulk receiving Systems-Sanitation and Monitoring

- a) Bulk ingredient hoses, piping, and storage tanks **Must** be capped, locked and maintained in a sanitary manner, with a documented cleaning procedure.
- b) Bulk storage units **Must** be cleaned as evidence dictates.

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

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

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

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G. PROCESS & PRODUCT EVALUATION (The Process and Product Control Prerequisite System)

The plant **Must** have written policies and procedures specifying the operational control practices required to assure that the manufacturing process operates in control on a continuing basis. Operating records **Must** be available to verify conformance to these policies.

1) Process Control and Documentation Procedures

Product **Must** be manufactured under documented control procedures. The procedures **Must** take into consideration all product safety aspects.

- a) Effective application of the HACCP plan **Must** be clearly evident by the presence of identified CCP and other control measure monitoring points with appropriate and complete documentation.
- b) HACCP CCP monitoring documents **Must** clearly identify the CCP being monitored, the responsible operator, the critical limit, monitoring frequency, the action to be taken when limits are exceeded, the corrective actions required, and the signatures required by operational and supervisory personnel.
- c) In-process raw materials, products and packaging materials **Must** be adequately protected and properly labeled with date and lot number.
- d) There **Must** be a pallet management program in place to assure that pallets do not present microbiological or foreign material risks.

2) Specification and Formulation Control and Accuracy

In addition to specification compliance, there **Must** be procedures for assuring control of product formulations.

- a) Documented finished product specifications **Must** be developed by the customer and/or plant that define acceptable product attributes.
- b) Records **Must** be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications, if applicable.
- c) Products with multiple raw materials **Must** have appropriate formulation controls available to the operators with regular verification of accuracy.
- d) Blending and mixing records **Must** show times, quantities and lot identification of ingredients used.
- e) Production records **Must** be maintained for twelve months beyond product shelf life. This is to assure continual compliance to customer, plant and regulatory requirements.
- f) Test protocols and frequencies **Must** be followed as identified in the specification.
- g) Issues, concerns or requests for changes regarding the accuracy, completeness, or frequency of testing **Must** be addressed with the customer, if applicable, with changes only permitted with written authorization.

3) Routine Calibration of Operational Equipment and Measuring Devices

It is essential that all measuring, metering or protective devices (such as thermometers, scales, flow meters, metal detectors, etc.) be properly calibrated to assure the accuracy of these activities and the effectiveness of their performance. The criteria below are minimum requirements for equipment monitoring HACCP CCPs.

- a) Key process control devices such as thermometers, scales, recording devices, etc., require routine calibration or certification by a credible authority at least annually. There **Must** also

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be a program to verify the performance of measuring devices to assure accuracy on a day-to-day basis.

- b) Assigned personnel **Must** check scales used for weighing raw materials, production components and finished product preparation daily. Standard weights in the range of the weights being produced **Must** be used for these verification checks. Daily verification checks **Must** be documented.
- c) Electronic measuring devices (i.e. temperature, pressure, conductivity) utilizing remote transmitting devices (RTDs), **Must** be calibrated at least annually by comparison with an NIST standard instrument (i.e. thermometer, pressure gauge, conductivity meter). The calibration **Must** be performed with the measuring system (RTD, electrical connections, and recorder/display) intact. The data **Must** be obtained and recorded in the appropriate units of measurement for the system.
- d) Flow meters, if critical to the HACCP plan, **Must** be regularly calibrated for accuracy, as recommended by the manufacturer.
- e) Calibration procedures **Must** describe the frequency of testing, the testing method and the acceptable range of variation.
- f) There **Must** be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used (thermometer, scale, flow meter, counting device, metal detector, coder, etc.). All product produced since the last acceptable check **Must** be assessed to determine if it **Must** be held for further evaluation.

4) Foreign Material Control

All finished product **Must** be inspected for potential metal contamination. The highly preferred method is for all finished product to be scanned through an electronic instrument calibrated to identify and separate contaminated product. Typical systems include metal detectors or x-ray units. If electronic devices are not used, other measures designed to prevent physical contamination **Must** be employed. Examples of such measures would include liquids that pass through a fine mesh screen, free-flowing items that pass over, under, or through rare earth magnets or product items that are secured in the final package with metal fasteners, but pass through metal detectors in the packaging process. These "other measures" **Must** be calibrated, if appropriate, monitored and documented. The plant **Must** have a documented procedure for monitoring their process and finished product for the presence of foreign material.

- a) Electronic Foreign Material Detectors, if used: There **Must** be a written procedure describing the maintenance, set-up and verification tests of detector systems. The procedure **Must** describe the initial set-up procedures and frequency of verification checks with actual product at start-up, during the shift and at the end of production. Test units to check equipment performance **Must** be used and appropriate for the nature of the product and the size of the package. Detectors **Must** be set-up at the beginning by qualified personnel and calibrated for the particular product being run. Documentation of calibration and set-up **Must** be part of daily production records along with initial, operational and final verification checks.
 - i. Detectors **Must** have calibration and set-up verified by placing the test units or cards containing them along with the first product or package through the detector. Calibration **Must** include the use of ferrous, non-ferrous and stainless steel test samples. Customer specifications **Must** be used, if available. At the start of the production run, the first product through **Must** be tested to verify performance and ability to detect and reject the specified test units. Test units **Must** be placed along with the product in a

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sanitary manner so as to avoid product contamination. Special care **Must** be given to make sure that test units are promptly recovered from the test packages.

- ii. A successful verification check **Must** detect and reject three successive challenges for each test unit. For those situations where three successive challenges may be difficult to accomplish, one challenge for each test unit is acceptable during the production run; however, three successive challenges are still required at start up and at finish. An example of this might be a system where detection is conducted just prior to packaging of a bulk ground meat product that is conveyed in line and insertion of the test unit is quite complicated.
- iii. If product used in the verification checks is not discarded, it **Must** be re-run through the detector after the test units have been removed from the package.
- iv. Frequency of verification checks during production and test metal samples used **Must** be sufficient to assure continued accurate performance. Some customers may require specified verification frequencies and test metal samples used.
- v. A verification check of the detector performance **Must** be made on the last product run during the shift or lot. This will provide documentation that the detector was functioning properly from beginning to the end of production.
- vi. Rejected units from the detector **Must** be retested and pass 3 successive times before accepted as a false positive. The detector **Must** be properly calibrated at the time the rejected product is retested. Reject units **Must** be opened promptly and examined to determine the source of the problem.
- vii. A record of detector rejects and the cause for rejection **Must** be recorded on the verification/test log.
- viii. In the event the detector fails a verification check, all product produced since the last documented successful verification check **Must** successfully pass through a properly functioning detector device.
- b) When magnets are used for the detection and removal of potential metal contaminants, the method of calibration **Must** be the manufacturer's recommended pull strength test.
- c) A program **Must** be in place to minimize foreign material contamination from the outside of bagged raw materials when being added in open mixing units.
- d) There **Must** be an accountability program in place for knives and similar hand tools.

5) Application of Statistical Control

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

6) Allergen and Sensitive Ingredient Controls

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

- a) If production of products containing allergens is not performed on dedicated lines or equipment, the following practices **Must** be in place:
 - i. Equipment used for allergen products **Must** be disassembled and chemically cleaned prior to use for non-allergen products.

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- ii. Verification of the cleaning processes' performance **Must** be documented.
- iii. A validation program confirming the effectiveness of the cleaning processes used to eliminate specific allergens **Must** be implemented and documented. (see C.5.c)
- b) Raw materials containing allergens **Must** be clearly identified as such and properly controlled or isolated in the production or blending areas to prevent cross-contamination.
- c) Use of rework containing allergens **Must** be carefully controlled to assure there is no cross-contamination of raw materials into non-allergen containing products.
- d) Formulation changes **Must** be carefully controlled to assure there is no inclusion of allergens into products that were not intended to contain them.
- e) Utensils used for these raw materials **Must** be dedicated and not used for other raw materials unless there is a thorough cleaning and sanitizing procedure applied between uses.
- f) There **Must** be a documented training program for employees on the proper handling of allergen sensitive raw materials and products.
- g) Employees handling raw materials and products that are, or contain, allergens **Must** not handle non-allergen or different allergen products without a complete change of outer garments, hair restraints, sanitary gloves and protective sleeve guards.
- h) Finished product specifications and shipping unit labels **Must** indicate the presence of the allergen or sensitizing agent.
- i) Shipping unit operations **Must** have a documented line clearance procedure to ensure labels and products are cleared from the line and labeling equipment during product changeovers.

7) Specification Compliance Documentation

Quality programs rely on documentation to confirm that the desired quality parameters were achieved. Records **Must** be maintained to assure that the appropriate product attributes were evaluated and that the results were consistent over time.

- a) Finished product **Must** have documentation verifying that the product meets specifications. Specification compliance documentation **Must** be available for review.
- b) A finished product evaluation procedure **Must** include frequency of testing, documentation of results and availability of records for 15 months beyond the product ship date.
- c) If the product fails to pass any inspection and/or test, the procedures for control of nonconforming product **Must** apply.

8) Rework and Carryover Products

The plant **Must** have a documented procedure for managing rework. Rework **Must** be treated as a raw material and the plant **Must** be able to trace rework to its original production lot and to component raw material lots.

- a) The plant **Must** be able to trace the usage of all rework products into finished product. Rework is defined as product not meeting initial specifications or retained line accumulation requiring reprocessing or product carry-over from one lot to a subsequent production lot thus commingling lots.
- b) The responsibility for assessment and release of rework product **Must** be specified.
- c) Rework **Must** be clearly identified with the date of production and original lot number, if appropriate. There **Must** be adequate documentation to assure that product tracking records are complete and can easily identify the lots where the product was used.
- d) Production dates and original lot numbers **Must** be carried forward in production documents when the material is ultimately used.

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- e) Rework **Must** be handled in accordance with documented procedures. Product awaiting disposition **Must** be stored in a dedicated place or exhibit an obvious physical indication of its status (i.e. on hold or rework).
- f) All rework **Must** be kept to a minimum and used promptly at the first opportunity. There **Must** be a routine and documented “clean break” in the rework cycle.
- g) A documented “same-into-same” policy regarding rework and carryover products **Must** be in place.

9) Analytical Records Management

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

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

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H. PACKAGING & LABELING

1) Label Accuracy and Regulatory Compliance

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

- a) Labels **Must** satisfy regulatory requirements and/or customer expectations and **Must** include an accurate product name and a lot identification understood by the customer.
- b) Sensitizing agents or allergenic raw materials **Must** be included on the label of products containing allergenic or sensitizing ingredients.
- c) There **Must** be some documented method of matching the proper unit label with the product or production schedule or formulation. The method chosen **Must** compare printed label codes and product container codes.

2) Net Weight or Count Compliance Policy and Performance

Plants **Must** have a documented policy for net weight, liquid contents or product count to verify compliance to customer requirements and/or specifications.

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

3) Clear Manufacturing Codes on Individual and Cased Product

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

- a) All product coding and label information **Must** be of such size, color and contrast to afford easy legibility at a reasonable distance.
- b) Code may be an open date code or a cryptic code, such as the Julian system, that is clearly understood by both the customer and plant operation.
- c) Each individual ship unit **Must** have a production or lot code. If the finished product is contained in cases in the ship unit, the cases **Must** be coded with the same lot code as the ship unit.

4) Package Integrity and Function

The shipping unit **Must** be designed and assembled to provide the necessary protection for the product from environmental and shipping conditions.

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

5) Label Security and Obsolete Label Control

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

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

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I. STORAGE & SHIPPING

Finished products **Must** be stored under controlled conditions. Products **Must** not be released for shipment without assuring that all product safety and quality evaluations have been completed. All product shipped **Must** be able to be tracked in case of a product recall.

1) Warehouse and Finished Product Management

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

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

2) Retained and Returned Products

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

- a) Policies and Practices for Retained and Returned Products.
 - i. The plant **Must** have a written policy for retained and returned products that describe individuals responsible for evaluating product and making decisions regarding disposition of it. The policy **Must** be understood by all authorized personnel.
 - ii. A Hold Tag procedure **Must** include a permanent written log of each product or item placed on hold.
 - iii. The plant **Must** have a policy and procedure for handling returned products.
 - iv. Returned products **Must** be identified and placed on hold immediately.
- b) Designated Areas for Retained and Returned Products.
 - i. Products retained or returned to a processing plant **Must** be handled securely.
 - ii. There **Must** be a designated, clearly identified area for returned or retained products or product **Must** exhibit an obvious physical indication of its status (i.e. on hold or returned). A computer block alone is not acceptable. There **Must** be some type of records indicating the product is returned or retained.
 - iii. Returned or retained products **Must** be clearly identified as such.
- c) Verification and Release Documentation.

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- i. Documents **Must** be available to show the current location of products not cleared for shipment as well as those that are authorized for shipment.
- ii. Disposition or corrective actions **Must** be commensurate with the seriousness of risk identified. Disposition **Must** be dated and signed.
- iii. All non-conforming products **Must** be handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.
- iv. Product destined for destruction **Must** be adequately secured and disposed of promptly.
- v. Disposition of non-conforming material **Must** be tracked to ensure that inventories are adjusted accordingly to facilitate recall.
- vi. Damaged, sampled or destroyed finished product **Must** be recorded and proper adjustments to the product inventory records **Must** be made to accurately account for the inventory loss.
- vii. An inventory log **Must** be maintained showing current product on hold and list the disposition of all released product with proper authorization.
- viii.

3) Storage Facility and Dock Maintenance

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

- a) Product **Must** not be stacked so that it blocks blowers or vents preventing the circulation of air.
- b) Items stored in all warehouses **Must** be a minimum of 6" off the floor (standard pallets heights are acceptable). Units of finished product may be stored on slip sheets or unit wrapping on the floor if there is evidence of effective sanitation and pest management programs.
- c) Wall perimeters **Must** be maintained in a clear and clean manner and allow for pest management inspections and sanitation/housekeeping requirements.
- d) Pallets, racks and shelving **Must** be clean and in good repair.
- e) Floors and walls **Must** be in good condition and free from holes or damage.
- f) Floors under pallets, racks and in aisle-ways **Must** be clean and free from dirt, accumulated debris, spilled product or broken pallets.
- g) Shipping docks, dock plates, dock levelers and areas around and under the docks **Must** be clean and free from accumulated debris, food materials, water, etc. These areas **Must** be on the Master Sanitation Schedule.
- h) Slip-sheets **Must** be used when double stacking palletized raw materials to prevent potential contamination from dirty or damaged pallets.

4) Transport Condition

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

- a) Written procedures describing acceptable and/or unacceptable carrier conditions **Must** be available to shipping personnel.
- b) All outbound trailers **Must** be inspected for condition, odors, sanitation, and potential contamination sources. Inspection results **Must** be documented on shipping documents.

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- c) Product **Must** not be loaded into unacceptable carriers. Trailers **Must** be cleaned, if necessary.
- d) Trailers and railcars **Must** not be cleaned at the dock, as this creates a warehouse sanitation problem and a potential for pest harborage.
- e) Slip-sheets **Must** be used when double stacking palletized finished products to prevent potential contamination from dirty or damaged pallets.

5) Release Authorization to Ship Product

Product can be shipped only with proper authorization.

- a) Product **Must** not be shipped until all the activities specified in the product safety and quality plans have been made available to and approved by management. Records **Must** be signed and dated by the person responsible for the release of product.

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J. Training Requirements (The Employee Training Prerequisite System)

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

1) New Hire Training

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

2) Training Language

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

3) Prerequisite Program Training

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

4) Refresher Training

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

5) Proof of Knowledge

- a) A method to document individual understanding, such as testing at the conclusion of the training or documented performance evaluations by supervision, conducted within a



reasonably short period of time (14 to 30 days), **Must** be an integral part of the training program.

6) Training Records

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

7) Training Program Review

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



K. LABORATORY SUPPORT (The Laboratory Capabilities Prerequisite System)

When applicable, laboratory support functions provide valuable information to assure process control, product safety and quality.

1) Laboratory Facility and Staffing

The plant laboratory for chemical and physical analytical testing of raw materials, in-process components and finished product **Must** be adequately equipped and staffed to provide the essential technical support to the plant.

- a) Laboratory staff **Must** have documented qualifications by way of specific training, certification or other forms of credentialing.
- b) Laboratory **Must** be clean, orderly and well lit. It **Must** have at least the appropriate equipment and instruments to provide effective evaluation for product safety and specification compliance of the raw materials and finished product.
- c) The laboratory **Must** be isolated from the production area if it contains hazardous chemicals or reagents and control procedures **Must** be implemented to ensure that it does not contribute to potential contamination. Laboratory drains **Must** be directed to the sanitary sewer system and not to production area drainage systems.
- d) Pathogen analyses **Must** 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. The pathogen testing laboratory **Must** comply with BSL2 requirements as well as the Good Laboratory Practices (GLP) requirements set forth in 21 CFR 58.
- e) All toxic supplies **Must** be securely stored and properly labeled.

2) Laboratory Procedures and Documentation

Laboratory procedures **Must** be documented with proper authorization and dates.

- a) Testing procedures **Must** be based on recognized and approved procedures.
- b) Documentation of all testing **Must** be available, including records of COAs where in-house testing is not performed.

3) Laboratory Equipment Calibration

It is essential that every laboratory have a detailed and documented calibration and verification programs for instruments and measuring devices.

- a) Balances and laboratory test equipment **Must** be calibrated (certified) by a demonstrably competent company or individual at a prescribed frequency as defined by the manufacturer. Records of this certification **Must** be maintained. Certification of reference standards, weights, and thermometers **Must** be available.
- b) There **Must** be an in-house policy for periodic verification of test equipment at appropriate frequencies. This **Must** include at least start of production checks of scales, balances and thermometers with appropriate test weights and calibrated thermometers. Documentation may be on routine data sheets.

4) Analytical Accuracy Verification

There **Must** be documented evidence that the results of the laboratory are accurate and reliable.

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- a) Quality manual test procedures, work instructions, training records and record keeping **Must** be established to verify that monitoring is occurring and that the results meet specifications and finished product requirements.
- b) Plant **Must** have documented detailed procedures for all microbiological, analytical, physical and chemical tests performed.
- c) Microbiological test procedures **Must** meet accepted standards (BAM, USDA or recognized authority).
- d) Chemical test procedures **Must** meet accepted standards (AOAC or recognized authority).

5) Third Party Laboratories

There **Must** be documented evidence that any outside laboratory performing tests or analyses of raw materials, packaging materials or finished products is competent and qualified to perform the specified work

- a) The plant **Must** be able to show proof of their third-party laboratories' qualifications. Acceptable examples include current ISO 17025 certificate, USDA certification or others relevant to the work being performed
- b) Records of all tests and analyses performed by third-party laboratories **Must** be available for review

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L. PRODUCT DEFENSE (The Food Defense Prerequisite System)

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

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

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

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

Additional product defense guidance, for program development purposes, can be found in the Product Security - Expectations and Criteria Manual available at www.nsf.org.

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

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

1. Management

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

- a) A Product Defense team **Must** be established that will evaluate the vulnerabilities and risks that exist from raw material sourcing, storage, processing, shipping of finished goods, and personnel.
- b) Each facility **Must** conduct and document a Product Defense Risk Evaluation utilizing an Operational Risk Management (ORM) process. This process will help prioritize the

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- preventive measures that are most likely to have the greatest impact on reducing the risk of tampering or other malicious, criminal, or terrorist actions against product.
- c) Based on the Product Defense Risk Evaluation and the priorities established by the Product Defense team, the facility **Must** identify and implement control measures that will eliminate or significantly reduce the risk of external and internal intentional adulteration of product. ***(No details of food defense facility control measures will be identified in the audit report unless requested by the plant)***
 - d) Product and facility security roles and responsibilities **Must** be documented and defined regarding the development and maintenance of guidelines, training and enforcement of requirements and procedures.
 - e) The Product Defense program **Must** be reviewed at least annually to verify and validate that the implemented product defense control measures are effective and no new product defense risks are present.
 - f) Required Product Defense Program Control Measures.
 - i. Raw Material Isolation — It is essential to isolate and remove any potentially compromised raw material or other materials. As dictated by the circumstances, a comprehensive assessment by product safety personnel, general management and the applicable regulatory agency **Must** be performed to determine the suitability of raw materials and plant security prior to resuming any production operations.
 - ii. Computers — A procedure to back-up computer systems and documentation critical to product safety **Must** be developed and implemented. Access to computer systems for the purpose of document changes **Must** be limited to identified, authorized personnel.
 - iii. Off site warehousing — All off-site warehousing, manufacturing, and distribution locations that are in the facility’s control **Must** be included in the facility’s Product Defense programs, unless it is documented that these locations have an independent Product Defense program.
 - iv. Unusual Occurrences — Employees **Must** be trained to report unusual product defense occurrences. There **Must** be a procedure in place that makes it easy to do so quickly and in an appropriate manner. Reported occurrences **Must** be documented and assessed by management and corrective actions taken, as necessary. An unusual occurrence could be an employee who acts unusual (i.e. unhappy, despondent, antagonistic or without an identifiable purpose), stays unusually late or arrives unusually early, accesses unauthorized files, information or areas of the facility outside of their areas responsibility or asks unusual questions.

2) Human Element

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

- a) Internal risk.
 - i. Screening: A written screening program **Must** be in place for all employees, including management, seasonal and temporary employees and contracted services (e.g., pest control, cleaning services, maintenance contractors, etc). Any persons not included in this pre-hiring screening program **Should** be covered by the facility visitor policy.
 - ii. Positive Employee Identification: There **Must** be a documented and implemented system for the positive identification and recognition of all employees entering the facility.

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- iii. Training: A written program **Must** be developed and implemented to train employees in the product defense rules of the facility. This program **Must** explain the severe criminal nature of tampering with or deliberate contamination of products and **Should** include: plant specific rules, how to recognize and address signs of and evidence of tampering, reporting instructions in the event of a product defense issue (threats, chemical spills, wrong doing, etc.).
 - iv. Employees: The plant **Must** maintain a current and accurate roster of employees and work assignments. Employees **Must** be prohibited from bringing personal items such as purses, cases, containers, lunch boxes, etc. into processing areas. Temporary employees **Must** be fully supervised at all times.
- b) External Risk.
- i. Contractors: The facility **Must** have documented policies and procedures that define product safety and product defense requirements for on-site contractor employees. There **Must** be a contractor employee sign-in and sign-out log that also verifies they have received a copy of the facility’s GMP, product safety, hygiene, and product defense rules. Contractor personnel **Must** be restricted to defined work areas and not allowed into other areas of the plant.
 - ii. Visitors: Facility **Must** have documented visitor policies and procedures. There **Must** be a visitor sign-in and sign-out log that also verifies they have received a copy of the facility’s GMP, product safety, personal hygiene, and product defense rules. Visitor authenticity **Must** be verified by photo identification. Visitors **Must** always be accompanied by a designated, responsible employee when in the plant.

3) Facility

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

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- ii. The product defense team **Must** identify potential sensitive areas within the plant's manufacturing and storage areas. Policies and procedures **Must** address how access to and from identified sensitive areas is restricted.

4) Operations

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

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DEFINITIONS

ALLERGEN: Certain compounds can cause an allergic or intolerance response in sensitive individuals. Allergic individuals can tolerate very little of the offending material.

United States

In the United States, allergens of concern include:

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

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

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

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

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

Canada

Canadian definition of allergens is as follows:

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

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

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



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

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

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

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

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

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

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

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

HACCP DEFINITIONS

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

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

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

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

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

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

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

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

Deviation – Failure to meet a critical limit.

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

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

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

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

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

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

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

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

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

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

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

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

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

MUST: A mandatory requirement of the standard.

POTABLE WATER: Water that is safe for human consumption.

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

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

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

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

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

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

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

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

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

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

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

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

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

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