

SUPPLIER ASSURANCE

PACKAGING MANUFACTURING AUDIT STANDARD

PROGRAM REQUIREMENTS MANUAL

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6.0	April 1, 2020	NSF International	<ul style="list-style-type: none">• Update to formatting, layout, sentence structure and grammar• Change in title• Inclusion of Essential elements• Scope redefined to packaging manufacturing only• Removed all “should” expectations or altered to “shall”• Updated to current customer, industry, and regulatory guidance and feedback
5.2	December 17, 2014	NSF International	<ul style="list-style-type: none">• Original Product Safety, Quality and Defense Expectations and Criteria for Manufacturing Facilities of Product Contact Packaging Materials, Product-Related Items, and Personal Care (Contact) Products

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INTRODUCTION

NSF International's Supplier Assurance audit for packaging manufacturing focusses on the development, implementation and control of systems that impact product safety, quality and defense. The expectations outline the management programs and performance criteria expected for a modern packaging facility to meet the basic safety, quality, and defense requirements of the public, regulatory agencies and customers.

The expectations are considered essential to producing safe, high quality products on a consistent basis. Demonstrating consistent conformance with these expectations is the expectation of our clients, who expect that the packaging materials they are purchasing are safe to use for the intended purpose and manufactured in line with agreed upon specifications.

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

This manual provides criteria and expectations that the facility will be audited against and is generic for all types of packaging manufacturing establishments. Some specific criteria may not be applicable. It is the responsibility of the manufacturer to provide proper justification in such cases. Likewise, additional criteria may be applied based on changing regulatory requirements, specific client needs or the ever-changing safety and defense environment.

This audit evaluates the ability of the facility, regardless of geographical location, to meet customer expectations and regulatory requirements as they apply to the facility involved. In all packaging manufacturing facilities audited against this standard, the expectations related to hazard and risk assessments (i.e., Section B of this audit standard) apply.

The packaging industry is very diverse. The scope of this audit standard includes the manufacturing of packaging material generally, including packaging considered higher risk (primary packaging) and lower risk (secondary and tertiary packaging). Packaging items included in the scope of this audit standard include:

Direct/primary product packaging materials (cans, bottles, flexible materials, paperboard packages, etc. that come into direct contact with food or hygiene-sensitive consumer products).

Indirect/secondary/tertiary contact packaging materials (corrugated cardboard, shipping containers, etc. that do not come in direct contact with food or hygiene-sensitive consumer products).

The expectations of this audit are divided into two parts:

- a) Required for all packaging manufacturing (primary, secondary and tertiary)
- b) Required for all direct contact packaging manufacturing (primary)

The expectations of this standard are based on customer specifications, industry best practices and regulatory acts, amendments and regulations, including, but not limited to, those enforced by agencies globally.

DOCUMENTATION

DOCUMENTS REVIEWED DURING THE AUDIT

The list included below is intended to provide guidance through examples of the type of documents and procedures the auditor may ask to review during the audit. Documents and records shall be reviewed as part of the duration of the audit. There may be additional documents, policies and procedures requested that are not included in the list included below. Some of these documents may not apply to every type of facility. When policies are stored electronically or held at a corporate location, it is the facility's responsibility to demonstrate to the auditor that they are aware of where and how to access documents related to the facility's operations, policies and procedures. Documents and records that cannot be produced on the request of the auditor during the duration of the audit shall be considered as not conforming to this standard.

Example documents and records that may be reviewed during an audit to this standard:

- Facility management organization chart and QA responsibilities
- Product Safety and Quality Policies and Procedures Manual
- Product list or proposed product list for client
- Product specifications for client or facility product specifications
- Policy and documentation of management and employee training
- Detailed Product Recall Manual, including records of mock recalls
- Regulatory compliance policies and documents of regulatory visits or comments
- Document management and record keeping policies and procedures
- Change management policies to address changes in management, process or procedures
- Emergency or catastrophic event product management program
- Policy compliance and effectiveness review program
- Consumer complaint policy and procedures and records
- Manufacturing capability evaluations/statistical process control data
- Monitoring and Corrective Action policies and documentation
- Rework policies and procedures
- Defense and security policies
- Documentation and records for prerequisite programs
- Current, signed HACCP/product safety plan with team members designated
- HACCP/product safety team members credentials
- Description of the product and its intended use
- Critical Control Point (CCP) validation studies
- Documented detailed hazard analysis and risk assessment (HARA) for all raw materials, process steps and finished product
- Detailed process flow charts, showing all inputs, outputs, and product rework/recycle pathways

- Documented records of HACCP/product safety team program oversight including annual review (at minimum)

ALTERNATE PROCEDURES AND PROCESSES

If a requirement in this standard specifies the need for a risk assessment (e.g., “based on risk”, etc.), that indicates that a risk assessment be carried out, documented and used to further develop procedures and processes related to the risks analyzed. At times it may be acceptable to have an alternative procedure or processes to those defined in the expectations in this standard. If this occurs, the alternative procedure shall accomplish the same degree of control as indicated in the criteria. The sub-section shall be considered applicable and rated based on the level of compliance to the intention of the criteria and the alternative procedure shall be noted in the comments.

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

If a specific client allows a facility’s deviation from an expectation of this standard, the facility shall obtain written approval from that client for the variance/deviation prior to the audit process so that it can be made available to the auditor during the audit visit. Variances are in effect for one calendar year from the date of issuance or as specified by the client. If there is an approved deviation from an expectation of this standard for a specific client, then the resultant audit report shall be valid only for that specific client (not valid for general distribution to other customers/clients who may not approve of the deviation).

TERMS AND DEFICIENCY CLASSIFICATIONS

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

- **Shall** – an absolute requirement.
- **Annually** – a 12-month period (for recurring audits, “annually” shall be the 12-month period since the previous audit was conducted)

The audit report will not contain recommendations or suggestions for enhancement for improvement, nor will nonconformances be cited for situations where best practices are not implemented in a facility (provided that the expectations of this standard are being met). Conversely, no additional points are awarded for best practices. The audit is intended as an objective assessment of the product safety management programs (both from documentation as well as implementation perspectives) in the facility.

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

“**Acceptable**” is the assessment made when the element being audited meets or exceeds the applicable expectations.

“**Non-conformance**” is the assessment made when:

- a. The element being audited only partially meets the expectations.
- b. Improvement is required to meet the expectations.

“**Major Non-conformance**” is the assessment made when:

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

“Critical Non-conformance” is the assessment made when:

- a. There is clear objective evidence of or direct observation that the product produced fails to comply with product safety (is unsafe for use) or fails to comply with legal requirement(s).
- b. There is a complete failure to meet an **ESSENTIAL** element of the expectations as listed in the **ESSENTIAL** elements chart in this section.
- c. There is direct observation and/or evidence of intentional record falsification.

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

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

The following are **ESSENTIAL** elements in this Supplier Assurance standard:

A 3.5 Traceability.	The lack of any system to trace raw materials and finished product as per regulatory requirements and customer expectations shall be assessed as a Critical Non-conformance
A 4.2 Records.	Evidence of intentional record falsification shall be assessed as a Critical Non-conformance.
B 6.1 Specific correction actions to deal with deviations shall be in place for each CCP.	Failure to take corrective action for a critical limit deviation shall be assessed as a Critical Non-conformance.
C 1.1. Potability of water supply.	Use of non-potable water as part of or in contact with direct contact packaging or other inappropriate use shall be assessed as a Critical Non-conformance.
C 2.2 Facility construction and layout is not a source of contamination	Any condition in the facility that, based on objective evidence or observation, results in product or raw material contamination and adulteration shall be assessed as a Critical Non-conformance.
C 6.1 Equipment is not a source of contamination.	Finding through observation or other objective evidence that equipment or materials are unsuitable for use with packaging or that equipment condition is a cause of product contamination shall be assessed as a Critical Non-conformance
C 9.2 Equipment affecting product safety is effectively calibrated.	Equipment found to be out of calibration leading to potential for illegal or unsafe product shall be assessed as a Critical Non-conformance.
E 1.3 Pests are not a source of contamination.	Observation of pests on or in raw materials, packaging, work in process, or finished goods shall be assessed as a Critical Non-conformance.

SCORING GUIDELINES

EXPLANATION OF SECTION SCORINGS:

Section scorings is calculated using the following formula. Note that the calculation of a section score is different than the calculation of the overall audit score. Section scores are provided as a general guideline of performance.

- **Non-Conformance** = deduction of 5% per finding
- **Major Non-Conformance** = deduction of 25% per finding
- **Critical** = deduction of 100%

EXPLANATION OF OVERALL AUDIT RESULT:

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

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

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

While a score is provided for this report, NSF strongly recommends putting the emphasis on identification and correction of non-conformances, to drive continuous improvements in product safety. NSF also offers an un-scored version of this Supplier Assurance Packaging Manufacturing Audit.

Scoring Example 1

Section A contains 2 nonconformance ratings and Section B contains 1 major non-conformance, giving Section Scores for Section A = 90% and Section B = 75%. If there are no further non-

conformances, then the overall audit score is 88% (-2% for the 2 non-conformances and -10% for the major nonconformance) and the overall audit rating is "Needs Improvement"

Scoring Example 2

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

CORRECTIVE ACTION AND IMPROVEMENT

It is important to implement and document all improvements and corrective actions for any finding noted in this audit. It is important to review the findings noted in the audit and effectively determine root cause of the issues regardless of the numerical score.

Corrective action is defined as the correction of the immediate problem as well as prevention of reoccurrence of the problem through effective root cause analysis and action.

REPEAT DEFICIENCIES

Repeat assessments of non-conformance, where the facility has not taken corrective action to effectively address previously cited deficiencies in the most recent NSF International Supplier Assurance packaging audit, will be noted by the auditor in the report. Repeat non-conformance ratings may cause an additional downgrade of the audit question's rating, depending on nature of the deficiency and its impact on product safety at the facility. In addition, repeat non-conformances without effective correction actions taken shall be reflected as a non-conformance against management commitment (A1.3)

EXPECTATIONS OF THIS STANDARD

A: ADMINISTRATION AND REGULATORY COMPLIANCE

A1. ADMINISTRATION, MANAGEMENT AND ORGANIZATION

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

- a. There shall be an up to date organizational chart outlining the overall organizational structure, including those responsible for product safety.
- b. The facility shall document job descriptions and competencies for job duties for the roles included in the organization chart.
- c. There shall always be a suitably trained member of the facility's management team available during production hours.

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

- a. A quality assurance program shall be fully described, and include a product safety, quality and security policy, as well as key quality objectives/key performance indicators that maintain and drive continuous improvement at the facility.
- b. The facility shall have a documented quality policy statement that is signed by senior management and communicated to all levels of the organization.
- c. Senior site management shall designate an individual with responsibility and authority to oversee, develop, implement and maintain the product safety and quality program.
- d. The facility shall have documented policies and procedures covering all aspects of raw material receipt (all inputs to the finished product), product manufacture, and storage and shipping. These policies and procedures shall be well organized, available, current, dated and approved by an authorized person.
- e. Policies and procedures shall be reviewed for effectiveness annually with reporting on this review to the facility's senior management.
- f. The facility shall have a documented policy to manage change. The policy shall describe how to effectively communicate changes in personnel and changes in documents and records (such as, but not limited to, specifications, policies, procedures, formulations and product safety plan) to all levels of the facility's organization (including to new and existing personnel).

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

- a. Adequate financial and staffing resources shall be provided for product safety, quality, and security programs, as well as for overall facility and equipment upkeep.

- b. There shall be management participation in the audit process and a commitment to the completion of corrective actions resulting from both outside and internal audits and inspections.
- c. There shall be documented management reviews (internal audits) to assess the level of conformance to operational policies. Management reviews of internal audits shall be conducted at least annually.

A2. REGULATORY AND CUSTOMER COMPLIANCE

2.1. FACILITY SHALL HAVE A PROCEDURE FOR MANAGING AUDITS AND INSPECTIONS AND MAINTAIN FILES OF AUDIT VISITS AND REPORTS (REGULATORY, THIRD PARTY AUDITS, CUSTOMERS).

- a. The facility shall have a documented procedure for managing audits conducted by external agencies (regulatory, third party, customer).
- b. The facility shall maintain a file of regulatory actions, audit visits, reports or other notifications received from any regulatory agency, third party audit company and/or customer.
- c. Written responses with appropriate corrective actions shall be documented for any audit or inspection conducted at the facility (regulatory, third party audit company and/or customer).
- d. The facility shall provide copies of the above reports to the auditor for the purposes of evaluation of corrective and preventive actions.

***FAILURE TO PROVIDE REGULATORY REPORTS AS WELL AS REQUESTED INFORMATION RELATED TO REGULATORY OR CUSTOMER AUDITS GENERALLY FOR THIS EXPECTATION OF THE AUDIT SHALL BE RATED AS A MAJOR NON-CONFORMANCE AS EFFECTIVE CORRECTIVE ACTION RESPONSES AND/OR RETURN TO REGULATORY COMPLIANCE CANNOT BE VERIFIED.**

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

- a. The facility shall have a documented procedure outlining how they ensure that all regulatory requirements are met for all applicable products and processes (e.g., 21 CFR for facilities under US FDA regulations, or any international equivalent regulation). The procedure shall also include how the facility ensures regulatory requirements are met when products are exported to other countries. The facility shall be able to show that they are properly licensed to operate as applicable.

A3. PRODUCT IDENTIFICATION AND TRACEABILITY

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

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

3.2. RECALL MANAGEMENT RESPONSIBILITY SHALL BE ASSIGNED

- a. There shall be a designated recall team.
- b. The recall team roster shall include the responsibilities for all team members including alternates.
- c. There shall be back up personnel assigned for each team role.
- d. There shall be a designated team leader or coordinator.
- e. There shall be a contact list of all personnel within the company who would be involved in a recall. The list shall include 24-hour contact numbers. The list shall be up to date and current. Additionally, a contact list shall be present for all customers, legal representation and regulatory entities who would need to be contacted in the event of a recall.

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

- a. Trace exercises shall be conducted at a minimum of twice annually, with at least one of these exercises completed outside of normal business hours. If the facility's operation is 24 hours a day, 7 days per week, the site shall perform at least one exercise outside the standard operating hours of 8:00 to 17:00 or perform an exercise on a weekend day or recognized holiday.
- b. Trace exercises shall be conducted on both finished product and raw materials, including the outer packaging used for the finished product.
- c. Traceability exercises shall demonstrate a 99.5% to 105% accounting within 4 hours, considering normal loss, waste or shrinkage.

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

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

- b. All corrective actions resulting from trace exercises are documented and implemented prior to a subsequent trace exercise. Failure to attain effective traceability shall necessitate repeat traceability exercises until the criteria are met.

NOTE: An effective raw material trace exercise is one where a received lot of raw material is traced to all the finished product it was used in and a mass balance calculation achieves 99.5-105% recovery considering normal yields, loss, waste or shrinkage. An effective finished product traceability exercise is one where a finished product lot is traced to the first level of distribution considering normal yields, loss, waste or shrinkage.

3.5. ESSENTIAL THERE SHALL BE EVIDENCE OF TRACEABILITY FOR ALL RAW MATERIALS, REWORK, CARRYOVER, WORK IN PROCESS, AND PACKAGING MATERIALS USED FOR FINISHED PRODUCT. FINISHED PRODUCT SHIPPING RECORDS SHALL BE AVAILABLE.

- a. Materials shall be traceable including:
- Raw materials
 - Rework or returned materials
 - Carryover materials
 - Work in process
 - Packaging materials (used to package the finished product)
 - Samples (e.g., reference, laboratory)
 - Finished product
- b. Bulk materials, when used or produced, shall maintain the same ability to be traced as other materials. If absolute traceability is not possible because of commingling, validated procedures shall be documented to ensure that traceability is attainable to best possible accuracy.
- c. The program shall identify how all materials are identified/labeled to ensure traceability from receipt through shipment.

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

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

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

A4. DOCUMENT CONTROL, RECORDKEEPING AND RETENTION

4.1. THE FACILITY SHALL HAVE A DOCUMENT CONTROL AND A RECORD RETENTION AND STORAGE PROGRAM.

- a. The facility shall have a policy and procedures for document control management and retention and storage of records relevant to the control of the process or evaluation of product safety, product quality and product defense. The policies and procedures shall identify the current revision status of all documents. No invalid or obsolete documents shall be in use. Obsolete documents shall be clearly identified and retained for historical purposes
- b. The period for retention of records shall be documented and shall take into account any customer requirements.

4.2. ESSENTIAL RECORDS RELEVANT TO THE CONTROL OF THE PROCESS OR EVALUATION OF PRODUCT SAFETY, PRODUCT QUALITY AND PRODUCT DEFENSE SHALL BE PROPERLY COMPLETED.

- a. All records shall be:
 - Genuine and legible.
 - Initialed by operator and independently verified for accuracy.
 - Records shall be self-explanatory and complete.
 - They shall be completed in ink on a timely basis with accurate date and time. There shall be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation shall be provided.
 - Errors shall be marked with single line-out and initialed
 - Records shall be marked to record out-of-control or out-of-specification conditions
 - Records shall be easily retrievable and secured. Quality systems shall be established to properly store and retrieve analytical information, documents, reports, records, etc. Records and reports of analytical information gathered by organizations (internal and external) shall be cataloged and maintained in a fashion that provides feedback for operational control.
 - If documents and/or records are managed electronically, applicable authority for change and change dates shall be a part of the documentation process. Electronic signatures are acceptable; however not mandatory if the system clearly identifies the individual with the authority to approve changes. Electronic records shall be effectively access controlled and stored securely with backup to prevent loss.
 - Records shall indicate disposition of product and corrective actions taken.

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

A5. CRISIS AND NATURAL DISASTER MANAGEMENT

5.1. CRISIS MANAGEMENT POLICIES AND PROCEDURES SHALL BE DEVELOPED TO ADDRESS ANY CRITICAL SITUATIONS THAT MAY OCCUR (E.G., PRODUCT RECALLS AND BUSINESS CONTINUITY INTERRUPTIONS, SUCH AS NATURAL DISASTERS, CATASTROPHIC EVENTS AND OTHER EMERGENCY SITUATIONS

INCLUDING, BUT NOT LIMITED TO, POWER OUTAGE, TAMPERING, EMERGENCY EVACUATION, ETC.)

- a. The policies and procedures shall be overseen by a trained crisis management team. This team is responsible for the following activities in the event of crisis:
 - Determine the status and disposition of raw materials, packaging materials, in-process materials, and finished product involved in a crisis event situation.
 - Ensure all raw materials and materials are suitable for use prior to the restart of production.
 - Ensure there is a documented evaluation of all product involved in a crisis event.
 - Ensure there is a documented release of any affected product prior to shipping.
 - Include a contingency plan for production in the event of crisis events.
 - Ensure that all communications are completed as needed during a crisis event. A current list of responsible team members shall be maintained, as well as current contacts for regulatory, corporate, client, supplier, and outside support as needed.
- b. Records of all crisis management program activities are maintained.

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

- a. These exercises shall include all the activities outlined in A5.1.

A6. CUSTOMER/CONSUMER COMPLAINT MANAGEMENT

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

- a. There shall be a written procedure for handling, documenting and trending customer and/or consumer complaints that addresses responsibilities, response time, root cause investigation and, where appropriate, corrective and preventive action.
- b. Records of complaints received, and actions taken shall be made available to the auditor.

B: HAZARD ANALYSIS AND RISK ASSESSMENT (PRODUCT SAFETY PLAN)

Codex Alimentarius Commission (CODEX) provides 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. HACCP is a tool to assess potential hazards and establish control systems that focus on prevention rather than relying on finished product testing.

A system and plan shall be developed, based on the principles of HACCP, by each facility and tailored to its individual products, processes, and storage and distribution conditions. This product safety plan shall 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, manufacturing, storage, distribution and intended use of the finished product. It is essential that the unique conditions within each facility be considered during the development of all components of the product safety plan.

Approval of the plan shall be documented. The plan shall be kept current with regular effectiveness reviews by the product safety management team. Individuals who are knowledgeable in HACCP principles, as well as the specific product and process shall either participate in or verify the completeness of the hazard analysis and the resultant plan.

As applicable, the product safety plan shall follow the regulatory requirements. Even if not required by regulatory bodies, the facility shall still comply with prerequisite programs and all HACCP requirements found in subsequent sections of this document. For the purposes of this packaging audit standard, the terminology of HACCP and product safety plan are considered interchangeable.

B1. PRELIMINARY TASKS

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

The HACCP/Product Safety Plan team shall:

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

- e. All members of the product safety team shall be able to demonstrate their knowledge of the principles of HACCP and their knowledge of the product safety plan implemented at the facility.

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

The HACCP/Product Safety Team shall:

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

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

The Process Flow Diagram shall:

- a. Outline each step involved in the process that is directly under the control of the facility. The same flow diagram may be used for products that are manufactured using similar processing steps.
- b. Indicate the raw material and material categories used in all preparation steps.
- c. Include all process equipment (including packaging equipment)
- d. Include all process steps
- e. Include introduction of rework and returned products, and packaging materials.
- f. Include the steps preceding and following the process.

1.4. THE PROCESS FLOW DIAGRAM SHALL INCLUDE CCPS, SHALL BE CURRENT AND SHALL BE VERIFIED.

- a. The HACCP/product safety team shall perform and document an on-site review of the operation to verify the accuracy and completeness of the process flow diagram during all stages and hours of operation. Modifications shall be documented on the flow diagram, as necessary.
- b. The process flow diagram shall remain current.

- c. Once CCPs have been determined, they shall be clearly identified on the flow diagram and numbered to correspond with the hazard analysis and CCP records and documentation.

B2. HAZARD ANALYSIS (HACCP PRINCIPLE 1)

2.1. THE HACCP/PRODUCT SAFETY PLAN TEAM SHALL 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 USE. EVALUATION SHALL INCLUDE ALL RAW MATERIALS, EQUIPMENT, PROCESSING STEPS, AND PACKAGING MATERIALS.

- a. The HACCP/product safety team shall conduct a hazard analysis to identify which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe product. Hazards shall include consideration for defects that affect product safety. Consideration should be given to what identified prerequisite control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specific control measure.
- b. The hazard analysis shall include:
- The likelihood of hazards and the severity of their adverse health effects.
 - The qualitative and/or quantitative evaluation of the presence of hazards.
 - Survival or multiplication of microorganisms of concern and the conditions that would lead to microbial contamination issues.
 - Production or persistence in products of hazardous toxins, chemicals or physical agents and the conditions that would lead to chemical or physical contamination issues.
 - All raw materials and process steps. The analysis shall include, but not be limited to, origin of raw materials, use of recycled materials, and potential hazards and risks of any inks, varnishes, coatings. print chemicals or similar used in the production of the product related to the intended use.
- c. Control measures based on prevention shall be identified for all significant hazards listed.

B3. CRITICAL CONTROL POINTS (HACCP PRINCIPLE 2)

3.1. THE HACCP/PRODUCT SAFETY PLAN TEAM SHALL DETERMINE THE CRITICAL CONTROL POINTS.

- a. Critical Control Points shall be determined using a logical, reasoned, documented approach, such as a decision tree. If a formal hazard analysis is not used to determine the need for CCPs, there shall be a documented risk assessment instead.
- b. Documentation for determining whether a step or process is a CCP shall be clear and thoroughly explained, defining the hazard and the specific controls that eliminate or reduce the hazard.

NOTE: If it has been determined that there are no hazards **OR** no CCPs, no further plan development is necessary. However, the HACCP/product safety plan team shall continue to conduct regular meetings to review any changes in the process or procedures that could affect the hazard analysis, risk assessment and CCP determination.

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

B4. CRITICAL LIMITS (HACCP PRINCIPLE 3)

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

- a. Critical limits shall be measurable. Variable or attribute measures are acceptable.
- b. There shall be a scientific or regulatory basis, with appropriate documentation or regulatory references, for both the hazard and the control required. Proprietary data may be acceptable, providing there are enough data approved by an appropriate, qualified authority.
- c. Documented process studies conducted in the facility shall be available to demonstrate that established CCP limits are compatible with the capability of the facility's processes. CCP monitoring records can be used to show that the facility's process and equipment are able of meeting CCP limits.

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

B5. CCP MONITORING (HACCP PRINCIPLE 4)

5.1. CCPS SHALL BE MONITORED.

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

5.2. CCP MONITORING RECORDS SHALL BE MAINTAINED.

- a. Documentation of the measured attribute shall be clearly identified in HACCP/product safety plan records.
- b. Records shall have CCPs identified by name and number, the item to be measured, the frequency of the measurement, the CCP limit, the responsible monitor and the corrective action required in the event that a measurement is not in compliance. All corrective action procedures shall clearly indicate where deviations are recorded and who is responsible for actions taken.
- c. A deviation log shall be maintained and available for review.

- d. All records and documents associated with monitoring CCPs shall be signed by the person(s) doing the monitoring.

B6. CORRECTIVE ACTIONS (HACCP PRINCIPLE 5)

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

- a. Corrective actions shall include instructions of necessary actions to take to secure and manage affected product, including who needs to be informed if a critical limit is exceeded.
- b. Corrective actions shall ensure that the CCP has been brought under control and require that an assessment be conducted to prevent a recurrence of the situation.
- c. There shall be documented product disposition procedures in the event of a CCP deviation.

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

B7. VERIFICATION AND VALIDATION (HACCP PRINCIPLE 6)

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

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

7.2. THERE SHALL BE DOCUMENTED VALIDATION OF THE EFFECTIVENESS OF THE HACCP/PRODUCT SAFETY PLAN.

- a. Validation of the plan shall be available through documentation or supporting data that confirms:
- The plan is scientifically and technically sound.
 - All hazards have been identified.
 - Prerequisite programs are effective and functioning as intended.
 - CCPs are effective and valid and that, if the plan is properly implemented, these hazards will be effectively controlled.
- b. The plan shall be reviewed and validated by the product safety team at minimum annually, or as needed based on changes to raw materials/processes/product change, and/or corrective and preventive actions. At the time of the plan review, the product safety team shall also include a

review of the training needs and competency of its members, to ensure that the expertise of the team remains current. The product safety team shall also ensure that that the plan review and validation, including any resultant changes, are communicated to senior management. This validation of the plan and review of the team shall be documented.

B8. DOCUMENTATION AND RECORD KEEPING (HACCP PRINCIPLE 7)

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

- a. Documentation and record keeping shall be sufficient to assist the business to verify that the HACCP/product safety plan controls are in place and being maintained.
- b. Documentation shall include:
 - Hazard analysis.
 - CCP determination.
 - Risk analysis (likelihood and severity).
 - Critical limit determination.
- c. Records shall include:
 - CCP monitoring activities.
 - Deviations and details of associated corrective actions, including product disposition.
 - Verification procedures performed.
 - Modifications to the plan.
 - Effective access control, in the event that the records are electronic.
 - Appropriate signing and initialing to verify compliance and completeness
- d. Deviations from the plan shall be thoroughly documented with detailed corrective actions and product dispositions. The documents and their data shall be self-explanatory and complete.
- e. All records and documents associated with the monitoring of the plan shall be signed by the person(s) doing the monitoring and verified by a responsible, trained employee of the facility.

C. FACILITIES AND EQUIPMENT

The following guidelines are provided as minimum requirements for packaging manufacturing facilities that shall be achieved. For many of the elements, more stringent requirements are required to be in place for manufacturing facilities that produce packaging designed for direct contact with food or hygiene-sensitive consumer products. These more stringent requirements, as they apply, are listed in the sections below under the heading Direct Contact Packaging Manufacturing Facilities.

C1. WATER SUPPLY

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

ALL PACKAGING MANUFACTURING FACILITIES

- a. There shall be an adequate supply of water for processing and sanitation.
- b. All water used in the processing of products or equipment cleaning shall be potable or suitably treated to prevent contamination. Potability shall meet relevant legal requirements at a minimum. Potability certificates available from municipal water suppliers are acceptable as proof of potability.

DIRECT CONTACT PACKAGING MANUFACTURING FACILITIES

- a. Potability testing of municipal water supplies shall be conducted by a certified laboratory at minimum annually. If the facility is using water from a private well, there shall be a potability test conducted by a certified laboratory that demonstrates water potability on a continuing basis (at least every six months).
- b. Facility shall have an identification system for potable and non-potable water lines and shall have current water system schematic available for review. Dead ends on potable water lines shall be eliminated.
- c. Discharge water from sinks shall not run directly onto the floor.
- d. Hose drops shall have back flow prevention devices installed. Backflow prevention devices shall have annual, documented inspections to demonstrate effectiveness. Hose nozzles do not provide effective backflow prevention. Hoses and hose nozzles shall not be left on the floor or in tanks. Wastewater systems shall not present a hazard due to contact or odor and wastewater shall be disposed of properly.
- e. Plant shall have a documented procedure for handling backed-up drains in the production areas. Drain cleaning equipment shall enter and exit the production area in such a way that it does not cause further contamination
- f. Steam and/or ice used for product manufacture and that touches product contact surfaces shall be from potable sources. Documentation shall be available that indicates all boiler water components meet approved boiler additive standards.

***ESSENTIAL ELEMENT—THE USE OF NON-POTABLE WATER IN ANY FORM AS PART OF**

OR IN CONTACT WITH DIRECT CONTACT PACKAGING (OR OTHER INAPPROPRIATE USE) SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.

C2. FACILITY CONSTRUCTION, DESIGN AND CONDITION

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

- a. The facility exterior (yards, grounds, parking lots and roads) is maintained free of debris and refuse and is adequately drained.
- b. External storage of waste shall be in designated areas and maintained in both design and frequency of service to minimize pest attraction and harborage.
- c. Building exteriors are designed and maintained to prevent contamination or entry of pests and contaminants (such as, but not limited to, dust and chemicals).
- d. Building structure shall be sound with no holes, unscreened exterior openings, broken windows, etc. that may allow pest entry into the facility. Exterior holes/cracks in walls, pipe, fan and vent openings, windows, etc. shall be filled or screened to prevent entry of pests.
- e. All drain and outside vent openings shall be covered or screened.
- f. The facility roof shall be uncluttered, free draining, and free of standing water, bird or pest harborages.
- g. Procedures and records shall be in place to support building maintenance.

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

- a. There shall be no evidence of potential for cross-contamination, due to facility layout or construction. Facilities shall be designed so that product and raw materials do not come into contact with non-product zones (i.e. floor, walls, etc.).
- b. Objectionable odors, fumes or vapors shall not be present
- c. Adequate environmental conditions shall be provided in all areas to maintain proper sanitary conditions for raw materials, finished product, equipment, and packaging materials. This maintenance of proper conditions includes, but is not limited to, minimizing risk of cross-contamination and condensate build up based on risk. Suitable ventilation shall be provided. All systems shall be clean, properly functioning and designed in such a manner to prevent product contamination.

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

C3. FACILITY CONDITION

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

ALL PACKAGING MANUFACTURING FACILITIES

- a. Materials used to construct walls, floors, overhead structures and ceilings shall be smooth, non-porous, nonabsorbent and easily cleanable.
- b. Walls, ceilings (including suspended ceilings), overhead structures and floors are maintained in good repair.
- c. Floors are sufficiently sloped, as needed, to provide drainage and to prevent the accumulation of liquid.
- d. Floor drains shall have grates that are easily removed for cleaning and inspection.
- e. Doors and windows shall be in suitable condition (see Pest Control section for additional requirements regarding doors and windows).
- f. Windows shall be closed if outside conditions exist that may expose the plant to airborne contamination.

DIRECT CONTACT PACKAGING MANUFACTURING FACILITIES

- a. Drainage is designed to flow away from higher risk areas and to minimize product contamination. Discharge water shall flow directly into drains.
- b. Windows in processing areas shall be shatter proof or properly sealed to prevent glass contamination.
- c. No unprotected glass shall be allowed in close proximity to processing areas.

C4. EMPLOYEE FACILITIES

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

- a. Cafeteria, locker rooms and toilet facilities shall be:
 - Adequate in size for the maximum number of employees,
 - Readily accessible by employees,
 - Physically separated from product production areas
 - Well lit
 - Effectively ventilated
 - Provide adequate storage for personal items as needed
 - Maintained in a clean and sanitary condition.

- b. There shall be a policy in place prohibiting food and product storage anywhere in locker rooms.
- c. Doors to toilet facilities shall be self-closing and shall not open directly into production areas or raw material storage areas.
- d. A procedure for immediately cleaning and re-opening clogged toilet facility drains shall be in place.
- e. A plan shall be available that specifies appropriate sanitation procedures to restore sanitary conditions following repair of overflowed drains or toilets.

5. HAND WASHING FACILITIES

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

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

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

ALL PACKAGING MANUFACTURING

- a. Hand wash stations shall be strategically located and have adequate room to accommodate the number of personnel in the area and prevent delays that may discourage proper hand washing procedures. Hand wash stations shall minimally be in toilet facilities.
- b. The hand washing stations shall deliver water at a suitably warm temperature within a suitable timeframe for comfortable and effective handwashing. There shall be an adequate supply of hand sanitizing soap. Single service towels shall be available and protected with an appropriate dispenser with convenient disposal at each station. Where specific customer requirements or country regulations apply to handwashing, these shall take precedence.
- c. Hand wash sinks shall be properly plumbed to drain lines.

DIRECT CONTACT PACKAGING MANUFACTURING

- a. Handwashing facilities minimally shall be adjacent to entrances to direct contact packaging production areas. Hand washing shall be performed on entry to the production areas and at a frequency as needed to minimize risk of product contamination.
- b. Hand washing stations in or adjacent to processing areas shall be 'hands-free' activated so that hand contact is not required to turn water 'On' or 'Off'.

C6. EQUIPMENT LAYOUT, DESIGN AND CONDITION

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

ALL PACKAGING MANUFACTURING FACILITIES

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

DIRECT CONTACT PACKAGING MANUFACTURING FACILITIES

- a. Equipment, including conveyor belts, shall be of suitable smooth, impervious, non-toxic, nonabsorbent and corrosion-resistant materials and maintained in suitable condition to minimize risk of product contamination.
- b. Product contact surfaces shall be effectively protected from contamination during operations.
- c. Equipment with sides or shields or scrapers or other items that are attached to product contact areas shall have sufficient clearance between the pieces to permit cleaning and prevent product accumulation.
- d. Equipment shall be free of oil leaks and excessive grease build-up on bearings and motor housings where they may contaminate packaging product. Bearings and motors near and above product areas shall have catch pans to protect product below. The pans shall be drained in a sanitary manner. Non-food grade lubricants, oils, greases shall be used only below product contact surface on equipment. Application of any lubricant shall not be able to contaminate the product.
- e. Open rollers that can be effectively cleaned or solid rollers or drums are required.
- f. Appropriate covers/lids shall be provided and used to protect product from contamination.
- g. Equipment shall be designed to preclude or divert condensate away from product and product contact surfaces.

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

C7. UTENSILS, AIDS AND TOOLS

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

- a. Utensils, tools and containers shall be properly identified for their intended use by labels and/or color coding, as well as maintained, cleaned and stored in order to prevent cross contamination of products.

7.2. AIR AND OTHER GASSES USED AS AIDS OR PART OF THE MANUFACTURING PROCESS SHALL BE APPROPRIATELY MANAGED

DIRECT CONTACT PACKAGING MANUFACTURING

- a. Facilities that utilize compressed air and/or other gasses that make direct contact with product contact packaging materials shall develop a program to assure the compressed gaseous material does not introduce any contaminants into the product. The necessary requirements for maintaining sanitary air shall be monitored and documented.

C8. FACILITY LIGHTING

8.1. FACILITY LIGHTING SHALL BE SUITABLE.

ALL PACKAGING MANUFACTURING

- a. Facility lighting shall be adequate and appropriate for sanitation, inspection and processing tasks being performed.

DIRECT CONTACT PACKAGING MANUFACTURING

- a. Light bulbs and fixtures in areas where material is exposed are shielded or protected against breakage (including bulbs in insect light traps).
- b. Light shields shall be maintained in sanitary condition (i.e., in good repair and free of debris and/or moisture buildup inside covers)

C9. MAINTENANCE STANDARDS

9.1. MAINTENANCE PROGRAM AND STANDARDS SHALL BE IN PLACE.

- a. Facility shall have a documented preventive maintenance program that covers all equipment and facilities.
- b. Repairs to facilities and equipment shall be addressed in a timely manner and consistent with good manufacturing practices.
- c. Temporary repairs/modifications shall only be permitted in emergencies and where product contamination is not at risk. All temporary repairs shall have specific timeline allotted and recorded (i.e., the permanent repair shall have a scheduled date when the temporary repair is removed, and the issue fixed).
- d. Repair parts and replacement equipment shall be stored in properly maintained storage areas.
- e. There shall be a procedure to ensure that cleaning and sanitation is done following maintenance as needed. This shall include a reconciliation of all tools and spare parts used during the maintenance work to ensure that the work site has been returned to conditions for safe processing.
- f. Records of all maintenance activity shall be maintained.

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

- a. There shall be a written program in place to ensure that equipment or control devices that impact product safety and quality are accurate on a day-to day basis (verification) and are effectively calibrated.
- b. There shall be a list of items that require calibration with item, serial number, frequency, last calibration, and verifications. Frequency of verification shall be based on risk.
- c. Calibration and verification procedures shall describe the frequency of testing, the testing method and the acceptable range of variation.
- d. Control and monitoring devices essential to the control, monitoring or testing of regulatory parameters, product safety critical limits, pre-requisite program parameters and/or quality parameters shall be calibrated by trained personnel according to a pre-determined schedule and as required by the written program. Key process control devices require routine calibration or certification by a credible authority at least annually.
- e. Appropriate action and investigation shall be taken if devices are found to be inaccurate or out of calibration and shall include a product safety or quality assessment where appropriate. There shall be documentation of corrective actions when an inaccurate or out of calibration measuring device has been used. All product produced since the last acceptable check shall be assessed to determine if it shall be held for further evaluation.
- f. Measuring devices for product safety and quality are traceable to a national standard.

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

D. CLEANING, SANITATION, HOUSEKEEPING, HYGIENE

D1. CLEANING AND SANITATION

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

- a. This schedule shall include:
 - Operational/production areas (floors, walls, drains, overheads).
 - Equipment (including portable and temporary equipment).
 - Warehouse.
 - Storage, including bulk storage tanks.
 - Maintenance areas.
 - Employee facilities (locker rooms, cafeteria, break areas and toilet facilities).
 - Other facility areas including the building, grounds and roof areas.
- b. The scheduled tasks shall be monitored for completion and documented with sign off on a consistent basis.

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

ALL PACKAGING MANUFACTURING

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

DIRECT CONTACT PACKAGING MANUFACTURING

- a. The facility shall have documented, detailed cleaning procedures for individual pieces of direct contact packaging manufacturing equipment that specifies and defines:
 - Specific preparation procedures for the specific chemicals or sanitizers being used (unless purchased as ready-to-use) and, where appropriate, verification testing and documentation.
 - Water temperature requirements for proper cleaning and sanitizing.
- b. Written procedures and schedules for routine cycle cleaning and sanitizing of packaging material production equipment shall be current and available.
- c. If machine operators are responsible for general maintenance and packaging material production equipment cleaning, procedures shall be available describing steps for cleaning and sanitizing and the cleaning shall be documented.
- d. Written procedures shall be available for cleaning and sanitizing packaging material production equipment after maintenance is performed and prior to returning equipment into service.

1.3. THERE SHALL BE A DOCUMENTED PRE-OPERATIONAL INSPECTION

- a. A pre-operational inspection (SSOP monitoring), including both visual and document review, shall occur prior to production activities after routine and spontaneous cleaning operations and after maintenance activities. A pre-operational checklist shall be used to verify that the production area (production equipment, containers, utensils, walls, floors, ceilings, light fixtures, miscellaneous overhead structures, etc.) is clean and sanitary prior to a routine cycle start-up.
- b. Deficiencies shall be documented.
- c. Corrective action procedures are established and documented for incomplete or inadequate sanitation practices. Records of corrective actions completed shall be maintained.

1.4. THERE SHALL BE VERIFICATION OF CLEANING EFFECTIVENESS AS NEEDED BASED ON RISK

DIRECT CONTACT PACKAGING MANUFACTURING

- a. Sanitation effectiveness shall be monitored at least visually prior to production startup. Results shall be documented.
- b. Consideration, based on documented, validated risk assessment, shall be given to the need for microbiological monitoring for indicator organisms and pathogens (e.g., environmental monitoring program).

1.5. OPERATIONAL HOUSEKEEPING SHALL BE EFFECTIVE.

- a. Accumulation of garbage, trash, unused equipment and waste materials inside the facility shall be kept at a minimum and removed in a manner that does not create any product safety risks.
- b. All containers shall be appropriately designated.
- c. Floors, walls, ceilings and overhead structures and equipment in all areas of the facility that impact the integrity of the product shall be cleaned as necessary to provide a hygienic environment ("clean-as-you-go" policy shall be in place).
- d. All equipment, utensils, containers shall be cleaned as necessary during and post operations and stored off the floor as applicable when not in use. This also includes cleaning and sanitizing equipment, which shall be stored properly when not in use.

D2. PERSONAL HYGIENE AND GOOD MANUFACTURING PRACTICE

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

ALL PACKAGING MANUFACTURING

- a. Eating, drinking, spitting, chewing or the use of smoking or similar products shall not be permitted anywhere in the facility except in designated areas. Personal medications shall also not be stored in the facility except in designated, controlled areas.
- b. Employees shall observe personal hygiene practices as outlined in the relevant regulations.
- c. Personal hygiene practices shall include a written dress code for all employees (including new and part-time), visitors, vendors and contractors. Employees shall wear clean clothing and shoes appropriate for the working conditions.

DIRECT CONTACT PACKAGING MANUFACTURING

- a. Personal hygiene practices shall include:
 - Fine mesh net hair restraints for head and facial hair shall be worn by all employees in all production areas and any other areas of the facility where the product is exposed.
 - False fingernails, fingernail polish, jewelry (e.g., rings, exposed body piercings, bracelets), watches, or any accessories with pieces that could potentially become dislodged shall not be worn.
 - No working in product handling/manufacturing areas for employees that have an infectious or communicable illness, or have open sores on hands, face, arms or other exposed skin areas.
 - Employees shall notify management if they are diagnosed with a communicable disease that may be transmitted through product or are experiencing symptoms of diarrhea, vomiting, fever or jaundice.
 - If gloves are worn, they shall be intact, with no holes, and kept clean. Non-disposable gloves shall be washed and sanitized if they become contaminated. Disposable gloves shall be replaced if they become contaminated.
 - Production area employees handling direct contact packaging materials shall wash their hands before starting to work, after each absence from the workstation and any time their hands may have become contaminated (i.e., touching equipment or other items that are unclean).
 - If dedicated uniforms, aprons, lab coats, gloves, or smocks are utilized, the facility shall provide these. Employees shall use a means to avoid contamination of their dedicated outer clothing when using the toilet facilities.
 - Plasters (bandages) shall be available as needed and shall be a contrasting color from the product being produced.

D3. FACILITY SELF INSPECTION

3.1. GMP SELF INSPECTIONS SHALL BE COMPLETED.

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

E. RODENT AND PEST CONTROL MANAGEMENT

E1. PEST CONTROL

1.1. THERE SHALL BE A DOCUMENTED AND SPECIFIC PEST CONTROL PROGRAM

- a. There shall be a current pest management program/manual and policy available for review.
- b. A current Pest Control Operator (PCO) applicator's license and letter of liability insurance shall be on file, along with a Safety Data Sheet (SDS) for all chemicals used. SDS documents shall be maintained for at least one year after the chemical becomes inactive.
- c. As part of the policy, there shall be written procedures to direct the activities conducted by the PCO and trained employees. They shall include:
 - Types of pests being controlled. Specific consideration shall be given to pests indigenous to the area
 - Frequency of monitoring/inspection
 - Method of labeling, inspecting and recording of inspections.
 - The record of service verification tag or bar code label shall be on the inside of the traps, bait stations or other devices
- d. Company employees engaged as PCOs shall have proof of appropriate training and licensing as required by local regulations. Training of company employees can be by the PCO or other qualified experts.
- e. An up-to-date site map of all pest control devices shall be maintained, including dates and signature of person responsible for reviewing the document.

1.2. OUTSIDE PREMISES MANAGEMENT SHALL MINIMIZE OPPORTUNITY FOR PESTS

- a. Outside premises shall be free of conditions (including, but not limited to, stored equipment, litter, waste, standing water, weeds, tall grass) that may provide harborage or attractants for insects, birds, rodents or other pests. There shall be a clean, clear, vegetation free perimeter around exterior of facility.
- b. Garbage/trash disposal areas outside the facility shall be managed so as not to promote pest harborage (e.g., kept in sanitary condition, containers maintained with covers).
- c. Outside bait stations shall be placed around the exterior perimeter of the building at intervals as directed by the Pest Control Company (PCO).
- d. Exterior pest control devices shall be tamper resistant, locked, labeled and secured.

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

- a. There shall be no evidence of pest infestation inside the facility.
- b. There shall be no observation of pests on raw materials, finished product packaging, work in process materials, or finished goods.
- c. Facility shall have documented procedures to follow in the case of an infestation.

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

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

1.4. PEST CONTROL DEVICES SHALL BE PROPERLY MANAGED.

- a. All devices shall be identified and placed to correspond to the map location.
- b. Devices shall be in proper working order.
- c. Exterior pest control devices shall be inspected, and inspection documented at frequency based on risk.
- d. Interior pest control devices shall be inspected, and inspection documented at frequency based on risk.
- e. Insect light traps (ILTs) shall be suitably located and not placed over, adjacent to, or within 8 feet (2.44 meters) of exposed direct contact packaging material. ILTs shall be serviced and bulbs changed as needed.
- f. Labelled mechanical rodent traps shall be placed based on recommendations of the Pest Control Service provider and, at a minimum, on either side of the interior side of exterior opening doors.
- g. There shall be no bait used inside the facility. Only glue boards and pheromone traps shall be used inside the facility as required.

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

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

1.6. PEST CONTROL REPORTS SHALL BE MAINTAINED.

Pest control records shall be available for every pest inspection and:

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

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

F1. APPROVED SUPPLIER PROGRAM

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

- a. The program shall require written criteria for approving suppliers based on risk assessment (based on the risk of the raw materials to the final product). Applicable regulatory requirements shall also be considered as part of the approved supplier program.
- b. The program shall indicate how suppliers are evaluated and/or approved for use and well as continually monitored for compliance. The program shall also include a robust vulnerability assessment that identifies the risks of fraud (i.e., the risk of purchasing fraudulent raw materials) and any resultant processes that are put in place to mitigate those identified risks.
- c. The program shall detail the allowable circumstances to deviate from an approved supplier.
- d. If the raw materials are supplied by a subcontractor, importer, broker or distributor, this same information required of an approved supplier shall be obtained from the original processor of the material (based on the risk of the raw material).

1.2. SUPPLIERS SHALL BE REQUIRED TO PROVIDE RELEVANT DOCUMENTATION TO SUPPORT THEIR STATUS AS AN APPROVED SUPPLIER (AS DETERMINED BY RISK ASSESSMENT).

- a. Suppliers shall provide information to the facility, based on validated risk assessment, that includes:
 - Process capabilities
 - Product description
 - Hazard and risk assessment/HACCP/product safety plan program information
 - Allergen information
 - Third party audit that includes hazard and risk assessment criteria
- b. Approved suppliers shall resubmit information at a frequency based on risk or if changes in their product occur. The date of expiry for the third-party audit shall be taken into consideration. If there is no expiration date on the third-party audit, then it shall be considered to have a one-year validity.
- c. Certificates of analysis (C of A), a testing report, or an inspection record, shall be provided for each batch of raw material received. In the absence of these records, there shall be current continuing letters of guarantee required for all raw materials and packaging.
- d. There shall be specifications for each raw material and packaging material supplied.
- e. If appropriate, raw material testing protocol, standards and documents shall be in place for all raw materials required.
- f. Corrective actions shall be implemented and documented for raw materials not meeting specifications

F2. VEHICLE AND MATERIALS INSPECTION

2.1. THERE SHALL BE A WRITTEN PROCEDURE FOR THE INSPECTION OF ALL TRANSPORT VEHICLES (RECEIVING AND SHIPPING CARRIERS). PROCEDURES SHALL DEFINE WHEN CARRIERS ARE TO BE REJECTED (ACCEPTABLE VERSUS UNACCEPTABLE CONDITIONS).

- a. The incoming and outgoing carrier inspection (including bulk carrier) procedure shall describe acceptable and unacceptable conditions including, but not limited to, being clean and intact, and free of moisture and offensive odors, pests, chemicals, and foreign material (glass, wood, metal etc.). Raw materials shall not be accepted from and product shall not be loaded onto unacceptable carriers.
- b. All receiving and shipping equipment (examples including loading and unloading equipment, hoses and ports, pumps, screens, and filters for bulk deliveries) shall be secure, clean and stored in sanitary manner.
- c. Cleaning procedures shall be in place where required for equipment and carriers (including bulk carriers).
- d. Receiving, unloading, loading, transfer and dispatch procedures for raw materials and finished products shall be present as needed including:
 - Any restrictions on the use of combined loads on the same transport.
 - Requirements for security of products during transport.
 - Requirements for cleaning certificates for tankers.
- e. Pallets shall be clean and free of infestation and debris. Condition of pallets shall be part of a pallet inspection program.
- f. Records of carrier inspection and acceptance or rejection shall be maintained.

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

- a. The procedures shall:
 - Confirm all receipts are from approved suppliers.
 - Verify that delivery requirements have been met and materials are in good condition, free from contamination and damage.
 - Include the inspection of incoming raw materials based on specification compliance, and the recording of results for any testing required at receipt (testing frequencies and accept/reject limits shall be available for confirmation).
 - Include sampling plans for raw materials that are subject to testing at the facility and identification of raw materials that are accepted based on Certificates of Analysis (COA).
 - Include confirmation of receipt of Certificates of Analyses or similar documentation where specified.
 - Include specific damage evaluation procedures with acceptance criteria.

2.3. THERE IS A WRITTEN PROCEDURE FOR APPROVAL FOR USE OF RAW MATERIALS AND PACKAGING

- a. There shall be a defined material release process that shall prevent inadvertent use of materials/ensure that non-conforming materials are not used.

F3. STORAGE AND INVENTORY CONTROL

3.1. RAW MATERIALS (INCLUDING PACKAGING OR FINISHED PRODUCT) AND FINISHED PRODUCT SHALL BE SECURE AND PROTECTED IN STORAGE.

- a. Procedures shall be established to ensure raw materials and supplies are not subjected to sources of contamination.
- b. Warehouse conditions, including any outside storage areas, shall be maintained and controlled in a manner to assure product integrity and security.
- c. Opened product containers shall not be stored in storage areas. Partially used or previously opened raw material containers shall not be stored with finished product and instead shall be stored in a designated separate storage area, properly identified and sealed to prevent contamination.
- d. Receiving, shipping and storage areas shall be clean, orderly and free from accumulated equipment, pallets, debris and damaged or exposed product.
- e. Pallets, racks and shelving shall be maintained clean and in good repair.
- f. Raw materials and finished product shall be stored off the floor based on risk assessment. 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.
- g. Wall perimeters shall be maintained in a clear and clean manner and allow for pest management inspections and sanitation/housekeeping requirements.
- h. Slip-sheets shall be used when double stacking palletized raw materials for packaging materials to protect the material from dirty or damaged pallets.

3.2. INVENTORY CONTROL SHALL BE IN PLACE.

- a. There shall be an inventory management process, either electronic or paper-based, that ensures that raw materials and finished products are used and shipped in rotation.
- b. No expired, obsolete or held materials shall be used.

F4. PRODUCT RELEASE, RETAINED PRODUCT AND RETURNS

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

Retained and Returned (hold) policy and procedure shall include:

- a. A permanent written log of each product or item placed on hold. The hold log shall list the:

- Date,
 - Product,
 - Quantity,
 - Reason for the hold,
 - Results of the evaluation,
 - Disposition,
 - Authorizing person.
- b. A designated area(s) for retained and returned products, product not cleared for shipment, or held for any other purpose, shall be clearly identified and not stored in a location in the warehouse where it may be shipped in error. Damaged product, as well as product returned to the facility, shall be immediately isolated and placed on hold for evaluation by designated personnel.
- c. Clear identification of returned or retained product (hold tags or equivalent, designated and clearly identified area for storage of returned or retained product)
- d. All non-conforming products shall be handled or disposed of (e.g., reject, rework, or put to alternative use) according to the nature of the problem and/or the specific requirements of the customer.
- e. Product destined for destruction shall be adequately secured and disposed of promptly, with records kept for verification.

4.2. PRODUCT CAN BE SHIPPED ONLY WITH PROPER AUTHORIZATION.

- a. There shall be a documented finished product release procedure.
- b. Product shall 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 shall be signed and dated by the person responsible for the release of product.
- c. Only properly packaged product in undamaged containers may be shipped.

G. PROCESS AND PRODUCT EVALUATION

G1. SPECIFICATION AND FORMULATION CONTROL

1.1 THERE SHALL BE WRITTEN SPECIFICATIONS AND OPERATING PROCEDURES TO MANAGE COMPLIANCE TO FORMULATION AND PROCESS PARAMETERS

- a. There shall be documented finished product specifications, developed by the customer and/or facility, that define acceptable product attributes. In addition to specification compliance, there shall be procedures for assuring control of product formulations.
- b. Specifications/formulations for raw materials, work in process and finished products shall be documented and shall accurately identify the materials or finished products and criteria for evaluation.
- c. Records shall be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications, if applicable.
- d. Products with multiple raw materials shall have appropriate formulation controls available to the operators with regular verification of accuracy.
- e. The facility shall have a procedure and documentation to ensure specification changes are properly implemented. Issues, concerns or requests for changes regarding the accuracy, completeness, or frequency of testing shall be addressed with the customer, if applicable, with changes only permitted with written authorization.
- f. Corrective actions shall be implemented and documented for product not meeting specifications.

1.2. RECORDS OF COMPLIANCE TO MANUFACTURING AND PRODUCT SPECIFICATIONS SHALL BE AVAILABLE

- a. Finished product testing protocol, standards and documents shall be in place for all products as required based on risk. Test protocols and frequencies shall be followed as identified in the specification, and record retention requirements shall be defined in the protocol.
- b. Records shall be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications, if applicable.
- c. Process records shall show process parameters such as equipment settings, raw material quantities and the lot identification of raw materials used.
- d. Finished product shall have documentation verifying that the product meets specifications. Specification compliance documentation shall be available for review. If the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply.

1.3. REWORK SHALL BE CONTROLLED

- a. There shall be defined process and procedure for the management and use of out-of-specification product, rework and carryover that shall include clean breaks in any carryover or rework cycle and includes a same-into-same policy.
- b. Rework shall be treated as a raw material, and the facility shall be able to trace rework to its original production lot and to component raw material lots.
- c. Rework shall be handled in accordance with documented procedures. Product awaiting disposition (including product that has been returned by customers) shall be stored in a dedicated place or exhibit an obvious physical indication of its status (see F4.1).

- d. All rework shall be kept to a minimum and used promptly at the first opportunity. There shall be a routine and documented “clean break” in the rework cycle. A documented “same-into-same” policy regarding rework and carryover products shall be in place.

G2. APPLICATION OF PROCESS CONTROL

2.1. THE FACILITY SHALL EMPLOY STATISTICAL PROCESS CONTROL PRINCIPLES TO REDUCE PROCESS VARIATION AND ENSURE PRODUCT IS BEING PRODUCED WITH ESTABLISHED SPECIFICATION PARAMETERS.

- a. A review of the manufacturing process by the facility shall identify process control points where control is necessary to minimize the risk of quality defects and create consistent finished product.
- b. Process limits related to those identified control points shall be attainable on the equipment that is utilized. This can be determined based on a documented, sound process capability study of the equipment or by process monitoring records that demonstrate ongoing achievement of control.
- c. Management of the process limits shall be based on individual data points and not on averaged data.

G3. ALLERGEN AND SENSITIVE MATERIAL MANAGEMENT

3.1. THERE SHALL BE A DOCUMENTED PROGRAM TO CONTROL ALLERGENS AND SENSITIVE MATERIAL CROSS CONTAMINATION.

- a. The site has a documented allergen/sensitive material control program that identifies, controls and manages potential allergen and sensitive material cross contamination risks to the product produced in the facility.

3.2 ALLERGEN AND SENSITIVE MATERIALS IN THE FACILITY SHALL BE CONTROLLED.

- a. Materials containing allergens and sensitive materials shall be clearly identified as such and properly controlled and segregated to prevent cross-contamination.
- b. Any spills involving allergenic or sensitive material shall be promptly cleaned.
- c. Food grade lubricants and chemicals used for maintenance and sanitation (including, but not limited, to hand soap), shall be allergen free.
- d. Personnel, when handling allergen-containing products and sensitive materials (including during breaks from the production area), shall take appropriate measures to minimize the risk of cross contamination.

H. FOREIGN MATERIAL CONTROL

H1. FOREIGN MATERIAL CONTROL

1.1 THERE SHALL BE A PROGRAM TO MANAGE GLASS, CERAMIC, BRITTLE PLASTIC AND SIMILAR MATERIALS

- a. Apart from facilities manufacturing glass, ceramic or brittle plastic packaging, these materials shall not be used in, above or near production or storage areas unless absolutely necessary. Plants manufacturing glass, ceramic or brittle plastic packaging shall be equipped to properly protect the finished product and provide shielding to protect product and raw materials in the event of breakage during production.
- b. Where it is essential to have glass, ceramic, brittle plastic and/or other similar materials in product areas, and there is a risk of contamination as determined by risk assessment, procedures for their management shall be in place.
- c. All essential glass, ceramic, brittle plastic and similar material, other than the product itself (including, but not limited to, cameras, emergency lighting, dial and gauge covers, insect light traps etc.) that pose a contamination risk shall be documented in a register that includes description, location and condition.
- d. Monitoring of the condition of the items identified on the register shall be completed and documented at a specified and documented frequency based on a valid risk assessment.
- e. If breakage does occur, there shall be a documented procedure in place for the clean-up. All breakage incidents shall be recorded.

1.2 THERE SHALL BE A PROGRAM TO MANAGE METAL CONTAMINATION

- a. Sieves, filters and screens that are designed to or that serve to capture or remove foreign objects from a product stream shall be appropriately sized, monitored, and inspected.
- b. When magnets are used for the detection and removal of potential metal contaminants, their effectiveness shall be verified periodically using the methodology and frequency recommended by the manufacturer.
- c. A program shall be in place to minimize foreign material contamination from the outside of bagged raw materials when being added in open mixing units.
- d. There shall be a documented policy for the use of sharp items in the facility, so they do not contribute to potential contamination. Sharp items include, but are not limited to, knives, needles, wires, pins, staples, cutters and other devices. The use of these items shall be controlled, and the items shall be clean, of proper design (snap off blades shall not be used), routinely inspected for damage and their condition recorded.
- e. Where metal detection systems (including X rays) have been determined to be required for safety or quality reasons, they shall be installed and operated properly. There shall be a written procedure describing the maintenance, set-up and verification tests of detector systems and reject devices. This procedure shall be adhered to as written. The procedure shall consider customer expectations, as needed.

1.3 WOOD, WHERE USED, SHALL BE CONTROLLED AND INSPECTED

- a. Wood pallets and items with wood components used in the facility shall be part of a management program at the facility. All wood items shall be dedicated for their defined purpose, clean, maintained in good order, inspected as needed based on risk assessment, and their condition documented.

I. CHEMICAL CONTROL

1.1. CHEMICAL CONTROL

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

- a. All restricted materials and chemicals shall be obtained from approved suppliers, maintained under strict control and stored separately to minimize the potential for accidental product contamination.
- b. The chemical storage area(s) shall be designated, properly vented, provide for adequate spill control and be secured with access restricted to properly authorized personnel.
- c. Safety Data Sheet (SDS), letters of guarantee or similar information shall be readily available for all chemical compounds in the facility.
- d. All personnel handling chemicals shall be trained in chemical control measures and safety.
- e. All chemical containers, whether original or secondary, shall be properly identified with the contents. Empty chemical containers shall be stored and disposed of in a manner that does not compromise product safety.
- f. If it is necessary to maintain pest management chemicals at the facility, they shall be stored in a secured location with limited access.
- g. Food grade lubricants shall be clearly identified and stored separately from non-food grade lubricants.
- h. There shall be a list of all approved chemicals used at the facility.

J. PACKAGING AND LABELING

J1. PACKAGING AND LABELING

1.1. LABELS SHALL BE ACCURATE AND COMPLY WITH ALL REGULATIONS.

- a. The facility shall have a program to assure that labels in use and product being produced are matched. Facilities with variable or optional product specifications shall be able to demonstrate that the proper label is always used.
- b. Labels shall satisfy regulatory requirements for the country of manufacture and/or for the country of sale.
- c. Labels shall satisfy customer expectations as appropriate. Labels shall include an accurate product name and lot identification understood by the customer.
- a. There shall be a documented method of matching the proper unit label with the product or production schedule or formulation. The method chosen shall compare printed label codes and product container codes. Lot codes and labels shall be verified prior to the production of each lot of product.
- d. Procedures shall be documented and implemented to ensure obsolete labels or labels from a prior production run are not used inappropriately (unauthorized or accidental use). The procedures shall detail how labels are controlled so that they are not used out of sequence or co-mingled in storage or at point of use, as well as how obsolete labels are isolated and secured/destroyed. There shall be documented procedures in place to ensure that the production line is clear of all previous work, labels and production documents before running a different product on the same line.

1.2. THE PRODUCT SHALL COMPLY WITH REGULATIONS AND SPECIFICATIONS FOR NET WEIGHT, NET QUANTITY OR PIECE COUNT.

- a. Net weight, volume, or count control checks shall be performed and documented at an appropriate frequency to assure ongoing label declaration compliance in alignment with customer requirements and/or specifications.
- b. Product counters shall be verified per manufacturer instructions or documented data-based performance studies.
- c. Failure of net weight, volume or count verification checks shall result in an investigation of product produced since last acceptable check.
- d. Records shall be available showing status of conformance and verification checks.

1.3. THERE SHALL BE CLEARLY VISIBLE AND LEGIBLE CODES ON INDIVIDUAL AND CASED PRODUCT.

- a. Clear coding shall be in place to ensure proper management of production lots and traceability and shall meet customer specifications.
- b. All product coding and label information shall be of such size, color and contrast to afford easy legibility at a reasonable distance
- c. Lot codes shall be present, legible, and contain accurate information. Codes shall be understood by facility employees and by the customer for whom the product is produced.

- d. Each individual ship unit shall have a production or lot code. If the finished product is contained in cases in the ship unit, the cases shall be coded with the same lot code as the ship unit.

1.4. THE PACKAGING INTEGRITY AND FUNCTION SHALL ADEQUATELY PROTECT THE PRODUCT.

- a. Both the sell unit package and the shipping unit shall be designed and assembled to provide the necessary protection for the product from environmental and shipping conditions.
- b. Plant shall have an effective program to assure that the product cases, if used, are properly closed and sealed. Shipping units shall be properly constructed and secure.
- c. Finished product cases, if used, shall be appropriately sized, intact, and provide adequate protection to the internal product

K. TRAINING REQUIREMENTS

K1. TRAINING

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

- a. Training shall be provided to new hires (operating and management personnel as well as temporary employees) for at minimum the topics below, as appropriate for the individual's oversight and responsibilities. This training shall be completed in a predefined, reasonable amount of time
 - Product safety (including HACCP/product safety plan overview as appropriate).
 - Product defense.
 - Personal hygiene and GMP's (training delivered before starting work).
 - Allergens, as they apply.
 - Plant process and product specific training, as appropriate.
- b. There shall be specific training for identified roles affecting product safety and quality. This shall include:
 - HACCP/product safety plan critical control point monitoring, corrective action and verification responsibilities prior to the individual being assigned sole responsibility for such activities.
 - Sanitation employees (including new sanitation employees, applicable operators, temporary sanitation employees, and contract sanitation employees). Training shall include master Sanitation Schedule, Standard Sanitation Operating Procedures (SSOPs), product sanitation, and sanitation chemical safety.
 - Laboratory staff shall have documented qualifications by way of specific training, certification or other forms of credentialing.
 - Training for new managers, supervisors, and quality technicians shall include the product safety, quality, and defense policies and procedures for which they will have implementation and oversight responsibilities
- c. The training program shall be reviewed, and content updated at least annually to take into consideration new regulatory, media, or customer issues, scientific and technological advances, or new or revised product safety, quality, or product defense programs

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

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

1.3. REFRESHER TRAINING SHALL BE CONDUCTED.

- a. Refresher training on the topics identified in K1.1 shall be provided to all employees and documented at minimum annually, or when changes take place in the facility where refresher training is required.

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

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

1.5. TRAINING RECORDS SHALL BE MAINTAINED.

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

L. LABORATORY SUPPORT

L1. LABORATORY SUPPORT

1.1. ON-SITE LABORATORY FACILITIES SHALL NOT CONTRIBUTE TO POTENTIAL CONTAMINATION.

- a. The laboratory shall be secured and isolated from the production areas.
- b. The laboratory shall be clean, orderly and well lit.
- c. Based on risk assessment of the laboratory activities, control procedures shall be implemented to ensure that the laboratory does not contribute to potential contamination (such as, but not limited to, restricted access to laboratory area and materials used within, appropriate signage, dedicated sinks for cleaning and handwashing, proper decontamination and disposal of waste, appropriate ventilation and plumbing systems). If chemicals are stored in the laboratory, there shall be a documented control program for the use of the chemicals.
- d. The plant laboratory for chemical and physical analytical testing of raw materials, in-process components and finished product shall be adequately equipped and staffed to provide the essential technical support to the plant.

1.2. ON-SITE LABORATORY PROCEDURES AND DOCUMENTATION SHALL MEET RECOGNIZED STANDARDS.

- a. A documented laboratory control and practices program shall be established and include procedures, calibration control, chemical control, access and appropriate records.
- b. Facility shall have documented and detailed procedures for all tests performed.
- c. Testing procedures shall be based on recognized and approved procedures.
- d. Documentation of all testing shall be available, including records of COAs where in-house testing is not performed.
- e. There shall be documented evidence that the on-site laboratory is competent to perform the work being done, and that the results of the laboratory are accurate and reliable.

1.3. LABORATORY EQUIPMENT SHALL BE CALIBRATED.

- a. Facility laboratories shall 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.
- b. Balances and laboratory test equipment shall be calibrated/certified by a demonstrably competent company or individual at a prescribed frequency as defined by the manufacturer.
- c. Records of calibration/certification shall be maintained.
- d. Certification of reference standards, weights, and thermometers shall be available.
- e. There shall be an in-house policy for periodic verification of test equipment at appropriate frequencies based on risk.

1.4. THERE SHALL BE EVIDENCE AVAILABLE THAT THIRD-PARTY LABORATORIES, WHERE USED FOR TESTS AND ANALYSIS OF RAW MATERIALS, PACKAGING MATERIALS OR FINISHED PRODUCT, ARE COMPETENT AND QUALIFIED TO PERFORM THE SPECIFIED WORK.

- a. For facilities that use third-party laboratories for testing, the facility shall be able to show proof of those third-party laboratory qualifications and competency. Acceptable examples include current ISO 17025 certificate, or other proof relevant to the work being performed.
- b. Records of all tests and analyses performed by third-party laboratories shall be available for review.
- c. When a third-party laboratory is used, documented procedures shall be available to properly interpret and manage the information provided.

M. PRODUCT DEFENSE

M1. PRODUCT DEFENSE

1.1. THERE SHALL BE A WRITTEN PROGRAM THAT DESCRIBES ASSIGNED RESPONSIBILITY FOR PRODUCT DEFENSE AND HOW IT IS MAINTAINED.

- a. Management shall develop and implement a comprehensive product defense program with specific emphasis on identifying those policies and procedures necessary for a comprehensive product 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.
- b. A Product Defense team shall be established that will evaluate the vulnerabilities and risks that exist from raw material sourcing, storage, processing, shipping of finished goods, and personnel.
- c. This team shall meet to review and validate the product defense plan at a minimum annually, as well as whenever changes are planned or made and after any incident.

1.2. EACH FACILITY SHALL CONDUCT AND DOCUMENT A DEFENSE RISK EVALUATION TO ELIMINATE OR SIGNIFICANTLY REDUCE THE RISK OF EXTERNAL AND INTERNAL MALICIOUS ACTIONS AND THREATS.

- a. The facility shall have conducted a documented defense evaluation that considers all aspects of the physical facility and the manufacturing process and their vulnerabilities to deliberate acts of contamination. All aspects of facility operations shall be evaluated for vulnerability to tampering and sabotage.
- b. Security inspections shall be conducted to measure effectiveness of the program and ensure buildings and grounds are secure, including outside storage areas.

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

The implemented defense plan shall include control measures that mitigate the identified risks from the defense evaluation, including for:

- a. Protection of off-site warehousing — All off-site warehousing, manufacturing, and distribution locations that are in the facility's control shall be included in the facility's product defense programs, unless it is documented that these locations have an independent product defense program.
- b. Protection of raw material and utility supplies, including any identified risks for incoming shipments.
- c. Protection of process control systems.
- d. Protection of sensitive electronic and computer systems and their data (e.g., formulations, specifications, business information),
- e. Identification and management of unusual occurrences.

1.4. EMPLOYEES SHALL BE SCREENED AND TRAINED IN DEFENSE AWARENESS.
ACCESS TO THE FACILITY SHALL BE CONTROLLED.

- a. An effective system shall be in place to assure that only authorized personnel have access to the facility and that their entrances and exits are monitored and recorded. Access to sensitive areas of the facility, internal and external, shall be restricted and controlled. All external storage tanks and silos shall be effectively secured. At all times, non-traffic doors (e.g. emergency exits), dock doors, railcar unloading areas, unloading pits, pneumatic pipes and hoses used for receiving bulk ingredients shall be secured when not in use.
- b. New and existing employees shall be screened to ensure they are appropriate for employment. Any persons not included in screening program shall be covered by the facility visitor policy. Temporary workers shall be adequately supervised while on site.
- c. Employee training programs are established to address product security issues. This includes:
 - Awareness for possible tampering occurrences in mail, raw materials, in-process materials and finished products.
 - Reporting requirements for unusual occurrences, observed behavior or unrecognized people in the facility.
- d. Visitor and contractor access to the facility shall be controlled. Facility shall have documented visitor policies and procedures. There shall be a visitor sign-in and sign-out log that also verifies visitors have received and understand the facility's GMP, product safety, personal hygiene, and product defense rules.
- e. Employee identification methods shall be used to ensure that only authorized personnel are allowed in the facility or in restricted areas.

DEFINITIONS

ALLERGEN: Product compounds can cause an allergic or product intolerance response in sensitive individuals. Globally, priority allergens requiring labelling vary. International regulatory information regarding allergens can be accessed through the University of Nebraska's Product Allergy Research and Resource Program. As of October 1, 2019, the international regulatory chart for priority allergens is provided below, and can be accessed through the following link...

<https://farrp.unl.edu/IRChart>

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

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

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

LETTER OF GUARANTEE/CONTINUING LETTER OF GUARANTEE: Document provided by supplier indicating that product provided by supplier (including packaging materials, inks, and coatings) comply with all regulatory requirements.

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

GOOD MANUFACTURING PRACTICES (GMPs): Good manufacturing guidelines for practice typically outlined at minimum by regulatory bodies.

HACCP DEFINITIONS (these may also be applied to product safety plans developed based on Codex principles)

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 an identified hazard can be controlled, reduced or eliminated.

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

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 shall 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 product safety hazards reasonably likely to occur.

HACCP Plan – The written document which is based upon the principles of HACCP and which delineates the procedures to be followed. May also be called a product safety plan.

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, physical or other 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 shall be addressed in the HACCP plan.

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

Prerequisite Programs – Required programs that shall be implemented by a facility in order to produce a safe and quality product and support a HACCP program. Examples would be Sanitation Programs, Good Manufacturing Programs, Pest Management Programs, etc.

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

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

Validation – Collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, is effectively controlling the hazards that are reasonably likely to occur.

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

HYGIENE-SENSITIVE PRODUCT: A product that is intended for direct consumption or that comes in direct contact with the body.

POTABLE WATER: Water that is safe for human consumption.

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

PRIMARY PACKAGING: Packaging that comes into direct contact with food or hygiene-sensitive consumer products (also referred to as direct contact packaging).

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

RECYCLED: Material that has been reprocessed from recovered/reclaimed materials, including post-consumer or post-industrial waste and sourced for use as a component in a new packaging product.

REPEAT FINDING: An exact deficiency cited at the most recent NSF International Supplier Assurance audit, which has not been effectively addressed with corrective action.

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

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

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

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

RISK ASSESSMENT: The identification, analysis and conclusions on the levels of risk involved in a process and determination of appropriate controls for the identified risks.

SECONDARY PACKAGING: Packaging that does not come into direct contact with food or hygiene-sensitive consumer products (also referred to as indirect contact packaging; may also be referred to as tertiary packaging).

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.

SHALL: A mandatory requirement of the Standard.

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.

TRACEABILITY: Ability to trace and follow raw materials, in-process materials, and finished products from receipt, through all stages of the production process, and to distribution (forwards and backwards).

TREND: An identified pattern shown through results analysis.