SUPPLIER ASSURANCE

GOOD MANUFACTURING PRACTICES FOR FOOD MANUFACTURING AUDIT STANDARD

PROGRAM REQUIREMENTS MANUAL

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REVISION HISTORY

Version	Date	Author	Description
1.2	August 1, 2019	NSF Supplier Assurance Technical Management	• Abbreviated SAFM audit expectations • Replaces GFTC GMP audit

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1 INTRODUCTION

This Supplier Assurance audit focusses on the important Good Manufacturing Practices (GMP's) that shall be in place in food manufacturing facilities. The expectations outline the performance criteria expected for a modern food manufacturing facility to meet the basic safety and quality requirements. This scope of this audit standard is particular to Good Manufacturing Practices, which are the prerequisites to a robust food safety plan. As such, while there is a question in this standard concerning HACCP/food safety plans, the intent of this audit is not evaluate the full effectiveness of the implementation of HACCP/food safety plans, but instead to focus on the key GMP elements that provide a foundation to the food safety system.

The expectations of this standard are considered essential to producing safe, wholesome and quality products on a consistent basis. Demonstrating consistent conformance with the requirements of this standard is the expectation of customers and consumers alike.

This audit evaluates the adequacy and effectiveness of, and compliance to, procedures and processes in the facility. This evaluation is done through assessment of documents and records, as well as observation and interviews, during the on-site visit.

This standard manual provides criteria and expectations that the facility will be audited against and is generic for all types of food manufacturing establishments. Some specific criteria may not be applicable. It is the responsibility of the facility being audited to justify that a specific criterion is not applicable. If a particular client allows a facility's deviation from an expectation within this standard, the facility shall obtain written approval from said client for the variance prior to the audit. This approval shall be made available to the auditor during the audit process. Variances are in effect for one calendar year from the date of issuance or as specified by associated clients.

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

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

2 DOCUMENTATION

DOCUMENTS REVIEWED DURING THE AUDIT

This list is to provide guidance to the type of documents and procedures the auditor may ask to review during the audit. Documents and records will be reviewed as part of the duration of the audit. There may be additional documents, policies and procedures requested that are not included in this list. Some of these documents may not apply to every type of facility. When policies are stored electronically 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 course of the on-site visit shall be considered as not conforming to this standard.

FACILITIES AND EQUIPMENT

- Verification of Water, Ice & Steam Potability (Certificates)
- Plant floor plan showing water and sewer lines, location of backflow prevention devices, HVAC units and plant traffic flow patterns
- Food contact water / steam boiler additives "suitability for food use"
- Glass control policies regarding area lighting
- Proof that lighting is shatter proof
- Documented preventive maintenance program, equipment design and construction standards
- Tool and maintenance hygiene policy and procedures, equipment release program

SANITATION, HOUSEKEEPING AND HYGIENE

- Master Sanitation Schedule for plant facilities and support areas
- Standard Sanitation Operating Plan (SSOP) and documentation including chemicals and usage
- Procedures for verifying cleaner and sanitizer control
- Pre-Operational Sanitation performance records
- Sanitation monitoring records with corrective actions and preventive measures
- Good Manufacturing Program and Employee Hygiene Policy
- GMP audit records and corrective action plan
- Employee dress code
- GMP self-inspection records

RODENT AND PEST CONTROL MANAGEMENT

- Rodent and Pest Control Policies, Program and Procedures
- Rodent and pest control activity records
- Pesticide chemical control and storage policy including pesticide application and usage
- PCO Applicators' License & liability insurance
- For employee-based PCO, appropriate training and licensing as per local or state regulations.
- PCO service and activity reports, as well as pest device map

RECEIVING, STORAGE, SHIPPING, INVENTORY CONTROL

- Incoming vehicle and material inspection policy and records
- Receiving policies; Inspection and acceptance plans
- Raw materials and ingredient acceptance criteria
- Storage and handling procedures for ingredients and materials including storage temperature records.
- Bulk ingredient system sanitation policies and documentation
- Restricted, sensitive or allergenic ingredient control policy
- Hold / Release records for retained or returned product and details of product disposition
- Finished product release records
- Finished product inspection policy, procedures, monitoring records, release criteria and authority
- Transport vehicle approval policy and documentation
- Inventory control procedures and records
- Policy and procedures for handling returned and retained product
- Product release policies & procedures

PROCESS & PRODUCT EVALUATION

- Policy and procedures for handling of rework and/or carry over product
- Allergen operational controls and records
- Policies and procedures for calibration of measuring devices
- HACCP/food safety plan documents (as available)
- Traceability procedures and records

FOREIGN MATERIAL CONTROL

- Metal detector and / or X-ray policy, verification procedures and records including corrective action logs, rejected material logs
- Filter / sieves / screen logs / change records
- Magnet inspection logs
- Glass & Brittle Plastic registers, inspections and breakage procedures and records
- Blade and wood condition inspection procedures, records and corrective actions

CHEMICAL CONTROL

- Chemical usage policies and approval records, SDS, letters of guarantee, verification of food grade items

PACKAGING AND LABELING

- Label accuracy and control policies
- Net weight/volume / count control policies and documentation
- Product coding policy for unit packaging and shipping cartons
- Labeling security and obsolete label control policy

TRAINING

- Training policies
- Training topics
- Training records

3 TERMS AND DEFICIENCY CLASSIFICATIONS

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

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

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

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 is able to document those immediate corrective actions in the audit report. Any documentation provided to the auditor after the conclusion of the exit meeting will not change scoring. All information required during the course of the audit shall be provided by the conclusion of the closing meeting

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

"Non-conformance" is the assessment made when:

a. The section of the standard being audited does not fully meet the expectations.
b. A section of the standard has only been partially developed, documented (if required) and/or implemented.
c. Improvements are required to meet the expectation**.**

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

a. Deficiencies found in a section of the standard present a high probability of food safety or regulatory failure.
b. Significant improvement is needed to meet the expectations of the standard.
c. An entire section of the standard has not been developed, documented (if required) and/or implemented.
d. A situation is observed where, based on objective evidence, there is significant doubt as to the conformity of product being supplied.
e. There are numerous findings of non-conformance that indicate a significant lack or failure in a section of the audit.

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

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

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

The following are **ESSENTIAL** elements in this audit standard:

A1.1. The plant shall demonstrate that the water, ice and steam supply is potable and that potability is maintained at all times. Potability criteria for microbiological, chemical and physical parameters shall be used	Use of non-potable water as part of or in contact with food, food contact equipment or other inappropriate use shall be assessed as a Critical Non-conformance.
A2.2 Plant construction and layout shall be such that exposed product is adequately separated and protected from any operations that could cause contamination	Any condition in the facility that, on the basis of objective evidence or observation, results in product or raw material contamination and adulteration shall be assessed as a Critical Non-conformance.
A6.1 All food production and packaging equipment shall meet food sanitary design requirements and be installed in such a manner as to permit proper operation and access for cleaning and inspection.	Finding through observation or on the basis of objective evidence that equipment or food contact materials are unsuitable for use with food or that equipment condition is a cause of product contamination shall be assessed as a Critical Non-conformance
A9.2 Equipment or control devices that impact on food safety and/or product compliance to quality and regulatory requirements are effectively calibrated.	Equipment found to be out of calibration leading to potential for illegal or unsafe food shall be assessed as a Critical Non-conformance.
F 1.4 Foreign material detection systems shall be managed.	Metal detectors or X-rays found to be out of calibration and/or not functioning properly with the potential result leading to production of illegal or unsafe food shall be a Critical Non-conformance.
C1.3 There shall be no evidence of infestation	Observation of pests, pest excreta or infestation in direct contact with ingredients, packaging, work in process, or finished goods shall be assessed as a Critical Non-conformance (direct contamination)
E3.5 Allergen cleaning shall be part of allergen management controls.	Evidence of cross-contamination with allergens that will result in a threat to health shall be assessed as Critical Non-conformance.

E3.6 Documents and products shall be properly labeled with allergen identification and labeling	Mislabeled product contain regulated allergens that are not declared on the label shall be assessed as a Critical Non-conformance.
E5.1 There shall be evidence of traceability for all ingredients, rework, carryover, work in process, and food contact packaging materials into finished product. Finished product shipping records shall be available.	The complete lack of a system to trace ingredients and finished product as per regulatory requirements and customer expectations shall be assessed as a Critical Non-conformance.
H1.1 Labels shall be accurate and comply with all regulations.	Evidence of systematic use of incorrect labels that misrepresent the product shall be a Critical Non-conformance.
H1.2 The product shall comply with regulation or specifications for net weight, net quantity or piece count.	Evidence of failure to meet regulatory standards for quantities on product shipped shall be a Critical Non-conformance

4 SCORING GUIDELINES

EXPLANATION OF SECTION SCORINGS:

Section scorings are provided as a tool to show the performance of the facility in each section and are calculated using the following formula:

- **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 audit score and final audit rating are based on the total number and severity 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, so as to drive continuous improvements in food safety. NSF also offers an unscored version of the Good Manufacturing Practices 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), one major non-conformance in Section D (75% Section Score) and 2 non-conformances in Section E (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 recommended for all audits that improvements and corrective actions for any finding noted be implemented and documented. It is important to evaluate and review the findings of the audit 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.

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 Good Manufacturing Practices for Food Manufacturing audit will be documented by the auditor in the report. A repeat non-conformance finding may cause an additional downgrade of the applicable question's rating, depending on nature of the deficiency and its impact on food safety at the facility. In addition, any repeat non-conformances without effective correction actions taken shall be reflected as a non-conformance against management commitment (E5.1).

5 EXPECTATIONS OF THIS STANDARD

The following expectation are provided as minimum requirements for food manufacturing facilities. They are general in nature and may not be appropriate for all operations, but the intent of the requirements, as stated, shall be achieved.

A. FACILITIES AND EQUIPMENT

A1. WATER, STEAM AND ICE

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

a. There must be an adequate supply of water for processing and sanitation. Ice produced in the facility from the facility's own water supply shall follow the potability requirements as per this section (1.1) subparts b-d.
b. Potability testing of municipal water supplies shall be conducted by a certified laboratory at minimum annually. Potability certificates available from municipal water suppliers are acceptable. If the facility is using water from a private well, there shall be a credible potability test at minimum every 3 months.
c. Plants operating their own water systems shall be able to demonstrate, through credible testing at minimum every 3 months, that plant water meets applicable regulatory standards for drinking water.
d. Potability shall meet local regulatory requirements at a minimum.
e. Steam used for product manufacture and that touches product contact surfaces, including food contact packaging materials, shall be potable. Documentation shall be made available that indicates all boiler water additives are approved for use with food.
f. Water treatment program shall be documented along with training or qualification of personnel involved in the process.

- All chemicals used shall have food grade approval and be documented as such.
- Treatment records shall include testing results, amounts used and when used.
- Water treatment shall be verified by 3rd party vendors.

g. Purchased ice (manufactured ice brought into the facility from an outside vendor) shall have annual certificates of potability or documented satisfactory microbiological testing results.
h. Potable water distribution systems shall be segregated or adequately protected from cross contamination.
    - There shall be no cross connections between potable and non-potable water supplies.
    - All hoses, taps or other similar sources of possible contamination shall be designed with properly maintained back flow preventers.
    - Water filters shall be kept effective as per the manufacturers' recommendations and maintained in a sanitary manner.

- Volume, temperature and pressure of water shall be adequate to meet operational and sanitation needs.
- Water storage, if necessary, shall be in adequately designed, maintained and identified storage facilities.
- Recirculated water shall be treated, monitored and maintained for its intended use. It shall be clearly identified.

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

A2. PLANT CONSTRUCTION AND DESIGN

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

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

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

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

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

A3. PLANT CONDITION (STATE OF REPAIR, CLEANABILITY)

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

a. Materials used to construct walls, floors, overhead structures and ceilings shall be smooth, non-porous, nonabsorbent and easily cleanable. Joints or cracks in walls, floors and ceilings shall be properly sealed.
b. Walls, ceilings, overhead structures and floors are maintained in good repair.
c. Floors are sufficiently sloped, as needed, to provide drainage and to prevent the accumulation of liquid.
d. Drainage is designed away from higher risk areas and to minimize product contamination.
e. Wet processing and wash areas shall have floor drains with grates that are easily removed for cleaning and inspection.
f. Windows in processing areas shall be shatter proof or properly sealed to prevent glass contamination.
g. No unprotected glass shall be allowed in close proximity to processing or storage areas.
h. Doors and windows shall be in suitable condition (see Pest Control section for additional requirements regarding doors and windows).
i. Facilities used to clean equipment, such as wash bays and sinks, are constructed of appropriate material, are identified with signage and provided with supplies and potable water at correct temperatures. They are adequately separated from storage, processing and packaging areas. Tiled and coved areas and stainless steel sinks are required.

A4. EMPLOYEE FACILITIES

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

a. Cafeteria, locker rooms and toilet facilities shall be:

- Adequate in size for the maximum number of employees,
- Readily accessible by employees,
- Physically separated from food production areas
- Maintained in a clean and orderly fashion.

A5. HAND WASHING FACILITIES

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

a. Signs shall instruct employees to wash their hands prior to returning to work. Signs shall be located at

- Locker room and toilet facility exits
- Entrances to food handling and food processing 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.

NOTE: Washing hands prior to exiting the locker room and toilet facilities does not substitute for washing hands just prior to or immediately upon entrance to food handling and food processing areas

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

a. Hand wash stations shall be strategically located and have adequate room to accommodate the number of personnel in the area and prevent delays that may discourage proper hand washing procedures
b. 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'.
c. The hand washing stations shall deliver water at a suitably warm temperature within 30 seconds. There shall be an adequate supply of hand sanitizing soap. Single service towels shall be available and protected with an appropriate dispenser with convenient disposal at each station. Where specific customer requirements or country regulations apply to hand-washing, these shall take precedence.

A6. EQUIPMENT LAYOUT, DESIGN AND CONDITION

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

a. All equipment is in good repair and does not pose a product contamination issue. No spot welding, flaking paint, excess lubrication, oil drips shall be evident.
b. Equipment in direct contact with food shall be of smooth, impervious, non-toxic, nonabsorbent and corrosion-resistant material. Seams on food contact surfaces shall be smoothly bonded.
c. Wood, where it is used due to process requirements (e.g., maturation of products in wooden containers) shall be continuously monitored to ensure it is free of damage or splinters and remains in overall good condition.

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

A7. UTENSILS

7.1. UTENSILS, TOOLS AND CONTAINERS USED TO HANDLE EDIBLE MATERIAL ARE NOT USED TO HANDLE INEDIBLE MATERIAL. 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.
b. Utensils, tools and containers used to handle edible material shall not be used to handle inedible material and are clearly identified and maintained.
c. Utensils, tools and containers shall be maintained, cleaned and stored in order to prevent cross contamination of products. An example of proper storage includes, but is not limited to, making provision for appropriate drying of utensils, tools and containers, as needed.
d. Single use containers used for microbiologically sensitive or allergenic products shall not be reused.

7.2. AIR AND OTHER GASSES USED AS AIDS OR PART OF THE PROCESS SHALL BE APPROPRIATELY SOURCED, TREATED AND FILTERS MAINTAINED

a. Air and other gasses used as a processing technique is appropriately sourced, treated and filters maintained.
b. Fans shall be on sanitation schedules and compressed air lubricants shall be food grade.

A8. PLANT LIGHTING

8.1. PLANT LIGHTING SHALL BE SUITABLE.

a. Plant lighting shall be adequate and appropriate for sanitation, inspection and processing tasks being performed. Where required by local regulatory and industry requirements, plant light levels shall be tested to confirm adequacy at least annually or when changes are made.
b. Light bulbs and fixtures in areas where food products and packaging material are exposed are shielded or protected against breakage.

A9. MAINTENANCE STANDARDS

9.1. MAINTENANCE PROGRAM AND STANDARDS SHALL BE IN PLACE.

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

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

a. Equipment or control devices requiring calibration could include, but are not limited to, temperature controllers and thermometers, flow meters, pressure regulators, divert devices, CIP instrumentation, scales, and speed controllers. There shall be a program to verify and record the performance of measuring devices to assure accuracy according to a pre-determined schedule by trained personnel.
b. Appropriate action and investigation shall be taken if devices are found to be out of calibration and shall include a food safety or quality assessment where appropriate.
c. Measuring devices for food safety and quality are traceable to a national standard.

NOTE: Calibration of metal detectors specifically is assessed under F1.4

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

B. CLEANING, SANITATION, HOUSEKEEPING, AND HYGIENE

B1. 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 areas (floors, walls, drains, ceilings and overheads),
- Equipment (including portable and temporary equipment)
- Warehouse,
- Storage,
- Maintenance,
- Employee facilities (locker rooms, cafeteria, break areas and toilet facilities),
- Other plant areas including the building, grounds and roof areas.

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

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

a. The plant shall have documented cleaning procedures for:
- Operational areas
- Individual pieces of food processing equipment
- Facility areas and structures.

1.3. THERE SHALL BE DOCUMENTED PRE-OPERATIONAL INSPECTIONS

a. A pre-operational inspection, including visual assessment, record completion/document review, and testing of surfaces as needed, shall occur prior to production activities and after the completion of the following activities:
- Production line clean-ups,
- Allergen clean-ups or changeovers,
- Maintenance activities due to breakdowns or preventative maintenance after planned sanitation activities.

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

1.4. OPERATIONAL HOUSEKEEPING SHALL BE EFFECTIVE.

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

B2. 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.

a. Employees shall observe personal hygiene practices as outlined in the relevant regulations.
b. Personal hygiene practices shall include:
    - A written dress code for all employees (including new and part-time), visitors, vendors and contractors. Employees shall wear clean clothing and shoes appropriate for the working conditions.
    - The use of fine mesh net hair restraints for head and facial hair in production, processing and warehouse areas by all employees.
    - No false fingernails, fingernail polish, jewelry (rings, exposed body piercings, bracelets), or watches.
    - No working in food handling/processing areas for employees that have an infectious or communicable illness, or have open sores on hands, face, arms or other exposed skin areas.
    - Employees shall notify management if they are diagnosed with a communicable disease that may be transmitted through food or are experiencing symptoms of diarrhea, vomiting, fever or jaundice.
    - Production area employees shall wash and sanitize their hands before starting to work, after each absence from the work station and any time their hands may have become contaminated.
    - 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.
    - If dedicated uniforms, aprons, lab coats, gloves, or smocks are utilized, the plant shall provide these. Employees shall use a means to avoid contamination of their dedicated outer clothing when using the toilet facilities. For example, coat hooks or other means can be made available for employees to store their outer protective garments before entering toilet facilities.
    - Eating, drinking, spitting, chewing or using tobacco products, including e-cigarettes or similar, shall only be permitted in designated areas.
    - Pens, combs, pencils, thermometers, tools and similar loose objects shall not be carried above the waist at any time while in food handling/processing areas.
    - Plasters (bandages) shall be available and shall be a contrasting color from the product being produced. In facilities that utilize metal detection, plasters (bandages) shall be metal detectable.
    - Personal hygiene monitoring records shall be maintained.

B3. SELF INSPECTION

3.1. GMP SELF INSPECTIONS SHALL BE COMPLETED.

a. There shall be routine facility inspections (can be completed by a cross functional team or by a designated individual at the facility) performed to assure management that GMP policies have been
   - Effectively implemented
   - Facilities and equipment are maintained to meet sanitary and operational needs.

b. Inspections shall be documented to show non-conformances identified and corrective actions taken.

C. RODENT AND PEST CONTROL MANAGEMENT

C1. PEST CONTROL

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

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

1.2. OUTSIDE PREMISES MANAGEMENT SHALL MINIMIZE OPPORTUNITY FOR PESTS

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

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

a. There shall be no evidence of pest infestation inside the facility.
b. There shall be no observation of pests on ingredients, packaging, work in process, or finished goods.

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

***ESSENTIAL ELEMENT--OBSERVATION OF PESTS, PEST EXCRETA OR INFESTATION IN DIRECT CONTACT WITH INGREDIENTS, PACKAGING, WORK IN PROCESS, OR FINISHED GOODS SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE (DIRECT CONTAMINATION)**

1.4. PEST CONTROL DEVICES SHALL BE PROPERLY MANAGED.

a. All devices shall be identified and placed to correspond to the map location.
b. Devices shall be in proper working order.
c. Exterior pest control devices shall be inspected and documented at minimum once/month in winter and twice per month in summer months.
d. Insect light traps shall be suitably located and not located over, adjacent to or within 8 feet (2.44 meters) of product, packaging or processing equipment.
e. Labelled mechanical rodent traps shall be placed based on recommendations of the Pest Control Service provider and, at a minimum, inside and on either side of doors that exit to the exterior, including all dock doors with wall signage indicating location.
f. Interior pest devices shall be inspected weekly. If less frequently, a documented risk assessment with supporting current trend data is required. Inspections can be carried out by trained company personnel in addition to scheduled visits by a service provider.
g. There shall be no bait used inside the facility other than pheromone traps where required.

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

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

1.6. PEST CONTROL REPORTS SHALL BE MAINTAINED.

Pest Control records shall:

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

D. RECEIVING, STORAGE, SHIPPING AND INVENTORY CONTROL

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

D1. VEHICLE AND MATERIALS INSPECTION

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

a. The carrier inspection (including bulk carriers) procedure shall describe acceptable and unacceptable conditions including, but not limited to, clean and intact, free of moisture and offensive odors, pests, chemicals, and glass.
b. All receiving and shipping equipment (including loading and unloading equipment, hoses and ports, pumps, screens, and filters for bulk deliveries) shall be secure, clean and stored in sanitary manner.
c. Bulk tankers shall have documented cleaning and sanitizing programs.
d. Receiving and transfer procedures for bulk ingredients or products shall include:

   - inspection and use of seals,
   - connection ports capped and locked when not in use,
   - hoses clean, capped and stored off the ground.

e. Cleaning procedures shall be in place where required for equipment and carriers.
f. Finished product requiring temperature control shall be shipped in vehicles capable of ensuring proper temperatures through all phases of transportation.
g. The temperature setting and operation of all outbound refrigerated trailers shall be verified.
h. Vehicles shall be pre-cooled prior to loading and shipping of finished product.
i. Records of carrier inspection and acceptance or rejection shall be maintained.

1.2. THERE SHALL BE A WRITTEN PROCEDURE FOR THE INSPECTION AND RECEIPT OF INGREDIENTS, RAW MATERIALS, AND PACKAGING

a. The procedures shall:
   - Confirm all receipts are from approved suppliers.
   - Verify that delivery requirements have been met and materials are in good condition, free from contamination and damage.
   - Include the recording of results for any testing required at receipt.
   - Include temperature verification at receipt and confirmation of receipt of Certificates of Analyses or similar documentation as needed.
b. Records of carrier inspection and acceptance or rejection shall be maintained.
c. Receiving areas for ingredients, chemical and supplies shall be adequately separated from processing areas such that product contamination is prevented.

1.3. THERE IS A WRITTEN PROCEDURE FOR APPROVAL FOR USE OF RAW MATERIALS, INGREDIENTS AND PACKAGING

a. There shall be a defined material release process that shall prevent use of ingredients before approval and ensure that non-conforming materials are not used.

D2. STORAGE, TEMPERATURE AND INVENTORY CONTROL

2.1. RAW MATERIALS, INGREDIENTS, PACKAGING AND FINISHED PRODUCT SHALL BE SECURE AND PROTECTED IN STORAGE.

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

2.2. STORAGE TEMPERATURES SHALL BE CONTROLLED AND MONITORED.

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

2.3. INVENTORY CONTROL SHALL BE IN PLACE.

a. There shall be an inventory management process that ensures that goods are used in rotation.
b. There shall be an inventory management process that ensures that finished product is shipped in rotation.
c. No expired or obsolete materials shall be used.

D3. PRODUCT RELEASE, RETAINED PRODUCT AND RETURNS

3.1. 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.
c. Clear identification of returned or retained product.

3.2. PRODUCT CAN BE SHIPPED ONLY WITH PROPER AUTHORIZATION.

a. There shall be a documented finished product release procedure.
b. Product shall not be released until all procedures and records are completed as required.

E. MANAGEMENT OF PROCESS

The plant shall have written policies and procedures in place to effectively manage the controls required to assure that the manufacturing process operates under control. Operating records shall be available to verify conformance to these policies.

E1. REWORK

1.1. 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.

E2. ALLERGEN MANAGEMENT PROGRAM

2.1. THERE SHALL BE A DOCUMENTED PROGRAM TO CONTROL ALLERGENS.

a. The site has a list of allergens in the facility and a documented allergen control program.
b. The program shall ensure compliance with allergen regulations of the country where the product is to be sold and consumed.

2.2. ALLERGEN INGREDIENTS SHALL BE CONTROLLED.

a. Ingredients containing allergens shall be clearly identified as such and properly controlled, segregated in receiving, storage, production or batching areas to prevent cross-contamination.
b. Use of allergen-containing rework or carryover shall be controlled so only same-into-same is used.
c. All ingredients in use, work-in-process (WIP) and rework and carryover shall be properly labeled with identification, date, lot number, allergen information so as to prevent accidental substitution, ensure traceability and prevent allergen cross-contact.

2.3. CONTROLS SHALL BE USED TO PREVENT ALLERGEN CROSS-CONTACT.

a. Production scheduling shall be used to minimize opportunities for allergen cross-contact.
b. Utensils used for allergens shall be dedicated or be thoroughly cleaned between uses.
c. Food grade lubricants and chemicals used for sanitation, including, but not limited to, hand soaps, shall be allergen free.

2.4. PERSONNEL SHALL NOT BE A SOURCE OF CROSS-CONTACT.

a. Personnel, when handling different allergen-containing products, shall take appropriate measures such as changing outer garments (e.g., coats, hair nets, gloves, sleeve guards).

2.5. **ESSENTIAL** ALLERGEN CLEANING SHALL BE PART OF ALLERGEN MANAGEMENT CONTROLS.

a. Cleaning procedures to remove allergenic residues from equipment and utensils shall be validated as effective. This validation shall be done utilizing (where available) objective and specific allergen-protein test methods.
b. Verification that allergen cleaning followed the validated process shall be documented.
c. Allergen spills shall be promptly cleaned.

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

2.6. **ESSENTIAL** DOCUMENTS AND PRODUCTS SHALL BE PROPERLY LABELED WITH ALLERGEN IDENTIFICATION AND LABELING.

a. Production documents, batch sheets, and formulas shall clearly identify the presence of allergens.
b. Labeling for allergen containing products shall meet legal and customer requirements.
c. Packaging and labeling operations shall have a documented line clearance procedure to ensure labels and products are removed from the line and labeling equipment during product changeovers.

***ESSENTIAL ELEMENT--MISLABELED PRODUCT THAT CONTAIN REGULATED ALLERGENS NOT DECLARED ON THE LABEL SHALL BE ASSESSED AS A CRITICAL NON-CONFORMANCE.**

E3. HACCP

3.1. A DOCUMENTED HACCP/FOOD SAFETY PLAN HAS BEEN DEVELOPED THAT FOLLOWS THE SEVEN PRINCIPLES OF HACCP AND/OR IS STRUCTURED IN COMPLIANCE WITH SPECIFIC REGULATORY REQUIREMENTS (I.E., FSMA).

a. The facility has a food safety management system in place that includes the following:

- An identified HACCP/food safety team
- A written HACCP/food safety plan that is verified and validated
- A process flow diagram for each plan
- A hazard analysis
- A decision making criteria to determine how the identified hazards are controlled
- A validation of any critical limits determined
- Monitoring for CCP's/PC's and defined corrective actions for deviations
- Appropriate documentation and recording keeping for the food safety management system

***The lack of a documented HACCP plan shall not cause the failure of this audit. The scope of this audit is not intended as a full assessment of HACCP/food safety plans. At most, if deficiencies are found during this audit regarding the facility's development of HACCP, this element shall be assigned a rating of nonconformance only (not Major or Critical). That said, for facilities that are successful in the implementation of robust Good Manufacturing Practices, the development of a HACCP/food safety plan system is recommended as the next step towards a stronger food safety management system overall.**

E4. TRACEABILITY

4.1 **ESSENTIAL** THERE SHALL BE EVIDENCE OF TRACEABILITY FOR ALL INGREDIENTS, REWORK, CARRYOVER, WORK IN PROCESS, AND FOOD CONTACT PACKAGING MATERIALS INTO FINISHED PRODUCT. FINISHED PRODUCT SHIPPING RECORDS SHALL BE AVAILABLE.

a. Materials shall be traceable including:

- Ingredients,
- Rework,
- Carryover,
- Work in process,
- Food contact packaging materials

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

E5. MANAGEMENT COMMITMENT

5.1 THERE SHALL BE MANAGEMENT COMMITMENT AND ACTIVE SUPPORT OF THE GOOD MANUFACTURING PRACTICES SYSTEMS AT THE FACILITY.

a. Adequate financial and staffing resources shall be provided 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 outside and internal audits and inspections, as well as from customer complaint investigations.

F. FOREIGN MATERIAL CONTROL

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

F1. FOREIGN MATERIAL CONTROL

1.1. OPEN PRODUCT SHALL BE PROTECTED

a. All processing vessels, ingredients in use and work-in-process (WIP) shall be adequately covered and or protected to reduce the risk of contamination by foreign material.
b. Plants packing product in glass containers shall provide shielding to protect product and ingredients in the event of glass breakage during production.

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

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

1.3. SIEVES, FILTERS, SCREENS AND MAGNETS SHALL BE USED WHERE APPROPRIATE AND PROPERLY MANAGED AND MAINTAINED.

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.

1.4. **ESSENTIAL** FOREIGN MATERIAL DETECTION SYSTEMS (METAL DETECTORS AND/OR X RAY DEVICES), WHERE THEY ARE USED DUE TO RISK AND TYPE OF PROCESSES, SHALL BE MANAGED (CALIBRATED, MAINTAINED AND CHECKED APPROPRIATELY).

a. There shall be a written procedure describing the maintenance, set-up and verification tests of detector systems and reject devices.
b. Metal detection verification shall include ferrous, non-ferrous and stainless steel test pieces.
c. X-ray verification test piece selection shall be based on risk assessment for the product and process. Test pieces could include glass, hard plastics, wood, stones and metal.
d. The system shall be verified at minimum at the start of production, at breaks, at the end of production and at any additional frequency determined by the customer or determined by risk assessment.
e. There shall be a deviation and corrective action procedure for failure of the metal detector or X-ray to detect and reject test pieces.
f. Rejected product shall be logged and investigated for the presence of foreign material.

ESSENTIAL ELEMENT—METAL DETECTORS OR X-RAYS FOUND TO BE OUT OF CALIBRATION AND/OR NOT FUNCTIONING PROPERLY WITH THE POTENTIAL RESULT LEADING TO PRODUCTION OF ILLEGAL OR UNSAFE FOOD SHALL BE A CRITICAL NON-CONFORMANCE.

NOTE: Having a metal detector is considered a good industry practice for the detection of foreign metal contaminants. However, metal detection systems (metal detectors and X-ray devices) may not be required or possible, depending on the product and process being evaluated. For certain industries, including, but not limited to, shell eggs, fluid processing, some whole muscle meat processors, the use of a metal detector or X-ray device is not common industry standard. However, all facilities must have assessed the foreign material contamination risk to their products and processes and employed suitable measures to control that contamination. If there is no metal detector or X-ray device utilized, the auditor must assess and document the facility's program that supports the detection of foreign material contamination.

1.5. BLADES, WHERE USED, SHALL BE CONTROLLED AND INSPECTED

a. Knives, blades, cutters, dicers, saws, and other devices are controlled, clean, of proper design and routinely inspected for damage and their condition recorded.

1.6 WOOD, WHERE USED FOR NON-FOOD CONTACT PURPOSES, SHALL BE CONTROLLED AND INSPECTED

a. Wooden pallets and other wooden components used in the facility for non-food contact purposes shall be dedicated for that purpose, clean, maintained in good order, inspected as needed based on risk assessment, and the condition of the wood documented.

NOTE: Wood used for food contact surfaces is considered under C6.1

G. CHEMICAL CONTROL

G1. CHEMICAL CONTROL

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

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

1.2. LUBRICANTS SHALL BE PROPERLY STORED AND IDENTIFIED.

a. Food grade lubricants shall be stored separately from non-food grade lubricants. Nonfood grade lubricants shall be clearly identified as not for use in food contact areas.

H. PACKAGING AND LABELING

H1. PACKAGING AND LABELING

1.1. **ESSENTIAL** 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 and do not lead to mislabeling or product adulteration.
b. Labels shall satisfy regulatory requirements for the country of manufacture and/or for the country of sale.
c. Procedures shall be documented and implemented to ensure obsolete labels or labels from a prior production run are removed before running another product on the same line.

***ESSENTIAL ELEMENT--EVIDENCE OF SYSTEMATIC USE OF INCORRECT LABELS OR LABELS THAT MISREPRESENT THE PRODUCT SHALL BE A CRITICAL NON-CONFORMANCE.**

1.2. **ESSENTIAL** THE PRODUCT SHALL COMPLY WITH REGULATION OR 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.

***ESSENTIAL ELEMENT--EVIDENCE OF FAILURE TO MEET REGULATORY QUANTITIES ON PRODUCT SHIPPED SHALL BE A CRITICAL NONCONFORMANCE.**

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

a. Each individual sell unit shall have a production or lot code. Packages within the sell unit shall have a lot code, except for single use consumer units such as condiments.
b. Lot codes shall be present, legible, and contain accurate information.
c. Lot codes and labels shall be verified prior to the production of each lot of product.

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.

I. TRAINING REQUIREMENTS

I1. TRAINING

1.1 ALL EMPLOYEES (INCLUDING TEMPORARY EMPLOYEES) SHALL BE TRAINED IN APPROPRIATE POLICIES AND PROCEDURES.

a. Training shall be provided to both operating and management personnel for these topics at minimum:

- Food safety, including safe food handling
- Food defense
- Food fraud
- Personal hygiene and GMP's (before starting work)
- Allergens
- Specialized technical training as required per employee's position (critical food safety roles, sanitation, maintenance)

b. Training shall be provided at initial hire, and then at appropriate intervals (at least annually and if there are changes in processes and procedures at the facility).

6 DEFINITIONS

ALLERGEN: Food compounds can cause an allergic or food intolerance response in sensitive individuals. Food allergens elicit serious adverse reactions in some individuals. Allergic individuals can tolerate very little of the offending food.

In the United States, allergens of concern include:

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

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

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

a. Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

b. A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

c. Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

d. A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).''.

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

In Canada, allergens of concern include:

- Peanut or its derivatives, e.g., Peanut - pieces, protein, oil, butter, flour, and Mancelona nuts (an almond flavored peanut product). Peanut may also be known as ground nut.
- Tree Nuts (almonds, Brazil nuts, cashews, hazelnuts (filberts), macadamia nuts, pecans, pine nuts (pinyon, piñon), pistachios and walnuts or their derivatives, e.g., nut butters and oils.
- Sesame or its derivatives, e.g., paste and oil.
- Milk or its derivatives, e.g., milk caseinate, whey and yogurt powder.

- Eggs or its derivatives, e.g., frozen yolk, egg white powder and egg protein isolates.
- Fish or its derivatives, e.g., fish protein and extracts.
- Crustacean shellfish (including crab, crayfish, lobster, prawn and shrimp)
- Mollusks (including snails, clams, mussels, oysters, cockle and scallops) or their derivative, e.g., extracts.
- Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates.
- Wheat and triticale or its derivatives, e.g., flour, starches and grains.
- Sulphites, e.g., sulphur dioxide and sodium metabisulphites.
- Mustard

Additional international regulatory information regarding allergens can be accessed through the University of Nebraska's Food Allergy Research and Resource Program. As of September 21 2017, the international regulatory chart for priority allergens is provided below, and can be accessed through the following link…

https://farrp.unl.edu/IRChart

International Allergens	USA	Canada	EU	Australia/New Zealand	Hong Kong	China	Japan*	Korea	Argentina	Bolivia	Chile	Colombia	Costa Rica	Cuba	Mexico	Nicaragua	Venezuela
Crustacean Shellfish	X	X	X	X	X	X	X (Crab, Shrimp, Prawn)	X (Crab, Shrimp, Prawn)	X	X	X	X	X	X	X	X	X
Egg	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Fish	X	X	X	X	X	X		X (Mackerel)	X	X	X	X	X	X	X	X	X
Milk	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Peanut	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Soy	X	X	X	X	X	X		X	X	X	X	X	X	X	X	X	X
Tree nuts	X	X	X	X	X	X			X	X	X	X	X	X	X	X	X
Wheat	X	X	X	X		X	X	X		X		X	X	X		X	X
Cereals with Gluten		X	X	X	X				X	X	X	X	X	X	X	X	X
Buckwheat							X	X									
Celery			X														
Lupin			X														
Molluscan Shellfish		X	X	X													
Mustard		X	X														
Sesame		X	X	X													
Sulfites	≥10 mg/kg	Directly added or ≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg				≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg	≥10 mg/kg
Bee Pollens/Propolis				X													
Royal Jelly				X													
Peach								X									
Pork								X									
Tomato								X									

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

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

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

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

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

GMP SELF-INSPECTION: Audits conducted of the company by the company or for the company that assess the company's compliance to GMPs (Good Manufacturing Practices).

SHALL: A mandatory requirement of the standard.

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.

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

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

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

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

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

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