Food Safety, Quality and Security

Expectations and Criteria for Food Processing Facilities

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NSF-Cook & Thurber audits are unique inasmuch as they focus on the development, implementation and control of systems that impact the Safety, Quality and Security of the product.

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

Specifically, this audit evaluates:

- Compliance to Regulatory Standards.
- Adherence to client specifications.
- Adherence to client policies and procedures.
- The ability to successfully execute a product recall.

The following manual provides criteria and expectations that the facility will be audited against. This manual is generic for all types of food processing establishments. Some specific criteria may not be applicable. It is the responsibility of the manufacturer to justify that a specific criteria is not applicable. Likewise, some criteria may be added based on changing regulatory requirements, specific client needs or the ever-changing food safety & food security environment.

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

The stated criteria and expectations are based on:

- Customer specifications and requirements
- Food, Drug and Cosmetic Act (21 CFR) and appropriate amendments
- Food Code, 2001 edition (FDA/USPHS) and appropriate supplements
- Federal Meat Inspection Act (9 CFR) and amendments
- Poultry Products Inspection Act (9 CFR) and amendments
- Egg and Egg Products Inspection Act (EPIA) and amendments

Links to these documents and other reference sources are available at our web site:

www.cookandthurber.com

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DEFICIENCY CLASSIFICATION GUIDE AND SCORING GUIDELINES

"Acceptable" scoring for each category is based on meeting all of the applicable listed expectations and criteria, which are based on best industry practices.

Any "Minor", "Major' or "Critical" assessment automatically drops the Category score to that level.

"Excellent" evaluations are reserved for those practices considered exceptional. If the program and activities are extremely well managed, extraordinarily documented and are considered to be well above the best industry practices, then they can be judged as "Excellent". If the practices are found to be innovative and truly among leading industry practices, they may be given a score up to 100. That means that the practices and controls exceed audit expectations.

To obtain a rating of "Acceptable", all of the best industry practices must be met at least at a minimal level. This would result in a score of 90-95. This includes performance that is judged to be "Acceptable" but may have comments that would improve the level of control and provide greater assurance of consistent performance. An acceptable rating means that the facility practices and controls meet audit expectations.

Within a category, if subcategory assessments are at least "Acceptable", and some subcategory assessments are "Excellent", then the Category score may be in the "Excellent" range, depending on the evaluation of the auditor.

One "Minor" assessment drops the Category score into the "Minor" category. For more than one "Minor" assessment in a category, the item maintains the "Minor" Category rating but at a lower numerical level. "Minor" assessments are those observed deficiencies that are of such frequency, scope and impact that they do not indicate a significant failure of the control process. Opportunities exist for system and process improvement.

One "Major" assessment drops the Category score into the "Major" level. "Major" assessments are those observed deficiencies that are of such frequency, scope and impact that process control is significantly compromised and there is a high likelihood that food safety or security could become severely jeopardized. The system needs improvement.

"Critical" assessments are indicative of direct observed contamination or serious failures of food safety or security systems or documentation. "Critical" observed deficiencies indicate product contamination and/or adulteration, operating in an unsanitary condition, significant deviation from identified CCP in the HACCP plan, mislabeled or misbranded product, records falsification and/or a significant deviation from specification. Plant is not operating in compliance with stated regulatory requirements.

Repeat Findings (R) are applicable to facilities that have been previously audited by NSF-Cook & Thurber. If the facility has not conducted corrective action to effectively address previously cited deficiencies of an NSF-Cook & Thurber audit, a repeat finding will be indicated by an "R" in the scoring grid and the auditor will adjust downward the category score. The extent of the adjustment will depend on the severity of the concern and typically will drop the rating to a "major" classification.

Note: At times it may be acceptable to have an alternative procedure or practice to those listed, but the alternative procedures must accomplish the same degree of control. When this occurs, it would be usual to give an "Acceptable" rating, but the alternative procedure must be noted in the comments.

Category Rating	Score	Category Description
Excellent	96-100	Exceeds Audit Expectations
Acceptable	90-95	Meets Audit Expectations
Minor	80-89	Opportunity for Improvement
Major	70-79	Needs Improvement
Critical	< 70	Immediate Improvement Needed

EXPECTATIONS AND CRITERIA FOR FOOD PROCESSING FACILITIES

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

The following criteria are considered essential to meeting these goals on a consistent basis. Of course, the intensity of food Safety, Quality and Security is being increased as leading companies, not just big companies, work to improve their level of performance to provide reliably safe and high quality products. Demonstrating consistent achievement of these criteria is the expectation of our clients.

If the plant has received approval from the client to deviate from an expectation or specification, the plant must obtain written approval for the variance/deviation prior to the audit process. This approval must be available to the auditor during the audit process.

The auditor will evaluate documentation available the day of the audit. Scoring will be based on this documentation. Documentation provided to the auditor after the conclusion of the exit meeting will not change scoring.

A. ADMINISTRATION & REGULATORY COMPLIANCE

1) **Food Safety, Quality and Security Organization and Responsibilities** — There shall be a plant management organization chart that shows the reporting structure of the plant operating departments. It must clearly show the reporting relationship of the Quality Manager both internally and to a corporate or head office if applicable. The document must be current, dated and signed by the appropriate responsible executive. Further, there should be an organizational chart showing the structure of the Quality organization.

   a) The Quality Manager must be responsible to local plant manager (not production manager) or to a designated corporate official to assure that quality and food safety decisions can be made independently. Consideration will be given for Small and Very Small plants where individuals have numerous organizational responsibilities.

   b) There must be a clear documentation of the responsibilities and authorities of the Quality department signed by management.

   c) The control and release of withheld and retained product must also be clearly designated as the responsibility of the Quality Manager.

2) **Food Safety, Quality and Security Policies and Procedures** — The plant must have detailed policies and procedures relevant to the receiving, handling, manufacturing, shipping, control and evaluation of food products to assure that they meet appropriate food Safety, Quality and Security requirements. These policies must be well organized, available, current, dated and signed by management. Changes should be clearly identified and appropriately signed and dated.

   a) Written policies for Food Safety, Quality, Security and Operating Procedures must address:

      - Document and Records Management Responsibilities
      - Regulatory Compliance Guidelines and Responsibilities
      - Hazard Analysis and Critical Control Point (HACCP) Plan
      - HACCP plan validation
      - Rework Control
      - Facilities and Equipment Management and Control
      - Sanitation, Housekeeping and Hygiene Programs
      - Good Manufacturing Practices (GMP) Management and Training
      - Management and Employee Training Programs
      - Product Recall Procedures
      - Ingredients Receiving and Control
      - Continuing Letters of Guarantee
      - Allergen and Sensitive Ingredient Control
      - Process and Product Evaluation Controls
      - Packaging and Labeling
      - Storage and Shipping

- Retained and Returned Product Control
- Consumer Complaints
- Rodent and Pest Management Programs
- Laboratory and Quality Evaluation Procedures and Controls
- Calibration of Operating and Testing Equipment
- Change Management Protocol for Personnel, Policies and Products
- Food Safety and Security Management during Emergency Situations
- Food Security Program

b) Plant must have detailed manuals that address the development, implementation and control of systems that control and assure food Safety, Quality and Security. The manuals should clearly define expectations through detailed product and process specifications. The manuals shall further define all testing procedures, sampling programs and accept/reject criteria.

3) **Specific Training Goals and Programs for Management and Operating Personnel** — Documents must be available to demonstrate management's commitment to a planned training program for both management and food production personnel.

a) This formalized plan shall include introductory training programs for new management as well as new operating personnel. The training policy must address the communication of basic food handling sanitation, refresher training for experienced employees and specific training for identified jobs such as oven operators or HACCP Critical Control Point monitoring responsibilities.

b) This plan shall be reassessed annually if necessary, to assure that management and supervision are aware of new food safety and security issues and control programs.

c) To assure food Safety, Quality and Security, operating personnel shall be given GMP, food safety, food security, personnel hygiene and plant and product specific training on a quarterly basis to review and update their understanding of food handling requirements. Training programs shall be given to all employees including new employees, temporary employees and contract employees in the appropriate languages reflecting the work force population.

d) A method to document understanding, typically testing or performance evaluations shall be an integral part of the training program.

e) Individual records shall be maintained and summaries of the training provided documented for both management and operating personnel.

4) **Recall Plan and Procedures** — The plant must have a comprehensive written recall plan specifically for that plant location. The recall plan procedures must be clear and concise and the plan must be reassessed and signed annually.

a) The plan must identify the recall team members and describe their responsibilities.

b) Current office and after-hour telephone contact numbers of all recall team members, both at the plant and head office, if appropriate, must be available to all team members.

c) Contact numbers for appropriate regulatory contacts should be included.

d) Contact numbers for clients and customers must be available.

e) A recall coordinator must be clearly identified.

f) A public relations spokesperson must be clearly identified.

g) Designation of appropriate records and documents that must be available for recall actions.

h) Identification of production codes and lot definition must be documented.

i) Traceability of all ingredients and food contact packaging to the finished product and shipping records must be achievable.

   i. Ingredient or component product-in-process, carryover product and rework. Production records must identify rework or carryover usage in specific lots as well as specific lots being capable of showing presence of specific rework.

   ii. Lot numbers of finished products must be accurately shown on shipping documents and indicate quantities of "split" pallets, if they are involved.

   iii. Bulk ingredients when used.

j) Traceability exercises must be conducted at least twice per year to the first level of distribution. Annually a traceability exercise through the first level of distribution should take place to assure continuity of product traceability and documented confirmation from the distribution center should be provided on the amount of the product received.

   i. The traceability exercise should involve those departments and personnel who would be involved in an actual recall. Back-up personnel should also be involved.

   ii. A management assessment of each traceability exercise after the exercise is completed must be conducted and provide a balance sheet of total quantity of product produced subject to the exercise vs. product shipped, product on hand and product otherwise documented (damaged, lost, samples, etc.), product unaccounted for, a calculated percent recovery and any corrective actions identified.

   iii. The expectation of a traceability exercises is that identified lots of ingredients or food contact packaging can be traced to lots of finished product and to the first level of distribution at a 99.5% to 105% level within 4 hours. Failure to meet these requirements necessitates a repeat traceability exercise until the criteria are met.

k) Recall accountability to the first level of distribution of at least 99.5% but not more than 105% recovery or location and hold of implicated product within 4 hours must be recorded.

l) The plan shall include an investigation that is conducted while the recall is underway to determine the cause of the problem and if there are other affected lots.

5) **Regulatory Compliance** — It is essential that food plants operate in total compliance to regulatory requirements and that a positive working relationship be evident with the assigned regulators. An evaluation of the plant's performance in complying with appropriate regulatory agency requirements (i.e. USDA, FDA, USDC, State or Local) involves an assessment of documents, "letters" of action, inspection reports and documented responses and corrective actions to issues reported by any regulatory agency. It is expected that each and every written inspection or notice from a regulatory agency will have a documented response and corrective action.

   An evaluation must be made of the number and nature of Noncompliance Report's (NRs) issued for USDA plants. An evaluation must be made of recent (within one year) FDA 483 Forms or similar documents. They should be evaluated for the nature of deficiencies, repeat deficiencies and effectiveness of corrective actions. "Corrective Actions" should be clearly distinct from responses to

fix the immediate problem. They should address long term plans to prevent a reoccurrence of the issue.

Note: Refusal by facility to show any requested regulatory report, including USDA NR's, is a "Major" deficiency, since an evaluation of regulatory compliance cannot be completed.

Regulatory compliance requirements may be FDA, USDA, USDC or state and/or local agencies.

a) The plant shall maintain a file of all regulatory actions, visits, reports or other notifications received from any regulatory agency.

b) If a USDA plant, NR's should indicate a prompt response with an immediate corrective action to address the existing situation and should also include a specific preventative action plan to prevent a reoccurrence of the problem. There should not be a pattern of repeat NR's for the same or similar issue.

c) A log of samples submitted for pathogen, antibiotic or environmental testing shall be maintained.

d) Written responses with appropriate corrective actions must be documented for every written inspection, audit or other official notification from any regulatory agency.

e) Written responses must be documented for any audit or inspection by customers, third party auditors or internal company auditors.

6) **Document and Records Management** — This requires a policy addressing Document Control. The policy shall specify procedures for preparing the process documents, identifying areas for control, collecting data, indexing completed forms, controlling distribution of documents, document filing, and file storage. The policy must identify a specific time limit for holding files and the proper disposition of outdated records. Locations for the storage of documents must be designated. Records maintained "off site" must be retrievable within a reasonable time. Access to records should be limited to designated individuals.

a) Documents, data, specifications, etc., should be assessed for adequacy on a scheduled basis and documented and authorized by dated signature of designated individuals.

b) A document control policy must be available that identifies the current revision status of all documents to avoid use of invalid or obsolete documents.

c) Any obsolete documents must be clearly identified and maintained for historical purposes. These may be needed if a question of historical nature is asked by a regulatory agency or a customer.

d) Changes to documents and specifications should be assessed by and approved by the designated individuals. Where practicable, the nature of the change should be indicated on the document or appropriate attachments.

e) It is expected that all records relevant to the control of the process or evaluation of food Safety, Quality and Security will be:

i. Complete with no missing data or blank blocks (Notes that explain lack of data are required.).

ii. Initialed by operator and signed by supervisor to verify accuracy.

iii. Recorded on a timely basis, with accurate date and time.

iv. Recorded in ink, not pencil. (Errors marked through and initialed.)

v. Marked to record, or chart, out of control or out of specification conditions. (Records must indicate disposition of product and corrective actions taken.

f) Records must be indexed and easily retrievable.

g) Evidence of records falsification is a critical deficiency for this category.

7) **Change Management** — The plant must have a documented policy to manage change in management and supervisory personnel and the implementation of changes in specifications, policies and procedures in order to maintain continuity and the control of systems already in place during the change.

a) There should be a documented procedure to assure that new management and supervisory personnel are aware of all plant policies and procedures impacting food safety, quality, security and wholesomeness.

b) Proposed changes to policies and procedures should be conducted through a prior notification process of all affected parties to solicit input and approval.

c) There should be a written procedure for insuring that all changes to policies, procedures, product formulations, processing equipment or product specifications are adequately communicated to the management and operational personnel.

d) There should be detailed plans to implement new changes and to remove obsolete material.

8) **Documentation to Track Effectiveness of Policies** — There shall be documented management audits, or monitoring programs, to evaluate the level of conformance to each of the category items listed above. Based on the level of activity, Category Audits should be periodic, but no less than annually, to assure that the policies are in fact being properly managed, that situations have not changed, and that the policies are still appropriate. There must be some documented evidence that management is aware of the level of compliance to and effectiveness of operational policies.

9) **Management Awareness and Commitment to Food Safety, Quality and Security** — Management commitment and active support is the foundation of an effective Food Safety and Quality Management system. This is an essential element, if the system is to function. Support can be shown by providing adequate financial resources for food safety programs, product quality programs, training programs, attendance at training programs or by personal commitment to the audit process. Management awareness of corrective action programs to outside audits, regulatory inspections and internal audits is expected. Management commitment can also be reflected by the general condition of the plant facilities, equipment and employee support facilities. Management's participation in the opening and closing audit meetings can indicate a degree of commitment.

10) **Crisis and Natural Disaster Management** — A crisis management team must be assembled. The team shall include a sufficient number of members representing the necessary departments needed to handle and resolve a multitude of critical situations that may occur, i.e. recalls, security issues, emergency situations (power outage, flooding, etc.).

a) Written procedures should be available to indicate the responsibilities of each member. The team must have responsibility for managing all aspects of a crisis situation, including contacting of regulatory officials, law enforcement, or media as necessary.

b) A current list of responsible team members that are available 24 hours a day and 7 days a week, as well as regulatory contacts, corporate contacts, client contacts, outside support (trade associations) contacts, supplier contacts and other key contacts for use by the Crisis Team must be available. The list must contain both office and after hours telephone numbers. Each team member should have a designated back up individual.

c) Team members must receive specific training in crisis management and response.

d) The crisis team must meet at least quarterly to evaluate the status of the program. All meetings and actions must be documented.

e) Detailed plans for handling emergency situations are to assure that finished product, in-process product and ingredients are protected and in case of prolonged interruptions, that there are plans for alternate product supply to the customer.

f) Policy should designate Quality Assurance as responsible for evaluating the status of ingredients, in-process materials and finished product involved in an emergency. Quality Assurance should make sure that all ingredients and materials are suitable for use prior to the start of production. Finished product involved in an emergency situation must be evaluated and released by Quality Assurance prior to shipping.

11) **Customer/Consumer Complaints** (Policies, Follow-up and Response) — The plant must have a written program for handling customer or consumer complaints. The policy must address responsibilities, response time and corrective actions based on an investigation of the complaint. A log is essential to track complaints by product identification, production dates, cause and origin of complaint. Customer information can be a valuable resource for validating HACCP criteria.

B. HACCP MANAGEMENT

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and the Codex Alimentarius Commission (CODEX) provide a great resource for understanding the principles of Hazard Analysis and Critical Control Point (HACCP).

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

A HACCP system must be developed by each food establishment and tailored to its individual products, processing and distribution conditions. The HACCP plan must analyze and control for the potential biological, chemical and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. It is essential that the unique conditions within each facility be considered during the development of all components of the HACCP plan.

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

NOTE: If the product is amenable to a mandatory HACCP requirement, then the Plan must be in compliance with the regulatory requirements. If ~~a~~ mandatory HACCP is not required, the facility must still comply with prerequisite programs and all HACCP requirements through the determination and documentation of whether any hazards and CCPs exist. If it is determined that CCPs do exist, a complete HACCP program is required whether mandated or not.

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

1) **Prerequisite Programs** - Through the application of GMPs, prerequisite programs provide the basic environmental and operating conditions that are necessary for the production of safe, wholesome food. The existence and effectiveness of prerequisite programs should be assessed during the design and implementation of each HACCP Plan. All prerequisite programs must be well developed, documented, monitored and readily available. Prerequisite programs are established and managed separately from the HACCP Plan. Certain aspects, however, of a prerequisite program may be incorporated into a HACCP Plan, such as preventive maintenance procedures for processing equipment to avoid unexpected equipment failure. Prerequisite programs need to be complete, thorough and effectively support the HACCP Plan, with clear policies and instructions. They must verify performance and provide documented corrective action. Common prerequisite programs may include but are not limited to the following.

    a) Educating and training management and employees in HACCP principles and GMPs.

    b) Specific training activities for the tasks of employees monitoring each CCP.

    c) Facilities location, construction, sanitary design, product flow and traffic control principles managed to minimize cross-contamination.

    d) Verification of effective supplier programs to control GMP and food safety and security programs.

    e) Specifications for all ingredients, products, and packaging materials.

f) Production equipment construction, installation, sanitary design, preventive maintenance and calibration.

g) Written cleaning and sanitation procedures and schedules for equipment and the facility.

h) Personal hygiene compliance for employees and visitors.

i) Chemical control procedures for non-food chemicals in the plant.

j) Receiving, Storage and Shipping procedures of all raw materials and products.

k) Traceability and recall procedures of all raw materials and products.

l) Effective pest control programs.

m) Allergen management.

n) Customer Complaint management.

o) Corrective action management.

p) Other examples might include quality assurance procedures; sanitation standard operating procedures, customer complaint procedures, product formulations and recipes; glass control; labeling; and employee food and ingredient handling practices.

2) **Preliminary HACCP Tasks –** Five preliminary tasks need to be accomplished before the application of the HACCP principles.

a) HACCP Team - A HACCP team must be assembled with individuals having the appropriate product specific knowledge and expertise necessary for the development of an effective HACCP Plan. This may be accomplished by assembling a multidisciplinary team that includes top management, operating department heads, quality management and appropriate operating personnel. Where such expertise is not available on site, expert advice should be obtained from other sources.

i. Team members and their responsibilities must be clearly identified as part of the HACCP plan. The entire team is to be involved in the development and final approval of the plan.

ii. Documented team meetings should occur on a regular basis to assess HACCP records and issues. The team must assess all deviations, documentation errors, corrective actions, and assure that corrective actions are monitored for effectiveness.

b) Product Description - A full description of the product should be drawn up, including relevant safety information such as: composition, physical and chemical attributes, processing, packaging, durability and storage conditions and method and conditions of distribution. Products with similar characteristics or processing steps may be grouped together for the purpose of development of the HACCP plan.

c) Intended Use - The intended use of the product must be determined and should be based on the expected uses of the product by the end user or consumer.

d) Process Flow Diagram - The HACCP Team must construct a clear and easy to understand flow diagram for each HACCP plan.

i. The diagram must outline each step involved in the process that is directly under the control of the establishment. The diagram must indicate the individual ingredients used, all preparation steps, all equipment used, blending steps, processing steps, rework and returned products, packaging equipment and the steps preceding and following the process.

ii. Once CCPs (Critical Control Points) have been determined, they must be clearly identified on the flow diagram and numbered to correspond with the Hazard Analysis and CCP records and documentation.

e) On-site Confirmation of Flow Diagram - The HACCP team must perform an on-site review of the operation to verify the accuracy and completeness of the flow diagram during all stages and hours of operation. Modifications should be made to the flow diagram as necessary and documented.

i. The flow diagram should be signed by knowledgeable operations management and dated to verify its completeness and accuracy. The chart must remain current.

3) **Hazard Analysis (HACCP Principle 1) –** There must be a detailed Hazard Analysis document for each type of product or product line. The scope of the HACCP plan should be identified and should describe which segment of the food chain is involved and the general classes of hazards to be addressed.

a) The HACCP team must prepare a list of all of the hazards (chemical, physical, biological or other) that may be reasonably expected to occur at each step, from primary production, processing, manufacture, and distribution until the point of consumption. Evaluation should include all ingredients, equipment, processing steps, and packaging.

b) The HACCP team must conduct a hazard analysis to identify for the HACCP plan, which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food. The hazard analysis should include.

i. The likely occurrence of hazards and severity of their adverse health effects.

ii. The qualitative and/or quantitative evaluation of the presence of hazards.

iii. Survival or multiplication of micro-organisms of concern.

iv. Production or persistence in foods of toxins, chemicals or physical agents.

v. Conditions leading to the above.

c) Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure.

4) **Critical Control Points (HACCP Principle 2) –** A logical reasoning approach should be used to determine Critical Control Points (CCPs) for hazards.

a) The determination of a CCP in the HACCP system should be facilitated by the application of a decision tree. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. It should be used for guidance when determining CCPs. Training in the application of the decision tree is recommended. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), “Decision Tree” or the CODEX decision tree should be applied in determination of CCPs. There may be more than one CCP at which control is applied to address the same hazard.

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

c) There must be a scientific or regulatory basis, with appropriate documentation or regulatory references, to both the hazard and the control required. Proprietary data may be acceptable, providing there is sufficient data that is approved by an appropriate, qualified process authority.

d) NOTE: If it has been determined that there are no hazards or CCPs, no further HACCP plan development is necessary. However, the HACCP Team must continue to conduct regular meetings to review any changes in the process or procedures that would affect the hazard or CCP determination.

5) **Critical Limits (HACCP Principle 3) –** Once a control measure has been established for a CCP, operating and critical limits must also be established.

a) Critical limits must be specified and validated for each CCP.

b) Critical limits must be measurable.

c) Process Capabilities must be documented to demonstrate that established CCP limits are compatible with the plant process and capable of being met. A minimum of 3 standard deviation units (σ) from the process mean is required for CCPs providing assurance of 99.7% compliance. For some heat process limits, the requirements may be greater. Low Acid Canned Foods (LACF), for example, requires 6σ from the process mean, assuring near 100% compliance.

6) **CCP Monitoring (HACCP Principle 4)** – Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits.

a) If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP is in control.

b) Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

c) Documentation of the measured variable must be on clearly identified HACCP Records, with the CCP identified by name and number, the item to be measured, the frequency of the measurement, the CCP limit, the responsible monitor and the corrective action required in the event that a measurement is not in compliance.

d) A deviation log must be maintained and available for review.

e) All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company. Signatures of the operator, supervisor and designated record reviewer are required in some regulated situations.

7) **Corrective Actions (HACCP Principle 5) -** Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

a) Corrective actions must include instructions of necessary actions to take to secure and manage affected product.

b) Corrective actions must ensure that the CCP has been brought under control and require that an assessment be conducted to prevent a reoccurrence of the situation.

c) Product disposition procedures that would become effective if a deviation were to occur must be developed.

8) **Verification and Validation (HACCP Principle 6) -** Verification documentation confirming that the products are achieving the level of safety required and that the HACCP plan is operating effectively, is required.

a) Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Examples of verification activities include:

   i. Review of the HACCP system and Plan and its records.

   ii. Review of deviations and product dispositions.

   iii. Confirmation that CCPs are properly monitored and kept under control.

b) Validation of the initial HACCP plan must be available through documentation or supporting data that confirms the Plan is scientifically and technically sound, that all hazards have been identified, that CCPs are effective and valid and that if the HACCP plan is properly implemented, these hazards will be effectively controlled.

c) Subsequent validation of the Plan must be performed and documented on an ongoing basis and must be performed at least annually.

9) **Documentation and Record Keeping (HACCP Principle 7) -** Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures must be documented.

a) Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to verify that the HACCP controls are in place and being maintained.

   i. Examples of documentation include Hazard analysis; CCP determination; Critical limit determination.

   ii. Example of Record Keeping include CCP monitoring activities; Deviations and associated corrective actions; Verification procedures performed; Modifications to the HACCP plan.

b) Deviations from the HACCP plan must be thoroughly documented with detailed corrective actions and product dispositions.

c) The documents and their data must be self-explanatory and complete. The records must be in ink (not pencil) and signed by the operator. There must be no blanks or missing data. In the event of down time, or no production during a specified monitoring time, an explanation must be provided.

d) The final record must be signed by the operator, the supervisor and by the designated HACCP records reviewer.

e) The records must be easily retrievable and secured in a safe storage area.

C. FACILITIES & EQUIPMENT

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

1) **Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management** Plant must demonstrate that the water supply is potable and that potability is maintained at all times. Potability must meet local requirements at a minimum.

   a) A certified laboratory must document potability testing at least annually. Potability certificates available from municipal water suppliers are acceptable, however, in house sampling is recommended. If the facility is using water from a private well, there must be an acceptable potability test every 6 months.

   b) Chlorinated water is required. Potable water in Ready-to-Eat (RTE) areas should be checked frequently for chlorine levels and at least monthly for microbiological levels.

   c) Plants using their own private wells must chlorinate the water for plant use.

   d) Plant should have a backflow prevention device on main water lines entering the plant, and must have backflow prevention devices on individual water lines within production areas. A trained inspector must verify the backflow prevention system annually.

   e) Plant must have identification system for potable and non-potable water lines and current schematics. Dead ends on potable water lines must be eliminated. Hose drops must not be submerged in water reservoirs.

   f) In-plant manufactured ice should be tested for microbiological potability semi-annually. Purchased ice must have annual certificate of potability. Weekly, ice from any source, should be melted to investigate for foreign material. Tests should be documented.

   g) Facility must have an adequate supply of both hot and cold water for production and sanitation. Handwash facilities must have an immediate supply of tempered water (90-105°F within 10 seconds).

   h) Hose drops must have back flow prevention devices installed. (High pressure lines (>80 psi) do not need backflow protection.) Hoses and hose nozzles must not be left on the floor or in tanks.

   i) Sewage disposal must be such that it does not compromise food safety or employee health.

   j) Plant must have a documented procedure for handling backed-up drains in the production areas. Drain cleaning equipment should be cleaned and sanitized before entering production areas. It must be removed from the production area in such a way that it does not cause further contamination.

   k) All steam used for product manufacture and that touches product contact surfaces must be from “edible” sources. Documentation must be available that indicate all boiler components meet approved boiler additive standards. A listing of registered Nonfood Compounds is available at http://www.nsf.org/business/nonfood_compounds/index.asp?program=NonFoodComReg

   l) Wastewater and sewer drains must not be vented inside the facility.

2) **Plant Construction and Design —** The construction of the facility must be such that it facilitates the production of wholesome product and that it meets the customer and regulatory food safety and quality requirements.

a) Exterior of plant and grounds must be constructed to minimize dust and be free of standing water.

b) With the exception for plants packing product in glass or brittle plastic, glass and/or brittle plastic shall not be used in, above or near processing or storage areas. (This includes glass thermometers, except on sterilizing vessels processing packaged product.)

c) Plants packing product in glass containers must be constructed and equipped to properly clean the containers and provide shielding to protect product and ingredients in the event of glass breakage during production.

d) All essential glass or brittle plastic that exists in cameras, etc. must be documented to indicate location, condition, maintenance and monitoring on at least a monthly basis.

e) Catwalks and other walkways over or adjacent to product zones must be designed to prevent product contamination. "Toe boards or rails" are not acceptable. Processing line protection shields should be knee high.

f) Plant construction and layout must be such that exposed product is adequately separated and protected from any operations that could cause contamination.

g) Facilities must be designed so that product and product ingredients do not come into contact with non-product zones (i.e. floor, walls, etc.).

h) Handwash and product wash sinks must be properly plumbed to drain lines. Discharge water from sinks must not run directly onto the floor.

i) Floors must be well drained, smooth, easy to clean with no aggregate exposed and no cracks, holes or broken areas.

j) Wall perimeters should have an uncluttered space to assure ease of access for cleaning, inspection and maintenance of equipment.

k) Floors must be maintained in clean and dry (if possible) condition.

l) Standing water must not be evident in processing or warehouse areas.

m) Tiles and grouting must be maintained to provide a smooth cleanable surface.

n) Drains must have traps and drain covers must be maintained in place. Drains must be free from odors.

o) Outside opening doors shall be self-closing, tight fitting and remain in good repair. Personnel and forklift doors must be effectively protected with air curtains, or by other effective means. Emergency doors must be alarmed.

p) Ceilings shall be constructed of a smooth, non-porous, non-absorbent and easily cleanable material.

q) 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. All systems must be clean, properly functioning and designed in such a manner to prevent product contamination from condensation, mold, bacteria, insects, dust or odors. Heating and ventilation must be balanced to prevent condensation on walls or ceilings in product areas.

r) Objectionable odors, fumes or vapors shall not be present.

s) All fans, fan guards, ductwork, louvers, and heat and air conditioning units will be clean and in good repair.

t) All ceiling and wall ventilation fans venting to the outside must have properly functioning self-closing louvers and be screened to prevent insect entry.

u) Processing area air supplies must be screened and filtered with filtering efficiencies of at least 90% at 3 microns. Air filters must be routinely inspected and replaced or cleaned as necessary, to maintain efficiency.

v) Facilities that utilize compressed air that makes direct contact with food, food contact surfaces or packaging materials (that make direct contact with food) must develop a program to assure the compressed air does not introduce any contaminants (including microorganisms) into the product. The necessary requirements for maintaining sanitary air must be monitored and documented.

w) The facility roof shall be uncluttered, free draining and free of standing water, bird or pest harborages.

3) **Plant Condition (Walls, Ceilings, Floors, etc.) —** Plant facilities must be well maintained in an orderly, clean condition with repairs to floors, walls, ceilings and equipment maintained so as not to provide undue obstacles to sanitation or present opportunities for foreign material contamination.

a) Ceiling surfaces as well as other overhead equipment, must be clean, in good repair, free of flaking paint, loose caulking, rust, holes or unsealed openings, or other conditions that could result in product contamination.

b) Overhead structures such as ventilation units, light fixtures, electrical raceways, piping, conveyors, etc., must be clean and free of product buildup, dust, mold, rust, peeling paint and condensation.

c) Ceiling panels, framework and supports must be properly secured with no missing or damaged parts.

d) Ceiling penetrations for pipes, conveyors, wiring, etc., must be sealed to prevent harborage, ceiling leaks and contamination.

e) There shall be no evidence of water leaks on ceilings.

f) Insulation materials shall be in good repair, smooth, non-absorbent and easily cleanable. Joint areas must be sealed.

g) Nails, staples or screws must not be used to secure ceiling material in processing, ingredient, packaging or warehouse areas.

h) All skylights, transoms, windows or similar openings must be free of damage, tight fitting and properly screened.

i) All ceiling and wall junctures must be sealed to preclude harborage or access.

j) String, rope, wire or tape must not to be used as pipe, line or equipment supports.

k) Pipes or other overhead equipment above product zones must be adequately protected to eliminate product contamination.

l) Temporary or unused hangers or other equipment support in production areas must be removed when no longer in use.

m) Walls should be of a smooth non-toxic and easily cleanable construction. They should be free from cracks, holes and crevices that would inhibit cleaning or provide harborage for soil and pest. They should be free of dust, dirt, product accumulation and flaking paint.

n) Walls shall be sealed and coved at wall/floor juncture.

o) Wall coverings must not be attached with exposed nails, staples or screws.

p) Openings in walls where pipes, equipment or conveyors pass must be sealed.

q) Windows must be closed if outside conditions exist that may expose the plant to airborne contamination. Ledges should be sloped to avoid storage and prevent accumulation of debris.

r) All windows shall be maintained in a clean and sound condition, with no broken panes and must be screened when open.

s) Electrical installations shall be sealed around the edges to prevent intrusion of moisture if directly on the wall. Offset installations to provide access for cleaning are recommended.

t) Electrical installations shall be in good repair and tightly sealed with no rust or flaking paint, clean, free of dust, and not used for accumulation of parts or supplies.

4) **Ready-To-Eat (RTE) Operational Areas** — RTE areas require additional consideration and protection from cross contamination since the products produced in them will be directly consumed.

a) RTE areas must be separated and effectively isolated from other operations and traffic flows that could compromise the high level of sanitation and hygiene essential to RTE product integrity.

b) RTE processing areas must have microbiologically filtered air supplies and be under positive air pressure to prevent dust, flying insect entry and cross contamination by unfiltered air. Air filters must be routinely inspected and replaced or cleaned as necessary, to maintain efficiency. HEPA filters should be 95% effective at 0.5 microns.

c) Personnel access to RTE areas should include facilities for personnel to make appropriate outer garment changes and either change footwear or put on appropriate footwear coverings prior to entering the RTE area. Access routes for personnel and materials should be free from exposure to raw processing areas or routes exposed to raw products. Entrances to high-risk RTE areas should include foamers, footbaths, powdered sanitizer, etc.

d) Brooms should not be used in RTE areas.

5) **Employee Support Facilities** — Cafeteria, Locker Rooms and Toilet facilities shall be adequate, convenient and physically separated from food production areas. They shall be well lit, clean, properly ventilated and maintained to set an example of clean and orderly food sanitation and housekeeping requirements.

a) Cafeterias and break areas shall be adequately sized, well lit, clean and effectively ventilated. Adequate storage for employee lunch items in easily cleaned areas shall be available. Food preparation areas shall meet restaurant standards for sanitation and cleanliness. Vending machines shall be maintained in a sanitary condition with easy access for cleaning underneath and behind.

b) Locker rooms shall be adequately sized, well lit and clean and orderly. Lockers shall be available for storing personal clothing items. Food and equipment or utensils shall not be stored in locker rooms. A monthly routine locker cleaning schedule shall be maintained. Locker tops should be sloped to prevent accumulation and facilitate cleaning.

c) Toilet facilities must be available in locker rooms and convenient to operational areas if located distant from the locker rooms. They shall be well ventilated, well lit, clean and orderly.

d) Doors to toilet facilities shall be self-closing and must not open directly into processing, ingredient or packaging areas.

e) All toilet facilities and locker rooms must be mechanically ventilated to the outside.

f) A procedure for immediately cleaning and re-opening clogged toilet facility drains must be in place.

g) A plan must be available that specifies appropriate sanitation procedures to restore sanitary conditions following repair of overflowed drains or toilets.

h) Signs in appropriate languages, or graphics, shall be clearly posted in locker rooms, toilet facilities and at entrances to work areas instructing employees in the proper handwashing and sanitizing procedures before starting work and when leaving toilet facilities.

6) **Handwashing Facilities** – Adequate and convenient handwashing facilities must be provided in locker rooms, toilet facilities and at entrances to work areas.

a) Handwash stations shall have adequate room to accommodate the number of personnel in the area to prevent delays that may discourage proper handwashing procedures.

b) In RTE areas, or areas where product is exposed or handled by employees, handwash and/or sanitizing stations must be convenient to the employee workstations.

c) The handwashing stations must deliver tempered water (90-105°F) within 10 seconds. Additionally there must be an adequate supply of hand sanitizing soap and/or sanitizing agent. Single service towels shall be available with convenient disposal at each station.

d) Additional sanitizing stations may be required near workstations in RTE areas.

e) In and adjacent to processing areas must be 'hands-free' activated so that hand contact is not required to turn water 'On' or 'Off'. Other handwashing stations should be the 'hands-free' activated type.

7) **Equipment Layout, Design and Condition** — All food production and packaging equipment must meet food sanitary design requirements and be installed in such a manner as to permit proper operation and access for cleaning and inspection. Compliance to 3-A or NSF Standards is recommended for food processing equipment. Small hand utensils should be NSF certified.

a) Processing, packaging and storage equipment shall be designed, installed and maintained in such a manner as to produce a safe, wholesome and quality product.

b) Equipment must be designed and maintained to provide easy access, disassembly and reassembly for thorough cleaning, sanitizing and inspection.

c) Equipment must be of smooth, impervious, non-toxic, non-absorbent and corrosion- resistant material where it has direct product contact.

d) Conveyor belts for product contact shall be of impervious, non-absorbent material. Fiber backed or sandwiched belts shall not be used for product contact conveyors. Belts shall be maintained in good condition with no holes, cuts, frayed edges or damage that renders the belt difficult to clean or present a foreign material hazard.

e) Product contact surfaces, such as conveyor belts shall not be closer than 18” to the floor or shall be effectively protected from contamination during operations.

f) Nonfood grade materials such as wire, tape, string, plastic or cardboard shall not be used for temporary repair.

g) Equipment must be free of cracks and non-continuous or rough welds where product may become embedded and make cleaning difficult.

h) Equipment with sides or shields or scrapers or other items that are attached to product contact areas must have sufficient clearance between the pieces to permit cleaning and prevent product accumulation. (Approximately ¼" is generally sufficient.)

i) Equipment shall be free of oil leaks and excessive grease build-up on bearings and motor housings where they may contaminate product. Bearings and motors near product areas must have catch pans to protect product below. The pans must be drained in a sanitary manner.

j) Equipment must be constructed in such a manner to preclude metal-to-metal contact between moving parts.

k) Hollow drums or rollers should not be used for food processing equipment. Open rollers that can be effectively cleaned or solid rollers or drums are required. If hollow drums/rollers are used, they must be completely sealed and the maintenance department must have a record of inspection and corrective actions instituted.

l) Appropriate covers/lids shall be provided to protect product from contamination. Tanks or vessels containing food products must be covered when they are not actually being filled, used or other activities requiring access.

m) Equipment shall be free of flaking paint, rust or other contaminants that could become detached.

n) Thermometers, recording charts and pressure gauges must be convenient to read, accessible and properly maintained.

o) Equipment shall be designed to preclude or divert condensate away from product and product contact surfaces.

p) Product and clean product containers shall be adequately protected to preclude contamination.

q) Gasket material shall be non-toxic, non-absorbent and in good condition.

r) Small support utensils and equipment shall have specific, convenient and sanitary storage hangers or shelves.

s) Tanks, vats and product lines that are Clean-in-Place (CIP) cleaned must be self-draining.

t) Refrigeration unit drip pans must be adequately sized to be effective and properly drained to prevent accumulation of standing water. Refrigeration drip pan overflow must not flow onto the floor. Drain lines into sewer or vent lines must be "trapped" (e.g., P-trap), or if drained into floor drains, must have an "air gap". Drip pans should contain anti-microbial chemicals (sanitizer blocks) to minimize microbial concerns.

8) **Plant Lighting and Protection** — Plant lighting shall be of such design and construction to provide adequate illumination in product areas, support areas and storage areas. The lighting fixtures shall provide adequate protection from breakage and possible contamination.

a) General plant lighting shall be a minimum of 30-foot candles.

b) Lighting at inspection and product sorting areas shall be a minimum of 50-foot candles.

c) All glass lighting shall be completely enclosed in shatterproof protective shields or manufactured with shatterproof materials to prevent glass contamination of product. This includes all operating

areas, warehouses, packaging, receiving and shipping docks, storage areas, maintenance, toilet areas, break rooms, and welfare areas. All lights must be protected, including but not limited to, emergency lights, fork lift lights, and adjustable trailer lights on the dock.

d) Light fixtures shall be maintained clean and free of cracks, dust or other materials that could cause contamination. Protective covers in processing areas shall be kept free of any evidence of moisture accumulation inside the covers.

e) A periodic assessment of this program is required.

9) **Maintenance Standard (Support of GMPs, Housekeeping, Lubricants)** — Engineering and maintenance support should be managed to provide a well-maintained, clean and orderly facility that presents a good image of sanitary food processing for employees and visitors. Equipment shall be maintained in sound working order as originally designed or with modifications meeting food sanitation requirements. Repairs to facilities and equipment must be current and consistent with good food manufacturing practices.

a) Plant must have a documented preventative maintenance program that covers equipment and facilities.

b) Plant must have regularly scheduled activities that identify and correct the following conditions before they become contamination or sanitation hazards: flaking, peeling paint, rust or grease buildups on equipment; condensation on equipment or ceilings; holes, cracks or loose ceiling or wall panels or supports; repair of fixed and wheeled equipment to prevent contamination or cleaning problems such as: cracks or rolled edges on totes, shovels, buckets or other utensils; frayed or damaged conveyor belt; cutting board conditions.

c) Temporary repairs must be consistent with GMPs and do not permit the use of inappropriate materials. Permanent repairs must be made promptly.

d) Plants that process heat processed items where temperature and time measurements are critical control points must maintain a maintenance log book of the cooking/heating and chilling process equipment, including calibration of temperature devices and timing controls. This is to verify that the heating media or chamber, and the chilling process, is maintained properly to assure delivery of the required process and to minimize process temperature variation.

e) There should be a maintenance response to address each facility or equipment deficiency. Needed repairs as noted in GMP audits, pest activity reports, housekeeping surveys or other reports should be conducted without delay and documented accordingly.

f) Foodgrade lubricants must be stored separately from non-food grade lubricants. Non-foodgrade lubricants must be clearly identified as not for use in food contact areas.

g) To avoid product contamination, shop scrap must be controlled.

h) Maintenance shop should have a parts and tools accountability program in place to identify potential product contamination.

D. SANITATION, HOUSEKEEPING & HYGIENE

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

1) **Master Sanitation List and Monitoring** — The plant must have documented cleaning procedures not only for the operational areas and equipment but also the warehouse, storage, maintenance, employee support areas (locker rooms, cafeterias and break areas and toilet facilities) and other plant areas including outside and roof areas. This is generally recognized as a "Master Sanitation Schedule". The scheduled tasks must be monitored for completion and documented with sign off on a regular basis.

2) **Standard Sanitation Operating Procedures and Monitoring** — The plant must have a documented Standard Sanitation Operation Procedure.

   a) The plant must have a documented Standard Sanitation Operation Procedure (SSOP) for food processing equipment which specifies and defines:

      i. Standard cleaning methods for individual pieces of equipment and facility structures including the level of disassembly required for cleaning and responsibility for each task.

      ii. Frequency of cleaning.

      iii. Specific chemicals, cleaner and sanitizers to be used.

      iv. Water temperature requirements for washing (>140°F for cleaning unless otherwise recommended in writing by chemical supplier).

   b) Plant must have detailed SSOP Monitoring Procedure with records of monitoring activity. Records must clearly show equipment condition and list all deficiencies found. When deficiencies are found there must be a clear explanation of the corrective action taken to bring the equipment into a sanitary condition and a detailed action plan to prevent a reoccurrence. (Note: that Corrective and Preventive actions are not the same.)

   c) Written procedures and schedules for cleaning and sanitizing equipment and facilities must be current and available.

   d) If machine operators are responsible for general maintenance and equipment cleaning, procedures should be available describing steps for cleaning and sanitizing.

   e) Written procedures must be available for cleaning and sanitizing equipment (and water/steam lines if applicable) after maintenance is performed and prior to returning equipment into service. Records of such maintenance and documentation of sanitation is required.

   f) All equipment taken out of service for maintenance must be properly cleaned and sanitized before being put back into service with appropriate documentation.

   g) When specified sanitation procedures are not performed on production equipment, comments should be included in SSOP program documentation.

   h) Final sanitizing of equipment should be performed following reassembly of equipment just prior to commencement of operations.

3) **Cleaning Chemical and Sanitizer Control** — The SSOP must have specific preparation procedures regarding dilution factors for the chemicals or sanitizers.

a) A log should be maintained, documenting the preparation and dilution of each chemical or sanitizer including the verification check.

b) All containers for cleaning chemicals and sanitizers must be properly labeled.

c) All containers for cleaning chemicals and sanitizers must be used for their intended purpose only.

d) Storage of chemicals used for cleaning and sanitizing must be securely stored during periods of non use.

4) **Pre-op Monitoring and Corrective Action** — A pre-operational checklist should be used to verify that plant and equipment are clean and sanitary. All equipment, containers, utensils, walls, floors, ceilings, light fixtures, miscellaneous overhead structures, etc., should be evaluated for visual cleanliness**.**

a) A routine documented inspection program must be in place to assess sanitation practices and conditions.

b) Deficiencies noted and corrective actions taken must be documented.

5) **Verification of Cleaning Effectiveness** — Sanitation effectiveness must be monitored visually prior to start-up and supplemented with an objective measurement such as Bioluminescence or microbiological evaluation. Results must be documented.

a) Plant should document testing of final rinse water to verify that cleaning chemicals have been effectively flushed from product contact surfaces. This is particularly vital for pipes and tanks. In the absence of a definitive test method, observation for clarity and residual odor should be observed and documented.

6) **Operational Housekeeping and Monitoring** — All areas of the plant must be kept clean, orderly and free from accumulation of litter, unused equipment parts, etc. There should be no storage of any items directly on the floor, unless the item has wheels or legs. All floors, nooks, crannies and corners should be clean and orderly with no accumulations of materials or equipment not in use.

a) Checklists specifically for each area should identify responsibility and frequency of monitoring to assure that housekeeping activities are conducted in accordance with established GMPs.

b) Garbage, trash and waste materials must be accumulated in identified containers and properly disposed of in designated, marked containers.

c) All blowers, fans, vents and grids shall be kept free of dirt and/or grease build-up.

d) Evidence of mold, mildew or slime on walls, floors, ceilings or equipment must be prevented.

e) Conduits, pipe runs and other electrical fixtures shall be sealed and free of dust and debris.

f) Rolling stock, totes, hand tools, utensils, etc. shall be cleaned and stored in designated areas. If color coding is used for small tools or containers, the color code scheme must be prominently displayed in the areas where the items are used.

g) Mops, brooms, squeegees, etc. must have hanging storage fixtures and not be stored on the floors. Squeegees used for condensate control may be stored in sanitizer solutions. No wooden handled utensils may be used in the production areas.

h) High-pressure hoses must not be used in production areas after sanitation is complete.

i) Stored product contact equipment must be re-sanitized immediately prior to using.

j) Floor drains shall be kept clean, odor free, covered and trapped. Quaternary ammonia rings or blocks or other effective sanitizing practices must be used in RTE drains.

k) Equipment and floors shall be cleaned as necessary during operations to provide a clean and orderly environment.

l) All reusable product containers must be effectively cleaned, sanitized and inspected before reuse.

m) Packaging supplies should be removed from the production area during cleanup. If not removed, they must be stored off of the floor and covered to prevent contamination. An effective procedure must be in place to avoid packaging materials from being contaminated by the cleaning process.

n) Tools shall be stored in clean toolboxes or in affixed positions. Tools and materials shall not be stored on top of equipment, electrical boxes or window ledges.

o) All tool pouches must be made of cleanable materials and used in a manner to avoid cross contamination.

7) **Personal Hygiene and Good Manufacturing Practices —** Food plant employees must observe the strictest of personal hygiene practices as outlined in the Code of Federal Regulations, Section 21, Part 110, Current Good Manufacturing Practices for food plants. This regulation establishes the minimum requirements for basic food handling, but many food products, such as Ready-to-Eat products require more stringent practices. The goal of high quality and long shelf life products also dictate adherence to a stricter standard. Consequently, a specific, documented, detailed and closely monitored management program is expected to cover this vital area of wholesome food production.

a) Plant must have a written training policy describing the training program (in appropriate languages) for sanitation employees (including new sanitation employees, temporary sanitation employees and contract sanitation employees). The program must cover basic food handling training, refresher training for experienced employees, and specific training for identified jobs such as oven operators or HACCP CCP positions. The training program should also describe training required for sanitation management and supervision and be updated annually to take into consideration new issues or technologies or management programs.

b) Plant must have a plant specific documented Good Manufacturing Practice (GMP) training program (in appropriate languages) for all employees. All new employees must be provided initial training covering basic GMPs and specific plant policies regarding sanitation, housekeeping and personal hygiene. Follow-up continuing refresher training should be provided at least quarterly. Special training to address operational deficiencies must be provided, as required.

c) Records must be kept showing individual training programs and topics covered for each employee including topics covered and issues discussed indicating the date and duration of the session and the instructor. Some documentation of the employee's understanding of the training is required.

d) Training must be presented in appropriate language to be clearly understood by all employees.

e) Training must be provided on the following subjects as a minimum:

i. Good Manufacturing Requirements and Regulatory Basics.

ii. Personal dress, hand sanitation and grooming requirements

iii. Plant sanitation policies and procedures

iv. Food Safety (HACCP) and Quality Control Policies

v. Product tampering awareness and consequences

f) Education outside of in-plant training sessions should be encouraged and documented in employee personnel files.

g) Employees performing critical jobs, such as associated with determining or monitoring HACCP CCPs, should be given additional training or certification. (e.g.; oven operators, retort operators).

h) The following constitute a minimum guideline for Personal Hygiene Practices:

i. A written dress code shall be clearly and prominently available for all employees. It shall be uniformly enforced for all employees, new and part-time, visitors, vendors and contractors.

ii. Employees must wear clean clothing and shoes appropriate for the working conditions.

iii. Dedicated footwear and outer clothing that is proper for the type of processing being conducted should be worn, and, should not be worn outside the plant or laundered at home.

iv. Fine mesh nets or other effective hair restraints for head and facial hair must be required in all production, processing and warehouse areas by all employees.

v. Employees working in production areas must not wear fake fingernails, fingernail polish, jewelry, rings, or watches, etc.

vi. Employees cannot work in food processing areas if they have an infectious or communicable illness, or have open sores on hands, faces or arms, etc. Employees are to notify management if they are diagnosed with a communicable disease transmitted through food or are experiencing symptoms of diarrhea, vomiting, fever or jaundice.

vii. Employees must wash and sanitize their hands before starting to work and at any time that they leave the production area or handle equipment or other items that are not clean or sanitary. If gloves are worn, they must be intact, with no holes, and kept clean. They must also be washed and sanitized, or replaced, if at any time unclean items are touched.

viii. The plant must provide and the employees must use means to avoid contamination of their outer clothing when using the toilet facilities. Coat hooks are generally made available for employees to hang their outer garments outside the toilet facilities.

ix. Eating, drinking or using tobacco products is not permitted except in designated areas.

x. Outside pockets above the waist on smocks, shirts or coats should not be used. No pens, combs, pencils, thermometers, etc. may be carried in these pockets at any time while in the operations area.

xi. Appropriate controls should be in place to prevent the contamination or adulteration of food products in the production areas.

8) **RTE Hygiene and Sanitation** — RTE areas require additional consideration and protection from cross contamination since the products produced in them will be directly consumed.

a) Personnel handling RTE food must wear sanitary gloves and protective sanitary sleeves.

b) In RTE areas, all employees, including maintenance individuals, should wear dedicated footwear and outer clothing that is proper for the type of processing being conducted and should not be worn outside the plant or laundered at home.

c) In RTE areas, maintenance personnel and maintenance tools should be dedicated to the RTE area only. There should be a specific tool sanitizing procedure daily.

d) There should be separate and dedicated tools that remain in the RTE area. A separate and specific parts and tools accountability program for the RTE area should be in place to identify potential product contamination.

9) **GMP Self-Inspections and Corrective Actions –** A key management responsibility is to verify that the policies and programs essential in the management of wholesome food products are routinely and effectively implemented. It is necessary that routine self-inspections of policies and procedures be conducted to assure management that the proper actions are being taken and that the facilities and equipment are maintained to meet sanitary and operational needs.

a) Facilities must have documented procedures for planning and implementing internal self-inspections to verify compliance to policies and to evaluate the effectiveness of the policies.

b) The self-inspections should identify facility, maintenance, pest control, process and sanitation conditions, housekeeping, and personnel hygienic practices for systematic evaluation, prevention and corrective actions.

c) Self-inspections should be detailed and cover the entire facility, inside and out.

d) GMP self-inspections should be scheduled routinely by responsible first line supervision and verified on a random basis by management. These audits should be documented with corrective actions attached. Frequency and verification should be based on need to assure effective control. At least a monthly frequency is recommended.

e) Audits results and corrective actions should be assessed and signed by management to assure timely responses to deficiencies and needed corrective actions.

f) Follow-up audit activities for deficiencies and repeat items shall record the effectiveness of the corrective actions taken. Repeat issues must receive top management priority to effect a timely corrective action.

g) All self-inspection reports showing deficiencies must include corrective actions.

E. RODENT & PEST CONTROL MANAGEMENT

It is required that all food processing, storage and distribution facilities operate under the authority of a licensed pest control contractor. Typically they are individuals from outside the company. They must have a proper license (or recognition), certification and insurance. They should be expected to provide aggressive support to the plant pest control, housekeeping and sanitation programs especially as they relate to potential pest harborages and conditions that compromise the evaluation of pest control. Since they are trained experts in recognizing and evaluating conditions that contribute to potential pest development such as sanitation, housekeeping, properly sealed doors and windows, perimeter accessibility and outside grounds conditions, it is expected that they will include observation comments on these situations in their activity reports with appropriate recommendations***.*** Any comments on the activity reports must have a documented response and corrective action if appropriate.

If pest management is internal, the same level of expertise must be provided. Likewise, the same aggressive approach to the above areas of concern must be required with documented activity reports and responses.

1) **Documented and Specific Pest Control Program** — A written detailed pest management policy and program must be available. The policy should outline and describe all procedures required to ensure that activities conducted by the Pest Control Operator (PCO) and trained employees are carried out in accordance with prescribed policy.

   a) A plant specific pest control manual should be current and updated at least annually.

   b) The policy should identify forms used by the PCO. The activity/action reports should document what chemicals are used, if any, where, why, and with relevant observations of activity.

   c) Management of the pest control program should be assigned to a qualified and trained company employee.

   d) Training of company employees can be by the PCO or other qualified experts. Forms used by the PCO and the company personnel should be the same for uniformity.

   e) A PCO applicator's license and letter of insurance must be on file along with appropriate Material Safety Data Sheet (MSDS) forms for all chemicals used.

   f) Company employees engaged as PCOs must have proof of appropriate training and licensing as required by state or local regulations.

   g) PCO should provide services as needed, based on history of pest activity.

   h) PCO service must be in compliance with contract and pest control policy and activity levels.

   i) Plant personnel assigned to work with the PCO should sign the pest control program and policy. This is to assure understanding of the rodent and pest control program and promote conformance of all pest control activities.

   j) Trained employees or the PCO should conduct effective inspections of outside bait stations at least monthly (weather permitting). Areas of current outside activity should be checked more frequently.

   k) Trained employees or the PCO should conduct effective inspections of glueboards, vector devices, traps, and the like at least weekly. Areas of current inside activity should be checked more frequently.

   l) Site maps for traps, glueboards, bait stations and ILT's (insect light traps) must be reviewed regularly, dated and initialed by the person having responsibility for the program.

m) Rodents should be destroyed and disposed of immediately upon discovery.

n) Subsequent reports should indicate effectiveness of actions.

o) If electronic scanners are used to check bait stations or traps the "tag" must be inside the station or trap.

p) Responsible plant personnel, noting PCO observations and comments, should sign activity reports.

2) **Outside Premises Management (Grounds, Waste Disposal Areas)** — Buildings and grounds must be well maintained. Open areas surrounding the plant should be clean. Grassy and vegetative areas should be cut short. There should be no evidence of litter or debris. Equipment, materials, pipes, pallets, etc. should not be stored directly adjacent to building or directly on the ground or pavement.

a) Outside premises should be free of discarded equipment, litter, pallets, weeds and other clutter that may provide harborage or breeding places or attractants for insects, birds, rodents or other pests or that may inhibit evaluation of premises for pest activity.

b) Around exterior of buildings, a clean or graveled perimeter of a minimum of two feet should be maintained for adequate control and evaluation of pest activity.

c) Adequate trash and waste disposal facilities must be available. Dumpsters should be covered and located so as not to create a pest attractant for the plant or permit odors detectable in the plant. Dumpsters should be emptied frequently enough to prevent development of odors and leakage. Cleaning around and underneath disposal units should be accomplished frequently enough to avoid a problem, typically daily. There should be no accumulation of drainage liquids.

d) Driveways and parking lots should be clean and/or treated to minimize dust and be free of standing water.

e) Grounds should be well drained. There must be no standing water to attract pests.

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

g) All entrances including employee doors, shipping and receiving dock areas should have appropriate protection to prevent the entrance of flying, crawling or running pests.

h) Bait stations used outside should be placed based on habitat and potential access. They should be positioned to prevent the intrusion of casual water and rain and firmly secured to prevent removal from the assigned position or opened by unauthorized personnel.

i) Bait should be "floated" within the bait station and secured to prevent removal from the station. Bagged or other unsecured baits should not be used.

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

a) Inside walls (perimeter and interior) must be maintained in a clear and clean manner to allow for full inspection.

b) Use of an ultraviolet (UV) light by a trained individual to evaluate incoming ingredients, palletized material stored at floor level and storage area perimeters for rodent activity on regular schedule is recommended.

c) All spilled, damaged product or ingredients shall be cleaned up or disposed of immediately to prevent pest attraction.

d) Flying insect control measures such as ILTs (insect light traps), fly paper, etc., should be used at locations near entrances to the operations areas. These devices should be cleaned frequently to avoid accumulation of insects. Control measures must be used at a distance from food or food contact surfaces to avoid any potential for contamination.

e) Only mechanical traps or glue boards may be used inside the facility. All trapping devices must be in proper working condition. No bait stations are permitted inside the plant or warehouse.

f) Trap locations should be recommended by the PCO based on potential access and knowledge of pest habits. Either side of exterior opening doorways must have traps on both sides of the opening inside the doorway.

4) **Pest Tight Doors and Entrance Closures** — All doors, including overhead doors, must be tight closing with no visible light observed between the floor or doorjambs.

5) **Secure Storage and Documentation of Chemicals** — Pest management chemicals should not be stored in the plant facility. It is preferred that these materials be stored by the PCO and brought to the plant location when needed and removed at the time the PCO leaves the facility. If it is necessary to maintain pest management chemicals at the plant, they must be stored in a secured location with limited access. It is recommended that they be stored in a secure structure or building away from the plant or warehouse.

a) A detailed inventory log of chemicals received, quantities used, the date used and for what purpose must be maintained if pest management chemicals are stored on plant grounds. Containers must be destroyed once empty.

b) This inventory must be evaluated regularly to verify that the quantities received, the amount used and the amount currently on hand balance. Any discrepancies must be evaluated and explained.

6) **Activity Reports Detailed with Corrective Actions** — Activity reports by the PCO and plant personnel must be available for each inspection and whenever activity is observed.

a) Activity reports should indicate the evidence of pest or activity such as gnawing, digging, droppings or stains from the outside bait stations, inside traps or glue boards and flying insect control units. They should also document any conditions outside or inside that would compromise the pest management program or make it difficult to evaluate.

b) PCO activity reports must indicate specific sites of activity, type of activity, recommended corrective action, specific chemicals used, quantities used, locations where used, the date used and for what purpose. Reports should indicate lot numbers of chemicals.

c) Activity reports should include recommendations for corrections of deficiencies. Repeat deficiencies or activity should be highlighted for specific management action.

d) Activity reports must be signed by the PCO and by a designated plant representative when the report is presented to the plant.

e) Each deficiency must be addressed with corrective action documentation. This may be on the activity report itself or attached to the report.

F. RECEIVING & INVENTORY CONTROL

The plant is expected to have detailed, written policies describing how the receiving, acceptance and handling of ingredients and materials is performed and documented.

1) **Incoming Vehicle Inspection and Documentation** — There must be a program to control materials received for plant use.

   a) Plant must have a written inspection program for all inbound carriers that fully describes acceptable and/or unacceptable conditions.

   b) All railcars, trucks, etc., must be inspected at time of receiving to assure condition, cleanliness, and that they are free of moisture and free of offensive odors. Carriers must be in good repair, with no evidence of pest activity and free of foreign substances such as glass, chemicals or odors.

   c) Interior of trailers, trucks or cars must be free of loose or broken boards, nails, and holes in sheet metal sides that could cause contamination or pest harborage.

   d) Trailer, railcar or tanker security seals must be verified as the original seal number applied at the original shipping point.

   e) For temperature sensitive ingredients, receiving vehicle temperature and product temperature must be documented on receiving documents.

   f) Documentation of condition of each inbound shipment must be shown on receiving documents.

2) **Specific Receiving Policies with Inspection and Acceptance Plans** — Materials for use should be from approved sources and purchased against established specifications.

   a) All ingredients and supplies must be purchased from approved vendors. The company should have a documented vendor approval system. Food safety and security evaluations of vendor manufacturing and warehouse sites is recommended.

   b) Current specifications for purchased ingredients and supplies must be available.

   c) Continuing Letters of Guarantee must be current and available for all ingredient and packaging materials, for which there is not a specific Certificate of Analysis (COA).

   d) Incoming materials, ingredients and other “goods” must be inspected for damage, contamination, etc. A policy describing acceptable and/or unacceptable conditions must be available to the receiving personnel. The inspection program must include:

      i. Specific damage evaluation procedures with acceptance criteria.

      ii. Sampling plans describing which ingredients are subject to in-plant testing and which ingredients are accepted based on Certificates of Analysis (COA).

      iii. Specifications for ingredients and tests to be performed with testing frequencies and accept/reject limits.

      iv. Foreign material contamination checks.

      v. Microbiological evaluation, if required.

      vi. Documentation records of all receipts and results of inspection evaluations.

      vii. Wash certificates must be provided for bulk containers.

e) When possible, tamper evident packaging should be used on the incoming ingredients and packaging materials from the suppliers.

i. Such packaging could consist of: sealed bags; sealed containers; stretch-wrapped pallets with a security band provided around the stretch-wrap; covered and sealed totes, etc.

ii. The presence of integrity of this packaging should be verified upon receipt at the facility and documented.

iii. Specifications should be provided to indicate which goods would have what types of seals. Trained persons should utilize this list at the time of receipt.

iv. Tamper-resistant/-evident packaging may not be feasible for all goods received, but the facility should provide a documented assessment to indicate it was evaluated for the various goods.

f) Records must be maintained to match supplier codes to the materials received. These codes are necessary for lot traceability. Records must be available to trace back to all sources of ingredients and supplies.

3) **Release Criteria for Ingredients —** All ingredients must be maintained in a secure fashion and released for use against a defined program.

a) Inventory management system must document that ingredients and goods are used in proper rotation.

b) Control procedures must be in place to prevent use of ingredients before approval and to assure that non-conforming materials are not used.

4) **Storage and Handling Policies and Practices** — Procedure must be established to assure ingredients and supplies do not become a source of contamination.

a) Incoming goods, ingredients and packaging materials should have traceable lot codes upon receipt. These lot codes must follow the item throughout storage.

b) An incoming material tracking program must be in place to trace ingredients and product contact packaging from receipt through use in finished product.

c) Receiving docks and areas around and under docks must be clean and free from litter, spilled material, food residues, standing water, etc. The docks and receiving areas must be maintained orderly, clean, and free of equipment or pallet accumulation that interferes with daily cleaning.

d) Dock levelers and dock plates must be included on the Master Sanitation Schedule.

e) Warehouse storage areas must be clean and orderly, with no spilled, damaged or exposed product. Opened product containers should not be stored in the receiving storage areas.

f) Slip sheets shall be used when double stacking palletized ingredients to protect the material from dirty or damaged pallets.

g) Temperature sensitive areas must be properly monitored with daily logs to verify that appropriate room temperatures are maintained.

5) **Bulk Receiving Systems – Sanitation and Monitoring** — Bulk ingredient hoses, piping, and storage tanks must be capped, locked and maintained in a sanitary manner, with a documented cleaning procedure. Flour silos must be cleaned at least annually or more frequently, based on sifter tailings documentation or other pertinent evidence. Ingredients should be filtered or screened as they are received into the bulk storage containers. Filter or screening size should be appropriate to the product and its intended use.

6) **Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds —** All restricted or sensitive ingredients, potentially toxic chemicals and allergenic materials must be maintained under strict control and stored separately to minimize the potential for accidental product contamination.

   a) Toxic chemicals and flammable solvents must be stored in areas away from the ingredient and packaging storage areas. The storage area should be locked, with access restricted to properly authorized personnel.

   b) Usage records and inventories should be maintained on toxic materials.

   c) Curing agents for meat products must be properly secured and placed in locked storage, with documentation of use.

   d) Sensitive ingredients and/or ingredients associated with allergenic reactions should be identified upon receipt and placed in designated areas with clearly visible marking identifying them as ingredients needing special control.

   e) Material Data Safety Sheet (MSDS) information must be readily available for all chemical compounds in the facility.

G. PROCESS & PRODUCT EVALUATION

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

1) **Process Control and Documentation Procedures —** Food must be manufactured under a documented control procedure. The procedures must take into consideration all food safety aspects.

   a) Effective application of the HACCP plan must be clearly evident by the presence of identified CCP monitoring points with proper and complete documentation.

   b) HACCP documents must be clearly identifiable showing the CCP being monitored, the responsible operator, the critical limit, monitoring frequency, the action to be taken when limits are exceeded, the corrective actions required, the signatures required by operational and supervisory personnel.

   c) Designated personnel should properly sign pre-shipment review of CCP records.

   d) Manufacturing processes that have measurable elements that are important to the quality or consistent production of food or packaging should have monitoring programs that provide operators and management with records of performance (i.e. dwell time, temperature, line or belt speed, pressure, count, weight, etc.) It is essential that specifications be developed by the customer and/or plant that define acceptable product attributes. Each specification should be maintained and tracked under a defined quality assurance program.

   e) Plants that produce Ready-to-Eat products by subjecting product to lethal heat processing steps must demonstrate that minimum temperature variation exists in the heating media or chamber. Likewise the plant must demonstrate that the minimum temperature of all products released for sale meet or exceed the HACCP critical limit control point or minimum temperature specifications.

   f) In-process ingredients and products must be adequately protected and properly labeled with date and lot number.

   g) A parts and tools accountability program for processing areas should be in place to identify potential product contamination.

2) **Specification and Formulation Control and Accuracy** — In addition to specification compliance, there must be procedures for assuring control of product formulations.

   a) Records must be available demonstrating compliance to all manufacturing and finished product specifications including customer specifications.

   b) Products with multiple ingredients must have appropriate formulation controls available to the operators with regular verification of accuracy.

   c) Blending and mixing records should show times and quantities and lot identification of ingredients used.

   d) Production records must be maintained for twelve months beyond product shelf life. This is to assure continual compliance to customer and plant and regulatory requirements.

   e) Both objective and subjective measurements may be used to evaluate each attribute as written in the specification.

f) Test protocols and frequencies must be followed as identified in the specification.

g) Issues, concerns or requests for changes regarding the accuracy, completeness, or frequency of testing must be addressed with the customer, with changes only permitted with written authorization.

3) **Routine Calibration of Operational Equipment and Measuring Devices** (such as thermometers, scales, flow meters, metal detectors, etc.) — It is essential that all measuring, metering or protective devices be properly calibrated to assure the accuracy of these activities and the effectiveness of their performance. Accurate measurements are critical for monitoring HACCP CCPs.

a) Key process control devices such as thermometers, scales, recording devices, etc., require routine calibration or certification by an outside contractor at least annually. There must also be a program to evaluate the performance of measuring devices on a regular basis to assure accuracy on a day-to-day basis.

b) There must be procedures in place to verify, on a daily basis, the accuracy of thermometers used for product evaluations. The thermometers must be identifiable with documentation of calibration results.

c) Thermometers should be calibrated at the temperature range at which they are used.

d) Thermometers must be calibrated. It is recommended that accurate intermediate thermometers be used to verify the daily calibrations where the intermediate thermometers are checked against the certified National Institute of Standards Testing (NIST) unit weekly to prevent excess use and handling of the certified thermometer. Full documentation of the calibration of the intermediate thermometers must be available. If applicable, the use of ice baths is allowable.

e) Assigned personnel must check Receiving and Distribution scales daily to verify that they are accurate. Documentation of these checks must be available and can be part of the routine daily records for the activity being measured. Test weights in the range of the measurements should be used.

f) Assigned personnel must check scales used for weighing ingredients, filling and finished product preparation daily. Standard weights in the range of the weights being produced must be used for these verification checks. Daily calibration checks must be documented.

g) Flow meters should be regularly calibrated for accuracy, as recommended by manufacturer.

h) Calibration procedures should describe the frequency of testing, the testing method and the acceptable range of variation. Corrective actions should be specified and noted when exercised.

i) There must be documentation of corrective actions when a non-calibrated or inaccurate measuring device has been used (thermometer, scale, flow meter, counting device, metal detector, coder, etc.). All products produced since the last acceptable check must be assessed to determine if it must be held for further evaluation.

4) **Foreign Material Control** — All finished packaged product must be scanned through a detector calibrated to identify and remove the contamination likely to occur. Typical detection systems include metal detectors and/or x-ray detection. Other measures that are in place to prevent physical contamination for certain food products are acceptable. Such measures would include liquids that pass through a fine mesh screen, free-flowing items that pass rare earth magnets or food items that are secured in the final package with metal fasteners, but pass through metal detectors in the filling process. These “other measures” must be calibrated, monitored and documented.

a) There must be a written procedure describing the maintenance, set-up and verification tests of detector systems. The procedure shall describe the initial set-up procedures and frequency of verification checks with actual product at start-up, during the shift and at the end of production.

Test units to check equipment performance must be used and appropriate for the nature of the product and the size of the package. Detectors must be set-up at the beginning by qualified personnel and calibrated for the particular product being run. Documentation of calibration and set-up must be part of daily production records along with initial, operational and final verification checks.

i. Detectors must have calibration verified by placing the test units or cards containing them along with the first product or package through the detector. For metal detectors, calibration must include the use of ferrous, non-ferrous and stainless steel test samples and the placement should be in a manner where the test units pass through the geometric center of the metal detector aperture. Customer specifications must be used if available. At the start of the production run, the first product through must be tested to verify performance and ability to detect and reject the specified test units.

ii. A successful verification check is considered to be three consecutive successful passes for each test unit.

iii. Product used in the verification checks must be re-run through the detector after the test units have been removed from the package. Test units must be placed along with the product in a sanitary manner so as to avoid product contamination. Special care must be given to make sure that test units are promptly recovered from the test packages.

iv. Frequency of verification checks should be at least every two hours or scheduled at break times, if appropriate. If the verification check occurs at an employee break, then the unit should be checked with last product produced prior to break and with first product when production resumes. Some customers may require more frequent verification checks.

v. A verification check of the detector performance shall be made on the last product run during the shift or lot. This will provide documentation that the detector was functioning properly from beginning to the end of production.

b) Initial reject units from the detector must be retested and acceptably pass 3 consecutive times before accepted as a false positive. The detector must be properly calibrated at the time the rejected product is retested. Reject units must be opened promptly and examined to determine the source of the problem.

c) A record of detector rejects and the cause for rejection shall be recorded on the calibration/test log.

d) In the event the detector fails a verification check, all the product since the last successful documented verification check must successfully pass through a properly functioning detector device.

5) **Application of Statistical Control** — Measurements of variable data from operational control points such as specifications, control points or critical control points should be based on statistical methods. Records of these measurements should be on control charts or other forms that indicate the level of performance on a continuing basis.

a) Basic statistical principles should be used in routine measurements of operational performance such as weight control, temperature control, sanitation, employee hygiene, etc.

b) Records should show the target or desired control point with upper and lower control limits and the critical limit if appropriate.

c) Responses and/or corrective actions should be made on both trends and major deviations from the control limits.

d) Process critical limits for CCPs must be based on sound process capability. Management of these limits must be based on individual data points and not on averaged data.

6) **Allergen and Sensitive Ingredient Controls** — In facilities where allergens or sensitive ingredients are used or stored and there is a potential for cross-contamination, there must be detailed procedures to prevent the contamination of other products.

a) Production of products containing allergens should be on dedicated lines or equipment. If this is not possible, then the following practices must be in place:

i. Allergen containing products should be scheduled at the end of a shift.

ii. Equipment used for allergen products must be disassembled and chemically cleaned prior to use for non-allergen products.

iii. Verification of the cleaning process must be documented.

b) Ingredients containing allergens must be clearly identified as such and properly controlled or isolated in the production or batching areas to prevent contamination.

c) Use of rework should be carefully scrutinized to assure there is no cross-contamination of ingredients into non-allergen containing products.

d) Formulation changes should be carefully scrutinized to assure there is no inclusion of allergens into products that were not intended to contain them.

e) Utensils used for these ingredients must be dedicated and not used for other ingredients unless there is a thorough cleaning and sanitizing procedure applied between uses.

f) Labeling for allergen containing products must indicate the presence of the allergen or sensitizing agent, as required by regulations.

g) Employees handling ingredients and products that are, or contain, allergens must not handle non-allergenic products without a complete change of outer garments, hairnets, sanitary gloves and protective sleeve guards.

h) Clothing used in allergen sensitive products should not be co-mingled with clothing from non-allergenic production.

7) **Documentation Showing Product Meets Specifications** – Quality programs rely on documentation to confirm that the desired quality parameters were achieved. Records must be maintained to assure that the appropriate product attributes were evaluated and that the results were consistent over time.

a) Finished product must have documentation verifying that the product meets specifications. Records validating inspection must be available for review.

b) A finished product evaluation procedure must include frequency of testing, documentation of results and availability of records for 12 months beyond the product shelf life.

c) If the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply.

d) No product shall be shipped until all the activities specified in the food safety and quality plan have been made available to and approved by management.

e) Records shall identify the inspection authority responsible for the release of product.

8) **Rework and Carryover Products —** The plant must have a documented procedure for managing rework. Rework should be treated as an ingredient and the plant must be able to trace rework to its original production and component ingredients.

   a) The plant must be able to trace the usage of all rework products into finished product. Rework is defined as product not meeting initial specifications and requiring reprocessing or product carried over from one lot to a subsequent production lot thus commingling lots.

   b) The responsibility for assessment and release of rework product must be specified.

   c) Rework or carryover product must be clearly identified with the date of production and original lot number if appropriate. There must be adequate documentation to assure that product tracking records are complete and can easily identify the batches and lots where the product was used.

   d) Production dates and original lot numbers must be carried forward in production documents when the material is ultimately used.

   e) Rework or nonconforming product must be handled in accordance with documented procedures. Product awaiting disposition must be stored in a dedicated place or exhibit an obvious physical indication of its status, i.e. on hold or rework. A computer block alone is not acceptable. Disposition may be as follows but must be clearly documented:

      i. Reworked to meet specified requirements.

      ii. Accepted with or without repair by written authorization from client.

      iii. Re-graded for alternative applications.

      iv. Rejected or scrapped.

   f) All rework/carry-over must be kept to a minimum and used promptly at the first opportunity. There must be a routine and documented “clean break” in the rework/carryover cycle. A rework cycle of one week is generally considered the maximum liability most companies should take if a recall becomes necessary.

   g) A documented “same-into-same” policy regarding rework and carryover products must be in place.

9) **Analytical Records Management** – An integral part of the food safety function centers on accurate, available product information used for decision making. Quality systems must be established to properly store and retrieve analytical information, documents, reports, records, etc. Records and reports of analytical information gathered by organizations (internal and external) must be cataloged and maintained in a fashion that can provided feedback for operational control. When an outside laboratory is used, documented procedures must be available to properly interpret and manage the information provided.

H. PACKAGING & LABELING

Procedures and policies must be in place to assure proper labeling of products. Labels used must accurately represent the product in the packages. Product coding systems must provide adequate information for recall purposes.

1) **Label Accuracy and Regulatory Compliance** — The facility should have a program to assure that labels in use and product being produced are matched. Plants with variable or optional product formulations must be able to demonstrate that the proper label is always used.

   a) Labels must satisfy regulatory requirements and must include: Accurate Product Name, Ingredients, in descending order of predominance, Handling Statement (Keep Frozen or Keep Refrigerated, if required), Appropriate "Manufactured by" or "Manufactured or Distributed for" signature line, Nutritional Labeling and Safe Handling information, if appropriate for meat or poultry products.

   b) Sensitizing agents or allergenic ingredients must be included on the label of products containing allergenic or sensitizing ingredients.

   c) There should be some method of matching the proper label with the product or production schedule or formulation, particularly where there are multiple products, customers or formulations that could be used.

2) **Documented Net Weight or Count Compliance Policy and Performance** — Plants must have a documented policy for net weight, liquid contents or product count to verify compliance to label requirements and/or specifications.

   a) Scales used to determine final product weight must be verified for accuracy by designated individuals. Standard weights in the range of the products being labeled must be used. Calibration checks must be documented on the production records. These calibrations checks must take place at the beginning of the production day, and at the end of the day, to assure all products are properly weighted. More frequent checks are recommended.

   b) All scales used for net weight control must have documented weight and tare weight verification checks at an appropriate frequency. Hourly intervals are recommended.

   c) Product counters must be verified per manufacturer instructions.

   d) Records must be available showing status of conformance and verification checks.

3) **Clear Manufacturing Codes on Individual and Cased Product** — Clear coding is essential for proper management of production lots and traceability and must meet customer specifications.

   a) All product coding and label information must be of such size, color and contrast to afford easy legibility at a reasonable distance.

   b) Code may be "open code", sell-by, use-by, or cryptic code, such as the Julian system, that is clearly understood by both the customer and plant operation.

   c) Each individual sell unit must have a production or lot code. The individual package code date and the case code date must be the same.

   d) Lot codes should be chosen to minimize food safety risk and generally should not designate a production run greater that one shift or a single day's production.

   e) The product information on the shipping case must agree with the product information on the individual packages in the shipping case. Each package in the case must bear the same information.

4) **Package Integrity and Function for Distribution** — Both the sell unit package and the shipping case must be designed and **assembled** to provide the necessary protection for the product from environmental and shipping conditions.

   a) Plant must have an effective program to assure that the product packages and the shipping cases (master cases) are properly closed and sealed.

   b) Documentation of test to assure proper closure should be available describing test methods and specifications.

   c) Master cases must be appropriately sized to provide adequate protection to the internal product.

   d) Master cases must be intact and adequately sealed to prevent contamination.

   e) Product cases in the warehouse should show no evidence of leaking or staining. They should not bulge or crease due to stacking. There should be no evidence of opened or partially open case flaps in the warehouse or when product is ready for shipment.

   f) There should be no evidence of opened or partially open case flaps in the warehouse or when product is ready for shipment.

5) **Label Security and Obsolete Label Controls** — There must be a written plan describing the security measures for labeling materials to prevent unauthorized or accidental use and to prevent the use of obsolete labels.

   a) Labels should be stored in a secure area with only authorized personnel having access and issuing labels.

   b) There should be a procedure for immediate isolation and securing or destroying obsolete labels. Obsolete labels should be obliterated or effectively destroyed so that they cannot be salvaged and reused.

6) **Tamper Evident Packaging —** When possible, tamper evident finished packaging should be employed. Such packaging could consist of: sealed bags; sealed containers; stretch-wrapped pallets with a security band provided around the stretch-wrap; covered and sealed totes, etc.

   a) When tamper evident packaging is used, monitoring programs shall be put in place to insure that tamper evident features are effectively applied.

   b) Specifications should be provided to indicate which goods would have what types of seals. Trained persons should utilize this list at the time of packaging.

I. STORAGE & SHIPPING

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

1) **Warehouse and Finished Product Management** — Warehouse conditions must be maintained and controlled in a manner to assure product integrity.

   a) Finished product, packaging materials, equipment or ingredients shall not be stored in close proximity to any chemical, cleaning product, pesticide or other nonfood materials. Such nonfood items must be stored in separate areas that can be closed and secured, away from any food materials or ingredients.

   b) Processed ready to eat products shall not be stored below or near unprocessed raw products.

   c) Only properly packaged product in undamaged containers may be stored in and shipped from the warehouse. Product not "cleared" for shipment, or held for any other purpose, must be clearly identified and not stored in a location in the warehouse where it is likely that it may be shipped in error.

   d) Damaged, leaking or unsound product shall be immediately isolated and placed on hold for evaluation by designated personnel. Product disposition should be timely.

   e) Partially used or previously opened ingredient containers must not be stored with finished product. Such product may be stored in a designated separate storage area, if it is properly identified and sealed to prevent contamination.

   f) There should be a policy requiring a first-in/first-out (FIFO) stock rotation practice.

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

   a) Policies and Practices for Retained and Returned Products.

      i. The plant must have a written policy for retained and returned products that describe individuals responsible for evaluating product and making decisions regarding disposition of it. The policy must be understood by all authorized personnel.

      ii. A Hold Tag policy must include a permanent written log of each product or item placed on hold. The log should list the date, the product, the quantity, the reason for the hold, the results of the evaluation and the disposition. Disposition must be dated and signed.

      iii. The plant must have a policy and procedures for handling returned products.

      iv. Returned products must be identified and placed on hold immediately.

      v. Documentation must be in place that identifies product that has been re-shipped.

   b) Designated Areas for Retained and Returned Products

      i. Products returning to a processing plant must be handled securely.

      ii. There must be a designated, clearly identified area for returned or retained products or product must exhibit an obvious physical indication of its status, i.e. on hold or returned. A computer block alone is not acceptable.

iii. Returned or retained products must be clearly identified as such.

c) Verification and Release Documentation

i. Documents must be available to show the current location of products not cleared for shipment, as well as those that are authorized for sale.

ii. The disposition of product should be designated by rejection, acceptance, acceptance with restrictions or re-grading for an alternative use.

iii. Disposition or corrective actions must be commensurate with the seriousness of risk identified.

iv. All non-conforming product must be handled or disposed of according to the nature of the problem and/or the specific requirements of the customer.

v. Product destined for destruction must be adequately secured and disposed of promptly.

vi. Disposition of non-conforming material must be tracked to ensure that inventories are adjusted accordingly to facilitate recall.

vii. Damaged or destroyed materials must be recorded and proper adjustments to the product inventory records must be made to accurately account for the damaged or destroyed materials.

viii. An inventory log must be maintained showing current product on hold and list the disposition of all released product with proper authorization.

ix. At least weekly there must be a physical accounting of the product on hold to verify that actual product quantities match records. Discrepancies should be treated as a serious food safety failure.

3) **Storage Facility and Dock Maintenance —** Warehouse storage areas must be clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Racks and pallets will be used as necessary.

a) Product shall not be stacked so that it blocks blowers or vents preventing the circulation of air.

b) Items stored in all warehouses must be a minimum of 6” off the floor (standard pallets are acceptable).

c) Wall perimeters must be maintained in a clear and clean manner to allow for full inspection.

d) Pallets, racks and shelving must be clean and in good repair.

e) Floors and walls shall be in good condition, free from holes or damage.

f) Emergency doors must be tightly fit with no evidence of light showing around the door to prevent the entrance of pests. Such doors should be alarmed and the alarm operable.

g) Floors under pallets, racks and in aisle ways must be clean and free from dirt, accumulated debris, spilled product or broken pallets.

h) Shipping docks, dock plates, dock levelers and areas around and under the docks must be clean and free from accumulated debris, food materials, water, etc. These areas should be on the Master Sanitation Schedule.

i) To avoid case contamination, the top of cases must be protected when stacked.

4) **Transport Condition —** Only acceptable carriers should transport food products. Procedures must be established to minimize concerns that could occur with improper product handling after the finished products leave the facility.

   a) Written procedures describing acceptable and/or unacceptable carrier conditions must be available to shipping personnel.

   b) All outbound trailers must be inspected for conditions, odors and sanitation. Inspection results must be documented on shipping documents.

   c) No product may be loaded into unacceptable carriers. Trailers must be cleaned if necessary.

   d) Trailers and railcars must not be cleaned at the dock, as this creates a sanitation problem and a potential for pest harborage.

   e) Transports should be dedicated for food products only. If non-dedicated carriers are used, trailer logs must be assessed to determine if unacceptable materials have been present.

   f) To avoid case contamination, the top of cases must be protected when stacked.

5) **Release Authorization to Ship Product —** Product can be shipped only with proper authorization.

   a) There should be a policy describing the release of finished product. This should be a controlled process that assures that no product is shipped until it has formally passed quality parameters, regulatory requirements and HACCP CCPs prior to shipment.

   b) Products produced under mandatory USDA HACCP programs must have an authorized signed release verifying that all HACCP records are complete, properly signed and that there are no CCP deficiencies prior to shipment.

6) **Product Traceability —** Plant must have procedures to effectively trace specific lots of ingredients, food contact packaging and finished products through the shipping and distribution channels. The plant must be able to demonstrate that the traceability plan works effectively by conducting "traceability exercises" as outlined in the "Recall Plan" requirements and restated here. Traceability exercises.

   a) Must be conducted at least twice per year to the first level of distribution. Annually a traceability exercise through the first level of distribution should take place to assure continuity of product traceability and documented confirmation from the distribution center should be provided on the amount of the product received.

      i. The traceability exercise should involve those departments and personnel who would be involved in an actual recall. Back-up personnel should also be involved.

      ii. A management assessment of each traceability exercise after the exercise is completed must be conducted and provide a balance sheet of total quantity of product produced subject to the exercise vs. product shipped, product on hand and product otherwise documented (damaged, lost, samples, etc.), product unaccounted for, a calculated percent recovery and any corrective actions identified.

      iii. The expectation of a traceability exercises is that identified lots of ingredients or food contact packaging can be traced to lots of finished product and to the first level of distribution at a 99.5% to 105% level within 4 hours. Failure to meet these requirements necessitates a repeat traceability exercise until the criteria are met.

J. LABORATORY SUPPORT

When conditions warrant, laboratory support functions provide very valuable information to assure process control, food safety and product quality.

1) **Laboratory Facility and Staffing —** The plant laboratory for chemical, physical and microbiological evaluation of ingredients, in-process components and finished product must be adequately equipped and staffed to provide the essential technical support to the plant. The laboratory should comply with the procedures outlined in Good Laboratories Practices (GLP) policy. (Reference 21CFR Part 58)

    a) Laboratory staff must have documented qualifications by way of specific training, certification or other forms of credentialing.

    b) Laboratory must be clean, orderly and well lit. It should have appropriate equipment and instruments to provide effective evaluation of the ingredients and finished product.

    c) The laboratory should be isolated from the production area so that it does not contribute to potential contamination.

    d) The laboratory should be vented directly to the outside and under negative pressure.

    e) Microbiological testing areas should be isolated and only designated personnel permitted access.

    f) Pathogen analyses must not be performed at a plant laboratory unless there is competent professional supervision and there is an effective program to secure pathogen organisms from misuse, i.e. locked, secured and restricted storage, documented inventory control and formal procedures to address any potential breach of security.

    g) The laboratory and laboratory supplies should be secured to prevent unauthorized entry during or outside of normal operational hours.

    h) All toxic supplies must be securely stored and properly labeled.

2) **Laboratory Procedures and Documentation** — Laboratory procedures shall be documented with proper authorization and dates.

    a) Testing procedures shall be based on recognized and approved procedures.

    b) Documentation of all testing shall be available, including records of COAs where in-house testing is not performed.

3) **Laboratory Equipment Calibration** — It is essential that every laboratory have a detailed and documented calibration program for instruments and measuring devices.

    a) Balances and laboratory test equipment should be calibrated (certified) by a competent certifying company at a prescribed frequency as defined by the manufacturer. Records of this certification shall be maintained.

    b) Additionally there should be an in-house policy for frequent calibration of test equipment including scales and thermometers. This should include daily checks of scales and thermometers with appropriate test weights and standard thermometers.

    c) The lab should have on hand at least one standard NIST certified thermometer that is used as the reference thermometer to calibrate other standard thermometers that are used in the daily calibration checks. Documentation logs of all calibrations must be complete showing date, instrument identification and person performing checks.

d) All thermometers and scales or balances should be checked at the beginning of the shift with adequate and complete documentation. Documentation may be on routine data sheets.

4) **Analytical Accuracy Verification** — There must be documented evidence that the results of the laboratory are accurate and reliable.

a) Quality manual test procedures, work instructions, training records and record keeping must be established to verify that monitoring is occurring and that the results meet specifications and finished product requirements.

b) Laboratory should participate in a check sample program with a recognized laboratory to verify reliability and accuracy.

c) Plant must have documented detailed procedures for all microbiological, physical and chemical tests performed.

d) Microbiological tests procedures must meet accepted standards (BAM, USDA or recognized authority).

e) Chemical test procedures must meet accepted standards (AOAC or recognized authority)

K. PRODUCT SECURITY

In the United States, the National Infrastructure Protection Center has identified the food system as one of the eight critical infrastructures that could be negatively affected by malicious attacks.

The following Security section is in part based on the FDA/CFSAN — Guidance for Industry: Food Producers, Processors, and Transporters: Food Security Preventive Measures Guidance. Key elements of this guidance have been included in this audit. For a full understanding of this guidance go to http://www.cfsan.fda.gov/~dms/secguid6.html

FSIS has also created a self-assessment guideline for food processors titled "Food Security Guidelines for Food Processors". These guidelines are available at the following link.

http://www.fsis.usda.gov/oa/topics/SecurityGuide.pdf

The associated self-assessment checklist is available at …
http://www.fsis.usda.gov/PDF/Self_Assessment_Checklist_Food_Security.pdf

The checklist is a very useful tool that helps drive you through the process of evaluating the security measures at your facility. It addresses all aspects of security including plan management; interior to exterior physical security; receiving, storage and shipping; utilities and personnel. In part, it has been used along with the guidelines listed above to establish the security criteria that follows.

In addition, the following criteria is based on accomplishing concerns already covered in this audit (receiving & shipping, allergens, labels, etc.) that would otherwise be listed as security concerns here if these were separate Food Security Criteria.

The specifics of a security program shall be considered confidential. Only the essential details should be made available to employees.

The FDA 24-hour Emergency Contact Number is 301-443-1240.

USDA Food Safety and Inspection Service, Emergency Response Division, 24-7 Emergency Operations Center number is 202-720-5711.

1) **Management —** Management must provide specific emphasis to identifying those existing policies and programs that can be applied to a product security program and identifying other areas of vulnerability that must be addressed to complete a comprehensive food supply protection program. Management must utilize both internal and external resources to identify, organize, communicate and implement a documented product security program that is fully understood by plant employees, suppliers, customers, and regulatory agencies.

    a) Product Security Risk Evaluation — Each facility shall implement a product security risk evaluation by conducting an Operational Risk Management (ORM), CARVER + Shock (program used by U.S. regulatory agencies) or similar process. This process will help prioritize the preventive measures that are most likely to have the greatest impact on reducing the risk of tampering or other malicious, criminal, or terrorist actions against food. A crisis team must be established that will evaluate the vulnerabilities and risks that exist from ingredient sourcing, storage, processing, shipping of finished goods and personnel.

    Product and facility security roles and responsibilities shall be documented and defined regarding the development and maintenance of guidelines, training and enforcement of requirements and procedures.

    Every element of the facilities process shall be evaluated for its potential risk to security from intentional internal and external factors. Appropriate management controls shall be initiated and

the process should be reassessed at least quarterly to help verify and validate security measures and assure that they are current with changes that may have occurred.

b) Ingredient Isolation — The crisis team shall develop a plan to isolate and remove any potentially compromised ingredient or material and to restore security of the manufacturing process that will facilitate a timely return to production of safe and wholesome product. As dictated by the circumstances, a comprehensive assessment by food safety personnel, general management and the applicable regulatory agency shall be accomplished to determine the suitability of ingredients and plant security prior to resuming any production operations.

c) Incoming mail and packages — Procedures should be written to describe how suspect packages must be handled. This program should include items received from the U.S. Postal Service and all private parcel services. Employees handling incoming mail and packages should be trained and training should be documented.

d) Computers — A procedure to back-up computer systems and documentation critical to food safety should be developed. Access to computer systems should be limited to authorized personnel only.

e) Off site warehousing — All off-site warehousing, manufacturing, and distribution that is in the facility's control should be included in the facility food security programs, unless it is documented that these locations have an independent food security program.

f) Plant Registration — The plant, warehouse or distribution center shall have registered their plant with the FDA under the PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002. The facility shall have obtained and shall demonstrate their registration number from the FDA or their facility ID number from USDA. Access the FDA Bioterrorism web site by going to: http://www.fda.gov/oc/opacom/hottopics/bioterrorism.html

Failure to register is a "Major" deficiency.

g) Unusual Occurrences — Employees should be encouraged to report unusual occurrences by having a procedure in place that makes it easy to do so quickly and in an appropriate manner. Occurrences shall be documented and assessed by management. An unusual occurrence could be an employee who acts unusual, i.e. unhappy, despondent, antagonistic or without an identifiable purpose. An employee who stays unusually late after or arrives unusually early, one who accesses files, information or areas of the facility outside of the areas of their responsibility or asks unusual questions. Other unusual occurrences could include processing irregularities, visible, microbiological and chemical changes in water quality. Non-daily events such as glass breakage, plant tours and third party inspections should receive management oversight.

h) Written policies and procedures should be developed for security patrols of the facility and grounds.

2) **Human Element —** An effective system must be in place to assure that only authorized personnel have access to the facility and that their whereabouts is monitored and recorded at all times.

a) Screening — A written screening program shall be in place for all employees, including management, seasonal employees, temporary, and contracted services, e.g., pest control, cleaning services, maintenance contractors, etc. Any persons not included in this pre-hiring screening program should be covered by the facility visitor policy.

b) Identification — A positive identification and recognition system shall be in place. All individuals entering the facility shall show proof of identification with the individual's name (badge with picture is recommended). The system utilized should be able to track which employees are present at all times in the facility.

c) Training — A written program shall be developed and used to train food security rules at the facility. This program should include plant specific rules, how to recognize and address signs of and evidence of tampering, reporting instructions in the event of a food security issue (threats, chemical spills, wrong doing, etc.), and the severe criminal nature of tampering with or deliberate contamination of food products. The training shall be documented for each individual at the facility.

d) Employees: Plant shall maintain a current and accurate roster of employees and work assignments. Employees shall be prohibited from bringing personal items such as purses, cases, containers, lunch boxes, etc. into processing areas. Temporary employees shall be fully supervised at all times. Arriving employees, including office personnel should not be allowed to enter production, warehouse, maintenance shops, laboratories, or other non-break areas prior to placing personal belongings in designated storage areas.

e) Contractors — Facility shall have a documented contractor policy and procedures. A contractor identification badge should be issued by the plant. There must be a contractor sign-in and sign-out log which verifies they have received a copy of the plant's GMP and food safety hygiene rules. Tool boxes and lunch containers should be subject to inspection upon entry to the premises. Contractor personnel must be restricted to defined work areas and not allowed to other areas of the plant.

f) Visitors — Facility must have documented visitor policy and procedures. A visitor sign-in and sign-out log must verify they have received a copy of the facility GMP, personal hygiene rules and plant policies. Visitor identification must be verified. Access to plant must only occur if accompanied by a designated employee.

3) **Facility** — Policies and procedures must address access to and from the plant grounds and the manufacturing and storage facility.

a) A schematic of the facility and outside grounds must be available that identifies all entrances into the building, accesses to the roof and sensitive areas (bulk storage tanks, bulk loading/unloading areas, etc.).

i. Access to sensitive areas shall be restricted and locked and a method should be developed by the facility to monitor employees entering sensitive areas. All employee entrances should be locked or manned. Any normal routes (unlocked or unalarmed) of personnel entry/exit should be monitored on a continuous basis to ensure unauthorized persons are not permitted access.

ii. Water supply, utilities, gas, bulk ingredient storage and chemical storage are some areas that shall be restricted.

iii. During off hours or times of shutdown; i.e., evenings, weekends, holidays or vacations, all ingredient, water and bulk storage tanks shall be effectively secured.

iv. At all times, the following shall be secured when not in use: non-traffic doors (e.g. emergency exits), dock doors, railcar unloading areas, unloading pits, pneumatic pipes and hoses used for receiving bulk ingredients.

b) Security Devices — The plant shall have a documented process for issuing, tracking and retrieving keys, identification badges and passes for the buildings and for secure areas.

c) A chain-link fence or other suitable barrier (sufficiently restricting unauthorized access) should be provided around transport vehicles and production plant buildings.

d) The facility should establish regular patrol of outside grounds, outbuildings, and roof. The patrols should be documented and suspicious activity investigated with law enforcement notified as deemed appropriate by the designated individual.

4) **Operations —** All aspects of facility operations must be evaluated for vulnerability to sabotage and documented policies and procedures developed to address those areas of concern. Specific procedures and responsibilities should be assigned.

   a) Documentation should be available that demonstrates that ingredient and packaging suppliers have undergone food security evaluations at their facilities and/or distribution centers.

   b) Vehicles entering the plant property, e.g., visitors, delivery and shipping vehicles, employees, management, etc., should be provided designated spaces where visitor vehicles are kept centralized and in highly visible areas. Non-employee drivers and other delivery personnel shall have a designated waiting area that restricts non-employees from operational areas, including warehouses.

   c) Policies shall be in place to inspect the truck and/or trailers before and after unloading.

      i. Trained individuals should conduct and document the inspection of the trucks and/or trailers for possible contaminants, evidence of tampering, unusual conditions, etc.

      ii. There shall be a procedure for receipt of damaged product. If the cause of the damage is unknown, the product shall not be used.

      iii. All carriers, including trailers, tankers and railcar doors/hatches, shall be kept secure when not in the process of loading or unloading. Procedures shall be in place in which carriers awaiting loading that require an off-premise washing prior to loading shall be instructed to do so. Washed carriers shall be re-secured by the driver. A wash ticket shall be provided to the loading personnel for verification prior to loading the carrier.

   d) A food security system should be in place for transporters of LTL (Less Than a Load) goods. The facility should verify the system with the carriers and monitor the documented results.

   e) Vehicles shall be secured after loading is completed at the facility. Seal numbers shall be recorded on the shipping documents. Security of the trucks/ trailers shall be maintained for vehicles making multiple stops or deliveries.

   f) Public storage warehousing and shipping companies must be required to verify food security measures while the manufacturer maintains ownership of the goods.

DEFINITIONS

The auditor will evaluate compliance against these definitions. If you feel these definitions are inappropriate, contact NSF-Cook & Thurber or the client representative.

ACCEPTABLE LABORATORY

A laboratory that is able to calibrate its performance standards. This must be accomplished by performing crosscheck sample analysis with an accredited lab on a quarterly basis.

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 and Soybeans) and in addition, Canadian Regulation also includes (Sesame, Molluscs, Sulphites and Others – as considered necessary).

The plant must identify all allergens present in the facility and must have a written program that will prevent cross-contamination of undeclared allergens.

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

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

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

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

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

``(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).".

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

CANADIAN definition of allergens is as follows:

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

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

Sesame or its derivatives, e.g., paste and oil etc.

Milk or its derivatives, e.g., milk caseinate, whey and yogurt powder etc.

Eggs or its derivatives, e.g., frozen yolk, egg white powder and egg protein isolates etc.

Fish or its derivatives, e.g., fish protein and extracts etc.

Shellfish (including crab, crayfish, lobster, prawn and shrimp) **and Molluscs** (including snails, clams, mussels, oysters, cockle and scallops) **or their** derivative, e.g., extracts etc.

Soy or its derivatives, e.g., lecithin, oil, tofu and protein isolates etc.

Wheat or its derivatives, e.g., flour, starches and brans etc.

Sulphites, e.g., sulphur dioxide and sodium metabisulphites etc.

Others (as considered necessary)

(See Sensitive Ingredients)

CALIBRATION OF INSPECTION, MEASURING AND TEST EQUIPMENT

The plant shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring, and test equipment (including test software) used by the plant to demonstrate the conformance of product to the specified requirements. Inspection, measuring, and test equipment shall be used in a manner to ensure that the measurement uncertainty is known and is consistent with the required

measurement capability. Calibration, against an accepted industry standard, shall be conducted at a frequency sufficient to confirm acceptability.

CERTIFICATES OF ANALYSIS

Specific microbiological, chemical or functional analysis requested by customer specifications that are required on lots of product or ingredients prior to acceptance. Verification of COA accuracy must be established by periodic testing of samples for conformance.

CERTIFIED LABORATORY

This is a laboratory that has met specific certification standards. (See Acceptable Laboratory)

CONTINUING LETTER OF GUARANTEE

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

CONTROL OF NONCONFORMING PRODUCT (Retained and Returned)

The plant shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from shipment. This control shall provide for identification, documentation, evaluation, segregation, and disposition of nonconforming product. This necessitates the need for conducting finished product verification.

The responsibility for assessing and authority for the disposition of nonconforming product shall be defined.

Nonconforming product shall be assessed in accordance with documented procedures. It may be:

- Reworked to meet specified requirements.
- Accepted with or without correction by written approval from the customer.
- Re-graded for alternative applications.
- Rejected or rendered inedible.

CORRECTIVE ACTION

The procedures for corrective action shall include:

- The effective handling of customer complaints and reports of product nonconformities.
- Investigation of the cause of nonconformities relating to sanitation, product, process, product safety and quality systems, and recording the results of the investigation.
- Determination of the corrective action needed to eliminate the cause of nonconformities.
- Application of controls to ensure that corrective action is taken and that the corrective action is effective to prevent reoccurrence of similar problems.
- Determination of appropriate disposition of nonconforming product.

DOCUMENT AND DATA CONTROL

The plant shall establish and maintain documented procedures to control all documents and data that relate to the requirements of the customer.

DOCUMENT AND DATA APPROVAL AND ISSUE

The documents and data shall be assessed and approved for adequacy by authorized personnel prior to use. A master list or equivalent document-control procedure identifying the current revision status of documents shall be established and be readily available to preclude the use of invalid and/or obsolete documents.

This control shall ensure that:

- Pertinent issues of appropriate documents are available at all locations where operations essential to effective functioning of production control or quality systems are performed.
- Invalid and/or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use.
- Any obsolete documents retained for legal and/or knowledge-preservation purposes are suitably identified.

- All documents shall be retained for twelve months beyond the shelf life of the product or per specific requirement of the customer. Records of document destruction, including all copies, shall be maintained.
- All documents are individually dated with effective dates and signed.
- All documents must indicate the date(s) of the replacement document(s).

DOCUMENT AND DATA CHANGES

- Changes to documents and data shall be assessed and approved by the same functions/organizations that performed the original assessment and approval, unless specifically designated otherwise. The designated functions/organizations shall have access to pertinent background information upon which to base their assessment and approval. For electronic copies and distribution, all files will be "read only", with authorization for amendments only granted to those individuals identified on the authorized personnel list.
- Where practicable, the nature of the change shall be identified in the document or the appropriate attachments.

FINISHED PRODUCT INSPECTION

The plant shall carry out all final inspection and testing in accordance with the plans and/or documented procedures to complete the evidence of conformance of the finished product to the specified requirements.

- The product safety and quality plan or documented procedures for final inspection and testing shall require that all specified inspections and tests, including those specified either on receipt of products or in-process, have been carried out and that the results meet specified requirements.
- No product shall be shipped until all the activities specified in the safety and quality plan or documented procedures have been satisfactorily completed and the associated data and documentation are available and verified by appropriate management.
- The plant shall establish and maintain records that provide evidence that the product has been inspected and/or tested. These records shall show clearly whether the product has passed or failed the inspections and/or tests according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product shall apply.
- Records shall identify the inspection authority responsible for release of product.

FOOD CODE

Reference Guide published by U.S. Dept. of Health and Human Services, Public Health Service and Food and Drug Administration, 2001 and appropriate supplements.

GOOD MANUFACTURING PRACTICES (GMPs)

These are Guidelines as cited in Code of Federal Regulation 21, Part 110.

HACCP DEFINITIONS

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

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

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

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

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

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

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

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

Deviation – Failure to meet a critical limit.
HACCP – A systematic approach to the identification, evaluation and control of food 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.
HACCP System – The result of the implementation of the HACCP plan.
HACCP Team – The group of people who are responsible for developing, implementing and maintaining the HACCP system.
Hazard – A biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
Hazard Analysis – The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.
Monitor – To conduct a planned sequence of observations or measurements to assess whether a CCP is under control and to produce an accurate record for future use in verification.
Prerequisite Programs – All procedures used in the facility, which address operational conditions providing the foundation for the HACCP system.
Severity – The seriousness of the consequences of exposure to the hazard.
Step – A point, procedure, operation or stage in the food system from primary production to final consumption.
Validation – That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented is effectively controlling the hazards that are reasonably likely to occur.
Verification – Those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

HANDLING, STORAGE, PACKAGING, PRESERVATION AND DELIVERY

The plant shall establish and maintain documented procedures for handling, storage, packaging, labeling and transportation of product.

Storage

- The plant shall provide methods of handling and storage of product that will prevent damage, deterioration, contamination or adulteration.
- The plant shall use designated storage areas, freezers or coolers, to prevent damage, deterioration or contamination of product pending use or delivery. Appropriate methods for authorization of receipt to and dispatch from such areas shall be stipulated.
- In order to detect deterioration and adulteration, the condition of product in inventory shall be assessed at appropriate intervals.

Packaging

- The plant shall control packing, packaging, and marking processes, including materials used, to the extent necessary to ensure conformance to regulatory requirements and customer specifications. All packaging materials will be considered as “food grade” items, and as such will be stored in a manner, which will prevent contamination.

Product Retention

- The plant shall apply appropriate methods for retention and segregation of defective product when the product is under the supplier’s control. Physical, as well as documented “hold” is required. Merely putting product on computer “hold” is not adequate.
- There must be an isolated “on hold” area that provides positive means of control and is properly identified in dry, refrigerated, and frozen storage areas.
- Documents must include retained product location, reason for retention and the personnel responsible for release.
- Both physical and document verification shall be performed at least monthly. Any discrepancy must be immediately investigated and corrected. Corrective and preventive measures must be documented.

Shipping

- The plant shall arrange for the protection of the safety and quality of product after final inspection and test. This protection must be extended to include delivery to destination.

Receiving inspection and testing

- The plant shall ensure that incoming product is not used or processed until it has been inspected or otherwise verified as conforming to specified requirements. Verification of the specified requirements shall be in accordance with the product Safety, Quality and Security plan and/or documented procedures.
- Systems shall be established to handle product that is in noncompliance along with documented verification as to the disposition of that product.
- In determining the amount and nature of receiving inspection, consideration shall be given to the amount of control exercised at the subcontractor's premises and the recorded evidence of conformance provided. Documented on-site visits to subcontractor premises are recommended.
- Where incoming product is released for urgent production purposes prior to verification, it shall be positively identified and recorded in order to permit immediate recall and replacement in the event of nonconformity to specified requirements.
- A code interpretation and shelf life manual or program must be developed for all incoming raw ingredients. The plant shall develop criteria for the amount of shelf life required for incoming materials. This manual will assist receiving personnel receiving raw ingredients to ensure proper shelf life remains for each product and the supplier is properly rotating their products.

INTERNAL G.M.P. AUDITS

- The plant must establish and maintain documented procedures for planning and implementing internal audits to verify whether activities and related results comply with company and regulatory requirements and to determine the effectiveness of the systems.
- Internal GMP audits must be scheduled as frequently as needed at least monthly and shall be carried out by personnel independent of those having direct responsibility for the operation being audited.
- When highly technical areas must be assessed (pasteurization, cooking, baking) it is recommended that a person familiar with the process being assessed be part of the team.
- The results of the audits shall be recorded and brought to the attention of the personnel having responsibility in the area audited, as well as designated upper management.
- The management personnel responsible for the area shall take immediate corrective action on deficiencies found during the audit and implement preventive measures as needed to prevent re-occurrence.
- This corrective action will be documented, and distributed to both the audit team and upper management.
- Follow-up audit activities shall verify and record the implementation and effectiveness of corrective action and preventive measures.
- All audit activities, including corrective actions, must be documented to indicate that deficiencies have been corrected. Evidence of documented management assessments of the audits and corrective actions is essential.

POTABLE WATER

- Water that is safe for human consumption.

PREREQUISITE PROGRAMS

These are programs that must be developed by a plant that support the implementation and control of a HACCP program. An occasional deviation from a prerequisite program would not by itself create a significant food safety hazard. Examples would be Sanitation Programs, Good Manufacturing Programs, Pest Management Programs, etc.

PREVENTIVE ACTION

The procedures for preventive action shall include:

- The use of appropriate sources of information such as processes and work operations that affect product safety and quality, audit results, records, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities.
- Determination of the steps needed to deal with any problems requiring preventive action.
- Initiation of preventive action and application controls to ensure that it is effective.

PROCESS CAPABILITY

Statistical variation of a manufacturing process measured to establish the probability (confidence) of the ability to maintain the process within specified limits. Basically, process capability is statistically determined variability of the process.

PROCESS CONTROL

The plant must identify and plan the production, installation and servicing processes that directly affect product safety and quality and must ensure that these processes are carried out under controlled conditions. Controlled conditions shall include the following:

- Documented procedures defining the manner of production, installation, and servicing, where the absence of such procedures could adversely affect product safety and quality.
- Use of suitable production, installation, and servicing equipment, and a suitable working environment.
- Compliance with reference performance standards and codes of safety and quality.
- Monitoring and control of suitable process parameters and product characteristics.
- The approval of processes and equipment, as appropriate.
- Criteria or workmanship, which shall be stipulated in the clearest practical manner (i.e., written standards, representative samples, or illustrations).
- Suitable maintenance of equipment to ensure continued process capability.

PROCESS CONTROL PROCEDURES

The plant shall:

- Determine the measurements to be made and the accuracy required, and select the appropriate inspection, measuring and test equipment that is capable of the necessary accuracy and precision.
- Identify inspection, measuring, and test equipment with a suitable indicator or approved identification record to show the calibration status.
- Identify all inspection, measuring, and test equipment that can affect product quality, and calibrate and adjust them at prescribed intervals, or prior to use, against certified equipment having a known valid relationship to internationally or nationally recognized standards. Where no such standards exist, the basis used for calibration shall be documented.
- Define the process employed for the calibration of inspection, measuring, and test equipment, including details of equipment type, unique identification, location, frequency of checks, check method, acceptance criteria, and action to be taken when results are unsatisfactory.
- Maintain calibration records for inspection, measuring and test equipment.
- Assess and document the validity of previous inspection and test results when inspection, measuring and test equipment is found to be out of calibration.
- Ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being conducted.

PRODUCT CHANGES

All product changes and modifications must be identified, documented, assessed and approved by authorized personnel (customer and manufacturer) prior to their implementation.

PRODUCT IDENTIFICATION AND TRACEABILITY

- The plant must establish and maintain documented procedures for identifying product by suitable means from receipt and during all stages of production, delivery, and warehousing. Records must be available to trace back to all sources of ingredients and supplies.
- This traceability must extend to the first customer (i.e. – distribution center, restaurant or secondary processor). Once each year, the plant should conduct a mock recall through the first level of distribution, to assure the organizations receiving products maintain continuity of traceability
- Ingredient, packaging material and product traceability are a specified requirement. The plant must establish and maintain documented procedures for unique identification of individual lots. This identification shall be recorded.
- Plant management must perform semi-annual mock recalls on randomly selected raw material including packaging materials. This study must include the amount of the original raw material code (production code, lot number, receipt date, etc.), and the amount of product identified throughout the production process. A reconciliation percentage must be determined, with corrective actions required if it is below the identified minimum level 99.5% within four hours.

PRODUCT SAFETY AND QUALITY PLANNING

The plant must define and document how the requirements for product safety and quality will be met. Product safety and quality planning must be consistent with all other requirements of a plant's product safety and quality system and must be documented in a format to suit the plant's method of operation. The plant must give consideration to the following activities, as appropriate, in meeting the specified requirements for products, projects, or contracts:

- Preparation of product safety and quality plans.
- Identification and acquisition of any controls, processes, equipment (including inspection and test equipment), fixtures, resources, and skills that may be needed to achieve the required product safety and quality.
- Ensuring the compatibility of the design, the production process, installation, servicing, inspection and test procedures, and applicable documentation.
- Updating, as necessary, of product safety and quality control, inspection, and testing techniques, including the development of new instrumentation.
- Identification of any measurement requirements involving capability that exceeds the known state of the art, in sufficient time for the needed capability to be developed.

PRODUCT SAFETY AND QUALITY SYSTEMS

The plant must establish, document, and maintain a product safety (HACCP and pre-requisite program) and quality system as a means of ensuring that product conforms to specified requirements. The plant must prepare a manual covering the product safety and quality requirements of customer. The product safety and quality manual shall include or make reference to product safety and quality system procedures. The manual must be assessed and updated annually.

PURCHASING

The plant shall establish and maintain documented procedures to ensure that purchased product ingredients and packaging conforms to specified requirements. Changes to specification requirements must follow a defined change approval process.

PURE FOOD GUARANTEES

Document provided by supplier that all shipments of food and food ingredients conform to all provisions of the Food, Drug and Cosmetic Act and Amendments.

QUALITY SYSTEM PROCEDURES

The plant must:

- Prepare documented procedures consistent with the requirements of the plant's stated product quality policy.
- Effectively implement the product quality system and its documented procedures.

- The range and detail of the procedures of the quality system shall be dependent on the complexity of the work, methods used, and the skills and training needed by personnel.
- Documented procedures must define how an activity is performed.

READY-TO-EAT PRODUCTS

All foods that when purchased do not require a pathogen "elimination step" prior to consumption, (i.e. cooking) are considered (RTE) Ready-to-Eat. Products that are required to be cooked prior to consumption must have detailed cooking instructions on the outer case for foodservice products, or on the individual inner packages for retail packaging, to heat product to a minimum internal temperature per regulation. (Review 2001 Food Code, Part 1-2).
Evaluations for RTE preparedness should be mitigated by concerns for food safety risk. While soft cheese and sugar cookies are both RTE products, less concern is necessary for the cookies.

RECORDS MANAGEMENT

- The plant must establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of records.
- Product safety and quality records shall be maintained to demonstrate conformance to specified requirements for twelve months beyond the shelf life of product or per customer-specific requirements.
- An annual assessment of the accuracy of the records management must be established. Corrective actions must be initiated and documented when non-conformities are identified.

REPACKAGING

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

REPEAT FINDING

A previously cited deficiency which has not been effectively addressed with corrective action.

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 AREAS

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

SENSITIVE INGREDIENTS

Food intolerances which affect a limited number of individuals and which do not involve immunologic mechanisms are considered to be caused by sensitive ingredients. For the most part, sensitive ingredient reactions involve less severe manifestations. Allergic individuals can usually tolerate limited quantities of the offending foods. (See Allergens)

SHALL

Shall is used to express what is mandatory or what must be done.

SHOULD

Should is used to express what is highly recommended, probable or expected in most situations

STATISTICAL TECHNIQUES

- The plant or customer shall identify the need for statistical techniques required for establishing, controlling, and verifying process capability and product characteristics.
- The plant shall establish and maintain documented procedures to implement and control the application of the statistical techniques.

TRAINING

The plant must establish and maintain documented procedures for identifying the training needs and provide for the training of all personnel performing activities affecting product Safety, Quality and Security. Personnel performing specific assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required.

- Retraining will be held at least quarterly with documented testing to measure knowledge retention. Appropriate records of training shall be available for assessment for the preceding twelve months.
- All new employees are required to undergo formal food safety and food training prior to beginning work. This training must address basic GMP and personal hygiene requirements, in addition to task-specific goals.

Training programs shall be updated annually with training goals developed for both operational personnel and management.

VALUE/LIMIT

A value that is greater than the critical limit, which must be used to take action and prevent occurrence of a deviation.