The AIB International

Consolidated Standards

for

Inspection

Food Contact Packaging Manufacturing Facilities

North America
Latin America
Europe/Middle East/Africa
Asia/Pacific

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Preface

Document Description

The AIB International Consolidated Standards for Inspection of Food Contact Packaging Manufacturing Facilities is a collection of information gathered to help a reader understand:

- What an inspection is
- The difference between an inspection and an audit
- How to read and use the AIB International Consolidated Standards
- How an AIB International inspection is scored
- How to prepare for and participate in an AIB International inspection
- Additional sources for understanding, implementing, and expanding Prerequisite and Food Safety Programs

Document Structure

For ease of use, this document is structured as follows:

- Consistent terminology used throughout the document
- Clear, unambiguous language that can be globally understood
- Current-use language and not "regulation speak"
- Related content grouped in one location
- Standards constructed with the same hierarchy:
  - ◊ Category
    - Standard
      - » Requirement
- As much as possible, one item measured per Standard
- Meaningful phrases highlighted to support quick scanning

Definitions of Inspection and Audit

An ***inspection*** is a thorough physical review of a food facility to assess what is actually happening in a facility at a moment in time. This snapshot gives a

realistic assessment of conditions that can be both positive and negative for food processing. An inspection focuses on ***physical review.***

An ***audit*** is a systematic evaluation of food facility documentation to determine if programs and related activities achieve planned expectations. An auditor looks at data over time to see if positive or negative trends are developing. An audit focuses on ***documentation review.***

Benefits of Inspection and Audit

Choosing an inspection or an audit depends on the facility's goal. Many organizations choose both because inspections and audits support each other.

Choose an inspection to:

- Reveal actual practices or issues that may not be apparent from paperwork
- Focus on root causes, not just on symptoms
- Educate personnel through interaction with an inspector
- Identify, reduce, eliminate, and prevent food hazards in a facility
- Prevent expensive and damaging recalls
- Comply with government regulations and industry expectations for safe food
- Improve and maintain a healthy, sanitary environment for food handling
- Produce safe food products

Choose an audit to:

- Comply with benchmarked standards
- Realize efficiencies through better management of documentation
- Achieve certification
- Analyze trends over time

Introduction to the Standards

The AIB International Consolidated Standards for Inspection of Food Contact Packaging Manufacturing Facilities are statements that represent key requirements a facility must meet in order to keep the food products in its facility wholesome and safe. The Standards also reflect what an inspector would expect to see in a facility that maintains a food-safe processing environment.

The Categories

The Standards include five categories:

1. Operational Methods and Personnel Practices

The receipt, storage, monitoring, handling, and processing of raw materials to manufacture and distribute safe final product.

Standards in this category are related to **food handling and processing.** Facilities need to be confident that personnel, processes, and conditions do not introduce a food safety concern as raw materials are received, transferred, stored, transported, manipulated, or processed to deliver a final product. The Operational Methods and Personnel Practices Standards show how a facility can prevent people and processes from contaminating a product.

2. Maintenance for Food Safety

The design, upkeep, and management of equipment, buildings, and grounds to provide a sanitary, efficient, and reliable manufacturing environment.

Standards in this category are related to **equipment, grounds, and structures**. The design, construction, and maintenance of equipment and buildings are critical to providing and maintaining a food-safe environment. The Maintenance for Food Safety Standards provide best practices for optimizing the design and care of the facility and equipment so that they are easy to manage and do not create sanitation or food safety issues.

3. Cleaning Practices

The cleaning and sanitizing of equipment, utensils, and buildings to provide a wholesome and safe processing environment.

Standards in this category are related to **cleaning and sanitizing**. The methods of cleaning and sanitizing, types of chemicals used, frequency of cleaning activities, and control of microbes must all be done expertly to protect products from food safety issues. The Cleaning Practices Standards provide cleaning guidelines to prevent contamination.

4. Integrated Pest Management

The assessment, monitoring, and management of pest activity to identify, prevent, and eliminate conditions that could promote or sustain a pest population.

Standards in this category are related to **pest management**. While it is important to remove pests from a facility, it is more important to prevent pests from ever having the opportunity to thrive in a food environment. The Integrated Pest Management Standards provide strategies for managing multiple approaches to ensure that pests do not adulterate food products.

5. Adequacy of Prerequisite and Food Safety Programs

The coordination of management support, cross-functional teams, documentation, education, training, and monitoring systems to ensure all departments of the facility work together effectively to deliver a wholesome and safe final product.

Standards in this category are related to **management and teamwork**. It is important to have programs in place, but if a program is not formalized through designing, planning, management, documentation, and review, then Prerequisite Programs will depend on who is undertaking a given activity or task that day. The Adequacy Standards make sure that Prerequisite Programs are carefully designed and implemented to ensure consistency across the entire facility.

Note: While other categories focus mainly on inspection, this category largely involves evaluation of program documentation. However, the observations made and documents reviewed in the first four categories will directly affect how the Inspector assesses the facility in the Adequacy category. Findings on the floor are a direct reflection of how well programs have been implemented.

How to Read the Standards

Category Name

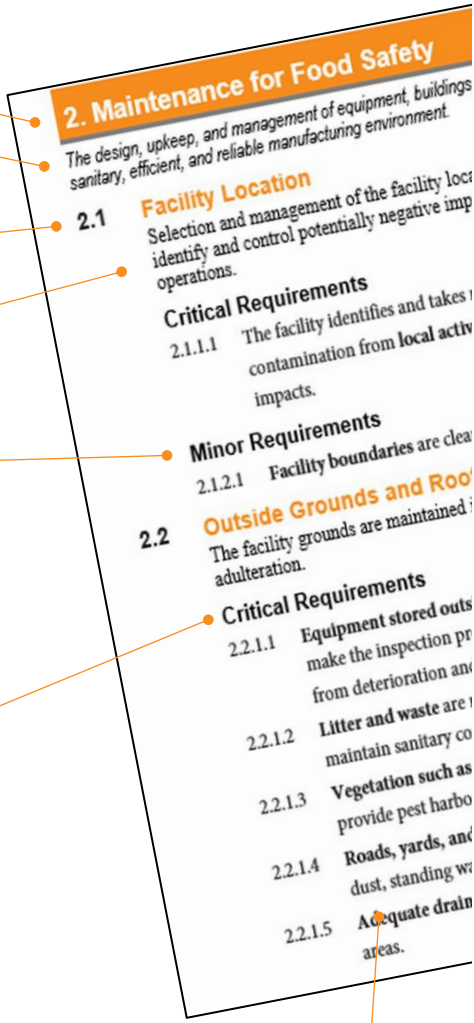
Category Description
A full sentence describing how the Standards in the category are related.

Standard
The key point of the Standard.

Standard Description
Why a facility would want to implement the standard.

Minor Requirements
These are the minor requirements against which a facility is scored. In many regulations, the minor requirements are described as **SHOULDS**. Minor requirement observations are assessed as Minor Issues Noted. A 4-place number with a 3rd place value of "2" identifies Minor Requirements.

Critical Requirements
These are the critical requirements against which a facility is scored. In many regulations, critical requirements are described as **SHALLS**. Critical requirement observations are assessed as Improvement Needed, Serious, or Unsatisfactory unless there is an alternate program in place that meets the intent of the requirements. A 4-place number with a 3rd place value of "1" identifies Critical Requirements.



Key Points
Bold type highlights key points to simplify scanning of Critical and Minor Requirements.

Θ — Indicates Standards Not Applicable to Food Contact Packaging Manufacturing Facilities

The Consolidated Standards for Inspection of Food Contact Packaging is a targeted version of the more general AIB International Consolidated Standards for Inspection of Prerequisite and Food Safety Programs. The numbering convention from the Prerequisite and Food Safety Programs Standard is preserved in the Food Contact Packaging Standard in order to keep numbering consistent. However, any Standards or requirements from the Prerequisite and Food Safety Program Standard that are not applicable to the food contact packaging industry are not included in this document. A symbol, Θ, signifies that missing numbers in the series of Standards or requirements are intentional.

Scoring

The scoring of the facility occurs in five steps:

1. The Inspection
2. Determining Risk and Assigning Category Scores
3. Evaluating the Adequacy of the Food Safety Program
4. Total Score
5. Recognition

The Inspection

Like a chain, the strength of a Food Safety Program depends on its weakest link.

To assess the food safety risks in a facility, an AIB Inspector conducts a thorough and fair physical inspection of the facility and concludes with a review of written programs. The Inspector notes observations based on the five categories of The AIB International Consolidated Standards for Inspection:

1. Operational Methods and Personnel Practices
2. Maintenance for Food Safety
3. Cleaning Practices
4. Integrated Pest Management
5. Adequacy of Prerequisite and Food Safety Programs

2 Determining Risk and Assigning Category Scores

The AIB Inspector will then assign a level of risk and a Category score to the five categories shown above. Use Table 1 as a guide.

Table 1—Risk Assessment

Risk Assessment	Description	Category Score Range
No Issues Observed	No identified risk	200
Minor Issues Noted	No potential for contamination	180–195
Improvement Needed	A potential hazard, partial program omission, or food safety finding that is inconsistent with the standards; if this hazard, omission, or finding is not corrected, it could lead to a program failure	160–175
Serious	A significant food safety risk or risk of program failure	140–155
Unsatisfactory	An imminent food safety hazard, program failure, or departure from the Good Manufacturing Practices	≤135

The Inspector uses a three-step process to determine risk. The Inspector:

1. Determines the most significant observation(s) in a category and assigns a score range.
2. Determines the severity of the most significant observation(s) and decides whether the initial score should be at the top or bottom of the score range assigned.
3. Lowers the initial score in five-point increments for each additional observation if the assigned score is at the top of the score range.

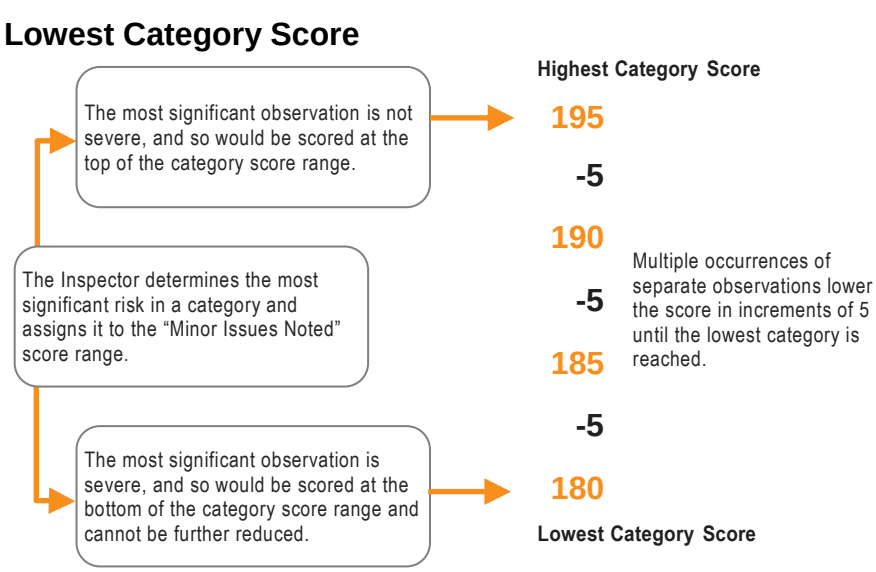


Figure 1—Example of Risk and Category Score Determination in the Minor Issues Noted Range

Here are some scoring guidelines:

- The initial score for a category is always either at the top or the bottom of the range.
- A category score can be adjusted from the top of the range, but will never go below the bottom of the range.
- All critical or minor findings associated with a single Standard of a category would be grouped together as a single observation. For example, any findings (single or multiple) noted under the following Standard and related requirements would only be counted as one observation:

  1.6 Pallets
  1.6.1.1
  1.6.1.2
  1.6.2.1
  1.6.2.2

- Findings assigned to several Standards within a category would be considered distinct and separate observations. For example, any findings (single or multiple) noted for each of the following Standards would be counted as two observations:
    - 1.1 Rejection of Shipments/Receipt of Dry Goods
    - 1.3 Storage Practices
- A single observation in a category may be severe enough to require the category to be scored at the bottom of the score range. Severity can be due to a single significant observation, or it can be due to multiple findings establishing a pattern within a single observation.
- Observations of Minor Requirements are always assessed in the Minor Issues Noted score range.
- If the initial score is at the top of the assigned score range, each additional observation lowers the score in five-point increments. Possible scores are listed in Table 2.

Table 2—Lowering an Initial Category Score for Multiple Observations

# of Observations	Category Scores for All Risk Assessments			
	Minor Issues Noted	Improvement Needed	Serious	Unsatis-factory
1	195	175	155	135
2	190	170	150	130
3	185	165	145	125
4	180	160	140	120
5+	180	160	140	115*

* Will be lowered an additional 5 points for additional observations.

Evaluating the Adequacy of the Food Safety Program

The evaluation of the written programs is not limited to determining if a written program and its records are in place and current. What the AIB Inspector sees in the facility determines whether or not the written Food Safety Programs actually work. A facility cannot have perfect programs if food safety observations are noted during the inspection.

The Inspector reviews the observations in the facility against the written programs to determine where the gaps in the program exist and what should be done to alleviate these conditions.

The score for the Adequacy Category is determined using the same method that is used for calculating the other four category scores. The Adequacy Score, however, is also guided by four additional rules.

Rules to Determine the Adequacy Score

Rule 1: The Adequacy Score cannot be the highest score. How can the programs that manage outcomes in the other categories be scored higher than the categories themselves?

Rule 2: The Adequacy Score can be no more than one Risk Level higher than the category with the worst observation. In other words, if the worst Risk Categorization is Serious, how could the Adequacy section be said to have only minor issues with its operation? Again, this relates to how well the program functions in a facility. See Table 3.

Table 3—Maximum Adequacy Score Based on Rule 2

Worst Risk Assessment	Related Score Range for Worst Risk Assessment	Maximum Adequacy Score Range
Minor Issues Noted	180–195	195*
Improvement Needed	160–175	180–195
Serious	140–155	160–175
Unsatisfactory	≤135	140–155**

*Rule 4 applies | **Rule 3 applies

Rule 3: If the worst score is at the bottom of the score range, the Adequacy Score can be no higher than the bottom category score, one level above. If observations require the score to be at the bottom of the category score range, this indicates that the related program is not effective.

Table 4—Maximum Adequacy Score Based on Rule 3

Worst Risk Assessment	Score of Worst Risk Categorization at Lowest Number in the Score Range	Maximum Adequacy Score
Minor Issues Noted	180	195*
Improvement Needed	160	180
Serious	140	160
Unsatisfactory	≤ 135	140

*Cannot be the highest category score

Note: This rule does not apply if scoring a category where the worst risk level is "Minor Issues Noted."

Rule 4: A 200 may only be assigned for Adequacy if the other four category scores are all assigned a 200; e.g., the only way it can be said that the programs are working perfectly is if there are no observations to indicate otherwise.

Total Score

The Total Score is the sum of the points assigned to each category: Operational Methods and Personnel Practices, Maintenance for Food Safety, Cleaning Practices, and Integrated Pest Management, but is not complete until aligned with the Adequacy of Prerequisite and Food Safety Programs because written programs drive the results from the other four categories.

Recognition

Recognition is based on the Total Score assigned to the facility. A recognition document will be awarded to the facility when:

- The inspection is based solely on the AIB International Consolidated Standards for Inspection (not customer-defined interpretations or guidelines)

- There is:
  - No category score less than or equal to 135
  - There are no unsatisfactory findings (even if the Total Score is at or above 700)

The AIB International Recognition Document:

- Recognizes that on the day of the inspection, the facility achieved a certain score according to the AIB International Consolidated Standards for Inspection
- Is not a certificate of compliance (like an ISO certificate)
- Does not have a specific expiration date
- Is labeled as announced, unannounced, or announced to corporate
- Defines which areas of the facility were included in the inspection

Sample Scoring with Explanations

Category Score Range	180–195	160–175	140–155	≤ 135	
Category	# Minor Issues Noted Observations	# Improvement Needed Observations	# Serious Observations	# Unsatisfactory Observations	Category Score
Operational Methods and Personnel Practices	6	0	0	0	180 A
Maintenance for Food Safety	8	3	0	0	165 B
Cleaning Practices	8	1	0	0	160 C
Integrated Pest Management	2	4	3		145
Adequacy of Prerequisite and Food Safety Programs	0	3	0	0	165
				Total Score	815
			D		E

A The Inspector noted six observations at the lowest risk of severity, but the category score does not go lower than the lowest possible score for the Minor Issues Noted category (180).

B Three observations are documented. There were actually five findings, but three of the findings were related to the same requirement in the Standard and were therefore grouped together as a single observation.

C The severity of the single observation was significant, so the score at the bottom of the score range (160) is assigned.

D The Serious observations that posed the most potential for contamination were at the lowest severity of risk, so the category score begins with the first observation at 155. There were two additional observations, so the score was lowered by five points for each to 145.

E The Adequacy Score is determined using the most constraining rules that apply:

- The observation with the most significant risk is in the Improvement Needed category so the score should fall in the 160–175 range.
- The most significant observation is not severe, so the initial score is 175.
- There are three separate observations, so five points are deducted for each additional observation beyond the first (175 to 170 to 165).
- **Rule 1:** The highest score in the other four categories is 180, but that is outside the 160-175 range so Rule 1 does not apply.
- **Rule 2:** The lowest score in the other four categories is 145, so the Adequacy Score can be no higher than the 160-175 range.
- **Rule 3:** The lowest category score (145) is not at the bottom of the range, so Rule 3 does not apply.
- **Rule 4:** The other four categories are not assigned a 200, so Rule 4 does not apply.

Automatic Assessment of Unsatisfactory

The following list includes examples of a few commonly found conditions that require an assessment of Unsatisfactory. This list *only represents examples* of unsatisfactory conditions, and is not complete. Similar conditions not specifically stated will be assessed by the Inspector.

1. Operational Methods and Personnel Practices
    a. Open sores or boils on personnel who have direct contact with product, ingredients, or product zones
    b. Ingredients that are internally infested
2. Maintenance for Food Safety
    a. Flaking paint, rust, or other materials in the product zone where product contamination is likely
    b. Maintenance activity or equipment condition resulting in oil, metal, or other foreign material in or over a product zone
3. Cleaning Practices
    a. The presence of extensive amounts of mold either on or near product zones
    b. Widespread infestation above sensitive or exposed ingredients, above product zones, or in equipment
4. Integrated Pest Management
    a. Insects
        i. Houseflies or fruit flies in excessive numbers with little control provided
        ii. Any cockroach activity on or in a product zone
    b. Rodents
        i. Visual presence of live rodent(s)
        ii. Evidence of rodent excreta or gnaw marks on raw materials or finished product
        iii. Decomposed rodent
    c. Birds
        i. Birds residing in processing areas or warehouses
        ii. Bird excreta on product zones, raw materials, or finished product
    d. Pesticides used inconsistently with label directions
5. Adequacy of the Prerequisite and Food Safety Programs
    a. Non-compliance with written programs

i. Failure to comply with HACCP critical limits or monitoring requirements

b. Poorly defined written Prerequisite Programs

i. Inadequate or ineffective implementation of a Prerequisite Program resulting in actual or likely product contamination

c. Failure to comply with regulatory mandates

Consolidated Standards for Inspection

1. Operational Methods and Personnel Practices

The receipt, storage, monitoring, handling, and processing of raw materials to manufacture and distribute safe final product.

1.1 Rejection of Shipments/Receipt of Dry Goods

A facility can safeguard its products by identifying and barring entry or shipment of potentially contaminated materials. Materials may include but are not limited to raw materials, ingredients, processing aids, finished products, returned goods, as well as equipment and/or returned containers, trays, dollies, and carts.

Critical Requirements

1.1.1.1 Damaged, infested, or **dirty transports/containers** or materials are rejected.

1.1.1.2 Materials shipped in damaged, infested, or **dirty vehicles** are rejected.

1.1.1.3 The facility maintains **documentation of rejected shipments** that includes defect specifications and reasons for rejection.

1.1.1.4 Shuttle vehicles are in **good condition, clean, and free of holes and infestation.**

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1.3 Storage Practices

Raw materials and finished products are stored in a way to meet program requirements for safe storage of materials.

Critical Requirements

1.3.1.1 Materials, including but not limited to raw materials, packaging, work-in-process and finished products are **stored and removed from storage in a manner that prevents contamination.**

1.3.1.2 **Systems to facilitate stock rotation** are present.

1.3.1.3 Materials are stored **off the floor** on pallets, slip-sheets, or stands.

1.3.1.4 A clear, **unrestricted perimeter** is provided at floor-wall junctions to ensure adequate access for cleaning, inspection, and IPM activities.

1.3.1.5 Adequate **spacing is provided** between rows to allow for cleaning and inspection.

1.3.1.6 If materials are **stored outside,** they are adequately protected against deterioration and contamination.

1.3.1.7 **Raw materials such as paper, paperboard, and plastic rollstock** may be stored on the floor as long as the ends are trimmed and several turns of the roll are discarded before processing to prevent product contamination.

Minor Requirements

1.3.2.1 Dates used for stock rotation are on a **permanent** part of the raw material packaging (e.g., not on the stretch wrap), where applicable.

1.3.2.2 There are at least **14 in or 35 cm** of space between pallet rows.

1.3.2.3 **Storage slots** and traffic lanes are provided for items stored at floor level.

1.4 Storage Conditions

Raw materials and finished products appeared to be stored in a clean storage area and were protected from contamination as observed during the inspection.

Critical Requirements

1.4.1.1 Storage areas are **clean, well ventilated, and dry.** Stored materials are protected from condensate, sewage, dust, dirt, chemicals, or other contaminants.

1.4.1.2 **Partially used packaging materials or raw materials** are protected before being returned to storage.

1.4.1.3 All chemicals, including cleaning and maintenance compounds, and **non-product materials,** including equipment and utensils, **are stored in a separate area.**

1.4.1.4 **Research and Development items** and infrequently used raw materials, packaging supplies, and finished products are regularly inspected for signs of infestation.

1.4.1.5 **Special handling procedures** are followed for packaging materials that pose a product safety risk if mishandled (e.g., glass packaging). Failures and Corrective Actions are documented.

1.4.1.6 **Returned products** are not available for use until they are inspected and dispositioned by authorized personnel.

Minor Requirements

1.4.2.1 **Packaging is stored away from raw materials** and finished product in a designated area, if possible.

1.4.2.2 Materials and supplies staged for use are **inspected for damage, contamination, and specification compliance**, as applicable, prior to use.

1.5 Raw Material/Finished Product Inventory

Raw material and finished product inventories are maintained at reasonable volumes to avoid excessive age and insect infestation.

Critical Requirements

1.5.1.1 Raw materials, packaging supplies, work-in-process, finished products, and other materials are rotated on a **First- In, First-Out (FIFO) basis** or other verifiable method (such as First Expired, First Out [FEFO]) to ensure stock rotation.

1.5.1.2 **Insect-susceptible** materials in storage longer than four weeks are regularly inspected, but no less than every four weeks.

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Minor Requirements

1.5.2.1 A **system is defined and followed** for identifying and tracking the inspection of insect-susceptible materials (e.g., aged stock inventory, re-palletizing dates, etc.).

1.6 Pallets

Clean and well-maintained pallets minimize opportunities for contamination.

Critical Requirements

1.6.1.1 Pallets are **clean,** in good repair, and used in a way that does not create hazard to materials.

1.6.1.2 When pallets are stored outside, they are **inspected for evidence of contamination** before being brought into the facility for use.

Minor Requirements

1.6.2.1 Pallets and other **wooden surfaces** are properly dried after being washed.

1.6.2.2 **Slip-sheets** are placed between pallets and bags of ingredients, and between double-stacked pallets to protect ingredients from damage by the pallet.

1.7 Carry-Over and Rework

Raw materials, rework, work-in-progress and carry-over, if not properly identified and managed, could be misused and cause product safety problems.

Critical Requirements

1.7.1.1 There is a **designated rework area.**

1.7.1.2 The rework area is **segregated** from usable materials.

1.7.1.3 There is an established **maximum storage time** for rework material. Rework is processed often enough to keep rework quantities at minimal levels.

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1.7.1.5 Carry-over product, work-in-progress, rework and raw materials are **properly identified and dated** for traceability purposes.

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1.7.1.9 **Materials such as resins, regrind, trim or cuttings** that will be used, are identified and protected from contamination.

1.7.1.10 Regrinding, shredding, packaging or baling of plastic or paper trim is segregated from fabrication areas to control dust and spillage.

1.8 Dust Collection and Filtering Devices

If not maintained, filters, screens, and socks may contribute to product safety issues.

Critical Requirements

1.8.1.1 Dust collection and filtering devices are **stored** in a dust-free environment.

1.8.1.2 Dust collection and filtering devices are **clean.**

1.8.1.3 Dust collection and filtering devices **are designed to prevent possible contamination** from threads, lint, and fibers.

1.9 Bulk Material Handling

Bulk systems and unloading areas are high-activity locations that could introduce external contaminants into the facility. Proper receiving practices ensure protection during unloading and loading.

Critical Requirements

1.9.1.1 Bulk systems and unloading areas are **installed and maintained to prevent adulteration** of raw materials and finished product.

1.9.1.2 **Outside receiving lines or caps** for bulk dry and liquid ingredients are locked, identified, or otherwise secured.

1.9.1.3 **Air is filtered or inspection hatches are covered** when bulk materials are unloaded to eliminate the potential for foreign material contamination during the process.

1.9.1.4 S**ecurity** seals on bulk container hatches or other shipping containers are **checked** against the seal number on the shipping document to verify that the numbers match during shipping and receiving.

1.9.1.5 Conveying tubes or hoses are on **supports off the ground or floor** to prevent contamination or submersion in water.

1.9.1.6 **Pneumatic** systems or **blowers** are provided with air filters.

1.9.1.7 Hoses, caps, and couplings are **cleaned before storage** in a secured area.

1.9.1.8 **Tanker wash tags** or prior load verification are verified and records are maintained.

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1.11 Processing Aids

Processing aids are product contact materials and therefore need to be managed to prevent contamination.

Critical Requirements

1.11.1.1 All product contact processing aids, such as antifoam, release agents and cooling bath additives are **segregated** from nonfood contact materials.

1.11.1.2 **Processing aids** are labeled for their intended use.

1.11.1.3 Food approval documentation for product contact processing aids is on file.

1.12 Material Transfer

Once received, materials are transferred to points of use within the facility. Sometimes, the materials are put into smaller containers to facilitate handling. The transfer of materials should be carefully managed to avoid introduction of contaminants.

Critical Requirements

1.12.1.1 The facility follows **procedures** for transferring and handling materials and includes a system to provide traceability information at all times.

1.12.1.2 **Containers are kept off the floor** at all times and covered when not in use.

1.12.1.3 **Raw material and ingredient storage containers** are properly identified to maintain the materials' integrity and traceability.

1.12.1.4 **Protective outer wrapping is removed** from raw materials and packaging in a manner that eliminates potential contamination.

1.12.1.5 **Food contact containers, closures and blanks** manufactured at another facility, that are received and then printed on, or are subject to additional manufacturing, are stored in the original cartons until used.

1.12.1.6 Partially used cartons are **resealed** before they are returned from the manufacturing area to the storage area.

1.12.1.7 The contents of **transfer containers** used for any material removed from its original container are clearly identified.

1.12.1.8 **Blanks and other work-in-process** materials are protected from contamination.

Minor Requirements

1.12.2.1 Personnel quickly **address spills, leaks, and waste** caused by transfer of raw materials.

1.12.2.2 **Materials** selected for transport to processing areas are **visually inspected and cleaned** prior to transport.

1.12.2.3 **Drums and barrels** are wiped clean.

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1.15 Foreign Material Control Devices

Sifters, magnets, strainers, X-ray machines, and metal detectors are installed at appropriate locations to prevent the inclusion of metal, wood, glass, and other foreign materials.

Critical Requirements

1.15.1.1 Precautions are taken to **minimize product contamination** when staples or similar items are used in **packaging materials.**

1.15.1.2 Foreign material control devices are **provided** as applicable and critical to the process, based on risk assessment.

1.15.1.3 Metal detectors or X-ray machines incorporate an **alarm and/or an automatic rejection device** that diverts contaminated product into a secured and controlled area accessible only to authorized personnel, or otherwise maintain control of the rejected product.

1.15.1.4 Product **rejections or unusual foreign material findings are investigated,** and Corrective Actions are taken to identify and eliminate contamination issues.

1.15.1.5 Foreign material control devices are **appropriate** to the product or process, and detect metal wear or contamination from the processing equipment.

1.15.1.6 For **continuously extruded product,** a mark is used to identify the location of contamination if automatic rejection or identification is not possible, or if a simple line stop is not acceptable.

1.15.1.7 The facility follows procedures to **operate, monitor, and test** foreign material control devices.

1.15.1.8 Foreign material control devices are **regularly monitored and documented.**

1.15.1.9 The facility follows **Corrective Action and Reporting Procedures** to respond to foreign material control device failures. These procedures may address:

- Isolating
- Quarantining
- Re-testing all products produced since the last acceptable test of the device

1.15.1.10 Magnets, where present and used for product safety purposes, are **tested for strength** on a defined frequency. Deviations from manufacturer requirements or specifications are addressed.

1.16 Waste Material Disposal

Waste materials and their removal are managed to avoid contamination.

Critical Requirements

1.16.1.1 Waste is stored in **properly identified** containers.

1.16.1.2 **Waste is managed** to prevent pest and microbial issues. Management techniques could include cleaning, covering and emptying containers regularly.

1.16.1.3 **Traffic routes** for waste disposal do not place product or product contact surfaces at risk.

1.16.1.4 Trash or inedible waste is **handled in a way that does not cause cross-contact or contamination** to raw materials, work-in-progress or finished product at any time.

1.16.1.5 **Licensed contractors** remove waste, where required.

1.16.1.6 Waste disposal meets **regulatory requirements.**

1.17 Ingredient Containers, Utensils, and Tools

Ingredient containers, utensils and tools may cause cross-contamination issues if they are not managed properly.

Critical Requirements

Θ

1.17.1.3 Containers and utensils used to transport, process, hold, or store raw materials, work-in-progress, rework, or finished products **are constructed, handled, and maintained** in a way that prevents contamination.

1.17.1.4 Containers for materials, including but not limited to raw materials, work-in-progress or finished products, are **only used for their designated purposes**.

1.17.1.5 Containers are **legibly labeled with contents**.

1.17.1.6 **Snap-off blades** are not used in production, packaging, or raw material storage areas.

1.17.1.7 Packaging manufactured at the facility is only used for its **intended purpose.**

Θ

1.19 Workspace Arrangement

A neat, efficient workspace promotes cleanliness and maintainability, both essential for product safety.

Critical Requirements

1.19.1.1 **Routine housekeeping activities** are ongoing throughout operating hours in production and support areas to maintain a sanitary environment.

Minor Requirements

1.19.2.1 Production equipment and supplies are **neatly arranged and installed.**

1.19.2.2 Portable, infrequently used **equipment is not stored** in production or raw material storage areas.

1.19.2.3 **Adequate workspace** and storage areas are provided to enable operations to be performed in safe, hygienic conditions.

1.19.2.4 **Operational debris** is kept at a minimum.

1.20 Single-Service Containers

Residue can contaminate any new materials or products added to an old container.

Critical Requirements

1.20.1.1 Single-service containers are **not reused.**

1.20.1.2 All single-service containers are **crushed, punctured, or otherwise disposed of** so that they cannot be reused.

Θ

1.23 Cross-contamination Prevention

Incompatible or hazardous materials require separate handling to prevent contamination.

Critical Requirements

Θ

1.23.1.3 **Systems** are set up to reduce any potential physical, chemical, or microbiological contamination risks.

Θ

1.23.1.9 **Color-coding** or another identifiable way of separating food-grade and non-food grade resins is defined and implemented to prevent product contamination with non-approved additives or resins.

1.23.1.10 Processing aids, inks, or other product contact components are **evaluated for allergen content** and appropriate control programs are implemented where allergen cross contact (contamination) may be a concern.

1.23.1.11 Procedures are in place to **identify and segregate** raw materials, work-in-process, rework, and finished products to prevent cross-contamination.

1.23.1.12 Equipment used to produce food contact containers and nonfood contact containers is thoroughly purged and cleaned between production of nonfood contact and food contact materials.

1.23.1.13 Documentation of the purging, cleaning process and release is **current and complete.**

1.24 Cans, Bottles, and Rigid Packaging

If used, cans, bottles, and other containers for packaging require extra cleaning and storage steps to prevent foreign material contamination.

Critical Requirements

Θ

1.24.1.5 **Box liners and other liners** used in product containers or packaging materials are suitably durable to prevent risk of product contamination.

1.24.1.6 Rigid packaging is **covered or inverted, or overhead structures are maintained,** to prevent contamination prior to filling.

Θ

1.24.1.8 Single-service containers that are not cleaned before receipt are stored in a way to protect them from **airborne or manual contamination.**

1.24.1.9 Molds and other product contact equipment are stored and adequately protected from contamination.

1.24.1.10 Washing processes, where applicable, are validated for effectiveness and verified as necessary.

1.25 Finished Product Transportation

Finished product is coded for traceability, and shipping requirements are in place to prevent product contamination.

Critical Requirements

1.25.1.1 Legible **code marks** that are easily seen by consumers are placed on all finished products.

1.25.1.2 Code marks satisfy **regulatory packaging requirements** and lot definitions, and are used in the Recall Program.

1.25.1.3 Distribution records identify the **initial point of distribution** as per regulatory requirements.

1.25.1.4 **Finished products are handled and transported** in a way that prevents actual or potential contamination.

1.25.1.5 Finished products are **loaded or transferred in covered bays** or canopies to protect the products from weather damage.

Θ

1.25.1.9 The facility enforces **transportation breakdown** procedures.

1.25.1.10 Prior to loading, **all shipping vehicles and products are inspected** for cleanliness, damage, or defects that could jeopardize the product.

1.25.1.11 Shipping **vehicle inspections are documented.**

Θ

1.25.1.14 **Security seals or padlocks** are provided, and their use is documented as per facility or customer requirements.

1.25.1.15 Transport vehicles have **not hauled garbage/waste or non-food** items that may cause product contamination. If non-food items, such as chemicals, are shipped, then adequate barriers to prevent contamination of products must be used.

Minor Requirements

1.25.2.1 Interior light bulbs in finished product transports are **shielded or coated** to prevent breakage.

Θ

1.26 Hand Washing Facilities

Personnel are provided the equipment to effectively remove contamination from their hands.

Critical Requirements

1.26.1.1 Suitable and properly maintained hand washing facilities are **located** at the entrance to production areas, and at other appropriate sites.

1.26.1.2 **Single-use towels or air dryers** are provided at hand washing stations.

1.26.1.3 **Hand sanitizing stations** are provided, as appropriate, based on risk assessment.

Θ

1.26.1.5 **"Wash hands"** signs appear above sinks and entries to production areas.

1.27 Washrooms, Showers, and Locker Rooms

Cleanliness diminishes chances of contamination being spread from personnel areas.

Critical Requirements

1.27.1.1 All washrooms, showers, and locker rooms are maintained in a **sanitary** condition.

1.27.1.2 There are **no open food, drinks, or items that pose a risk to product safety** in lockers or locker rooms.

1.27.1.3 **"Wash hands" signs** are displayed in all restrooms, lunchrooms and smoking areas.

Minor Requirements

1.27.2.1 Company-owned **personnel lockers are inspected** on a defined frequency as allowed by national or local regulations.

1.28 Personal Hygiene

Personnel conform to hygiene practices to avoid becoming a source of contamination.

Critical Requirements

1.28.1.1 **Trained supervisors** are responsible for ensuring that all personnel are complying with facility policies regarding personnel practices.

1.28.1.2 **Personnel wash hands** before beginning work, and after eating, drinking, smoking, using the restroom, or otherwise soiling hands.

1.28.1.3 Personnel are required to practice **good personal hygiene** at all times.

Minor Requirements

1.28.2.1 **Hand washing practices** are checked periodically for effectiveness (e.g., visual inspection, swabbing, observation, etc.).

1.29 Work Clothes, Changing Facilities, and Personnel Areas

Clothing may contaminate products if the clothing is dirty or made of unsuitable material. Changing facilities are provided to allow personnel to keep work clothes clean.

Critical Requirements

1.29.1.1 Personnel wear suitable, **clean outer garments or uniforms.**

1.29.1.2 Personnel wear **suitable footwear.**

1.29.1.3 Personnel wear effective **hair restraints** to fully contain hair, if applicable. Hair restraints may include head, beard, or moustache covers.

1.29.1.4 If worn, **gloves** are adequately controlled to avoid product contamination.

1.29.1.5 Items such as pens, pencils, and thermometers are carried in pockets or pouches **below the waist** in production areas.

1.29.1.6 **Changing facilities are provided** for all employees, visitors, and contractors to allow personnel to change clothes before entering production areas, if necessary.

1.29.1.7 **Work clothes are stored** separately from outdoor clothing and personal items in changing facilities.

1.29.1.8 Where **protective clothing is required**, it is available at all times, and laundered or cleaned in a controlled environment.

Minor Requirements

1.29.2.1 There are **no pockets above the waist** on outer garments.

1.29.2.2 Suitable **break rooms and dining facilities** are provided for all personnel.

Θ

1.31 Personal Items and Jewelry Control

Personal items and jewelry present product contamination risks if not controlled.

Critical Requirements

1.31.1.1 Personnel in contact with food contact packaging **remove jewelry and cosmetic items** including, but not limited to:

- Visible or exposed piercings and body jewelry
- Watches
- Earrings
- Necklaces
- Bracelets
- Rings with settings
- False fingernails
- False eyelashes
- Fingernail polish

1.31.1.2 **Plain wedding bands** are acceptable if permitted by the Personnel Practices Program.

1.31.1.3 Personnel eat, drink, chew gum, and use tobacco products **only in designated areas.**

1.31.1.4 **Personal food and belongings** are not brought into production or storage areas.

1.31.1.5 All **personal property is stored** in a designated area.

1.31.1.6 The facility Personnel Practices Program defines and explains any **exceptions** to personal items and jewelry control.

Θ

1.32 Health Conditions

Facility policies are in place and enforced to prevent disease, illness, or infection from contaminating product.

Critical Requirements

1.32.1.1 No person with exposed boils, sores, infected wounds, or any other **infections or communicable disease** is permitted to contact product.

1.32.1.2 All **exposed cuts and grazes** are covered by a facility-issued metal detectable strip bandage.

1.32.1.3 All **personnel health cards** are current and properly posted if required by local regulations.

1.32.1.4 The facility follows procedures requiring personnel, including temporary workers, **to notify supervisory personnel of any relevant infectious disease** or conditions to which they may have been exposed.

1.32.1.5 A written policy specifies the procedures for handling/disposition of products or product contact surfaces that have come into contact with **blood or other bodily fluids.**

Minor Requirements

1.32.2.1 **If appropriate, each lot is verified** as being detectable with the facility's foreign material detection device**.**

1.32.2.2 If appropriate, the facility uses detectable gloves, earplugs, or other **detectable protective equipment.** If used, detectable equipment is regularly tested and documented.

1.33 Non-Facility Personnel

Visitors and contractors are required to comply with facility policies to protect product from contamination.

Critical Requirements

1.33.1.1 Non-facility personnel conform to the facility **Personnel Practices and company policies programs.** Non-facility personnel include, but are not limited to:

- Visitors
- Temporary personnel
- Regulatory authorities
- Outside contractors
- Tour groups
- Family and friends of personnel

1.33.1.2 Where appropriate, visitors and contractors undergo **medical screening and appropriate training** before entering raw material, preparation, processing, packaging, and storage areas.

Θ

1.35 Glass Container Breakage

Procedures are in place to address glass container breakage at receiving, storage, depalletizing, washing, rinsing, filling, and capping stages to prevent product contamination.

Critical Requirements

1.35.1.1 **Procedures are defined** to address glass container breakage in manufacturing, packaging, and storage areas.

1.35.1.2 Records are current and document that **procedures for glass breakage** clean-up in storage, handling, production, and packaging areas are effectively followed.

Θ

1.41 Waxes, Sealants, Adhesives and Inks

Identification, control and use of waxes, sealants and adhesives appeared to be properly carried out to prevent contamination of materials.

Critical Requirements

1.41.1.1 Waxes, adhesives, sealants and inks are **properly covered and stored** off the floor in identified containers in a clean and well ventilated area.

1.41.1.2 **Waxing** is performed to ensure that the container or closure is completely coated.

1.41.1.3 Wax is maintained at a **temperature of 140 deg. F or 60 deg. C** or higher.

1.41.1.4 When **cold water baths** are used to cool wax, film, or extruded pellets, effective measures are taken to prevent microbial contamination.

2. Maintenance for Food Safety

The design, upkeep, and management of equipment, buildings, and grounds to provide a sanitary, efficient, and reliable manufacturing environment.

2.1 Facility Location

Selection and management of the facility location will allow personnel to identify and control potentially negative impacts of surrounding operations.

Critical Requirements

2.1.1.1 The facility identifies and takes measures to prevent product contamination from **local activities** that could have adverse impacts.

Minor Requirements

2.1.2.1 **Facility boundaries** are clearly defined and controlled.

2.2 Outside Grounds and Roof

The facility grounds are maintained in a way that prevents product adulteration.

Critical Requirements

2.2.1.1 **Equipment stored outside** is placed to prevent pest harborage, make the inspection process easier, and protect equipment from deterioration and contamination.

2.2.1.2 **Litter and waste** are removed from the property as necessary to maintain sanitary conditions.

2.2.1.3 **Vegetation such as trees, shrubs, weeds and tall grass** do not provide pest harborage or access to the building.

2.2.1.4 **Roads, yards, and parking areas** are maintained to be free of dust, standing water, and other potential contaminants.

2.2.1.5 **Adequate drainage** is provided for grounds, roofs, and other areas.

2.2.1.6 Outside wet and dry **waste or scrap compactors, modules, and containers** are installed in a way that prevents product contamination. Containers are maintained to minimize and contain leakage, and are removable so that the area can be cleaned.

2.2.1.7 Waste containers and compactors are **closed or covered**, and located on a concrete pad or in a manner to minimize pest attraction and harborage.

2.2.1.8 The **roof, structures, and outside grounds** are well maintained.

Minor Requirements

2.2.2.1 **Truck bays and garage areas** are maintained and cleaned to prevent pest attraction or harborage.

2.3 Layout

Spacious layout and placement of equipment, materials, and structures facilitates inspection, cleaning, and maintenance activities.

Critical Requirements

2.3.1.1 Space is maintained **between** equipment and structures to enable dismantling and maintenance activities.

2.3.1.2 Adequate space is provided between equipment or structures to **allow access** for cleaning, inspection, and IPM activities.

2.4 Floors

The floors of the facility are designed and maintained to provide structural integrity, facilitate cleaning, prevent contamination, and eliminate pest harborage or entry.

Critical Requirements

2.4.1.1 Floors are **impervious** and easily cleaned.

2.4.1.2 Wall/floor junctions and corners are **maintained** to facilitate cleaning.

2.4.1.3 **Holes, cracks, and crevices** in floor surfaces are repaired to prevent debris from lodging and to avoid pest or microbial harborage.

2.4.1.4 **Floors are designed,** constructed, and maintained to meet the demands of facility operations and withstand cleaning materials and methods.

2.4.1.5 **Floors are sloped** to direct the flow of water or effluent toward drains.

2.5 Drains

The drains in the facility are designed and maintained to provide structural integrity, facilitate cleaning, prevent contamination, and eliminate pest harborage or entry.

Critical Requirements

2.5.1.1 Drains are made of **materials** that are easily cleaned and kept in good repair.

2.5.1.2 **Floor drains** with grates are installed, maintained, and operational in all wet processing or wash areas.

2.5.1.3 Floor drain grates are **easily removable** for cleaning and inspection.

2.5.1.4 **Drainage** is designed and maintained to minimize the risk of product contamination.

Minor Requirements

Θ

2.5.2.2 **Floor drains** can be easily accessed for cleaning and inspection.

2.6 Walls

The walls of the facility are designed and maintained to provide structural integrity, facilitate cleaning, prevent contamination, and eliminate pest harborage or entry.

Critical Requirements

2.6.1.1 Walls are made of **materials** that are easily cleaned and kept in good repair.

2.6.1.2 **Holes, cracks, and crevices** in wall surfaces are repaired to prevent debris from lodging and to avoid pest or microbial harborage.

2.6.1.3 Walls are **designed, constructed, finished, and maintained** to:

- Prevent dirt accumulation
- Reduce condensation and mold growth
- Facilitate cleaning
- Withstand operation environment (e.g., high moisture)

2.7 Ceilings and Overhead Structures

Structural elements such as ceilings, beams, supports, fixtures, ducts, pipes, or equipment do not threaten product with leaking, loose, chipping, flaking, or peeling material.

Critical Requirements

2.7.1.1 Ceilings are made of **materials** that are easily cleaned and kept in good repair.

2.7.1.2 Access to the void in **hollow or suspended** ceilings is provided to facilitate cleaning, maintenance, and inspection activities.

2.7.1.3 Ceilings and overheads are **designed, constructed, finished,** and maintained to:

- Prevent dirt accumulation
- Reduce condensation and mold/microbial growth
- Facilitate cleaning

2.7.1.4 **Roof leaks** are promptly identified, controlled, and repaired.

2.7.1.5 Fixtures, ducts, pipes, and overhead structures are installed and maintained so that **drips, leaks, and condensation do not contaminate** products, raw materials, or product contact surfaces.

2.7.1.6 Drips and condensation are **controlled to prevent** establishment of an environment suitable for microbial growth.

2.7.1.7 There is no **flaking paint or rust** on equipment or overhead structures. Only normal mild oxidation on non-product contact surfaces is acceptable.

2.7.1.8 **Other materials** (such as loose insulation) do not threaten products or product contact surfaces.

2.8 Glass, Brittle Plastics, and Ceramics Control

The Glass, Brittle Plastics, and Ceramics Program manages not only lighting to ensure that it is adequate for the safe production of packaging products, but the program also takes into consideration breakable materials that are used for other purposes within the facility.

Critical Requirements

2.8.1.1 **Adequate lighting** is provided in all areas.

2.8.1.2 Light bulbs, fixtures, windows, mirrors, skylights, and other glass suspended over product zones, product areas, and material storage areas are of the **safety type** or are otherwise protected to prevent breakage.

2.8.1.3 **Light fittings and glass** are replaced in a way that minimizes the potential for product contamination.

2.8.1.4 Only **essential glass, brittle plastics (acrylic), and ceramics are present** in the facility. If these materials must be used, they are addressed in the Glass, Brittle Plastics, and Ceramics Program.

2.9 Air Makeup Units

Air used in the facility is filtered or screened, and filters and screens are maintained to prevent product contamination.

Critical Requirements

2.9.1.1 Air makeup units are fitted with **clean filters** and are free of mold and algae.

2.9.1.2 Air return ducts for HVAC systems and air makeup units are fitted with **cleaning and inspection hatches.**

2.9.1.3 **Fans, blowers, filters, cabinets, and plenums** are on the Preventive Maintenance Schedule to prevent mold, the development of microbes, insect activity, and foreign material collection.

2.9.1.4 **Air blowing equipment** is located, cleaned, and operated in a way that does not contaminate raw materials, work-in-process, packaging materials, product contact surfaces, and finished products.

2.9.1.5 Filters are capable of removing particles of **50 microns/**Minimum Efficiency Reporting Value [MERV] 4 or larger.

2.9.1.6 Adequate **dust and exhaust extraction equipment** is installed and maintained, as appropriate to the process.

Minor Requirements

2.9.2.1 **Ventilation** is provided in product storage and processing areas to minimize odors, fumes, and vapors.

2.10 Pest Prevention

The materials, structure, and maintenance of the building and equipment support the Integrated Pest Management Program.

Critical Requirements

2.10.1.1 The building has **barriers** in place to protect against birds, rodents, insects, and other pests.

2.10.1.2 **External doors, windows, or other openings** are close-fitting or otherwise **pest-proofed** to less than ¼ inch or 6 mm.

2.10.1.3 **Windows, doors, and skylights** that must be kept open for ventilation are screened to prevent pest entry.

2.11 Leaks and Lubrication

Leaks, oil, and lubrication are managed so they do not contaminate products.

Critical Requirements

2.11.1.1 The facility **prevents, identifies, and eliminates** leaks (oil and lubricants) and excessive lubrication.

2.11.1.2 **Catch pans** or deflector plates are installed in areas where drive motors and gearboxes are mounted over product zones and where conveyors cross or run parallel at different levels.

2.11.1.3 There are no **grease smears or excess lubricant** on equipment.

2.12 Lubricants

Lubricants that are essential for effective equipment operation are managed to ensure they do not get into products.

Critical Requirements

2.12.1.1 Only **food grade** lubricants are used on packaging equipment, or on any other equipment where incidental product contact may occur.

2.12.1.2 **Lubricants** are labeled, segregated, and stored in a designated, secure area. Food grade and non-food grade lubricants are kept separate from each other.

2.13 Cross-contamination Prevention

Different steps in the production of packaging products can negatively impact processing in other areas. Segregation of operations minimizes opportunities for product hazards to arise.

Critical Requirements

2.13.1.1 **Operations are separated** based on risks posed by process flow, material types, equipment, personnel, airflow, air quality, and services needed.

2.13.1.2 The **process flow**, from receiving to shipping, is arranged to prevent product contamination. High-risk and low-risk operations are segregated to minimize product cross-contamination.

2.13.1.3 Areas for **washing and cleaning** are located away from production activities, as appropriate based on risk.

2.13.1.4 **Toilet rooms** are provided with functional exhaust fans that exhaust to the outdoors or do not open directly into production, packaging, or raw material storage areas.

2.13.1.5 **Cleaning and production areas are segregated** with air curtains, partitions, doors, or other sanitary exclusionary systems.

2.13.1.6 Water installations and equipment are constructed and maintained to **prevent back siphonage and backflow.**

2.13.1.7 The **sewage disposal system** is adequate for the process and maintained to prevent direct or indirect product contamination.

Θ

2.14 Equipment and Utensil Construction

Equipment and utensils designed for easy maintenance ensure compliance with Prerequisite and Food Safety Programs. Surfaces that deteriorate, or cannot be cleaned or maintained, may present product contamination hazards.

Critical Requirements

2.14.1.1 All **equipment and utensils** are designed and made of materials that are **easily cleaned and maintained**.

2.14.1.2 Ingredient, product-holding, packaging, conveying, processing, and bulk **equipment** are designed and made of materials that are easily cleaned, inspected, and maintained.

2.14.1.3 Product contact surfaces are **corrosion-free, durable**, and made of **non-toxic** materials.

2.14.1.4 Seams on product contact **surfaces are smooth** and free of spot or tack welds.

2.14.1.5 Pipelines, mixing, and holding tanks are **free of defects**.

2.14.1.6 Pipelines, mixing, and holding tanks are **self-draining.**

2.14.1.7 Grinders, shredders, and similar equipment are **installed above the floor** or protected to prevent floor sweepings or other contaminants from entering the equipment.

Minor Requirements

2.14.2.1 Processing equipment for exposed raw materials, work-in-process, and unwrapped finished product is **not made of wood**, wherever possible and practical. If processing equipment is made of wood, it is maintained.

2.15 Temporary Repair Materials

Temporary repairs are sometimes needed or unavoidable. Procedures to ensure that they do not become a contamination hazard are defined.

Critical Requirements

2.15.1.1 **Tape, wire, string, cardboard, plastic, and other temporary materials** are not used for permanent repairs. If used for emergency repairs, they are dated, controlled and replaced with a permanent repair as soon as possible.

2.15.1.2 Any temporary repairs on product contact surfaces are constructed of **food-grade material.**

2.15.1.3 The facility maintains a **record of work orders** or repair requests, which include progress and status.

2.15.1.4 The facility follows **temporary repair procedures,** which include a list of materials approved for use as temporary repairs.

Minor Requirements

2.15.2.1 Temporary repair issues are **resolved as soon as possible** and practical.

Θ

2.17 Compressed Air/Product Contact Gases

Compressed air or other gases can contain particulate matter, microbes, mold, water, or oil, and may contaminate product.

Critical Requirements

2.17.1.1 Compressed air used in processing areas is **properly filtered** to remove particles of 5 microns or larger, or as required by equipment manufacturer. Compressed air equipment does not contain dirt, oil, or water.

2.17.1.2 **Air traps and filters** are inspected and changed routinely. Air traps and filters are located and designed so that when inspected or changed, they do not contaminate product.

2.17.1.3 **Other gases** used for product contact are of **suitable purity** to protect the finished material or are **filtered** to remove contaminants.

2.17.1.4 **Records of filter inspection** and replacement are maintained.

Minor Requirements

2.17.2.1 Filters for air used on product contact surfaces are located as **close to the point of use** as practical.

2.18 Transporting Equipment

Equipment such as forklifts may introduce cross-contamination issues if they are not maintained.

Critical Requirements

2.18.1.1 **Transporting equipment**, including pan trucks, pallet jacks, carts, trolleys, and forklifts, are maintained to prevent contamination of products being transported.

2.19 Parts Storage

Improperly maintained or dirty repair parts may pose a risk of product contamination from improper storage or cleaning.

Critical Requirements

2.19.1.1 All product contact **parts are stored** in a clean environment off the floor.

2.19.1.2 **Used and soiled conveyor belts** are discarded and not stored for future use.

2.19.1.3 Only **clean repair parts and equipment** are stored in parts storage areas.

Minor Requirements

2.19.2.1 Small items such as nuts, bolts, washers and other, are **properly stored to prevent contamination** of product or damage to equipment.

2.20 Hand Washing Facilities Design

Personnel are provided the equipment to effectively remove contaminants from their hands.

Critical Requirements

2.20.1.1 **Hot and cold running water** is provided in all washrooms, hand sinks, and locker rooms.

2.20.1.2 **Hand washing facilities** have an adequate water supply.

2.20.1.3 Hand washing facilities are **labeled and separated** from utensil washing facilities.

Θ

Minor Requirements

2.20.2.1 **Mix valves** are provided so that water temperatures can be adjusted.

2.21 Bulk Systems and Unloading Areas

Bulk systems and unloading areas may lead to product contamination if improperly installed and maintained.

Critical Requirements

2.21.1.1 Bulk systems and unloading areas are **installed and maintained to prevent contamination** (e.g., roof, covering, canopy, umbrella, inclement weather procedures, etc.).

Θ

2.23 Wastewater Treatment and Sewage Disposal

Wastewater treatment and sewage disposal are conducted in a way that does not present contamination or pest management issues that impact the facility, ingredients, or products.

Critical Requirements

2.23.1.1 Wastewater treatment systems are managed and maintained to **prevent development of microbial or pest management issues.**

2.23.1.2 Sewage disposal systems are **adequate and appropriate** for the process.

2.23.1.3 Sewage disposal systems are maintained to **prevent direct or indirect product contamination.**

3. Cleaning Practices

The cleaning and sanitizing of equipment, utensils, and buildings to provide a wholesome and safe processing environment.

3.1 Cleaning

Cleaning is more than making the facility look good. Cleaning methods and scheduling take product safety into account.

Critical Requirements

3.1.1.1 Cleaning is done in a way that prevents **contamination** of raw materials, products, and equipment.

3.2 Cleaning Compounds and Sanitizers

Cleaning compounds and sanitizers are considered chemicals under the Chemical Control Program.

Critical Requirements

3.2.1.1 All cleaning compounds and sanitizers used to clean product contact surfaces **have food contact surface approval documentation.**

3.2.1.2 **Sanitizer concentrations** are tested to make sure they are consistent with the product label.

3.2.1.3 All cleaning chemicals are **properly labeled**.

3.2.1.4 All cleaning chemicals **are stored** in a secure compartment away from production and product storage areas when chemicals are not in use.

3.2.1.5 The facility follows **verification procedures** and maintains records of chemical concentration testing, retesting, and Corrective Actions.

3.2.1.6 **Equipment is rinsed** as required by label directions to remove chemical residues.

3.3 Cleaning Tools and Utensils

Cleaning tools and utensils may have a negative impact on product safety if not managed properly.

Critical Requirements

3.3.1.1 Cleaning tools and utensils **are available for use**.

3.3.1.2 Cleaning tools and utensils are **maintained and stored** in a way that does not contaminate product or production equipment.

3.3.1.3 **Separate and distinct tools and utensils** are used to clean product contact surfaces (product zones) and structures (product areas).

3.3.1.4 Tools and utensils used to **clean restrooms or floor drains** are never used for any other cleaning purpose.

3.3.1.5 All cleaning tools and utensils are **cleaned and properly stored** after use. Proper storage includes segregation to ensure that cross-contamination does not occur.

3.3.1.6 A **color-code** or other type of classification is in place to identify and separate cleaning tools and utensils based on their intended usage.

3.3.1.7 **Clean tools** and cloths are used on product zones.

3.3.1.8 **Cleaning tools and utensils that may create debris**, such as wire brushes, sponges, and scrub pads, are not used unless absolutely necessary. If used, the area is inspected after use to identify and eliminate any remaining debris that could contaminate the product.

Θ

3.4 Cleaning Equipment

Cleaning equipment may have a negative impact on product safety if not managed properly.

Critical Requirements

3.4.1.1 **Water** used for cleaning in wet production areas is restricted and used in a way that does not contaminate raw materials, work-in-process, packaging, or production equipment with droplets, mist, or direct contact.

3.4.1.2 **Compressed air** used for cleaning is restricted and used in a way that does not contaminate materials, packaging, equipment, and overheads.

3.4.1.3 **Designated ladders** and cleaning equipment are used in contact with interior product contact surfaces and bulk transport vessels (e.g., rail cars, tankers).

3.4.1.4 Designated ladders and cleaning equipment used in contact with interior product contact surfaces and bulk transport vessels (e.g., rail cars, tankers) **are stored** in a clean and sanitary manner.

3.4.1.5 Suitable **clothing, head coverings, and foot coverings** are worn when entering rail cars or other vessels for cleaning, repair, or other purposes to prevent contamination of internal product contact surfaces with hair or foreign material.

3.4.1.6 **Auxiliary equipment** (e.g. forklifts, pallet jacks, aerial lifts, and similar equipment) are cleaned and well maintained.

3.5 Daily (Housekeeping) Cleaning

Daily cleaning focuses on keeping the facility consistently neat and clean.

Critical Requirements

3.5.1.1 Daily cleaning tasks are completed in a way that **prevents contamination**.

3.5.1.2 Daily cleaning tasks **are clearly assigned** and completed.

3.5.1.3 Daily cleaning tasks ensure that **work and support areas remain clean** during working hours.

3.6 Operational Cleaning

Operational cleaning tasks, such as line change-over cleaning, if not addressed properly might cause cross-contamination problems.

Critical Requirements

3.6.1.1 **Operational cleaning tasks** are completed in a way that keeps equipment and production lines clean during working hours.

3.6.1.2 **Line change-over cleaning** is completed, verified as to the cleanliness of equipment and absence of chemical residues as applicable, and documented as defined based on risk assessment.

Θ

3.7 Periodic Cleaning Tasks/ Product Zone Cleaning

Periodic cleaning tasks involve a less frequent deep cleaning that may only be conducted when the area is not in production. These tasks require personnel who have been trained, and they often demand the assistance of maintenance or production personnel to properly disassemble equipment and provide effective cleaning of the product zone to prevent product contamination.

Critical Requirements

3.7.1.1 Periodic cleaning tasks **comply with applicable equipment cleaning procedures,** which are being followed.

3.7.1.2 Periodic cleaning tasks **are scheduled** on a Master Cleaning Schedule, or equivalent.

3.7.1.3 Periodic cleaning tasks **are assigned and completed.**

3.7.1.4 **Equipment guards, trims, and panels** are removed and replaced to inspect and clean the interior of all equipment, as applicable.

3.7.1.5 Equipment and structural overheads (including lights, pipes, and beams) are scheduled for periodic cleaning on the Master Cleaning Schedule to **prevent mold, insect development, or other product contamination issues.**

3.7.1.6 **Ventilation, air extracting ducts and vent grids** are dismantled and cleaned on a defined frequency to prevent contamination issues.

3.7.1.7 Product contact surfaces, product zones, and equipment that require sanitizing are **cleaned and sanitized.**

3.7.1.8 Equipment and utensils that do not require sanitizing are cleaned on a **predetermined schedule.**

3.7.1.9 **Utensils and containers** are washed and dried between uses, or as appropriate, and stored in an inverted position off the floor.

3.7.1.10 **Product handling equipment and product zones** are cleaned often enough to prevent residue from being transferred to products.

3.7.1.11 **Idle lines and equipment** that are not regularly used are kept clean to eliminate pest and microbial issues.

Θ

3.7.1.14 Pipelines, mixing, and holding tanks can be **flushed, cleaned, and sanitized,** as needed.

3.8 Maintenance Cleaning

Debris created during maintenance work as well as small maintenance tools and parts may create contamination issues if effective cleaning does not take place after maintenance work is completed and before start-up of the line.

Critical Requirements

3.8.1.1 **Maintenance cleaning tasks** are completed in a way that does not compromise product safety. This includes, but is not limited to, removal of debris after maintenance tasks are complete (such as nuts, bolts, washers, wire pieces, tape, welding rods, and other small items) that could contaminate product, and accounting for these materials.

3.9 Non-Product Zone and Support Area Cleaning

Cleaning of non-product zones and support areas eliminates product residues that may allow insect development, mold, or other contaminants that could affect the product or impact production.

Critical Requirements

3.9.1.1 **Non-sealed electrical panels** and boxes located in areas that are susceptible to insect development are cleaned and inspected every four weeks.

3.9.1.2 **Equipment guards, trims, and panels** are removed and replaced to inspect and clean the interior of all equipment that is not in direct product zones.

3.9.1.3 **Support areas** that may impact equipment, production, or storage of raw materials or finished products (e.g., washrooms, maintenance shops, tray or pan wash areas, etc.) are cleaned to prevent product contamination or insect development.

3.9.1.4 Non-production areas **used for the storage** of equipment, raw materials, finished products, packaging, or product contact utensils are cleaned and maintained to prevent contamination of product, materials, or equipment.

3.9.1.5 **Dock leveler pits** are cleaned frequently enough to prevent excessive accumulation of debris, product spillage, or other materials.

3.9.1.6 **Racks and storage shelves** are cleaned frequently enough to prevent excessive accumulation of debris, product spillage, or other materials.

Θ

3.9.1.9 **Drains** are **routinely cleaned and sanitized** to prevent microbial and pest development.

Minor Requirements

3.9.2.1 **Non-product contact surfaces** are cleaned regularly and as needed.

Θ

3.11 Clean Out of Place (COP) Systems

Properly designed and followed COP activities and programs allow efficient and effective cleaning of product contact surfaces.

Critical Requirements

3.11.1.1 **Reuse of COP solutions** does not pose a risk to product safety.

3.11.1.2 **Tanks** i.e. soak, boiling, COP, used to clean production equipment, parts, tools, or utensils are cleaned in a manner and frequency to prevent contamination.

4. Integrated Pest Management

The assessment, monitoring, and management of pest activity to identify, prevent, and eliminate conditions that could promote or sustain a pest population.

4.1 Integrated Pest Management (IPM) Program

A written IPM Program ensures the facility has effective controls and processes in place to minimize pest activity.

Critical Requirements

4.1.1.1 The facility has a **written** Integrated Pest Management Program.

4.1.1.2 The IPM Program **incorporates the requirements** of the facility's other written Prerequisite and Food Safety Programs.

4.1.1.3 The IPM Program is written and implemented by trained **in-house personnel or by registered, trained, or licensed contractors.**

4.1.1.4 If the IPM Program development and implementation is outsourced to contractors, the program includes responsibilities for **both in-house personnel and contractors.** An in-house, technically responsible person is appointed to monitor the execution of the program.

4.2 Facility Assessment

An annual assessment of the facility provides an evaluation of the IPM Program to ensure that it is effective.

Critical Requirements

4.2.1.1 Internal or external **trained IPM personnel** conduct an assessment of the facility at least annually. Training includes at a minimum Pest Biology and applicable IPM regulations.

4.2.1.2 The assessment evaluates all areas **inside and outside** the facility, and includes:

- Historical data from prior 12 months at a minimum
- Identification of pest species present, including extent and distribution of presence
- Assessment of the environment that could provide opportunity for pest harborage and proliferation
- Previously applied corrective actions and their effectiveness

4.2.1.3 Assessment **results and Corrective Actions** are documented and used to develop and update the IPM Program.

4.3 Scope of Service

A clearly defined scope of service details all applicable pest management activities and responsibilities and serves as the foundation for an effective IPM program.

Critical Requirements

4.3.1.1 The defined **scope of service** includes:

- Both the facility and the IPM company name
- IPM contact person both for the facility and the contractor
- Frequency of services
- Description of contracted services and how they will be completed
- Term of the contract
- Equipment and material storage specifications, where applicable
- List of approved chemicals, prior to use
- Emergency call procedures (when, why, whom to call)
- Service records to be maintained
- Requirement to notify facility of any changes in service or materials used

4.4 Credentials and Competencies

The facility protects its products by verifying that IPM service providers, whether in-house or contractors, are qualified.

Critical Requirements

4.4.1.1 The facility keeps a copy of the **certification or registration document** for each person who performs pest management services in the facility, as required by regulation.

4.4.1.2 If regulation does not require certification or registration, **IPM service providers are trained** in the proper and safe use of pest management materials by attending a recognized seminar or some other documented training. Evidence of training is on file or available electronically.

4.4.1.3 Persons conducting IPM services have **documented GMP Training**.

4.4.1.4 IPM service providers are **supervised** by a licensed applicator, if required or allowed by regulation.

4.4.1.5 The facility maintains a current copy of the **pest management company license** issued by the appropriate government body, if required.

4.4.1.6 The facility maintains a current copy of the **certificate of insurance** that specifies the liability coverage, where available.

Minor Requirements

4.4.2.1 IPM service providers maintain **evidence of competency** by exam from a recognized organization.

4.5 Pesticide Documentation

The facility maintains current pesticide label and other technical information as applicable, to ensure proper usage of the pesticide chemicals.

Critical Requirements

4.5.1.1 **Pesticide Specimen Labels** are on file for all pesticides used in the facility. Documentation is available for review on request as hard copy or electronic files.

Minor Requirements

4.5.2.1 The **language** of the country is taken into consideration when providing Technical Safety Data Sheets and labels.

4.6 Pesticide Application Documentation

The facility maintains records to identify, verify, and document compliance to regulatory and IPM requirements.

Critical Requirements

4.6.1.1 Documented **pesticide application activities** include:

- Product names of materials applied
- The EPA, PMRA, or product registration number as required by law
- Target pest
- Rate of application or percent of concentration
- Specific location of application
- Method of application
- Amount of pesticide used at the application site
- Date and time of application
- Printed name and signature of applicator

Minor Requirements

4.6.2.1 The facility keeps a **record of additional information** that may be required by regulation, including lot number of product used and the applicator's certification or registration number.

4.7 Pesticide Control

Pesticides are managed as part of the Chemical Control Program.

Critical Requirements

4.7.1.1 **Pesticides are stored** in a limited access, locked area. Storage areas are adequate in size and construction, and are properly ventilated.

4.7.1.2 **Pesticides are stored** according to label directions.

4.7.1.3 Pesticide **containers and application equipment** are labeled to identify contents. Application equipment is not used across multiple pesticides.

4.7.1.4 **Pesticide containers are disposed of** according to label directions and regulatory requirements.

4.7.1.5 **Warning signs** are posted at the entrance of each pesticide storage area.

4.7.1.6 The facility maintains a complete **inventory of all stored pesticides**.

4.7.1.7 **Spill control** materials and procedures are available.

4.8 Trend Analysis

Documentation of pest sightings and activity are reviewed and used to identify and eliminate areas where pest activity is observed, and to document Corrective Actions taken.

Critical Requirements

4.8.1.1 Accurate and complete **service records** describe current levels of pest activity and recommendations for additional Corrective Actions.

4.8.1.2 The **pest-sighting log or reporting system** provides information about the response taken by pest management personnel.

4.8.1.3 All records pertaining to pest management activities are **available as hard copy or electronic files** for review on request.

4.8.1.4 The **pest-sighting log** or reporting system is available to facility personnel.

4.8.1.5 Information gathered through the **pest-sighting log or reporting system includes**:

- Date
- Time
- Type of pests observed
- Location
- Actions taken
- Names of reporting personnel

4.8.1.6 **Pest sightings and activity evidence are reviewed** by pest management personnel at least quarterly or more frequently to identify trends. A report of findings is submitted to designated facility personnel.

4.8.1.7 **Corrective Actions** for identified issues are applied and documented as complete.

4.9 Monitoring Device Documentation

Monitoring device documentation is maintained to ensure that devices are properly placed and inspected, and to allow trend analysis of activity.

Critical Requirements

4.9.1.1 A **detailed survey** of the entire facility is completed, and the results are documented and used to determine **placement of monitoring devices**.

4.9.1.2 A current and accurate **site map** that lists the locations of all monitoring devices used for target pests is on file.

4.9.1.3 **Temporary placement** of any pest monitoring devices for short-term monitoring is also mapped. Device checks are documented according to the frequency defined by the IPM Program. Devices that are no longer needed are accounted for and removed.

4.9.1.4 **Records of all services** performed on all pest-monitoring devices are available.

4.9.1.5 Service records for monitoring devices **match** IPM Program requirement.

4.10 Exterior Rodent Monitoring Devices

Management of exterior rodent monitoring devices deters rodents from entering the facility.

Critical Requirements

4.10.1.1 The **placement of exterior rodent monitoring devices is based on the detailed facility survey** and activity history or as required by country or local regulatory requirements. In the absence of an assessment, devices are placed at intervals of 50–100 ft or 15–30 m.

4.10.1.2 All exterior monitoring devices are inspected **at least monthly** or more often if activity levels dictate.

4.10.1.3 Exterior **monitoring devices containing rodenticides are locked** with single-use plastic ties, padlocks, or devices provided by the manufacturer, such as key systems.

4.10.1.4 Exterior rodent monitoring devices are **tamper resistant** and are positioned, anchored in place, locked, and labeled.

4.10.1.5 Only **baits that are approved** by the regulatory body with authority for IPM (e.g., EPA in the United States) or that are labeled for use in a food facility are used in exterior bait stations.

4.10.1.6 **Baits are secured** inside bait stations, in **good condition**, and **replaced** as needed based on the label directions or manufacturer recommendation to avoid deterioration.

4.10.1.7 When **mechanical traps or non-toxic bait** are used for exterior monitoring, they are checked frequently enough to identify rodent pressure outside the plant and provisions are in place for the detection of rodent activity, effectiveness, cleanliness and placement of the devices.

4.10.1.8 Where prohibited by regulations, **rodenticides are not used** for regular monitoring.

Minor Requirements

4.10.2.1 Evidence of **non-target wildlife** feeding at the exterior monitoring locations, where rodenticides are used, is evaluated and addressed as required by regulations.

4.11 Interior Rodent Monitoring Devices

Interior rodent monitoring devices identify and capture rodents that gain access to the facility.

Critical Requirements

4.11.1.1 **Toxic bait is not used** for interior monitoring.

4.11.1.2 Based on the detailed facility survey, interior monitoring devices are placed in **sensitive areas** specific to the rodent species, and other areas of rodent activity, which may include:

- Incoming materials warehouses or primary storage areas for raw materials
- Maintenance areas with exterior access
- Staging areas where materials are placed after delivery from the warehouse
- Finished product warehouse areas
- Areas with the potential for rodent access due to traffic patterns or activities that take place
- Overhead areas where roof rat activity is evident or likely
- High traffic areas
- Both sides of doors that open to the exterior of the facility. In the absence of an assessment, monitoring devices are placed at intervals of 20–40 ft or 6–12 m along exterior walls and are strategically placed in sensitive areas toward the interior of the facility.

4.11.1.3 Interior monitoring devices are placed along **perimeter walls**. The spacing and number of traps are based on activity levels.

4.11.1.4 Interior monitoring devices are appropriately positioned, cleaned, and inspected at least weekly, or as otherwise defined in the IPM program based on the detailed facility assessment, if the facility can **demonstrate the consistent performance of the equipment and effectiveness of the IPM program**.

4.11.1.5 Unless prohibited by regulation, **interior monitoring devices include:**

- Mechanical traps
- Extended trigger traps
- Glue boards

4.11.1.6 Facilities in countries that prohibit the use of mechanical traps may consider the use of **alternative devices** on a case-by-case basis. These devices may include:

- Gassing traps (e.g., CO_2) traps
- Live catch traps
- See-saw tubes
- Electrocution traps
- Extended trigger traps that send alert e-mails or text messages

4.11.1.7 When **non-toxic monitoring/tracking bait** is used for interior monitoring, a documented proactive program is in place that defines frequency of inspections, identification of non-toxic bait placement, use according to label directions, and corrective action plans for identification and tracking of resident pest populations and elimination of activity when detected.

4.12 Insect Light Traps

When used, insect light traps assist in the identification and monitoring of flying insects.

Critical Requirements

4.12.1.1 Insect light traps, when used, are installed farther than **10 ft or 3 m from product contact surfaces**, exposed products, packaging, and raw materials in processing or storage areas.

4.12.1.2 Insect light traps are installed in a way that does **not attract insects** to the facility.

4.12.1.3 **Service checks** are performed on all units on a weekly basis during the active season and on a monthly basis during colder seasons or as dictated by climate and activity rates. These checks include:

- Emptying collection devices
- Cleaning the units
- Repairs
- Checks for tube breakage

4.12.1.4 **Shatter-resistant lights** are used in all units located in raw materials and production areas. Other lights are managed in the facility's Glass, Brittle Plastics, and Ceramics Program.

4.12.1.5 All services provided to light traps are **documented**.

4.12.1.6 Insect light traps are used to **monitor flying insect activity** at locations identified by the annual IPM assessment.

4.12.1.7 The facility **documents the types and quantities of insects** found in the light traps, and uses the information to identify and eliminate the source of activity. This can include, but is not limited to identifying insect types (e.g., night-flying insects, flies, stored product insects, etc.) and quantities captured (specific or relative numbers [i.e., high, medium, low]) to evaluate the risks and determine appropriate control measures to be taken.

Minor Requirements

4.12.2.1 Insect light trap **tubes are changed** at least annually at the beginning of the active season or based on the manufacturer's recommendations.

4.13 Pheromone Monitoring Devices

Pheromone monitoring devices assist in the identification of stored product insect pests in areas prone to this type of infestation (e.g., grains, cereals, spices, or herbs).

Critical Requirements

4.13.1.1 When used, pheromone monitoring devices, appropriate to the pest species are **installed, maintained and replaced** according to label requirements and the annual IPM assessment.

4.13.1.2 Pheromone monitoring devices **are inspected** on a defined frequency.

4.13.1.3 The facility **documents the types and quantities of insects** found during device inspections and uses the information to identify and eliminate the source of activity.

4.14 Bird Control

Bird control is addressed as part of the IPM Program to prevent contamination of products.

Critical Requirements

4.14.1.1 Birds are **controlled by exclusion** with:

- Nets
- Traps
- Appropriate structural modifications
- Other approved legal methods

4.14.1.2 Avicides are **used** only **if legal**.

4.15 Wildlife Control

In addition to rodents, insects, and birds, other animals can become pests if left unmanaged.

Critical Requirements

4.15.1.1 **Wildlife** establishing habitat on the facility grounds or in the facility **are removed** in accordance with regulations and local ordinances. Wildlife can include dogs, cats, or other domestic animals.

Minor Requirements

4.15.2.1 **Wildlife control measures** are considered, where appropriate. Optional devices include:

- Wire
- Netting
- Distracting devices
- Repellents
- Materials that prevent entry

4.16 Identified Pest Activity

Identified pest activity and attractive habitat in or around a facility, if not addressed effectively, increase the chances of pest problems with severe impact on product safety.

Critical Requirements

4.16.1.1 The facility **addresses and eliminates** any rodent burrows, rodent runs, and conditions that provide harborage or may attract rodents or other pests to the facility or outside grounds.

4.16.1.2 Implementation of an effective pest management program is **demonstrated through the lack of identified pest activity**. Specifically, pest activity whose identification and control is managed as part of the IPM Program.

5. Adequacy of Prerequisite and Food Safety Programs

The coordination of management support, cross-functional teams, documentation, education, training and monitoring systems to ensure all departments of the facility work together effectively to deliver a wholesome and safe final product.

5.1 Accountability

Management authorizes and supports a qualified, supervisory-level person to ensure facility compliance to Programs, law, and regulation.

Critical Requirements

5.1.1.1 Supervisory personnel **monitor the effectiveness of the implementation** of the Prerequisite and Product Safety Programs.

5.1.1.2 The facility has documented procedures to keep the Prerequisite and Product Safety Programs **current and accurate,** which include accountability and compliance to statutory and regulatory laws and guidelines pertaining to product safety and legality. Important new information could include:

- Legislation
- Product safety issues
- Scientific and technical developments
- Industry codes of practice

5.1.1.3 Companies define written procedures to **identify new product safety regulations**. Facilities **register with appropriate Government Agencies** based on site location and countries of export.

5.1.1.4 Procedures define:

- Job description that identify **responsibilities** related to Prerequisite and Product Safety Programs
- **Alternates/Deputies** that are designated to cover for the absence of key personnel.

5.2 Support

Management supplies human and financial resources to support the Prerequisite and Product Safety Programs.

Critical Requirements

5.2.1.1 **Adequate resources are provided** to support effective implementation of the Prerequisite and Product Safety Program.

5.3 Training and Education

Regularly scheduled and tracked training and education ensure that the facility appropriately implements Prerequisite and Product Safety Programs. Training and education is for all personnel, from entry level workers to management.

Critical Requirements

5.3.1.1 There are **written procedures** for developing and delivering Prerequisite, Product Safety (HACCP) and Food Defense training and education to all personnel. Procedures include training as required by regulations.

5.3.1.2 **Training and education records** for all personnel are maintained.

5.3.1.3 The training includes **established means for verification** of competency of the information presented (e.g., testing, supervisor verification, verbal responses, etc.).

5.3.1.4 Prior to beginning work, **new employees, temporary personnel, and contractors** are trained and educated on Prerequisite and Product Safety Programs, as related to their job function and level of responsibility. These personnel are then supervised for compliance.

5.3.1.5 **Refresher training and education** are done at a minimum of annually or more often as needed.

5.4 Self-Inspections

Responsible personnel regularly assess how well the facility implements and monitors Prerequisite and Product Safety Programs.

Critical Requirements

5.4.1.1 The facility has a formal Product **Safety Committee**.

5.4.1.2 The Product Safety Committee schedules and conducts self-inspections of the entire facility and outside grounds at least **monthly**.

5.4.1.3 The Product Safety Committee **documents the results** of the self-inspection. The documentation includes:

- Identified observations
- Corrective Actions
- Root Cause Analysis and Preventive Actions for significant product safety risks
- Specific assignments
- Actual accomplishments

5.4.1.4 Results of the self-inspection are brought to the **attention of the personnel responsible** for the activity inspected.

5.4.1.5 The Product Safety Committee and the responsible key personnel set **deadlines** for Corrective Action implementation and Preventive Action as applicable.

5.4.1.6 The results of Corrective and Preventive Actions are **verified** to ensure satisfactory completion.

Minor Requirements

5.4.2.1 The Product Safety Committee has members from **multiple functions** of the facility.

5.4.2.2 **Follow-up inspections** ensure that findings are addressed.

5.4.2.3 Self-inspections include **down time assessments** to ensure in-depth inspection of equipment and structures.

5.5 Written Procedure Audits

Once procedures are written and personnel are trained, the facility regularly audits the written procedures to ensure they are still valid and effective.

Critical Requirements

5.5.1.1 The **scope and frequency** of the audit is based on risk assessment or importance of activity. Audits are conducted at least annually and assess execution of the program.

5.6 Customer Complaint Program

A written Program for evaluating customer complaints allows the facility to respond to customer concerns. Complaints involving product safety issues, such as adulteration, require an immediate response.

Critical Requirements

5.6.1.1 The facility has a **written** Customer Complaint Program.

5.6.1.2 Complaint information is used to **implement ongoing improvements** to avoid issue recurrence and to ensure product safety.

5.7 Chemical Control Program

A written Program for managing all chemicals in the facility provides a centralized approach to identifying and controlling purchase and use of non-food chemicals.

Critical Requirements

5.7.1.1 The facility has a **written** Chemical Control Program that addresses all chemicals used in the facility (e.g., chemicals for Integrated Pest Management, Maintenance, Sanitation, Hygiene, and Laboratories).

5.7.1.2 **Procedures address, as applicable:**

- Chemical approval
- Purchase authority
- Controlled and segregated storage
- Handling
- Labels/Labeling and/or Technical Data Sheets
- Identification of where and how the chemicals are to be used
- Concentration verification
- Prevention of cross-contamination
- Training and education
- Actual usage
- Inventory control
- Chemical disposal
- Container disposal
- Contractor chemicals
- Allergen declarations

5.8 Microbial Control Program

Pathogens and spoilage organisms can contaminate products if not managed for raw materials, packaging materials, work-in- process, finished product, or micro-sensitive processes.

Critical Requirements

5.8.1.1 If needed, a **written** microbial control program that addresses microbiological analysis for raw materials, finished product, production and packaging is in place, as dictated by the assessment.

5.8.1.2 If required, the Microbial Control Program includes **monitoring, which may include but is not limited to,** procedures to address:

- Sanitation/Hygiene practices
- Harborage site detection
- Corrective/Preventive Actions
- Raw materials
- Finished product

5.8.1.3 **Records** are maintained of laboratory analyses and/or environmental samples that document compliance with the Microbial Control Program.

5.8.1.4 On-site **laboratory facilities**, if present, do not jeopardize product safety.

5.8.1.5 Contract labs maintain appropriate **accreditation** to carry out the analyses performed.

5.8.1.6 All products being **tested for pathogens** are placed on hold and not released until results indicating the food safety of the product have been obtained.

5.8.1.7 Products that **test positive (or above set legal limits) for pathogens are appropriately reprocessed or destroyed**. Documentation of the disposition of these materials is maintained.

5.8.1.8 **Microbiological testing requirements** as defined by country are documented. Testing records are on file, current, and indicate compliance to country-defined requirements.

5.9 Allergen Control Program

The Allergen Control Program controls known allergens throughout the production process from receiving to distribution.

Critical Requirements

5.9.1.1 An Allergen Control Program is in place that addresses allergens as **handled in the facility and as required by regulations in the country of manufacture and country of export**.

5.9.1.2 **Procedures address**:

- Identification and segregation of allergens during storage and handling
- Prevention of cross-contact or contamination during processing by using measures such as:
  - ◊ Production run scheduling
  - ◊ Control of rework
  - ◊ Dedicated production lines
  - ◊ Comprehensive changeover procedures
  - ◊ Equipment and utensils management
- Product label reviews and control
- Personnel awareness training and education
- Verification of cleaning procedures for product contact equipment
- Approved Supplier Program for ingredients and labels
- Validation as applicable or available

5.9.1.3 The Program is **updated** when there are changes in:

- Ingredients
- Processing aids
- Ingredient suppliers
- Products
- Processes
- Labeling
- Applicable regulations

5.9.1.4 **Records** demonstrating program conformance and effective Corrective Actions are maintained.

5.10 Glass, Brittle Plastics, and Ceramics Program

A program supports proactive steps to prevent contamination from glass, brittle plastics, and ceramics.

Critical Requirements

5.10.1.1 The facility has a **written** Glass, Brittle Plastics (acrylic), and Ceramics Program.

5.10.1.2 The program includes the following **policy statements**:

- No glass, brittle plastics, or ceramics are to be used in areas where potential for contamination might exist, except where absolutely necessary or where removal is not immediately feasible.
- No glass, brittle plastics, or ceramics will be brought in with personal belongings.

5.10.1.3 **Procedures address**:

- Handling breakage (including stored glass, brittle plastics, and ceramics)
- A register/list of essential glass, brittle plastics, and ceramics where potential for contamination might exist
- Scheduled inspections of essential glass, brittle plastics, and ceramics to check for accidental breakage or damage

5.11 Cleaning Program

A Cleaning Program with schedules and procedures for accomplishing tasks is critical for maintaining a wholesome and safe processing environment.

Critical Requirements

5.11.1.1 The facility has a **written** Cleaning Program.

5.11.1.2 The written Cleaning Program includes the following **schedules:**

- A Master Cleaning Schedule (MCS) for periodic cleaning assignments
- A Housekeeping Schedule for daily cleaning assignments

5.11.1.3 The **Master Cleaning Schedule** addresses all equipment, structures, and grounds that impact products. The MCS is current and accurate, and includes the following:

- Frequency of activities
- Personnel responsible
- Post-cleaning evaluation techniques, which could include:
  - ◊ Visual inspections
  - ◊ Allergen testing
  - ◊ Preoperative inspections
  - ◊ Adenosine triphosphate (ATP) testing
  - ◊ Equipment swabs
- Documented Corrective Actions

5.11.1.4 The facility has **written cleaning procedures** for all equipment, structures, and grounds that impact the storage, processing, and packaging of products.

5.11.1.5 Equipment **cleaning procedures address**:

- Chemicals
- Chemical concentrations
- Tools
- Disassembly instructions

Minor Requirements

5.11.2.1 The cleaning **tasks are divided** into three general areas and are included on the appropriate schedule:

- Daily (Housekeeping Schedule)
- Periodic (Master Cleaning Schedule)
- Maintenance (Master Cleaning Schedule)

5.12 Preventive Maintenance Program

The Preventive Maintenance Program addresses building, utensil, and equipment maintenance to ensure a safe food contact packaging production environment.

Critical Requirements

5.12.1.1 The facility has a **written** Preventive Maintenance Program and work order system that prioritizes structural, equipment or utensil maintenance problems that could cause product contamination.

5.12.1.2 **Procedures address**:

- Post-maintenance cleaning
- Notification to production, sanitation, hygiene, and/or quality assurance personnel as appropriate
- Tools and parts reconciliation
- Records of evaluation and sign-off by authorized personnel

5.12.1.3 **Records** indicating compliance are maintained.

5.13 Receiving Program

The Receiving Program ensures that raw materials are reviewed and received to prevent product contamination.

Critical Requirements

5.13.1.1 The facility has a **written** Receiving Program.

5.13.1.2 Trained personnel, using appropriate equipment, **inspect** all incoming raw materials, packaging, and vehicles.

5.13.1.3 The facility has **written procedures** for inspecting incoming raw materials.

5.13.1.4 Procedures for **tractor trailer, lorry, or rail deliveries** include steps for evaluation of:

- Raw material condition
- Presence of pest evidence
- Presence of other objectionable materials
- Trailer or rail car condition

5.13.1.5 Procedures for **bulk material deliveries** include steps for:

- Presence of pest evidence
- Presence of other objectionable materials
- Visual inspection of ports, hatches, hoses, and transport interiors before and after bulk deliveries
- Collection of current wash tickets or supplier proof of prior load guarantees if inspection of top hatches is not possible
- Installation of receiving strainers and inspection after each delivery
- Inspection of portable strainers (if used) before and after delivery
- Inclement weather

5.13.1.6 Incoming vehicle procedures include handling **Less Than Load (LTL) vehicles**.

5.13.1.7 The results of inspections are **documented**.

5.13.1.8 **Documented results** of inspections include:

- Date of receipt
- Carrier
- Lot number
- Temperatures (if required)
- Amount
- Intact and verified seal numbers (if used)
- Product condition
- Trailer, lorry, or transport condition

Θ

5.14 Regulatory Affairs and Inspections Program

The Regulatory Affairs and Inspections Program prepares the facility to handle regulatory, third-party, and customer inspections.

Critical Requirements

5.14.1.1 The facility has a **written** Regulatory Affairs and Inspections Program that includes:

- A list of personnel delegated to accompany all Inspectors
- A policy regarding recording devices and cameras
- A policy regarding record and sample taking

5.15 Food Defense Program

The Food Defense Plan identifies and reduces the risk of intentional harm to products.

Critical Requirements

5.15.1.1 The facility has a written **Vulnerability Assessment,** which is performed by person(s) trained in Food Defense. Vulnerability assessment is reviewed on a frequency based on regulation or at least annually.

5.15.1.2 The Food Defense Plan includes **mitigation measures** based on the Vulnerability Assessment.

5.16 Traceability Program

The Traceability Program enables the facility to quickly locate suspect raw materials, product contact packaging materials, rework, and related finished product.

Critical Requirements

5.16.1.1 The facility has a **written** Traceability Program that is regularly reviewed.

5.16.1.2 The facility identifies and documents **lot numbers and traceability information** for:

- Raw materials
- Rework
- Product contact packaging materials
- Work-in-process
- Finished product
- Distribution to the customer
- Processing aids

5.16.1.3 All finished products are **coded and recorded**.

5.16.1.4 The facility tests the program **twice annually** and documents the results:

- Actual test results (including a test for ingredients or product contact packaging material)
- Success rate
- Test timings
- Corrective actions and process improvements where gaps in the program have been identified

Θ

5.17 Recall/Withdrawal Program

Once a suspect product is located, the Recall or Withdrawal Program outlines the procedures for the quick and controlled removal of the product from the market.

Critical Requirements

5.17.1.1 The facility has a **written** Recall/Withdrawal Program that is regularly reviewed.

5.17.1.2 The facility maintains **distribution records** of the initial point of distribution for all products by specific lot.

5.17.1.3 The written **Recall/Withdrawal Program includes** information related to:

- Recall/Crisis Management team contact information: corporate, emergency, and after hours
- Roles and responsibilities for team members
- Type of crisis: product safety/food defense
- Key regulatory agency representative emergency contact information
- Supplier (including product contact packaging) and customer emergency contact information
- Sample recall/withdrawal notification letters

5.18 Non-Conforming Product Program

The Non-Conforming Product Program provides guidelines for isolation, investigation, and disposition of raw materials, packaging materials, work-in-process, returned goods, and finished products that do not meet product safety requirements.

Critical Requirements

5.18.1.1 The facility has a **written** Non-Conforming Product Program.

5.18.1.2 **Procedures address**:

- Investigation of the cause of non-conformity and whether there is a product safety risk
- Time-sensitive Corrective Actions based on the seriousness of the risk identified
- Documentation of actions taken
- Handling and disposal according to the nature of the problem and/or the specific requirements of the Customer
- Personnel authorized to determine product disposition

5.18.1.3 Disposition of non-conforming material is **traceable** for recall or withdrawal.

Minor Requirements

5.18.2.1 **Disposition** can include:

- Rejection
- Acceptance with restrictions
- Regrading

5.18.2.2 The facility **documents** damaged or destroyed materials, and adjusts inventories as necessary.

5.19 Approved Supplier Program

Through an Approved Supplier Program, the facility evaluates suppliers of goods and services that may impact the safety of products.

Critical Requirements

5.19.1.1 The facility has a **written** Approved Supplier Program.

5.19.1.2 **Procedures address**:

- A current and accurate list of approved and non-approved suppliers based on product safety and economically motivated adulteration risks
- Evaluation, selection, and maintenance of approved suppliers
- Actions to take when inspections or monitoring have not occurred (exception handling)
- Standards of performance and criteria for initial and ongoing assessment of suppliers
- Supply chain control program as required by regulations

5.19.1.3 **Methods and frequency** of supplier performance monitoring is based on risk to the facility.

5.19.1.4 **Laboratories** used for analyses are independently accredited by a competent body. Labs can be internal or external.

Minor Requirements

5.19.2.1 Supplier **performance monitoring** can include:

- In-house checks
- Third-party audits
- Certificates of Analysis (COA)
- Supplier inspection
- Evaluation of HACCP Programs
- Product safety information
- Legislative requirements

5.20 Specification Program

Specifications define product safety requirements for raw materials, product contact packaging materials, processing aids, work- in-process, and finished products.

Critical Requirements

5.20.1.1 The facility has **written specifications** for raw materials, product contact packaging materials, processing aids, work-in-process, and finished product.

5.20.1.2 The specifications and procedures include adequate and **accurate information** related to:

- Product Safety Information
- Compliance with regulation
- Agreements between relevant parties
- Defined review frequencies

Θ

5.20.1.4 Where **product labels are printed** on packaging, a procedure for managing the correct version or statements and accuracy of the labels is in place. Records are maintained.

5.21 Letters of Guarantee or Certifications

Letters of Guarantee or Certifications provide statements of assurance, and evidence of compliance to regulatory requirements. This documentation ensures the safety of received materials and shipped finished product.

Critical Requirements

5.21.1.1 Letters of Guarantee or Certifications **provide the following**:

- A statement of compliance to regulations
- Records of examinations and certifications that verify compliance

Θ

5.21.1.3 Specifications or regulatory **approval documentation** indicate that all components used to manufacture food-grade packaging are approved according to local or national codes. Documentation of material approval is available and current.

Θ

5.23 Food Safety Plan

The Food Safety Plan evaluates hazards associated with the raw materials and process steps related to a product or product category. It includes a Hazard Analysis which typically assesses risk by determining the severity of a hazard and its likelihood of occurrence. The goal of a food safety plan is to prevent, eliminate or reduce hazards to an acceptable level.

Critical Requirements

5.23.1.1 The facility has identified all applicable **regulatory requirements** for food safety plans.

5.23.1.2 **Written food safety plans** are in place where required by regulation.

5.23.1.3 For products that aren't required to have a regulated food safety plan, a **HACCP Program**, based on Codex Alimentarius, must be written and implemented. The HACCP Program includes the 12 tasks as defined by FAO:

- Establish a HACCP Team
- Describe the Product
- Identify the product's intended use
- Draw up the commodity flow diagram
- On-site confirmation of the flow diagram
- Identify and analyze hazards
- Determine the critical control points
- Establish critical limits for each CCP
- Establish a monitoring procedure
- Establish corrective action for identified deviation
- Verify the HACCP Plan
- Keep records

5.23.1.4 Records demonstrate **compliance** with food safety plans.

5.23.1.5 Only **qualified personnel who have defined responsibility** for program compliance authorize the following:

- Amendments to records
- Corrective Actions
- Verification of Corrective Actions

5.23.1.6 Food Safety plans and procedures are **reviewed** as required on a frequency as defined by regulation. In the absence of regulation, reviews are conducted when there are product or process changes and at least annually.

5.25 Release Procedures

The facility defines and follows release procedures for materials on positive hold. Examples could include, but are not limited to, pending receipt of product safety testing results, document review, or other protocols.

Critical Requirements

5.25.1.1 The facility defines and follows **release procedures**.

5.25.1.2 Products are not released unless all release **procedures have been followed.**

5.25.1.3 Raw materials, work-in-process, and/or finished product are only **released by authorized personnel**.

5.26 Design Standards

Structural and equipment design standards offer a consistent approach to designs, repairs, modifications, and purchases, and take into account Prerequisite and Product Safety Programs.

Critical Requirements

5.26.1.1 The facility has an effective mechanism in place to ensure that **sanitary design principles are considered** as part of all structural and equipment designs, repairs, modifications, or purchases to reduce the potential for contamination, cross-contact, and pest infestations, and to facilitate cleaning efforts.

5.27 Water Quality

Water, water sources, and water management strategies provide clean water that is safe for product contact activities.

Critical Requirements

5.27.1.1 The facility's water supply **complies with regulatory requirements**.

5.27.1.2 The facility has a safe and/or **potable water supply** from an approved source.

5.27.1.3 **Documentation** of the results of water testing is on file.

5.27.1.4 **Water, steam, and ice** that contacts product and product contact surfaces are regularly monitored to ensure there is no risk to product safety.

5.27.1.5 **Routine checks** verify that back siphonage and backflow prevention units are functioning properly. Results are documented.

5.27.1.6 **Water treatment chemicals** used in steam or water that comes into direct or indirect contact with product are approved for food contact.

5.27.1.7 Water treatment chemicals are used according to **label directions**. Results of concentration testing and verification procedures are documented.

5.27.1.8 **Back siphonage and backflow prevention units** are identified in the Preventive Maintenance Program.

5.27.1.9 Regular **water samples** are taken from underground well water supplies and surface water sites according to local health department codes and government requirements.

5.27.1.10 Controls based on risk assessment are in place when **recycled water** is used.

5.28 Testing Requirements

Defined testing requirements indicate that food contact packaging does not transfer odor, taste, or chemicals to the food products contained within.

Critical Requirements

5.28.1.1 Where applicable, **testing procedures are defined for evaluation** of transfer of chemical, odor, and taste to food products that will be packaged using these materials.

5.28.1.2 Chemical testing demonstrates that **finished product chemicals** will not migrate into food products above the established tolerances defined for the chemical being tested.

5.28.1.3 Testing **indicates compliance** to the requirements and records are current.

5.28.1.4 Procedures are defined to demonstrate that processes and equipment are capable of consistently **producing safe and legal products** as defined by country requirements. (Europe Only)

Appendix A—Documents to Have Ready for an Inspection

The following is a list of documentation that an inspector may ask to review during an inspection. Documentation is listed by Standard. Many facilities find it convenient to gather these documents ahead of time and have them printed in a binder or collected electronically in one central location.

1. Operational Methods and Personnel Practices

1.1 Rejection of Shipments/Receipt of Dry Goods

- ❑ Rejected shipment records

1.3 Storage Practices

- ❑ Procedures for cleaning, inspection, and pest monitoring

1.4 Storage Conditions

- ❑ Procedures for managing packaging with special handling requirements
- ❑ Failure and Corrective Actions documentation for packaging with special handling requirements
- ❑ Documentation of disposition decisions for returned products

1.5 Raw Material/Finished Product Inventory

- ❑ Inspection documentation for insect-susceptible materials in storage for longer than four weeks

1.6 Pallets

- ❑ Inspection of pallets when they are stored outside

1.7 Carry-Over and Rework

- ❑ System to establish maximum storage time for rework.

1.9 Bulk Material Handling

- ❑ Seal verification documentation
- ❑ Tanker wash tags/prior load verification

1.11 Processing Aids

- ❑ Food approval documentation

1.12 Material Transfer

- ❑ Procedures for transferring and handling materials, including traceability information

1.15 Foreign Material Control Devices

- ❑ Procedures to operate, monitor, and test foreign material control devices
- ❑ Test records, Corrective Actions, and procedures for foreign material control devices
- ❑ Investigation and Corrective Actions documentation for product rejections

1.23 Cross-Contamination Prevention

- ❑ Procedures that identify and segregate raw materials, work-in-process, rework and finished products to prevent cross-contamination.
- ❑ Documentation of purging, cleaning process and release of the line between nonfood contact and food contact packaging manufacturing

1.24 Cans, Bottles, and Rigid Packaging

- ❑ Validation and verification records for washing processes where applicable.

1.25 Finished Product Transportation

- ❑ Distribution records that identify the initial point of distribution
- ❑ Transportation breakdown procedures
- ❑ Shipping vehicle inspection documentation
- ❑ Security seal or padlock documentation

1.31 Personal Items and Jewelry Control

- ❑ Personnel Practices Program
- ❑ Exceptions to Personnel Practices Program

1.32 Health Conditions

- ❑ Personnel health cards
- ❑ Blood/Bodily fluid policy/procedures
- ❑ Documentation of testing metal-strip bandages or other detectable protective devices

1.35 Glass Container Breakage

- ❑ Procedures to address glass container breakage

- ❑ Records documenting glass container breakage procedures were followed

2. Maintenance for Food Safety

2.8 Glass, Brittle Plastics, and Ceramics Control

- ❑ Glass, Brittle Plastics, and Ceramics Program

2.9 Air Makeup Units

- ❑ Preventive Maintenance Schedule for fans, blowers, filters, cabinets, and plenums
- ❑ Filter size documentation: 50 microns/MERV 4 or larger

2.12 Lubricants

- ❑ Evidence that lubricants are food-grade

2.15 Temporary Repair Materials

- ❑ Temporary repair procedures
- ❑ Work orders and repair requests

2.17 Compressed Air/Product Contact Gases

- ❑ Micron rating of compressed air filter
- ❑ Purity/filter documentation for other gases for product contact
- ❑ Records of filter inspection and replacement.

3. Cleaning Practices

3.2 Cleaning Compounds and Sanitizers

- ❑ Food contact surface approval documentation for cleaning compounds and sanitizers
- ❑ Records of testing of cleaning chemical concentrations
- ❑ Verification procedures for testing chemical concentrations, and corrective actions

3.3 Cleaning Tools and Utensils

- ❑ Documentation of color-code or other classifications

3.4 Cleaning Equipment

- ❑ Cleaning of auxiliary equipment

3.5 Daily (Housekeeping) Cleaning

- ❑ Documentation of daily cleaning task assignments, schedules and completion records

3.6 Operational Cleaning

- ❑ Cleaning and verification records for line change-over cleaning

3.7 Periodic Cleaning Tasks/Product Zone Cleaning

- ❑ Documentation of periodic cleaning task assignments, schedules and completion records

4. Integrated Pest Management

4.1 Integrated Pest Management (IPM) Program

- ❑ IPM Program
- ❑ Written responsibilities for trained in-house and outside contractors

4.2 Facility Assessment

- ❑ Documentation of the facility assessment
- ❑ Training records for personnel conducting the assessment
- ❑ Documentation of Corrective Actions

4.3 Scope of Service

- ❑ Scope of service records, including all elements as listed in the Standard

4.4 Credentials and Competencies

- ❑ A copy of the certification or registration document for each person who performs pest management activities
- ❑ A copy of the pest management company license
- ❑ A current copy of the certificate of insurance
- ❑ Records to prove that applicators have had training in:
    - The GMPs
    - IPM in food facilities
    - Evidence of competency by exam from a recognized organization

4.5 Pesticide Documentation

- ❑ Records of pesticide specimen labels

4.6 Pesticide Application Documentation

- ❑ Pesticide application records that address the requirements listed in 4.6.1.1 of the AIB International Consolidated Standards
- ❑ Records of the lot number of the pesticide used, or applicator's certificate or registration number, as applicable

4.7 Pesticide Control

- ❑ Inventory of stored pesticides

4.8 Trend Analysis

- ❑ Records pertaining to pest management activities
- ❑ Service records describing current levels of pest activity
- ❑ Pest-sighting logs or other reporting system
- ❑ Written reports of quarterly (or more frequent) reviews of activity evidence
- ❑ Documented Corrective Actions

4.9 Monitoring Device Documentation

- ❑ Facility survey for use in determining placement of monitoring devices
- ❑ Site map that lists the locations of all pest-monitoring devices used for targeted pests
- ❑ Records of services performed on all pest-monitoring devices

4.11 Interior Rodent Monitoring Devices

- ❑ Facility survey to establish frequency of device inspections, if not weekly
- ❑ Records demonstrating efficiency of the IPM program

4.12 Insect Light Traps

- ❑ Records of services performed on light traps
- ❑ Documentation of the types of insects captured in the light traps

4.13 Pheromone Monitoring Devices

- ❑ Documentation of the types of insects captured in the pheromone monitoring devices

5. Adequacy of the Food Safety and Prerequisite Programs

5.1 Accountability

- ❑ A procedure to keep the Prerequisite and Product Safety Programs current and accurate
- ❑ Written procedures to meet legislative requirements
- ❑ Procedures that define responsibilities related to PRP and product safety, alternates and deputies

5.3 Training and Education

- ❑ Written procedures for developing and delivering Prerequisite, Product Safety (HACCP) and Food Defense training
- ❑ Training records for all personnel
- ❑ Training criteria for competency requirements to confirm understanding of the information presented

5.4 Self-Inspections

- ❑ Identified observations, corrective actions, root cause analysis and preventive actions (as applicable), specific assignments, actual accomplishments

5.5 Written Procedure Audits

- ❑ Results of the audits and Corrective Actions

5.6 Customer Complaint Program

- ❑ Customer Complaint Program

5.7 Chemical Control Program

- ❑ Chemical Control Program
- ❑ Procedures that address the requirements listed in 5.7.1.2 of the AIB International Consolidated Standards

5.8 Microbial Control Program

- ❑ Microbial Control Program
- ❑ Records of lab analysis and/or environmental sample testing results
- ❑ Contract lab accreditation
- ❑ Hold/release records for pathogen testing
- ❑ Records of destruction/reprocessing for products with positive pathogen testing results
- ❑ Microbial testing requirements as defined by country, and associated testing records

5.9 Allergen Control Program

- ❑ Allergen Control Program
- ❑ Procedures that address the requirements listed in 5.9.1.2 of the AIB International Consolidated Standards
- ❑ Records of Program updates
- ❑ Records demonstrating conformance and Corrective Actions

5.10 Glass, Brittle Plastics, and Ceramics Program

- ❑ Glass, Brittle Plastics, and Ceramics Program

- ❑ Statements that address essential glass, brittle plastics, and ceramics as they relate to personal belongings
- ❑ Procedures that address handling of glass, brittle plastics, and ceramics breakage
- ❑ A list of essential glass, brittle plastics, and ceramics
- ❑ Scheduled inspections list

5.11 Cleaning Program

- ❑ Cleaning Program
- ❑ The Master Cleaning Schedule
- ❑ The Housekeeping Schedule
- ❑ The cleaning procedures for equipment, structures, and grounds

5.12 Preventive Maintenance Program

- ❑ Preventive Maintenance Program
- ❑ Work order system
- ❑ Procedures for:
    - Post-maintenance cleaning
    - Notification of production, sanitation, and/or QA personnel
    - Parts and tools reconciliation
    - Evaluation and sign-off
- ❑ Records of compliance

5.13 Receiving Program

- ❑ Receiving Program
- ❑ Procedures for tractor, trailer, lorry, and rail deliveries
- ❑ Procedures for bulk material delivery
- ❑ Procedures for the handling of LTL vehicles
- ❑ Documented inspection results
- ❑ Procedures for mycotoxins and pathogen susceptible raw materials

5.14 Regulatory Affairs and Inspections Program

- ❑ Regulatory Affairs and Inspections Program

5.15 Food Defense Program

- ❑ Vulnerability Assessment and mitigation measures
- ❑ Food Defense Plan

5.16 Traceability Program

- ❑ Traceability Program

- ❑ Records of lot numbers for raw materials, rework, ingredients, work-in-process, finished product, processing aids, product contact packaging, etc.
- ❑ Records of finished product coding
- ❑ Results of program testing twice annually, including elements as described at requirement 5.16.1.4

5.17 Recall/Withdrawal Program

- ❑ Recall/Withdrawal Program
- ❑ Distribution records to the initial point of distribution by specific lot

5.18 Non-Conforming Product Program

- ❑ Non-Conforming Product Program
- ❑ Procedures that address non-conforming product investigation, Corrective Actions, handling, and disposal
- ❑ Disposition records for recall
- ❑ Documentation for damaged or destroyed materials and adjusted inventories

5.19 Approved Supplier Program

- ❑ Approved Supplier Program
- ❑ Approved Supplier Program procedures including: list of approved and non-approved suppliers, evaluation of suppliers, actions when audit/monitoring has not occurred, standards of performance for ongoing assessment, Supply Chain Control Program
- ❑ Records of supplier performance monitoring
- ❑ Documentation of the methods and frequency for supplier performance monitoring

5.20 Specification Program

- ❑ Written specifications for raw materials, packaging materials, processing aids, work-in-process, and finished product
- ❑ Procedure for managing the correct version or statements and accuracy of the labels

5.21 Letters of Guarantee or Certifications

- ❑ Letters of Guarantee or Certifications
- ❑ Documentation of material approval according to local or national codes, for all components used to manufacture food-grade packaging

5.23 Food Safety Plan

- ❑ Written food safety plan/HACCP including 12 tasks as defined by FAO and associated records
- ❑ Records of program review

5.25 Release Procedures

- ❑ Release procedures
- ❑ Records of compliance with release procedures

5.26 Design Standards

- ❑ Procedure/mechanism for considering sanitary design principles in designs, repairs, modifications, purchases

5.27 Water Quality

- ❑ Records of routine checks of backflow prevention devices
- ❑ Results of water sample testing or documents proving potability
- ❑ Evidence that boiler chemicals are approved for food contact
- ❑ Preventive Maintenance Schedule for back siphonage and backflow prevention units

5.28 Testing Requirements

- ❑ Testing procedures for evaluation of transfer of chemical, odor and taste to food products
- ❑ Testing records
- ❑ Procedures demonstrating that processes and equipment are capable of consistently producing safe and legal products as defined by country requirements (Europe only)

Appendix B—Conflict Resolution Process

If there is a concern about an inspection experience or scoring:

1. Contact Customer Service:
    - **North America** + 1-785-537-4750 or 1-800-633-5137
    - **Latin America** + 52-442-135-0912 or 1-800-300-5608
    - **Japan** + 81-3-5659-5081
    - **Europe** + 44 0-1372 365-788
    - **China** + 86 021-60959606
    - info@aibonline.org
2. The Customer Service Associate will gather information about the concern and forward it to our Quality Assurance Team for review.
3. The Quality Assurance Representative will assess the concern and determine the course of action.
    - The client may be contacted to further define the concern and to assist with the investigation.
    - A Quality Manager, or designee, will determine corrective and preventive actions to be taken.
    - When there is a scoring dispute:
        - The report is placed on hold.
        - The report is sent for blind review, in which:
            - The Category Scores, the Total Score, and the name of the Inspector will be removed from the initial inspection report.
            - Five independent parties will review the report impartially, and with no outside influences.
            - A consensus of opinion will be gathered by the Quality Manager.

Appendix C—Glossary

Acceptance with Restrictions—Non-conforming product is accepted within a limited scope of use.

Adenosine Triphosphate Testing (ATP)—ATP is found in all animal, plant, bacterial, yeast, and mold cells. It occurs in food and in microbial contamination. The ATP test uses bioluminescence to detect the presence of ATP left on a surface after cleaning to validate the removal of product that could contribute to microbiological contamination on product contact surfaces.

Adulteration—To make imperfect by adding extraneous, improper, or inferior ingredients.

Air Makeup Unit—Equipment that tempers outside air and introduces it into a building to eliminate negative pressure and provide positive operating pressure within a facility.

Air Return Duct—Ductwork that takes air from inside the facility and returns it to the main air handling or makeup unit.

Aseptic—Free of pathogenic microorganisms.

Aseptic Packaging—The process through which food products and packaging are sterilized separately and then combined and sealed in a sterilized atmosphere.

Audit—A systematic evaluation of food facility documentation to determine if programs and related activities achieve planned expectations.

Auditor—A person who conducts an audit.

Avicide—A pesticide that targets birds.

Back Siphonage—The flowing back of used, contaminated, or polluted water from a plumbing fixture or vessel into the pipe which feeds it; caused by reduced pressure in the pipe.

Bioluminescence—Emission of visible light by living organisms, such as fireflies, fish, fungi, bacteria, or others.

Body Jewelry—Adornments to the face or body that are seemingly suspended on the skin with no visible piercings or other attachment point. These are typically suspended on the body or face through the implantation of a magnet below the skin to hold the jewelry in place.

Brittle Plastics—Non polycarbonate-based plastics such as acrylic or Plexiglas.

Bulk Materials—Materials that are delivered or shipped via means of a tank truck, hopper truck, rail tank car, hopper car, cargo tank, portable tank, freight container, hopper bin, or any other vehicle in which food is shipped in large quantities, with the food coming into direct contact with the vehicle.

Carry-Over Product—Product from one production run that is carried over into the next production run.

Catch Pan—A shallow or open container placed under a gearbox to collect any leakage to prevent product contamination.

Category—The AIB International Consolidated Standards for Inspection are divided into five categories: Operational Methods and Personnel Practices, Maintenance for Food Safety, Cleaning Practices, Integrated Pest Management, and Adequacy of Prerequisite and Food Safety Programs.

Category Score—The numerical score for each of the following categories: Operational Methods and Personnel Practices, Maintenance for Food Safety, Cleaning Practices, Integrated Pest Management, and Adequacy of Prerequisite and Food Safety Programs.

Category Score Range—The numerical range within which a category will be scored. The five category score ranges align with the five risk assessment categories: No Issues Observed (200), Minor Issues Noted (180–195), Improvement Needed (160–175), Serious (140–-155), or Unsatisfactory (≤135).

Clean Out of Place (COP)—The manual cleaning of dismantled parts of equipment.

Cleaning Types—

Deep—Cleaning that typically requires skilled personnel and involves the disassembly of equipment or entry into equipment housings for safe removal of food residues to eliminate the potential for cross-contamination and prevent mold, microbiological, or insect development.

Operational—Cleaning of production lines and equipment within operational hours i.e. line change-over cleaning.

Housekeeping—Cleaning of exterior surface areas to keep a facility neat and clean.

Maintenance—Cleaning that requires specialized assistance from skilled maintenance personnel to remove food residues, maintenance chemicals, foreign material, or contamination resulting from maintenance activities.

Personnel Areas—Cleaning of bathrooms, locker rooms, break areas, or other similar areas.

Certificate of Analysis (COA)—A document containing test results that are provided to the customer by the supplier to demonstrate that product meets the defined test parameters, and complies with the ingredient specifications.

Chemical Safety Data Sheet (CSDS)—A document designed to provide workers and emergency personnel with the proper procedures for working with or handling a chemical substance. The CSDS provides information such as physical and chemical data, toxicity, health effects, emergency and first aid procedures, storage, disposal, protective equipment requirements, routes of exposure, control measures, precautions for safe handling and use, and spill/leak procedures.

Competency—A range of skill, knowledge, or ability.

Contamination—The act or process of making something harmful or unsuitable. The presence of extraneous, especially infectious, material that renders a substance or preparation impure or harmful.

Corrective Action—A change implemented to address an identified weakness.

Critical Control Points (CCPs)—A point, step, or procedure at which controls can be applied and a food safety hazard can be prevented, eliminated, or reduced to an acceptable level.

Deflector Plate—An angled piece of metal or plastic with a lip on either side that is placed under a bearing or gearbox to divert lubrication or other leakage away from the product or food contact surface to prevent contamination.

Environmental Protection Agency (EPA)—The US government agency tasked with developing and enforcing regulations that implement environmental laws enacted by Congress. This includes, but is not limited to, regulations such as: pesticide laws and registration, The Clean Water Act, and drinking water requirements.

Essential Glass—Glass in a facility that is unavoidable or that cannot be replaced with another material.

FAO—Food and Agriculture Organization of the United Nations

Findings—Notes made by an inspector that are indexed to a Standard or related requirement. There may be multiple findings in an observation.

Floor/Wall Junction—The point at which the floor and wall meet.

Food Grade—A material or product that will not transfer non-food chemicals into the food and contains no chemicals that would be hazardous to human health.

Food Safety Modernization Act (FSMA)—The act signed into law on January 4, 2011 that aims to ensure the safety of the US food supply by shifting the focus from responding to contamination to preventing it.

Food Safety Plan—A plan which identifies, evaluates, and proactively controls hazards which are significant for food safety.

Foreign Supplier Verification Program—The import requirement of FSMA that deals with verification of the safety of food offered for import into the United States. Importers that fail to comply with this program are prohibited from importing food into the United States.

Global Food Safety Initiative (GFSI)—GFSI is the organization/technical committee that has established the criteria against which to benchmark certification standards. The criteria are also used to benchmark food safety management schemes.

Good Manufacturing Practice (GMP)—A food manufacturing practice that, when followed, protects food from contamination. Sometimes a "c" is placed in front of the abbreviation, GMP, to indicate that the practice is current.

Hazard Analysis Critical Control Point Program (HACCP)—A system that identifies, evaluates and controls hazards significant to food safety.

HVAC — Heating, Ventilation, and Air Conditioning.

Imminent—Likely to occur at any moment.

Infestation—The presence of live or dead life cycle stages of insects in a host product, the evidence of insect presence, or the establishment of an active breeding population.

Initial Category Score—This is the first score assigned based on severity. The total number of single and separate observations may bring the initial category score down.

Inspection—A thorough physical review of a food facility to assess what is actually happening in a facility at a moment in time.

Inspector—A person who conducts the inspection.

Integrated Pest Management (IPM)—An effective and environmentally sensitive approach to pest management that relies on a combination of common sense practices. The information in combination with available pest control methods is used to manage pest damage by the most economical means and with the least possible hazard to the people, property, and environment.

Intermediate Containers—Containers used to transfer a raw material or food product.

Less Than Load (LTL)—A shipment that contains materials that will be delivered to multiple sites.

Materials—Includes but is not limited to raw materials, packaging, work-in-progress, finished products, food contact processing aids, and other as applicable.

Minimum Efficiency Reporting Value (MERV)—The measurement scale developed by the American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) to rate the effectiveness of air filters.

Morgue/Salvage Area—A specific area set aside to accumulate, sort, and repackage or discard damaged products.

Multiple Observations—Findings (single or multiple) noted under more than one Standard and related requirements. For example: All findings noted in 1.1 Rejection of Shipments/Receipt of Dry Goods and 1.3 Storage Practices will be counted as two observations. An observation will be counted for each Standard involved.

Mycotoxins—A toxin produced by an organism in the fungus kingdom, which includes mold and yeast.

Non-toxic—Not toxic; a non-toxic substance is not considered a food, but would not cause injury or death if consumed.

Organoleptic—Any sensory properties of a product to include taste, color, texture, odor, or feel. Organoleptic testing is the process of evaluation of product through visual examination, feeling, and smelling of products.

Pathogen—An agent that causes disease, especially a living microorganism such as a bacterium or a fungus.

Pest Harborage—Any condition or structural defect that provides a place for pests to live and reproduce.

Pesticide—A chemical used to kill harmful animals or plants. Pesticides are used especially in agriculture and around areas where humans live. Some are harmful to humans, either from direct contact or as residue on food, or they are harmful to the environment because of their high toxicity, such as DDT (which is now banned in many countries). Pesticides include fungicides, herbicides, insecticides, and rodenticides.

PMRA: Pest Management Regulatory Agency (Canada).

pH—The numerical measure of acidity or alkalinity of a solution. Numbers decrease for acidity and increase for alkalinity. A neutral solution has a pH measure of 7.

Pheromone—A chemical secreted by an animal, especially an insect, that influences the behavior or development of others of the same species, and often functions as an attractant of the opposite sex.

Pheromone Trap—A trap that uses a pheromone to attract insects to a glue board so that the insects are captured. Pheromone traps are used to determine the presence and quantity of insects in order to identify activity or infestation in a facility.

Plenums—A space, usually above a ceiling or below a floor, that can serve as a receiving chamber for heated or cooled air to be distributed to inhabited areas.

Policy—Statements that reflect decisions made by management. Policies are frequently strategic statements from facility leadership that demonstrate the direction of the organization and prove senior management support.

Potable—Fit to drink. In food safety, this usually refers to water.

Practices—Physical evidence that a Program is being followed in a facility. For example, if an inspector sees that a facility keeps chemicals segregated and secure, this is proof that a facility is implementing a Chemical Control Program through practice.

Prerequisite Programs—Food facility Programs that lay the foundation for food safety and HACCP and create the environment required for producing clean and safe food.

Preventive Control—Risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis.

Preventive Maintenance Program—A schedule of planned maintenance activities.

Prior Load Verification—Documentation indicating that the same material was shipped in a bulk vessel to demonstrate that no cross-contamination of non-like materials shipped in the same vessel occurred. This is typically done when a wash or dry cleaning step is not conducted between loads.

Procedures—Step-by-step instructions on how to execute a task in a Program. For example, in a facility's Chemical Control Program, there may be a procedure on how to clean up a chemical spill.

Processing Aid—A substance or material, not including apparatus or utensils and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods, or its ingredients to a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

Product Area—The area close enough to the product zone that, if an issue were found there, would impact the safety of the product zone.

Product Zone—All food contact surfaces, and all unprotected areas directly above food contact surfaces. The product zone includes areas directly above exposed to raw materials, work-in-process, or finished product.

Program—A collection of documentation related to the management of an element in a facility that impacts food safety. For example, a Chemical Control Program documents everything related to the control of chemicals in a food facility. This might include procedures, policies, personnel responsible, lists of approved chemicals, storage requirements, documentation requirements, or other documents. All Prerequisites in a facility have a documented Program.

Purity—The condition or quality of being pure; freedom from anything that debases, contaminates, pollutes, etc.

Recall—The voluntary removal of a product from the marketplace when the product is either in violation of regulations or regulatory agencies could take legal action against the product.

Regrading—The process by which product that does not meet specification, or is deemed substandard, is reassessed and diverted to another use for which it can meet a defined specification or be used for another purpose.

Rejection—To refuse to accept non-conforming product.

Reportable Food Registry (RFR)—An electronic portal maintained by the US FDA for industry to report when there is a reasonable probability that an article of food will cause serious adverse health consequences. This applies to all FDA-regulated categories of food and feed, except dietary supplements and infant formula. Registered food facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are subject to this act.

Rework—Clean, unadulterated product that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and is suitable for use as packaging material.

Risk Assessment—A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

Security Seal—A closure to prove no tampering of contents has occurred.

Sensitive—Readily affected or vulnerable. In this document, sensitive is used to describe foods that are affected by temperature and areas of a facility that are vulnerable to pests or contamination.

Severity—The level of risk within a risk assessment category (e.g., how severe is an observation within the risk category of Improvement Needed?).

Single Observation—Findings (single or multiple) noted under a single Standard and related requirements. Example: All findings noted in Standard 1.6 Pallets or in any of its requirements (1.6.1.1, 1.6.1.2, 1.6.2.1, 1.6.2.2) will be evaluated as one observation.

Single-Service Container—A container that is designed to be used once and discarded.

Socks—Typically a cloth material enclosure provided on the top of a silo, mixer, or tanker transport to

allow airflow to occur while protecting the interior product and product contact surfaces from contamination.

Supplier Guarantees/Letter of Guarantee (LOG)—A letter provided to the customer from the supplier stating that their product meets all regulatory requirements, and that they intend to continue to meet these guidelines for all products that they will produce and sell to the customer.

Total Score—The total of all category scores.

Toxic—Capable of causing injury or death, especially by chemical means; poisonous.

Traceability—The identification of any suspect ingredient or finished product and its initial shipment location. While related to recall, traceability is a separate program.

Transportation Breakdown Procedures—Procedures to ensure the safety of refrigerated or frozen food products in the event of a vehicle breakdown or cooling unit malfunction during product transportation.

Validation—To establish whether a Program or procedure is correct or not.

Verification—To establish whether a Program or procedure is being followed or not.

Wash Certificates/Tags—A certificate stating that a trailer or vessel was appropriately cleaned and/or sanitized prior to loading to prevent contamination of the product contained within. Wash certificates may contain information related to the date the cleaning occurred, the party performing the cleaning, wash temperatures, or any other relevant information.

Water Activity (a)—The amount of water that is not bound chemically to other chemicals within the product. This water may also be referred to as "free, active, or unbound" water and, because it is not chemically bound, it is available to allow microbiological growth or other undesirable chemical changes in the product.

Withdrawal—The voluntary removal or correction of a product in the marketplace that involves a minor infraction that does not warrant legal action.

Work-in-Process—Products that are in-between machines, processes, or activities, and are waiting further processing

Standards Index

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Operational Methods and Personnel Practices