



The AIB International
**Consolidated
Standards**
for
Inspection

**Prerequisite
and
Food Safety
Programs**

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

www.aibonline.org

Call AIB International World Headquarters
+1-785-537-4750
for international contact information

Disclaimer

The information provided in this or any other version of the AIB International Consolidated Standards is not legal advice, but general information based on good manufacturing practices, common regulatory requirements, and food safety practices typically encountered in a food manufacturing facility. These Standards have been developed as a guide to best practices and are not intended, under any circumstances, to replace or modify the requirement for compliance with applicable laws and regulations. These Standards are not intended to meet all existing laws and regulations, nor those laws or regulations that may be added or modified subsequent to the publication of these Standards. AIB International shall not be liable for any damages of any kind, arising in contract, tort, or otherwise, in connection with the information contained in these Standards, or from any action or omission or decision taken as a result of these Standards or related information. Further, AIB International expressly disclaims any and all representations or warranties of any kind regarding these Standards.

Copyright

© AIB International 1956, 1978, 1985, 1990, 1995, 2000, 2008, 2012. All rights reserved.

Users of these Standards and associated documents are reminded that copyright subsists in all AIB International publications and software. Except where the Copyright Act allows and except where provided for below no part of this publication may be transmitted or reproduced, stored in a retrieval system in any form, or transmitted by any means without prior permission in writing from AIB International.

All requests for permission should be addressed to the Vice President of Administration at the address below.

No part of this publication may be translated without the written permission of the copyright owner.

The use of this material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. AIB International may vary this policy at any time.

AIB International
1213 Bakers Way
PO Box 3999
Manhattan, KS 66505-3999
United States

The AIB International Consolidated Standards for Inspection. January 2013

ISBN 978-1-880877-02-9

13.1.A

TABLE OF CONTENTS

Prefaceiv
Introduction to the Standards v
The Categories..... v
How to Read the Standards.....vi
Scoringvii
Consolidated Standards for Inspection..... 1
Appendix A—Documents to Have Ready for an Inspection 39
Appendix B—Conflict Resolution Process 44
Appendix C—Glossary 45
Standards Index 50

Preface

Description of the Document

The AIB International Consolidated Standards for Inspection of Prerequisite and Food Safety Programs 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

Design of the Document

The design of the document employs the following strategies to support ease of use:

- Consistent terminology used throughout the document
- 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

Inspection and Audit

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 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 regulation 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
- Look at trends over time

Introduction to the Standards

The AIB International Consolidated Standards for Inspection of Prerequisite and Food Safety Programs are statements that represent key requirements that a facility must meet in order to keep the food products in a 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, the types of chemicals used, the frequency of cleaning activities, and the control of microbes must all be done expertly to protect products from food safety issues. The Cleaning Practices Standards give 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 give strategies for managing multiple approaches to ensure that pests do not adulterate food products.

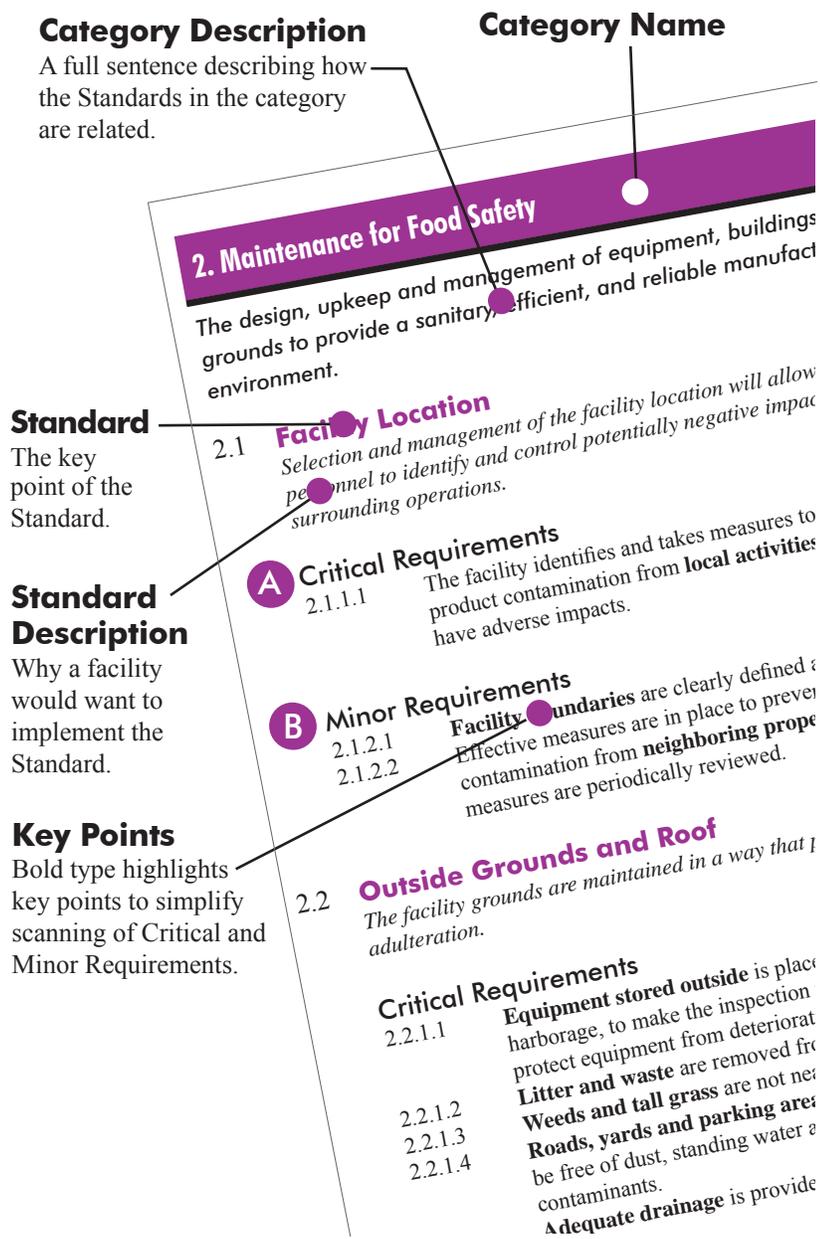
5. Adequacy of Prerequisite and Food Safety Programs

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 will assess 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



A 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.

B Minor Requirements

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

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

1 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 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 assess 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 5 point increments for each additional observation if the assigned score is at the top of the score range.

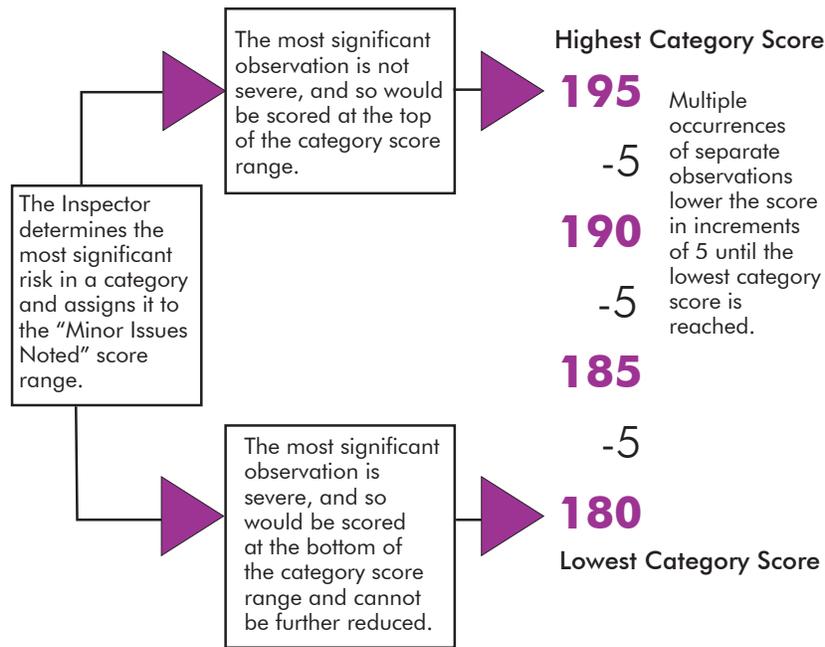


Figure 1—Example of Risk and Category Score Determination in the Minor Issues Noted Range

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 2 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 scores in 5 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	Unsatisfactory
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.

3 Evaluating the Adequacy of the Food Safety Program

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 Assessment Category higher than the category with the worst observation. In other words, if the worst Risk Assessment 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 Assessment 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 assessment 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.

4 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.

5 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
Maintenance for Food Safety	8	3	0	0	165
Cleaning Practices	8	1	0	0	160
Integrated Pest Management	2	4	3	0	145
Adequacy of Prerequisite and Food Safety Programs	0	3	0	0	165
				Total Score	815

A B C
D E

Sample Scoring with Explanations

- 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. Holding temperatures (refrigerators or coolers) in excess of 40°F or 4°C for microbiologically sensitive ingredients or products (**Note:** the exact temperature limit may vary depending on country regulation)
 - b. Open sores or boils on personnel who have direct contact with product, ingredients, or product zones
 - c. Torn liquid receiving strainer
 - d. Ingredients that are internally infested
2. Maintenance for Food Safety
 - a. Flaking paint, rust, or other materials in 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 food products by identifying and barring entry or shipment of potentially contaminated raw materials or finished products.

Critical Requirements

- 1.1.1.1 Damaged, infested, or **dirty transports/containers** 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 the reasons for rejection.
- 1.1.1.4 Shuttle vehicles are in **good condition, clean, and free of holes and infestation**.

1.2 Rejection of Shipments/Receipt of Perishables

A facility can safeguard its food products by identifying and barring entry or shipment of potentially contaminated raw materials or finished products.

Critical Requirements

- 1.2.1.1 Damaged, infested, or **dirty transports/containers** are rejected.
- 1.2.1.2 Materials shipped in damaged, infested, or **dirty vehicles** are rejected.
- 1.2.1.3 Perishable or frozen materials **meet specific minimum temperature requirements** at points of shipment, transportation, and receipt.
- 1.2.1.4 The facility maintains **documentation of temperature checks for perishable goods** at receiving points.
- 1.2.1.5 The facility maintains **documentation of rejected shipments** that includes the reasons for rejection.
- 1.2.1.6 Shuttle vehicles are in **good condition, clean, and free of holes and infestation**.

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 **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 **Dates to facilitate stock rotation are visible** on the pallet or individual container.
- 1.3.1.3 Raw materials, packaging, work-in-process, and finished products are stored **off the floor** on pallets, slip-sheets, or stands.
- 1.3.1.4 Raw materials, packaging, work-in-process, and finished products are stored at least **18 in. or 45 cm** away from walls and ceilings.
- 1.3.1.5 Adequate **space is maintained between rows** of stored raw materials, packaging, work-in-process, and finished products to allow cleaning and inspection. Procedures are followed to guarantee the proper cleaning, inspection, and monitoring for pest activity in storage areas, where an 18 in. or 45 cm inspection perimeter cannot be provided.
- 1.3.1.6 If materials are **stored outside**, they are adequately protected against deterioration and contamination.

Minor Requirements

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

- 1.3.2.4 If an 18 in. or 45 cm clearance from walls is impossible due to aisle widths and forklift turning space, a **rack system** can be installed against the wall. In this case, a bottom rail is installed 18 in. or 45 cm off the floor so that no pallets are stored on the floor.

1.4 Storage Conditions

Raw materials and finished products are stored in a clean storage area to protect them from contamination sources.

Critical Requirements

- 1.4.1.1 Storage areas are **clean, well ventilated, and dry**. Raw materials, work-in-process, packaging materials, and finished products 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 toxic 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., aseptic or glass packaging). Failures and Corrective Actions are documented.
- 1.4.1.6 **Products returned by customers** are not returned to finished goods storage area until they are inspected and released for use 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 Ingredients, 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.
- 1.5.1.3 Containers are **covered or inverted** while in storage to protect against contamination from overhead structures.

Minor Requirements

- 1.5.2.1 A **system is defined and followed** for identifying and tracking of 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** and in good repair.
- 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 Designated Rework Areas

Rework or salvage, if not segregated and managed properly, can cause contamination of raw materials, work-in-process, packaging, or finished product.

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 Rework is processed **weekly** or often enough to keep rework quantities at minimal levels.
- 1.7.1.4 Rework is identified for **traceability** purposes.
- 1.7.1.5 A **break** in the rework process is defined. Records demonstrate that the break and clean process is followed.

1.8 Dust Collection and Filtering Devices

If not maintained, filters, screens, and socks may contribute to food 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** to 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 If present, **security** seals on bulk container hatches or other shipping containers are **checked** against the seal number on the bill of lading to verify that the numbers match during shipping and receiving.
- 1.9.1.5 Storage tanks are **waterproof**.
- 1.9.1.6 Conveying tubes or hoses are on **supports off the ground or floor** to prevent contamination or submersion in water.
- 1.9.1.7 **Pneumatic** systems or **blowers** are provided with air filters.
- 1.9.1.8 Hoses, caps, and couplings are **cleaned before storage** in a secured area.
- 1.9.1.9 **Tanker Wash Tags** or prior load verification are verified and records are maintained.

1.10 Sampling Procedures

Because sampling involves direct contact with raw materials, finished product, or work-in-process, procedures are defined to prevent product contamination.

Critical Requirements

- 1.10.1.1 The facility has documented aseptic sampling **procedures** in place for obtaining samples of materials.
- 1.10.1.2 All **openings** created for sampling in bags, boxes, or containers are properly resealed and identified as such.
- 1.10.1.3 **Staples and other items** likely to cause product contamination are not used to reseal packaging materials.

1.11 Processing Aids

Processing aids are food contact materials and therefore managed to prevent contamination of product.

Critical Requirements

- 1.11.1.1 All food contact processing aids, such as antifoam and release agents, are **segregated** from nonfood materials.

- 1.11.1.2 **Processing aids** are labeled for their intended use.
- 1.11.1.3 **Food approval documentation** for food contact processing aids is on file.

1.12 **Raw Material Transfer**

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

Critical Requirements

- 1.12.1.1 The facility follows **procedures** for transferring and handling food materials.
- 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 storage containers** are properly identified to maintain ingredient integrity and traceability.

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.
- 1.12.2.4 Packaging material is **removed from the protective outer package** outside of production areas to eliminate potential contamination.

1.13 **Bulk Material Sifting**

Dry materials are sifted to identify and eliminate foreign material or insects. The equipment used for sifting is monitored to ensure effectiveness.

Critical Requirements

- 1.13.1.1 All **bulk dry materials** are sifted before use.
- 1.13.1.2 All **bulk finely milled** dry materials are sifted with a 30-mesh (600-micron) screen or finer.
- 1.13.1.3 All **other bulk dry materials** are sifted with a 16-mesh (1000-micron) screen or the smallest mesh size through which the particle will pass.
- 1.13.1.4 Sifters, sieves, rebolters, and scalpers for finely milled dry materials are **inspected** for torn screens and other defects at least weekly.
- 1.13.1.5 The facility maintains **records of equipment inspections**.
- 1.13.1.6 **Reject materials** (tailings) are visually inspected no less than daily.
- 1.13.1.7 The **source of any unusual foreign objects** in sifter tailings is identified and addressed.
- 1.13.1.8 The facility maintains **records** of tailing findings and Corrective Actions.
- 1.13.1.9 If **foreign material that could damage** the sifter, sieve, rebolter, or scalper screens is found in the tailings, those screens are immediately inspected for damage.

1.14 **Bulk Liquid Materials**

Liquid materials (including processing aids) are strained and strainers are regularly checked to identify foreign material and prevent contamination of liquids.

Critical Requirements

- 1.14.1.1 All bulk liquid materials are filtered with **inline receiving strainers**.
- 1.14.1.2 Strainers are **cleaned and inspected** for integrity after each load.
- 1.14.1.3 **Strainer mesh sizes** are sufficiently restrictive to remove foreign material from liquid material deliveries.
- 1.14.1.4 **Strainer inspections, findings, and Corrective Actions** are documented and kept on file.
- 1.14.1.5 If strainers are provided on the truck, or portable strainers are used at the site, the **presence of a clean and intact strainer** is verified prior to pumping of material.

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 located at the **last possible point on all production lines**.
- 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 food produced since the last acceptable test of the device

1.16 Waste Material Disposal

Waste materials and their removal are managed to avoid contamination.

Critical Requirements

- 1.16.1.1 Trash or inedible waste is **stored** in properly covered, labeled containers.
- 1.16.1.2 Waste containers are **emptied** at least daily.
- 1.16.1.3 Trash or inedible waste does not come in **contact** with raw materials, work-in-process, or finished product at any time.
- 1.16.1.4 **Licensed contractors** remove waste, where required.
- 1.16.1.5 Waste disposal meets **regulatory requirements**.

1.17 Ingredient Scoops

Ingredient scoops may cause cross contamination if they are used for multiple ingredients.

Critical Requirements

- 1.17.1.1 All in-use ingredient containers have **individual transfer scoops** (where needed) to prevent cross contamination.
- 1.17.1.2 Ingredient scoops are **color-coded or identified**, as necessary, to prevent cross contamination from allergens or other non-related materials.
- 1.17.1.3 Ingredient scoops are clean and in **good condition**.

1.18 Product Identification

If work-in-process and raw materials are not identified, they could be misused and cause food safety problems.

Critical Requirements

- 1.18.1.1 Carry-over product, work-in-process, rework, and raw materials are properly **identified and dated**.
- 1.18.1.2 **Carry-over is minimal** and used at the first opportunity.
- 1.18.1.3 Reworked or blended materials are **lot traceable**.
- 1.18.1.4 Reworked or blended materials are **strained/sifted prior to use**.

1.19 Workspace Arrangement

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

1.21 Hand Contact

A facility can eliminate, where possible and practical, potential sources of contamination by minimizing the need for direct human handling in food processing.

Critical Requirements

- 1.21.1.1 Production facilities, equipment, and accessories **are designed** so that minimum hand contact is made with raw materials, work-in-process, and finished product, where possible and practical.

1.22 Temperature-Sensitive Materials

Temperature controls prevent the growth of pathogens in susceptible materials.

Critical Requirements

- 1.22.1.1 Raw materials, work-in-process, and finished product capable of supporting the rapid growth of pathogenic microorganisms are **properly stored**.
- 1.22.1.2 Temperature-sensitive materials are stored to **maintain appropriate internal temperatures**:
- 40°F or 4°C or below
 - 140°F or 60°C or above
 - Or in accordance with country-specific regulation
- 1.22.1.3 The facility maintains a **record** of temperature monitoring activities.

Minor Requirements

- 1.22.2.1 **Continuous recording thermometers** are placed in all rooms or areas where perishable foods are stored and handled.
- 1.22.2.2 Freezers and coolers are provided with vinyl strip doors, self-closing devices, or other **methods to maintain temperatures**.

1.23 Cross Contamination Prevention

Incompatible or hazardous materials require separate handling to prevent contamination.

Critical Requirements

- 1.23.1.1 Incompatible materials (such as raw and cooked products) **are stored** under conditions that prevent cross contamination.

- 1.23.1.2 Measures are taken to prevent cross contamination by **hazardous ingredients**, such as allergens in manufacturing, packaging, and storage areas.
- 1.23.1.3 **Systems** are set up to reduce any potential physical, chemical, or microbiological contamination risks.
- 1.23.1.4 Where required, **hand sanitizers, foot baths, or automatic floor sanitizer** sprays are provided to prevent microbiological contamination of product and processing areas.
- 1.23.1.5 When used, **verification of effective concentration** of the foot bath or sanitizers is monitored and documented, including Corrective Action and re-verification of concentration, as required.
- 1.23.1.6 Where foot baths and sanitizers are not used for cross contamination control in a sensitive operation, a **captive shoe program** is defined and implemented to prevent microbial contamination of product and processing areas.
- 1.23.1.7 Measures are taken to prevent cross contamination that can cause **customer complaints**, such as meat in vegetarian products, or non-organic ingredients in organic foods.

1.24 Containers and Utensils

If not managed, any food contact containers or utensils have the potential to create food safety hazards.

Critical Requirements

- 1.24.1.1 Containers and utensils used to transport, process, hold, or store raw materials, work-in-process, rework, or finished products are **constructed, handled, and maintained** in a way that prevents contamination.
- 1.24.1.2 Containers for work-in-process or finished products are **only used for their designated purposes**.
- 1.24.1.3 Containers are **legibly labeled with contents**.
- 1.24.1.4 **Snap-off blades** are not used in production, packaging, or raw material storage areas.

1.25 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

- 1.25.1.1 If cans, bottles, food contact barrels, or other **rigid packaging** containers are used, the rigid container is inverted and cleaned with an air or water blast before filling to remove foreign material.
- 1.25.1.2 **Filtering systems** and/or air/water traps are provided for cleaning systems used with rigid packaging.
- 1.25.1.3 The filtering systems or air/water traps on cleaning systems used with rigid packaging are **regularly monitored** and maintained as part of the Preventive Maintenance Program.
- 1.25.1.4 After cleaning, rigid packaging is maintained in an **inverted position or covered** to prevent foreign material contamination until filled and capped.
- 1.25.1.5 **Box and other liners** used in product containers or packaging materials are suitably durable to prevent risk of product contamination.
- 1.25.1.6 Rigid packaging is **covered or inverted, or overhead structures are maintained**, to prevent contamination prior to filling.
- 1.25.1.7 Single-service containers that are not washed or air or water rinsed are received covered with a **tight-fitting protective cover**.
- 1.25.1.8 Single-service containers that are not cleaned before receipt are stored in a way to protect them from **airborne or manual contamination**.

1.26 Finished Product Transportation

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

Critical Requirements

- 1.26.1.1 Legible **code marks** that are easily seen by consumers are placed on all finished products.
- 1.26.1.2 Code marks satisfy **regulatory packaging requirements** and lot definitions, and are used in the Recall Program.
- 1.26.1.3 Distribution records identify the **initial point of distribution** as per regulatory requirements.
- 1.26.1.4 **Finished products are handled and transported** in a way that prevents actual or potential contamination.
- 1.26.1.5 Finished products are **loaded or transferred in covered bays** or canopies to protect the products from weather damage.

- 1.26.1.6 **Staging and loading** of perishable materials does not pose a food safety risk.
- 1.26.1.7 Documentation validates that temperature-sensitive products are loaded into pre-cooled vehicles that are designed to **sustain required temperatures** during delivery.
- 1.26.1.8 Temperatures of vehicles are **checked and recorded** before loading.
- 1.26.1.9 The facility enforces **transportation breakdown** procedures.
- 1.26.1.10 Prior to loading, **all shipping vehicles are inspected** for cleanliness and structural defects that could jeopardize the product.
- 1.26.1.11 Shipping **vehicle inspections are documented**.
- 1.26.1.12 **Local delivery trucks and route trucks** are inspected and cleaned at least weekly to identify potential sources of foreign material contamination.

Minor Requirements

- 1.26.2.1 **Common carriers and customers** are encouraged to maintain their delivery vehicles in sanitary condition, and in good repair.
- 1.26.2.2 **Security seals or padlocks** are provided, and their use is documented as per facility or customer requirements.
- 1.26.2.3 Interior light bulbs in finished product transports are **shielded or coated** to prevent breakage.
- 1.26.2.4 **No odors or other contaminants** are present in transports.
- 1.26.2.5 Transport vehicles have **not hauled garbage/waste or nonfood** items that may cause product contamination. If nonfood items, such as chemicals, are shipped, then adequate barriers to prevent contamination of food products must be used.
- 1.26.2.6 Transport refrigeration devices have **recording devices**. In the absence of recording devices, manual temperature checks are documented at appropriate frequencies to ensure maintenance of refrigeration temperatures.
- 1.26.2.7 **Adequate free air circulation** is provided all around the load during perishables transportation. Pallets with slip-sheets or another way to allow adequate air circulation is in place unless the transport has a channeled floor to maintain air circulation.
- 1.26.2.8 If applicable, the vehicle's **refrigeration unit is turned on** and the doors are closed when loading and unloading is not taking place.

1.27 Hand Washing Facilities

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

Critical Requirements

- 1.27.1.1 Suitable and properly maintained hand washing facilities are **located** at the entrance to production areas, and at other appropriate sites.
- 1.27.1.2 **Single-use towels or air dryers** are provided at hand washing stations.
- 1.27.1.3 **Hand sanitizing stations** are provided, where appropriate.
- 1.27.1.4 Hand sanitizers are regularly monitored for **proper concentration** to ensure effectiveness.
- 1.27.1.5 **“Wash hands”** signs appear above sinks and entries to production areas, where appropriate.

Minor Requirements

- 1.27.2.1 Dispensers for **disposable paper towels** are covered.

1.28 Washrooms, Showers, and Locker Rooms

Cleanliness diminishes chances of contamination being spread from personnel areas.

Critical Requirements

- 1.28.1.1 All washrooms, showers, and locker rooms are maintained in a **sanitary** condition.
- 1.28.1.2 **No pests or mold** are present.
- 1.28.1.3 There are **no open food or drinks** in lockers or locker rooms.
- 1.28.1.4 **“Wash hands”** signs are displayed in all restrooms, lunchrooms, smoking areas, and appear above sinks and entries to production areas where appropriate.

Minor Requirements

1.28.2.1 Company-owned **personnel lockers are inspected** on a defined frequency.

1.29 Personal Hygiene

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

Critical Requirements

- 1.29.1.1 **Trained supervisors** are responsible for ensuring that all personnel are complying with facility policies regarding personnel practices.
- 1.29.1.2 **Personnel wash hands** before beginning work, and after eating, drinking, smoking, using the restroom, or otherwise soiling hands.
- 1.29.1.3 Personnel are encouraged to practice **good personal hygiene** at all times.

Minor Requirements

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

1.30 Work Clothes, Changing Facilities, and Personnel Areas

Clothing may contaminate food 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

- 1.30.1.1 Personnel wear suitable, **clean outer garments or uniforms**.
- 1.30.1.2 Personnel wear **suitable footwear**.
- 1.30.1.3 Personnel wear effective **hair restraints** to fully contain hair, if applicable. Hair restraints may include head, beard, or moustache covers.
- 1.30.1.4 If worn, **gloves** are adequately controlled to avoid product contamination.
- 1.30.1.5 Items such as pens, pencils, and thermometers are carried in pockets or pouches **below the waist** in production areas.
- 1.30.1.6 **Changing facilities are provided** for all employees, visitors, and contractors to allow personnel to change clothes before entering food-processing areas, if necessary.
- 1.30.1.7 **Work clothes are stored** separately from outdoor clothing and personal items in changing facilities.
- 1.30.1.8 Where **protective clothing is required**, it is available at all times, and laundered or cleaned in a controlled environment.

Minor Requirements

- 1.30.2.1 There are **no pockets above the waist** on outer garments.
- 1.30.2.2 Suitable **break rooms and dining facilities** are provided for all personnel.

1.31 High-Risk Clothing Management

Special handling is required in high-risk operations to ensure that work clothing is distinctive for different processes, and managed to prevent product contamination.

Critical Requirements

- 1.31.1.1 Personnel in high-risk operations **follow specified procedures** for dressing in visually distinctive clean outer garments, headwear, and footwear.
- 1.31.1.2 Personnel enter high-risk operations through **specially designated changing areas**.
- 1.31.1.3 **Changing facilities are located** to allow direct access to production, packaging, and storage areas.
- 1.31.1.4 High-risk work clothing is only **removed in a specially designated changing area**.

Minor Requirements

- 1.31.2.1 Personal clothing **above the knee** is completely covered by work clothes (e.g., smocks).
- 1.31.2.2 All **protective clothing is regularly cleaned** on-site or by a contract laundry.

1.32 Personal Items and Jewelry Control

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

Critical Requirements

- 1.32.1.1 Personnel in contact with food products **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
- 1.32.1.2 **Plain wedding bands** are acceptable if permitted by the Personnel Practices Program.
- 1.32.1.3 Personnel eat, drink, chew gum, and use tobacco products **only in designated areas**.
- 1.32.1.4 **Personal food and belongings** are not brought into production or storage areas.
- 1.32.1.5 All **personal property is stored** in a designated area.
- 1.32.1.6 The facility Personnel Practices Program defines and explains any **exceptions** to personal items and jewelry control.

Minor Requirements

- 1.32.2.1 Personnel in contact with food products are prohibited from wearing **perfume and aftershave**.

1.33 Health Conditions

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

Critical Requirements

- 1.33.1.1 No person with boils, sores, infected wounds, or any other **infections or communicable disease** is permitted to contact food as defined by regulations.
- 1.33.1.2 All **exposed cuts and grazes** are covered by a facility-issued detectable metal-strip bandage.
- 1.33.1.3 All **personnel health cards** are current and properly posted if required by local regulations.
- 1.33.1.4 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.
- 1.33.1.5 A written policy specifies the procedures for handling/disposition of food or product contact surfaces that have come into contact with **blood or other bodily fluids**.

Minor Requirements

- 1.33.2.1 Each lot of metal-strip bandages is **tested in the metal detector**.
- 1.33.2.2 If appropriate, the facility uses detectable gloves, earplugs, or other **detectable protective equipment**. If used, detectable equipment is regularly tested and documented.

1.34 Non-Facility Personnel

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

Critical Requirements

- 1.34.1.1 Non-facility personnel conform to the facility **Personnel Practices Program**. Non-facility personnel include, but are not limited to:
- Visitors
 - Temporary personnel
 - Regulatory authorities
 - Outside contractors
 - Tour groups
 - Family and friends of personnel

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

1.35 **Multiple-Service Shipping Containers**

Multiple-service shipping containers are cleaned and maintained so that they do not contaminate the primary product container or the product.

Critical Requirements

1.35.1.1 **Dry or wet cleaning processes or an inspection program** are in place to identify or remove contaminants so that multiple-service shipping containers are maintained in a clean and satisfactory condition.

1.36 **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

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

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

1.37 **Filling, Capping, and Sealing**

Filling, capping, and sealing of single-service or multiple-service containers is monitored to meet specifications.

Critical Requirements

1.37.1.1 Performance of the filling, capping, and sealing operations is **monitored visually or electronically**. Visual or electronic inspections indicate that filled containers are sound and properly sealed.

1.37.1.2 Sealed and filled containers that do not meet specifications are **reprocessed or rejected**. Documentation is maintained.

1.38 **Examination of Materials**

Materials that cannot be examined using foreign material devices are visually examined prior to use to prevent product contamination.

Critical Requirements

1.38.1.1 Fruits, nuts, coconut, and similar materials are **visually examined** before use.

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.

2.1.2.2 Effective measures are in place to prevent product contamination from **neighboring properties**. These measures are periodically reviewed.

2.2 Outside Grounds and Roof

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

Critical Requirements

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

2.2.1.2 **Litter and waste** are removed from the property.

2.2.1.3 **Weeds and tall grass** are not near 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 and structures** are well maintained.

Minor Requirements

2.2.2.1 **Outdoor equipment storage** is minimal.

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

2.3 Security Equipment

Installing and maintaining the equipment and structures that support a Food Defense Program help guard against intentional product contamination.

Minor Requirements

2.3.2.1 **Physical security measures** that require maintenance or design can include:

- Perimeter fences
- Surveillance cameras
- Locked doors
- Security guard stations
- Controlled access
- Controlled bulk storage areas

2.4 Layout

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

Critical Requirements

- 2.4.1.1 Space is maintained **between** equipment and structures to enable cleaning and maintenance.
- 2.4.1.2 There is adequate space **to place** equipment and raw materials.

2.5 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

- 2.5.1.1 Floors are made of **materials** that are easily cleaned and kept in good repair.
- 2.5.1.2 Wall/floor junctions and corners are **maintained** to facilitate cleaning.
- 2.5.1.3 **Holes, cracks, and crevices** in floor surfaces are repaired to prevent debris from lodging and to avoid pest or microbial harborage.
- 2.5.1.4 **Floors are designed** to meet the demands of facility operations and withstand cleaning materials and methods.
- 2.5.1.5 Floors are **impervious**.
- 2.5.1.6 **Floors are sloped** to direct the flow of water or effluent toward drains.

2.6 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

- 2.6.1.1 Drains are made of **materials** that are easily cleaned and kept in good repair.
- 2.6.1.2 **Floor drains** with grates are installed, maintained, and operational in all wet processing or wash areas.
- 2.6.1.3 Floor drain grates are **easily removable** for cleaning and inspection.
- 2.6.1.4 **Drainage** is designed and maintained to minimize the risk of product contamination.
- 2.6.1.5 **For high-risk operations**, drainage flows away from high-risk areas (e.g., raw vs. cooked).

Minor Requirements

- 2.6.2.1 Equipment and drains should be placed in a way that any processing discharge or overspill **goes directly into a drain** rather than on the floor.
- 2.6.2.2 **Floor drains** can be easily accessed for cleaning and inspection.

2.7 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

- 2.7.1.1 Walls are made of **materials** that are easily cleaned and kept in good repair.
- 2.7.1.2 **Holes, cracks, and crevices** in wall surfaces are repaired to prevent debris from lodging and to avoid pest or microbial harborage.
- 2.7.1.3 Walls are **designed, constructed, finished, and maintained to:**
 - Prevent dirt accumulation
 - Reduce condensation and mold growth
 - Facilitate cleaning

2.8 Ceilings and Overhead Structures

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

Critical Requirements

- 2.8.1.1 Ceilings are made of **materials** that are easily cleaned and kept in good repair.
- 2.8.1.2 Access to the void in **hollow or suspended** ceilings is provided to facilitate cleaning, maintenance, and inspection activities.
- 2.8.1.3 Ceilings and overheads are **designed, constructed, finished**, and maintained to:
 - Prevent dirt accumulation
 - Reduce condensation and mold growth
 - Facilitate cleaning
- 2.8.1.4 **Roof leaks** are promptly identified, controlled, and repaired.
- 2.8.1.5 Fixtures, ducts, pipes, and overhead structures are installed and maintained so that **drips and condensation do not contaminate** foods, raw materials, or food contact surfaces.
- 2.8.1.6 Drips and condensation are **controlled to prevent** establishment of an environment suitable for microbial growth.
- 2.8.1.7 There is no **flaking paint or rust** on equipment or overhead structures. Only normal mild oxidation on nonfood contact surfaces is acceptable.
- 2.8.1.8 **Other materials** (such as loose insulation) do not threaten food products or food contact surfaces.

2.9 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 food products, but the Program also takes into consideration breakable materials that are used for other purposes within the facility.

Critical Requirements

- 2.9.1.1 **Adequate lighting** is provided in all areas.
- 2.9.1.2 Light bulbs, fixtures, windows, mirrors, skylights, and other glass suspended over product zones, product areas, ingredients, or packaging supplies are of the **safety type**, or are otherwise protected to prevent breakage.
- 2.9.1.3 **Light fittings and glass** are replaced in a way that minimizes the potential for product contamination.
- 2.9.1.4 Glass that cannot be fully protected is addressed in the **Glass, Brittle Plastics, and Ceramics Program**.
- 2.9.1.5 Only **essential glass** is present in the facility. If glass must be used, it is addressed by the Glass, Brittle Plastics, and Ceramics Program.

2.10 Air Makeup Units

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

Critical Requirements

- 2.10.1.1 Air makeup units are fitted with **clean filters** and are free of mold and algae.
- 2.10.1.2 Air return ducts for HVAC systems and air makeup units are fitted with **cleaning and inspection hatches**.
- 2.10.1.3 **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.
- 2.10.1.4 **Air blowing equipment** is located, cleaned, and operated in a way that does not contaminate raw materials, work-in-process, packaging materials, food contact surfaces, and finished products.
- 2.10.1.5 Filters are capable of removing particles of **50 microns** (Minimum Efficiency Reporting Value [MERV] 4) or larger.

Minor Requirements

- 2.10.2.1 **Dust extraction equipment** for dry powder handling equipment is installed.
- 2.10.2.2 **Ventilation** is provided in product storage and processing areas to minimize odors, fumes, and vapors.

2.11 Pest Prevention

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

Critical Requirements

- 2.11.1.1 The building has **barriers** in place to protect against birds, rodents, insects, and other pests.
- 2.11.1.2 **External doors, windows, or other openings** are close-fitting or otherwise **pest-proofed** to less than ¼ in. or 6 mm.
- 2.11.1.3 **Windows, doors, and skylights** that must be kept open for ventilation are screened to prevent pest entry.

2.12 Leaks and Lubrication

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

Critical Requirements

- 2.12.1.1 The facility **prevents, identifies, and eliminates** leaks (oil and lubricants) and excessive lubrication.
- 2.12.1.2 **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.
- 2.12.1.3 There are no **grease smears or excess lubricant** on equipment.

2.13 Lubricants

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

Critical Requirements

- 2.13.1.1 Only **food-grade** lubricants are used on food processing and packaging equipment, or on any other equipment where incidental food contact may occur.
- 2.13.1.2 **Lubricants** are labeled, segregated, and stored in a designated, secure area. Food-grade and non food-grade lubricants are kept separate from each other.

2.14 Cross Contamination Prevention

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

Critical Requirements

- 2.14.1.1 **Operations are separated** based on process flow, material types, equipment, personnel, airflow, air quality, and services needed.
- 2.14.1.2 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.
- 2.14.1.3 Areas for **washing and cleaning** are located away from production activities, where appropriate.
- 2.14.1.4 **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.
- 2.14.1.5 **Cleaning and production areas are segregated** with air curtains, partitions, doors, or other exclusionary systems.
- 2.14.1.6 Water installations and equipment are constructed and maintained to **prevent back siphonage and backflow**.
- 2.14.1.7 The **sewage disposal system** is adequate for the process and maintained to prevent direct or indirect product contamination.
- 2.14.1.8 **Clean In Place systems** meet the following design requirements to prevent contamination:
 - Allow proper drainage
 - No dead ends
 - No cross connections
 - Contain line disconnects
- 2.14.1.9 Dust, dirt, and microorganisms in the air and condensation are **controlled in filling and sealing areas** to prevent product contamination.

Minor Requirements

- 2.14.2.1 Control measures include the **enclosures around the filling and sealing areas**.

2.15 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

- 2.15.1.1 All **equipment and utensils** are designed and made of materials that are **easily cleaned and maintained**.
- 2.15.1.2 Ingredient, product-holding, packaging, conveying, processing, and bulk **equipment** are designed and made of materials that are easily cleaned, inspected, and maintained.
- 2.15.1.3 Food contact surfaces are **corrosion-free, durable**, and made of **non-toxic** materials.
- 2.15.1.4 Seams on food contact **surfaces are smooth** and free of spot or tack welds.
- 2.15.1.5 Pipelines, mixing, and holding tanks are **free of defects** and have smooth seams.
- 2.15.1.6 Pipelines, mixing, and holding tanks are **self-draining**.

Minor Requirements

- 2.15.2.1 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.

2.16 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

- 2.16.1.1 **Tape, wire, string, cardboard, plastic, and other temporary materials are not used** for permanent repairs. If used for emergency repairs, they are dated and replaced with a permanent repair as soon as possible.
- 2.16.1.2 Any temporary repairs on food contact surfaces are constructed of **food-grade material**.
- 2.16.1.3 The facility maintains a **record of work orders** or repair requests.
- 2.16.1.4 The facility follows **temporary repair procedures**.

Minor Requirements

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

2.17 Temperature Measuring Devices

Processes that require temperature controls need measuring devices that are functioning and accurate.

Critical Requirements

- 2.17.1.1 **Temperature measuring devices**, including thermometers, regulating, and recording controls, are installed on any equipment that sterilizes, pasteurizes, or otherwise prevents pathogenic microorganism growth. These devices are routinely calibrated.
- 2.17.1.2 If used in a process critical to food safety, temperature measuring devices are **calibrated** to a national standard.
- 2.17.1.3 Temperature measuring devices are **monitored** on a frequent basis.
- 2.17.1.4 The facility uses **monitoring systems** that trigger alarms when temperatures exceed set limits.
- 2.17.1.5 **Thermometers are located** inside coolers, freezers, and other temperature-controlled storage areas.

Minor Requirements

- 2.17.2.1 Temperature measuring devices used in processes **not critical to food safety** are calibrated using established calibration methods.

2.18 Compressed Air/Product Contact Gases

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

Critical Requirements

- 2.18.1.1 Compressed air used in processing areas is **properly filtered** to remove particles of 5 microns or larger. Compressed air equipment does not contain dirt, oil, or water.
- 2.18.1.2 **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.
- 2.18.1.3 **Other gases** used in product contact are of **suitable purity** to protect the finished material or are **filtered** to remove contaminants.
- 2.18.1.4 **Records of filter inspection** and replacement are maintained.

Minor Requirements

- 2.18.2.1 Filters for air used on food contact surfaces are located as **close to the point of use** as practical.

2.19 Transporting Equipment

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

Critical Requirements

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

2.20 Parts Storage

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

Critical Requirements

- 2.20.1.1 All food contact **parts are stored** in a clean environment off the floor.
- 2.20.1.2 **Used and soiled conveyor belts** are discarded and not stored for future use.

Minor Requirements

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

2.21 Hand Washing Facilities Design

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

Critical Requirements

- 2.21.1.1 **Hot and cold running water** is provided in all washrooms, hand sinks, and locker rooms.
- 2.21.1.2 **Hand washing facilities** have an adequate water supply.
- 2.21.1.3 Hand washing facilities are **labeled and separated** from utensil washing facilities.
- 2.21.1.4 **Hands-free** hand washing equipment is provided in production areas where essential to product safety.

Minor Requirements

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

2.22 Bulk Systems and Unloading Areas

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

Critical Requirements

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

2.23 Ammonia Control

Ammonia leakage in processing areas may lead to product contamination.

Critical Requirements

- 2.23.1.1 Procedures are in place to **identify and prevent ammonia leaks** in the process.
- 2.23.1.2 Inspection **records with documented Corrective Actions** are current.

2.24 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

- 2.24.1.1 Wastewater treatment systems are managed and maintained to **prevent development of microbial or pest management issues.**
- 2.24.1.2 Sewage disposal systems are **adequate and appropriate** for the process.
- 2.24.1.3 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 food 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 Food Contact 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 food contact surfaces **have food contact 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 food 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 Equipment and Tools

Cleaning equipment and tools may have a negative impact on food safety if not managed properly.

Critical Requirements

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

3.3.1.2 Cleaning equipment is **maintained and stored** in a way that does not contaminate foods or production equipment.

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

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

3.3.1.5 All cleaning 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 utensils based on their intended usage.

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

3.3.1.8 **Cleaning 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.

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

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

3.3.1.11 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.

3.3.1.12 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.

Minor Requirements

- 3.3.2.1 **Air hoses** with restricted head pressure are used only to clean inaccessible equipment.
- 3.3.2.2 Air hoses are used for cleaning when the facility is **not in operation** in order to prevent potential product contamination.
- 3.3.2.3 Forklifts, pallet jacks, and similar equipment are **cleaned and the cleaning is tracked** on the Master Cleaning Schedule or Preventive Maintenance Schedule.

3.4 Daily (Housekeeping) Cleaning

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

Critical Requirements

- 3.4.1.1 Daily cleaning tasks are completed in a way that **prevents contamination**.
- 3.4.1.2 Daily cleaning tasks **are assigned** to the appropriate department.
- 3.4.1.3 Daily cleaning tasks ensure that **work and support areas remain clean** during working hours.

3.5 Product Zone Cleaning

Cleaning addresses structures and equipment interiors that may only be cleaned during times when the area is not in production. This requires personnel who have been trained, and often demands the assistance of maintenance or production personnel to properly disassemble equipment to provide effective cleaning of the product zone and prevent product contamination.

Critical Requirements

- 3.5.1.1 Cleaning tasks **comply with applicable equipment cleaning procedures**.
- 3.5.1.2 Periodic cleaning tasks **are scheduled** on a Master Cleaning Schedule, or equivalent.
- 3.5.1.3 Periodic cleaning tasks **are assigned**.
- 3.5.1.4 **Equipment guards, trims, and panels** are removed and replaced to inspect and clean the interior of all equipment, as applicable.
- 3.5.1.5 Equipment and structural overheads (including lights, pipes, beams, and vent grids) are scheduled for periodic cleaning on the Master Cleaning Schedule to **prevent mold, insect development, or other product contamination issues**.
- 3.5.1.6 Food contact surfaces, product zones, and equipment that require sanitizing are **cleaned and sanitized**.
- 3.5.1.7 Equipment and utensils that do not require sanitizing are cleaned on a **predetermined schedule**.
- 3.5.1.8 **Utensils and containers** are washed and dried between uses, or as appropriate, and stored in an inverted position off the floor.
- 3.5.1.9 **Product handling equipment and product zones** are cleaned often enough to prevent residue from being transferred to products.
- 3.5.1.10 **Sanitary trays and dollies** are cleaned and maintained.
- 3.5.1.11 Maintenance cleaning tasks are completed in a way that does not compromise product safety. This includes, but is not limited to, **removal of debris**, such as nuts, bolts, washers, wire pieces, tape, welding rods, and other small items that could contaminate product, and accounting for these materials.
- 3.5.1.12 Equipment or other ice **contact** surfaces used for **production, storage, and transport of ice** used for cooling of product or as an ingredient are cleaned and sanitized on a predetermined schedule.
- 3.5.1.13 Pipelines, mixing, and holding tanks can be **flushed, cleaned, and sanitized**, as needed.

3.6 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

- 3.6.1.1 **Non-sealed electrical panels** and boxes located in areas that are susceptible to insect development are cleaned and inspected every four weeks.
- 3.6.1.2 **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.

- 3.6.1.3 **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.
- 3.6.1.4 Non-production areas **used for the storage** of equipment, raw materials, finished products, or product contact utensils are cleaned and maintained to prevent contamination of product, raw materials, or equipment.
- 3.6.1.5 **Dock leveler pits** are cleaned frequently enough to prevent excessive accumulation of debris, product spillage, or other materials.
- 3.6.1.6 **Racks and storage shelves** are cleaned frequently enough to prevent excessive accumulation of debris, product spillage, or other materials.
- 3.6.1.7 **Recoup and salvage areas** are cleaned on a frequency to control spillage and damaged product to prevent development of sanitation issues that could lead to product contamination or pest activity.
- 3.6.1.8 **Refrigeration equipment** (e.g., condensers, fans, etc.) are cleaned on a defined frequency to prevent microbial and dirt accumulation.
- 3.6.1.9 **Drains** are **routinely cleaned and sanitized** to prevent microbial and pest development.

Minor Requirements

- 3.6.2.1 **Nonfood contact surfaces** are cleaned regularly and as needed.

3.7 Clean In Place (CIP) Systems

Properly maintained and functioning CIP systems allow efficient and effective cleaning of product contact surfaces.

Critical Requirements

- 3.7.1.1 **Indicating and recording thermometers and pressure sensors** are used to monitor the CIP system.
- 3.7.1.2 Minimum requirements for **time/temperature and flow rate** are established and documented.
- 3.7.1.3 **Chemical concentration requirements** are established and documented.
- 3.7.1.4 **Spray balls, pipes, clamps, couplings, and connections** are completely disassembled to allow proper cleaning and inspection.
- 3.7.1.5 Tanks, lines, fillers, etc., are emptied, cleaned, and sanitized to **comply with regulatory or industry standards**.
- 3.7.1.6 The system is completely cleaned out during **changeover from allergen-containing formulas** to non-allergen formulas or formulas that contain different allergens.
- 3.7.1.7 **CIP records and recording charts** are maintained and current.
- 3.7.1.8 CIP records and recording charts are **reviewed to determine** if defined time/temperature, flow rate, and chemical concentration requirements are applicable to the process and are being met.
- 3.7.1.9 **CIP operators are trained** on the use of cleaning compounds and sanitizers and proper operation of CIP equipment.
- 3.7.1.10 Verification of **proper rinsing** is completed and documented on a defined frequency.

Minor Requirements

- 3.7.2.1 **Strainers** are provided in the CIP system to prevent foreign material contamination of the spray balls or product contact surfaces.

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.**

Minor Requirements

- 4.1.2.1 If the IPM Program development and implementation is outsourced to contractors, the Program includes responsibilities for **both in-house personnel and contractors.**

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 Personnel conduct **an annual assessment** of the facility.
- 4.2.1.2 The assessment evaluates all areas **inside and outside** the facility.
- 4.2.1.3 Assessment **results and Corrective Actions** are documented and used to develop and update the IPM Program.
- 4.2.1.4 Assessments are conducted by internal or external **trained IPM personnel.**

4.3 Other Guidelines

Facilities that use alternative guidelines (such as organic, green, or sustainable) are also held accountable for having IPM Programs.

Critical Requirements

- 4.3.1.1 IPM Programs established under **alternative guidelines** (such as organic, green, or sustainable) demonstrate effective pest management through the lack of evidence of pest management issues, and by meeting the criteria in the IPM section of this Standard.

4.4 Signed Contracts

A signed contract between the facility and external IPM providers holds both the provider and the facility accountable for effective pest management activities.

Critical Requirements

- 4.4.1.1 The facility has a **signed contract** that includes:
 - Facility name
 - Facility contact person
 - 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

4.5 Credentials and Competencies

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

Critical Requirements

- 4.5.1.1 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.
- 4.5.1.2 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.
- 4.5.1.3 Applicators provide **verification of GMP training**.
- 4.5.1.4 IPM service providers are **supervised** by a licensed applicator, if required or allowed by regulation.
- 4.5.1.5 The facility maintains a current copy of the **pest management company license** issued by the appropriate government body, if required.
- 4.5.1.6 The facility maintains a current copy of the **certificate of insurance** that specifies the liability coverage, where available.

Minor Requirements

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

4.6 Pesticide Documentation

The facility maintains current pesticide label and Chemical Safety Data Sheet information to ensure proper usage of pesticide chemicals.

Critical Requirements

- 4.6.1.1 **Chemical Safety Data Sheets** or equivalent are on file for all pesticides used in the facility by in-house personnel or contractors. Documentation is available for review on request as hard copy or electronic files.
- 4.6.1.2 **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

- 4.6.2.1 The **language** of the country is taken into consideration when providing Chemical Safety Data Sheets and labels.

4.7 Pesticide Application Documentation

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

Critical Requirements

- 4.7.1.1 Documented **pesticide application activities** include:
 - Product name 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
 - Signature of applicator

Minor Requirements

- 4.7.2.1 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.

4.8 Pesticide Control

Pesticides are managed as part of the Chemical Control Program.

Critical Requirements

- 4.8.1.1 **Pesticides are stored** in a limited access, locked area. Storage areas are adequate in size and construction, and are properly ventilated.
- 4.8.1.2 **Pesticides are stored** according to label directions.
- 4.8.1.3 Pesticide **containers and application equipment** are labeled to identify contents. Application equipment is not used across multiple pesticides.
- 4.8.1.4 **Pesticide containers are disposed of** according to label directions and regulatory requirements.
- 4.8.1.5 **Warning signs** are posted at the entrance of each pesticide storage area.
- 4.8.1.6 The facility maintains a complete **inventory of pesticides**.
- 4.8.1.7 **Spill control** materials and procedures are available.

4.9 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

- 4.9.1.1 Accurate and complete **service records** describe current levels of pest activity and recommendations for additional Corrective Actions.
- 4.9.1.2 The **pest-sighting log** provides information about the response taken by pest management personnel.
- 4.9.1.3 All records pertaining to pest management activities are **available as hard copy or electronic files** for review on request.
- 4.9.1.4 The **pest-sighting log** has a designated location.
- 4.9.1.5 The **pest-sighting log includes**:
 - Date
 - Time
 - Type of pests observed
 - Actions taken
 - Names of reporting personnel
- 4.9.1.6 Pest management personnel **review the log each quarter** to identify trends in pest activity. A report of findings is submitted to designated facility personnel.
- 4.9.1.7 **Corrective Actions** are documented for identified issues.

4.10 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

- 4.10.1.1 A **detailed survey** of the entire facility is completed, and the results are documented and used to determine **placement of monitoring devices**.
- 4.10.1.2 A current and accurate **site map** that lists the locations of all pest-monitoring devices used in rodent and insect control is on file.
- 4.10.1.3 **Temporary placement** of any pest monitoring devices for short-term monitoring is mapped separately. Findings are documented according to the frequency defined by the IPM Program.
- 4.10.1.4 The facility **records all services** performed on all pest-monitoring devices.
- 4.10.1.5 Services for monitoring devices are **documented with recording mechanisms**, such as punch cards, bar codes, or ledgers, and may be maintained in hard copy or electronic format.
- 4.10.1.6 Service records in monitoring devices **match documentation** on file in the facility.

4.11 Exterior Rodent Monitoring Devices

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

Critical Requirements

- 4.11.1.1 Based on the detailed facility survey, exterior monitoring devices are placed along the **foundation walls** on the exterior of the facility.
- 4.11.1.2 All exterior monitoring devices are inspected **at least monthly**. These devices are checked more often when activity levels increase.
- 4.11.1.3 Exterior **bait stations** that contain rodenticides **are locked** with single-use plastic ties, padlocks, or devices provided by the manufacturer, such as key systems.
- 4.11.1.4 Exterior bait stations are **tamper resistant** and are positioned, anchored in place, locked, and labeled.
- 4.11.1.5 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.
- 4.11.1.6 **Baits are secured** inside bait stations, in **good condition**, and **replaced** as needed based on the label directions or manufacturer recommendation to avoid deterioration.

Minor Requirements

- 4.11.2.1 Monitoring devices are placed at **intervals of 50-100 ft. or 15-30 m**. Areas of high rodent activity should have a higher concentration of devices.

4.12 Interior Rodent Monitoring Devices

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

Critical Requirements

- 4.12.1.1 **Toxic and non-toxic commercial baits (blocks, liquids, etc.) are not used** for interior monitoring.
- 4.12.1.2 Based on the detailed facility survey, interior monitoring devices are placed in **sensitive areas** specific to the rodent species, and other areas of pest activity, including:
 - 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 when roof rat activity is evident or likely
 - High traffic areas
 - Both sides of doors that open to the exterior of the facility
- 4.12.1.3 Interior monitoring devices are placed along **perimeter walls**. Spacing and number of traps are based on activity levels.
- 4.12.1.4 Interior monitoring devices are positioned, cleaned, and **inspected weekly**.
- 4.12.1.5 Unless prohibited by regulation, **interior monitoring devices include:**
 - Mechanical traps
 - Extended trigger traps
 - Glue boards
- 4.12.1.6 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 (e.g., CO₂) traps
 - Live catch traps
 - See-saw tubes
 - Electrocutation traps
 - Extended trigger traps that send alert e-mails or text messages

Minor Requirements

- 4.12.2.1 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.

4.13 Insect Light Traps

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

Critical Requirements

- 4.13.1.1 Insect light traps are installed farther than **10 ft. or 3 m from food contact surfaces**, exposed products, packaging, and raw materials in processing or storage areas.
- 4.13.1.2 Insect light traps are installed in a way that does **not attract insects** to the facility.
- 4.13.1.3 **Service checks** are performed on all units on a weekly basis during the active season and a monthly basis during colder seasons or as dictated by climate. These checks include:
 - Emptying collection devices
 - Cleaning the units
 - Repairs
 - Checks for tube breakage
- 4.13.1.4 **Shatter-resistant lights** are used in all units or otherwise explained in the facility's Glass, Brittle Plastics, and Ceramics Program.
- 4.13.1.5 All services provided to light traps are documented. **Service records** are kept in the device and on file with the pest management documentation.
- 4.13.1.6 Insect light traps are used to **monitor flying insect activity** at locations that are likely to allow access to the facility.
- 4.13.1.7 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

- 4.13.2.1 Insect light trap **tubes are changed at least annually** at the beginning of the active season.

4.14 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

- 4.14.1.1 Pheromone monitoring devices are **installed** according to label requirements.
- 4.14.1.2 Pheromone monitoring devices **are inspected** on a defined frequency.
- 4.14.1.3 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.

4.15 Bird Control

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

Critical Requirements

- 4.15.1.1 Birds are **controlled by exclusion** with:
 - Nets
 - Traps
 - Appropriate structural modifications
 - Other approved legal methods
- 4.15.1.2 Avicides are only **used if legal**.
- 4.15.1.3 Avicides are used **according to label directions and local regulations**.

4.16 **Wildlife Control**

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

Critical Requirements

4.16.1.1 **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

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

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

4.17 **Pest Habitat**

Attractive habitat in or around a facility increases the chances of pest problems.

Critical Requirements

4.17.1.1 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.

4.17.1.2 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 Written Policy

The facility emphasizes its commitment to safe and legal food products through clearly defined and documented statements.

Critical Requirements

5.1.1.1 There is a **written Policy Statement** that outlines the facility's commitment to produce safe, legal products for consumers.

Minor Requirements

5.1.2.1 Senior management **signs** the Policy Statement.

5.1.2.2 The Policy Statement is **regularly communicated** throughout the facility.

5.1.2.3 **Senior management regularly reviews** the Policy Statement.

5.1.2.4 Supervisory staff and key personnel are trained to **understand and implement** the Policy Statement.

5.2 Accountability

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

Critical Requirements

5.2.1.1 Supervisory personnel **monitor the effectiveness of the implementation** of the Prerequisite and Food Safety Programs.

5.2.1.2 The facility has a current and accurate **organizational chart** that shows who is responsible for ensuring compliance to regulatory laws and guidelines.

5.2.1.3 The facility has a documented procedure to keep the Prerequisite and Food Safety Programs **current and accurate**. Important new information could include:

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

5.2.1.4 Facilities **define written procedures to meet legislative requirements** as defined by country or export requirements (e.g., allergen labeling and control, Reportable Food Registry, Food Safety Modernization Act, etc.). The facility is aware of the program and its role in implementing the requirements.

5.3 Support

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

Critical Requirements

5.3.1.1 All departments directly involved in implementing Prerequisite and Food Safety Programs have **budget and labor support** to maintain the proper and timely acquisition of appropriate tools, materials, equipment, monitoring devices, chemicals, or other support.

5.4 Written Procedures

All Prerequisites in the facility have written Programs that include procedures. Procedures are critical to food safety because they specify owners, actions, and timelines.

Critical Requirements

5.4.1.1 **Procedures define:**

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

5.4.1.2 The written procedures are **readily available** to facility personnel.

5.5 Training and Education

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

Critical Requirements

- 5.5.1.1 There are **written procedures** for developing and delivering Prerequisite and Food Safety training and education to all personnel.
- 5.5.1.2 **Training and education records** for all personnel are maintained.
- 5.5.1.3 The training includes **established means for verification** of competency of the information presented (e.g., testing, supervisor verification, verbal responses, etc.).
- 5.5.1.4 Prior to beginning work, **new employees, temporary personnel, and contractors** are trained and educated on Prerequisite and Food Safety Programs. These personnel are then supervised for compliance.
- 5.5.1.5 **Refresher training and education** are done at a minimum of annually or more often as needed.

5.6 Self-Inspections

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

Critical Requirements

- 5.6.1.1 The facility has a formal **Food Safety Committee**.
- 5.6.1.2 The Food Safety Committee schedules and conducts self-inspections of the entire facility and outside grounds at least **monthly**.
- 5.6.1.3 The Food Safety Committee **documents the results** of the self-inspection. The documentation includes:
- Identified observations
 - Corrective Actions
 - Specific assignments
 - Actual accomplishments
- 5.6.1.4 Results of the self-inspection are brought to the **attention of the personnel responsible** for the activity inspected.
- 5.6.1.5 The Food Safety Committee and the responsible key personnel set **deadlines** for Corrective Action implementation.
- 5.6.1.6 The results of Corrective Actions are **verified** to ensure satisfactory completion.

Minor Requirements

- 5.6.2.1 The Food Safety Committee has members from **multiple functions** of the facility.
- 5.6.2.2 **Follow-up inspections** ensure that observations are corrected.
- 5.6.2.3 Self-inspections include **down time assessments** to ensure in-depth inspection of equipment and structures.

5.7 Written Procedure Audits

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

Critical Requirements

- 5.7.1.1 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.
- 5.7.1.2 The audits are carried out by **competent auditors** that are independent of the area of operation being evaluated.
- 5.7.1.3 The auditor **documents the results** of the audit. The documentation includes:
- Identified observations

- Corrective Actions
 - Specific assignments
 - Actual accomplishments
- 5.7.1.4 Results of the audit are brought to the **attention of the personnel responsible** for the activity being audited.
- 5.7.1.5 Responsible key personnel set **deadlines** for Corrective Action implementation.
- 5.7.1.6 The results of Corrective Actions are **verified** to ensure satisfactory completion.

5.8 Customer Complaint Program

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

Critical Requirements

- 5.8.1.1 The facility has a **written** Customer Complaint Program.
- 5.8.1.2 The Customer Complaint Program includes a procedure for **quick distribution** of complaint information to all departments responsible for implementing Prerequisite and Food Safety Programs.
- 5.8.1.3 **Actions** appropriate to the seriousness and frequency of the complaint are carried out promptly and effectively.
- 5.8.1.4 Complaint information is used to **implement ongoing improvements** to avoid issue recurrence, and to ensure product safety.

5.9 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 nonfood chemicals.

Critical Requirements

- 5.9.1.1 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).
- 5.9.1.2 **Procedures address, as applicable:**
- Chemical approval
 - Purchase authority
 - Controlled and segregated storage
 - Handling
 - Labels/Labeling
 - Identification of where and how the chemicals are to be used
 - Concentration verification
 - Training and education
 - Actual usage
 - Inventory control
 - Chemical disposal
 - Container disposal
 - Spill containment and control
 - Chemical Safety Data Sheet archiving
 - Contractor chemicals

5.10 Microbial Control Program

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

Critical Requirements

- 5.10.1.1 The facility has completed a risk assessment and has a **written** Microbial Control Program that addresses microbiological analysis for raw materials, finished product, production, and packaging as dictated by the assessment.
- 5.10.1.2 Based on Risk Assessment, the Microbial Control Program includes **monitoring which may include, but is not limited to**, procedures to address:

- Sanitation/Hygiene practices
 - Harborage site detection
 - Corrective Actions
 - Raw materials
 - Finished product
- 5.10.1.3 **Records** are maintained of laboratory analyses and/or environmental samples that document compliance with the Microbial Control Program.
- 5.10.1.4 On-site **laboratory facilities**, if present, do not jeopardize product safety.
- 5.10.1.5 Contract labs maintain appropriate **accreditation** to carry out the analyses performed.
- 5.10.1.6 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.
- 5.10.1.7 Products that **test positive for pathogens are appropriately reprocessed or destroyed**. Documentation of the disposition of these materials is maintained.

5.11 Allergen Control Program

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

Critical Requirements

- 5.11.1.1 The facility has a **written** Allergen Control Program that addresses allergens specific to country regulations.
- 5.11.1.2 **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 food contact equipment
 - Approved Supplier Program for ingredients and labels
- 5.11.1.3 The Program is **updated** when there are changes in:
- Ingredients
 - Processing aids
 - Ingredient suppliers
 - Products
 - Processes
 - Labeling
- 5.11.1.4 **Records** demonstrating Program conformance and effective Corrective Actions are maintained.

5.12 Glass, Brittle Plastics, and Ceramics Program

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

Critical Requirements

- 5.12.1.1 The facility has a **written** Glass, Brittle Plastics, and Ceramics Program.
- 5.12.1.2 The written Glass, Brittle Plastics, and Ceramics Program includes the following **policy statements:**
- No glass, brittle plastics, or ceramics are to be used in the facility, except where absolutely necessary or where removal is not immediately feasible.
 - No glass, brittle plastics, or ceramics will be brought in with personal belongings.
- 5.12.1.3 **Procedures address:**
- Handling breakage (including stored glass, brittle plastics, or ceramics)
 - A register/list of essential glass, brittle plastics, and ceramics
 - Scheduled inspections of essential glass, brittle plastics, and ceramics to check for accidental breakage or damage

5.13 Cleaning Program

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

Critical Requirements

- 5.13.1.1 The facility has a **written** Cleaning Program.
- 5.13.1.2 The written Cleaning Program includes the following **schedules**:
 - A Master Cleaning Schedule (MCS) for periodic cleaning assignments
 - A Housekeeping Schedule for daily cleaning assignments
- 5.13.1.3 The **Master Cleaning Schedule** addresses all equipment, structures, and grounds that impact food 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
- 5.13.1.4 The facility has **written cleaning procedures** for all equipment, structures, and grounds that impact the storage, processing, and packaging of food products.
- 5.13.1.5 Equipment **cleaning procedures address**:
 - Chemicals
 - Chemical concentrations
 - Tools
 - Disassembly instructions

Minor Requirements

- 5.13.2.1 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)

5.14 Preventive Maintenance Program

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

Critical Requirements

- 5.14.1.1 The facility has a **written** Preventive Maintenance Program and work order system that prioritizes structural, equipment, or utensil maintenance problems that could cause food adulteration.
- 5.14.1.2 **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
- 5.14.1.3 **Records** indicating compliance are maintained.

5.15 Receiving Program

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

Critical Requirements

- 5.15.1.1 The facility has a **written** Receiving Program.
- 5.15.1.2 Trained personnel, using appropriate equipment, **inspect** all incoming ingredients, packaging, and vehicles.
- 5.15.1.3 The facility has **written procedures** for inspecting incoming raw materials (ingredients and packaging).

- 5.15.1.4 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
- 5.15.1.5 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
- 5.15.1.6 Incoming vehicle procedures include handling **Less Than Load (LTL) vehicles**.
- 5.15.1.7 The results of inspections are **documented**.
- 5.15.1.8 **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
- 5.15.1.9 The facility has **written procedures** for mycotoxin and pathogen-susceptible raw materials.

5.16 Regulatory Affairs and Inspections Program

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

Minor Requirements

- 5.16.2.1 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

5.17 Food Defense Program

The Food Defense Program identifies and reduces the risk of intentional harm to the facility, its personnel, and food products.

Critical Requirements

- 5.17.1.1 The facility maintains evidence of FDA **registration under the Bioterrorism Act** and re-registers at the frequency defined by the FDA. This requirement applies only if the facility manufactures, processes, packs, holds and distributes, or exports food for human or animal consumption in the USA.
- 5.17.1.2 The facility conducts a **Vulnerability Assessment**, and documents the results. Acceptable Vulnerability Assessments may include:
- Operational Risk Management (ORM)
 - Threat Evaluation Assessment and Management (TEAM)
 - CARVER + Shock
 - Internal assessment form
 - C-TPAT

- 5.17.1.3 The **written** Food Defense Program considers the Vulnerability Assessment results and includes information related to:
- A trained Coordinator
 - Food Defense Team members and contact information
 - Key regulatory agency representatives and contact information
 - First responders and contact information
 - Annual documented Food Defense training and education
 - Annual Food Defense Program review

5.18 Traceability Program

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

Critical Requirements

- 5.18.1.1 The facility has a **written** Traceability Program that is regularly reviewed.
- 5.18.1.2 The facility identifies and documents **lot numbers** for:
- Raw materials
 - Rework
 - Food contact packaging materials
 - Work-in-process
 - Finished product
 - Distribution to the customer, where appropriate
 - Processing aids
- 5.18.1.3 All finished products are **coded and recorded**.

5.19 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

- 5.19.1.1 The facility has a **written** Recall/Withdrawal Program that is regularly reviewed.
- 5.19.1.2 The facility maintains **distribution records** of the initial point of distribution for all food products by specific lot.
- 5.19.1.3 The facility **tests** the Program twice annually, and documents the results:
- Actual test results (including a test for ingredients or food contact packaging material)
 - Success rate
 - Test timings
- 5.19.1.4 Testing supports the recall to the **first level of distribution** outside of the control of the facility.
- 5.19.1.5 One of the recall tests includes **traceability** of the ingredient or food contact packaging material.
- 5.19.1.6 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
 - Location of the Traceability Program
 - Key regulatory agency representative emergency contact information
 - Supplier (including food contact packaging) and customer emergency contact information
 - Sample recall/withdrawal notification letters

5.20 Nonconforming Product Program

The Nonconforming 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 food safety requirements.

Critical Requirements

- 5.20.1.1 The facility has a **written** Nonconforming Product Program.
- 5.20.1.2 **Procedures address:**
- Investigation of the cause of nonconformity, and whether there is a food 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

5.20.1.3 Disposition of nonconforming material is **traceable** for recall or withdrawal.

Minor Requirements

5.20.2.1 **Disposition** can include:

- Rejection
- Acceptance with restrictions
- Regrading

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

5.21 Approved Supplier Program

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

Critical Requirements

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

5.21.1.2 **Procedures address:**

- A current and accurate list of approved and non-approved suppliers
- 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

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

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

5.21.1.5 Facilities that manufacture or ship products to the USA include **foreign supplier verification and import requirements** as part of the approval program.

Minor Requirements

5.21.2.1 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

5.22 Specification Program

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

Critical Requirements

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

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

- Compliance with regulation
- Agreements between relevant parties
- Defined review frequencies

5.22.1.3 **Documentation** from the supplier states that bag or box materials were sifted or liquid ingredients were strained prior to packaging. In the case that sifting or straining is not the appropriate or recognized method of foreign material control for the product, documentation from the supplier is provided stating the method of foreign material control used.

5.23 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

- 5.23.1.1 Letters of Guarantee or Certifications **provide the following:**
- A statement of compliance to regulations
 - Records of examinations and certifications that verify compliance
- 5.23.1.2 Agricultural products (e.g., fruits, vegetables, herbs, etc.) that are received **identify the grower location and picking date** as part of the certification process.

Minor Requirements

- 5.23.2.1 Letters of Guarantee or Certifications provide an indication of compliance to **Defect Action Levels (DALs)** for raw materials, packaging, and finished goods (USA only).

5.24 High-Risk Processing Record Program

The High-Risk Processing Record Program provides a written approach for documenting records and implementing procedures for changing processing parameters. This Program supports food safety practices in facilities with a microbiological kill step. Examples include, but are not limited to: cooked meat products, pasteurized products, thermal processing, nut roasting, acidified foods, etc.

Critical Requirements

- 5.24.1.1 The facility has a **written** High-Risk Processing Record Program.
- 5.24.1.2 The facility maintains **processing records**.
- 5.24.1.3 The records are **legible**, genuine, in good condition, and contain sufficient information to comply with government regulations.
- 5.24.1.4 The facility has procedures for collection, review, maintenance, **storage, and retrieval** of records.
- 5.24.1.5 The facility **retains** records for an appropriate amount of time.
- 5.24.1.6 Only **qualified personnel** who have defined responsibility for Program compliance authorize the following:
- Amendments to records
 - Corrective Actions
 - Verification of Corrective Actions
- 5.24.1.7 Procedures are **legible, unambiguous, and sufficiently detailed** to enable personnel to associate the procedure with the corresponding process.
- 5.24.1.8 Current and accurate authorized versions of Programs are **available to personnel**.
- 5.24.1.9 When **changes** are made to product formulation, processing methods, equipment, or packaging, the following actions are completed to ensure product safety:
- Reestablish processing characteristics
 - Validate product data
 - Justify reasons for changes or amendments to the documents critical to product safety
- 5.24.1.10 The **procedures ensure:**
- The processes and equipment used produce consistently safe products with the desired characteristics
 - Coverage of all processes critical to product safety
- 5.24.1.11 In the case of equipment failure or process **deviation**, procedures are in place to establish the food safety status of the product prior to release.
- 5.24.1.12 Written procedures are in place to investigate the cause of the **nonconformity** to standards, specifications, and procedures critical to product safety and legality.
- 5.24.1.13 **Corrective Action documentation:**
- Is completed in a timely manner to prevent further occurrence
 - Is approved by personnel with the defined responsibility and accountability for the activity
 - Provides verification of completion of the Corrective Action
 - Documents the person responsible and accountable for completion
- 5.24.1.14 When the facility undertakes or subcontracts **analyses**, the procedures address:
- Using appropriate procedures and facilities
 - Ensuring the reliability of test results
 - Employing qualified and/or trained personnel

- 5.24.1.15 Documentation of the **validation of the kill step** is on file and demonstrates the efficacy of the process.
- 5.24.1.16 The facility has a procedure to ensure **obsolete documentation** is removed and, if appropriate, replaced with a revised version.

5.25 HACCP Program

The HACCP Program evaluates the biological, chemical, and physical hazards associated with the raw materials and process steps related to a product or product category. The HACCP Program includes a Hazard Analysis which typically assesses risk by determining the severity of a hazard and its likelihood of occurrence. The goal of HACCP is to prevent, eliminate, or reduce hazards to an acceptable level.

Critical Requirements

- 5.25.1.1 Specific **Prerequisite Programs** are in place and functioning:
 - GMPs
 - Personnel Practices
 - Customer Complaint
 - Chemical Control
 - Cleaning
 - Preventive Maintenance
 - Transportation and Storage
 - Integrated Pest Management
 - Receiving
 - Traceability
 - Recall/Withdrawal
 - Allergen Control
 - Approved Supplier
- 5.25.1.2 The facility has a **written HACCP Program** that has been signed by senior management.
- 5.25.1.3 The facility has a **HACCP Team** with members from multiple functions of the facility. The team has the following characteristics:
 - The team members have been trained
 - The HACCP coordinator has documented HACCP training
- 5.25.1.4 The facility has **Finished Product Profiles** for each product type produced.
- 5.25.1.5 The facility has a **Process Flow Diagram** for each product type produced.
- 5.25.1.6 The facility follows the **Seven Principles of HACCP**:
 1. The facility has **conducted and documented a Hazard Analysis** for each raw material and process step. In the case of facilities producing or exporting to the USA or other countries with regulations, regulatory (FDA) requirements for HARPC (Hazard Analysis Risk-Based Preventive Controls) will be evaluated taking into consideration the defined hazard categories or country-defined requirements.
 2. Based on the Hazard Analysis, the **Critical Control Points (CCPs)** are identified, and the procedures for controlling the hazards are described.
 3. The **Critical Limits** for the CCPs are scientifically established and recorded.
 4. The facility has established procedures for **Monitoring** the HACCP Program that include identification of frequency of activities and responsible person(s).
 5. The facility has established procedures for **Deviation** from the HACCP Program that include identification of short-term and long-term Corrective Actions.
 6. The facility has established procedures for **Verification** of the HACCP Program that include identification of frequency of activities and responsible person(s).
 7. The facility has legible **documented records** of monitoring, deviation, and verification activities.
- 5.25.1.7 The facility conducts and documents **training** on the HACCP Program. The training targets:
 - Responsibility for management
 - Awareness for non-management personnel
 - Job-specific procedures for personnel working at a designated Critical Control Point (CCP)
- 5.25.1.8 The Critical Control Points (CCPs) identified are **controlled and monitored** within the HACCP Master Plan.
- 5.25.1.9 The facility conducts a **review** of the HACCP Program annually or as changes (e.g., products or process) occur:
 - Records are available
 - Records are kept one year or two times the shelf life of the product, whichever is longer or as defined by regulatory requirement.

5.25.1.10 Facilities that must comply with **regulatory HACCP** meet the defined requirements.

5.26 Specialized Testing

Specialized testing requirements that are defined by country are implemented and followed.

Critical Requirements

5.26.1.1 The facility has a defined and implemented **testing program** to meet country requirements, where applicable.

5.26.1.2 **Where required by country**, the facility maintains current records of raw material testing, which may include, but are not limited to:

- Pesticide residues
- Genetically Modified Organisms (GMO)
- Heavy metals
- Radioactivity
- Allergens
- Mycotoxins

5.27 Release Procedures

Release procedures ensure that materials are checked for defined food safety hazards before being released into the facility or shipped to a customer.

Critical Requirements

5.27.1.1 The facility follows **release procedures**.

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

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

5.28 Design Standards

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

Critical Requirements

5.28.1.1 The facility has **design standards** that apply to all structural and equipment designs, repairs, modifications, or purchases to reduce the potential for contamination and pest infestations and make cleaning easier.

5.29 Water Quality

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

Critical Requirements

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

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

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

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

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

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

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

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

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

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

1.2 Rejection of Shipments/Receipt of Perishables

- Temperature check records
- 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 release 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 Designated Rework Areas

- Records to demonstrate the break and clean process

1.9 Bulk Material Handling

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

1.10 Sampling Procedures

- Sampling procedures

1.11 Processing Aids

- Food approval documentation

1.12 Raw Material Transfer

- Procedures for transferring and handling food materials

1.13 Bulk Material Sifting

- Records of weekly sifter screen inspections
- Records of daily tailings log checks, findings, and Corrective Actions

1.14 Bulk Liquid Materials

- Records of strainer inspections, findings, and Corrective Actions

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

1.22 Temperature-Sensitive Materials

- Records of temperature monitoring

1.23 Cross Contamination Prevention

- Verification of sanitizer concentration and Corrective Actions, if needed
- Captive Shoe Program, if implemented

1.25 Cans, Bottles, and Rigid Packaging

- Preventive maintenance records for monitoring of air/water filtration systems

1.26 Finished Product Transportation

- Distribution records
- Records of temperatures of perishable items upon loading
- Records of temperatures of pre-cooled vehicles for temperature-sensitive materials
- Transportation breakdown procedures
- Shipping vehicle inspection documentation
- Security seal or padlock documentation

1.27 Hand Washing Facilities

- Records of hand sanitizer concentration monitoring

1.31 High-Risk Clothing Management

- Procedures for dressing in visually distinctive clothing

1.32 Personal Items and Jewelry Control

- Personnel Practices Program
- Exceptions to Personnel Practices Program

1.33 Health Conditions

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

1.36 Glass Container Breakage

- Procedures to address glass container breakage
- Records documenting glass container breakage procedures were followed

1.37 Filling, Capping, and Sealing

- Documentation of reprocessing or rejection of sealed or filled containers

2. Maintenance for Food Safety

2.9 Glass, Brittle Plastics, and Ceramics Control

- Glass, Brittle Plastics, and Ceramics Program

2.10 Air Makeup Units

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

2.13 Lubricants

- Evidence that lubricants are food-grade

2.16 Temporary Repair Materials

- Temporary repair procedures
- Work orders and repair requests

2.17 Temperature Measuring Devices

- Records of temperature monitoring activities
- Records of temperature measuring device calibration traceable to a national standard

2.18 Compressed Air/Product Contact Gases

- Micron rating of compressed air filter (5 microns)
- Purity/filter documentation for other gases for product contact

2.23 Ammonia Control

- Inspection records and Corrective Actions

3. Cleaning Practices

3.2 Food Contact Cleaning Compounds and Sanitizers

- Food contact approval documentation for cleaning compounds and sanitizers
- Records of testing of cleaning chemical concentrations
- Verification procedures for testing chemical concentrations

3.3 Equipment and Tools

- Documentation of color-code or other classifications
- Cleaning of forklifts/pallet jacks

3.4 Daily (Housekeeping) Cleaning

- Documentation of daily cleaning task assignments and schedules

3.5 Product Zone Cleaning

- Documentation of periodic cleaning task assignments and schedules

3.7 Clean in Place (CIP) Systems

- Documentation of time/temperature/flow rates
- Documentation of chemical concentration

4. Integrated Pest Management

4.1 Integrated Pest Management (IPM) Program

- IPM Program
- Written responsibilities for trained in-house or outside contractors

4.2 Facility Assessment

- Documentation of the annual assessment of the facility
- Documentation of Corrective Actions

4.3 Other Guidelines

- Certificate or demonstration of alternative guideline

4.4 Signed Contracts

- A signed contract that addresses the requirements listed in 4.4.1.1 of the AIB International Consolidated Standards

4.5 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

4.6 Pesticide Documentation

- Records of pesticide Chemical Safety Data Sheets and labels

4.7 Pesticide Application Documentation

- Pesticide application records that address the requirements listed in 4.7.1.1 of the AIB International Consolidated Standards
- Records of the lot number of the pesticide used, or applicator's certificate or registration number, as applicable

4.8 Pesticide Control

- Inventory of pesticides

4.9 Trend Analysis

- Records pertaining to pest management activities
- Service records describing current levels of pest activity
- Pest-sighting logs
- Written reports of quarterly reviews of pest-sighting logs
- Documented Corrective Actions

4.10 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 in rodent and insect control
- Separate site map that lists temporary placements of pest-monitoring devices
- Records of services performed on all pest-monitoring devices

4.13 Insect Light Traps

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

4.14 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 Written Policy

- A signed, written policy statement that outlines the commitment to produce safe and legal foods

5.2 Accountability

- The current organizational chart
- A procedure to keep the Prerequisite and Food Safety Programs current and accurate
- Written procedures to meet legislative requirements

5.4 Written Procedures

- Job descriptions
- Alternates/Deputies assignments

5.5 Training and Education

- Written procedures for developing and delivering Prerequisite and Food Safety training
- Training records for all personnel
- Training criteria for competency requirements to confirm understanding of the information presented

5.6 Self-Inspections

- Results of the self-inspections and Corrective Actions

5.7 Written Procedure Audits

- Results of the audits and Corrective Actions

- 5.8 Customer Complaint Program**
 - Customer Complaint Program
 - Procedure for quick distribution of complaint information
- 5.9 Chemical Control Program**
 - Chemical Control Program
 - Procedures that address the requirements listed in 5.9.1.2 of the AIB International Consolidated Standards
- 5.10 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
- 5.11 Allergen Control Program**
 - Allergen Control Program
 - Procedures that address the requirements listed in 5.11.1.2 of the AIB International Consolidated Standards
 - Records of Program updates
 - Records demonstrating conformance and Corrective Actions
- 5.12 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
- 5.13 Cleaning Program**
 - Cleaning Program
 - The Master Cleaning Schedule
 - The Housekeeping Schedule
 - The cleaning procedures for equipment, structures, and grounds
- 5.14 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
- 5.15 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
- 5.16 Regulatory Affairs and Inspections Program**
 - Regulatory Affairs and Inspections Program
- 5.17 Food Defense Program**
 - FDA registration under the Bioterrorism Act, where necessary
 - Vulnerability Assessment
 - Food Defense Program
- 5.18 Traceability Program**
 - Traceability Program
 - Records of lot numbers for raw materials, rework, ingredients, work-in-process, finished product, processing aids, food contact packaging, etc.
 - Records of finished product coding

5.19 Recall/Withdrawal Program

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

5.20 Nonconforming Product Program

- Nonconforming Product Program
- Procedures that address nonconforming product investigation, Corrective Actions, handling, and disposal
- Disposition records for recall
- Documentation for damaged or destroyed materials, and adjusted inventories

5.21 Approved Supplier Program

- Approved Supplier Program
- Approved Supplier Program procedures
- Records of supplier performance monitoring
- Documentation of the methods and frequency for supplier performance monitoring
- Foreign supplier verification and import requirements documentation

5.22 Specification Program

- Written specifications for raw materials, packaging materials, processing aids, work-in-process, and finished product
- Documentation of sifting/straining of bag, box, or liquid ingredients

5.23 Letters of Guarantee or Certifications

- Letters of Guarantee or Certifications

5.24 High-Risk Processing Record Program

- Processing Record Program
- Processing records
- Written procedures for collection, review, maintenance, storage, and retrieval of records
- Records show that qualified personnel authorized amendments, Corrective Actions, and verification activities
- Procedures for defining actions resulting from changes made to formulas, processing methods, equipment, or packaging
- Procedures for equipment failure and process deviation
- Procedures for investigation of nonconformity
- Documentation of Corrective Actions and verification of completion
- Procedures for undertaking or subcontracting analyses
- Procedures to rescind and replace obsolete documentation

5.25 HACCP Program

- Written Programs for HACCP-required Prerequisites
- A signed HACCP Program
- Finished Product Profiles
- Process Flow Diagram
- Hazard Analysis
- Records of CCP monitoring
- HACCP Master Plan
- Training records
- Records of the annual review of the HACCP Program

5.26 Specialized Testing

- Defined testing program
- Records of testing as required by program

5.27 Release Procedures

- Release procedures
- Records of compliance with release procedures

5.28 Design Standards

- Design standards for structural repairs or modifications

5.29 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

Appendix B—Conflict Resolution Process

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

1. Contact an AIB International support staff member:
 - North America + 1-785-537-4750 or 1-800-633-5137
 - Latin America + 52-442-135-0912
 - Japan + 81-03-5659-5081
 - Europe + 44 1372 360-553
2. The AIB International staff member will begin a Customer Complaint Tracking Form.
3. The inspection report, if applicable, will be put on hold.
4. The Form will be e-mailed, along with a copy of the inspection report in question (if applicable), to the responsible Regional Director or Manager.
5. The Regional Director or Manager will contact the customer for further details:
 - These details will be used to investigate the issue.
 - The inspector or staff member involved in the complaint will be contacted for his or her information.
6. If the complaint concerns an inspection report, it may be sent out for a blind review:
 - 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 Director or Manager.
7. The Director or Manager will contact the facility to discuss the final results of the review:
 - If the scoring is changed, the Director or Manager will:
 - ◇ Advise AIB International administration of the change.
 - ◇ Issue an apology letter to the customer.
 - ◇ Follow up with the appropriate inspector to prevent recurrence of the scoring discrepancies.
 - ◇ Reissue the inspection report.
 - If the scoring remains unchanged, the Director or Manager will:
 - ◇ Follow up with the customer and explain why the scoring is justified in accordance with the AIB International Consolidated Standards.

Appendix C—Glossary

21 CFR 110—U.S.A. Code of Federal Regulations; Chapter 21, Part 110. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. The 21CFR 110 is the U.S.A.'s core food safety regulation under the authority of the Federal Food Drug and Cosmetic Act.

Acceptance with Restrictions—Nonconforming 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.

Bioterrorism Act (2002)—U.S. Regulation that requires key components to protect the nation's food supply chain from acts of intentional contamination.

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.

Captive Shoe Program—Footwear that is specifically designated to be kept and worn in one area to prevent cross contamination.

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

CARVER+Shock—An offensive targeting prioritization tool adapted from the military version (CARVER) for use in the food industry. It allows the user to think like an attacker to identify the most attractive targets for an attack. CARVER is an acronym for the following 6 attributes used to evaluate the attractiveness of a target for attack: Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognizability. A seventh attribute, Shock has been added to the original 6 to assess the combined health, economic, and psychological impacts of an attack on the food industry.

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 in Place (CIP)—The removal of soil from product contact surfaces in a stationary position by circulating, spraying, or flowing chemical solutions and water rinses onto and over surfaces to be cleaned.

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.
- **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.

Customs-Trade Partnership Against Terrorism

(C-TPAT)—A voluntary supply chain security program led by U.S. Customs and Border Protection (CBP) and focused on improving the security of private companies' supply chains with respect to terrorism.

Defect Action Levels (DALs)—The levels of natural or unavoidable defects in foods that present no health hazards for humans.

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)—This is the US government agency that is 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.

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 Facility—Any facility that manufactures, processes, packs, or holds food for human consumption.

Food Grade—A material or product that will not transfer nonfood 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 United States food supply is safe by shifting the focus from responding to contamination to preventing it.

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.

Genetically Modified Organism (GMO)—This is an organism whose genetic material has been altered using genetic engineering techniques.

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. Examples are defined in the U.S. 21 CFR 110. 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)—The 7 step process used to identify, eliminate, or reduce to an acceptable level any physical, chemical, or microbial hazards identified in the ingredients, process, or product being manufactured. HACCP is based on risk assessment, and identifies the points within the process where controls may be put in place and monitored to control the identified hazards.

Hazard Analysis Risk-Based Preventive Controls

(HARPC)—The analysis that identifies a hazard and the preventive control for that hazard.

Heating, Ventilation, and Air Conditioning (HVAC).

High-Risk Operation—Operation that involves food at risk of contamination because it is processed and stored within temperature ranges from 40°F (4°C) to 140°F (60°C) in a non-sterile environment.

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 the environment.

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

Kill Step—The relationship of temperature (e.g., cooked product), temperature and time (e.g., pasteurization), or temperature, pressure, and time (e.g., canning) that effectively destroys pathogens within a cooked food product. The temperature, and/or pressure, and/or time requirements for processing are science-based.

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

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.

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

Operational Risk Management (ORM)—A simplified risk assessment process for food defense that helps to identify risks, and determine the best course of action for any situation.

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.

Pasteurize—To expose a food product to an elevated temperature or pressure for a period of time to destroy certain microorganisms that can produce disease or cause spoilage. The result is partial sterilization to destroy disease-causing or other undesirable organisms.

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 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.

Pest Management Regulatory Agency (PMRA) (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 in the hazard analysis. They are consistent with 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 on 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 Aids—

- Substances that are added during the processing of a food, but are removed in some manner from the food before it is packaged in its finished form.
- Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.
- Substances that are added to a food for their technical or functional effect in the processing, are present in the finished food at insignificant levels, and do not have any technical or functional effect on that food.

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 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 nonconforming 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.

Risk Assessment—The categorization of observations in a facility into one of five categories: No Issues Observed, Minor Issues Noted, Improvement Needed, Serious, or Unsatisfactory.

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.

Threat Evaluation, Assessment, and Management (TEAM)—A six step approach to threat evaluation that includes:

- Identify potential threats in all aspects of the operation
- Assess the threats to determine those with the highest risk (greatest negative impact)
- Establish threat control measures and management control procedures to eliminate the threat or reduce the risk level
- Implement control measures and establish monitoring of each critical exposure point
- Take Corrective Action if there is a break in control of a management point
- Supervise and verify that TEAM is working

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_w)—This is 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

1

Operational Methods and Personnel Practices

1.1	Rejection of Shipments/Receipt of Dry Goods	1
1.2	Rejection of Shipments/Receipt of Perishables	1
1.3	Storage Practices	1
1.4	Storage Conditions	2
1.5	Raw Material/Finished Product Inventory	2
1.6	Pallets	2
1.7	Designated Rework Areas	3
1.8	Dust Collection and Filtering Devices	3
1.9	Bulk Material Handling	3
1.10	Sampling Procedures	3
1.11	Processing Aids	3
1.12	Raw Material Transfer	4
1.13	Bulk Material Sifting	4
1.14	Bulk Liquid Materials	4
1.15	Foreign Material Control Devices	5
1.16	Waste Material Disposal	5
1.17	Ingredient Scoops	5
1.18	Product Identification	5
1.19	Workspace Arrangement	6
1.20	Single-Service Containers	6
1.21	Hand Contact	6
1.22	Temperature-Sensitive Materials	6
1.23	Cross Contamination Prevention	6
1.24	Containers and Utensils	7
1.25	Cans, Bottles, and Rigid Packaging	7
1.26	Finished Product Transportation	7
1.27	Hand Washing Facilities	8
1.28	Washrooms, Showers, and Locker Rooms	8
1.29	Personal Hygiene	9
1.30	Work Clothes, Changing Facilities, and Personnel Areas	9
1.31	High-Risk Clothing Management	9
1.32	Personal Items and Jewelry Control	10
1.33	Health Conditions	10
1.34	Non-Facility Personnel	10
1.35	Multiple-Service Shipping Containers	11
1.36	Glass Container Breakage	11
1.37	Filling, Capping, and Sealing	11
1.38	Examination of Materials	11

2

Maintenance for Food Safety

2.1	Facility Location	12
2.2	Outside Grounds and Roof	12
2.3	Security Equipment	12
2.4	Layout	13
2.5	Floors	13
2.6	Drains	13
2.7	Walls	13
2.8	Ceilings and Overhead Structures	14

2.9	Glass, Brittle Plastics, and Ceramics Control	14
2.10	Air Makeup Units	14
2.11	Pest Prevention	15
2.12	Leaks and Lubrication	15
2.13	Lubricants	15
2.14	Cross Contamination Prevention	15
2.15	Equipment and Utensil Construction	16
2.16	Temporary Repair Materials	16
2.17	Temperature Measuring Devices	16
2.18	Compressed Air/Product Contact Gases	17
2.19	Transporting Equipment	17
2.20	Parts Storage	17
2.21	Hand Washing Facilities Design	17
2.22	Bulk Systems and Unloading Areas	17
2.23	Ammonia Control	18
2.24	Wastewater Treatment and Sewage Disposal	18

3

Cleaning Practices

3.1	Cleaning	19
3.2	Food Contact Cleaning Compounds and Sanitizers	19
3.3	Equipment and Tools	19
3.4	Daily (Housekeeping) Cleaning	20
3.5	Product Zone Cleaning	20
3.6	Non-Product Zone and Support Area Cleaning	20
3.7	Clean In Place (CIP) Systems	21

4

Integrated Pest Management

4.1	Integrated Pest Management (IPM) Program	22
4.2	Facility Assessment	22
4.3	Other Guidelines	22
4.4	Signed Contracts	22
4.5	Credentials and Competencies	23
4.6	Pesticide Documentation	23
4.7	Pesticide Application Documentation	23
4.8	Pesticide Control	24
4.9	Trend Analysis	24
4.10	Monitoring Device Documentation	24
4.11	Exterior Rodent Monitoring Devices	25
4.12	Interior Rodent Monitoring Devices	25
4.13	Insect Light Traps	26
4.14	Pheromone Monitoring Devices	26
4.15	Bird Control	26
4.16	Wildlife Control	27
4.17	Pest Habitat	27

5

Adequacy of Prerequisite and Food Safety Programs

5.1	Written Policy	28
5.2	Accountability	28
5.3	Support	28
5.4	Written Procedures	28
5.5	Training and Education	29
5.6	Self-Inspections	29
5.7	Written Procedure Audits	29
5.8	Customer Complaint Program	30
5.9	Chemical Control Program	30
5.10	Microbial Control Program	30
5.11	Allergen Control Program	31
5.12	Glass, Brittle Plastics, and Ceramics Program	31
5.13	Cleaning Program	32
5.14	Preventive Maintenance Program	32
5.15	Receiving Program	32
5.16	Regulatory Affairs and Inspections Program	33
5.17	Food Defense Program	33
5.18	Traceability Program	34
5.19	Recall/Withdrawal Program	34
5.20	Nonconforming Product Program	34
5.21	Approved Supplier Program	35
5.22	Specification Program	35
5.23	Letters of Guarantee or Certifications	36
5.24	High-Risk Processing Record Program	36
5.25	HACCP Program	37
5.26	Specialized Testing	38
5.27	Release Procedures	38
5.28	Design Standards	38
5.29	Water Quality	38

Appendices

Appendix A	Documents to Have Ready for an Inspection	39
Appendix B	Conflict Resolution Process	44
Appendix C	Glossary	45