**Change Document to Accompany the 2013 AIB International Consolidated Standards for Inspection of Food Contact Packaging Manufacturing Facilities**

Regulatory developments, including the passage of the US Food and Drug Administration Food Safety Modernization Act (FSMA) and other industry best practices impacting the food industry worldwide, have necessitated a thorough updating process to the AIB International *Consolidated Standards for Inspection*.

The Standards were last updated, with a completely new format, and introduced in 2009. The intent was to achieve improved functionality in the capture of specific data that would assist in pinpointing areas of opportunity within the facility and allow for trending of this data. With the introduction of our Automated Quality Management System in 2011, we again evaluated how the data within the Standards was structured.

For the 2013 updates we have implemented several sets of changes:

1. Changed the way the data is arranged to better capture findings in like areas so that comparisons and data capture can be centralized. To this end, some clause numbers have changed.
2. Items have been grouped differently to provide a more cohesive picture of what is happening in the facility and to make data capture and trending of findings easier.
3. In some cases, criteria were moved to a different category within the Standards to provide a better fit with the evaluation of programs and findings.
4. Made minor changes to headings, or changes to numbering, that are not changes to the criteria evaluated in the previous version of the Standards.

The purpose of the Change Document is to highlight the changes and identify additional criteria and changes to content and to outline expectations during an inspection. Minor changes, referred to in 4 above, will not be described in the document. As always, AIB International wishes to provide transparency behind the reasons for changes to the Prerequisite and Food Safety Programs, and the necessary clarification to understand and implement them. By so doing, together we will continue to ensure the ongoing successful implementation of food safety programs worldwide.

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# Operational Methods and Personnel Practices

## 1.1 Rejection of Shipments/Receipt of Dry Goods

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

- *Explanation of the change*: The language was edited to clarify the need to document the reason for rejection of the material. The number was changed from 1.1.1.5 to 1.1.1.3.
- *Guidance on evaluation of criteria*: No additional guidance required. Minor edit to criteria text only.

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

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance required.

**1.1.2.1 Minor** - ~~**Vehicles used to shuttle product** between facility and warehouse locations are maintained so that they do not contaminate the material being transferred.~~

- *Explanation of the change*: This requirement was deleted because it is covered in 1.1.1.4.
- *Guidance on evaluation of criteria*: No additional guidance required.

## 1.3 Storage Practices

**1.3.1.2 Critical** - ~~**Receiving**~~ **Dates to facilitate stock rotation are visible** on the ~~bottom unit of the~~ pallet or individual container.

- *Explanation of the change:* The language was edited to take into consideration other methodologies of stock rotation beyond the use of manually placed receiving dates.
- *Guidance on evaluation of criteria*: No additional guidance required. Minor edit to criteria text only.

**1.3.2.1 Minor** - ~~Receiving~~ Dates used for stock rotation are on a **permanent** part of the ~~raw material~~ packaging (i.e., not on the stretch wrap).

- *Explanation of the change:* The language was edited to not just limit this requirement to receiving dates or raw materials only.
- *Guidance on evaluation of criteria*: No additional guidance required. Minor edit to criteria text only.

## 1.4 Storage Conditions

**1.4.1.1 Critical** - 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.

- *Explanation of the change:* The language was expanded to include work-in-process and finished products.
- *Guidance on evaluation of criteria*: The auditor would rate any issues with work-in-process and finished products based on the risk to product.

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

- *Explanation of the change:* Expanded the scope of the requirement to include protection of raw materials being returned to storage.
- *Guidance on evaluation of criteria*: The auditor would rate any issues regarding protection of raw materials being returned to storage based on risk to product.

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

- *Explanation of the change:* Expanded the scope of the requirement to include finished products.
- *Guidance on evaluation of criteria*: The auditor would expand rating of issues with stock rotation to finished products.

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

- *Explanation of the change:* Added a requirement to ensure that appropriate examination of materials is carried out prior to use of the material.
- *Guidance on evaluation of criteria*: The auditor would rate no more than a minor improvement, if applicable as these materials should have already been subject to incoming materials examination and verification.

**1.5 Raw Material/Finished Product Inventory**

**1.5.1.1 Critical** - 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.

- *Explanation of the change:* Added work-in-process and finished product to the requirements for stock rotation.
- *Guidance on evaluation of criteria*: The auditor will rate findings as they relate to work-in-process and finished product with relation to the identified risk to the product.

**1.5.2.1 Minor** - 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.). ~~If appropriate, the~~ ~~**repalletizing date** or inspection date is located near the original receiving date.~~

- *Explanation of the change:* Revised the requirement to allow greater flexibility for defining and managing how a facility identifies and tracks inspection of insect-susceptible materials.
- *Guidance on evaluation of criteria*: The auditor will rate this issue based on whether or not the system defined for the facility is followed and ensures examination and tracking of these materials is effective.

**1.6 Pallets**

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

- *Explanation of the change:* Changed severity from minor to critical.
- *Guidance on evaluation of criteria*: The auditor will randomly review pallets to determine if pallet inspection programs are effective.

**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.*

- *Explanation of the change:* Expanded the italicized text to include loading and expand the scope of the requirement.
- *Guidance on evaluation of criteria*: The auditor review of the Standard would also include evaluation and rating of the criteria with relation to bulk material handling during loading.

**1.9.1.4 Critical** - 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 or receiving.

- *Explanation of the change:* Expanded the scope to include both shipping and receiving of bulk containers.
- *Guidance on evaluation of criteria*: The auditor will review this with relation to ensuring that seals are reviewed to adequately identify any tampering with shipped or received materials.

**1.9.1.8 Critical** - Hoses, caps, and couplings are **cleaned before storage** in a secured area.

- *Explanation of the change*: This was added to ensure that equipment used for unloading was adequately cleaned and protected to prevent contamination of materials.
- *Guidance on evaluation of criteria*: The auditor will rate this based on the cleanliness and security of the storage of the equipment and the likelihood of product contamination.

**1.9.1.9 Critical** - **Prior load verification** is completed and records are maintained.

- *Explanation of the change*: This requirement was added to ensure that the shipping vessel used to transport bulk materials was either adequately cleaned or did not contain materials from a prior load that could contaminate product.
- *Guidance on evaluation of criteria*: The auditor will evaluate the execution of this program for randomly selected loads either received or shipped from the facility, as applicable to ensure that program requirements are effective.

**1.15 Foreign Material Control Devices**

**1.15.1.3 Critical** - Metal detectors or X-ray machines ~~either contain~~ 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 maintains control of the rejected product.

- *Explanation of the change*: Minor edits to the language were made and language regarding how reject materials are to be handled was added to this clause to allow more flexibility in how a facility chooses to manage rejected material.
- *Guidance on evaluation of criteria*: The auditor will challenge the program defined by the facility to evaluate that rejected product is adequately controlled to prevent reintroduction of rejected materials into the product stream.

**1.23 Cross Contamination Prevention**

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

- *Explanation of the change*: Changed from minor to critical requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: Changed from minor to critical requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required

**1.24 Containers and Utensils**

**1.24.1.7 Critical** ~~Containers used for storage are **clearly labeled with contents.**~~

- *Explanation of the change*: This is a duplication of 1.24.1.3.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.24.1.8 Critical** ~~**Precautionary statements** are provided on labels, when required.~~

- *Explanation of the change*: This element is a Program and was revised and included as clause 5.22.13 in this update.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.25 Can, Bottles, and Rigid Packaging**

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

- *Explanation of the change*: This Standard was added to address conditions for manufacture of cans, bottles, and rigid packaging.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.25.1.6 Critical** - Rigid packaging is **covered, inverted, or overhead structures are maintained** to prevent contamination.

- *Explanation of the change*: The requirement was added to ensure that structures over open, unfilled packaging materials were adequately maintained or protected.
- *Guidance on evaluation of criteria*: The auditor will evaluate overhead structures to ensure that they are adequately maintained to prevent contamination of open, unfilled packaging materials.

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

- *Explanation of the change*: This requirement was added to ensure proper protection from contamination is provided for packaging while it is in storage.
- *Guidance on evaluation of criteria*: The auditor will evaluate the storage conditions to ensure that packaging materials are adequately protected in storage.

**1.26 Finished Product Transportation**

**1.26.1.13 Critical** - ~~Transport vehicles are **clean and dry before** loading.~~

- *Explanation of the change*: This requirement is captured in 1.26.1.10.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.26.2.3 Minor** - ~~**Seal numbers are recorded** for tracking purposes on the bill of lading (BOL) or other shipping documentation~~.

- *Explanation of the change*: This requirement is addressed in element 1.9.1.4 and 1.26.2.2 in the 2013 version.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.26.2.5 Minor** - 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.

- *Explanation of the change*: Edited requirement to ensure that transport vehicles that have hauled nonfood items that could provide a potential for product contamination are addressed or that adequate protective barriers are provided in the case that there is commingling in a load.
- *Guidance on evaluation of criteria*: Auditors will randomly review transports for evidence of this and will evaluate if barriers are provided, where applicable.

**1.27 Hand Washing Facilities**

**1.27.2.1 Minor** - Dispensers for **disposable paper towels** are covered. ~~Hands-free design is desirable.~~

- *Explanation of the change*: The language was edited to provide clarity of what is required for paper towel dispensers.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.30 Work Clothes, Changing Facilities, and Personnel Areas**

**1.30.1.8 Critical** - Where **protective clothing is required**, it is available at all times ~~when required~~, and laundered or cleaned in a controlled environment. ~~under controlled circumstances.~~

- *Explanation of the change*: Minor edits were made to the language to provide additional clarity.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.32 Personal Items and Jewelry Control**

**1.32.1.1 Critical** - 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

- *Explanation of the change*: Body jewelry was added to the list of items.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.32.2.1 ~~Minor~~** - ~~Personnel in contact with products are prohibited from wearing~~ **~~perfume or aftershave~~**.

- *Explanation of the change*: Given the nature of the products manufactured, transfer of odors is typically not an issue in this type of manufacturing.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.33 Health Conditions**

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

- *Explanation of the change*: The requirement was added to address handling and disposal of food stuffs or product contact surfaces that have come in contact with blood and other bodily fluids.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to provide the program that demonstrates this and any records that show that the procedures were followed, as applicable.

**1.33.2.1 Minor** – If appropriate, each lot of metal-strip bandages **is tested in the metal detector**.

- *Explanation of the change*: The word metal-strip was added to better define the bandages for which testing in the metal detector is required.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**1.36 Glass Container Breakage**

*Procedures are in place to address glass container breakage in manufacturing, packaging, and storage areas to prevent product contamination.*

- *Explanation of the change*: This new Standard was added to address facilities that package product in glass containers.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that procedures are defined to address glass container breakage to prevent potential for product contamination.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to provide their glass container breakage procedures.

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

- *Explanation of the change*: This requirement was added to ensure that glass clean up records reflect that glass breakage procedures were followed.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to provide the records indicating when glass container breakage occurred and documentation to demonstrate procedures were followed.

### 1.43 Waxes, Sealants, Adhesives and Ink

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

- *Explanation of the change*: The language was edited to include storage off the floor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

## Maintenance for Food Safety

### 2.2 Outside Grounds and Roof

**2.2.1.8 Critical** – The **roof and structures** are well maintained.

- *Explanation of the change*: Added requirement specifically addressing the roof and structures.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change:* This element was added to include evaluation of garages and truck bays where trucks are serviced that could impact the food safety of the products transported in these vehicles.
- *Guidance of evaluation of criteria:* The auditor will examine these areas as part of the inspection process and rate findings based on identified risk.

### 2.4 Layout

**2.4.1.2 Critical** - There is adequate space **to place** equipment and raw materials.

- *Explanation of the change*: The severity of the item was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

### 2.5 Floors

**2.5.1.2 Critical** - Wall/floor junctions and corners are **maintained** to facilitate cleaning.

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.2.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.3.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.5.1.4 Critical - Floors are designed** to meet the demands of facility operations and withstand cleaning materials and methods**.**

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.4.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.5.1.5 Critical** - Floors are **impervious.**

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.5.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.5.1.6 Critical** – **Floors are sloped** to direct the flow of water or effluent toward drains.

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.6.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.7 Walls**

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

- *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.3.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.7.1.3 Critical** – Walls are **designed, constructed, finished, and maintained** to:

- Prevent dirt accumulation
- Reduce condensation and mold growth
- Facilitate cleaning
    - *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.1.
    - *Guidance on evaluation of criteria*: No additional guidance is required.

**2.8 Ceilings and Overhead Structures**

**2.8.1.3 Critical** – Ceiling and overheads are **designed, constructed, finished, and maintained** to:

- Prevent dirt accumulation
- Reduce condensation and mold growth
- Facilitate cleaning
    - *Explanation of the change*: The severity of the item was changed from minor to critical. Formerly 2.5.2.1.
    - *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change:* This element was added to differentiate contamination leading to a microbiological issue, such as mold.
- *Guidance on evaluation of criteria:* No additional guidance is required.

**2.10 Air Makeup Units**

**2.10.1.5 Critical** - Filters are capable of removing particles of 50 microns (Minimum Efficiency Reporting Value [MERV] 4) or larger.

- *Explanation of the change*: Added the equivalent MERV rating to meet the 50 micron requirement for filtering of makeup air.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.11 Pest Prevention**

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

- *Explanation of the change:* This requirement was combined from 2.8.1.4 and 2.8.2.1 in the previous version.
- *Guidance on evaluation of criteria*: No additional guidance required.

**2.9.1.4 Critical** – ~~**Transformers and electrical services** that enter the facility from underground conduits are sealed to prevent rodents, insects, or other pests from entering the facility.~~

- *Explanation of the change:* This requirement was deleted. This is already addressed in 2.11 Pest Barriers.
- *Guidance on evaluation of criteria*: No additional guidance required.

**2.12 Leaks and Lubrications**

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

- *Explanation of the change*: Added oil to expand the scope of lubricants evaluated as part of the product safety program.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: Expanded the scope of the requirement to include oil.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.14 Cross Contamination Prevention**

**2.14.1.3 Critical** – Areas for **washing and cleaning** are located away from production activities, where appropriate.

- *Explanation of the change*: This was added to address segregation of cleaning areas to ensure that they do not provide a source of contamination to products, processing, raw materials, or finished products, if applicable to the facility.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.14.1.4 Critical** - **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.

- *Explanation of the change*: Added language to include exhausting to the outdoors to this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.14.1.5 Critical** - **Cleaning and production areas are segregated** with air curtains, partitions, doors, or other exclusionary systems.

- *Explanation of the change*: Changed severity from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.15 Equipment and Utensil Construction**

**2.15.1.1 Critical** - All **equipment and utensils** are designed and made of materials that are **easily cleaned and maintained**.

- *Explanation of the change*: Expanded the requirement to include equipment.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.15.1.5 Critical** - Pipelines, mixing, and holding tanks are **free of defects**.

- *Explanation of the change*: Added requirement to address the condition of seams in equipment.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: Added requirement to ensure that liquids do not stagnate in equipment.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.15.1.8 Critical** ~~Hangers, guides, supports, baffles, and fasteners are constructed of materials that are **easily cleanable and in good repair**.~~

- *Explanation of the change*: This element is a duplicate of 2.15.1.1.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.15.1.9 Critical** ~~**Take-off tables and container contact materials** are constructed of cleanable material and in good repair.~~

- *Explanation of the change*: This element is a duplicate of 2.15.1.1.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.18 Compressed Air/Product Contact Gases**

**2.18.1.4 Critical** - **Records of filter inspectio**n and replacement are maintained

- *Explanation of the change:* This requirement was added to ensure inspection and replacement frequencies were defined to ensure product integrity.
- *Guidance on evaluation of criteria.* No additional guidance is required.

**2.19 Transporting Equipment**

**2.19.1.2 Critical** - ~~Forklifts, pallet jacks, and similar equipment are listed on the **Preventive Maintenance** and/or Master Cleaning Schedules for cleaning and follow up.~~

- *Explanation of the change*: This requirement was removed because it is already captured in the Cleaning Practices section of the Standards.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.20 Parts Storage**

**2.20.1.2 Critical** – **Used and soiled conveyor belts** are discarded and not stored for future use.

- *Explanation of the change:* This requirement was added to ensure that conveyor belts used for product contact are clean and maintained in storage to prevent product contamination when installed for use on processing lines.
- *Guidance on evaluation of criteria.* No additional guidance is required.

**2.21 Hand Washing Facilities Design**

**2.22.2.1 Minor** ~~**Hands-free** hand washing equipment is desirable.~~

- *Explanation of the change*: The expectation is that hands are clean at all times. The intent of hands-free hand washing equipment is to prevent recontamination of hands in a microbiologically sensitive production environment to reduce potential for contamination of foodstuffs from contamination by the hands. This criteria was deleted.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.22 Bulk Systems and Unloading Areas**

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

- *Explanation of the change*: This requirement was edited to provide examples of coverings.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**2.23.2.1 Minor**- A **roof or covering is provided** over the unloading area to prevent raw material or product contamination during loading and unloading.

- *Explanation of the change*: This requirement was deleted because it is covered in 2.22.1.1.
- *Guidance on evaluation of criteria*: No additional guidance is required.

## Cleaning Practices

### 3.2 Food Contact Cleaning Compounds and Sanitizers

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

- *Explanation of the change*: This was added to ensure that chemical residues are properly removed as directed by label requirements to prevent cross contamination of product contact surfaces.
- *Guidance on evaluation of criteria*: No additional guidance is required.

### 3.3 Equipment and Tools

**3.3.1.9 Critical** - **Water** used for ~~daily~~ cleaning ~~in wet production areas~~ 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.

- *Explanation of the change*: The text was edited to expand the criteria to address water uses in all areas and not just wet production areas.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that ladders and equipment used in product zones of bulk vessels and transports are specifically designated for use in these areas.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.3.1.11 Critical** - 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.

- *Explanation of the change*: This new requirement addresses storage of ladders and equipment used to clean and access bulk storage vessels and transports.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.3.1.12 Critical** - Suitable **clothing and 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.

- *Explanation of the change*: This new requirement was added to ensure that protective clothing is worn by personnel entering bulk vessels or transports.
- *Guidance on evaluation of criteria*: No additional guidance is required.

### 3.5 Product Zone Cleaning

**3.5.1.1 Critical** - ~~Periodic~~ Cleaning tasks **comply with applicable** ~~safety laws, regulations, and~~ **equipment cleaning procedures**.

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment cleaning.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.5.1.4 Critical - Equipment guards, trims, and panels** are removed and replaced ~~according to local and national regulations~~ to inspect and clean the interior of all equipment.

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment cleaning where dismantling of equipment may occur.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.5.1.6 Critical** – Product contact surfaces, product zones, and equipment that require sanitizing are **cleaned and sanitized.** ~~to destroy pathogenic microorganisms and remove contaminants.~~

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment that requires both cleaning and a sanitizing step in the process.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.5.1.7 Critical** - Equipment and utensils that do not require sanitizing ~~are cleaned and sanitized~~ on a **predetermined schedule.** ~~to prevent microbiological contamination.~~

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures and schedules for cleaning of equipment that does not include a requirement for sanitizing of the product contact surface.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.5.1.10 Critical** – **Sanitary trays and dollies** are cleaned and maintained.

- *Explanation of the change*: This requirement was added to address cleaning and maintenance of intermediate trays or dollies used for the transport of raw materials or finished products.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.5.1.11 Critical** - 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.

- *Explanation of the change*: Three similar requirements from the 2009 version of the Standard were combined into one cohesive requirement. Requirements 3.6.1.1, 3.6.1.3 and 3.6.1.4 were combined into one single requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.5.1.13 Critical** - Pipelines, mixing, and holding tanks can be **flushed, cleaned, and sanitized**, as needed.

- *Explanation of the change*: This new requirement was added to ensure that the ability to adequately clean and sanitize vessels and pipelines was addressed.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**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.*

- *Explanation of the change*: A new Standard was created to address cleaning of non-product contact zones and support areas that may impact the food safety of products produced at the site.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The requirement has been edited to broaden the scope to meet the applicable procedures for equipment cleaning where dismantling of equipment may occur.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.6.1.3 Critical** - **Support areas** that may impact equipment, production, or storage of raw materials or finished products (e.g., washrooms and maintenance shops) are cleaned to prevent product contamination or insect development.

- *Explanation of the change*: This requirement was added to ensure that issues in non-production areas that could impact the production or storage of raw materials or finished products were captured in the scope of the inspection.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.6.1.4 Critical** - 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.

- *Explanation of the change*: This new requirement was added to address storage areas for items such as equipment and raw materials that may impact product safety.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This new requirement addresses cleaning of dock leveler pits to prevent product accumulations and potential for pest development or attraction.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that cleaning of the structures used for storage is addressed as part of the cleaning program.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**3.6.1.9 Critical** - **Drains** are routinely **cleaned and sanitized** to prevent microbial and pest development.

- *Explanation of the change*: This requirement was added to address cleaning of drains.
- *Guidance on evaluation of criteria*: No additional guidance is required.

## Integrated Pest Management

### 4.6 Pesticide Documentation

**4.6.1.1 Critical** - ~~**Material Safety Data Sheets (MSDS)**~~ **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.

- *Explanation of the change*: The text was edited to reflect the change in naming convention from Material Safety Data Sheet to Chemical Safety Data Sheets.
- *Guidance on evaluation of criteria*: No additional guidance is required.

### 4.8 Pesticide Control

**4.8.1.2 Critical** - **Pesticides are ~~applied,~~** ~~and if required,~~ **stored** according to label directions.

- *Explanation of the change*: The requirement text was edited to address pesticide storage.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.8.1.5 Critical** - ~~Pesticides **are approved** by the designated facility representative before application, and are incorporated into the Chemical Control Program.~~

- *Explanation of the change*: This requirement was removed, as it was a duplication of requirement 4.7.1.1.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.9 Trend Analysis**

**4.9.1.2 Critical** - ~~When used,~~ The **pest-sighting log** provides information about the response taken by pest management personnel.

- *Explanation of the change*: The requirement was updated to clarify the language regarding the use of the pest-sighting log.
- *Guidance on evaluation of criteria*: The auditor will be evaluating the program to ensure that a pest-sighting log is in place.

**4.9.1.4 Critical** - The **pest-sighting log** has a designated location.

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.9.1.5 Critical** - The **pest-sighting log includes**:

• Date
• Time
• Type of pests observed
• Actions taken
• Names of reporting personnel

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.9.1.6 Critical** - Pest management personnel **review the log each quarter** to identify trends in pest activity. A report of findings is submitted to designated facility personnel.

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.9.1.7 Critical** - **Corrective Actions** are documented for identified issues.

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.11 Exterior Rodent Monitoring Devices**

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

- *Explanation of the change*: Minor edits were provided to the text to further clarify this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.12 Interior Rodent Monitoring Devices**

**4.12.1.6 Critical** - 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 ~~cage~~ catch traps
• See-saw tubes
• Electrocution traps
• Extended trigger traps that send alert e-mails or text messages

- *Explanation of the change*: Minor edits were made to better clarify the requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.13 Insect Light Traps**

**4.13.1.6 Critical –** Insect light traps are used to **monitor flying insect activity** at locations that are likely to allow access to the facility.

- *Explanation of the change*: Changed severity from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.13.1.7 Critical** - The facility **documents the types and quantities of insects** found in 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 pests, etc.) and quantities captured (specific or relative numbers [i.e. high, medium, low]) to evaluate the risks and determine the appropriate control measures to be taken.

- *Explanation of the change*: Changed severity from minor to critical and edited the text to ensure that data is evaluated to address any pest control issues based on insect findings in these devices.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.14 Pheromone Monitoring Devices**

~~*When used,*~~ *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).*

- *Explanation of the change*: The explanation of the requirement was edited to add types of facilities where use of pheromone monitoring is required.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**4.17 Pest Habitat**

**4.17.1.2 Critical** - 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.

- *Explanation of the change*: Added the requirement to easily capture identified pest activity for which the identification and control would be managed as part of the IPM program.
- *Guidance on evaluation of criteria*: No additional guidance is required.

## Adequacy of Prerequisite and Food Safety Programs

**5.1 Written Policy**

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

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The severity was reduced from critical to minor.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.2 Accountability**

**5.2.1.4 Critical** - 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.

- *Explanation of the change*: This requirement was added to ensure that any new requirements regarding legislative or regulatory changes are identified and the role of the facility in their implementation or reporting is understood.
- *Guidance on evaluation of criteria*: The auditor will request procedures written and designed to meet legislative or regulatory requirement to verify that the site is aware of their location when they are needed and to ensure that plant personnel responsibilities are clearly defined.

**5.4 Written Procedures**

**5.4.1.1 Critical** - ~~The facility has **written procedures** that define step-by-step processes to ensure the safety of facility products.~~ ~~The~~ Procedures ~~further~~ 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.

- *Explanation of the change*: Edited the text to eliminate redundancy with review of programs included as part of the written procedure audits.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.4.1.2 Critical** - ~~Management **regularly reviews** written procedures to ensure continued effectiveness and suitability.~~

- *Explanation of the change*: The text was eliminated as this would be reviewed as part of the written procedure audits.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The severity was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.4.2.1 Minor** - ~~The written procedures address **all requirements in the AIB International Consolidated Standards for Inspection**.~~

- *Explanation of the change*: The text was eliminated, as this would be reviewed as part of the written procedure audits.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.5 Training and Education**

**5.5.1.3 Critical** - The training includes **~~exit criteria~~ established means for verification** of competency ~~requirements used to confirm~~ of the information presented (e.g., testing, supervisor verification, verbal responses, etc.).

- *Explanation of the change*: The text was edited to further clarify this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.6 Self-Inspection**

**5.6.1.5 Critical** - The Product Safety Committee and the responsible key personnel set ~~time~~ **deadlines** for Corrective Action implementation.

- *Explanation of the change*: Minor edits were made to the text to clarify the requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that adequate access was provided to thoroughly examine equipment and structures.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.7 Written Procedure Audits**

**5.7.1.1 Critical** - 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.

- *Explanation of the change*: Minor edits were added to the text to further clarify the intent of this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.7.1.5 Critical** - Responsible key personnel set ~~**time**~~ **deadlines** for Corrective Action implementation.

- *Explanation of the change*: Minor edits were provided to the text to further clarify the intent of this requirement.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.9 Chemical Control Program**

**5.9.1.2 Critical** - 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
• Material Safety Data Sheet (MSDS) or Chemical Safety Data Sheet archiving
• Contractor chemicals

- *Explanation of the change*: Minor edits were made to further clarify the requirement text.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.10 Microbial Control Program**

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

- *Explanation of the change*: This requirement was added to ensure that labs used for testing for quality or product safety are adequately maintained to prevent product contamination.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.10.1.5 Critical** - Contract labs maintain appropriate **accreditation** to carry out the analyses performed.

- *Explanation of the change*: This requirement has been added to require proof of the competency of the lab providing the testing results.
- *Guidance on evaluation of criteria*: The auditor will ask to see the current accreditation documents for any contract labs providing testing results.

**5.10.1.6 Critical** - 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.

- *Explanation of the change*: This requirement was added to address the hold and release program for products undergoing pathogen testing to ensure that they are not prematurely released.
- *Guidance on evaluation of criteria*: The auditor will select a product(s) for which pathogen testing is being or has been completed. They will challenge the system by evaluating if the product was placed on hold and then will look at the date of the return of results and the release of the product for use based on this.

**5.10.1.7 Critical** - Products that **test positive for pathogens are appropriately reprocessed or destroyed**. Documentation of the disposition of these materials is maintained.

- *Explanation of the change*: This requirement was added to address the disposition of materials that test positive for pathogens.
- *Guidance on evaluation of criteria*: The auditor will look at the disposition records for any materials that were tested and had positive pathogen results returned to ensure appropriate disposition of these materials.

**5.15 Receiving Program**

**5.15.1.5 Critical** - 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 ticket or supplier load out~~ 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

- *Explanation of the change*: Minor edits were made to clarify the requirement and to include considerations for unloading in inclement weather.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.17 Food Defense Program**

**5.17.1.3 Critical** - The **written** Food Defense Program considers the Vulnerability Assessment 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

- *Explanation of the change*: The severity of the requirement was changed from minor to critical and development of a formal Food Defense Program based on the findings in the Vulnerability Assessment was added.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.19 Recall/Withdraw Program**

**5.19.1.3 Critical** - The facility **tests** the Program twice annually, and documents the results:
• Actual test results (including a test for ingredients or product contact packaging material)
• Success rate
• Test timings

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.19.1.4 Critical** - Testing supports the recall to the **first level of distribution** outside of the control of the facility.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.19.1.5 Critical** - One of the recall tests includes **traceability** of the raw material for product contact packaging material.

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.19.1.6 Critical** - The written **Recall or 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

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.21 Approved Supplier Program**

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

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: The severity of the requirement was changed from minor to critical.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that foreign supplier verification is incorporated into the Supplier Approval Programs to meet FSMA requirements.
- *Guidance on evaluation of criteria*: The auditor will challenge the Program by asking the facility to demonstrate how foreign material supplier verification and import requirements are addressed at the facility.

**5.22 Specification Program**

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

- *Explanation of the change*: The requirement was added to ensure that a program was in place and implemented to ensure that label contact is correct and that processes are in place to verify this.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.25 HACCP Program**

**5.25.1.6 Critical** - 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 other countries with regulations, regulatory requirements will be evaluated taking into consideration the 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 includes 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- 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.

- *Explanation of the change*: Language was added to this requirement to ensure that the Hazard Analysis meets regulatory guidelines that are country dependent.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.25.1.9 Critical** - 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.

- *Explanation of the change*: Additional text was added to ensure that if there are defined regulatory requirements for record keeping, they are added.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to demonstrate that records are maintained for the amount of time required.

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

- *Explanation of the change*: The additional requirement was added to capture compliance where HACCP is a regulatory requirement.
- *Guidance on evaluation of criteria*: The auditor will ask the facility to demonstrate how they understand and meet the appropriate regulatory requirement.

**5.27 Release Procedures**

**5.27.1.1 Critical** - The facility follows **release procedures.**

- *Explanation of the change*: This requirement was added to ensure that any materials maintained on hold for testing were addressed as part of the facility release procedures.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to specify that materials are not released until verification of the release requirements has been completed.
- *Guidance on evaluation of criteria*: No additional guidance is required.

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

- *Explanation of the change*: This requirement was added to ensure that release of materials is completed only by those person(s) who have the authority to do so.
- *Guidance on evaluation of criteria*: No additional guidance is required.

**5.29 Water Quality**

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

- *Explanation of the change*: The severity was upgraded from minor to critical. Formerly 2.21.2.1.
- *Guidance on evaluation of criteria*: No further guidance needed.