Preface

This document provides general guidance for SQF suppliers, consultants and auditors when implementing and auditing module 2 of the SQF Code, edition 7 and can be used where no specific industry sector guidance is available.

The purpose of SQF Code implementation is not only to achieve certification, but to assure constant and continual validate and review of a supplier's SQF System for currency and completeness.

Effective implementation of the SQF Code requires the commitment of the site management and the constant involvement and participation of site staff to maintain the safety and quality of SQF certified products. The results of effective SQF implementation are not only the protection of public health and company brands, but real improvement in margins by reduction of waste, recalls and withdrawals, and improved productivity through "doing it right the first time."

The SQF Institute is grateful to the SQF Institute Technical Advisory Council and SQF stakeholders for their assistance in reviewing and contributing to this document.

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SQF Code, Edition 7.2 – Module 13: Food Safety Fundamentals – Good Manufacturing
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Section 1. Introduction

1.1   Purpose of the Guidance Documents

The purpose of this series of SQF Guidance Documents is to assist suppliers with designing, developing, documenting, implementing and maintaining an SQF System using the SQF Code, edition 7, and to assist SQF registered auditors in auditing the SQF Code, edition 7.

The relevant Code version number is identified in the document header. Terms used in these documents are defined in Appendix 2: Glossary of the SQF Code edition 7.

Guidance is intended to support the SQF Code, but does not replace it. It is not an auditable document, nor is it definitive and applicable in every situation. Suppliers, consultants, and auditors are required to understand the food safety (and quality, where applicable) risks in a given industry sector and are able to apply the SQF Code to effectively control those risks.

1.2   Layout of the SQF Code

The SQF Code, edition 7 consists of two parts and three appendices. Part A contains the criteria for implementing and maintaining the SQF Code. Part B, the heart of the SQF Code, is made up of modules. Within each module are clauses or elements, which the supplier must implement as their SQF System. In Module 2, the clauses encompass the system elements. Each element outlines where procedures need to be documented, where record keeping is required or where actions must be taken. Modules 3-15 are the Good Agricultural, Aquacultural, Manufacturing and Distribution Practices (GAP/GMP/GDP) requirements applicable to various food industry sectors. Producers and suppliers must meet the requirements of the module or modules applicable to their food industry sector.
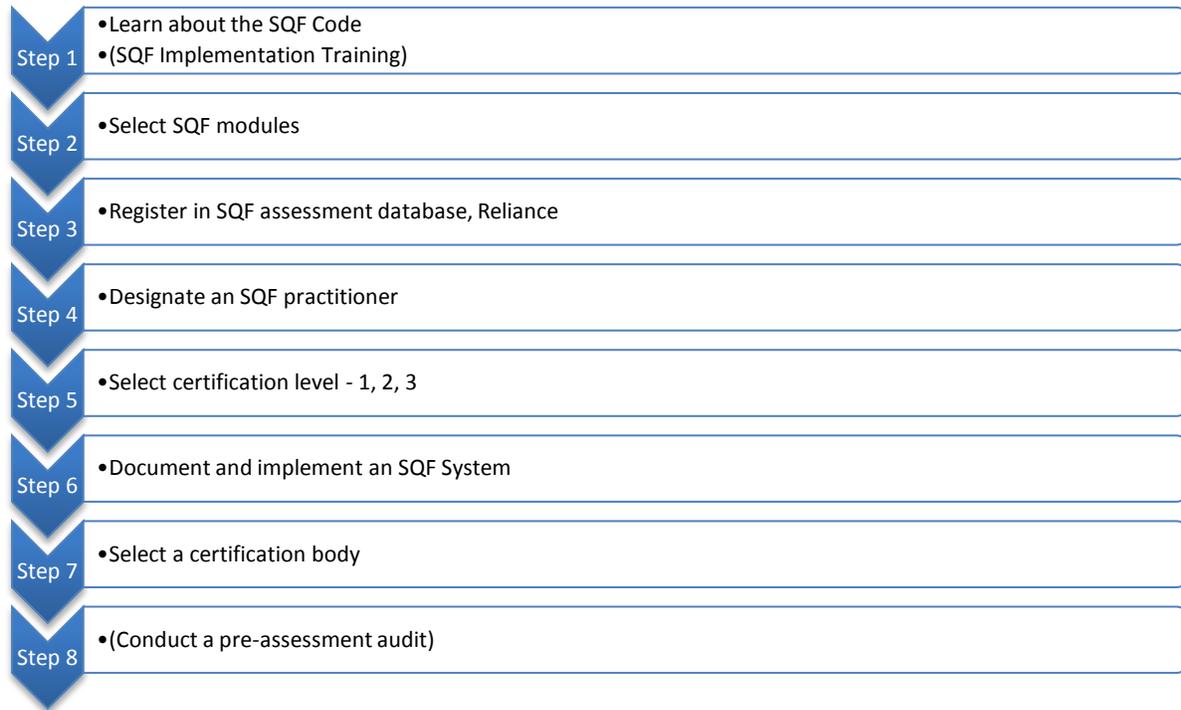
The three appendices in the SQF Code provide additional information needed to implement an SQF System:

o   Appendix 1: SQF Food Sector Categories

o   Appendix 2: Glossary of Terms

o   Appendix 3: SQF Quality Shield and Logo Rules of Use

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Section 2. The SQF Certification Process

The steps for the process of preparing for SQF certification are shown below. Optional steps or other options are indicated in parenthesis. This process is outlined in section 1 of Part A of the SQF Code, 7th edition.

Step 1
- Learn about the SQF Code
- (SQF Implementation Training)

Step 2
- Select SQF modules

Step 3
- Register in SQF assessment database, Reliance

Step 4
- Designate an SQF practitioner

Step 5
- Select certification level - 1, 2, 3

Step 6
- Document and implement an SQF System

Step 7
- Select a certification body

Step 8
- (Conduct a pre-assessment audit)

The first step is for the supplier to learn about the SQF Code. The SQF Code suggests several options for doing this, including completing an "Implementing SQF Systems" training course either online or through a licensed SQF training center. Be sure to download the SQF Code available free of charge from the SQFI website (sqfi.com).

In step two, select the relevant modules to be implemented by the supplier. To aid in doing this, Table 1 SQF Food Sector Categories and Applicable Modules and Appendix 1: Food Sector Categories are available in the SQF Code for reference.

Please note that module 2 is applicable to all industry sectors and will need to be implemented by all suppliers.

The third step is to register the supplier's company or site in the SQF assessment database. For new users, the registration link is housed on the SQFI website (sqfi.com). Choose the "Suppliers" tab from the home page, and then select "New Users." Suppliers must register with SQFI prior to achieving certification and must remain registered at all times to retain their certification.

In step four, the supplier will need to designate an SQF practitioner to oversee the development, implementation, review and maintenance of the SQF System. The requirements for an SQF practitioner are described in 2.1.2.4 and 2.1.2.5 of the SQF Code.

The fifth step is for the supplier to select a certification level – 1, 2 or 3 based on the needs of customers and the stage of development of the food safety and quality management system.

At the sixth step, the supplier must document and implement the relevant modules of the SQF Code in their SQF System. This step will be explained further in the next section.

In step seven, the supplier will choose a certification body. Certification bodies are licensed by SQFI to conduct SQF audits and issue the SQF certificate of registration. A current list of licensed certification
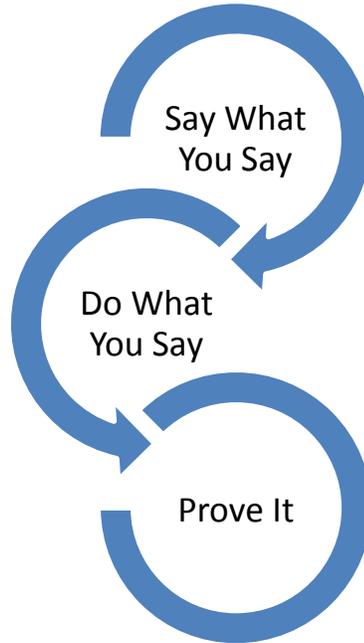
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bodies is available on the SQF website (sqfi.com) and includes their countries of operation. Certification bodies are also listed on the SQF assessment database and suppliers can request a quote or select a certification body online once they have registered.

In the final step, the supplier may wish to conduct a pre-assessment of their systems, procedures and protocols already in place to determine existing gaps requiring action in order to reach the level of SQF certification desired. This assessment, while voluntary is essential to the development of the SQF System and may be conducted by a consultant, a certification body or by the supplier's staff under direction of an SQF practitioner.

Section 3. The SQF Implementation Process

To achieve SQF certification, the supplier must document and implement the relevant modules of the SQF Code, at the level required. It's also important to provide evidence of the System in the form of documents and records. The implementation process is shown below.

Say What
You Say

Do What
You Say

Prove It

Document the SQF System – prepare policies, procedures, work instructions and specifications that address the relevant modules of the SQF Code. In other words "say what you do."

Implement the SQF System – put into place the prepared policies, procedures, work instructions and specifications. In other words, "do what you say."

Provide records the SQF System – keep records to demonstrate compliance to the relevant modules of the SQF Code. These records provide evidence of the function and control of the System. In other words, "prove it."

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Section 4. Introduction to This Guide

1. Purpose and Scope of This Guide

The purpose of this series of SQF Guidance Documents is to assist suppliers with designing, developing, documenting, implementing and maintaining an SQF System using the SQF Code, edition 7, and to assist SQF registered auditors in auditing the SQF Code, edition 7.

The relevant Code version number is identified in the document header. Terms used in this document are defined in Appendix 2: Glossary of the SQF Code, edition 7.

This particular guide covers the requirements of *Module 13: Food Safety Fundamentals – Good Manufacturing Practices for Production of Food Packaging.* It covers the Good Manufacturing Practices requirements for the production of food packaging.

Suppliers implementing this module must also meet the requirements of *Module 2: SQF System Elements*. Module 2 guidance is a separate document and suppliers are advised to understand the System Elements, e.g. the requirements of Module 2 before addressing Module 13.

Applicable food sector categories (FSCs) for Module 13 are:

FSC27: Manufacture of Food Sector Packaging Materials

Guidance is intended to support the SQF Code, but does not replace it. It is not an auditable document, nor is it definitive and applicable in every situation. Suppliers, consultants, and auditors are required to understand the food safety (and quality, where applicable) risks in a given industry sector and are able to apply the SQF Code to effectively control those risks.

2. The Structure of the SQF Code, Edition 7

The SQF Code is a process and product certification standard that uses Hazard Analysis Critical Control Points (HACCP) as its foundation. HACCP is a food safety management system based on the principles defined in either:

- The CODEX Alimentarius Commission HACCP principles and guidelines, or

- The National Advisory Committee on Microbiological Criteria for Food (NACMCF)

The main feature of the SQF Code is its emphasis on the systematic application of HACCP to identify, monitor and control food safety hazards as well as food quality hazards in the process flow to manage identified food safety risks and/or quality threats.

This guide references the HACCP (Hazard Analysis and Critical Control Point) technique but does not explain the HACCP method in any detail. It requires that those implementing and auditing an SQF System to have completed HACCP training as defined in *Appendix 2: Glossary* of the SQF Code, edition 7 and have extensive knowledge of the HACCP guidelines of either of the above documents, the application of the HACCP principles and experience in implementing HACCP systems. It is not meant to deliver prescribed, absolute rules for implementation, but to be utilized by suppliers, SQF consultants and SQF auditors as recommendations on practical applications for implementation and certification of the SQF Code.

The SQF Code also recognizes that food safety practices differ depending on the food safety risk to the product or process, and has designed the Code to meet the individual requirements of each industry sector. Modules 3 through 15 prescribe the Good Agricultural Practices, Good Aquaculture Practices, Good Manufacturing Practices, or Good Distribution Practices that may apply to particular industry sectors. The particular modules that apply to each industry sector are as follows:

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SQF Food Sector Category (FSC)	Category (Supplier Scope of Certification)	Applicable SQF Code Modules
1	**Production, Capture and Harvesting of Livestock and Game Animals**	Module 2: System elements Module 5: GAP for farming of animal products
2	**Growing and Harvesting of Animal Feeds**	Module 2: System elements Module 3: GMP for animal feed production
3	**Growing and Production of Fresh Produce**	Module 2: System elements Module 7: GAP for farming of plant products (fruit and vegetables) Or Module 7H: GAP for farming of plant products
4	**Fresh Produce Packhouse Operations**	Module 2: System elements Module 10: GMP for pre-processing of plant products
5	**Extensive Broad Acre Agriculture Operations**	Module 2: System elements Module 8: GAP for farming of grains and pulses
6	**Harvest and Intensive Farming of Fish**	Module 2: System elements Module 6: GAP for farming of fish
7	**Slaughterhouse, Boning and Butchery Operations**	Module 2: System elements Module 9: GMP for pre-processing of animal products
8	**Processing of Manufactured Meats and Poultry**	Module 2: System elements Module 13: GMP for processing of food products
9	**Seafood Processing**	Module 2: System elements Module 13: GMP for processing of food products
10	**Dairy Food Processing**	Module 2: System elements Module 13: GMP for processing of food products
13	**Honey Processing**	Module 2: System elements Module 13: GMP for processing of food products
12	**Egg Processing**	Module 2: System elements Module 13: GMP for processing of food products
13	**Bakery and Snack Food Processing**	Module 2: System elements Module 13: GMP for processing of food products
14	**Fruit and Vegetable Processing**	Module 2: System elements Module 13: GMP for processing of food products
15	**Canning, Pasteurizing, UHT and Aseptic Operations**	Module 2: System elements Module 13: GMP for processing of food products
16	**Ice, Drink and Beverage Processing**	Module 2: System elements Module 13: GMP for processing of food products
17	**Confectionary Manufacturing**	Module 2: System elements Module 13: GMP for processing of food products
18	**Preserved Foods Manufacture**	Module 2: System elements Module 13: GMP for processing of food products
19	**Food Ingredient Manufacture**	Module 2: System elements Module 13: GMP for processing of food products
20	**Recipe Meals Manufacture**	Module 2: System elements Module 13: GMP for processing of food products

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SQF Food Sector Category (FSC)	Category (Supplier Scope of Certification)	Applicable SQF Code Modules
21	**Oils, Fats, and the Manufacture of Oil or Fat-based Spreads**	Module 2: System elements Module 13: GMP for processing of food products
22	**Processing of Cereal Grains and Nuts**	Module 2: System elements Module 13: GMP for processing of food products
23	**Food Catering and Food Service Operations**	Not available[1]
24	**Food Retailing**	Not available[1]
25	**Fresh Produce Wholesaling and Distribution**	Module 2: System elements Module 12: GMP for transport and distribution of food products
26	**Food Wholesaling and Distribution**	Module 2: System elements Module 12: GMP for transport and distribution of food products
27	**Manufacture of Food Sector Packaging Materials**	Module 2: System elements Module 13: GMP for production of food packaging
28	**Provision of Crop Spray Services**	Not available[1]
29	**Provision of Field Harvest Services**	Not available[1]
30	**Provision of Sanitation and Hygiene Services**	Not available[1]
31	**Manufacture of Dietary Supplements**	Module 2: System elements Module 13: GMP for processing of food products
32	**Manufacture of Pet Food**	Module 2: System elements Module 4: GMP for processing of pet food products
33	**Manufacture of Agricultural Chemicals and Food Processing Aides**	Module 2: System elements Module 13: GMP for processing of food products
34	**Manufacture of Animal Feeds**	Module 2: System elements Module 4: GMP for animal feed production
35	**Broker or Agent**	Module 2: System elements Module 14: GMP for brokers or agents

[1] These modules will be completed when the GFSI guidance becomes available.

This guidance document describes the requirements of Module 13, which applies to GMP requirements for most food processing facilities.

3.   The Structure of Module 13

An SQF System is a risk management system documented and implemented by a supplier of food (or related) products to control food safety risks (and food quality risks at Level 3) using the SQF Code, edition 7. It can be audited and certified by an SQF licensed certification body.

The process of how to document and implement the SQF Code, edition 7 and achieve SQF certification can be found in the most current version of Part A of the SQF Code, edition 7.

Module 2 defines the core elements of the SQF Code that provide protection and assurance and are required to be implemented by all suppliers seeking SQF certification. It forms the foundation of the supplier's SQF System. It includes the commitment of site management to maintain a safe, quality food supply and the management processes that must be in place to do so; the HACCP plan(s) that identify and control hazards; the HACCP food quality plan (s) that identifies quality threats and defines their control; product traceability and recall; control of foods containing allergens and other foods requiring identity preservation; and staff training requirements.

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Module 13 expands on element 2.4.2.2 of the system elements (Module 2) and details the specific GMP requirements for the production of food packaging.

Module 2

Module 13

13.1 Site requirements and approval

13.2 Construction and control of product handling and storage areas

2.4.2.2 The supplier shall ensure the food safety fundamentals described in the relevant subsequent modules of this Code (i.e. modules 3 – 15) are applied, or excluded according to a detailed risk analysis outlining the justification for exclusion or evidence of the effectiveness of alternative control measures to ensure that food safety is not compromised.

13.3 Personnel hygiene and welfare

13.4 Personnel practices

13.5 Water and air supply

13.6 Storage and transport

13.7 Control of foreign matter contamination

13.8 Waste disposal

13.9 Exterior

It is recognized that not all elements of Module 13 are applicable to all food packing facilities. Some elements can be exempted if they are not relevant, and as long as the supplier has submitted a written request to the certification body prior to the audit, to exclude that element. For example, if the operation does not store packaging then elements under 13.6.1.1 would not apply.

There are no mandatory elements in Module 13.

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4.   The Format of the Module 13 Guidance

The following section explains the elements and sub-elements of Module 13 and provides guidance on what a supplier needs to do to develop, document and implement Module 13 requirements, and provides information on what the auditor may be looking for to confirm compliance.

The following format is used throughout:

Element Number and Name

Sub-element Number and Name.

This section will describe what the SQF Code, edition 7 requires for Module 13. This is the text from the SQF Code, and is the auditable standard. Where there is disagreement between the text of the SQF Code and the guidance or a translation, the SQF Code in English prevails.

Implementation Guidance

What does it mean?

This will include the interpretative comments of what the sub-element requires or definitions of the terms used.

What do I have to do?

This will include suggestions of what is required to be done by the supplier to document and implement this sub-element. The information provided is not considered exhaustive and may not apply in every situation. It is meant to provide guidance and interpretation.

Auditing Guidance

This will include suggestions of what the auditor may seek as evidence of compliance for this sub-element. The information provided is not exhaustive and may not apply in every situation.

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Section 5. Guidance for Module 13: Food Safety Fundamentals – Good Manufacturing Practices for Processing of Food Products

This module covers the Good Manufacturing Practices requirements for the production of food packaging.

Suppliers implementing this module must also meet the requirements of Module 2: SQF System Elements.

Implementation Guidance

Packaging intended to package food for human consumption must be produced, processed and handled in a safe and efficient manner. In order to accomplish this, food package manufacturing premises shall be designed to facilitate proper processing, handling and storage of food packaging materials. Module 13 outlines the general requirements for the construction of premises and equipment in which food is processed, handled, stored and/or transported with guidance on each aspect provided to assist in understanding various requirements. It also details some of the fundamental practices that must be in place to protect the safety and quality of food packaging materials.

While the SQF requirements for Module 13 are "shall do…," meaning the element MUST be accomplished, where applicable to the supplier's specific processing operation, element 2.4.2.2 provides a method to seek exclusion, provided the exclusion is supported by a detailed risk analysis. It is the supplier's responsibility to develop and present this risk analysis outlining justification for exclusion or evidence of the effectiveness of alternate control measures to the certification body and/or SQF auditor for review when questioned.

13.1   Site Requirements and Approval

13.1.1 Premises Location

13.1.1.1 The location of the premises shall be such that adjacent and adjoining buildings, operations and land use do not interfere with safe and hygienic operations.

13.1.1 Implementation Guidance

What does it mean?

The location and construction of the premises are to be such that neighboring buildings, farms, or factories do not introduce factors that could adversely affect the safety and quality of the product (e.g., spray drift from neighboring farms, air-borne pollutants from adjacent factories, etc.).

What do I have to do?

The supplier must ensure the premises and its surroundings are kept free of liquids, vapours or other physical airborne contaminants to the packaging from the external environment. The supplier shall maintain structures, instructions, procedures, etc. that verifies the control of external environmental conditions and for the safety or quality of the process and/or packaging materials produced if applicable.

For packaging manufacturing and storage facilities, measures may include protection of exposed resin, finished packages or processing materials from air-borne contaminants from neighboring facilities. Measures may include physical barriers, sealed factories, positive air pressure, covering with plastic film, etc.

13.1.1 Auditing Guidance

Any applicable documented protection measures shall be reviewed initially at the desk audit. However, compliance to this requirement shall be reviewed by observation of adjacent facilities and land use and interviews with operational staff at each facility audit. Evidence may include:

- Internal audits and records of observations on external facility and ground conditions;
- Review of supplier's risk assessment on external environment and adjacent facilities.

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> Understanding of the supplier to the risk from the external environment;
>
> • Physical measures in place to manage exterior environmental risks;
>
> • Procedural measures to manage exterior environmental risks;
>
> • Risk assessment that considers the potential risks from the environment and adjacent areas on the safety on the manufacturing of packaging material.

13.1.2 Construction and Operational Approval

13.1.2.1 The construction and on-going operation of the premises on the site shall be approved by the relevant authority.

13.1.2 Implementation Guidance

What does it mean?

In most jurisdictions, the building and operation of the premises is governed by local, state, and/or federal regulations. The supplier must be familiar with the applicable regulations and ensure that relevant permits, approvals and notifications are in place.

What do I have to do?

Suppliers must check with local authorities to establish the requirements. However plans and specifications submitted to a local authority for approval may include:

• Current state license to manufacturer;

• Locality map showing the site in relation to the area;

• Site plan showing all salient features of the site and a description of adjoining sites including the location of the premises north compass points, roads, storm water, waste water;

• Floor plans showing the layout of the premises, processing areas, permanent fixtures, and layout of equipment;

• Details of major items of equipment used in the processing area;

• A diagram of product/process flow;

• Specifications generally include details of construction materials, surface finishes (walls, floors, ceilings, etc.), product contact surfaces, essential services and the number of personnel.

All applicable certificates or inspection documents from local, state, federal or international governing agency shall be current and kept on file.

13.1.2 Auditing Guidance

The auditor shall be familiar with the regulatory requirements applicable to the site and check the certificates and inspection documents from the government agency.

To determine compliance, the auditor must walk around the site, inside and out to determine if there are any outside factors that would impact the certified product. This would include potential threats from neighboring facilities or other environmental conditions.

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13.2   Construction and Control of Product Handling and Storage Areas

13.2.1 Materials and Surfaces

13.2.1.1 In facilities where food contact packaging is manufactured, product contact surfaces shall be constructed of materials that will not contribute a food safety risk.

13.2.1 Implementation Guidance

What does it mean?

The construction of the material and surfaces used at the site shall be constructed in a way that would be easily cleanable and prevent contamination to the finished product or the process.

What do I have to do?

The main feature of an acceptable product contact surface is that it is non-porous, non-corrodible, smooth, easy to clean, light colored, nontoxic and impact resistant. All surfaces must be capable of being kept clean and preferably a light colour.

Documentation of product contact surfaces being maintained in good condition can be accomplished by making this item a part of a monthly facilities checklist or other type of check list or the internal audit program.

13.2.1 Auditing Guidance

Compliance to this requirement shall be reviewed at each facility audit by interviews, observations and reviews of records. Evidence may include:

- Current license to operate and recent regulatory inspections;
- Knowledge of local, state, and federal regulations on the construction and operation of the premises;
- The site has been approved by relevant authorities for construction if applicable;
- Review regulatory approval for changes to facilities or equipment, if applicable.

13.2.2 Floors, Drains and Water Traps

13.2.2.1 Floors shall be constructed of smooth, dense impact resistant material that can be effectively graded, drained, impervious to liquid and easily cleaned.

13.2.2.2 Drains shall be constructed and located so they can be easily cleaned and not present a hazard.

13.2.2.3 Waste trap system shall be located away from any food packaging and material handling area or entrance to the premises in order to prevent contamination.

13.2.2 Implementation Guidance

What does it mean?

Floors, drains and waste traps shall be designed and constructed in such a way as to minimize the risk to product or process safety.

What do I have to do?

Drains shall be easily accessible for cleaning. Grates need to be removable for access and cleaning. Practices must be demonstrated by the supplier to assess the risks to products and to control those identified food safety risks.

Documentation of floor materials shall be included in the site plan or description of the plant/processing area. Floors shall be provided with proper drainage. Drains need to be positioned and constructed to allow the effective removal of overflow or waste water under normal working conditions. Where drainage and gradients are not ideal, a written SOP shall address the timely and effective removal of waste water to a drain.

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13.2.2 Auditing Guidance

Compliance to this requirement shall be reviewed at each facility audit primarily through observations. Evidence may include:

- Product contact surfaces are constructed of materials that do not pose a food safety risk;

- Floors are smooth and easy to clean;

- Floors are correctly graded to allow for water run-off;

- Floors are made of appropriate, smooth, dense, impact-resistant material;

- There are no areas of water pooling or build-up;

- Procedures are in place to deal with floor areas that are not correctly designed or constructed;

- Drain locations do not pose a safety risk;

- Drains and grates are free of debris and pooling water;

- Drain construction does not pose a safety risk;

- Waste traps are located away from product handling areas or entrances to the site.

13.2.3 Walls, Partitions, Doors, and Ceilings

13.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction and fit for purpose.

13.2.3.2 Wall to wall and wall to floor junctions shall be designed to be easily cleaned and sealed to prevent the accumulation of food debris.

13.2.3.3 Doors shall be of solid construction and windows shall be made of shatterproof glass or similar material.

13.2.3 Implementation Guidance

What does it mean?

This clause is concerned with the design, construction and condition of the floors, partitions, doors and ceilings in the buildings that house food packaging manufacturing. They must be designed and constructed in such a way as to minimize the risk to product safety and in some instances to offer protection to the product. The extent to which these elements are relevant will depend on the type of processes conducted and whether the raw materials or food packaging is enclosed or exposed.

What do I have to do?

Walls, partitions, doors and ceilings need to be described in the site plan. Ceiling design and construction must not pose a threat of product contamination. Wall-to-ceiling, wall-to-wall and wall-to-floor junctions must be sealed and easy to clean.

Walls, partitions, doors and ceilings must be kept clean.

The supplier must, as part of their foreign matter control program, identify any windows that could pose a hazard to product if shattered. Windows away from the immediate manufacturing areas are generally not recognized as posing a hazard to product packaging. Windows close to manufacturing areas and skylights that are located immediately above food package manufacturing can pose a hazard. Such windows must be constructed of shatterproof material or otherwise covered to prevent glass or plastic fragments from contaminating packaging. Window ledges need to be sloped downwards for ease of cleaning and to prevent their use for unwanted storage of utensils or other materials.

Doors routinely subjected to water must be of solid construction, impact-resistant, non-corrosive materials preferably with a smooth, light colored surface. Doors between processing rooms used to transport product for processing need to be protected against damage by crates, trolleys, fork lifts or similar traffic.

For efficiency and ease of cleaning, walls with cement render and smooth-finish glazed tiles, fabricated insulated panels or similar materials are examples of acceptable surfaces. Where light colored finishes do not exist, a written Standard Operating Procedure (SOP) shall address the timely and effective inspection of the

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adequacy of cleaning and resultant corrective actions when discrepancies are noted.

It is recommended that if light colored finishes do not exist, an inspection shall be included in the internal audit and/or cleaning sanitation schedule. Where floor junctions in facilities are not rounded to enable easy cleaning and prevent the build-up of waste, a written SOP shall address the cleaning protocol to meet acceptable hygienic standards for these areas.

Service ducting, conduit and pipes ideally need to be recessed into walls or ceilings, suspended from ceilings, housed inside drop ceilings with vertical drops to their point of use, or mounted a sufficient distance from walls or ceilings. In other words, they should be constructed to avoid build-up of debris, prevent rodent runs and allow ease of cleaning.

Drop ceilings offer some advantages and disadvantages. They can provide a clean, smooth, impervious ceiling surface in the processing area and an area for service runs. However, they can also allow for an "out of sight, out of mind" mentality and can accumulate dust and provide harborage for pests. Drop ceilings, if used, must be checked and cleaned regularly (refer 13.2.7).

Where drop ceilings are not used, cleaning regimes and inspections must check for dust on ledges, loose fittings, glass windows, light fittings, or other areas where dust can accumulate and fall onto product.

13.2.3 Auditing Guidance

Compliance to this requirement shall be reviewed at each facility audit primarily though observation. Evidence may include:

- Walls and partitions are of sound construction and made of suitable materials;

- Wall and floor junctions are clean and free of debris;

- Doors are of sound construction for the volume and type of traffic;

- Ceilings are of sound construction and made of suitable materials;

- Walls, partitions, ceilings, and doors are kept clean;

- Drop ceilings are kept clean with no cracked or damaged tiles;

- Service lines are designed and constructed for ease of cleaning;

- The condition of walls, partitions, doors, ceilings, does not pose a food safety risk.

13.2.4 Lighting and Light Fittings

13.2.4.1 Lighting in premises where food contact packaging is manufactured shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

13.2.4.2 Light fittings in such areas shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling.

13.2.4.3 Light fittings in other areas where product is stored shall be designed such as to prevent breakage and product contamination.

13.2.4 Implementation Guidance

What does it mean?

Adequate light intensity is required for processing operations, cleaning and inspection tasks. However, the design and construction of lighting can pose a risk to product due to breakage or dust accumulation.

What do I have to do?

Lighting shall provide minimum lux (foot candle) intensity as prescribed by applicable legislation or in their absence, meet good manufacturing best practices appropriate to the commodity being processed. In general, processing and product handling areas are illuminated to a minimum intensity of 200 lux (18.58 ft.c.). Inspection areas require higher illumination; 500 lux (46.45 ft.c.) is generally recommended.

Light fittings in product processing and handling areas are required to be fitted with protective covers or have

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shatterproof lights installed. Documentation needs to be kept on file and is to include specifications from the manufacturer with a description of the product. An acceptable practice is to recess the light into the ceiling, where possible or have it fitted flush to the ceiling. Where light fittings are not able to be recessed, they must be protected from accidental damage. In circumstances where light fittings are suspended from cables, the top of the fitting needs to be sloped at an angle that permits easy cleaning. Exposed light fittings must be included in a cleaning and sanitation schedule (refer 13.2.13).

13.2.4 Auditing Guidance

Compliance to this requirement shall be reviewed at each facility audit primarily through observation. Evidence may include:

- Lighting intensity is sufficient in product processing and inspection areas;

- Lighting intensity is sufficient in warehousing and storage areas;

- Light fixtures are shatterproof or protected, and pose no threat to product safety;

- Light bulb order receipts that show bulbs are shatterproof;

- Light fittings are intact – there is no sign of breakage;

- Light fittings are clean and part of a regular cleaning regime.

13.2.5 Dust, Fly, and Vermin Proofing

13.2.5.1 All external windows, ventilation openings, doors and other openings shall be effectively sealed when closed and proofed against dust, vermin and flies.

13.2.5.2 Personnel access doors shall be provided. They shall be effectively fly-proofed and fitted with a self-closing device.

13.2.5.3 External doors, including overhead dock doors, used for product, pedestrian or truck access shall be fly-proofed.

13.2.5.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to packaging, or manufacturing equipment.

13.2.5 Implementation Guidance

What does it mean?

This element is closely related to *13.2.9 Management of Pest and Vermin*. This element provides the requirements for physical barriers to pest and dust ingress into product production areas – via external doors, windows or other means. It also covers the location and use of control measures to trap pests within the premises and outside areas.

What do I have to do?

Doors opening directly into processing areas must be effectively sealed to prevent dust and/or entry of pests.

Doors used for personnel access shall be self-closing unless used exclusively as a fire exit.

All pest devices used must be approved and used per applicable legislation so as not to present a contamination risk to the product, packaging containers or equipment.

In 13.2.5.4, "bait" refers to poison baits or glue boards. Indicator baits that conform to local regulations may be used inside processing areas.

13.2.5 Auditing Guidance

Compliance to this requirement shall be reviewed at each facility audit primarily through observation, and records of pest activity (refer 13.2.9). Evidence may include:

- Windows are closed and sealed against dust or pests;

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- No visible gaps around doors or dock doors;

- Dock doors are kept closed when not in use;

- Personnel doors have self-closing devices or other method to ensure effective protection;

- External doors are adequately fly-proofed;

- Sealing around trucks in docking areas prevents pests from entering the facility;

- Insect devices are located so as not to pose a threat to product, tools or equipment;

- Poison baits or glue boards are not used in processing areas.

13.2.6 Ventilation

13.2.6.1 Adequate ventilation shall be provided in areas where food contact packaging is manufactured and stored.

13.2.6 Implementation Guidance

What does it mean?

Poor ventilation can result in condensate in production areas or other areas where heat or steam are applied, and can result in contamination due to condensate dripping onto raw materials, packaging or product-contact surfaces.

What do I have to do?

Steam shall be adequately ventilated to the outside. Ventilation in enclosed packaging manufacturing areas must meet applicable design and construction legislation and prevent condensation over product and surfaces of product contact equipment. Vents and exhausts must be screened to prevent ingress of flying insects.

13.2.6 Auditing Guidance

Compliance to this requirement shall be reviewed at each facility audit primarily through observation and interview. Evidence may include:

- Package manufacturing areas have adequate ventilation;

- Production areas are adequately exhausted;

- There is no condensation present over product or product contact surfaces in production areas;

- Exhaust vents are screened and fly-proofed.

13.2.7 Premises and Equipment Maintenance

13.2.7.1 The methods and responsibility for the maintenance and repair of plant, equipment and buildings shall be documented planned and carried out in a manner that minimizes the risk of product, packaging or equipment contamination.

13.2.7.2 Maintenance staff and contractors shall observe the following practices when undertaking maintenance and repairs in any handling or storage area:

i.   Routine maintenance of plant and equipment shall be performed according to a maintenance-control schedule and recorded;

ii.   Failures of plant and equipment shall be documented, reviewed and their repair incorporated into the maintenance control schedule;

iii. Compliance with the personnel and process hygiene requirements (refer to elements 13.3.1, 13.3.2, 13.3.3, 13.3.4) by maintenance staff and contractors;

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iv. Ensure area supervisors are notified when maintenance or repairs are to be undertaken in any packaging manufacturing area;

v. Inform the maintenance supervisor and the facility supervisor if any repairs or maintenance that pose a potential threat to product safety (i.e. pieces of electrical wire, damaged light fittings, and loose overhead fittings). When possible, maintenance is to be conducted outside manufacturing times;

vi. Remove all tools and debris from any maintenance activity once it has been completed and inform the area supervisor and maintenance supervisor so appropriate hygiene and sanitation can be completed prior to the commencement of facility operations.

13.2.7.3 The maintenance schedule shall be prepared to cover building, equipment and other areas of the premises critical to the maintenance of product safety and quality.

13.2.7.4 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled so as to minimize the contamination of the product. Machinery lubricant controls shall be in place to prevent contamination of packaging materials from gear box oils, bearing lubricants, hydraulics, or any other source.

13.2.7.5 Paint used in a production area shall be suitable for use and in good condition and shall not be used on any product contact surface.

13.2.7 Implementation Guidance

What does it mean?

Maintenance activities – both planned and breakdown – can have a major impact on food safety and quality, if not effectively implemented. Maintenance procedures must be carefully planned, designed, documented and implemented to avoid contamination of product, materials or equipment and to ensure that maintenance staff, including contractors, have an understanding of the safety and quality implications of maintenance activities.

What do I have to do?

The protocol must outline and document that maintenance staff and service contractors engaged to complete work in product production areas must observe all personnel and process hygiene requirements. Service contractors must be provided with protective clothing, as required. The procedures must describe the practices under which repairs are to be completed in any product handling or storage areas including the following requirements that maintenance staff must observe:

- Maintenance of equipment or building structures must be completed in a manner that does not pose a risk to the product, materials (including packaging materials) or equipment;

- The maintenance supervisors must ensure they are notified by all contractors engaged to complete work in any product handling areas. They must ensure that all service contractors are aware of the supplier's personnel hygiene requirements and that they are provided with any necessary protective clothing, or that protective clothing meets the same requirements as those of the supplier staff;

- Maintenance staff and service contractors must ensure that they account for and remove all tools and debris from any maintenance activity once it has been completed in any product handling area and inform the area supervisor so appropriate sanitation can be completed;

- Service contractors are to inform the maintenance supervisor if any required work poses a potential threat to product, packaging or equipment safety (i.e. pieces of electrical wire, damaged light fittings, loose fittings overhead, etc.). When necessary, maintenance must be conducted outside processing times;

- Service contractors shall notify the maintenance supervisor in the event of any breakage or damage that could expose products, packaging or equipment to contamination;

- Service contractors must notify the maintenance supervisor when work has been completed;

- Plant supervisors and operators must ensure appropriate and effective clean up measures are taken once all maintenance or service contractor activity is completed and prior to the commencement of plant operations.

It is essential that supplier staff, maintenance personnel and service contractors adhere to the correct procedures when completing maintenance on all equipment. As part of maintenance procedures, repaired

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equipment must be inspected for missing parts (nuts, bolts, springs, etc.) prior to use.

Those responsible for reporting and completing repairs and cleaning the equipment after repairs must be specified in maintenance procedures.

The use of temporary fasteners such as string, wire or tape is not permitted (refer 13.7.1.2).

Where machinery that exists over product lines or product contact surfaces requires lubrication, food grade lubricant is to be used or line is to be adequately covered to prevent contamination. Even then, food-grade lubricant is still a quality hazard and must be used sparingly to avoid contact with product.

Where paint is used on equipment, roofs, walls or floors, it must be in good condition and suitable for use. Paint must not be used on product contact surfaces.

13.2.7 Auditing Guidance

Maintenance schedule and procedures shall be reviewed at the initial desk audit. Subsequently, compliance to this requirement and the supplier maintenance schedule and procedures shall be reviewed at each facility audit through observation, review of records and interview with operational, maintenance staff and contractors. Evidence may include:

- There is a planned maintenance schedule;

- The maintenance program include all packaging manufacturing equipment and areas of the site;

- The planned preventative maintenance schedule is being followed;

- GMP training records for maintenance employees and contract service providers;

- Unsecured tools, nuts, bolts, etc. found on the manufacturing floor are not found;

- String, wire, tape, cardboard, etc. as a temporary repair is not used for temporary or permanent repairs;

- Closed and outstanding work orders;

- Maintenance procedures afford no risk to product safety and integrity;

- Maintenance procedures are known by maintenance personnel and contractors;

- Supervisor or line personnel knows procedure to follow when the manufacturing equipment breaks down;

- Maintenance procedures are being followed;

- Maintenance procedures include food packaging safety and hygiene practices;

- Maintenance staff follow food packaging safety and hygiene practices;

- Maintenance contractors follow food packaging safety and hygiene practices;

- Preventative maintenance activities are documented;

- Plant and equipment failures are documented and include temporary intervention to mitigate risks;

- The maintenance schedule is adjusted for plant and equipment failures;

- Operating staff and supervisors are notified when repairs are made/completed;

- Sanitation activity occurs after maintenance repair in product processing areas has been completed;

- Notification occurs when potential risk to product is evident through maintenance activities or breakdowns;

- Food grade lubricant is used where necessary;

- Food grade lubricant, if used, is used sparingly and does not come into contact with product,

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materials, or product contact surfaces;

- Conveyor lines are properly protected from non-food grade lubricant, if used;

- Paint is not used on product contact surfaces;

- Maintenance records are available and complete.

13.2.8 Calibration

13.2.8.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in the pre-requisite program, food safety plans and food quality plans and other process controls, or to demonstrate compliance with customer specifications shall be documented and implemented.

13.2.8.2 Procedures shall be documented and implemented to address the disposition of potentially affected product should measuring, test and inspection equipment be found to be out of calibration state.

13.2.8.3 Calibrated measuring, test and inspected equipment shall be protected from damage and unauthorized adjustment.

13.2.8.4 Equipment shall be calibrated against national or international reference standards and methods or to accuracy appropriate to its use. In cases where standards are not available the supplier shall provide evidence to support the calibration reference method applied.

13.2.8.5 Calibration shall be performed according to regulatory requirements and/or to the equipment manufacturers recommended schedule.

13.2.8.6 Calibration records shall be maintained.

13.2.8 Implementation Guidance

What does it mean?

The accuracy of measuring, and inspection equipment that is used to test raw materials and food packaging safety and quality parameters (e.g., temperature, pH, product weight) is essential in ensuring that product meets regulatory, legal and customer requirements. The equipment itself must itself be tested to ensure correct information is provided to make operational decisions.

What do I have to do?

Test equipment used to confirm regulatory requirements (e.g., weight scales) must be calibrated against a national or international standard.

In cases where a national or international standard does not exist or is not arranged, a reference standard can be purchased or created and/or a standard method (often supplied by the equipment supplier) used.

- pH meters are calibrated against reference buffer solutions according to the manufacturer instructions.

- Thermometers can be calibrated against boiling water or ice-water if these approximate the temperatures the thermometer is required to measure when in use.

To ensure that measuring equipment gives reliable results, the supplier must:

- Identify all the equipment that requires calibration (e.g., thermometers, scales, pH meters, etc.).

- Ensure the equipment, once calibrated, is protected so that measurements remain accurate.

- Ensure the equipment is only operated by authorized personnel and using approved methods.

- Determine how accurate the measurements need to be. Does the supplier need to comply with industry or national standards? If the calibration is designed to check measurements implemented to improve a process the supplier may determine the level of measurement required and apply calibration parameters to ensure consistent measurement.

- Calibrate equipment regularly. The calibration frequency will vary depending upon the type of equipment and its usage. Calibration frequency must be adjusted in light of experience or manufacturer's instructions.

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- Develop a corrective action to address products produced between the time equipment "out-of–calibration" is discovered and the last calibration check with normal tolerances recorded.

- Clearly identify who is responsible for undertaking calibration, recording the results of all calibrations and labeling equipment to indicate when it was last calibrated and when recalibration is due.

13.2.8 Auditing Guidance

Calibration procedures shall be reviewed at the initial desk audit. Subsequently, compliance to this requirement and the supplier calibration procedures shall be reviewed at each facility audit through observation, review of records and interviews with operational staff responsible for calibration. Evidence may include:

- Calibration records for monitoring measurement equipment;

- Training records of associates responsible to conduct calibration activities;

- Associates responsible for conducing calibration activities;

- Observation of associates performing a calibration activity;

- All measuring, test and inspection equipment is identified;

- Calibration standards are known and followed;

- Calibration methods and frequency are documented for all available measuring, test, and inspection equipment;

- Calibration methods and frequency meet national or international standards where appropriate;

- Calibration methods and frequency meet customer requirements where appropriate;

- Calibration methods and frequency meet manufacturer's instructions where appropriate;

- Methods for calibration of equipment include responsibility for conducting calibration;

- Authorized personnel understand the methods for conducting calibration;

- There are procedures in place to address disposition of potentially affected product;

- Potentially affected product is adequately disposed of;

- Calibrated equipment is protected from damage;

- Calibrated equipment is not subject to unauthorized adjustment;

- Calibration records are available and complete.

13.2.9 Management of Pests and Vermin

13.2.9.1 The methods and responsibility for integrated pest management shall be documented and effectively implemented. The premises, its surrounds, storage facilities, machinery and equipment shall be kept free of waste or accumulated debris so as not to attract pests and vermin.

13.2.9.2 The pest and vermin management program shall:

i.   Describe the methods and responsibility for the development, implementation and maintenance of the pest and vermin management program;

ii.   Identify the target pests for each pesticide application;

iii. Outline the methods used to prevent pest problems;

iv.   Outline the pest elimination methods;

v.   Outline the frequency with which pest status is to be checked;

vi.   Include on a site map the identification, location, number and type of bait stations set;

vii.	List the chemicals used (they are required to be approved by the relevant authority and their Safety Data Sheets (SDS) made available);
viii.	Outline the methods used to make staff aware of the bait control program and the measures to take when they come in contact with a bait station;
ix.	Outline the requirements for staff awareness and training in the use of pest and vermin control chemicals and baits; and
x.	Measure the effectiveness of the program to verify the elimination of applicable pests.

13.2.9.3 Inspections for pest activity shall be undertaken on a regular basis by trained personnel and the appropriate action taken if pests are present.

13.2.9.4 Records of all pest control applications shall be maintained.

13.2.9.5 Pesticides and other toxic chemicals shall be clearly labeled and stored as described in element 13.6.3 and handled and applied by properly trained personnel. They shall be used by or under the direct supervision of trained personnel with a thorough understanding of the hazards involved, including the potential for the contamination of food contact packaging.

13.2.9.6 Pest control contractors shall be:

i.	Licensed and approved by the local relevant authority;
ii.	Use only trained and qualified operators who comply with regulatory requirements;
iii.	Use only approved chemicals;
iv.	Provide a pest control management plan (see Contract Services 2.3.3) which will include a site map indicating the location of bait stations and traps;
v.	Report to a responsible senior management person on entering the premises and after the completion of inspections or treatments; and
vi.	Provide a written report of their findings and the inspections and treatments applied.

13.2.9.7 The supplier shall dispose of unused pest control chemicals and empty containers in accordance with regulatory requirements and ensure that:

i.	Empty chemical containers are not reused;
ii.	Empty containers are labeled, isolated and securely stored while awaiting collection; and
iii.	Unused and obsolete chemicals are stored under secure conditions while waiting authorized disposal by an approved vendor.

13.2.9 Implementation Guidance

What does it mean?

Integrated pest management (IPM) is a holistic approach that integrates a range of practices to minimize the incidence of pest activity.

The Food and Agriculture Organization (FAO) of the United Nations defines IPM as "the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment."

In other words, a range of integrated measures are required to minimize pest populations, including mechanical preventions (e.g., sealed doors and windows, air curtains, etc.), mechanical controls (e.g., baits, traps, etc.), waste minimization, appropriate use of pesticides, etc.

This element covers primarily traditional pest management activities, including pesticide application. However it is related to *13.2.5 Dust, fly, and vermin proofing,* which is also part of an overall IPM approach.

What do I have to do?

A fully maintained pest and vermin control program is essential to the safe function of any food packaging

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operation. The pest and vermin control program must:

- Identify the target pest (s) for each pesticide application;

- Outline the frequency with which pest status is to be checked;

- Identify the location of bait stations, traps and chemical sites for ease of checking;

- Outline the methods used to prevent pest problems (the recommendation is to be proactive);

- Outline the methods used when pests are found;

- Maintain a copy of the licenses and credentials of the pest control operator (s), and verify that they are current;

- List the chemicals used;

- Assure chemicals used are approved by the relevant authority and that SDS are accessible; and

- Outline the requirements for staff awareness and training in the use of pest control chemicals.

The location of internal and external pest control devices must be completed based on the risk to the site and the product. Factors that can affect this include product type, processing type, location of site, surrounding environment, types of facilities, external storage of equipment (such as equipment graveyards), neighboring facilities and land use. The site and surrounding areas must be kept free of waste, redundant equipment and associated debris to minimize harborage for vermin.

Pest control devices should be located at all product storage, material and packaging storage facilities in addition to the main processing facilities. Inspections for pest activity must take place on a regular basis, the results recorded and the actions taken if pests are present. This can be incorporated into the operation's internal audit program.

Examples of records of pest control applications include service reports, pesticide usage logs, pest-sighting logs, corrective action reports and trending of activity by the service provider.

In addition to the pests most commonly seen in product manufacturing facilities (i.e., flies, mice, rats, roaches, etc.), pest management procedures need to also consider and control domestic and feral animals and birds where applicable.

Personnel handling pest control chemicals must be trained and authorized to do so. Where external pest management contractors are used, they must be licensed by the relevant local authority and use only approved pest control chemicals. Pest contractors must be trained on the supplier's GMP policy and procedure. Chemicals must be stored appropriately and separate from any food materials or products (refer 13.6.3), and used chemical containers disposed of correctly.

13.2.9 Auditing Guidance

Pest management procedures shall be reviewed at the initial desk audit. Subsequently, compliance to this requirement and the supplier pest management procedures shall be reviewed at each facility audit through observation, review of records and interviews with operational staff and possibly the pest contractor (if applicable). Evidence may include:

- The potential pests are known and interventions have been implemented to control and eliminate pests;

- Pest records and inspection sheets completed by the pest contractor;

- Visual observation for the presence of pests (i.e., check along the wall and floor junction within the facility);

- Implementation of integrated pest management program (i.e., traps, review site map, etc.);

- There is a documented pest management program that integrates a number of preventative as well as control measures;

- The documented pest management program:

  o Targets all known pests;

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- o Assigns responsibilities for pest management;

- o Includes methods to eliminate or minimize all known pests;

- o Includes frequencies for checking pest status;

- o Includes the exterior or surrounding areas of facility;

- The methods, frequencies and responsibilities identified in the pest management program are effectively implemented;

- External areas are kept clear and free from waste and debris;

- There are no observed pest harborage areas observed within the facility or in the immediate surrounds;

- There is a site map of pest control devices;

- Pest control devices meet regulatory requirements;

- There is a list of approved pest control chemicals with SDS available for all chemicals;

- Only approved pest control chemicals are used;

- Pesticides are correctly labeled;

- Empty or redundant pest control chemical containers are correctly disposed of;

- Pest control contractors are trained, with a current license;

- Pest control inspections are thorough and conducted at the correct frequency;

- Supplier's staff are aware of pest control devices;

- Line associate have been trained on procedures applicable to their role within the integrated pest management program;

- Appropriate corrective action is taken in response to pest control inspections;

- Pest control records are current and maintained.

13.2.10 Equipment, Utensils, and Protective Clothing

13.2.10.1 Equipment and utensils shall be designed, constructed, installed, operated and maintained so as not to pose a contamination threat to the product.

13.2.10.2 Where required, protective clothing shall be manufactured from material that is not liable to contaminate food and can be easily cleaned.

13.2.10.3 When protective clothing is used, hooks or other forms of off-floor storage shall be provided for protective clothing when staff leaves the processing area and shall be provided in close proximity or adjacent to the personnel access doorways and hand washing facilities.

13.2.10 Implementation Guidance

What does it mean?

This is a general provision covering the condition and use of equipment, including utensils, benches, tables, bins, and protective clothing, so that they do not pose a threat to product safety or quality.

What do I have to do?

Product processing equipment shall be designed, constructed and maintained in accordance with manufacturer and/or industry standards. Metal frames, supports and brackets supporting sinks, wash basins, benches, tables and shelves are generally constructed of solid materials such as hot dipped galvanized iron, stainless steel or aluminium and securely fixed to the walls or on metal frames. Equipment shall be smooth-finished, free from angles, ledges and crevices and easy to clean. The open ends of tubular legs or rails must be sealed to prevent the accumulation of process waste and residues.

Where equipment is dismantled for cleaning, it is to be designed free of loose bolts or nuts or other objects

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that could inadvertently find their way into the product or provide points for accumulation of waste.

Containers (e.g., tubs, bins, etc.) used for production or waste materials must be clearly identified (i.e., color-coded or labeled). Containers previously used for pesticides, insecticides or other deleterious materials must not be re-used for product handling (refer 13.2.11.7).

Where protective clothing (e.g., gloves, face shields, etc.) is provided and used, it must be made of a material that will not contaminate the product and is easily cleaned. There must be a cleaning regime in place for protective clothing.

13.2.10 Auditing Guidance

This element shall be reviewed at each facility audit through observation and interview with operational staff. Evidence may include:

- Processing equipment is properly designed and maintained;

- Product contact utensils are properly designed and properly maintained;

- Containers for production or waste materials are correctly labeled;

- Waste water and overflow from tanks and tubs is properly drained;

- Protective clothing is provided that is fit for purpose, made of material that will not contaminate raw ingredients or packaging materials, and is easily cleaned;

- There is a cleaning process for protective clothing that has been implemented and is effective

- Properly designed storage is provided for protective clothing;

- Protective clothing is stored in an area accessible to staff;

- Single-use protective clothing is properly maintained and replaced when appropriate.

13.2.11 Cleaning and Sanitation

13.2.11.1 The methods and responsibility for the cleaning of manufacturing and storage areas, staff amenities and toilet facilities shall be documented and implemented.

13.2.11.2 Provision shall be made for the effective cleaning of processing equipment, utensils and protective clothing.

13.2.11.3 Racks or other off-floor storage areas shall be designated for cleaning product containers, utensils and cleaning staff's protective clothing. Storage for cleaned utensils and protective clothing shall be provided as required.

13.2.11.4 Pre-operational hygiene and sanitation inspections shall be conducted by qualified personnel to ensure manufacturing and storage areas, staff amenities and sanitary facilities and other essential areas are clean.

13.2.11.5 The responsibility and methods used to verify the effectiveness of the cleaning procedures shall be documented and implemented. A verification schedule shall be prepared.

13.2.11.6 Detergents and sanitizers shall be purchased in accordance with applicable legislation. The organization shall ensure:

i.   An inventory of all chemicals purchased and used shall be maintained;

ii.   Detergents and chemicals are stored as outlined in element 13.6.3;

iii.   Safety Data Sheets (SDS) are provided for all detergents and sanitizers purchased; and

iv.   Only trained staff handles sanitizers and detergents.

13.2.11.7 The supplier shall dispose of unused detergents and sanitizers and empty containers in accordance with regulatory requirements and ensure that:

i.   Empty detergent and sanitizer containers are appropriately cleaned, treated and labeled before use;

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ii.   Empty detergent and sanitizer containers are labeled, isolated and securely stored while awaiting collection; and

iii.   Unused and obsolete detergents and sanitizers are stored under secure conditions while waiting authorized disposal by an approved vendor.

13.2.11 Implementation Guidance

What does it mean?

Cleaning and sanitation methods will vary depending on the nature of the operation, and the microbiological and allergen risk. This element covers cleaning and sanitation protocols generically, but specifies the correct use and type of cleaning detergents, sanitizers (also referred to as disinfectants) and the requirement for post-clean inspections.

It is important to stress that, irrespective of the type of production and risk, all facilities require an appropriate documented and implemented cleaning program. The program must be verified to ensure its effectiveness.

What do I have to do?

A written cleaning program shall be in place and fully implemented that includes provisions for effective cleaning of equipment, facilities, utensils, amenities and external areas. The cleaning program shall identify the what, how, when and who for every item of equipment and part of the facility. Responsibilities shall be identified, including responsibility for the visual or test inspection, and the verification of cleaning methods.

For small items of equipment such as tools, knives, tubs, cutting boards, etc., a wash area shall be provided with sufficient hot and cold running water, a suitable detergent and sanitizer for cleaning and when necessary, suitable racks for draining/drying equipment, utensils, and protective clothing. These areas shall be identified and constructed so they do not present a hazard to other product processing operations. Temporary storage is provided for protective clothing, gloves, aprons and other items when staff needs to leave the processing area for meals or other short breaks (refer13.2.10.3). Used disposable protective clothing must be immediately disposed of in an appropriate manner. Non-disposable protective clothing shall be cleaned according to the written procedures.

The cleaning and sanitation protocol shall include the following detail:

- List all the areas and equipment to be cleaned;

- The frequency for cleaning and sanitizing different areas of the premises and all associated equipment including pre-operative cleaning and cleaning between breaks;

- A full description of the cleaning and sanitation procedures for each piece of equipment or area of the operation. This should include:

  ◦ Physically remove solid particles by sweeping or wiping;

  ◦ Apply a suitable detergent in the correct concentration to remove grease and other product residues;

  ◦ Rinse off residual product residue and detergent;

  ◦ Apply a suitable sanitizer in the correct concentration to reduce or eliminate microbiological contaminants;

  ◦ Rinse to remove residual sanitizer, if indicated on product label;

  ◦ Dry, as indicated, in a manner that will prevent recontamination.

- Ensure operators involved in cleaning, including contract cleaners, are fully trained in cleaning and sanitation procedures;

- Chemicals must be approved for use by the appropriate authority; maintain on file Safety Data Sheets (SDS) for each chemical used.   Describe the chemicals used, their dilution rate and method of application;

- Chemical cleaners and sanitizers must be used and stored in an approved manner (refer 13.6.3);

- Evaluation of cleaning. Monitor the effectiveness of cleaning and keep records of all inspections implemented to verify the effectiveness of the cleaning program;

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- Maintain an inventory of chemicals purchased and used;

- Outline requirements for the disposal of unused compounds and empty containers in accordance with regulatory requirements.

To verify the effectiveness of sanitation, a visual pre-operational inspection of equipment and facility is to be conducted prior to the start of operations, after a sanitation activity or the beginning of a shift. To verify the facility is operating in a sanitary manner throughout the shift, sanitation shall be monitored and documented regularly by the shift supervisor or a designated employee.

Any corrective actions taken when inspection reveals a problem must be recorded.

13.2.11 Auditing Guidance

Cleaning and sanitation procedures and schedule shall be reviewed at the initial desk audit. Subsequent compliance to this requirement and the supplier cleaning and sanitation procedures shall be reviewed at each facility audit through observation, review of records, and interviews with operational staff and cleaning contractors if applicable. Evidence may include:

- Cleaning program is effective and complete and includes corrective actions;

- All critical equipment and areas of the facility are covered in the cleaning program;

- Interviews of sanitation associates on procedures, including frequency of cleaning for a critical piece of equipment;

- Pre-operational checklist reports are complete and address failures;

- The cleaning program includes log reports of measures that verify the effectiveness of the sanitation program;

- The cleaning of processing equipment is effective;

- The cleaning of utensils and protective clothing is effective;

- The building grounds, external buildings, and surrounding areas, are clean;

- Utensils are cleaned   in an area separate from processing;

- Areas for storing cleaned utensils are provided and appropriate;

- All critical areas of the facility are include in pre-operational inspections;

- Personnel conducting pre-operational inspections are trained and qualified;

- A sanitation verification program and schedule is available;

- The program:
    o Defines methods for verification of sanitation;
    o Assigns responsibility for verification of sanitation.

- An inventory of purchased chemicals is available and is current;
    o Detergents and sanitizers meet local regulatory requirements;
    o SDS sheets are available for all cleaning chemicals purchased;
    o Personnel handling cleaning chemicals are properly trained;
    o Cleaning chemicals are disposed of as per regulatory requirements.

- Empty cleaning chemical containers are labeled and securely stored;

- Records of cleaning and sanitation activities are maintained and complete;

- Records of hygiene inspections are maintained and complete.

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13.3   Personnel Hygiene and Welfare

13.3.1 Personnel

13.3.1.1 Personnel suffering from infectious diseases or are carriers of, any infectious disease shall not engage in the manufacture of food contact packaging, or storage areas where food contact packaging is exposed.

13.3.1.2 Personnel with exposed cuts, sores or lesions shall not be engaged in handling packaging materials. Minor cuts or abrasions on exposed parts of the body shall be covered with colored bandage containing a metal strip or an alternative suitable waterproof and colored dressing.

13.3.1.3 Smoking, chewing, eating, drinking or spitting is not permitted in areas where product is produced, stored or otherwise exposed.

13.3.1 Implementation Guidance

What does it mean?

In many jurisdictions, personnel requirements in food manufacturing plants are covered by food safety legislation. Where this applies, the legislative requirements must underpin the requirements of 13.3.1. This element covers the basic personal hygiene requirement for working in food contact packaging facility.

What do I have to do?

Staff identified as carriers of infectious diseases are not to be permitted to handle raw materials, work in progress, or finished product.

Employees must be aware of risks to the products from the potential transmission of pathogens from ill employees. An example of a control program could be the removal of an employee from direct contact with product to non-product contact activities when the employee reports potential illness. Ideally, an employee will not be penalized for reporting illness to the facility. This will be supported by introductory training with all employees on reporting illnesses and a questionnaire on illnesses for visitors.

Staff in food contact manufacturing facilities with exposed cuts is not permitted to handle products unless suitable protective coverings are applied. These coverings must be monitored regularly by responsible personnel to ensure they remain effective. Bandages are to be brightly colored and protected to ensure they can be easily seen and include a metal strip for ease of detection if the facility uses metal detection.

Dressings on hands and fingers are required to be covered with a suitable glove or finger cot or stall which is disposable, colored and waterproof.

Smoking, eating, chewing and drinking are not permitted in areas where product is produced, stored or otherwise exposed. A risk analysis for drinking water must be conducted and controls must be developed by the facility to minimize the risk to the safety and quality of the product if it is provided in a production area where product is exposed. If water is consumed in the processing area, it is recommended that employees wash hands before returning to their station, or hand sanitizer needs to be applied prior to returning to their work station.

13.3.1 Auditing Guidance

Medical screening and personal hygiene policies and procedures shall be reviewed at the initial desk audit, and the effective implementation checked at each facility audit though observation, review of records and interviews with staff. SQF auditors will question employees on hygiene practices to ensure they are understood and applied. Evidence may include:

- Medical screening and personal hygiene policies and procedures are in place and effectively implemented;

- Employees notify the business of illness;

- Personnel engaged in raw materials and packaging manufacturing do not exhibit any signs of illness or open cuts or sores;

- Personnel who are known to have been ill with an infectious illness are not involved in packaging manufacturing or handling stored product;

- Personnel sores or cuts on hands are redeployed to low risk areas or have cuts suitably

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bandaged and gloved;

- Bandages provided to staff are brightly colored and have a metal strip (where metal detection is used);

- The company monitors the usage of bandages, metal detectable dressings, etc.;

- There is no smoking, eating or drinking in product processing, storage or handling areas;

- Drinking water in processing areas is controlled and managed to minimize risk to the product.

13.3.2 Hand Washing

13.3.2.1 Hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout manufacturing area as required.

13.3.2.2 Hand wash basins shall be constructed of stainless steel or similar non-corrosive material, and as a minimum supplied with:

   i.   A potable water supply at an appropriate temperature;

   ii.   Liquid soap contained within a fixed dispenser;

   iii.   Paper towels or effective hand dryer; and

   iv.   A means of containing used paper towels.

13.3.2.3 A sign instructing people to wash their hands, and in appropriate languages, shall be provided in a prominent position adjacent to hand wash stations.

13.3.2.4 Personnel shall have clean hands and hands shall be washed by all personnel, including staff, contractors and visitors:

   i.   On entering product contact areas;

   ii.   After each visit to a toilet;

   iii.   After using a handkerchief;

   iv.   After smoking, eating or drinking; and

   v.   After handling contaminated material.

13.3.2.5 When gloves are used, personnel shall maintain the hand washing practices outlined above.

13.3.2 Implementation Guidance

What does it mean?

Employees, contractors and visitors must have clean hands upon entering product handling or processing areas; after each visit to a toilet; after using a handkerchief; after smoking, eating or drinking; and after handling wash down hoses, dropped product or contaminated material. Hand wash stations must therefore be correctly equipped and available at convenient locations for use.

What do I have to do?

Hand wash basins must be provided in close proximity to pedestrian entry points at each area of the facility, with instructions for all staff, contractors and visitors to wash hands immediately before entering the processing area. Additional hand basins are required where hands could become contaminated prior to working with product.

Potable water at a suitable temperature, liquid soap, single-use paper towels and a means of disposing of used paper towels need to be provided at each station.   Where alternative methods of hand-drying are preferred (e.g. high-speed air dryers). Their use must be justified and their effectiveness validated (refer 2.4.2.2).

Hand-wash basins are to be constructed of stainless steel or similar non-corrodible material. Hand-wash basins constructed of porcelain or similar materials must be located at a distance from product handling areas.

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13.3.2 Auditing Guidance

The location and construction of hand-wash stations and their use by staff, contractors and visitors shall be reviewed at each facility audit. Evidence may include:

- Hand wash basins are available for staff, contractors, and visitors at entry points to the processing floor;

- Hand wash basins are located at personnel access points and areas where hands could become contaminated;

- Hand wash basins are constructed of an appropriate material, and have potable water at appropriate temperatures;

- There is liquid soap, water, paper towels and waste can for used paper towels. available at hand wash stations;

- There is hand wash signage near hand wash stations instructing people to wash their hands;

- Personnel have clean hands and have washed their hands before entering the manufacturing area;

- Personnel wash their hands at appropriate times including when leaving the restroom, locker room, etc.;

- Personnel wash their hands after handing products, hoses, waste or chemicals;

- Personnel wash their hands after eating, drinking or smoking;

- Personnel who use gloves also follow hand washing requirements.

13.3.3 Clothing

13.3.3.1 Clothing worn by staff engaged in handling food contact packaging shall be maintained, stored, laundered and worn so as not to present a contamination risk to products.

13.3.3.2 Clothing shall be clean at the commencement of each shift and maintained in a serviceable condition. Excessively soiled uniforms shall be changed where they present a product contamination risk.

13.3.3 Implementation Guidance

What does it mean?

Clothing must be sufficiently clean to protect materials, work-in-progress, finished product and product contact surfaces.

What do I have to do?

Employees and visitors must wear clean clothing and footwear while in the processing area. Employees and visitors with excessively soiled clothing are not to handle products or packaging materials. Employees engaged in low risk processes can wear uniforms off site provided they are properly cleaned at the beginning of their work operation.   The facility is to instruct personnel in the requirements of home laundering of garments as appropriate.

Clothing includes outer garments such as work clothes, overalls, boots, shoe coverings, head coverings, hair nets, smocks, frocks, beard snoods and coats.   When required, gloves and aprons shall be kept in an intact and sanitary condition when used. When not in use, gloves and aprons shall be stored in a designated area (e.g. such as a rack or locker), not on products or equipment. Soiled garments are to be stored separately from clean, unused garments.

Disposable gloves shall be removed before each break, changed upon re-entry into the processing area and when damaged. Employees must comply with hand washing practices even when gloves are used.

Disposable garments are to be controlled to minimize the risk of contamination prior to use. Any disposable clothing must be changed between breaks, upon entry into processing areas and when damaged. This includes aprons, frocks, smocks, boots, gloves, etc. When clothing is to be reused, it must be properly

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cleaned and stored on racks or hangers. It cannot be stored on boxes, product or packaging materials. Hairnets and beard snoods are to be worn by employees working on the packing or processing line or who work around exposed product. Disposable clothing is to be removed and disposed of in a manner that does not pose a risk to the packaging product.

13.3.3 Auditing Guidance

Company policies on clothing, including uniforms, gloves, hairnets, snoods and footwear shall be reviewed at the initial desk audit. Clothing worn by staff, contractors and visitors (where appropriate) shall be reviewed at each facility audit through observation and interview. Evidence may include:

- Company policies on clothing including uniforms, gloves, hairnets, snoods and footwear are in place and are appropriate for the type of operation;

- Personal clothing is removed and stored separately and appropriately as necessary;

- Company clothing policies are implemented by all staff;

- Clothing, if provided to staff, is appropriate and properly maintained;

- Clothing worn by staff is clean at the start of the shift, changed when soiled and properly segregated, as appropriate;

- Items such as hair nets, snoods and disposable gloves are available at accessible locations;

- Clothing requirements for contractors and visitors are followed:

- Disposable gloves, hairnets, and protective clothing are correctly disposed of;

- Non-disposable gloves and/or aprons are properly cleaned and stored appropriately between uses.

13.3.4 Jewelry and Personal Effects

13.3.4.1 Jewelry and other loose objects shall not be worn or taken into a product handling area or any area where packaging is exposed.

13.3.4.2 The wearing of plain bands with no stones and medical alert bracelets that cannot be removed can be permitted, however the supplier will need to consider their customer requirements and the applicable food legislation.

13.3.4 Implementation Guidance

What does it mean?

Loose jewelry, mobile phones, keys, false fingernails, etc. can fall into exposed product and cause a physical hazard. Also, pathogenic bacteria can multiply in the warm, humid areas under false fingernails, watchbands, rings and bracelets.

The application of the jewelry policy in manufacturing is therefore dependent on the risk to the product and exposure to the product. Where product is exposed, company policies shall require the removal of all jewelry and loose objects prior to entering the processing areas.

What do I have to do?

Jewelry and other loose objects, including watches, worn or carried, must comply with local regulatory authority and proper employee hygiene practices. If such hand jewelry cannot be removed, it may be covered with material which can be maintained intact, in a clean and sanitary condition and which effectively protects against the contamination by these objects to the product, product-contact surfaces or food-packaging materials. Facilities can adjust their good employee hygiene practices based on customer requirements, risk to their product, product exposure and processing conditions.

13.3.4 Auditing Guidance

As with clothing, company policies on jewelry shall be reviewed at the initial desk audit, and the

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implementation of that policy reviewed at each facility audit through observation and interview.
Evidence may include:

- Employees, visitors, and contractors are not wearing jewelry and understand the jewelry policy.

13.3.5 Visitors

13.3.5.1 All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any packaging handling or storage area.

13.3.5.2 Visitors shall enter and exit packaging handling or storage area through the proper staff entrance points and comply with all hand washing and personal practice requirements.

13.3.5 Implementation Guidance

What does it mean?

A visitor is considered a non-employee of the company or facility. Examples of visitors would be vendors, service providers, contractors, truck drivers, tours and guests. Some facilities may define visitors to include anyone who does not work in the facility, thus, corporate personnel could be considered visitors.

Visitors pose the same risk to product safety as company staff and in some cases a greater risk because they may not understand the operation or hygiene requirements.

What do I have to do?

The requirements for visitors in product manufacturing are dependent on the risk to the product, exposure to the product and the proximity of visitors to the process.   Where product is exposed, visitors must follow exactly the same provisions as staff.

The facility shall have specific good hygiene practices for visitors, contractors and tours; have a means to communicate those expectations to visitors, contractors and tours; and monitor visitors, contractors and tours to ensure all visitors are in compliance with the company's good hygiene practices. All visitors are required to wear clean clothing and foot wear, and must remove jewelry and other loose objects, including watches that may fall into equipment.

Visitors shall enter and exit product packing and processing areas through designated staff entrance points using designated walkways as instructed and must comply with all hand washing and personal requirements. Visitors must not be permitted to handle any product or equipment.

Visitors shall sign in the visitor log, comply with medical screening procedures and shall be accompanied at all times by a company employee. For their personal safety, as well as the security of the product and process, they cannot be unsupervised.

13.3.5 Auditing Guidance

The company policy on visitors shall be reviewed at the initial desk audit and the implementation of that policy reviewed at each facility audit through observation and interviews. As someone external to the company, the auditor will be able to partly ascertain compliance by their personal experience on entering the facility.   Evidence may include:

- The visitor policy is implemented and applied to visitors, and service contractors.

- The visitor policy is appropriate to the risk, product exposure and processing conditions and the type and number of visitors visiting the site.

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13.3.6 Staff Amenities

13.3.6.1 Staff amenities supplied with appropriate lighting and ventilation shall be made available for the use of all persons engaged in the handling and storage of food contact packaging.

13.3.6 Implementation Guidance

What does it mean?

This is a header element, which leads to the further descriptions in 13.3.7 – 13.3.9 addressing change rooms, laundry, restrooms, and lunch rooms.

What do I have to do?

Provide adequate lunchroom and restroom facilities, as appropriate for the number of employees in the operation based on applicable legislation relevant to the commodity being processed.

Provided amenities must have adequate lighting and ventilation.

13.3.6 Auditing Guidance

This element will be audited as part of each facility audit through observation and interviews with operational staff. Evidence may include:

- Amenities are provided commensurate with the type of operation and the number of employees;

- Amenities are available for all employees who handle product;

- Staff amenities have adequate lighting;

- Staff amenities have adequate ventilation;

- Staff amenities have adequate hand wash sinks;

- Staff amenities provide storage for employee lunches and meals.

13.3.7 Change Rooms

13.3.7.1 Facilities shall be provided to enable staff and visitors to change into and out of protective clothing as required.

13.3.7.2 Provision shall be made for staff to store their street clothing and personal items separate from packaging handling or storage areas.

13.3.7 Implementation Guidance

What does it mean?

Provide a designated area (i.e., locker room) for employee and visitor garments and personal items.

What do I have to do?

Change rooms (i.e., locker rooms) must be provided with lockers for staff and visitors when they are required to change from street clothing to protective clothing to enter the product processing operation. The areas shall be designed so materials and personal items cannot be stored on top of the lockers. The area around and under lockers if not fully sealed, must be able to be easily cleaned. It is generally recommended that lockers be fitted flush with the ceiling and placed on stands raised off the floor to allow ease of cleaning. Segregation of personal items, soiled protective clothing and clean protective clothing shall be achieved through the supply of facilities as appropriate.

Showers are only required for those product processing plants required by legislation to have such facilities available or if the supplier's risk assessment indicates the facilities are required for high risk processes. The number is to be based on the maximum number of staff likely to use the facilities at one time.

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13.3.7 Auditing Guidance

This element will be audited as part of each facility audit through observation and interview with operational staff. Evidence may include:

- Change rooms are provided commensurate with the type of operation and the number of employees;

- Change rooms are available and are sufficient for all employees;

- Change rooms are designed to avoid storage on top of lockers, and ease of cleaning;

- If showers are provided, they are sufficient in number to accommodate staff on duty;

- There are areas for returning soiled clothing, if provided;

- There are facilities for staff to secure personal items.

13.3.8 Sanitary Facilities

13.3.8.1 Toilet rooms shall be:

    i.   designed and constructed so that they are accessible to staff and separate from any packaging handling or storage operations;

    ii.   accessed from the manufacturing area via an airlock vented to the exterior or through an adjoining room;

    iii.   sufficient in number for the maximum number of staff;

    iv.   constructed so that they can be easily cleaned and maintained; and

    v.   kept clean and tidy.

13.3.8.2 Sanitary drainage shall not be connected to any other drains within the premises and shall be directed to a septic tank or a sewerage system. Procedure shall be documented and implemented to properly manage sewage back-ups in order to minimize the potential for contamination.

13.3.8.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 13.3.2.3.

13.3.8 Implementation Guidance

What does it mean?

Sufficient restrooms/toilets are required to accommodate the number of staff. Their location and design must be such that they do not cause a contamination risk to product, product contact surfaces, areas where product is exposed or to product handlers.

What do I have to do?

Restroom/toilet facilities must be located so that they do not open directly into the processing area. In existing facilities where they are in close proximity to areas where product is exposed, an airlock vented to the exterior must be maintained (negative pressure). Staff shall enter toilet rooms from processing areas through either an intervening change room or air lock which is ventilated to external air.

Where exhaust fans are fitted, they must be exhausted to the outside and not into a production area. The light and exhaust fan can be inter-wired to create negative pressure as an option or the light and exhaust fan can be left on continuously.

To eliminate the risk of air flow from restrooms into the processing room, exhaust fan off-switches may be on timer delay. The light and exhaust fan may be on a single switch located on the outside of the restroom.

Separate toilet rooms shall be provided for each gender and are typically located adjacent to and separate from the change room. The number of toilet cubicles to be provided depends on the number of staff or is based on applicable legislation. Suppliers must be aware of local legislation, but as a guide:

Persons of the same sex	No. of bowls

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1-15	1
16-35	2
36-55	3
56-80	4
>80 for each additional 30 persons	1

In male toilets, urinals can substitute for up to one-third of the total number of bowls.

Employee restrooms shall be properly equipped with hand wash facilities (refer 13.3.2).

Signage may consist solely of icons (such as those published by the US-based International Association for Food Protection) to accomplish these requirements, with exception of restroom signage, where other regulatory requirements must be applied.

Sanitary drainage must be kept separate from drainage from product production areas.

13.3.8 Auditing Guidance

This element will be audited as part of each facility audit through observation and interviews with operational staff. Evidence may include:

- There are sufficient toilets available for each gender and the number of employees;
- Toilets do not open directly into processing areas;
- Toilets can be easily cleaned;
- Toilets are clean and tidy;
- Sufficient hand wash basins are available near the toilets;
- Sanitary drainage is separated from processing facility drains.

13.3.9 Lunch Rooms

13.3.9.1 Separate lunch room facilities shall be provided away from packaging handling or storage areas. Lunch rooms shall be kept clean and tidy and free from waste materials and pests.

13.3.9.2 Signage in appropriate languages instructing people to wash their hands before entering the food processing areas shall be provided in a prominent position in lunch rooms and at lunch room exits.

13.3.9 Implementation Guidance

What does it mean?

Employees, contractors and visitors are not permitted to eat or drink in product handling areas (refer 13.3.1.3). Designated lunch rooms must therefore be available for staff to take breaks and eat meals. These areas must be physically separated from product handling areas.

What do I have to do?

The supplier may provide additional outdoor lunchroom facilities (e.g., picnic tables) where they do not pose a dust or pest hazard to the processing area of the site. Covered facilities and sealed paths are one way to address these hazards. Where hazards presented by such facilities are minimal, the supplier may employ alternative controls such as routine cleaning of tables and steps to minimize dust on non-sealed paths.

Foot baths also provide another means to ensure that foot traffic does not bring dust or other contaminants into the processing area, if practical to do so.

Each site shall be equipped with a ventilated and well-lit lunch/break room for employees. The room must be equipped with a sink serviced with hot and cold potable water, a refrigerator and a microwave. The area must be kept clean.

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13.3.9 Auditing Guidance

This element will be audited as part of each facility audit through observation and interviews with operational staff. Evidence may include:

- Observation of staff removing protective clothing and storing it properly prior to leaving manufacturing area and entering lunch room facility;

- Separate lunch facilities are provided;

- Lunch room facilities are adequate for the number of staff;

- Lunch facilities are separated from processing, product storage or handling areas;

- Lunch room facilities are properly ventilated;

- Lunch room facilities are well lit;

- Lunch room facilities include a sink with hot and cold running water;

- Lunch room facilities are clean and tidy and all waste is properly controlled and managed;

- Proper heating or cooling facilities are provided in lunch facilities;

- Hand wash signage is available at the exit of the lunch facilities;

- Hand wash signage at the exit of lunch facilities is in appropriate languages;

- There are no signs of insects or pest infestation.

13.3.10 First Aid

13.3.10.1 First aid facilities shall be provided to treat minor injuries and suitable arrangements shall be provided in circumstances when a patient requires more specialized care.

13.3.10 Implementation Guidance

What does it mean?

The supplier site shall have first aid equipment available to treat minor injuries and arrangements in place to deal with more serious injuries.

What do I have to do?

First aid materials must be provided and made available to treat injuries involving minor burns, cuts or wounds. There needs to be a designated person on site who is trained in first aid procedures. First aid kits must be located so they do not present a hazard to products or product contact surfaces of equipment; typically, they are located in change rooms. Staff must be aware of first aid procedures and the location of first aid stations. As per 13.3.1.2, bandages need to be brightly colored to ensure that they can be easily seen and include a metal strip for ease of detection, where metal detection is applied in the facility.

A procedure must be in place to deal with more serious injuries, including having a trained, designated first-aider available on all shifts. Applicable phone numbers of contact persons or suitable arrangements made when staff requires more specialized care shall be listed in close proximity to the first aid facility.

13.3.10 Auditing Guidance

This element will be audited as part of each facility audit through observation and interviews with operational staff. Evidence may include:

- Interviews of staff on procedures to handle a cut or injury;

- Interviews of staff on the location of the first aid kit or facilities;

- First aid facilities are available;

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- Staff are aware of the location of first aid facilities;

- Arrangements are in place to provide for more specialized care as required.

13.4   Personnel Practices

13.4.1 Staff Engaged In Handling of Food Contact Packaging

13.4.1.1 All personnel engaged in any packaging handling and storage operations shall comply with the following practices:

   i.   Personnel entry to manufacturing areas shall be through the personnel access doors only;

   ii.   All doors are to be kept closed. Doors shall not be left open for extended periods when access for waste removal or receiving of product/ingredient/packaging is required;

   iii. Packaging material shall be kept in appropriate containers as required and off the floor;

   iv.   Waste shall be contained in the bins identified for this purpose and removed from the processing area on a regular basis and not left to accumulate.

13.4.1.2 The manufacturing process shall be controlled such that the packaging material produced is food safe and free from contamination. Procedures shall be in place to prevent cross contamination of food contact packaging from raw materials, recycled materials, or chemicals.

13.4.1.3 All personnel engaged in the manufacture, storage, transport and handling of packaging materials shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination.

13.4.1   Implementation Guidance

What does it mean?

Proper product handling practices combined with sanitary conditions result in:

- Extended storage life of product;

- Reduced risk of product contamination; and

- Fewer product returns or complaints.

While management has overall responsibility for ensuring that sanitary processing practices are adopted, and for establishing hygiene procedures, line operators have a responsibility for ensuring these procedures are carried out properly and effectively.

What do I have to do?

Management must develop a list of good hygiene practices of "dos and don'ts." This list must be consistent with sections 13.3 and 13.4 of the SQF Code. This will be part of the documented procedures and work instructions. All staff, contractors, and visitors (where applicable) must be made aware of these requirements before entering the site.

The site shall have designated access points for personnel to enter and exit. Access points are defined as dock doors, pedestrian doors, office doors and any door that enters into the site from the outside or from a lower risk area. Doors that are opened for ventilation must be screened. All processing areas must have areas for employees to be able to wash their hands upon entry into production areas.

Appropriate containers for waste storage are containers that are considered easily cleanable, properly labelled, not absorbable and designed for the purpose. No packaging container is to be used for the storage of waste or scrap. Waste containers are to be clearly labelled or designated as waste in languages relevant to the employee workforce.

13.4.1   Auditing Guidance

Good hygiene practices will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each facility audit through observation and interviews with operating

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personnel. Evidence may include:

- Good hygiene practices have been developed and implemented;
- Staff are aware of the company's good hygiene practices;
- Staff adhere to the company's good hygiene practices;
- All exterior doors have protective controls in place;
- Exterior doors have not been propped open or left open when not in use;
- Hand wash stations are available at designated access points;
- Employees, contractors and visitors wash their hands at designated access points;
- Employees, contractors and visitors follow hygiene protocols when entering the facility;
- Employees do not wear false fingernails in product handling areas;
- Products, chemicals or raw materials are stored in appropriate containers and not on the floor;
- Packaging materials are stored appropriately and not on the floor;
- Waste containers are properly identified;
- Waste is not left to accumulate in waste containers and is removed at appropriate intervals;
- Wash down hoses are stored correctly and not left on the floor.

13.5   Water and Air Supply

13.5.1 Water Supply

13.5.1.1 Adequate supplies of clean water shall be provided for use during manufacturing operations, as an ingredient and for cleaning the premises and equipment.

13.5.1.2 Supplies of hot and cold water shall be provided as required to enable the effective cleaning of the premises and equipment.

13.5.1   Implementation Guidance

What does it mean?

Potable water supply at the correct temperature and pressure prescribed by applicable legislation must be of sufficient capacity for all scheduled production needs and meet cleaning and sanitation requirements (refer 13.2.11).

What do I have to do?

Potable water, or drinking water, is water that is safe enough to be consumed by humans or used with low risk of harm. In most developed countries, sufficient quantities of potable water are delivered to product manufacturing facilities for operational purposes. In some countries however, and some regions in developed countries, the potability of municipal water cannot be relied on. The supplier must ensure the availability of sufficient supplies of water both as a processing ingredient and for cleaning purposes.

13.5.1   Auditing Guidance

This element will be audited as part of each facility audit through observation, review of records and interviews with operational staff. Evidence may include:

- Water used in processing is from a potable source;
- Potable water availability is adequate for processing needs;
- Potable water availability is adequate to meet cleaning requirements;
- Hot water is available for cleaning purposes.

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13.5.2 Monitoring Water Microbiology and Quality

13.5.2.1 Water used for

    i.   The manufacture of food contact packaging;

    ii.   Cleaning product contact surfaces;

    iii.   The manufacture of steam that will come in contact with packaging;

shall comply with local, national or internationally recognized potable water microbiological and quality standards as required.

13.5.2   Implementation Guidance

What does it mean?

Any water that is used in the process that could come in contact with the resin, rework or finished packages must be verified to be in compliance with local and national standards. In the US and Australia for example, the potability standard for drinking water is <1 coliform / 100 mL water and membrane filtration is the preferred method. However, standards also apply for *Salmonella* spp, *Shigella* spp, enterovirulent *E.coli*, *Vibrio cholera*, *Yersinia enterocolitica*, *Campylobacter jejuni*, and protozoa.

What do I have to do?

This element elaborates on 13.5.1 and identifies the areas where potable water must be used, e.g. as a resin or recycle plastic, rinsing and, cleaning and the manufacture of steam that comes into contact with packaging or the product contact surfaces of the packaging.

Where grey water is available (i.e. non-potable, recycled water), it must not be used in any of these areas and must be kept separate from potable water supply. The only exception here may be where potable water used for blanching, fluming or washing may be recycled and used in an earlier stage of the same process.

The supplier must be aware of the national and/or international potable water standards and any microbiological or chemical water standards imposed by customers.

13.5.2   Auditing Guidance

This element will be audited as part of each facility audit through observation, review of records and interviews with operational staff. Evidence may include:

- Current annual municipal water report for potable water;

- Well-water current test results, if used as a water source in the facility;

- Water test frequency and test parameters that ensure potability of water;

- The supplier is aware of the relevant water potability standards;

- Only potable water is used to treat, wash or rinse resin, recycle, rework or finished packages;

- Water used as ingredient processing aid meets quality requirements;

- Only potable water is used to clean package contact surfaces;

- Only potable water is used to make ice (where applicable);

- Only potable water used to make steam that will come in contact with the package food contact surfaces.

13.5.3 Water Delivery

13.5.3.1 The delivery of water within the premises shall ensure potable water is not contaminated.

13.5.3.2 The use of non-potable water shall be controlled such that:

    i.   There is no cross contamination between potable and non-potable water lines;

    ii.   Non-potable water piping and outlets are clearly identified.

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13.5.3   Implementation Guidance

What does it mean?

Even though potable water may be available to the site, the supplier must ensure that the delivery systems for water within the premises are safe with no risk of cross-contamination.

What do I have to do?

The supplier must ensure that water reticulation lines within the site are constructed of suitable material and in good condition, with no rust or corrosion.

All water systems must be protected against backflow. Backflow prevention devices shall be installed on all water and steam lines in the processing facility. Except where justified, "grey" or non-potable water is not to be used in any product processing or handling area. At no time can non-potable water be substituted for potable water where potable water is required to be used by applicable legislation.

If non-potable water is used on the premises, a map indicating potable and non-potable water lines shall be maintained and updated as needed. Descriptions of the mechanisms used to prevent cross-contamination shall be fully described.

13.5.3   Auditing Guidance

This element will be audited as part of each facility audit through observation, review of records and interviews with operational staff. Evidence may include:

- Annual test results in backflow prevention devices.

- Water delivery lines within the premises are in good condition;

- The supply of potable water is adequately protected;

- Potable and non-potable water lines and outlets are clearly labeled;

- When grey water is used, there is no opportunity for cross-contamination between potable and non-potable water lines;

- There is no opportunity for non-potable water to be used in lieu of potable water.

13.5.4 Air Quality

13.5.4.1 Compressed air that contacts packaging products shall be clean and present no risk to food safety;

13.5.4.2 Compressed air systems used in the manufacturing process shall be maintained and regularly monitored for purity.

13.5.4   Implementation Guidance

What does it mean?

This applies to compressed air that comes into contact with resin, rework, recycle or exposed (e.g. pneumatic conveying, dust blower), product contact surfaces and interior surface packaging. It does not apply to air that does not come into contact with packages or product contact surfaces.

Purity means absence of contaminants that could cause a product safety hazard. Pure air means the air is free of risk for contamination of the products. Essentially, the air must not contribute any contamination to the packages that ultimately comes in direct contact with food.

What do I have to do?

13.5.4.1
Compressed air can be a source of chemical and microbiological contamination. Potential contaminants can include particulates, including dirt (microorganisms, atmospheric dirt and solid particulates, rust and pipe scales), water (water vapor, condensed liquid water and water aerosols) and oil (oil vapor, liquid oil and oil aerosols).

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The operation must verify and validate that the compressed air used is appropriate and does not serve as a source of contamination. When compressed air comes in contact with exposed product or direct product contact surfaces, the air compressor must use food grade oil.

Preventive maintenance (PM) programs need to ensure that an appropriate filtration program is in place at the point of use and the filters are cleaned or changed at a frequency appropriate to the product and process or following any maintenance to air supply source or equipment. Any maintenance must be done in a hygienic manner.

Wherever the compressed air comes in direct contact with food contact surfaces of the packaging or indirectly contacts resin, recycle plastics or in process rework (defects), high efficiency filters are to be in place at point-of-use where the air enters the final section of tubing (not in the compressor room). This will significantly reduce the risk of microbial contamination of the product from the air. The recommended final stage of filtration in these product contact areas should have a rating of 0.01 micron with an efficiency of 99.999% (or as determined by appropriate risk analysis). Sufficient filtration is to be in place directly upstream of the final stage to protect the final stage from oil and water aerosols.

Nozzles and air hoses are to be in good condition, properly repaired and maintained in a hygienic state (e.g., cleaned and sanitized). Hoses and nozzles are to be kept off the ground.

It is generally advisable to locate the filtration as close as practically possible (near the "point of use," or the point where air contacts the product contact surfaces), so as to not have long lengths of piping/tubing between the microbial removal filter and the air/product contact point.

13.5.4.2
Testing can be conducted to validate the compressed air-filtration control system's effectiveness based on the risk to the product; however, testing must be conducted at a minimum of once a year. Testing can be done in-house or by a contracted party. Test requirements and number of samples will be based on the risk to the product and process. Microbiological testing can include testing for aerobic plate count and/or indicator organisms as appropriate to the operation. Testing for moisture is to be considered if moisture is a potential risk to the product (e.g., dry operations).

Aseptic sample collection needs to be used. There are a wide variety of measures available, including the use of air sampling equipment, use of sterile sponges, membrane filtration and others.

The site may consider the following controls for particulates
   i.   Intake filters to remove atmospheric dirt and solid particulates.
   ii. Microorganisms – A point-of-use filter, minimum 0.01 micron, prevent pathogenic microorganisms from contaminating the product. An effective PM program should be in place to maintain the integrity of the filter. Validation from the filter manufacturer is often considered adequate validation.
   iii. Water, including vapor, liquid, condensed. A dryer in the compressed air system provides effective control. An effective PM program should be in place.
   iv. Oil, including vapor, liquid and aerosols. The presence of coalescing filters in the compressed air system effectively removes contamination. An effective PM program should be in place to maintain the integrity of the filter.

Industry Standards of Reference:

For general compressed air quality standards within a food plant, ISO 8573-1 standards are a very good reference. These standards provide a good baseline for quantifying compressed air quality relative to moisture, oil content (carryover from compressor), as well as general particulate contamination. ISO 8573-1 does not, however, provide guidance for microbial contamination. For areas where the compressed air comes in direct contact with food or food contact surfaces, ISO 8573-7 provides a standardized method for collecting compressed air samples for microbial testing; however, it leaves the user to determine the acceptable type and level of CFU content.

13.5.7   Auditing Guidance

Air quality program and test procedures will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each facility audit through observation, review of records and interviews with operating personnel. Evidence may include:

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- The condition of air compressors and compressed air used to transport product, or otherwise to come into contact with exposed product, product contact surfaces, resin, rework (defects) or finished packaging materials;

- Compressed air that is in contact with product in process packaging (i.e. resin) or finished packaging is filtered in accordance with the site's risk assessment or otherwise treated;

- Filters are checked or changed at a frequency based on the air quality program; review corrective actions;

- Staff understands the proper maintenance and handling of filtered air;

- The site has a standard for microbiological purity of compressed air that contacts product packaging as well as a process for testing including frequency and testing protocols;

- Compressed air test protocols and results for microbial purity;

- Maintenance staff has the data specification sheet for the filter housing;

- Follow up with preventative maintenance, filter integrity checks, and SSOPs;

- Performance characteristics of the filters are in place and match the risks identified in the site's assessment;

- Identification of the level of filtration at the point-of-use for commercially sterile air.

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13.6   Storage and Transport

13.6.1 Storage of Food Contact Packaging

13.6.1.1 Rooms used for the storage of food contact packaging shall be located away from wet areas and constructed to protect the product from contamination and deterioration.

13.6.1.2 Equipment used for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room.

13.6.1.3 Vehicles used in storage rooms shall be designed and operated so as not to present a food safety hazard.

13.6.1   Implementation Guidance

What does it mean?

Rooms where raw materials, ingredients, packaging and other dry goods - apart from hazardous chemicals, (refer 13.6.4) are stored, must be clean, dry and accessible.

What do I have to do?

Ingredients, raw materials, packaging and packing materials must be stored in designated storage areas which protect the materials from contamination and deterioration. These materials shall be stored only in dry areas of the processing room when staged for use during processing or packing. Ensure that packaging storage areas are adequately protected from the elements, rodents and other pests. Packaging materials which become product contact surfaces must be protected from dust and other contaminants while in storage. This can be accomplished by the use of plastic wrap or other means to protect the packaging material.

Materials used in the construction of storage rooms must comply with 13.2.1.1 and light fittings in storage areas must comply with 13.2.5.2.

The storage for packaging shall be constructed of impervious materials and designed to be easy to clean. The supplier must limit the use of wooden racks for storage of packaging and packing materials to dry areas only. Stands and the lower shelves of stands should be at least 150 mm (6 inches), or as required by applicable regulation above floor level to facilitate proper cleaning.

Fork lifts, hand-forks and other vehicles used in storage areas must be safe to use, hydrocarbon emissions must be controlled and operated in a manner that does not cause damage to product and equipment.

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13.6.1   Auditing Guidance

This element will be audited as part of each facility audit through observation and interviews with operational staff. Evidence may include:

- Product storage rooms are located away from wet processing areas;

- Storage rooms are adequately designed to protect , raw ingredients, materials, packaging and finished packaging materials;

- Packaging storage racks are made of material that is easily cleanable; no materials are stored on the floor;

- Packaging storage racks allow access to floor/wall junction for cleaning; no evidence of presence of insect or debris under storage racks;

- Absence of pest infestation within the storage and warehouse areas;

- Vehicles used in product processing, storage or cold storage areas do not release hydrocarbon emissions or present a hazard to product, ingredients or product packaging materials.

13.6.2 Storage of Equipment

13.6.2.1 Storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment.

13.6.2   Implementation Guidance

What does it mean?

Rooms and areas designated as storage areas for equipment, tools, and re-useable containers must be designed and constructed to protect clean equipment.

What do I have to do?

Materials used in the construction of storage rooms must comply with 13.2.1.1 and light fittings in storage areas must comply with 13.2.4.2.

Equipment storage rooms may be adjacent to equipment cleaning areas but kept separate to ensure there is no commingling of dirty and cleaned tools, and equipment.

Off-floor storage is to be provided to ensure tools and equipment are not stored on the floor.

13.6.2   Auditing Guidance

This element will be audited as part of each facility audit through observation. Evidence may include:

- There is a dedicated storage area for clean tools, and equipment; unclean or dirty tools and equipment are not stored in the same area as clean tools;

- The equipment storage area allows access for cleaning;

- Storage racks used in the storage area are cleanable and tools and equipment are stored off the floor;

- Staff responsible for storage room are aware of appropriate protocols for storing clean equipment;

- The equipment storage area protects equipment against contamination during storage.

13.6.3 Storage of Hazardous Chemicals and Toxic Substances

13.6.3.1 Hazardous chemicals and toxic substances with the potential for contamination of packaging materials shall be stored so as not to present a hazard to staff, packaging, or areas in which packaging is handled, stored or transported.

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13.6.3   Implementation Guidance

What does it mean?

Cleaning chemicals, pesticides, agricultural chemicals, lubricants, oil, grease, boiler chemicals, etc. plus any other toxic substances must be stored in designated separately secure storage areas.

What do I have to do?

There must be clearly visible means of separation of these groups of chemicals or toxic substances. They must not be stored on the same shelf or above each other on the same rack. Pest management chemicals shall be stored separate from cleaning chemicals and separate from engineering chemicals. Bulk containers of hazardous chemicals or toxic substances must have sufficient spill-proof procedures that ensure that no cross-contamination can occur.   There must be signage indicating this area is a hazardous chemical storage area.

Chemical delivery systems installed in manufacturing areas will be clearly labelled to identify their use and all chemical containers connected to these systems will remain connected while in use and identified through proper labels. Only personnel who have been properly trained in the use of the system will be authorized for access and use of the system.

Chemical storage areas must comply with local or national regulations, be designed to contain spillages, and be ventilated, secure and lockable. Only approved and authorized chemicals are to be stored. An inventory of stored chemicals must be available at all times.

Chemicals must be stores in their original containers or transferred to specifically designed bulk storage units that are correctly labeled.

Tools or equipment used for product must not be stored in the same room as hazardous chemicals.

The supplier must ensure that Safety Data Sheets (SDS) are readily available and accessible to personnel handling or coming into contact with hazardous chemicals. The supplier must also ensure that personnel have been trained in the safe handling and use of all hazardous chemicals in use on site as required by legislation.

Please refer to 13.2.9.5 for pest control chemicals and 13.2.11.7 for cleaning chemicals.

13.6.3   Auditing Guidance

This element will be audited as part of each facility audit through observation and interviews with operators, cleaners and pest control personnel. Evidence may include:

- There is one or more designated storage rooms for storing of chemicals;
- Chemical storage rooms are correctly designed and constructed, and meet regulatory standards;
- Chemical storage rooms are ventilated, secure and lockable;
- Details inventory records of stored chemicals are available and accurate;
- The inventory agrees with the actual chemicals stored in the storage room;
- Only authorized chemicals are stored;
- There is appropriate signage indicating the area as a hazardous storage area and that is visible to the staff;
- The chemical storage areas are separate from production areas, and secured;
- There is spill control and spill kits available in the chemical storage rooms;
- There are no product processing tools, utensils or equipment stored with hazardous chemicals;
- Daily/shift supplies of cleaning chemicals, if used, are stored correctly;
- Packaging is not stored in an area used to store hazardous chemicals;
- Sanitizers and detergents are not stored with pesticides or other toxic chemicals;
- Chemicals are stored in labeled, original containers or properly labeled secondary containers;

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- There are instructions on safe handling of chemicals and that they are readily available to the staff;

- Confirm that SDS are available for all available chemicals.

13.6.4 Alternative Storage and Handling of Goods

13.6.4.1 Where goods described in 13.6.1 to 13.6.3 are held under temporary or overflow conditions that are not designed for the safe storage of goods, a risk analysis shall be undertaken to ensure there is no risk to the integrity of those goods or contamination or adverse effect on food safety and quality.

13.6.4   Implementation Guidance

What does it mean?

There may be times when temporary or overflow storage is required for goods, ingredients, packaging materials or chemicals. This must be an occasional occurrence only and must not become the status quo. Temporary storage must be evaluated according to a risk analysis.

What do I have to do?

Where temporary or overflow storage is used, a risk analysis must be undertaken to ensure the stored product is not at risk or pose a risk to products, processes or personnel. The risk analysis must be documented and be available every time overflow storage is applied.

In particular:

- Product must be held at the required temperature and in clean and sanitary conditions;

- Dry ingredients, and packaging materials must be held in a dry, clean area that is free from pests;

- Chemicals must be stored in a safe secure area that complies with local regulations and does not pose a risk to personnel or other products.

13.6.4   Auditing Guidance

This element will be audited as part of each facility audit through observation and interviews with operators. Evidence may include:

- Alternative storage is being properly used;

- There is no evidence of pest infestation;

- Receiving and loading docks meet food safety standards (i.e., no gaps or pest entry around dock doors and dock doors are in good condition);

- Food safety and pest control management procedures are implemented in alternative storage;

- Risk analysis that has been conducted for alternative storage;

- Materials or products are not being stored continuously in temporary storage;

- Staff understands when alternate storage is to be used;

- There is no risk of product contamination from the use of temporary storage.

13.6.5 Loading, Transport and Unloading Practices

13.6.5.1 The practices applied during loading, transport and unloading of food contact packaging shall be documented, implemented and designed to maintain appropriate storage conditions and product integrity. Packaging shall be loaded, transported and unloaded under conditions suitable to prevent cross contamination.

13.6.5   Implementation Guidance

What does it mean?

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The duty of assuring product safety and quality of the supplier's product continues from when ingredients and materials are first unloaded at the site through when the finished product is placed into storage and loaded ready for distribution. Loading, unloading and distribution procedures must be documented and implemented.

What do I have to do?

Conditions for storage, loading and unloading will vary depending on the type, nature and temperature of the commodity. Documented procedures must cover each type (e.g., bulk, bagged, packaging,) of product delivered into or out from the site.

Some suppliers have their own transport, some suppliers use contract transport. Where contract services are used, the transport protocol will be referenced in the contract with the provider (refer 2.3.3).

13.6.5   Auditing Guidance

Transport (i.e., loading, unloading and distribution) procedures will be reviewed as part of the initial desk audit. Subsequently, this element will be audited as part of each facility audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Methods used to load and unload materials and products are in compliance with company procedures;

- Methods used for the transportation of products including trailer checks prior to loading are documented;

- Receiving staff is aware and properly executes the procedure to accept raw materials and ingredients, and can execute corrective actions for noted concerns;

- The documented methods are effectively implemented and protect the product.

13.6.6 Loading

13.6.6.1 Vehicles (trucks/vans/containers) used for transporting of food contact packaging shall be inspected prior to loading to ensure they are clean, in good repair, suitable for the purpose and free from odors or other conditions that may impact negatively on the product.

13.6.6.2 Loading practices shall be designed to minimize unnecessary exposure of product to conditions detrimental to maintaining product integrity.

13.6.6   Implementation Guidance

What does it mean?

Loading practices shall be documented as per 13.6.6. They shall include conditions and inspections for outbound refrigerated and ambient trucks and trailers.

What do I have to do?

For all outbound trucks and trailers a visual inspection must be conducted for cleanliness, pest infestation and structural conditions and to verify that all trucks/trailers are free of offensive odors. All inspection findings are to be maintained in records.

13.6.6   Auditing Guidance

This element will be audited as part of each facility audit by observations, review of records and interview with warehouse operators and drivers Evidence may include:

- Pre-shipment inspections are conducted on transportation vehicles for cleanliness, maintenance, and suitability;

- The requirement for pre-shipment inspection is included in the transport protocol (refer 13.6.5) and the transport contract (refer 2.3.3);

- Loading and staging of product does not expose product to potential abuse or contamination;

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> • Warehouse and loading staff is aware of and can execute procedures and requirements for loading packaging onto trailers.

13.7   Control of Foreign Matter Contamination

13.7.1 Process Flow

13.7.1.1 The process flow shall be designed to prevent cross-contamination and organized so that there is a continuous flow of product through the process.

13.7.1.2 The flow of personnel shall be managed such that the potential for contamination is minimized.

Implementation Guidance

What does it mean?

The process flow shall be designed to prevent cross-contamination and organized so that there is a continuous flow of product through the process.

The flow of personnel shall be managed such that the potential for contamination is minimized.

What do I have to do?

The design of the facility must prevent contamination to raw materials or finished packaging from production activities or personnel, including foot-traffic. The supplier shall conduct a risk assessment to determine areas of highest risk and interventions used to mitigate the risk. Methods and protocols to monitor interventions to ensure risks are correctly managed must be included in the procedures.

Auditing Guidance

This element will be audited as part of each facility audit by observations, review of records and interview with warehouse operators and drivers Evidence may include:

- Risk assessment is accurate and interventions are appropriate;
- Personnel follow procedures for access and foot traffic;
- Production flow ensures there is no potential contamination;
- Staff understands proper access to the facility.

13.7.2 Control of Foreign Matter

13.7.2.1 The responsibility and methods used to prevent foreign matter contamination of product shall be documented, implemented and communicated to all staff.

13.7.2.2 Inspections shall be performed to ensure plant and equipment remains in good condition and potential contaminants have not detached or become damaged or deteriorated. The use of temporary fasteners such as string, wire or tape to fix or hold equipment shall not be permitted.

13.7.2.3 The following preventative measures shall be implemented where applicable to prevent glass contamination:

i.   All glass objects or similar material in product handling/contact zones shall be listed in a glass register including details of their location;

ii.   Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where product is contained in packaging made from these materials, or measurement instruments with glass dial covers or MIG thermometers required under regulation) shall not be permitted in product processing /contact zones;

iii.   Conduct regular inspections of product handling/contact zones to ensure they are free of glass or other like material and to establish no changes to the condition of the objects listed in the glass register; and

iv.   Inspect glass instrument dial covers on processing equipment and MIG thermometers at the start and finish of each shift to confirm they have not been damaged.

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13.7.1.4 Wooden pallets and other wooden utensils used in packaging handling and storage shall be dedicated for that purpose, clean, maintained in good order and their condition subject to regular inspection.

13.7.2.5 Loose metal objects on equipment, equipment covers and overhead structures shall be removed or tightly fixed so as not to present a hazard.

13.7.2   Implementation Guidance

What does it mean?

Foreign matter can originate from:

- External sources such as pests, raw material and packaging material (e.g., plastic and/or cardboard embedded in product by the supplier);

- Internal sources of foreign matter include the building (e.g., rust, insects and insulation), surface coatings (e.g., flaking paint, damaged render), equipment (e.g., nuts, pins, screws, washers, etc.), metal swarf, glass (e.g., from windows, or) and wood (e.g., from pallets or brooms or other equipment).

In all cases, where there is risk for potential foreign matter contamination, procedures must be in place to eliminate or minimize the risk of foreign materials entering the product. The supplier needs to be aware of potential sources of foreign matter contamination, however, customer complaints (refer 2.1.5) may provide an indication of the prevalence and priority.

What do I have to do?

The foreign matter (including glass) protocol must outline the sources of foreign materials, the methods of control and the responsibility for taking action when foreign materials or glass are detected in the manufacturing environment.

The protocol shall include removal of all tools and machine parts from the processing areas when maintenance has been completed (refer 13.2.7.2 vi) and this shall be implemented and supervised.   Plant and equipment must be inspected regularly to ensure it remains in good condition so that nothing has detached, damaged or deteriorated. Personnel must be encouraged to report all recognized sources of potential contaminants. This includes potential deterioration of e.g. metal blades in mixers and other areas where metal/metal wear can cause metal swarf to tear off.

Fabricated equipment covers shall be used wherever possible to prevent potential contamination from nuts, bolts, etc. Temporary repairs shall not be utilized within general processing facilities. The use of plastic, tape, string, cardboard or other non-permanent materials as a means to repair or alter the operation or equipment must be avoided. The site shall have included within its maintenance process (refer 13.2.7) control measures to be taken when repairs are needed during process to protect product from foreign materials that could impact product safety and quality. Containers, equipment and other utensils made of glass, porcelain, ceramics or other like material must not be permitted in any processing or product handling area.

Quality assurance staff must replace all laboratory glass containers with plastic containers if possible and avoid using glass instruments in processing areas. Regular inspections must be made to ensure that these areas are free of glass and staff must be made aware of their responsibility to adhere to the company foreign matter and glass protocol. All overhead lighting must be protected and shielded (refer 13.2.4).

The risk assessment of foreign material contamination and preventative controls shall be included within the product safety plan (2.4.3) and product quality plan (2.4.4) development. Each site must assess its risks of foreign material contamination to product and develop specific controls within its environment.

Wooden pallets are part of the food packaging industry and are not expected to be banned from processing environments. Depending on the type of operation and the products being produced, the types of controls for the management of pallets can vary from one facility to another. At a minimum, all general processing facilities should have a pallet management program in place where pallets undergo inspection for broken slats or wood pieces protruding which could pose a risk to products. If pallets are stored for prolonged periods outdoor, then the pallets need to be cleaned and inspected for vermin prior to entry into the processing area.

For wet processing environments, the use of clean slip sheets or plastic pallets may be utilized to help to minimize the risk of foreign material or microbiological contamination to the products.

Knives and cutting instruments must be counted and controlled and kept clean to avoid cross-contamination.

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13.7.2 Auditing Guidance

Foreign matter control (including glass) procedures shall be reviewed as part of the initial desk audit. Subsequently, foreign matter control procedures will be audited as part of each facility audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Foreign matter control procedures are documented;

- Foreign matter control procedures identify all potential sources of foreign matter contamination;

- Foreign matter control procedures are effectively implemented;

- Foreign matter control procedures include responsibility for foreign matter control;

- Foreign matter control procedures are communicated to staff;

- Inspections including corrective actions for noted discrepancies are conducted to prevent foreign material contamination of product;

- Temporary repairs are not used within the processing areas or where product is handled or stored;

- Line staff is familiar with the proper response procedure on damaged or broken equipment, tools or utensils;

- A glass and brittle plastic register is in place and covers all glass and brittle plastic at the site;

- Glass inspections are conducted regularly including instrument dial covers and thermometers;

- The condition of glass, brittle plastic, light shields, and instrument dial covers and thermometers is regularly inspected for integrity;

- Wood used in processing / handling area including pallets are well maintained and clean;

- There are no loose materials, tools, or debris on processing equipment;

- Knives and cutting instruments, if used, are clean and sanitized and in good repair.

13.7.3 Managing Foreign Matter Contamination Incidents

13.7.3.1 In all cases of foreign matter contamination the affected batch or item shall be isolated, inspected, reworked or disposed of.

13.7.3.2 In circumstances where glass or similar material breakage occurs the affected area is to be isolated, cleaned and thoroughly inspected (including cleaning equipment and footwear) and cleared by a suitably responsible person prior to the commencement of operations.

13.7.3   Implementation Guidance

What does it mean?

The site must have established criteria for the identification, isolation and disposition of product affected when a foreign material issue is detected. The supplier must manage the incident with established procedures consistent with element 2.5.5 (Corrections and Preventative Actions).

What do I have to do?

The supplier must have a procedure in place to identify, isolate, inspect and rework or dispose of product that is known to be at risk of foreign matter contamination. This shall include isolation, labeling, quarantine of affected product, and depending on the nature of the suspected contaminant, further inspection or examination of the product to determine the source and extent of the contamination so that a decision can be taken on its disposition.

Where a glass or similar breakage occurs, the procedure (refer 13.7.2) must include a glass clean-up process that covers the footprint of the tramp glass. For example, breakage on high speed beverage bottling lines can spray glass over a wide area. The procedure must include a shut-down of the whole area, and a thorough

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clean-up to eliminate all broken glass. Brooms, brushes, vacuums and footwear must be included in the clean-up. The area must be thoroughly inspected before recommencing operations.

13.7.3   Auditing Guidance

The foreign matter control (including glass) procedures shall be reviewed as part of the initial desk audit. Subsequently, the procedure including glass clean-up protocols will be audited as part of each facility audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Isolation and rework/disposition of packaging materials, when involved is included in a foreign matter control procedure;

- Staff can execute clean-up procedures for glass and brittle plastic breakage;

- Glass breakage clean-up protocols and equipment are documented and implemented;

- Glass and brittle plastic breakage procedure is included in the foreign matter control procedure;

- Glass and brittle plastic breakage procedure includes clean-up of footwear, tools, brooms, brushes and other equipment;

- Staff training records on glass and brittle plastic breakage and proper clean-up are complete.

13.8   Waste Disposal

13.8.1 Dry and Liquid Waste Disposal

13.8.1.1 The responsibility and methods used to collect and handle dry, wet and liquid waste and store prior to removal from the premises shall be documented and implemented.

13.8.1.2 Waste shall be removed on a regular basis and not build up in food handling or storage areas. Designated waste accumulation areas shall be maintained in a clean and tidy condition until such time as external waste collection is undertaken.

13.8.1.3 Trolleys, vehicles waste disposal equipment, collection bins and storage areas shall be maintained in a serviceable condition and cleaned and sanitized regularly so as not to attract pests and other vermin.

13.8.1.4 A documented procedure shall be in place for the controlled disposal of trademarked or other printed materials. Where a contracted disposal service is used, the disposal process shall be reviewed regularly to confirm compliance.

13.8.1.5 Reviews of the effectiveness of waste management will form part of daily hygiene inspections and the results of these inspections shall be included in the relevant hygiene reports.

13.8.1   Implementation Guidance

What does it mean?

The procedures for storage and disposal of all types of waste – solid, molten and liquid processing aids (including water) – must be documented and implemented. The procedure will include how waste is contained in appropriate, covered and labeled containers; the frequency of disposal; how it is disposed of; and who is responsible for it. Local regulations and community expectations concerning recycling and waste disposal and transport must also be considered.

What do I have to do?

As with solid waste, the disposal of any liquid waste from production and handling areas is essential to the maintenance of a clean and safe working environment. Procedures are to be in place to monitor the effective removal of liquid and solid wastes per written plant procedures.

On-site incinerators, compactors or other waste collecting/disposal equipment need to be designed, sited, constructed and operated so as not to create a hazard to product or the surrounding environment. Compactors and other waste storage areas must not be sited adjacent to any area where finished packages are exposed.

Cafeteria/lunch room food waste shall be stored separately from packaging waste in covered pest-proofed

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containers and emptied on a basis that prevents the attraction of pests.

At the end of the each shift or day (depending on the site and operation), all office trash, processing trash, packaging material trash, etc. needs to be removed by designated employees and disposed of in the external trash receptacle. All trash generated in the manufacturing and handling areas must be separated for recycling where possible.

Empty chemical drums shall be collected and transported to secured storage (refer 13.2.11.7).

Exterior waste containers need coverage or lids to prevent attracting flies or vermin. It is also advisable to secure waste containers in regards to site security requirements (refer 2.7)

Review of the waste collection and handling system should be incorporated as part of the internal audit program of the site (refer 2.5.7).

13.8.1   Auditing Guidance

Waste handling, storage and disposal procedures shall be reviewed as part of the initial desk audit. Subsequently, waste storage and removal will be audited as part of each facility audit through observation, review of records and interviews with operating personnel. Evidence may include:

- Waste handling, storage and disposal procedures are fully documented and implemented;

- Waste handling, storage and disposal procedures adequately dispose of waste without risk of product contamination;

- Waste is regularly removed from processing and product handling areas and there is no debris or waste found on the floors or under equipment;

- Waste collection and storage areas are maintained and cleaned;

- Containers for waste are properly labeled, maintained and cleaned with no overflow of waste or leaking of liquid waste;

- Trolleys, vehicles and equipment used for waste are properly cleaned;

- Daily inspections are conducted to monitor handling of waste;

- Records are maintained of waste disposal;

- The waste system is included in the internal audit program and corrective actions are implemented in a timely manner.

13.9   Exterior

13.9.1 Grounds and Roadways

13.9.1.1 The grounds and area surrounding the premises shall be maintained to minimize dust and be kept free of waste or accumulated debris so as not to attract pests and vermin.

13.9.1.2 Paths, roadways and loading and unloading areas shall be maintained so as not to present a hazard to the food safety operation of the premises.

13.9.1.3 Surroundings shall be kept neat and tidy and not present a hazard to the hygienic and sanitary operation of the premises.

13.9.1   Implementation Guidance

What does it mean?

Unkempt surrounds (including the accumulation of unused equipment, pallets, bins, drums or waste) can provide harborage for vermin and other pests and in turn pose a serious hazard to the hygienic operation of the premises.

What do I have to do?

The provision of lawn and landscaping is effective for sealing large traffic areas. High vehicle traffic areas are

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also required to be effectively sealed to prevent dusty conditions.

Exterior construction projects that impact sealed areas should be reviewed, and controls established on a temporary basis during the project timeline.

Where employee amenities are external to the site, the access to the amenities must be sealed, and should be covered to allow for weather conditions.

13.9.1   Auditing Guidance

This element shall be reviewed as part of each facility audit. Evidence may include:

- Internal audit records on inspection of exterior grounds and buildings are maintained;
- Out buildings are clean of debris and do not provide a pest harborage area;
- Exterior grounds are properly maintained, tidy and uncluttered and do not provide pest harborage areas;
- Exterior grounds including dock areas are managed to minimize dust or other hazards;
- Exterior trash cans are clean and contain the waste;
- There is no waste, waste water, trash or debris on the exterior grounds;
- Exterior paths and roadways are managed to minimize dust or other hazards;
- Exterior loading and unloading areas are maintained to minimize hazards;
- Grass and vegetation is kept under control in surrounding areas and do not provide a pest harborage area;
- Equipment that is stored outside is protected from the weather and does not provide a pest harborage area;
- External paths from amenities to the site are sealed.