Suggestions for improvements to this Code are encouraged from all parties. Written comments are to be sent to SQFI at 2345 Crystal Drive, Suite 800, Arlington, VA, 22202, USA.

Contents

Part A: Introduction and Code Protocols

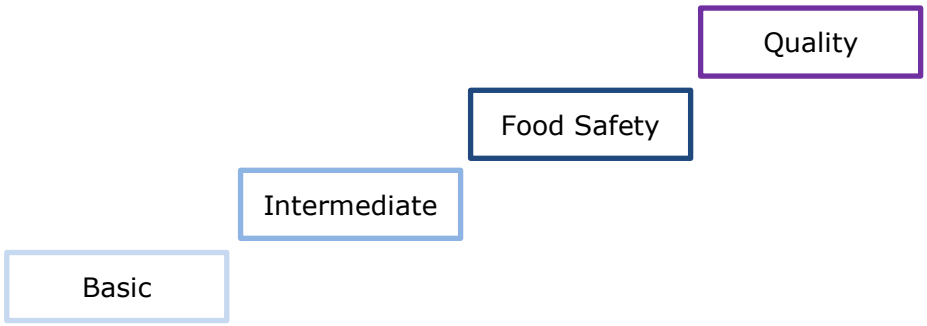
Introduction
The SQF family of food safety and quality codes are designed to meet industry, customer and regulatory requirements for all sectors of the food supply chain from primary production through to food retailing and the manufacture of food packaging. The food safety codes are recognized by retailers, manufacturers and food service companies when assessing the food safety programs for their suppliers. The Food Safety codes are also benchmarked against the requirements for food safety standards from the Global Food Safety Initiative (GFSI).

The stakeholders of GFSI recognized that the full requirements of the benchmarked standards, including SQF's codes, where difficult to achieve for small and less developed farms and businesses. As a result a more step-wise approach to building food safety programs that could lead to certification in a full GFSI recognized standard was created. It is called the GFSI Global Markets programme and SQF has aligned some of it introductory codes to this programme. The small and less developed manufacturing sector can use the basic and intermediate Fundamental codes as certifications that ultimately can lead to certification to the full SQF Food Safety Code for Manufacturing

Benefits of SQF Basic and Intermediate Fundamental Manufacturing Codes (SQF Code)
Manufacturing site can benefit from certification to the SQF Basic and Intermediate Fundamental Codes in the following manner:

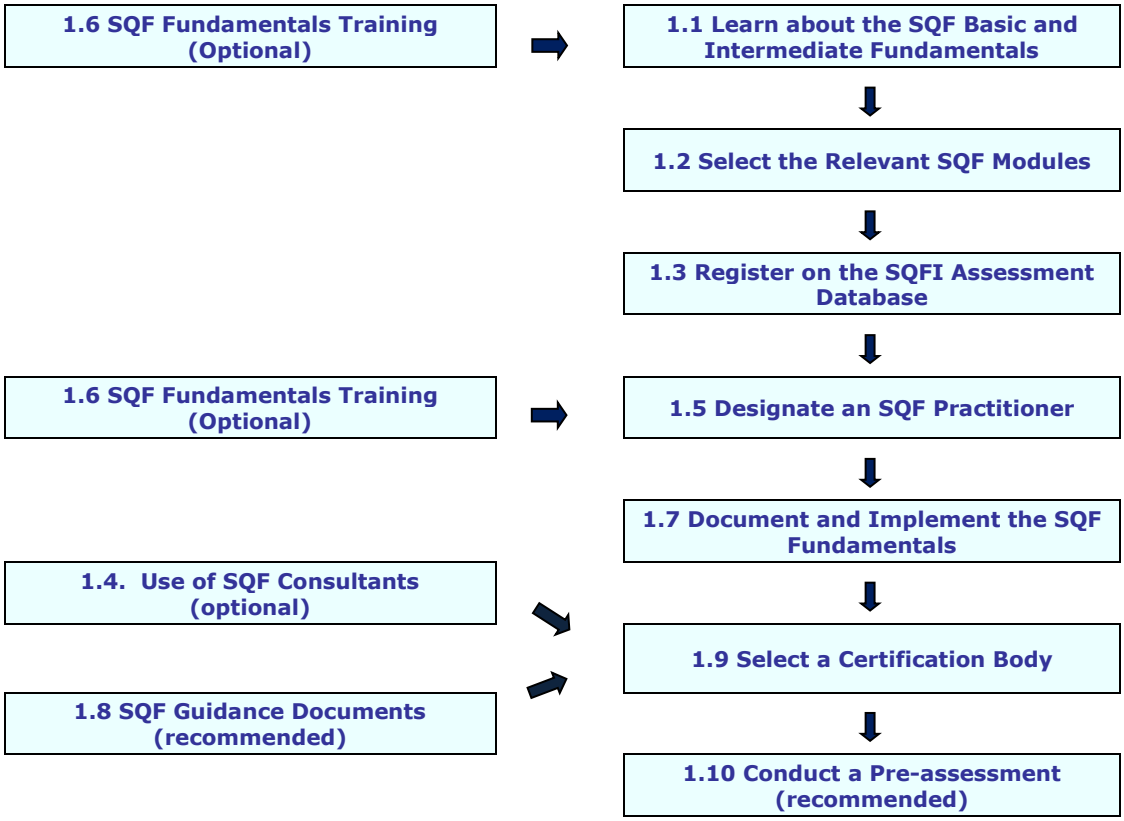
- Alignment with GFSI Global Markets progamme which can be supported or approved by customers and regulators.
- Provides certification under an accredited 3rd party audit program, i.e. SQFI, that ensures auditors and certification bodies are competent and approved.
- Certificates and audit reports can be available to buyers through the SQF database.
- Provides sites with a framework to document their Good Manufacturing Practices (GMP's) and build on them to achieve certification to the SQF Food Safety Code for Manufacturing.

The SQF Basic and Intermediate Fundamental Codes are aligned with the full SQF Food Safety Code for Manufacturing code in that modules required for certification (see below) are similarly numbered as are the requirement sections. The basic and intermediate codes are separate such that certification can be granted to each separately. The intermediate codes builds on the basic code and any additional requirements will be ***bolded and italicized***.



1. Preparing for Certification

Figure 1: Steps for Certification



1.1 Learn about the SQF Basic and Intermediate Fundamentals

There are several ways to learn how to implement the SQF Codes within your site. The following options are available:

- Attend a training course SQF Fundamentals Training (refer Part A, 1.6) through a licensed SQF training center (recommended);
- Take the online training course SQF Fundamentals Training available from the SQFI website (sqfi.com);
- Train yourself by downloading the SQF Codes from the SQFI website (sqfi.com) free of charge, and read how to apply it to your industry sector.

1.2 Select the Relevant SQF Modules

SQFI recognizes that food safety practices differ depending on the food safety risk to the product and the process, and has designed the SQF Codes to meet the individual requirements of each industry sector.

The SQF food sector categories and applicable modules are listed in full in Appendix 1. It includes a more detailed description with examples, level of risk, and the relationship with the GFSI industry scopes outlined in the GFSI Requirements Document.

However, the following provides a guide to the SQF Codes and modules that apply to each food manufacturing sector or groups of industry sectors.

SQF Basic and Intermediate Fundamentals - Manufacturing **Entry level Food Safety Code for small or developing food and pet food manufacturers**		
FSC	**Category**	**Applicable GMP Modules**
8	Processing of Manufactured Meats and Poultry	Module 11: GMP for processing of food products
9	Harvest and Intensive Farming of Seafood Processing	Module 11: GMP for processing of food products
10	Dairy Food Processing	Module 11: GMP for processing of food products
11	Apiculture and Honey Processing	Module 11: GMP for processing of food products
12	Egg Processing	Module 11: GMP for processing of food products
13	Bakery and Snack Food Processing	Module 11: GMP for processing of food products
14	Fruit, Vegetable and Nut Processing, and Fruit Juices	Module 11: GMP for processing of food products
15	Canning, UHT and Aseptic Operations	Module 11: GMP for processing of food products
16	Ice, Drink and Beverage Processing	Module 11: GMP for processing of food products
17	Confectionery Manufacturing	Module 11: GMP for processing of food products
18	Preserved Foods Manufacture	Module 11: GMP for processing of food products
19	Food Ingredient Manufacture	Module 11: GMP for processing of food products
20	Recipe Meals Manufacture	Module 11: GMP for processing of food products
21	Oils, Fats, and the Manufacture of oil or fat-based spreads	Module 11: GMP for processing of food products
22	Processing of Cereal Grains	Module 11: GMP for processing of food products
25	Repackaging of products not manufactured on site	Module 11: GMP for processing of food products
26	Food Storage and Distribution	Module 11: GMP for processing of food products
31	Manufacture of Dietary Supplements	Module 11: GMP for processing of food products
33	Manufacture of Food Processing Aides	Module 11: GMP for processing of food products

1.3 Register on the SQF Database

To be considered for SQF certification, sites are required to register in the SQFI assessment database. The database can be accessed from the SQFI website (sqfi.com).

Registration is annual, and there is a fee per site payable at registration and renewal. The fee scale is dependent on the size of the site as determined by gross annual sales revenue. The fee scale is available on the SQFI website (sqfi.com).

Sites must register with SQFI prior to achieving certification, and must remain registered at all times to retain their certification. If the site fails to maintain registration, the certificate will be invalid until the site is properly registered in the SQFI assessment database.

1.4 Use of SQF Consultants

Sites can choose to develop and implement their SQF Code using their own qualified resources or they can utilize the services of a registered SQF consultant. All SQF consultants are registered by the SQFI to work in specific food sector categories (refer Part A, Table 1 and Appendix 1). They are issued with an identity card indicating the food sector categories in which they are registered. Sites are encouraged to confirm an SQF consultant's registration details on the SQFI website (sqfi.com) before engaging their services. The criteria outlining the requirements necessary to qualify as an SQF consultant and the application forms are available on the SQFI website (sqfi.com). The SQF Consultant Code of Conduct outlines the practices expected of SQF consultants.

1.5 Food Safety Responsibility

Whether or not an SQF consultant is used, the SQF Code requires that every site has a suitably qualified full time employee to oversee the development, implementation, review and maintenance of the SQF System, including the Good Manufacturing Practices (GMP). The requirements for a qualified person responsible for implementing and maintaining the SQF system are described in the system elements, 2.1.2.4 and 2.1.2.5.

Some sites may choose to have more than one person responsible for the SQF System to meet shift and operational requirements.

1.6 SQF Fundamentals Training

An SQF Fundamentals training course is available through the SQFI network of licensed training centers. Employees who are responsible for designing, implementing and maintaining the requirements of the SQF Food Safety Fundamentals are encouraged to participate in a training course. Details about the training centers and the countries in which they operate are available on the SQFI website (sqfi.com). The dates and locations of the courses can be obtained by contacting the training centers.

The SQF Fundamentals training course is not mandatory for the person responsible for implementing and maintaining the SQF Code, but is strongly recommended.

The SQFI also has an SQF Fundamentals online training course which can be accessed from the SQFI website (sqfi.com). The online training solution is a web-based education portal where staff can enroll and complete SQF Systems training in their own time and at their own pace.

Training in other food industry disciplines, such as HACCP, Good Manufacturing Practices (GMP) and Internal Auditing may also be required and licensed SQF training centers can provide details of the other training courses they provide.

1.7 Document and Implement the SQF Code

To achieve SQF certification, the site must document and implement the system elements and the relevant GMP Modules of the SQF Code (refer Part A, 1.2). This requires a two stage process:

Document the SQF System – prepare policies, procedures, work instructions and specifications that meet the system elements and Good Manufacturing Practices (GMP) modules of the SQF Code. In other words, "say what you do."

Implement the SQF System – implement the prepared policies, procedures, work instructions and specifications, and keep records to demonstrate compliance to the relevant modules of the SQF Code. In other words, "do what you say." SQFI recommends that a minimum of two months of records be available before a site audit is conducted.

1.8 SQF Guidance Documents

Guidance documents are available for some SQF modules and food sector categories from the SQFI website (sqfi.com). These documents are available to help the site interpret the requirements of the SQF Code and assist with documenting and implementing an SQF System. The documents are developed with the assistance of food sector technical experts.

The guidance documents are available to assist the site, but are not auditable documents. Where there is a divergence between the guidance document and the SQF Code, the SQF Code in English prevails.

1.9 Select a Certification Body

Certification bodies are licensed by SQFI to conduct SQF audits and issue the SQF certificate. SQFI licensed certification bodies are required to be accredited to the international standard ISO/IEC 17065:2012 (or subsequent

versions as applicable) and be subject to annual assessments of their certification activities by SQFI licensed accreditation bodies.

The site is required to have an agreement with a certification body in place at all times which outlines the SQF audit and certification services provided. These include as a minimum:

i. The scope of certification (refer Part A, 2.2);

ii. The expected time to conduct and finalize the audit and the reporting requirements;

iii. The certification body's fee structure;

iv. The conditions under which the SQF certificate is issued, withdrawn or suspended; and

v. The certification body's appeals, complaints and disputes procedure.

A current list of licensed certification bodies is available on the SQFI website (sqfi.com). Certification bodies are also listed in the SQFI assessment database and sites can request a quote or select a certification body online once they have registered.

1.10 Conduct a Pre-assessment Audit

A pre-assessment audit is not mandatory, but is recommended to provide a "health check" of the site's implemented SQF food safety System. A pre-assessment audit can assist in identifying gaps in the site's SQF food safety system so that corrective action can occur before engaging the selected certification body for a full certification audit. It can be conducted using internal resources, a registered SQF consultant, or a registered SQF food safety auditor.

2. The Initial Certification Process

2.1 Selection of the SQF Auditor(s)

SQF food safety auditors must be employed by or contracted to an SQFI licensed certification body, and must be registered with the SQFI.

The certification body shall select the most appropriate qualified SQF food safety auditor(s) for the site's SQF certification audit, including vertically integrated sites. The certification body shall ensure no SQF food safety auditor conducts audits of the same site for more than three consecutive certification cycles.

The certification body must advise the site of the name of the SQF food safety auditor at the time that the SQF audit is scheduled. The site may check the registration and food sector category (ies) of the SQF food safety auditor in the register on the SQFI website (sqfi.com).

2.2 Identifying the Scope of Certification

The scope of certification shall be clearly identified and agreed upon between the site and certification body prior to the initial certification audit and included in the scope of the initial certification audit and all subsequent audits (refer Part A, 2.4). The scope of certification shall determine the relevant system elements and GMP modules to be documented and implemented by the site and audited by the certification body, and cannot be changed during or immediately following a certification or re-certification audit.

For requirements on changing the scope of certification, refer Part A, 5.1.

The scope of certification shall include:

> **The site.** SQF certification is site specific. The entire site, including all premises, support buildings, silos, tanks, loading and unloading bays and external grounds must be included in the scope of certification. Where a site seeks to exempt part of the premises, the request for exemption must be submitted to the certification body in writing prior to the certification audit, detailing the reason for exemption. If approved by the certification body, exemptions shall be listed in the site description in the SQFI assessment database and in audit reports(s). However, all parts of the premises and process that are involved with the production, processing and storage of products included in the scope cannot be exempted.

When activities are carried out in different premises but are overseen by the same senior, operational, and technical management, and are covered by the one SQF System, the site can be expanded to include those premises.

Exempted parts of the site must not be promoted as being covered by the certification. Instances where promotion of exempted equipment or areas of the site are identified and substantiated (either by regular audit or by other means) shall result in immediate withdrawal of the SQF certification.

> **The products.** SQF certification is product specific. The food sector category (ies) and products processed and handled on site shall be identified and agreed in the scope of certification. Where a site seeks to exempt any products processed or handled on site, the request for exemption must be submitted to the certification body in writing prior to the certification audit, explaining the reason for exemption. If approved by the certification body, product exemptions shall be listed in the site description in the SQFI assessment database and in audit reports(s).

2.3 Identifying the Scope of the Audit

The site and the certification body shall agree on the audit scope before the certification audit begins. The scope of the audit shall include:

- The agreed scope of certification including any approved exemptions (refer Part A, 2.2);
- The version of the SQF basic or intermediate Fundamentals – Manufacturing Code, and the applicable GMP Modules;
- The audit duration (refer Part A, 2.5);
- The designated registered SQF food safety auditor; and
- The certification body's fees structure including travel time, report writing, ancillary costs, and costs for close-out of non-conformities.

Once the audit scope is agreed between the site and the certification body, it cannot be changed once the audit has commenced.

2.4 Audit Duration Guide

Once the certification body and site have agreed on the scope of certification, and relevant information to support the scope, the certification body shall provide the site with an estimate of the time it will take to complete the certification audit.

The audit times will vary according to the size and complexity of the site operations. Factors that can impact on the audit duration include:

i. The scope of the audit;

ii. The size of the site and the design of product, and/or people flows;

iii. The number and complexity of product lines, and the overall process;

iv. Whether the product is high or low risk;

v. The complexity of the SQF System design and documentation;

vi. The level of mechanization and labor intensiveness;

vii. The ease of communication with company personnel (consider different languages spoken);

viii. The cooperation of the site's personnel.

Table 1 provides a guide to the duration of an SQF certification audit. Justification is required if the certification body deviates from this guide by greater than thirty (30) percent.

This is a guide only, and the certification body must determine the duration of each certification audit based on the scope of certification, the food safety risk, and the complexity of the processes.

Table 1: SQF Basic and Intermediate Fundamentals Manufacturing Site Audit Duration Table

Step 1	Step 2	Step 3
Code	Basic duration (days) (includes three HACCP plans)	Additional Days based on Size of site
SQF Basic Fundamentals - Manufacturing	0.5 days	0 – 200,000 ft^2 = 0 (0 – 19,000 m^2 = 0) 200,001 – 300,000 ft^2 = 0.5 (19,001 – 27,000 m^2 = 0.5) 300,001 – 500,000 ft^2 = 1.0 (27,000 – 46,000 m^2 = 1.0)
SQF Intermediate Fundamentals - Manufacturing	0.75 days	
Additional time for each HACCP plan(s) *(where there are multiple / different plans)*	0.25 day per additional 3 HACCP plans or 3 additional production/manufacturing processes	

In addition to audit time, the certification body shall provide the site with the time and expected costs for planning, travel, report writing, and close out of non-conformities.

2.5 The Site Audit

The site audit is conducted on site by the SQF food safety auditor appointed by the certification body. It is conducted at a time agreed between the site and the certification body when the main processes are operating. The site audit must include a review of the entire site, including the inside and outside of the building, regardless of the scope of certification and agreed exemptions. The site audit shall include a review of all operational and cleaning shifts and pre-operational inspections, where applicable.

The site audit determines if the SQF Code is effectively implemented as documented. It establishes and verifies the:

i. Effectiveness of the SQF food safety system in its entirety;

ii. Food safety hazards are effectively identified and controlled;

iii. Effective interaction between all elements of the SQF system; and

iv. Level of commitment demonstrated by the site to maintaining an effective SQF system and to meeting their food safety regulatory and customer requirements; and

v. The exempted products or areas of the site do not pose a food safety risk to the products covered under certification.

2.6 Seasonal Production

Initial certification audits for sites involved in seasonal production (i.e. a period in which the major production activity is conducted over not more than five consecutive months) shall be conducted during the peak operational part of the season.

Where sites seek to include products from more than one season within their scope of certification, the site and certification body shall agree to conduct the initial certification audit during the highest risk and/or highest volume production operation. Documentation and records for other seasonal production shall be reviewed as part of the certification audit.

2.8 Non-conformities

Where the SQF food safety auditor finds deviations from the requirements of relevant modules of the SQF Code, the SQF food safety auditor shall advise the site of the number, description, and extent of the non-conformities. Non-conformities may also be referred to as non-conformances.

Non-conformities against the SQF Code shall be graded as follows:

- **A minor non-conformity** is an omission or deficiency the SQF Code that produces unsatisfactory conditions that if not addressed may lead to a risk to food safety but not likely to cause a system element breakdown.
- **A major non-conformity** is an omission or deficiency from the SQF Code producing unsatisfactory conditions *that carry a food safety risk and are likely* to result in a system element breakdown.
- **A critical non-conformity** is a breakdown of control(s) at a critical control point, a pre-requisite program, or other process step and judged likely to cause a significant public health risk and/or where product is contaminated.

A critical non-conformity is also raised if the site fails to take effective corrective action within the timeframe agreed with the certification body, or if the certification body deems that there is systemic falsification of records relating to food safety controls and the SQF System.

Timelines for the resolution of corrective actions are addressed in Part A, 3.2.

2.9 Audit Evidence Record and Audit Report

The SQFI provides the certification body with the electronic audit checklist to be used by the SQF food safety auditors when conducting SQF Code audits. The SQF audit checklist is available from the SQFI assessment database and is customized for SQF industry sector. The SQF checklist is designed to ensure the uniform application of SQF audit requirements. It is used by SQF food safety auditors to record their findings and determine the extent to which site operations comply with stated requirements (i.e. the audit evidence record).

Good Manufacturing Practices (GMP) modules(s) shall be assessed as part of the SQF Basic/Intermediate Fundamentals audit. Where an element is not applicable and appropriately justified, it shall be stated as "not applicable" (N/A) by the SQF food safety auditor in the audit report.

Non-conformities identified during the SQF audit shall be accurately described in the SQF audit report and shall fully describe the clause of the SQF Code and the reason for the non-conformity. Non-conformity reports shall be left provided to the site by the SQF food safety auditor before the close of the site audit.

The electronic audit evidence record shall be completed by the SQF auditor and provided to the certification body for technical review.

The certification body shall review and approve the audit evidence record and make it available to the site within ten (10) calendar days from the last day of the audit. A final audit report, with completed and approved corrective actions shall be made available to the site before the final certification decision is made (45) calendar days from the last day of the site audit (refer Part A, 3.4).

The SQF audit reports shall remain the property of the site and shall not be distributed to other parties without the permission of the site.

3. The Initial Certification Decision

3.1 Responsibility for the Certification Decision

It is the responsibility of the certification body to ensure that audits undertaken by their SQF food safety auditors are thorough, that all requirements are fulfilled, and the audit report is complete. The audit report is in draft form and the audit evidence is only recommended until technically reviewed and approved by the authorized certification manager of the certification body.

The certification decision shall be made by the certification body based on the evidence of compliance and non-conformity recommended by the SQF food safety auditor during the SQF audit. Although SQFI provides guidance on certification, the certification body is responsible for deciding if certification is justified and granted based on the objective evidence provided by the SQF food safety auditor.

Any certification decisions that are made outside the scope of this clause require the certification body to provide written justification to SQFI.

3.2 Site Audit Corrective Actions

All non-conformities and their resolution shall be documented by the SQF food safety auditor. The close-out timeframe for major and minor non conformities are identified below.

- **A minor non-conformity** shall be corrected, verified and closed out by the SQF food safety auditor within thirty (30) calendar days of the completion of the site audit. Extensions may be granted by the certification body where there is no immediate threat to product safety, and alternative, temporary methods of control are initiated. The site shall be advised of the extended timeframe. Where an extension is granted, the non-conformity shall still be closed out and the SQF food safety auditor shall document all details of justification of the extension, how the risk is being controlled, and the agreed completion date.
- **A major non-conformity** shall be corrected and appropriate corrective action verified and closed out within thirty (30) calendar days of the completion of the site audit.

  In circumstances where the corrective action involves structural change or cannot be corrected due to seasonal conditions or installation lead times, this period can be extended provided the corrective action time frame is acceptable to the certification body and temporary action is taken by the site to mitigate the risk to product safety. However, in such cases, the non-conformity shall be closed out and the SQF food safety auditor shall document all details of justification of the extension, how the risk is being controlled, and the agreed completion date.
- If the SQF food safety auditor considers that a critical non-conformity exists during a certification audit, the SQF food safety auditor shall immediately advise the site and notify the certification body. A critical non-conformity raised at an initial certification audit results in an automatic failure of the audit, and the site must re-apply for certification (refer Part A, 3.5).

3.3 Audit Score and Rating

There is no scoring or rating issued for SQF Basic or Intermediate Fundamentals Manufacturing Code audits. The score and ratings that apply to SQF Food Safety certification audits do not extend to the SQF Basic and Intermediate Fundamentals Manufacturing Code certification audit. Where a score or audit rating is required by site customers then the certification body will apply the scoring/rating system used for SQF Food Safety Codes (see appropriate SQF Food Safety Codes available on the SQFI website).

3.4 Granting Certification

Sites are deemed to have successfully implemented the SQF Basic and Intermediate Fundamentals Manufacturing Code if:

- The site closes out all non-conformities within thirty (30) days.

The certification decision shall be made within forty-five (45) calendar days of the last day of the SQF Code audit. The site's unique certification number shall apply to their fundamentals certification of completion.

Within ten (10) calendar days of granting fundamental certification, the certification body shall provide an electronic and/or hard copy of the site's fundamental certificate of completion. The certificate is valid for seventy-five (75) days beyond the anniversary of the initial certification audit date. The certificate shall be in a form approved by the SQFI and include:

i. The name, address and logo of the certification body;

ii. The heading "certificate of completion;"

iii. The phrase "(site name) is registered as meeting the requirements of the SQF Basic Fundamentals - Manufacturing Code, edition 1;"

iv. The food sector categories and products included in the scope of registration;

v. Dates of audit (last day), date of next re-certification audit, date of certification decision, and date of certificate expiry;

vi. The SQF logo; and

vii. Signatures of the authorized officer and issuing officer.

Certified sites information shall be posted to the SQFI website.

3.5 Failure to Comply

Where a site fails to close out non-conformities within the required timeframe, the site is considered to have failed the SQF Code certification audit. The site must then re-apply for another site audit.

4. Surveillance and Re-certification

4.1 Maintaining Certification

To maintain SQF certification sites must ensure that surveillance and/or re-certification audits occur within the required timeframe, ensure that no critical non-conformities are raised at surveillance or re-certification audits, and that all major and minor non-conformities are corrected within the time frame specified.

All re-certification audits shall be considered announced unless otherwise indicated as unannounced on the audit report and certificate.

4.2 Surveillance Audit

The surveillance audit is conducted when the site has two (2) or more major deviations and/or ten (10) or more minor deviations raised at a certification or re-certification audit. (Note that all non-conformities must be closed out within 30 days to achieve or maintain certification. Refer Part A, 3.4).

The surveillance audit shall be conducted within forty-five (45) calendar days either side of the six (6) month anniversary of the last day of the previous certification or re-certification audit.

The surveillance audit is intended to:

i. Verify the continued efficacy of corrections and corrective actions closed out at previous food safety audits;

ii. Verify that the SQF Code continues to be implemented as documented;

iii. Consider and take appropriate action where changes to the site's operations are made and the impact of those changes on the site's GMP's and any applicable food safety plans;

iv. Confirm continued compliance with the requirements of the SQF Code;

v. Verify all critical process and food safety steps remain under control; and

vi. Contribute to continued improvement of the site's GMP's and business operation.

Major or minor non-conformities raised at the surveillance audit shall be closed out as indicated in Part A, 3.2.

The site's certificate shall be suspended by the certification body if:

i. The site fails to permit the surveillance audit within the required timeframe; or

ii. The site fails to close out non-conformities, raised at the surveillance audit within the agreed timeframe.

4.3 Surveillance Audit – Seasonal Operations

Seasonal operations are sites whose major activity is conducted over not more than five consecutive months in any calendar year.

Where the due surveillance audit date falls within the operational season, the surveillance audit shall occur within forty-five (45) days either side of the six (6) month anniversary of the last day of the previous certification or re-certification audit.

Where the due date of the surveillance audit falls outside the operational season, the certification body shall conduct a pre-operational audit no less than forty-five (45) days prior to the next season. The pre-operational audit shall comprise a full review of corrective actions from the last audit, and preparedness for the next re-certification audit.

4.4 Re-certification Audit

The re-certification audit of the SQF System is undertaken to verify the continued effectiveness of the site's SQF System in its entirety.

The re-certification audit shall be conducted within forty-five (45) calendar days either side of the anniversary of the last day of the initial certification audit.

Written approval by the SQF Compliance Manager is required to issue a temporary extension to a site's re-certification audit timeframe and certificate expiry date including instances in extreme circumstances such as acts of nature or extreme weather. Seasonal sites shall refer to Part A, 4.5.

Situations that require a permanent change to the re-certification audit date require written approval by the SQF Compliance Manager and the site's new re-certification date may be moved earlier than the anniversary and the new re-certification date fixed as the new initial certification audit date.

All extension requests shall come from the certification body that issued the site's SQF certificate.

The purpose of the re-certification audit is to:

i. Verify the continued efficacy of corrections and corrective actions closed out at previous audits;

ii. Verify that the SQF Code continues to be implemented as documented;

iii. Verify system, and management reviews have been effectively completed;

iv. Verify that corrective and preventative actions have been taken on all non-conformities;

v. Consider and take appropriate action where changes to the site's operations are made and the impact of those changes on the site's GMP's;

vi. Verify all critical steps remain under control and the effective inter-action between all elements of the SQF Code;

vii. Verify the overall effectiveness of the SQF System in its entirety in the light of changes in operations;

viii. Verify that the site continues to demonstrate a commitment to maintaining the effectiveness of the SQF Code and to meeting regulatory and customer requirements; and

ix. Contribute to continued improvement of the site's SQF System and business operation.

4.5 Re-certification Audit – Seasonal Operations

The re-certification audit of seasonal operations shall follow the requirements of Part A, 4.4. However, where there is a significant change in seasonal operations whereby the re-certification audit ninety (90) day window cannot be met, the certification body and site shall temporarily reset the re-certification audit date so that it falls during the peak operational part of the season.

If the site wishes to permanently change the re-certification audit date due to seasonal conditions, the request must be made to the SQF Compliance Manager in writing as per Part A 4.4.

4.6 Suspending Certification

The certification body shall suspend the SQF certificate if the site:

i. fails to permit the re-certification or surveillance audit,

ii. fails to take corrective action within the timeframe specified for major non-conformities,

iii. fails to take corrective action within the timeframe specified in Part A, 3.2,

iv. where in the opinion of the certification body, the site fails to maintain the requirements of the SQF Code.

Where the site's certificate is suspended, the certification body shall immediately amend the site details on the SQFI assessment database to a "suspended" status indicating the reason for the suspension and the date of effect; and in writing:

i. inform the site of the reasons for the action taken and the date of effect;

ii. copy the SQF Compliance Manager on the notice of suspension sent to the site,

iii. request that the site provides to the certification body, within forty-eight (48) hours of receiving notice of the suspension, a detailed corrective action plan outlining the corrective action to be taken.

When the site's certificate is suspended, the certification body shall upon receipt of the detailed corrective action plan:

i. Verify that the immediate correction has been taken by the means of an on-site visit within thirty (30) calendar days of receiving the corrective action plan;

ii. When corrective action has been successfully implemented, re-instate the site status on the SQFI assessment database and give written notice to the site that their certificate is no longer suspended;

iii. Not more than six (6) months after suspension, the certification body shall conduct a site visit to verify the effective implementation of the corrective action plan and that the site's SQF System is achieving stated objectives; and

iv. Copy SQFI on the notice indicating lifting of the suspension sent to the site.

When a certification body has suspended a site's SQF certificate, for the duration of suspension, the site shall not represent itself as holding an SQF certificate.

4.7 Withdrawing Certification

The certification body shall withdraw the certificate when the site:

i. Has been placed under suspension and fails to submit approved corrective action plans as defined by the certification body within forty-eight (48) hours of receiving notice of the suspension, or fails to take approved corrective action as determined by the certification body within the time frames specified;

ii. Has falsified its records;

iii. Fails to maintain the integrity of the SQF certificate; or

iv. Has an administrator, receiver, receiver and manager, official manager or provisional liquidator appointed over its assets or where an order is made or a resolution passed for the closure of the site (except for the purposes of amalgamation or reconstruction) or the site ceases to carry on business or becomes bankrupt, applies to take the benefit of any law for the relief of bankrupt or insolvent debtors or makes any arrangement or composition with its creditors.

When the site's certificate is withdrawn, the certification body shall immediately amend the site's details on the SQFI assessment database to a "withdrawn" status indicating the reason for the withdrawal and the date of effect; and in writing:

i. Inform the site that the SQF certificate has been withdrawn, the reason for such action and the date of effect;

ii. Copy SQFI on the notice of withdrawal sent to the site; and

iii. Instruct the site to return the certificate within thirty (30) days of notification.

A site that has their certificate withdrawn will not be permitted to apply for certification for twelve (12) months from the date the certificate was withdrawn by the SQFI certification body. The withdrawn site will be posted on the SQFI website (sqfi.com) for twelve (12) months.

5. Obligations of Sites and Certification Bodies

5.1 Changing the Scope of Certification

When a site wishes to add food sector categories or new products to their scope of certification, the site may request the increased scope of certification in writing to the certification body.

The certification body shall conduct a site audit of the additional process or products and shall either issue a new certificate, or advise the site in writing why the new certificate cannot be issued.

An audit for an increase in scope shall not change the re-certification date or certificate expiry date. When a new certificate is issued, the re-certification audit date and certificate expiry date shall remain as per the original certificate.

The certification body shall make the appropriate scope changes to the site record in the SQFI assessment database.

Where the scope change is a new process or a major change to an existing process, a new product line, commodity or a significant change in personnel, raw materials, packing materials or ingredients, the certification body shall be advised in writing.

Where the request is received within forty-five (45) days prior to the re-certification audit window, the certification body shall defer the scope extension to the next re-certification audit and shall advise the site. No new certificate shall be issued until after a successful re-certification audit.

5.2 Changing the Certification Body

A site can change its certification body after one certification cycle and only when there has been closure of all outstanding non-conformities, provided that the certification is not suspended or under threat of suspension or withdrawal.

Sites that require a surveillance audit are permitted to change certification bodies only after the surveillance audit is conducted or by written approval from the SQFI Compliance Manager.

When a site changes certification bodies, the certificate issued by the previous certification body remains valid until the expected expiration date.

The certification number and re-certification date are transferred with the site to the new certification body.

The new certification body shall undertake a pre-transfer review of the site's certification to:

i. Confirm the certificate is current, valid and relates to the SQF System so certified;

ii. Confirm the site's food sector category falls within the new certification body's scope of accreditation;

iii. Confirm any complaints received are actioned;

iv. Review the site's audit history (where the site can demonstrate such history to the satisfaction of the new certification body by way of copies of audit reports completed by any previous certification body) and the impact of any outstanding non-conformities;

v. Confirm the stage of the current certification cycle.

5.3 Notification of Product Recalls and Regulatory Infringements

Upon identification that a certified site initiates a food safety event that requires public notification (such as Class I or Class II recall, or the receipt of a regulatory warning letter), the site shall notify the certification body and the SQFI in writing at foodsafetycrisis@sqfi.com within twenty-four (24) hours of the event.

The site's certification body and SQFI shall be listed in the site's essential contacts lists as defined in system element 2.6.3 of the SQF Code.

The certification body shall notify the SQFI within a further forty-eight (48) hours of any action it intends to take to ensure the integrity of the certification.

5.4 Compliance and Integrity Program

To meet the requirements of SQFI's Compliance and Integrity Program, SQFI may from time to time monitor the activities of the certification bodies and their auditors. These monitoring techniques include, but are not limited to validation audits and/or witness audits. While conducting these additional monitoring activities, sites shall be required to allow additional SQFI-authorized representatives, staff or auditors into their site during the audit or after the audit has taken place. The attendance of an SQFI representative shall not interfere with operations, or result in additional audit time or non-conformities, and will not increase the cost charged by the certification body for the audit.

5.5 Change of Ownership

When a certified site's business has been sold and the business name is retained, the new owner shall, within thirty (30) calendar days of the change of ownership, notify the certification body and apply to retain the SQF certification and the existing certification number. In cases where the ownership of a certified site changes, but the staff with major responsibility for the management and oversight of the SQF System has been retained, the certification body may retain the existing audit frequency status. In making this application, the certification body shall determine that staff with major responsibility for the management and oversight of the SQF System has been retained.

If there are significant changes in site management and personnel, the certification body shall complete a certification audit and issue a new certificate and a new certification number. The audit frequency applicable to a new certification shall apply.

5.6 Relocation of Premises

When a certified site relocates their business premises, the site's certification does not transfer to the new site. A successful certification of the new premises must be conducted. Although the site's certificate number shall remain the same, an initial certification audit of the new premise shall apply.

5.8 Language

The certification body shall ensure that the SQF food safety auditor conducting the audit can competently communicate in the oral and written language of the site being audited.

In circumstances where a translator is required, the translator shall be provided by the certification body and shall have knowledge of the technical terms used during the audit; be independent of the site being audited and have no conflict of interest. The site shall be notified of any increase in audit duration and cost associated with the use of a translator.

For the purpose of resolving a conflict, the English version of the SQF Code shall be the deciding reference.

5.9 Conflict of Interest

The certification body shall ensure that all certification activities are separately controlled and managed (including the development of policy and practices) from any consulting activity. It shall preclude any prospective SQF food safety auditor from undertaking any audit in relation to the certification of SQF System that constitute a conflict of interest as outlined below or any other condition that could lead to a conflict of interest.

SQF food safety auditors shall not audit anywhere they have participated in a consulting role involving the site in question, or anybody related to the site, within the last two (2) years (considered to be participating in an active and creative manner in the development of the SQF System to be audited, including the development of food safety plans). Consulting includes, but is not limited to, activities such as:

i. Producing or preparing food safety plans, manuals, handbooks or procedures;

ii. Participating in the decision making process regarding SQF System;

iii. Giving advice – as a consultant or otherwise – toward the design, documentation, development, validation, verification, implementation or maintenance of SQF System; and

iv. Deliver or participate in the delivery of an "in-house" food safety training service at which advice and instruction on the development and implementation of food safety plans and SQF system for eventual certification is provided.

The certification body shall ensure that an SQF food safety auditor discloses any existing, former or proposed link between themselves or their organization and the site.

The certification body shall ensure through organizational structure that no potential conflict of interest, consulting, or training occurs from auditors contracted or employed by the certification body to existing or potential sites within the SQF Program.

A site can refuse the service of an SQF food safety auditor when they consider the auditor has a conflict of interest, or for other reasons. In such circumstances, the site shall outline the reasons in writing to the certification body.

5.10 Complaints, Appeals and Disputes

The certification body shall document, and provide to the site, its procedure for handling and resolving appeals, complaints and disputes made by a site, or made by another party about a site.

When a site has cause to register a complaint about a certification body's activities, or appeals or disputes a decision made by a certification body, including the activities and decisions of its auditors, the certification body shall investigate and resolve these matters without delay and keep a record of all complaints, appeals and disputes and their resolution.

When a certification body receives a complaint about a site from other parties, the certification body is required to investigate and resolve the matter without delay and keep a record of all complaints, appeals and disputes and their resolution.

Appeals regarding decisions on the suspension and/or withdrawal of the SQF certification by a certification body shall not delay the decision to suspend or withdraw the certification.

When upon investigation of a complaint it is determined that there has been a substantiated breakdown of a site's SQF System or any other condition not in accordance with the SQF Food Safety Code for manufacturing and/or other supporting documents, the certification body shall suspend certification as outlined in Part A, 4.8.

Where a complaint is registered about the conduct or behavior of an auditor or certification body personnel, the certification body shall investigate and resolve the complaint without delay and keep a record of all complaints and their resolution.

Records of complaints made to certification bodies and their investigations shall be available to the SQFI upon request. Where a complaint, appeal or dispute cannot be satisfactorily resolved between the site and the certification body, the matter shall be referred to the SQFI complaints and appeals procedure via the SQF website (sqfi.com). Complaints and comments about the SQF Code, the SQF assessment database, SQF training centers and consultants can also be registered at this address.

Part B: The SQF System Elements for SQF Basic Fundamentals - Manufacturing

2.1 Management Commitment

2.1.1 Food Safety Policy

2.1.1.1 Senior site management shall prepare and implement a policy statement that outlines as a minimum the:

i. The site's commitment to supply safe food;

ii. Methods used to comply with its customer and regulatory requirements, and

iii. The site's commitment to establish and review food safety objectives.

2.1.2 Management Responsibility

2.1.2.1 The senior site management shall be responsible for verifying and documenting the completion of:

i. An annual review of the SQF System to ensure control measures for identified hazards have been completed and are appropriate;

ii. A policy statement that states the commitment to supply safe food;

iii. Corrective actions and/or records that support compliance to relevant food legislation in the country of its origin and destination.

2.1.2.2 The senior site management shall ensure adequate resources are available to achieve food safety objectives and support the development, implementation, maintenance and ongoing improvement of the SQF System. An organizational chart shall identify the positions that significantly impact and job descriptions for those positions.

2.1.2.3 Senior site management shall designate a person who shall:

i. Be employed by the site on a full time basis;

ii. Be responsible for the development, implementation and maintenance of the SQF food safety system;

iii. Have an understanding of the SQF Food Safety Fundamentals and the requirements to implement and maintain the SQF system relevant to the site's scope of certification.

iv.

2.2 Document Control and Records

2.2.1 Food Safety Management System

2.2.1.1 A food safety management system shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the organization will use to meet the requirements of the SQF Food Safety Fundamentals Code, be made available to relevant staff and include:

i. The food safety policy statement and organization chart;

ii. The scope of the certification;

iii. A list of the products covered under the scope of certification;

iv. Include or reference the written procedures, pre-requisite programs and other documentation necessary to support the development and the implementation, maintenance and control of the SQF System.

2.2.2 Document Control

2.2.2.1 Documents shall be controlled in a manner that ensures employees use up to date and current policies, procedures and forms when documented food safety related activities.

2.2.3 Records

2.2.3.1 All records shall be legible and suitably authorized by those undertaking monitoring activities that demonstrate inspections, analyses and other essential activities have been completed.

2.2.3.2 Records shall be readily accessible, retrievable, securely stored to prevent damage and deterioration and shall be retained in accordance with periods specified by a customer or regulations.

2.3 Specifications and Supplier Approval

2.3.1 Raw and Packaging Materials

2.3.1.1 Specifications for raw materials and packaging materials including, but not limited to ingredients, additives, hazardous chemicals and processing aids, that impact on finished product safety shall be documented, comply with relevant legislation, and kept current.

2.3.1.2 Raw materials, ingredients, packaging materials, and services that impact on finished product safety shall meet the agreed specification and be supplied by an approved supplier. Inspections and analysis shall conform to standard reference methods and records of audit, inspections and analyses shall be maintained.

2.3.1.3 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and may include:

i. Microbiological and chemical limits; and

ii. Labeling and packaging requirements.

iii.

2.4 Food Safety System

2.4.1 Food Legislation

2.4.1.1 The site shall ensure that, at the time of delivery to its customer, the food supplied shall comply with the legislation that applies to the food and its production in the country of its origin and destination if known. This includes compliance with legislative requirements applicable to maximum residue limits, food safety, packaging, product description, net weights, nutritional, allergen and additive labeling, any other criteria listed under food safety legislation, and to relevant established industry codes of practice.

2.4.2 Food Safety Plan

2.4.2.1 The site shall have a HACCP-based reference Food Safety plan, developed by a responsible authority to meet regulatory and customer requirements or has developed their own plan following the Codex Alimentarius model.

The site's written food safety plan shall include at minimum:

i. An established a multi-disciplinary food safety team.

ii. A description of the product and product category of all ingredients (including raw materials, packaging, finished product) and the required conditions for storage and distribution.

iii. A description of the intended use of the product and identify the target consumer.

iv. A description of all of the steps taken to produce the product in a process flow diagram.

v. A comparison of the process flow diagram with the production process to ensure it is accurate.

2.4.3 Complaints, Corrective Action and Non-conforming Product or Equipment

2.4.3.1 The responsibility and methods for corrective actions resulting from food safety non-conformities and complaints shall be documented and implemented. Records shall include issues, complaint or the cause of food safety incidences and resulting corrective actions to resolve them.

2.4.3.2 Non-conforming product, raw material, ingredient, work-in-progress, packaging or equipment shall be quarantined, handled, re-worked or disposed of in a manner that minimizes the risk of inadvertent use, improper use or risk to the integrity of finished product. Records of the handling and disposal of non-conforming product shall be maintained.

2.4.4 Product and Process Testing and Verification

2.4.4.1 The methods, responsibility and criteria for sampling, inspecting and/or analyzing raw materials, finished product and work in progress shall be documented and implemented. The methods applied shall ensure:

i. Inspections and analyses are completed at regular intervals as required and to agreed specification and legal requirements;

ii. Inspections are conducted to ensure raw materials, work in process and finished products comply with the relevant specification, regulatory requirements and are true to label; and

iii. All analyses are conducted to nationally recognized methods or alternative methods which are validated as equivalent to the nationally recognized methods.

iv. Records of all inspections and analyses shall be maintained.

2.4.4.2 The responsibility and methods for releasing products shall be documented and implemented. The methods applied shall ensure the product is released:

i. By authorized personnel; and

ii. Once all inspections and analyses are successfully completed and documented to verify legislative and other established food safety controls have been met.

iii. Records to support product release are completed.

2.4.4.3 On-site personnel that conduct environmental or product testing shall participate in an applicable proficiency testing program at least annually to ensure accuracy of results.

2.4.4.4 Where external laboratories are utilized to conduct input or product analysis, the laboratories shall be accredited to ISO 17025 or an equivalent national standard, and shall be included on the site's contract service specifications register (refer to 2.3.3.1).

2.4.4.5 Verification of adherence to Good Manufacturing Practices shall be documented and implemented. Activities can include:

i. Periodic inspections of all process, buildings, grounds and storage facilities

ii. Review and possible corrective action follow-up of all records that support evidence of compliance to the sites document GMP procedures and product/process testing.

2.5 SQF System Verification

Not applicable for SQF Basic Fundamentals - Manufacturing

2.6 Product Identification, Trace, Withdrawal and Recall

2.5.1 Product Identification

2.5.1.1 A product identification system shall be implemented to ensure:

i. Product is clearly identified during all stages of receipt, production, storage and dispatch; and

ii. Finished product is labeled to the customer specification and/or regulatory requirements.

2.5.2 Product Trace

2.5.2.1 A product trace system shall be implemented to ensure:

i. Finished product is traceable to the customer (one up) and provides traceability through the process to the manufacturing supplier and date of receipt of raw materials, food contact packaging and materials and other inputs (one back);

ii. Traceability is maintained where product is reworked;

iii. The effectiveness of the product trace system shall be reviewed at least annually; and

iv. Records of raw and packaging material receipt and use, and finished product dispatch and destination shall be maintained.

2.5.3 Product Withdrawal and Recall

2.7.3.1 The site shall outline the methods and responsibility for notifying their customers and other essential bodies where circumstances arise that require product to be withdrawn or recalled from distribution. This could include failures in the food safety system or a crisis caused by unplanned events such as floods, water advisory, fire etc. Records of all product withdrawals, recalls and mock recalls shall be maintained. SQFI and the certification body shall be notified in writing within 24 hours upon identification of a food safety event that requires public notification. SQFI shall be notified at foodsafetycrisis@sqfi.com.

2.7 Food Defense and Food Fraud

Not applicable for SQF Basic Fundamentals - Manufacturing

2.8 Allergen Management

2.6.1 Allergen Management for Food Fundamentals

2.8.1.1 The responsibility and methods used to control allergens and to prevent sources of allergens from contaminating product shall be documented and implemented. The allergen management program shall include:

i. A risk analysis of those raw materials, ingredients and processing aids, including food grade lubricants, that contain food allergens;

ii. An assessment of workplace-related food allergens from locker rooms, vending machines, lunch rooms, visitors;

iii. A register of allergens which is applicable in the country of manufacture and the country(ies) of destination if known;

iv. A list of allergens and instructions on how to handle them is accessible by relevant staff.

v. The hazards associated with allergens and their control incorporated into the food safety plan.

vi. A management plan for control of identified allergens.

2.6.1.2 Provision shall be made to clearly identify and segregate foods that contain allergens. Segregation procedures shall be implemented and continually monitored.

2.6.1.3 Where allergenic material may be intentionally or unintentionally present, cleaning and sanitation of product contact surfaces between line changeovers shall be effective, appropriate to the risk and legal requirements, and sufficient to remove all potential target allergens from product contact surfaces, including aerosols as appropriate, to prevent cross contact. Separate handling and production equipment shall be provided where satisfactory line hygiene and clean-up or segregation is not possible

2.6.1.4 Based on risk assessment, procedures for validation and verification of the effectiveness of the cleaning and sanitation of areas and equipment in which allergens are used shall be effectively implemented.

2.6.1.5 Where allergenic material may be present, product changeover procedures shall be documented and implemented to eliminate the risk of cross-contact.

2.6.1.6 The product identification system shall make provision for clear identification and labeling in accordance with regulatory requirements of those products produced on production lines and equipment on which foods containing allergens were manufactured.

2.6.1.7 The site shall document and implement methods to control the accuracy of finished product labels (or consumer information where applicable) and assure work in progress and finished product is true to label with regard to allergens. Such measures may include label approvals at receipt, label reconciliations during production, destruction of obsolete labels and verification of labels on finished product as appropriate and product change over procedures.

2.9 Training

2.7.1 Training Program

2.7.1.1 An employee training program shall be documented and implemented. It shall outline the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with:

i. Developing and applying, Good Manufacturing Practices

ii. Applying food regulatory requirements.

2.9.1.2 Instructions and training materials shall be available in the languages relevant to the staff, explaining how all tasks critical to meeting regulatory compliance, the maintenance of food safety and hygiene practices.

2.9.1.3 The training program shall include provision for identifying and implementing the refresher training needs of the organization which shall include all temporary, seasonal and full time employees/contractors. Refresher training shall minimally include personal hygiene, allergen awareness and site security.

Module 11: Good Manufacturing Practices for SQF Basic Fundamentals – Manufacturing

This module covers the Good Manufacturing Practices requirements for the processing of perishable animal products, perishable plant products, processing of animal and plant perishable products, processing of ambient stable products, and production of bio-chemicals.

Sites implementing this module must also meet the requirements of the SQF System Elements for Basic Fundamentals Manufacturing Code.

Applicable food sector categories (FSCs) are:

FSC 8: Processing of manufactured meats and poultry
FSC 9: Seafood processing
FSC 10: Dairy food processing
FSC 11: Apiculture and honey processing
FSC 12: Egg processing
FSC 13: Bakery and snack food processing
FSC 14: Fruit, vegetable, and nut processing, and fruit juices
FSC 15: Canning, UHT and aseptic operations
FSC 16: Ice, drink, and beverage processing
FSC 17: Confectionery manufacturing
FSC 18: Preserved foods manufacture
FSC 19: Food ingredient manufacture
FSC 20: Recipe meals manufacture
FSC 21: Oils, fats and the manufacture of oil or fat-based spreads
FSC 22: Processing of cereals, grains, and nuts
FSC 25: Repackaging of products not manufactured on site
FSC 31: Manufacture of dietary supplements
FSC 33: Manufacture of food processing aides

All applicable elements of Module 11 shall be implemented. Where an element is not applicable a request for exemption must be appropriately justified, and submitted to the certification body in writing before the audit.

11.1 Site Location and Construction

11.1.1 Premises Location and Approval

11.1.1.1 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.

11.1.1.2 The construction and ongoing operation of the premises on the site shall be approved by the relevant authority.

11.2 Construction of Premises and Equipment

11.2.1 Materials and Surfaces

11.2.1.1 Product contact surfaces and those surfaces not in direct contact with food in food handling areas, raw material storage, packaging material storage, and cold storage areas shall be constructed of materials that will not contribute a food safety risk.

11.2.2 Floors, Drains and Waste Traps

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

11.2.2.2 Drains and waste trap systems shall be constructed and located so they can be easily cleaned and not present a hazard.

11.2.3 Walls, Partitions, Doors and Ceilings

11.2.3.1 Walls, partitions, ceilings and doors shall be of durable construction. Internal surfaces shall be smooth and impervious with a light-colored finish, and shall be kept clean (refer to 11.2.13.1).

11.2.4 Stairs, Catwalks and Platforms

11.2.4.1 Stairs, catwalks and platforms in food processing and handling areas shall be designed and constructed so as not to present a product contamination risk, and with no open grates directly above exposed food product surfaces. They shall be kept clean (refer to 11.2.13.1).

11.2.5 Lightings and Light Fittings

11.2.5.1 Lighting in food processing and handling areas and at inspection stations shall be of appropriate intensity to enable the staff to carry out their tasks efficiently and effectively.

11.2.5.2 Light fittings in processing areas, inspection stations, ingredient and packaging storage areas, and all areas where the product is exposed shall be shatterproof, manufactured with a shatterproof covering or fitted with protective covers and recessed into or fitted flush with the ceiling. Where fittings cannot be recessed, structures must be protected from accidental breakage, manufactured from cleanable materials and addressed in the cleaning and sanitation program.

11.2.6 Inspection/Quality Control Area

11.2.6.1 A suitable area shall be provided for the inspection of the product if required.

11.2.7 Dust, Insect and Pest Proofing

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

11.2.7.2 External personnel access doors shall be provided. They shall be effectively insect-proofed and fitted with a self-closing device and proper seals to protect against ingress of dust, vermin and other pests.

11.2.7.3 External doors, including overhead dock doors in food handling areas used for product, pedestrian or truck access shall be insect-proofed by at least one or a combination of the following methods:

i. A self-closing device;
ii. An effective air curtain;
iii. An insect-proof screen;
iv. An insect-proof annex.
v. Adequate sealing around trucks in docking areas

11.2.7.4 Electric insect control devices, pheromone or other traps and baits shall be located so as not to present a contamination risk to the product, packaging, containers or processing equipment. Poison rodenticide bait shall not be used inside ingredient or product storage areas or processing areas.

11.2.8 Ventilation

11.2.8.1 Adequate ventilation shall be provided in enclosed processing and food handling areas.

11.2.8.2 All ventilation equipment and devices in product storage and handling areas shall be adequately cleaned as per 11.2.12, to prevent unsanitary conditions.

11.2.8.3 Extractor fans and canopies shall be provided in areas where cooking operations are carried out or a large amount of steam is generated and shall have the following features:

i. Capture velocities shall be sufficient to prevent condensation build up and to evacuate all heat, fumes and other aerosols to the exterior via an exhaust hood positioned over the cooker(s);
ii. Fans and exhaust vents shall be insect-proofed and located so as not to pose a contamination risk; and
iii. Where appropriate, positive air-pressure system shall be installed to prevent airborne contamination.

11.2.9 Equipment, Utensils and Protective Clothing

11.2.9.1 Specifications for equipment, utensils and protective clothing, and procedures for purchasing equipment shall be documented and implemented.

11.2.9.2 Equipment and utensils shall be designed, constructed, installed, operated and maintained to meet any applicable regulatory requirements and not to pose a contamination threat to products.

11.2.9.3 Benches, tables, conveyors, mixers, mincers, graders and other mechanical processing equipment shall be hygienically designed and located for appropriate cleaning. Equipment surfaces shall be smooth, impervious and free from cracks or crevices.

11.2.10 Premises and Equipment Maintenance

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

11.2.10.2 Routine maintenance of plant and equipment in any food processing, handling or storage area shall be performed according to a maintenance-control schedule and recorded.

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.

11.2.10.3 Failures of plant and equipment in any food processing, handling or storage area shall be documented, reviewed and their repair incorporated into the maintenance control schedule.

11.2.10.4 Maintenance staff and contractors shall comply with the site's personnel and process hygiene requirements (refer to 11.3.1, 11.3.2, 11.3.3, 11.3.4).

11.2.10.5 All maintenance and other engineering contractors required to work on site shall be trained in the site's food safety and hygiene procedures, or shall be escorted at all times, until their work is completed.

11.2.10.6 The maintenance supervisor and the site supervisor shall be informed if any repairs or maintenance 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 processing times.

11.2.10.7 Temporary repairs, where required shall not pose a food safety risk and shall be included in the cleaning program. There shall be a plan in place to address completion of temporary repairs to ensure they do not become permanent solutions.

11.2.10.8 Maintenance staff and contractors shall 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 and a pre-operational inspection conducted prior to the commencement of site operations.

11.2.10.9 Equipment located over product or product conveyors shall be lubricated with food grade lubricants and their use controlled to minimize the contamination of the product.

11.2.10.10 Paint used in a food handling or contact zone shall be suitable for use and in good condition and shall not be used on any product contact surface.

11.2.11 Calibration

11.2.11.1 The methods and responsibility for the calibration and re-calibration of measuring, test and inspection equipment used for monitoring activities outlined in 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. Software used for such activities shall be validated as appropriate.

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

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

11.2.11.4 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 site shall provide evidence to support the calibration reference method applied.

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

11.2.11.6 Calibration records shall be maintained.

11.2.12 Pest Prevention

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

11.2.12.2 Identified pest activity shall not present a risk of contamination to food products, raw materials or packaging.

11.2.12.3 The pest prevention program shall:

i. Describe the methods and responsibility for the development, implementation and maintenance of the pest prevention program;
ii. Record pest sightings and trend the frequency of pest activity to target pesticide applications;
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 into 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.

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

11.2.13 Cleaning and Sanitation

11.2.13.1 The methods and responsibility for the cleaning of the food handling and processing equipment and environment, storage areas, staff amenities and toilet facilities shall be documented and implemented. Consideration shall be given to:

i. What is to be cleaned;
ii. How it is to be cleaned;

iii. When it is to be cleaned;
iv. Who is responsible for the cleaning;
v. Methods used to confirm the correct concentrations of detergents and sanitizers, and
vi. The responsibility and methods used to verify the effectiveness of the cleaning and sanitation program.

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

11.2.13.3 Suitably equipped areas shall be designated for cleaning product containers, knives, cutting boards and other utensils and for cleaning of protective clothing used by staff. These cleaning operations shall be controlled so as not to interfere with manufacturing operations, equipment or product. Racks and containers for storing cleaned utensils shall be provided as required.

11.2.13.4 Pre-operational inspections shall be conducted following cleaning and sanitation operations to ensure food processing areas, product contact surfaces, equipment, staff amenities and sanitary facilities and other essential areas are clean before the commencement of production. Pre-operational inspections shall be conducted by qualified personnel.

11.3 Personnel Hygiene and Welfare

11.3.1 Personnel

11.3.1.1 Personnel who are known to have been known to be carriers, or are carriers, of infectious diseases that present a health risk to others through the packing or storage processes shall not engage in the processing or packing of food, or enter storage areas where food is exposed.

11.3.1.2 The site shall have measures in place to prevent contact of materials, ingredients, food packaging, food, or food contact surfaces from any bodily fluids from open wounds, coughing, sneezing, spitting, or any other means.

In the event of an injury which causes spillage of bodily fluid, properly trained employee shall ensure that all affected areas including handling and processing areas have been adequately cleaned and that all materials and products have been quarantined and disposed of.

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

11.3.1.4 Smoking, chewing, eating, or spitting is not permitted in areas where product is produced, stored, or otherwise exposed. Drinking of water is permissible only under conditions that prevent contamination or other food safety risks from occurring.

Drinking water containers in production and storage areas shall be stored in clear, covered containers, and in designated areas away from raw materials, packaging or equipment.

11.3.2 Hand Washing

11.3.2.1 Suitable and sufficient hand wash basins shall be provided adjacent to all personnel access points and in accessible locations throughout food handling and processing areas as required.

11.3.2.2 The following additional facilities shall be provided in high risk areas:

i. Hands free operated taps; and
ii. Hand sanitizers.

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

11.3.3 Clothing

11.3.3.1 The site shall undertake a risk analysis to ensure that the clothing and hair policy protects materials, food and food contact surfaces from unintentional microbiological or physical contamination.

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

11.3.3.3 Clothing including shoes, shall be clean at the commencement of each shift and maintained in a serviceable condition.

11.3.3.4 Excessively soiled uniforms shall be changed or replaced where they present a product contamination risk.

11.3.3.5 Disposable gloves and aprons shall be changed after each break, upon re-entry into the processing area and when damaged.

Non-disposable aprons and gloves shall be cleaned and sanitized as required and when not in use stored on racks provided in the processing area or designated sealed containers in personnel lockers and not on packaging, ingredients, product or equipment.

11.3.4 Jewelry and Personal Effects

11.3.4.1 Jewelry and other loose objects shall not be worn or taken into a food handling or processing operation or any area where food is exposed. The wearing of plain bands with no stones and prescribed medical alert bracelets can be permitted, however the site will need to consider their customer requirements and the applicable food legislation.

11.3.5 Visitors

11.3.5.1 All visitors, including management and maintenance staff, shall wear suitable clothing and footwear when entering any food processing or handling area.

11.3.5.2 All visitors shall be required to remove jewelry and other loose objects.

11.3.5.3 Visitors exhibiting visible signs of illness shall be prevented from entering areas in which food is handled or processed.

11.3.5.4 Visitors shall enter and exit food handling areas through the proper staff entrance points and comply with all hand washing and personnel practice requirements.

11.3.5.5 All visitors shall be trained in the site's food safety and hygiene procedures before entering any food processing or handling areas, or shall be escorted at all times in food processing, handling and storage areas.

11.3.6 Staff Amenities

This clause does not apply.

11.3.7 Change Rooms

11.3.7.1 Facilities with sufficient provisions shall be provided to enable staff and visitors to change into and out of protective clothing as required.

11.3.8 Laundry

This clause does not apply.

11.3.9 Sanitary Facilities

11.3.9.1 Toilet rooms shall be:

i. Designed and constructed so that they are accessible to staff and separate from any processing and food handling operations;
ii. Accessed from the processing 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;
v. Include an area inside or nearby, for storing protective clothing, outer garments and other items while using the facilities; and
vi. Kept clean and tidy.

11.3.9.2 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 in accordance in regulations.

11.3.9.3 Hand wash basins shall be provided immediately outside or inside the toilet room and designed as outlined in 11.3.2.2.

11.3.10 Lunch Rooms

11.3.10.1 Separate lunch room facilities shall be provided away from a food contact/handling zone.

11.4 Personnel Processing Practices

11.4.1 Staff Engaged in Food Handling and Processing Operations

11.4.1.1 All personnel engaged in any food handling, preparation or processing operations shall ensure that products and materials are handled and stored in such a way as to prevent damage or product contamination. They shall comply with the following processing practices:

i. Personnel entry to processing 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, product, and ingredients 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;
v. Staff shall not eat or taste any product being processed in the food handling/contact zone, except as noted in element 11.4.1.2;
vi. The wearing of false fingernails, false eyelashes, eyelash extensions, long nails or fingernail polish is not permitted when handling exposed food;
vii. Hair restraints are used where product is exposed.

11.4.1.2 In circumstances where it is necessary to undertake sensory evaluations in a food handling/contact zone the site shall implement proper controls and procedures to ensure:

i. Food safety is not compromised;

ii. Sensory evaluations are conducted by authorized personnel only;

iii. A high standard of personal hygiene is practiced by personnel conducting sensory evaluations;

iv. Sensory evaluations are conducted in areas equipped for the purpose; and

v. Equipment used for sensory evaluations is sanitized, maintained and stored separate from processing equipment.

11.4.1.3 All wash down hoses shall be stored on hose racks after use and not left on the floor.

11.5 Water, Ice and Air Supply

11.5.1 Water Supply

11.5.1.1 Adequate supplies of hot and cold potable water drawn from a known clean source shall be provided for use during processing operations, as an ingredient and for cleaning the premises and equipment.

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

11.5.2 Water Treatment

11.5.2.1 Water treatment methods, equipment and materials, if required, shall be designed, installed and operated to ensure water receives an effective treatment.

11.5.2.2 Water treatment equipment shall be monitored regularly to ensure it remains serviceable.

11.5.2.3 Treated water shall be regularly monitored to ensure it meets the indicators specified.

11.5.2.4 Water used in as an ingredient in processing, or in cleaning and sanitizing equipment, shall be tested, and if required, treated to maintain potability (refer to 11.5.2.1).

11.5.3 Ice Supply

11.5.3.1 Ice provided for use during processing operations or as a processing aid or an ingredient shall comply with 11.5.4.1.

11.5.3.2 Ice rooms and receptacles shall be constructed of materials as outlined in elements 11.2.1, 11.2.2 and 11.2.3 and designed to minimize contamination of the ice during storage and distribution.

11.5.4 Monitoring Water Microbiology Quality

11.5.4.1 Water shall comply with local, national or internationally recognized potable water microbiological and quality standards as required when used for

i. washing, thawing and treating food;

ii. handwashing

iii. to convey food;

iv. as an ingredient or food processing aid;

v. cleaning food contact surfaces and equipment;

vi. the manufacture of ice; or

vii. the manufacture of steam that will come into contact with food or used to heat water that will come in contact with food.

11.5.5 The Quality of Air and Other Gases

11.5.5.1 Compressed air or other gasses (e.g. nitrogen, carbon dioxide) that contacts food or food contact surfaces shall be clean and present no risk to food safety.

11.5.5.2 Compressed air systems, and systems used to store or dispense other gasses used in the manufacturing process that come into contact with food or food contact surfaces shall be maintained and regularly monitored for quality and applicable food safety hazards.

11.6 Storage and Transport

11.6.1 Storage and Handling of Goods

11.6.1.1 The site shall document and implement an effective storage plan that allows for the safe, hygienic storage of raw materials (i.e. frozen, chilled, and ambient), ingredients, packaging materials, equipment, and chemicals.

11.6.1.2 The responsibility and methods for ensuring effective stock rotation principles are applied shall be documented and implemented.

11.6.1.3 Procedures shall be in place to ensure that all ingredients, materials, work-in-progress, rework, and finished product are utilized within their designated shelf-life.

11.6.1.4 Equipment storage rooms shall be designed and constructed to allow for the hygienic and efficient storage of equipment and containers.

11.6.1.5 Where goods described in 11.6.2 to 11.6.4 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.

11.6.1.6 Records shall be available to validate alternate or temporary control measures for the storage of raw materials, ingredients, packaging materials, equipment, chemicals, or finished products.

11.6.2 Cold Storage, Freezing and Chilling of Foods

11.6.2.1 The site shall provide confirmation of the effective operational performance of freezing, chilling and cold storage facilities. Chillers, blast freezers and cold storage rooms shall be designed and constructed to allow for the hygienic and efficient refrigeration of food and easily accessible for inspection and cleaning.

11.6.2.2 Sufficient refrigeration capacity shall be available to chill, freeze, store chilled or store frozen the maximum anticipated throughput of product with allowance for periodic cleaning of refrigerated areas.

11.6.2.3 Discharge from defrost and condensate lines shall be controlled and discharged to the drainage system.

11.6.2.4 Freezing, chilling and cold storage rooms shall be fitted with temperature monitoring equipment and located to monitor the warmest part of the room and be fitted with a temperature measurement device that is easily readable and accessible.

11.6.2.5 Loading and unloading docks shall be designed to protect the product during loading and unloading.

11.6.3 Storage of Dry Ingredients, Packaging, and Shelf Stable Packaged Goods

11.6.3.1 Rooms used for the storage of product ingredients, packaging, and other dry goods shall be located away from wet areas and constructed to protect the product from contamination and deterioration.

11.6.3.2 Racks provided for the storage of packaging shall be constructed of impervious materials and designed to enable cleaning of the floors and the storage room. Storage areas shall be constructed to prevent packaging from becoming a harborage for pests or vermin.

11.6.3.3 Vehicles used in food contact, handling or processing zones or in cold storage rooms shall be designed and operated so as not to present a food safety hazard.

11.6.4 Storage of Hazardous Chemicals and Toxic Substances

11.6.4.1 Hazardous chemicals and toxic substances with the potential for food contamination shall be stored so as not to present a hazard to staff, product, packaging, product handling equipment or areas in which the product is handled, stored or transported.

11.6.5 Loading, Transport and Unloading Practices

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

11.6.6 Loading

11.6.6.1 Vehicles (e.g. trucks/vans/containers) used for transporting food 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.

11.6.6.2 Loading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity during loading and transport.

11.6.6.3 Vehicles (e.g. trucks/vans/containers) shall be secured from tampering using a seal or other agreed upon, acceptable device or system.

11.6.7 Transport

11.6.7.1 Refrigerated units shall maintain the food at required temperatures and the unit's temperature settings shall be set, checked and recorded before loading and product temperatures recorded at regular intervals during loading as appropriate.

11.6.7.2 The refrigeration unit shall be operational at all times and checks completed of the unit's operation, the door seals and the storage temperature checked at regular intervals during transit.

11.6.8 Unloading

11.6.8.1 Prior to opening the doors, the refrigeration unit's storage temperature settings and operating temperature shall be checked and recorded. Unloading shall be completed efficiently and product temperatures shall be recorded at the commencement of unloading and at regular intervals during unloading.

11.6.8.2 Unloading practices shall be designed to minimize unnecessary exposure of the product to conditions detrimental to maintaining the product and package integrity.

11.7 Separation of Functions

11.7.1 Process Flow

11.7.1.1 The process flow shall be designed to prevent cross contamination and organized so 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.

11.7.2 Receipt of Raw and Packaging Materials and Ingredients

11.7.2.1 Dry ingredients and packaging shall be received and stored separately from frozen and chilled raw materials to ensure there is no cross contamination. Unprocessed raw materials shall be received and segregated to ensure there is no cross contamination.

11.7.3 Thawing of Food

11.7.3.1 Thawing of food shall be undertaken safely in equipment and rooms appropriate for the purpose.

11.7.4 High Risk Processes

11.7.4.1 The processing of high risk food shall be conducted under controlled conditions such that sensitive areas in which high risk food has undergone a "kill" step, a "food safety intervention" or is subject to post process handling, are protected/segregated from other processes, raw materials or staff who handle raw materials to ensure cross contamination is minimized.

11.7.4.2 Areas in which high risk processes are conducted shall only be serviced by staff dedicated to that function.

11.7.4.3 Staff access points shall be located, designed and equipped to enable staff to don distinctive protective clothing and to practice a high standard of personal hygiene to prevent product contamination.

11.7.4.4 Staff engaged in high risk areas shall change into clean clothing or temporary protective outerwear when entering high risk areas.

11.7.4.5 Product transfer points shall be located and designed so as not to compromise high risk segregation and to minimize the risk of cross contamination.

11.7.5 Control of Foreign Matter Contamination

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

11.7.5.2 Inspections shall be performed to ensure plant and equipment remains in good condition, equipment has not become detached or deteriorated and is free from potential contaminants.

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

11.7.5.4 Containers, equipment and other utensils made of glass, porcelain, ceramics, laboratory glassware or other like material (except where the 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 food processing /contact zones.

11.7.5.5 Regular inspections of food handling/contact zones shall be conducted to ensure they are free of glass or other like material and to establish changes to the condition of the objects listed in the glass register.

11.7.5.6 Glass instrument dial covers on processing equipment and MIG thermometers shall be inspected at the start of each shift to confirm they have not been damaged.

11.7.5.7 Wooden pallets and other wooden utensils used in food handling/contact zones shall be dedicated for that purpose, clean, maintained in good order. Their condition shall be subject to regular inspection.

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

11.7.5.9 Knives and cutting instruments used in processing and packaging operations shall be controlled, and kept clean and well maintained. Snap-off blades shall not be used in manufacturing or storage areas.

11.7.6 Detection of Foreign Objects

11.7.6.1 The responsibility, methods and frequency for monitoring, maintaining, calibrating and using screens, sieves, filters or other technologies to remove or detect foreign matter shall be documented and implemented.

11.7.6.2 Metal detectors or other physical contaminant detection technologies shall be routinely monitored, validated and verified for operational effectiveness. The equipment shall be designed to isolate defective product and indicate when it is rejected.

11.7.6.3 Records shall be maintained of the inspection of foreign object detection devices and of any products rejected or removed by them. Records shall include any corrective actions resulting from the inspections.

11.7.7 Managing Foreign Matter Contamination Incidents

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

11.7.7.2 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.

11.8 On-Site Laboratories

11.8.1 Location

11.8.1.1 On site laboratories conducting chemical and microbiological analysis that may pose a risk to product safety, shall have proper signage and be located separate from any food processing or handling activity and designed to limit access only to authorized personnel.

11.8.1.2 Provisions shall be made to isolate and contain all laboratory waste held on the premises and manage it separately from food waste. Laboratory waste water outlet shall as a minimum be down stream of drains that service food processing and handling areas.

11.9 Waste Disposal

11.9.1 Dry and Liquid Waste Disposal

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

11.10 Exterior

11.10.1 Grounds and Roadways

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