SQF INSTITUTE
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General Guidance for Developing, Documenting, Implementing, Maintaining, and Auditing an SQF Quality System

Quality Code

SQF Quality Code, Edition 8

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SQF Institute is a division of the Food Marketing Institute (FMI).

Preface

This document provides general guidance for SQF sites, consultants and auditors when implementing and auditing SQF Quality Code, Edition 8 and can be used where no specific industry sector guidance is available.

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

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

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

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Section 1. Introduction

1.1 Purpose of the Guidance Documents

The purpose of this series of SQF Guidance Documents is to assist sites with designing, developing, documenting, implementing and maintaining an SQF System using the SQF Quality Code, Edition 8 (SQF Code), and to assist SQF registered auditors in auditing against the code.

The relevant Code version number is identified in the document header. Terms used in these documents are defined in Appendix 2: Glossary of the SQF Quality Code, edition 8.

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

1.2 Layout of the SQF Quality Code

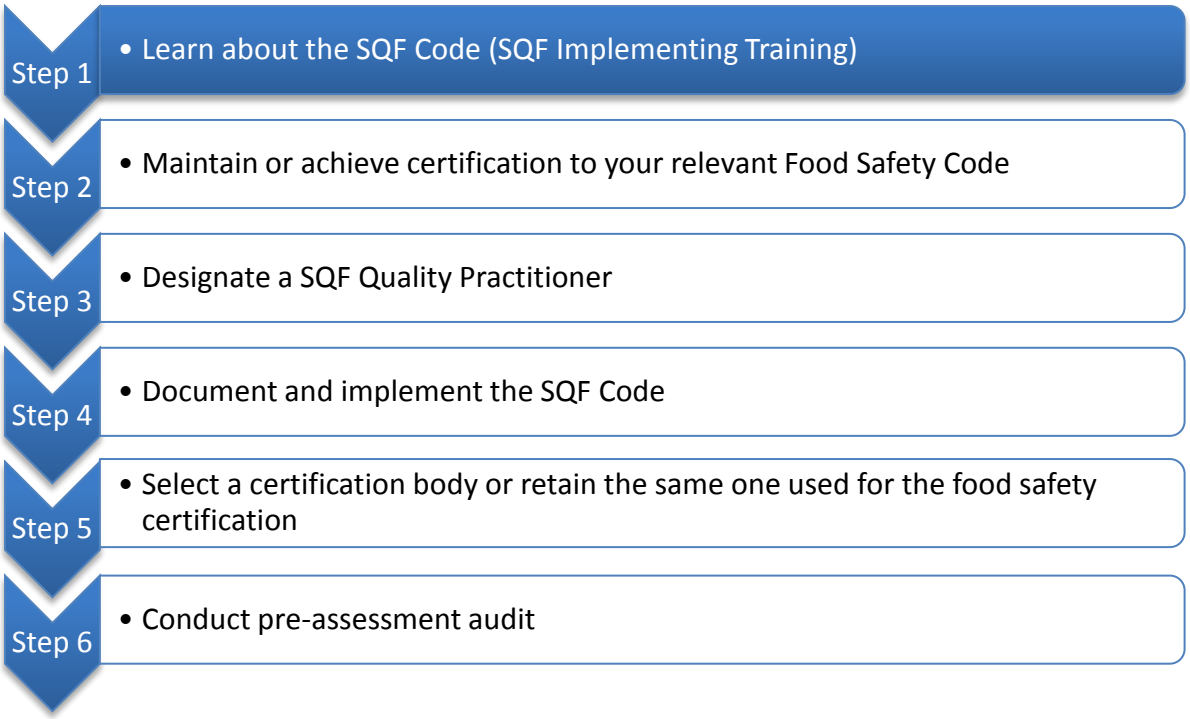
The SQF Quality Code consists of two parts and five appendices. Part A contains the criteria for implementing and maintaining the SQF Quality Code. Part B, the heart of the SQF Code, is made up of clauses or elements, which the site must implement as their SQF Quality System. The clauses and elements are ensigned to the system Elements, a designation that aligns with SQF Food Safety Code elements and assists in system design and auditing to the SQF Code. Each element outlines where procedures need to be documented, where record keeping is required or where actions must be taken.

The four appendices in the SQF Quality Code provide additional information needed to implement an SQF Quality System:

- Appendix 1: SQF Food Sector Categories
- Appendix 2: Glossary
- Appendix 3: SQF Logo Rules of Use
- Appendix 4: Requirements for SQF Multi-site Certification
- Appendix 5: Quality Shield Rules of Use

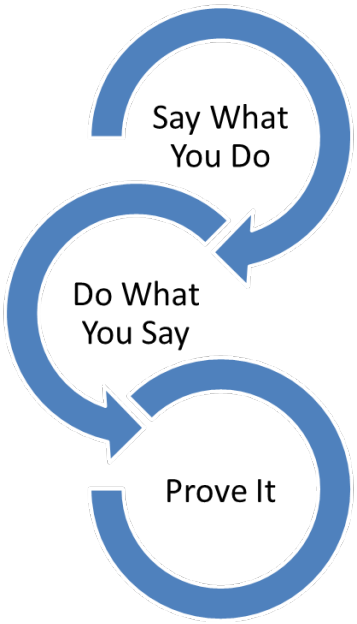
Section 2. The SQF Quality Certification Process

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



Section 3. The SQF Implementation Process

To achieve SQF quality certification, the site must document and implement the requirement stated in the SQF Quality Code. It's also important to provide evidence of the Quality System in the form of documents and records. The implementation process is shown below.



Document the SQF Quality System – prepare policies, procedures, work instructions and specifications that address the requirements of the SQF Code. In other words “say what you do.”

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

Provide records the SQF Quality System – keep records to demonstrate compliance to the requirements of the SQF Code. These records provide evidence of the function and control of the Quality System. In other words, “prove it.”

Section 4. Introduction to this Guide

1. Purpose and Scope of this Guide

The purpose of this SQF guidance document is to assist sites with designing, developing, documenting, implementing and maintaining an SQF Quality System using the SQF Quality Code and to assist SQF registered auditors in auditing against the SQF Quality Code.

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

This particular guide covers the requirements of the SQF Quality System Elements. All sites seeking certification to the SQF Code must document, implement and maintain these elements irrespective of their industry sector.

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

2. The Structure of the SQF Quality Code

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

The main feature of the SQF Code is its emphasis on the systematic application of HACCP to identify, monitor and control food quality threats in the process.

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

3. The Structure of an SQF Quality System

An SQF Quality System is a risk management system documented and implemented by a site producing food (or related) products to control food quality risks using the SQF Code. It can be audited and certified by an SQF licensed certification body.

The process of how to document and implement the SQF Quality Code and achieve certification can be found in the most current version of Part A of the SQF Quality Code and is outlined above.

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

The elements that the site must address in their SQF Quality System are as follows:

2.1 Management Commitment

2.2 Document Control and Records

2.3 Specification and Product Development

2.4 Food Quality System

2.5 Food Quality System Verification

2.6 Product Identification, Trace, Withdrawal and Recall

2.7 Food Fraud

2.8 Identity Preserved Foods

2.9 Training

4. Format of the Guidance

The following section explains the elements and sub-elements of the SQF Quality Code, provides guidance on what a site needs to do to develop, document and implement an SQF Quality System and provides information on what the auditor may be looking for to confirm compliance.

The following format is used throughout:

Element Number and Name

Sub-element Number and Name

This section will describe what the SQF Quality Code requires. This is the text from the SQF Quality Code, and is the auditable standard. Where there is disagreement between the text of the SQF Quality Code and the guidance, the SQF Quality Code in English prevails.

Implementation Guidance
What does it mean? This will include the interpretative comments of what the sub-element requires or definitions of the terms used. **What do I have to do?** This will include suggestions of what is required to be done by the site to document and implement this sub-element. The information provided is not considered exhaustive and may not apply in every situation. It is meant to provide guidance and interpretation.
Auditing Guidance
This will include suggestions of what the auditor may seek as evidence of compliance for this sub-element. The information provided is not exhaustive and may not apply in every situation.

Section 5. Module 2: SQF Systems Elements

2.1 Management Commitment

2.1.1 Quality Policy

What the SQF Code says

2.1.1.1 The policy statement prepared and implemented by senior site management to communicate their commitment to food safety shall also include at a minimum:

i. The site's commitment to establish quality objectives;
ii. The site's commitment to comply with customers' quality requirements;
iii. The methods used to measure the site's quality objectives, and
iv. The site's commitment to continually improve its quality performance.

2.1.1.2 The site's vision and mission statement shall also be displayed in a prominent position and communicated to all staff. The vision and mission statement may be included in, or separate from, the organization's food safety policy.

2.1.1 Implementation Guidance

What does it mean?

Commitment to a policy by senior management is a visible sign of leadership – the creation of a "culture of food safety and quality" within the site. The policy statement provides a focus on what the site aspires to and is working to achieve in terms of food safety and quality.

"Senior" means the person who has operational control within the site. It is considered to be the senior person on site. Some larger sites may be influenced by a Board of Directors or senior management team based at Head Office. However as considered in the SQF Code, it is the site senior management that is referred to, and the person who must sign the policy.

Senior management must sign the document as an indication of their commitment to implement it. The policy statement sets out the objectives of the site's SQF System, and provides the framework for achieving objectives at an operational level. Objectives must be written in a way that every employee at the site can contribute toward achieving them.

Commitment to regulatory and customer requirements underpins the site's SQF System and must be included in the policy statement.

Display of the vision and mission statement in location that all staff have access to on a regular basis will assist in communication of implementation of them. These statements must refer specifically to quality and can be separate from or include with those required for food safety, as per the food safety codes.

What do I have to do?

The policy statement is generally the first part of the site's food safety and quality manual (refer 2.1.3). The owner or most senior responsible person within the site is required to:

- document and sign a policy statement that clearly demonstrates their understanding of their food safety and/or quality responsibility under the SQF System;
- outlines how the site will achieve and maintain food safety and quality;
- includes a stated commitment to comply with regulatory and customer requirements; and
- includes a stated commitment to continually improve the SQF System.

The policy statement must be reviewed at least annually by senior management. This review is normally done when the review of the SQF System is undertaken.

The policy statement, vision and mission statements must be available to all or most staff in a form and language that is understood by all staff. A typical location would be on communication boards, intranet devices or employee entrance locations.

2.1.1 Auditing Guidance

The content of the policy statement will be reviewed by the auditor initially at the desk audit. However,

during the first and subsequent facility audits, the auditor will check to confirm that the contents of the policy statement are applied in practice on a daily basis.

The auditor will seek evidence of compliance to management commitment and thereby a "culture of food safety" through observation and interview. Evidence may include:

- A documented policy statement, signed by the senior site manager, that commits to meeting regulatory and customer requirements and indicates how those requirements shall be met; setting and achieving food safety and quality objectives; reviewing food safety and quality objectives on a regular (at least annual) basis; and continually improving their SQF food safety and quality management System.
- The currency (dating) of the policy statement.
- The availability of the policy statement to all staff within the facility. This includes confirming employee understanding of the policy statement.
- Food safety and quality objectives are established and realistic.
- Activities within the facility meet regulatory and customer expectations.
- Activities within the facility reflect established food safety and quality objectives. The auditor may seek company food safety meeting minutes and check if management participated in these meetings.
- The policy statement, including food safety and quality objectives, is reviewed at least annually.
- The vision and mission statements are posted in a prominent location that all or most staff can see and read on a regular basis.

The policy statement need not only be posted, however the actions for management commitment must be implemented.

There are also situations that may either singly or in combination indicate poor management commitment such as:

- A plant environment in which employees and management are not engaged or have no awareness of food safety objectives;
- Staffing positions that are recently created (indicating they were created simply to meet the element of the Code and not proactively to address food safety objectives), outdated or have been vacant for an extended period of time;
- Recent recalls or ongoing audit pressure;
- Plant is for sale or a public announcement has been made that the plant or division will be sold;
- The use of a large, temporary labor pool.

2.1.2 Management Responsibility

What the SQF Code says

2.1.2.1 The reporting structure shall identify personnel performing key process steps and responsible for achieving quality requirements.

2.1.2.2 The senior site management shall develop quality objectives and a process by which quality performance is measured.

2.1.2.3 The senior site management shall ensure adequate resources are available to achieve quality objectives and customer quality requirements, and to support the development, implementation, maintenance and ongoing improvement of the SQF Quality System.

2.1.2.4 Senior site management shall designate an SQF quality practitioner for each site with responsibility and authority to:

i. Oversee the development, implementation, review and maintenance of the SQF Quality System including quality fundamentals outlined in 2.4.2, and the quality plan outlined in 2.4.3;

ii. Take appropriate action to ensure the integrity of the SQF Quality System;

iii. Communicate to relevant personnel all information essential to ensure the effective implementation and maintenance of the SQF Quality System; and

iv. Ensure that site personnel have the required competencies to carry out those functions affecting product quality.

2.1.2.5 In addition to the SQF Food Safety Code requirements, the SQF quality practitioner shall:

i. Be competent to implement and maintain HACCP-based food quality plans;

ii. Understand the SQF Quality Code and the requirements to implement and maintain a quality management system; and

iii. Be competent in statistical process control (SPC) and/or other quality tools to reduce process variation and drive root cause analysis of non-conformities.

2.1.2.6 Senior site management shall ensure site personnel responsible for performing key process steps and meeting customer requirements, and corporate quality requirements where applicable, have the required competencies to carry out those functions.

2.1.2.7 Senior site management shall develop and implement a quality communication program to ensure that all staff are informed of their quality responsibilities, are aware of their role in meeting the requirements of the SQF Quality Code, and are informed of the organization's performance against quality objectives. The program shall include:

i. the defined vision and mission statement of the site;

ii. the site's quality objectives and the process by which quality performance is measured, and

iii. The methods by which customer quality requirements, and corporate quality requirements where applicable, are met.

2.1.2.8 Job descriptions for personnel performing key process steps and responsible for achieving quality requirements shall be documented and include provision to cover for the absence of key personnel.

2.1.2.9 Senior site management shall establish a process to trend progress in quality performance against agreed measures. Benchmarking shall be part of this process and the performance data shall be reported at least annually to demonstrate effectiveness of the quality management System, and communicated to all staff.

2.1.2.10 Sites that are certified to the SQF Quality Code may use the SQF quality shield. Use of the SQF quality shield shall follow the requirements outlined in Appendix 5: SQF Quality Shield Rules of Use.

2.1.2 Implementation Guidance

What does it mean?

Tangible actions must follow commitment. Management must ensure that the resources required to implement the policy and food safety and quality objectives, are available. Resources are often scarce in many organizations. Regardless, management must demonstrate that employees understand their responsibility for food safety and quality and be allowed the time, tools and authority to carry out these responsibilities.

By providing and communicating an organizational chart and position descriptions that demonstrate the interrelationships and responsibilities within the site's facility, each employee will know his/her role in assuring food safety, quality and continuous improvement. This must be understood by all employees and staff members of the site. Management must clearly identify and provide the resources to achieve food safety and quality objectives and meet customer requirements.

This element also includes the requirements for, and responsibilities of, the SQF Quality practitioner. This is a key role within the site's facility, being the person designated by senior management to manage the development, implementation, daily operation, validation and verification of the SQF Quality System.

What do I have to do?

The senior responsible person is required to document the organizational reporting structure that describes each position that has responsibility for food safety and quality. The organisational structure provides a snapshot of how these positions interact and share that responsibility.

Senior management must convey this to every employee. This will be written into job descriptions for all roles within the facility that impact food safety and quality. Job descriptions for key personnel must include a provision for coverage on all shifts and replacement during absence. There must be documented instructions and training for all staff to report food safety and quality problems to personnel with the authority to initiate actions.

Senior management must also document how they will provide resources to achieve food safety and quality objectives. They must demonstrate their support of the development, implementation, maintenance and ongoing improvement of the SQF Quality System.

The SQF Quality practitioner is the individual designated by senior management to develop, validate, verify and maintain the company's quality program, and assume control of the daily operation of the SQF Quality System. The SQF practitioner may engage the services of an SQF consultant to assist with the development of the SQF Quality

System, or support its validation and verification, but overall responsibility remains with the site through the SQF Quality practitioner.

The requirements of the SQF practitioner are clearly outlined in 2.1.2.5, and are further described in the SQFI guideline on SQF practitioners. Note that SQF Quality practitioners are not required to complete an Implementing SQF Quality Systems training course or Implementing SQF Quality Systems examination. It is not compulsory although either or both is recommended. However, the practitioner is required to understand and demonstrate knowledge of the SQF Code and its application within the site. They are also required to have a working knowledge on the application and use of Statistical Process Control (SPC) and/or other quality tools to measure and control critical quality points or other control points in the process.

The various tools used by senior management to communicate food quality objective, roles etc must be collated into an effective communication program that ensure all methods and metrics are understood by staff and other stakeholders. The program/plan must also clear methodologies on how customer and/or corporate requirements will be met.

The commitment of management to ensuring that employees are trained and assessed as competent to carry out job functions pertaining to food safety and quality must be documented. The job descriptions must reflect the competencies required of each employee to carry out their food safety and quality responsibilities and the training that is necessary to assure those competencies (refer 2.9).

Also, management must be able to demonstrate that the goal is not simply to achieve SQF Certification, but that they have processes in place to continuously improve their food safety and quality processes. They must have measures and a benchmarking process in place to monitor the effectiveness of their SQF Quality System and have programs and activities in place to improve the outcomes. Measures may include, but are not limited to:

- customer complaints (2.1.5),
- critical quality point measurements,
- process capability studies,
- audit results (2.5.7),
- product analysis (2.5.6),
- corrective actions (2.5.5), and
- product withdrawal and recall (2.6.3).

2.1.2 Auditing Guidance

The auditor must avoid making a quick decision on *2.1.2 Management Responsibility*. Although this element is at the beginning of the Code, the auditor is unlikely to make a full judgment on compliance with this element until the end of the audit.

The documented organizational structure and job descriptions shall be audited through confirmation that the contents of the organizational structure and job descriptions are applied in practice on a daily basis – that a "culture of food safety" has been created. Interviews with key personnel will be used to gather information to determine understanding of their jobs and the relevancy to the SQF Quality System.

The credentials of the SQF practitioner shall also be checked and the competency and his/her ability to effectively manage the SQF Quality System shall be confirmed during the audit. Note that formal SPC or Quality Code training is not required however, the auditor is to determine competency throughout the audit process and the collection of evidence (interviews, document reviews and observations.)

The auditor will seek evidence of compliance to this requirement by observation and interview. Evidence may include:

- There is a current, documented organizational structure in place that identifies those responsible for food safety and quality, and their interrelationship, and is agreed by senior management.
- Job descriptions are in place for positions that have responsibility for food safety and quality. The auditor may question why positions have been vacant for a long period of time or the site chooses to use a large, temporary labor pool.
- Adequate resources are in place to meet food safety and quality objectives and the requirements of the SQF System. This includes coverage for all operational shifts and absences.
- Employees within the facility with responsibility for food safety and quality are clearly identified, are aware of their responsibilities and are trained and competent to carry out these responsibilities.

- Senior management ensures that all designated food safety and quality practices and activities are correctly documented, meet the requirements of the SQF Code and are correctly and fully implemented on all shifts. This would include a review as to the timeliness of implementation of corrective actions, action on complaints, and addressing identified gaps in the facility's programs.
- The designated practitioner has the support of senior management and has the time and availability to monitor the effectiveness of the SQF Quality System; is competent and has the authority to take appropriate corrective actions when necessary; and communicates to relevant employees any information necessary to maintain or improve the System.

It is expected that the site have in place a quality communication program that portrays the site's food quality program for all employees. The communication program should be designed to incorporate a variety of communication tools that engages employee awareness and successful implementation of the site's food quality plan. Tools may vary but may include the following:

- • posters, signs, symbols or slogans
- • videos
- • Job aides
- • Shift huddles

Senior management has processes in place to measure the effective implementation of the SQF Quality System and initiate, resource and review improvement programs.

2.1.3 Management Review

What the SQF Code says

2.1.3.1 The senior site management shall be responsible for reviewing the SQF Quality Code. Reviews shall include actions required to:

i. Monitor specification compliance and corrective actions taken;
ii. Reduce process and product variation;
iii. Meet customer requirements;
iv. Ensure sufficient resources are allocated to maintain, and improve the performance of the Quality System.

2.1.3.2 The senior site management and SQF quality practitioner shall meet to review the implementation and maintenance of the Quality System at least monthly, and the SQF Quality System in its entirety shall be reviewed at least annually.

2.1.3.3 The Quality System, including food quality plans, shall be reviewed when any changes are implemented that have an impact on the site's ability to meet customer requirements and corporate quality requirements where applicable.

2.1.3.4 Senior site management shall ensure the integrity and continued operation of the Quality System in the event of organizational or personnel changes within the company or associated facilities.

2.1.3.5 The senior site management shall document and implement a change management process that details how changes in specifications, materials, equipment or resources are evaluated for their impact on quality, communicated to customers and effectively implemented.

2.1.3.6 Records of all Quality System reviews and reasons for amending documents, and changes to the SQF Quality System shall be maintained. Records shall include decisions for actions related to improvement of the Quality System and process effectiveness.

2.1.3 Implementation Guidance

What does it mean?

This element is closely linked to 2.1.2 and is one of the tangible actions which demonstrate management commitment and involvement.

The site must review their SQF Quality System when any changes occur that impact quality. This may include changes to product formulations, raw or packaging materials, processing or packaging equipment or changes to personnel. The SQF Quality practitioner is responsible for managing such changes, but senior management is responsible for authorizing and approving these changes. Senior management must also ensure that when there changes to processes, people or business operations that the integrity of the quality systems is

maintained and that change management procedures are maintained on a consistent basis. To ensure the practitioner and senior management are effectively communicating there must meet at least monthly to review SQF Quality System performance.

Ideally, the SQF System is reviewed on a regular basis as part of a management review of all operational activities. However at a minimum, a full review of the SQF System must be completed annually by senior management.

What do I have to do?

Senior management must ensure the entire SQF Quality System is reviewed. This should be conducted on a regular basis, however as an absolute minimum, annually. This review shall include the policies outlined in company's policy statement, findings from the regularly scheduled internal and external audits, customer complaints, test records, deviation reports and outcomes of corrective actions.

A procedure documenting how the review of SQF System is conducted shall be included in the food safety and quality manual. The review must be conducted by senior management with the objective of ensuring the continued integrity of the food safety and quality management system.

The review shall measure the effectiveness of the SQF System against the food safety and quality objectives established by senior management and the effectiveness of corrective actions taken in response to deficiencies in the System. The focus shall also be on the effectiveness of quality programs and the ongoing accuracy and validation of the Food Quality Plan(s).

All reviews and major changes to the SQF System shall be recorded by the SQF practitioner, including the reasons for any changes and the actions taken as a result of changes or reviews. A record of monthly meetings and/or communication with senior management about changes and performance of the SQF Quality system shall be available.

Major changes to a process, a process control or any changes that could impact on the ability of the SQF Quality system to deliver a safe quality food shall trigger a review of the Food Quality Plan in addition to the annual review. Any major changes to Food Quality Plans shall be validated and verified before implementation.

A documented change management process shall ensure that any changes are correctly cascaded to all who need to know of such changes and that the change is managed in a way to maintain the integrity of the quality system at all times.

2.1.3 Auditing Guidance

The auditor will seek evidence of the existence of a management review procedure and compliance to this requirement through a review of records and interviews with senior management and the SQF Quality practitioner. Evidence may include:

- Review of the management review procedure.
- Records of SQF Quality System reviews by senior management and the depth of coverage of the review meetings (e.g., quality objectives, quality points measurement, customer complaints, test records, product and process changes, etc.).
- Records and outcomes of monthly meetings of the SQF Quality practitioner and senior management.
- Identified actions from review meetings, and follow up on progress and outcomes of corrective actions.
- Changes to the products and/or operational processes since the last audit, and the extent to which these changes are reflected in the quality manual.
- The extent to which changes in materials, process or products have been validated.
- Records and documents supported change management protocol and its effectiveness in communicating changes to those who are required to know.
- Records of product and process changes and their validation.

2.1.4 Complaint Management

What the SQF Code says

2.1.4.1 The complaint management process shall include a requirement to identify and resolve the cause of all quality complaints resulting from activities at the site.

2.1.4.2 Trends in quality complaints shall be included in the performance measures established for the Quality System.

2.1.4.3 Corrective action shall be implemented based on the seriousness of the incident and as outlined in 2.5.3.

2.1.4.4 Records of quality complaints, their investigation and resolution (if applicable) shall be maintained.

2.1.4 Implementation Guidance

What does it mean?

Customer complaints provide an important measure of how well the SQF Quality System is performing. By accurately recording customer complaint types, a site can objectively measure changes in their management system and show improvements in a process. Customer complaints may also show trends that have not been identified during processing and normal process control checks. The SQF Code requires the site to implement a procedure for resolving customer quality complaints. The procedure shall outline the methods used and identify responsibilities for ensuring complaints are investigated and appropriate action is taken.

What do I have to do?

The site shall develop a procedure showing how customer quality complaints are received, investigated and responded to and the methods used to investigate complaint trends.

The procedure must detail the responsibility for investigating customer quality complaints, initiating follow up actions and communicating back to the customer how the complaint has been resolved. The procedure should include criteria for the determination of the validity of complaints.

Any trending or data management of quality complaints need to be included in the procedure. The procedure can include criteria when trends show issues that require corrective action plan development and/or process adjustment. Complaints may be locally received or received from a central site, call center, or corporate entity and shall include complaints from customers, consumers and/or regulatory authorities. All should be available for use in the complaint procedure.

When the site's corporate entity is responsible for creating and executing the complaint management program, the procedure must describe how the site is made aware of the program, how it is communicated to the site, how the site has implemented the program, and how the site verifies that the program is being followed. The site will need to verify how it is using the information that is provided by corporate to develop corrective action plans.

Records of complaints must be retained and include corrective actions and resolutions taken by the site.

2.1.4 Auditing Guidance

Customer quality complaints may be the first record that an auditor asks to review when beginning the facility audit. Customer quality complaints can provide an auditor insight into the performance of the site's SQF System and any trend areas that may require greater focus. The complaint procedure and its implementation (including follow-up and corrective actions) shall be audited through interview, observation and review of records. Evidence may include:

- Review of customer quality complaint records (i.e., complaints from customers, consumers and/or regulatory authorities);
- Review of the customer quality complaint procedure including the responsibility for collecting customer complaint data, investigating complaints and managing corrective action (refer 2.5.3);
- Investigation of the interface between a corporate reporting function and facility knowledge and investigation of customer complaints (where applicable);
- Investigation of outcomes of corrective actions taken as a result of customer complaint investigations (refer 2.5.3).

2.1.5 Crisis Management Planning

What the SQF Code says

2.1.5.1 The crisis management plan prepared by senior management shall include the methods by which the site shall, in the event of a crisis, maintain continuity of supply that meets the customers' product and service quality requirements.

2.1.5.2 The site shall contact their customers in the event of a crisis that impacts their ability to supply quality product.

2.1.5 Implementation Guidance

What does it mean?

A "business continuity plan" or what is now referred to as the Crisis Management Plan, is often confused with a "product withdrawal and recall plan" (2.6.3). They are two separate functions and programs. A crisis management plan describes actions that will be taken as a result of external, environmental, climatic, equipment failure or other potential business threats that will impact the ability of the site to provide their customers with safe, quality products. These threats, depending upon the site's product, location and other factors, may include fire, flood, power failure, storm damage, acts of terrorism, etc.

A recall plan however prescribes actions to be taken when sub-standard product, i.e. product that deviates from established safety and quality limits, is distributed and is to be recovered from the market (refer 2.6.3).

For some smaller sites, the crisis management team and recall team may be one and the same. For larger sites, they may differ.

It is expected that all SQF sites have considered the potential threats to their business and the controls necessary to ensure continuous, safe, quality food supply. Food safety and quality are commonly included together, however the SQF Quality Code will look specifically on ensuring quality aspect are considered when evaluating the various threats.

What do I have to do?

The site is required to identify a crisis management team including a senior decision maker and ensure the team is trained in crisis management procedures. The team shall identify known threats to the business which could disrupt or impact its ability to produce and provide safe, quality food and prepare a plan describing the methods and controls the site will implement to address these threats if they were to occur and how to maintain continuity of product supply during the crisis.

The plan must document in detail the controls the site will implement to assure that quality is not compromised and that if the integrity of any product is compromised, how the product will be isolated and controlled. The plan should ensure that everyone on the crisis management team is familiar with the withdrawal and recall procedures the site has documented under 2.6.3.

The plan needs to include criteria for when controls will be implemented (e.g., numbers of hours with no power, rise in product temperature prior to moving to alternative storage locations, etc.) and how criteria will be monitored during the business threat condition. Criteria are to be product specific, as appropriate. Also included are product review and disposition criteria to determine what product is recoverable, what is salvageable and what is to be destroyed. Methods for recovery, salvage, and destruction shall be described within plan.

Communication during a crisis is important. Methods for communication with customers, stakeholders and news media must be described and the individual (s) who is/are responsible for communication (s) must be identified. Specifically is must include when and how customers will be notified should the site be unable to supply products that meet their customer quality requirements.

The plan shall include a crisis alert contact list, sources of legal and practitioner assistance which may counsel senior management in a crisis situation and designation of responsibilities for internal and external communication during a crisis.

The crisis management plan shall be reviewed at least annually. All elements of the plan need to be tested. This could include a mock press release, mock incident, requirement to contact external storage locations, etc. The key provision is to have a mock crisis identified, product identified, criteria for monitoring of affected product, actions that would be taken based on results from monitoring, and final disposition of identified product. If a mock communication is created, it is not recommended to contact customers for fear of confusion.

Records of this review are required.

2.1.5 Auditing Guidance

The crisis management plan shall be reviewed and the implementation of the plan, and its annual review (including follow-up and corrective actions) audited through interview, observation and review of records. Evidence may include:

- A crisis management team has been established, trained and includes a senior decision maker;
- A crisis management plan is in place and has been tested at least annually;
- The crisis management plan includes known business threats and threats to meeting customer requirements and product and service quality levels, controls that need to be implemented, measures

to isolate affected product and a contact list of relevant authorities, legal advice and other key stakeholders;

- The crisis management plan includes identification of the individual (s) responsible for communication, including communication within the facility and to customers should they be unable to supply products meeting customer requirements;
- Where the annual review of the crisis management plan has identified non-compliances or areas requiring improvements, corrective actions (refer 2.5.3) have been identified and implemented;
- Records of crisis management plan reviews and their corrective actions are available.

2.2 Document Control and Records

2.2.1 Quality Management System

What the SQF Code says

2.2.1.1 A quality manual shall be documented and maintained in either electronic and/or hard copy form. It shall outline the methods the site uses to meet the requirements of the SQF Quality Code, be made available to staff, and include:

i. A summary of the organization's quality policies and the methods it will apply to meet the requirements of the SQF Quality Code;
ii. The policy statement and site organization chart;
iii. A list of the products covered under the scope of certification;
iv. Finished product specifications agreed with customers' or corporate quality requirements where applicable; and
v. Statistical process control methods and other quality tools that are used to control and reduce process variation.

The quality manual may be incorporated into, or independent from the SQF food safety manual, and shall be signed by senior management.

2.2.1 Implementation Guidance

What does it mean?

In general, quality management systems involve "saying what you do," e.g., documenting policies, specifications, procedures, Quality plans and work instructions that agree with the standard (in this case, the SQF Code), and "doing what you say," e.g., operating based on those documented policies and procedures. This is reflected throughout the SQF Code in the use of the terms "documented and implemented."

In the SQF Code the food quality manual is the documented system ("saying what you do") that must be implemented ("doing what you say").

The quality manual must be practical, usable, and available to all employees with a responsibility for food quality. It can be stored electronically or in hard copy, and the currency and security of the manual must be controlled (refer 2.2.1). The form and structure of the manual is determined entirely by the site. It must be in a language and a form that is understood by all relevant employees.

What do I have to do?

The site must prepare a quality manual that documents the policies, procedures, Food Quality Plan(s), specifications and work instructions necessary to support the development, implementation, maintenance and control of the SQF Quality System. Note that the quality manual and food safety manual may be combined since they will be similar in structure and design. It is the sites preference whether to combine or not.

The manual will include the company policy statement and an organizational chart. It will include the Food Quality Plan(s) (refer 2.4.3) for all products included in the site's scope of certification. It will also include reference too or a listing of finished product specifications and description of how SPC or other quality tools are used to measure conformance to specifications.

There is no prescribed format for how the manual (s) is/are to be constructed. Format is determined by the site. It can be divided into a policy manual, food safety manual and quality manual, or combined into one manual. It can be integrated with other operational procedures, or housed in a separate SQF manual - the choice depends on what

best suits the site's business.

The main criteria are to ensure that the manual conforms to the requirements of the SQF Code that are relevant for that industry sector and site, and that it is readily useable by the staff located at the site. It therefore is to be brief and concise and be available in a form and language that meets the access needs, language and literacy levels of the operating staff.

2.2.1 Auditing Guidance

The quality manual shall be thoroughly audited for its content as well as its implementation. Formatting and whether or not it is combined with food safety is not to be considered as this is the sites preference. The auditor shall review changes and conduct checks of the documentation, including specifications or procedures that may impact on quality.

The auditor will seek evidence of compliance to this requirement by reviewing documentation. Evidence may include:

- The manual includes the company policy statement (refer 2.1.1) and organizational structure and job descriptions (refer 2.1.2)
- The manual includes a summary of the site's quality policies, and covers all relevant elements of the SQF Code.
- The manual includes procedures and/or work instructions for all programs that effect product quality included within the site's scope of certification.
- The manual includes specifications for all products included within the site's scope of certification.
- The manual includes description of the application of SPC and/or other quality tools in measuring conformance to customer requirements and specifications.
- The manual includes the Food Quality Plan(s) for all products included in the site's scope of certification.
- The manual is current, concise, available, and usable by employees within the site's facility.

2.2.2 Document Control

What the SQF Code says

2.2.2.1 The methods and responsibility for maintenance, storage, and distribution of quality documents shall be the same as those required for SQF Food Safety System documentation.

2.2.2 Implementation Guidance

What does it mean?

This element relates back to *2.1.3 Food Safety and Quality Management System.* All management system documents (e.g., policies, procedures, specifications, food safety plans, food quality plans, work instructions), plus any other operational reference documents (e.g., external codes, regulations, customer requirements, equipment instructions, etc.), must be controlled to ensure their currency and relevance. This includes forms which are the templates for records that are used to report test, inspection and audit results.

Documents can be stored electronically or be paper-based, or a blend of both. However, the current copy of the relevant documents must be available to staff and employees that need to use them. A list of documents and amendments to documents must be maintained to identify the current documents in use.

What do I have to do?

To comply with this requirement, the site must designate a staff member who is responsible for document storage and security and how documents are controlled; distributing current versions to relevant employees; and ensuring that documents are up-to-date. Worn, illegible or out-of-date documents must be replaced. A written procedure describing how documents will be maintained, updated and replaced must be developed and in place. The procedures must specifically include reference to quality documents as well as food safety documents.

A register of all documents must be maintained including when they were issued, updated and who has a copy of each document. Documents referred to include, for example, quality programs, food quality plans, SOPs, other work instructions and raw material and finished product specifications, etc.

Any requirements for corrections or maintenance of records must be recorded in document control procedures,

including the appropriate methods for addressing corrections.

2.2.2 Auditing Guidance

The auditor will seek evidence of the existence of a document control procedure and compliance to this requirement by observation, interview with the responsible person and interviews with staff to ensure they have current documents available that are specific to quality and that such controls are equivalent to those used on food safety documents. Evidence may include:

- Review of the document control procedure;
- Review of the document register and list of amendments, and their accuracy;
- Availability and currency of documents in use;
- Security and storage of documents;
- All personnel who need access to specific documents such as food quality plans, procedures and customer specifications have such access.

2.2.3 Records

What the SQF Code says

2.2.3.1 The methods and responsibility for authorization, accessibility, retention and storage of quality records shall be the same as those required for SQF Food Safety System records.

2.2.3 Implementation Guidance

What does it mean?

Records are the information about operations recorded on forms, which must be clear, concise, legible and accurate. Records must be stored in a manner that does not lead to being damaged so they can be retrieved for investigation purposes. Storage can be electronic or paper-based. The SQF Code states that records must be suitably authorized and must be stored as required by the corporation, customer or legislation.

Various roles within the business may be responsible for completing records, including those who are responsible for monitoring, testing, and/or auditing. Other staff members (including the SQF practitioner) may be responsible for verifying the accuracy of records (refer 2.5.4), and one or more may be responsible for retrieving and storing records. All such individuals must be identified and made aware of their responsibilities.

What do I have to do?

The site must develop a written procedure that documents responsibilities for completing quality related records (e.g., monitoring records, inspection and test records, etc.) and identifying those responsible for verifying the records. Such procedures shall minimally be the same or equal to those being applied to food safety documents.

Records must be retained under secure conditions as required by customer specifications and legislation.

Employees who are responsible for monitoring and recording activities must be made aware of the importance of maintaining all records in a clear and legible manner and the importance of recording the information at the time the activity is performed.

The employees responsible for monitoring critical quality points (CQPs) in the process are required to sign the record indicating the entry and the date it was made (or electronically authorize the entry). In addition, the site is required to ensure that staff responsible for verifying quality records sign and date each record they review as part of their verification activities (refer 2.5.4). These responsibilities and actions must be documented in the procedure.

Electronic records are acceptable. The site must have the means to manage electronic security of records, electronic signatures of monitors and reviewers and the means for electronic review.

On paper-based records, the use of correction fluid to address corrections is not recommended. A line through the inaccurate recording, with accurate recording and initials of the monitor is recommended.

There is no prescribed duration for retention of records. For some sites it may be prescribed by legislation, customer requirements or insurance coverage. Apart from those requirements, the general rule is to retain records for the

commercial shelf-life of the product (i.e., the maximum time before consumption). However, for short shelf-life products, sites must retain records beyond the next recertification audit, as a minimum.

2.2.3 Auditing Guidance

The auditor will seek evidence of the existence of procedures or work instructions for monitoring activities, verification activities, and record storage for those related to the quality system. The auditor will review a sample of records selected and may interview employees who complete the records. Evidence may include:

- Documented procedures defining the methods and responsibilities for undertaking activities to monitor critical quality points and other activities necessary to maintain food quality, and accurately and legibly recording results;
- Documented procedures defining the methods and responsibilities for verifying monitoring activities and accurately and legibly recording results;
- Documented procedures defining the methods and responsibilities for undertaking testing and/or auditing activities and accurately and legibly recording results;
- Accurate and legible records for all required activities;
- Understanding of actions required when recorded results show deviations from required values (e.g., outside critical limits);
- Records are securely stored and accessible.

It must also be mentioned that intentional, systemic falsification of records can result in suspension and/or withdrawal for the SQF Quality Code certificate.

2.3 Specification and Product Development

2.3.1 Product Development and Realization

What the SQF Code says

2.3.1.1 The methods for designing, developing and converting product concepts to commercial realization shall include a process capability analysis to ensure that processes are able to consistently supply products that meet customer specifications.

2.3.1.2 Product formulation, manufacturing processes and the fulfillment of product quality requirements shall be validated by facility trials and product testing.

2.3.1.3 Shelf life trials shall be conducted to establish and validate a product's packaging, handling, storage and customer use requirements through to the end of its commercial life and consumer use.

2.3.1.4 A food quality plan shall be validated and verified for each new product and its associated process from conversion to commercial production and distribution, or where a change to ingredients, process, or packaging occurs that may impact food quality.

2.3.1.5 Records of all quality tests, product design, process development, and shelf life trials associated with product changes or new product development shall be maintained.

2.3.1 Implementation Guidance

What does it mean?

New products and revisions to existing products are generally developed in the food research laboratory or at best, in pilot scale. However, commercially produced products are likely to have more process variability than bench or pilot products. The site must have a procedure in place to ensure the quality of products escalated from bench/pilot scale production to full commercial production. This will include a food quality plan for new or revised products, shelf-life trials, process capabilities and validation, label declarations, allergen cross-contact trials, raw material, ingredient and packaging trials.

This applies to new products, changes to existing products and introduction of new materials or pack sizes.

This is not a mandatory element as not all facilities are involved in product changes or new product introductions. However, any SQF certified facility that does introduce new products, packages or product revisions must have a documented procedure in place and implemented.

What do I have to do?

The site must describe the methods and people responsible for the process by which new products are converted into commercial applications. Methods should include specific procedures required for transition from pilot plants and test kitchens to full-scale in-plant production.

Even if the site's corporate function is responsible for creating the product development program, that program is the responsibility of the site once it reaches commercial development and products are being produced, sold and distributed into the market.

Any product claims must be substantiated by means of product research and/or testing, and shelf-life testing will be carried out as required. Any testing that is required may be focused on product performance, customer handling or new packaging conditions. If the site determines that shelf-life testing is not required, the site must document the reason for this decision and any supporting evidence.

As the product is being prepared for transition from pilot or test phase to commercial production, any new processes, equipment, additional handling, new packaging or storage conditions must be reviewed with identification of any possible food quality risks associated with new conditions. These risks must be assessed, and adjustments made to food quality plans prior to implementation. Additionally, process capability studies must be conducted to ensure customer requirements and compliance to specifications are achievable.

Any adjustments to food quality plans must be validated and verified by the SQF Quality practitioner prior to commercial production of the subject product.

Safe handling information must be included on all packaging, as required by legislation (regulation) and/or customer use.

2.3.1 Auditing Guidance

The auditor will seek evidence of the existence of a product realization procedure at the desk audit and compliance to this requirement by observation, interview and review of amendments and records at the facility audit. Evidence may include:

- Review of the product realization procedure include process capability analysis;
- Review of shelf-life studies to ensure products meet customer requirements through to the end of stated shelf life;
- Review of product, process, material and/or equipment changes or introductions;
- Amendments to food quality plans, procedures or specifications as a result of product changes or introductions;
- Verification of changes to documentation;
- Communication of changes to relevant staff.

2.3.2 Raw and Packaging Materials

What the SQF Code says

2.3.2.1 Specifications for all raw and packaging materials, including, but not limited to ingredients, additives, hazardous chemicals and processing aids that impact on finished product quality shall be documented and kept current.

2.3.2.2 Raw and packaging materials and ingredients shall be validated to ensure product quality is not compromised and the material is fit for its intended purpose.

2.3.2.3 Product labels that are designed or specified by customers shall be approved by those customers. Records shall be maintained of customer approvals.

2.3.2.4 The register of current raw and packaging material specifications shall include those raw and packaging materials impacting product quality and customer labels.

2.3.2 Implementation Guidance

What does it mean?

This element links with *2.4.5 Incoming Goods and Services.* Before a site program can be implemented, specifications must be in place for all materials that could impact product quality. This relates to raw materials, ingredients, packaging materials, processing aids, additives and chemicals used within their facility including cleaning compounds. The site is required to keep Material Safety Data Sheets (MSDS) and labels for all chemicals that are in use on-site.

What do I have to do?

Specifications must fully describe the materials provided. Quality related detail included in material specifications could include information such as color, grade, nutritional data, size, weight, type of packaging, etc. Quality requirements may be determined by customers.

A register of all raw material and packaging specifications (including finished product labels) must be kept, including a version number and date so that there is proof that specifications are updated as needed. The site must ensure that all relevant departments and employees have the most current information.

All raw and packaging materials must be validated to ensure threats and risks to finished product quality are identified and controlled. Raw and packaging materials should be included in the Food Quality Plan (refer 2.4.3) to ensure that controls are in place to control threats or reduce them to an acceptable level.

Validation is testing over and above daily monitoring to ensure that established quality limits are effective, i.e., they achieve the desired results, so that the site can have confidence that the product and process are capable of meeting customer requirements. Validation methods will vary depending on the risk to finished product quality. Validation for low risk materials may include certificates of analysis or certificates of conformance, provided by a trusted vendor. For high risk materials, testing and analysis is required for validation, and must be carried out annually (refer 2.5.2).

All current specifications for materials that could impact food quality must be included on a register (list) or referenced database.

2.3.2 Auditing Guidance

The auditor will seek evidence of the existence and currency of material specifications and a procedure for developing and approving specifications. During the certification and re-certification audits, the auditor will confirm compliance to this procedure; the material specification register and the process for checking compliance to specifications, validating specifications and ensuring relevant employees have access to current copies of specifications (refer also 2.2.1). Evidence will be sought by interview, review of specifications and record review, and may include:

- Review of the procedure for developing and approving specifications;
- Confirmation that the register of raw and packaging material specifications includes all on-site materials;
- Review of a selected sample of material specifications to confirm agreement with relevant legislation, if applicable for quality;
- Review of a selected sample of material specifications, in particular for high risk materials, to ensure potential factors impacting on product quality are included;
- Availability of current copies of specifications to relevant staff;
- Interview of staff conducting validation activities;

- Review of records of validation checks.

2.3.3 Contract Service Providers

What the SQF Code says

2.3.3.1 Specifications for contract services that have an impact on in-process or finished product quality shall be documented, current, include a full description of the service to be provided and detail relevant training requirements of contract personnel.

2.3.3.2 The register of contract service specifications shall include those services impacting product quality.

2.3.3 Implementation Guidance

What does it mean?

Many duties within the food production or processing facility may be conducted by individuals or organizations that are not employed by the business, but are contracted to provide specialist services. These may include companies involved in transport, construction, contract labor hire, engineering, pest control, sanitation, chemical management, trash collection, refrigerated storage or uniform cleaning.

The contract service does not need to directly involve product quality, but could still indirectly affect the product or facility. For example, construction engineers may not have direct contact with food manufacturing, but their work and presence in a food handling facility can indirectly impact food quality.

This element of the Code addresses how the services from these outside organizations are controlled, monitored and verified to ensure that food quality is maintained and customer specifications are achieved.

What do I have to do?

Just as with raw and packaging materials, specifications must also be in place for all providers of contract services. The specification may be included in the contract, and will describe fully the services provided, and how the quality of product are protected from the actions and presence of contract personnel. This will include, as necessary, the qualifications of contract personnel and the equipment, tools, and chemicals permitted on site.

Contractors working within the facility will be subject to the same personal hygiene and welfare conditions as employees. These conditions shall be included in the contract specification.

The specification must include the training required by contract service providers. Training examples could be training done by service providers, training completed by site or certification as demonstration of training.

All current specifications for contract service providers must be included on a register (list).

2.3.3 Auditing Guidance

The auditor will seek evidence of the existence of a register of contract service specifications and will review a sample of specifications to ensure compliance with the requirements of the Code. Evidence will be sought by interview, review of specifications, and observation, and may include:

- Review of selected sample of contract service specifications to confirm compliance with the SQF Code requirements;
- Qualifications and credentials of contract staff;
- Knowledge of contract service and Code requirements by contract personnel.

2.3.4 Contract Manufacturers

What the SQF Code says

2.3.4.1 The methods and responsibility for ensuring all agreements relating to customer product requirements and its realization and delivery are specified and agreed shall be documented and implemented.

2.3.4.2 The site shall:

i. Ensure that the processes in place at the contract manufacturer are capable of consistently meeting customer requirements, or corporate quality requirements where applicable;

ii. Verify compliance with the SQF Quality Code and that all customer requirements are being met at all times;

iii. Audit the contract manufacturer annually at a minimum to confirm compliance to the SQF Quality Code and agreed arrangements, or accept the manufacturer's certification to the SQF Quality Code or equivalent; and

iv. Ensure changes to contractual agreements are approved by both parties, agreed with customers where necessary, and communicated to relevant personnel.

2.3.4.3 Records of all contract reviews and changes to contractual agreements and their approvals extend to quality records.

2.3.4 Implementation Guidance

What does it mean?

Contract manufacturers are facilities that are contracted by the SQF certified site to produce, process, pack, and/or store part of all of one or more products included in the site's product scope. In some cases, a product may be manufactured interchangeably on site and at a contracted facility. In other cases, a contract manufacturer may only be used intermittently to fulfill or supplement the site's production.

Whatever the situation, any contract facility used to manufacture, in part or in whole, an SQF certified product MUST fulfill the same requirements as the SQF certified site. The responsibility for ensuring that these conditions are met is part of the primary site's SQF System.

What do I have to do?

The site must have a documented procedure detailing how they will ensure that product in the care of the contact manufacturer meets their customer specifications and the requirements of the SQF Code. Control quality management system in an external facility that is under different management is not an easy task. However, the site must ensure that facilities selected to contract manufacturer are committed to meeting SQF System requirements. This includes management commitment, pre-requisite programs, document control and records, adhering to specifications, food quality plans and all other quality controls.

The site may simply require the contract manufacturer themselves to be independently SQF certified, or may choose to control the conditions in the contract facility via sampling, testing, inspections and internal auditing. In the latter case, a verification schedule, including a sampling plan and internal audit procedure must be included.

If the contract manufacturer is processing or packing high risk product on behalf of the site, then the contract manufacturer must undergo an audit to the requirements of the SQF Code for the particular food sector category. The audit may be conducted by the site, or by an independent third party agency, and must be conducted at least annually. The audit does not necessarily require certification but must confirm compliance to the requirements of the SQF Code.

An annual SQF audit of the contract manufacturer does not replace the need for other regular checks and inspections at regular intervals.

Any changes to customer specifications must be fully documented. Procedures must include a communication plan to contract manufacturer(s) with changes to specification identified. The site's procedure must include verification that the contract manufacturer is aware of the changes to specification and that product produced after the change has been implemented reflects those required changes.

2.3.4 Auditing Guidance

The auditor will seek evidence of the existence of a documented arrangement binding the contract manufacturer to the SQF Code and detailing the methods by which the site confirms those arrangements.

Evidence will be sought by interview, observation and review of records. Evidence may include:

- Review of the contract agreement and procedure for monitoring and verification of contracted product;
- Records of certification, internal audits, product sampling and testing from contracted facilities.
- Records of SQF audits of facilities contracted to manufacture high risk food.

Note: in situations where the auditor feels that there is product risk from the contracted facility, the auditor may require a visit to that facility to confirm compliance to the Code and the agreed arrangements.

2.3.5 Finished Product Specifications

What the SQF Code says

2.3.5.1 Finished product specifications shall be documented, current, approved by the site and their customer, accessible to relevant staff and shall include product quality attributes, service delivery requirements, and labelling and packaging requirements.
2.3.5.2 Customer product specifications and delivery requirements shall be communicated to appropriate departments and staff within the site.

2.3.5 Implementation Guidance

What does it mean?

A written finished product specification must be provided for all products covered under the supplier's SQF Certification. In some cases, industry sector specifications may apply for example for bulk consignments exported to world commodity markets. In other cases, the specification may be provided by the customer. It is important that the supplier does not undertake to supply goods where the specification is not consistently achievable under all processing and raw material supply conditions.

What do I have to do?

The supplier must develop a written finished product specification for each product (or group of similar products) covered under the scope of certification. The specification must, as a minimum, comply with the appropriate food safety legislation (including labeling requirements) and must be updated as required. The supplier must keep a copy of all finished product specifications and a register of all versions of these documents.

A finished product specification can include physical (e.g., size/grade, color, net weight, etc.), microbiological (e.g., aerobic plate count, yeast and mold, lactic, coliforms), chemical (e.g., salt, moisture, titratable acidity, pH, fat content, brix, viscosity, etc.) and the packaging specifications for the product.

The supplier needs to ensure that the annual review of the SQF System (refer 2.1.4.2) includes a review of the finished product specifications and that the list of specifications is maintained and kept current in a register (list).

Customers will normally provide finished product specifications and if this is the case, it is advisable that both the supplier and their customers agree the specification is achievable and agree on the quality attributes of the product to be supplied. For stock items that are not customer specific, the supplier is expected to develop finished product specifications for those items.

The specification must be made available to relevant processing staff in production, process control and QA personnel

2.3.5 Auditing Guidance

Finished product specifications will be included in the quality manual. At each certification audit, the auditor will ensure that all specifications exist for all products included in the scope of certification and that the site is capable of and ensures compliance with the specifications. Evidence may include:

- Every product covered by the scope of certification is covered by a specification;
- Specifications are current and agreed with customers;
- Specifications include all significant parameters required to ensure the quality of the product;
- Current versions of specifications are available to all relevant staff;
- The site has methods and criteria for sampling and testing finished product (refer 2.5.4) to ensure compliance with finished product specifications;

- The site has processes in place to ensure that product released(refer 2.4.7) meets specifications;

Specifications are reviewed as part of the management review process (refer 2.1.4.2).

2.4 Food Quality System

2.4.1 Customer Requirements

What the SQF Code says

2.4.1.1 The requirements and expectations of customers and final consumers shall be continually reviewed to ensure the accuracy of specifications and the ability to supply to customer needs. A full review of customers' expectations for product and delivery shall occur at least annually.

2.4.1.2 The site shall have a procedure in place to notify essential customers where their ability to supply product that meets customer specifications is temporarily suspended or halted.

2.4.1.3 Where customer products, materials or equipment are used within the facility, the site shall have measures in place to safeguard customer property and ensure its correct and proper use.

2.4.1 Implementation Guidance

What does it mean?

Understanding customer requirements and continually meeting them and reviewing them for any changes is an essential element of the SQF Quality system. Key metrics, such as specifications, are derived from them and will contribute to the establishment of critical limits for Critical Quality Points (CQP's) or other possible control points within the Food Quality Plan.

What do I have to do?

The site must develop a review process that enables it to continually and at least annually ensure it has the ability to supply products that conform to all customer requirements that are part of contractual obligations. Where sites produce their own brands then finished products specification or other industry benchmarked quality requirements will service as the requirements to adhere to. Service requirements (e.g. delivery, lead times etc) that are part of contractual requirements must also be reviewed and measured to conformance.

In situations where the site cannot supply product that meets specifications the site shall have a procedure that they follow that outlines how they will notify and communicate with their customer. This could be part of a procedure used in the Crisis Management Plan (ref 2.1.5).

In situations where customer products, materials or equipment are used or stored within a facility, they shall be maintained and protected so they ensure proper use. This may include segregation, identification, separate cleaning procedures etc. The site should ensure they follow any directions from the customer in this regard thay may or may not be included in their customer requirements or contracts.

2.4.1 Auditing Guidance

The auditor focus on customer requirements will be essential reference point in the audit. The procedure, protocols and results relating to review of and adherence to customer requirements and specifications will be audited through documents, interviews and process capability analysis. Evidence may include:

- Customer requirements review procedures and resulting records;
- Process capability analysis to ensure compliance to meeting specifications;
- Notification protocols if unable to supply products; and
- Observation of controls placed on customer products, material or equipment if used on the site.

2.4.2 Quality Fundamentals

What the SQF Code says

2.4.2.1 The buildings and equipment shall be constructed, designed and maintained to facilitate the manufacture, handling, storage and/or delivery of food that meets customer specifications or corporate quality requirements.

2.4.2.2 The methods and responsibility for the calibration of measuring, test and inspection equipment used for quality testing of raw materials, work-in-progress, and finished product, 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.

2.4.2.3 Storage and transport of raw materials, work-in progress, and finished product shall be suitable to maintain the integrity of the product without loss, waste or damage.

2.4.2 Implementation Guidance

What does it mean?

The SQF Food Safety Codes contain requirements to ensure that certified sites have Good Manufacturing Practices in place that provide for controls of risk to the safety of the products produced. Within the SQF quality system there are some specific elements of GMP's that are quality fundamentals which are outlined in 2.4.2. These include building and equipment design and maintenance that impact quality, calibration of testing and measuring equipment used to demonstrate compliance to specifications and any storage or transportation that ensure products or ingredients/raw materials continue to meet quality requirements.

What do I have to do?

The site should review any customer requirements that might include reference to how building and equipment designs and maintenance need to be altered in order to continually meet customer requirements. Results of conformance monitoring or quality complaints could also be used to influence any structural or on-going maintenance practices that may need to be altered in order to achieve continual compliance to requirements.

Measurement devices or equipment are an importance tools used to ensure compliance to specification. It is imperative that operators or other staff that use them have confidence in their reliability and repeatability so that resulting measurements can be confidently used to monitor and/or adjust process to meet specifications. The calibrations and on-going maintenance of these devices must be recorded and adjustment or replacement made accordingly. These protocols could be similar to those used for food safety devices, that would be included in a sites SQF food safety system. The site should review all devices or equipment used to monitor any process points or finished product that measure conformance to specifications and ensure they are calibrated and/or functioning with accuracy. If software, such as preventative maintenance programs, are used they will need to validated to ensure they deliver required functionality that aligns with written procedures.

In the same way that storage and transportation activities are assessment for their potential risk to food safety, they must also be assessed for any quality threats that could impact the integrity of the product. The assessment should be included in the Food Quality Plan and the resulting control measure documented and implemented accordingly. The site should consider conditions that might affect shelf-life, packing material performance to protect product, legibility of graphics and date codes, pallet configuration to minimize damage etc.

2.4.2 Auditing Guidance

The auditor will confirm compliance to this element at the audit by interview, observation and sampling and checking records. Cross reference to GMP's and/or prerequisite programs from the food safety system is likely since the quality threats of concern would align with them. Evidence may include:

- Observation of the condition and design of buildings and equipment and how it aligns with any specific customer requirements or threats assessed within the food quality plan;
- Measurement devices or equipment used to assess quality monitoring points or verification and to ensure they are included in calibration activities. Observation of calibration, reference to SOP's and interviews with employees can be used;
- Records of calibration activities and adherence to stated schedules and frequencies;
- Software validation records and on-site challenge testing to ensure functionality support written

procedures for calibration activities; and

- Observation of storage and transportation conditions and activities and its impact on quality, losses or waste.

2.4.3 Food Quality Plan

What the SQF Code says

2.4.3.1 A food quality plan shall be developed, effectively implemented, and maintained in accordance with the Codex Alimentarius Commission HACCP method. The food quality plan may be combined with, or independent from, the food safety plan, but must separately identify quality threats and their controls, and critical quality points.

2.4.3.2 The food quality plan shall outline the means by which the site controls and assures the quality attributes of the products or product groups and their associated processes.

2.4.3.3 The food quality plan shall be developed and maintained by a multidisciplinary team that includes the SQF practitioner and those site personnel with technical, production, and marketing knowledge of the relevant products and associated processes. Where the relevant expertise is not available on site, advice may be obtained from other sources to assist the food quality team. The composition of the food quality team may be different from the food safety team.

2.4.3.4 The scope of the food quality plan shall be developed and documented including the start and end-point of the process under consideration and all relevant inputs and outputs.

2.4.3.5 Product descriptions shall be developed and documented for all products included in the scope of the food quality plan. This shall include information in the finished product specifications (refer to 2.3.5.1) plus any additional quality or service attributes established by agreement with the customers.

2.4.3.6 The intended use of each product shall be determined and documented by the food quality team. This shall include as appropriate target consumer groups, ease of use by consumers, consumer instructions, tamper evidence, and other applicable information affecting product quality.

2.4.3.7 The food quality team shall review the flow diagram developed and confirmed as part of the food safety plan, and ensure process steps, process delays, and inputs that impact product quality are included.

2.4.3.8 The food quality team shall identify and document all quality threats that can reasonably be expected to occur at each step in the processes, including raw materials and other inputs.

2.4.3.9 The food quality team shall conduct a quality threat analysis for every identified quality threat, to identify which threats are significant, i.e. their elimination or reduction to an acceptable level is necessary to ensure or maintain product quality. The methodology for determining threat significance shall be documented and used consistently to assess all potential quality threats.

2.4.3.10 The food quality team shall determine and document the control measures that must be applied to all significant quality threats. More than one control measure may be required to control an identified threat, and more than one significant threat may be controlled by a specific control measure.

2.4.3.11 Based on the results of the threat analysis (refer to 2.4.3.9), the food quality team shall identify the steps in the process where control must be applied to eliminate a significant threat or reduce it to an acceptable level. These steps shall be identified as Critical Quality Points or CQPs.

2.4.3.12 For each identified CQP, the food quality team shall identify and document the quality limits that separate acceptable from unacceptable product. The food quality team shall validate the critical quality limits to ensure the designated level of control of the identified quality threat (s); and that all critical quality limits and control measures individually or in combination effectively provide the level of control required.

2.4.3.13 The food quality team shall develop and document procedures to monitor CQPs to ensure they remain within the established limits (refer to 2.4.3.12). Monitoring procedures shall identify the personnel assigned to conduct testing, the sampling and test methods, and the test frequency.

2.4.3.14 The food quality team shall develop and document deviation procedures that identify the disposition of affected product when monitoring indicates a loss of control at a CQP. The procedures shall also prescribe actions to correct the process step to prevent recurrence of the quality failure.

2.4.3.15 The documented and approved food quality plan shall be fully implemented. The effective implementation shall be monitored by the food quality team, and a full review of the documented and implemented plans shall be conducted at least annually, or when changes to the process, equipment, specifications or inputs occur which may affect product quality.

2.4.3.16 Implemented food quality plans shall be verified as part of SQF Quality System verification (refer to 2.5).

2.4.3 Implementation Guidance

What does it mean?

The Food Quality Plan is the foundation of the site's SQF Quality System. The Food Quality Plan (FQP) must be prepared using the HACCP method, which means that all products and processes included in the SQF scope of certification must be addressed in one or more FQP's. The Codex HACCP method must be used. All HACCP method principles and implementation steps must be included in the FQP(s). The FQP(s) must be fully developed by the site, meaning the site may use the services of an SQF consultant, but takes full responsibility for the FQP.

It is self-apparent but important to recognize that the FQP cannot just be paper-based, but must be fully implemented. The FQP implemented by the site must be similar in its rigor to the Food Safety Plan and, in the words of the GFSI Guidance Document, sixth edition, be "systematic, comprehensive, and thorough."

What do I have to do?

The site must develop and fully implement a Food Quality Plan (Plan) using the Codex HACCP method, that at a minimum follows the twelve HACCP method implementation steps:

1. A multi-disciplinary team must be implemented which includes expertise on the process and product quality. A team leader must be appointed that is fully trained in the HACCP method. This team leader may be the SQF quality practitioner. Training must also be provided for all team members (refer 2.9.4). The scope of the Plan must also be determined, e.g. the products included in the plan and the start and end points of the process under consideration. Note the scope must be similar to that used to develop the Food Safety Plan.
2. Product descriptions must be prepared for all products included in the Plan that includes all relevant product quality information. This may or may not already be included in the product specifications (refer 2.3.5).
3. The intended use of each of the products included in the scope must be identified, e.g. is the product intended to be further processed, or prepared by the consumer prior to consumption, or is it ready-to-eat. Is the product intended for consumption by a vulnerable group, or by the general population (remembering that general population includes vulnerable consumers).
4. Construct a process flow diagram that covers the agreed scope (see step 1 above) of the process and includes all process inputs (e.g., raw materials, packing materials, processing aids), and outputs (including second grade product, product for rework). Every step in the process must be identified.
5. The team must walk the process and confirm the flow diagram, including any variations on back shifts or overtime shifts. The team leader must sign off on the flow diagram.
6. Steps 1 through 5 allow the team to gather all the necessary information to complete step 6, which is also Principle 1 of HACCP. This step can be separated into three components:
    a) For each step of the process identified in step 5, the team must identify **all** food quality threats, including potential food quality threats and what would be considered the most likely cause. Threats should be those that can affect the finished product quality and its compliance to customer/consumer requirements.
    b) For each identified threat, conduct an analysis to determine the potential likelihood of the hazard occurring and the business risk if it did occur (collectively referred to as the significance). There is no specified methodology for conducting this analysis, although there are many methodologies used within the food industry. SQFI expects that the method used is logical, evidence based, consistently applied across all identified threats in the Plan, and documented.
    c) Determine the control measures required for each identified significant threat, and ensure procedures (SOPs) and/or work instructions are in place to apply this control.
7. Critical Quality Points (CQPs) are steps in the process where control is essential to eliminate an identified threat or reduce it to an acceptable level, e.g. weights, colour, dimensions, viscosity etc. Codex includes a decision tree for determining CCPs in food safety plan, which will works well for CQP determination. Again, the methodology chosen for determining CQPs must be applied consistently.

   If a threat has been identified as significant and no control measure exists for that threat, then the process must be changed to ensure control can be applied at some point in the process.
8. All subsequent steps in the Plan relate to CQPs. Critical limits are according to the Codex definition, "criteria that separate acceptability from unacceptability." They are values that are set and easily measured, that identify "quality" from "non-compliant" product. Critical limits must be established for each QCP and must be validated (refer 2.5.2), or justified by regulation, customer requirements or industry code of practice.
9. Monitoring is the regular testing, or measurement of critical limits to ensure the process continues to make quality product. The Plan must identify, for each CQP, what is to be measured; who (i.e., which position) is responsible for testing/measuring; when testing is to be carried out (e.g., every hour, once per shift), and how the testing is to

be carried out. Monitoring applies to each CQP and must be supported by test work instructions and training of operators designated to carry out monitoring.

10. For each CQP, corrective actions must be established to identify action that will be taken for every deviation from critical limits (refer 2.5.3). The HACCP method is a proactive system – it pre-determines actions that will be taken before they occur. Therefore, corrective actions detailed in the Plan must be clear, concise and unambiguous. They must include actions to address or dispose of affected product (i.e., back to the last "good" check), and actions necessary to correct the process and prevent recurrence. Responsibilities for corrective actions must be identified.
11. Verification applies to the application of testing, audits and other procedures, other than monitoring, to determine compliance with the Plan. Verification is covered in element 2.5.
12. The Plan must be included in the quality manual (refer 2.2.1.1) and controlled as per 2.2.1. Records of monitoring, corrective actions and verification activities must be secured and retained according to 2.2.2.

The Food Quality Plan is not a static document. Critical limits must be re-validated at least annually by the SQF quality practitioner, and the entire Food Quality Plan verified annually. When changes occur in the process, the Plan must be updated and re-validated to reflect the changes (refer 2.1.3.3).

2.4.3 Auditing Guidance

The Food Quality Plan shall be reviewed by the auditor to ensure all products within the site's scope are covered, all potential threats are identified and the implementation steps have been followed. The Food Quality Plan, plus any changes to the plan, shall be reviewed in full at every recertification audit. Implementation of the plan will be checked by interview, observation and review of records. Evidence may include:

- The team is in place, includes expertise of the subject process, and members are trained in HACCP principles;
- The team has been fully involved in the development and review of the food quality plan;
- The product and process scope of the quality plan is defined;
- Product descriptions are available and include relevant product quality information;
- The intended use of the product is clearly defined;
- A process flow diagram has been developed and includes all process steps, inputs and outputs. It has been confirmed by the team;
- Potential threats have been identified for all process steps and an analysis conducted using a consistent and valid method to determine threats that are significant;
- Control measures are in place for all identified significant threats and procedures/work instructions are effectively implemented;
- CQPs are correctly identified using a valid methodology;
- Critical limits are in place for every CQP, and are validated to ensure consistent product quality;
- All critical limits are monitored and test procedures, responsibilities, and frequency fully documented and implemented;
- Corrective actions are documented, are clear and unambiguous, and determine the disposition of product and action required to prevent recurrence (refer 2.5.3);
- The corrective action procedure has been followed when monitoring shows deviation from critical limits (refer 2.5.3);
- Staff with responsibility for monitoring, validation, verification of critical limits, or any other food quality control measures are aware of their responsibility, trained, and are carrying out their functions correctly;
- The SQF quality practitioner ensures that the Food Quality Plan is effectively developed, implemented, maintained, and verified (refer 2.1.2.4 i).

2.4.4 Approved Supplier Program

What the SQF Code says

2.4.4.1 Raw materials, ingredients, packaging materials, and services that impact on finished product quality shall be supplied by an approved supplier.

2.4.4.2 Material suppliers shall be selected and approved based on their ability to supply materials that meet quality specifications. The evaluation program shall require suppliers to:

i. Maintain controlled and current copies of specifications;

ii. Have processes that are capable of consistently supplying materials that meet specification and other defined quality metrics (e.g. delivery. service, adherence to specifications, etc.);

iii. Be certified to a second or third party quality management system; and

iv. Have a complaints and corrective action process in place.

2.4.4.3 Material suppliers shall only be accepted into the facility based on either certificates of analysis for every lot received, or inspection at receipt to ensure materials comply with specification.

All receipts shall be visually inspected for damage and product integrity.

2.4.4.4 The approved supplier program shall include an agreement with suppliers for the return or disposal of materials that fail to meet specifications or are damaged or contaminated.

2.4.4 Implementation Guidance

What does it mean?

The objective of this element is to ensure that all incoming materials and services meet specifications and are safe. This element links with 2.3.2, which defines specifications for raw and packaging materials and 2.3.3, which defines specifications for contract service providers.

An approved supplier program is a set of procedures implemented by the site to assure the safety and quality of incoming goods and services. It may be based on the quality risk presented by the raw material, or based on historical performance or prior history of the supplier.

What do I have to do?

The site must be able to provide documented evidence that incoming materials have either been inspected or that they come from an approved supplier. The methods for selecting, evaluating, approving and monitoring an approved supplier must be documented. This will be risk-based and may be as simple as a good supply history, sourcing from certified suppliers (e.g. SQF certified suppliers) or personally auditing/inspecting the material supplier's operations, depending on risk, site knowledge and past history. Approved suppliers must have a documented and implements quality system that has been certified by a 2nd or 3rd party to ensure its validity.

The site must require their material suppliers to verify they are complying with specifications for the products supplied. The methods of analyses must conform to recognized industry standards (refer 2.5.4). Every lot of materials from approved suppliers must either be accompanied by a certificate of analysis or be inspected at receipt to ensure it meets specifications. The job functions responsible within the site business for material inspections and supplier approval must be included in the job descriptions outlined in 2.1.3.2.

The approved supplier program must include providers of contract services such as transport, pest control, maintenance, labor hire, etc. The program will identify methods to ensure service providers and their staff adhere to the specifications outlined in 2.3.3.

The site must maintain a list of approved suppliers, including contract service providers. All providers of goods and services must be included on the register. Corresponding agreements or contracts must be available for review and include terms and conditions that allow for the return or disposal of materials that fail to meet specifications or are damaged or contaminated at arrival at the site.

The approved supplier program shall be reviewed at least annually (refer 2.1.4.3) or more frequently, based on supplier performance.

The receipt of raw materials from non-approved suppliers is acceptable, but only in an emergency situation, and provided the materials are inspected before use. Records of the use of non-approved suppliers and their inspections shall be maintained.

2.4.4 Auditing Guidance

The approved supplier will be audited by interview, observation and review of records. Evidence may

include:

- Review of the documented approved supplier program to ensure all materials and services that may impact on product quality are included;
- The risk rating applied to suppliers is identified and controls implemented;
- There is a register of approved suppliers;
- All materials or services in-use are included on the site register or listed as a non-approved supplier;
- Approval methods test for compliance with agreed specifications (refer 2.3.2, 2.3.3);
- The program specifies actions to be taken when non-compliance is identified;
- Documented test/inspection methods and corrective actions have been followed;
- Relevant staff are aware of their responsibilities and duties with regard to inspection and receiving of incoming goods including confirmation of certificates of analysis or testing for each lot;
- The approved supplier program is modified based on supplier performance;
- Where non-approved suppliers have been used, goods have been inspected and a record kept;
- Contracts/agreements include provisions for the return of non-compliant or damaged/contaminated materials;
- The approved supplier program is reviewed at least annually (refer 2.1.4).

2.4.5 Non-conforming Product or Equipment

What the SQF Code says

2.4.5.1 Non-conforming product shall include products that fail to meet quality specifications.

2.4.5.2 Non-conforming equipment shall include equipment that is not suitable for use, and is not capable of producing products that meet quality specifications.

2.4.5.3 The site shall document and implement a procedure to accept returned product that does not meet finished product specifications. The procedure shall include handling of returned goods to prevent redistribution or contamination of other products.

2.4.5 Implementation Guidance

What does it mean?

Non-conforming product is product at any stage in the process that does not meet agreed quality criteria. This can apply to raw materials, ingredients, packaging materials, work-in-progress or finished product. It can also apply to any other material used in the facility that can impact product quality, e.g. cleaning chemicals, processing aids.

This element also includes how the site deals with non-conforming equipment.

What do I have to do?

The site must document the procedure that outlines how to label and identify products that are rejected or quarantined as a result of inspection, audit or process deviation. The site must describe how non-conforming product is isolated in order to avoid its re-use or shipment.

In circumstances where product is adulterated or condemned, the site must detail how the condemned product is identified and disposed of. When product is being returned from commerce the site must have a specific procedure to outline how this will occur and how it will ensure returned products to not contaminate other products or get redistributed to commerce.

The site must also document a procedure for equipment that has been found to be non-conforming. This procedure may be combined with, or separate from, that for non-conforming product. The equipment must be identified and placed out of production until it is repaired or otherwise disposed of.

The means of identification of non-conforming product and equipment must be communicated to relevant staff. This can be a system of tags, signs, designated storage locations, system holds or other methods that meet the intent of this section.

The site is required to keep all records of the disposition of non-conforming product and equipment including product that is reworked, repackaged, condemned and/or disposed of.

2.4.5 Auditing Guidance

The auditor will review the non-conforming product/equipment procedure and by observation, interview and review of records at each facility audit. Evidence may include:

- Review of the procedure for non-conforming product/equipment;
- Identification of non-conforming product and/or equipment and the action taken;
- Records of product that has not met specification
- Records of product disposition;
- Records, storage, and disposition on returned products;
- Records of repair of non-conforming equipment.

2.4.6 Product Rework

What the SQF Code says

2.4.6.1 Procedures shall be documented and implemented to ensure product quality or formulation is not compromised by the rework process.

2.4.6 Implementation Guidance

What does it mean?

The objective of this element is to ensure the products which are reworked or are of the same quality and standards as first run product. The same applies to finished products in a warehouse that are recouped (i.e., warehouse finished product that is repackaged into new secondary packaging for distribution).

If the site's process allows product to be reworked or recouped, the process must be defined and documented to ensure consistent application. This process must ensure that reworked or recouped product (s) meet the same requirements and specifications as first run product (s).

What do I have to do?

The site must document that the product has been reworked or recouped under qualified supervision and under an approved procedure.

Traceability is to be retained and product is to be clearly identified. Evidence is to be provided that each lot is released only after inspection.

An important element of the rework procedure is the criteria for determination when product is to be reworked, how much can be reworked, under what conditions it can be reworked, and how is it to be identified and traced. Product, after being reworked, must be reviewed per company-designated food quality checks to ensure that it meets all applicable specifications.

Reworking of perishable product must take into consideration the shelf-life of the product being reworked (i.e., the oldest product).

Recouping operations must ensure that recouped product is not damaged (i.e. packaging) and meets company and/or customer specifications.

Records of all reworking/recouping operations shall be maintained.

2.4.6 Auditing Guidance

Rework and/or recoup policy, procedures and work instructions shall be reviewed (if applicable) as part of the initial desk audit. The implementation policies, procedure and/or work instructions for reworking of materials or products shall be reviewed by the auditor. Evidence collected or reviewed may include:

- A policy statement on rework/recoup included in the food quality manual;

- Where applicable, procedures and/or work instructions that detail reworking/recouping methods;
- Observation of reworking/recouping operations;
- Interview of operators and supervisors involved with reworking/recouping operations;
- Confirmation of the quality and integrity of work in progress and finished product that includes rework;
- Confirmation that the shelf-life of work in progress and finished product containing rework reflects the shelf-life of the included rework;
- Sampling and analysis of reworked product is conducted;
- Recoup operations discard damaged product;
- Records of rework, recoup and/or returned product operations are maintained.

2.4.7 Product Release

What the SQF Code says

2.4.7.1 The site shall document and implement a positive product release procedure to ensure that, at the time of delivery to its customer, the food supplied complies with all agreed customer requirements including, but not limited to, product specifications, sensory, packaging and package integrity, labelling, delivery and service requirements.

2.4.7.2 Records of all product release shall be maintained.

2.4.7 Implementation Guidance

What does it mean?

A product release program ensures that only compliant products are released to the market. The site must prepare a procedure outlining the responsibility and protocols for the release of products and effectively implement that procedure. This includes compliance with quality, including sensory, requirements.

Product release also applies to the procedures for releasing quarantined or held product (refer 2.4.5).

Refer also to 2.5.4 *Product sampling, inspection, and analysis*, 2.6.1 *Product identification* and 2.6.2 *Product trace.*

What do I have to do?

A site may do this by outlining in-line process measures that demonstrate that products are compliant with specified requirements. In this procedure, the site will identify those personnel responsible for collecting samples and carrying out inspections, or ensuring that inspections are carried out, and the methods for doing so.

The product release procedure not only applies to positive release of compliant products, the site must also outline the procedure for releasing products from quarantine or hold status.

In all cases, the site shall identify those staff positions with responsibility for releasing products and indicate the action they will take when results are outside specification, including reference to other procedures for holding, reworking or disposing of product.

The site must ensure that:

- All products are confirmed as compliant and meet company or customer specifications before release to the market;
- All staff are familiar with product release procedures and that personnel authorized to release product are aware of their responsibilities; and that
- All products under quarantine or hold status are released by authorized personnel only after the product has successfully passed inspection.

All products released for distribution must have records maintained. These records should record the product name and identification, confirmation of product checks, and the product disposition (e.g., release, quarantine, hold).

Products released from hold must also be recorded. Records must include the amount of product that was held and the reason for the hold. Records should be reviewed routinely to ensure that holds are closed out. Any product that is still on-hold must be physically or visually verifiable.

2.4.7 Auditing Guidance

Procedures shall be reviewed for compliance to this requirement by observation, interview and review of records at audit. Evidence may include:

- Review of product release procedure;
- Review of product release records;
- Understanding of personnel responsible for release, quarantine and hold of product release procedures;
- Visual confirmation and follow-up on held or quarantined product.

2.5 Food Quality System Verification

2.5.1 Validation & Effectiveness

What the SQF Code says

2.5.1.1 Validation activities shall include those necessary to authenticate critical quality limits, process controls, and other quality tests established to meet customer requirements.

2.5.1.2 Records of validation of quality criteria shall be maintained.

2.5.1 Implementation Guidance

What does it mean?

Confirmation of the effectiveness of quality programs and critical quality limits is vital to ensuring that the programs and limits achieve their intended purpose, resulting in the production of quality food that meets specifications and customer requirements.

Validation involves testing over and above daily monitoring to ensure that established quality limits are effective, i.e. achieve the desired results, so that the site can have confidence that the product and process are of sufficient quality. Validation methods will vary depending on the risk to finished product quality. For threats assessed as high risk (i.e CQP's), the critical limits must be re-validated annually.

Critical quality limits are said to be validated because they have been confirmed by independent or additional analysis. Quality programs and other quality controls, however are confirmed by observation, inspection, trend analysis or audit to ensure that they are achieving the desired result.

What do I have to do?

The SQF quality practitioner is responsible for documenting and implementing the methods, responsibility and criteria for confirming the effectiveness of quality programs and validating critical quality limits to ensure they achieve their intended purpose. The site must demonstrate how the validation methods ensure that the selected critical limits achieve the level of control required for the targeted threat to product quality. The site must also have documentation showing that the methods and control measures provide the level of control needed.

Some potential methods for confirming the effectiveness of specific quality programs are listed below. The implementation of these specific methods is not necessarily required, but confirmation of the effectiveness of the program is required. This is not an exhaustive list, but provides some examples:

- Personnel practices: Observe employees during the internal audit or daily operational inspection to ensure they are meeting the requirements of the site's program.
- Personnel processing practices: Observe employees during the internal audit or daily operational inspection to ensure they are meeting the requirements of the program.
- Training of personnel: Interview employees to ensure that job training has been effective and that key points are understood.
- Calibration of equipment: Engage an outside contractor to confirm that equipment is properly calibrated.
- Premises and equipment maintenance: Trend equipment breakdowns for signs of repeat problems.

Validation methods for CQP's must demonstrate that the threat is adequately controlled. It is required for the critical limits identified for ALL CQPs. Validation of a CQP must prove that the chosen intervention controls the identified threat to the quality of the product.

All validation activities must be recorded to confirm and demonstrate they have been completed.

2.5.1 Auditing Guidance

Validation procedures shall be reviewed as being compliant to this requirement by observation, interview with the SQF quality practitioner, interviews with other relevant staff responsible for validation activities and review of records at each facility audit. Evidence may include:

- Documentation of the methods and responsibility and criteria for ensuring the effectiveness of the quality programs;
- Implementation of the methods and responsibility and criteria for ensuring the effectiveness of the quality programs;
- Quality programs achieve their intended purpose;
- Critical quality limits are validated annually or when changes to process occur;
- Methods used to validate critical limits ensure that quality criteria achieved if critical limits are met;
- Critical limits effectively provide the designated level of control;
- Personnel conducting validation activities understand their roles and responsibilities;
- Records of all verification activities are current and accurate.

2.5.2 Verification Activities

What the SQF Code says

2.5.2.1 The verification schedule shall include activities designed to ensure the effectiveness of process controls and quality tests.

2.5.2.2 The methods, responsibility and criteria for verifying the effectiveness of monitoring critical quality points and other process and quality controls shall be documented and implemented. The methods applied shall ensure that personnel with responsibility for verifying monitoring activities authorize each record.

2.5.2.3 Records of the verification of quality activities shall be maintained.

2.5.2 Implementation Guidance

What does it mean?

A verification schedule is simple enough to create, but sometimes difficult to implement. The SQF quality practitioner is responsible for all verification activities, but is not necessarily the one to conduct those activities. The practitioner must set the schedule to ensure all required verification activities are conducted and the frequency of these activities. The practitioner must also ensure that resources are available and suitably competent to conduct these activities.

What do I have to do?

This element requires the site (i.e., the SQF quality practitioner) to identify when verification activities will occur and who is responsible.

The site must have a verification schedule that:

- describes SQF quality System verification activities;
- outlines the frequency of verification;
- designates the person responsible for each verification activity; and
- provides for a log of verification activity.

2.5.2 Auditing Guidance

The verification schedule shall be reviewed for compliance by observation, interview with the SQF quality practitioner, interviews with other relevant staff responsible for validation and verification activities and review of records at each facility audit. Evidence may include:

- Review of the verification schedule including identification of those responsible for verification

activities;

- Interview with those designated as responsible for verification activities;
- Designated personnel are trained and competent to conduct verification activities;
- Verification activities conducted as per schedule.

2.5.3 Corrective and Preventative Action

What the SQF Code says

2.5.3.1 Corrective and preventative action methods shall include the identification of the root cause and resolution of non-compliance of critical quality limits and deviations from quality requirements.

2.5.3.2 Verification activities shall include a comparison of process control limits (+/- 3σ) with specification limits to ensure alignment and appropriate process control corrections.

2.5.3 Implementation Guidance

What does it mean?

Corrective action is an important part of any management system. Corrective actions are proactive, rather than reactive responses to a deviation from regular operations. It requires the development a procedure that describes, before the event, who, what, when, where and how the site will address an identified problem or deviation. Identifying a means to address a problem prior to its occurrence requires the site to consider immediate action to resolve the problem and deal with any affected product, and preventative action to prevent a recurrence of the problem.

What do I have to do?

When problems or issues that involve quality arise, the site is required to take corrective and preventive action to deal with any affected product (s) and to fix the process (es). The site must document a procedure describing the responsibility for investigating and identifying the causes of problems, including a breakdown of critical limits relating to quality. Further, the site must document how these problems are to be resolved if and when they occur, the methods used to correct and control the situation and what action is to be taken to prevent the recurrence of the problem.

Corrections are considered a short-term fix, i.e. a quick action taken to remediate a specific problem and make adjustments to regain immediate control. A corrective action is a longer term fix designed to identify the root cause of the problem and to take actions that will prevent recurrence. This process is designed to minimize the risk that the situation will occur again.

When monitoring activities show that critical limits have been exceeded, the site's corrective actions must describe what happens to the affected product (s) (i.e., the product processed since the last good result), as well as the preventative action to correct the process. These corrective actions are proactive – they are described in the quality plan before the event.

Corrections should be made when there is any observation within a facility that leads one to believe that product quality is at risk. After the correction is made, the site must investigate to determine the root cause of the issue. When the root cause of the problem is identified, corrective actions can be taken.

Corrective actions associated with deviations from critical limits from CQPs must be documented on the quality plans (refer 2.4.3). This shall describe responsibilities and actions required to deal with or dispose of affected product (e.g., back to the last good check) and actions necessary to correct the process. However, the site must also prepare a corrective action procedure (and log) to ensure corrections and corrective actions are documented, assigned, followed up, and confirmed.

Correction and corrective action when monitoring a process control point commonly occurs through the use of SPC control charts. The process control limits established for the process are used to enable an operator to be preventative in avoiding out of control conditions that may lead to product conformance issues. (e.g trending rules) The comparison of process control limits with specification limits (e.g Process Capability analysis) shall be used by the site to determine the effectiveness of control charts in reducing process variation and adherence to product specifications.

This type of preventive action helps to assure the continuous improvement of the Quality System, resulting in fewer future problems since the root causes have been addressed. Corrective actions shall also be reviewed as part of the management review process (refer 2.1.4.1 iii).

The site is also required to maintain records of corrections and corrective action taken.

Essentially, the site is asked to outline and demonstrate how they will manage corrective action, identify who is responsible for managing it and describe what methods are used to resolve any safety or quality issues.

2.5.3 Auditing Guidance

The quality plan and its corrective action procedure shall be reviewed for compliance to this requirement by observation, interview with the SQF quality practitioner, interviews with other relevant staff responsible for carrying out corrective actions and review of corrective action records at each audit. Evidence may include:

- Responsibilities and methods outlining how corrections and corrective actions are investigated/ resolved/managed/controlled are documented;
- Responsibilities and methods outlining how corrections and corrective actions are investigated/ resolved/managed/controlled/implemented;
- Root cause analyses have been carried out for non-compliance to critical quality limits;
- Corrective actions have correctly dealt with affected product;
- Corrective actions have achieved resolutions that will prevent recurrence of process issues;
- Corrective actions have reduced process variation as shown through continued improvement in process capability analysis and conformance to specification;
- Personnel carrying out corrective actions understand their roles and responsibilities;
- Records of corrective actions are current and accurate.

2.5.4 Product Sampling, Inspection and Analysis

What the SQF Code says

2.5.4.1 Processing parameters or in-process measurements shall be established, validated, and verified at a determined frequency to meet all customer requirements.

2.5.4.2 On-site laboratories and inspection stations shall be equipped and resourced to enable testing of in-process and finished products to meet customer expectations and meet quality objectives.

2.5.4.3 Statistical process control methods shall be used to effectively control and optimize production processes to improve process efficiency and product quality and reduced waste. Control charts shall be in use for control of key processes and have defined upper and lower (process) control limits (+/- 3σ).

2.5.4.4 A sensory evaluation program shall be in place to ensure alignment with agreed customer requirements. Sensory evaluation results shall be communicated with relevant staff and with customers where appropriate.

2.5.4.5 Records of all quality inspections and analyses, and statistical analyses, shall be maintained.

2.5.4 Implementation Guidance

What does it mean?

During the normal course of food production and manufacturing, product must be sampled and analyzed either during or after production, to ensure that it meets specifications and to verify quality aspects.

The site must determine what raw materials, work-in-progress and finished product is to be analyzed (usually part of verification and detailed in the verification schedule) and what variables and/or attributes they will be specifically measuring. An appropriate location to conduct any measurements and testing will also need to be available.

What do I have to do?

The site shall document a procedure outlining the methods established to test finished product, work-in-progress and/or raw materials to ensure they meet specification in relation to food quality. Inspections, test or analysis of

finished product must be finalized before delivery to a customer. Finished product testing may be defined by the site and their customer.

The site must identify those with responsibility for sampling, inspecting and testing finished product, work-in-progress and/or raw materials and identify the methods used to collect samples and complete these tests, inspection and analyses.

The types of testing that are conducted on finished product should be determined by the finished product specification. Examples are varied and can include sensory analysis (e.g., taste, color, flavor, odor), physical (e.g., count, weight, size, texture), chemical (e.g., fat, salt, moisture, brix, pH), or microbiological (e.g., aerobic plate count, yeast and mold, coliforms, lactics). It should be noted that if pathogens (e.g., *Salmonella*, pathogenic *E. coli*, *Listeria*) are found on finished product, that product should not be released into the marketplace until test results are obtained and negative results are verified as per the site's food safety system.

The site must also determine which attributes are to be measured and control using control charts. Typical application for in-process monitoring (batch or continuous) as well as finished products are individual-moving range charts or x-bar & R charts. Process data will be used to determine and calculate process control limits which are representative of +/- 3σ.

On-site labs or inspection stations that are used in measuring quality attributes and to conduct sensory evaluation will require appropriate measurement devices and resources to ensure results can confidently be used to meet customer requirements.

The site must ensure that staff is qualified, trained and competent to complete sampling inspection and analyses.

Records must be maintained of all inspections, tests and analyses.

2.5.4 Auditing Guidance

Product sampling and testing procedures shall be reviewed for compliance to this requirement by observation, interview with the SQF quality practitioner and other relevant staff responsible for sampling and testing, and review of records at each facility audit. Evidence may include:

- Methods for sampling, inspecting, and/or analyzing raw materials, finished product and work in progress are documented;
- Documented methods are approved methods and meet regulatory and customer requirements;
- Inspections are conducted as documented, and at intervals sufficient to maintain control;
- Inspections confirm specifications, label requirements and trade weights and measures;
- Control charts are correctly applied and interpreted to reduce process variation;
- Analyses are conducted by qualified individuals and to approved methods;
- On-site labs and inspection stations are appropriately staffed and resourced with calibrated equipment or sensory evaluation tools;
- Sensory evaluations are completed to internal and customer specifications;
- Records of all inspections and analyses (including sensory analyses) are accurate and maintained.

2.5.5 Internal Audits and Inspections

What the SQF Code says

2.5.5.1 Internal audit plans and methods shall include food quality plans, process controls, quality tests, and other activities implemented to meet finished product specifications and customer requirements.

2.5.5.2 Staff conducting the quality internal audits shall be trained and assessed in internal audit procedures and have knowledge and experience in the quality process and process control methods as they relate to the scope of certification.

2.5.5 Implementation Guidance

What does it mean?

Internal audits are an in-house check to identify gaps or deficiencies in the SQF Quality System and provide a sound basis for deciding on measures for improvement. Internal auditing is a verification method and when used properly, can reduce the uncertainty and risk of external audits.

This element requires the site to audit the activities in their Quality System on a regular basis to ensure that everything is running smoothly. Internal audits help the site to identify faults in their Quality System so that it can be improved.

What do I have to do?

The site is required to prepare an internal audit procedure describing how internal audits of the entire SQF Quality System are conducted and identify who is responsible for scheduling and conducting internal audits.

The internal audits must cover the entire SQF Quality System, including the application of quality programs and the Food Quality Plan and quality controls that have been implemented.

The audit program must include:

- An audit schedule (i.e., when audits will be conducted);
- Audit criteria (i.e., the area and requirements assessed);
- Responsibility (i.e., who will conduct the audit);
- Corrections and corrective actions (i.e., the response to the audit);

There must be at least one complete SQF Quality System internal audit per year. Preferably this is conducted throughout the year or the season, depending on the length of the season within the facility.

For internal audits to be effective, staff conducting internal audits must be trained in internal auditing techniques, information gathering and objective observation. This training need not be “formal” training provided by an external source. Internal auditor training covers internal audit procedures, including the planning and scheduling of internal audits, preparing internal audit reports and initiating and following up on audit findings. Internal audits should combine several information gathering techniques, including interview of personnel, review of records and observation of current conditions.

To ensure the objectiveness of the internal audit the site is required, where possible, to use personnel who are separate from the area being audited to conduct internal audits. The inclusion of the words “where possible” illustrates that in the case of some very small sites this may not be possible. In such cases, the site is required to demonstrate that the alternative internal audit arrangement meets the objective of this requirement and is communicated to all affected parties.

Finally, the outcomes of all internal audits, including any corrective actions taken, must be recorded. Any audit tool that is developed by the site can be utilized to perform the internal audits provided it covers the required areas and programs.

2.5.5 Auditing Guidance

The internal audit procedure and schedule shall be reviewed for compliance to this requirement through observation and interviews with staff conducting internal audits and review of records at each facility audit. The SQF auditor will verify that the audit schedule is adequate based on the observations from the assessment of the facility. Evidence may include:

- There is an internal audit procedure and schedule that adequately covers all SQF Quality System elements;
- Sufficient resources are allocated to conduct internal audits as per schedule;
- Staff conducting internal audits are adequately trained;
- Staff conducting internal audits are independent of the area being audited;
- Corrections and corrective actions of identified deficiencies are correctly allocated, followed up, and completed (refer 2.5.3);
- Internal audit results are communicated to relevant management and staff;
- Internal audit reports and their follow-up are reviewed as part of the management review process

(refer 2.1.4.1);

- Records are kept of internal audits and the corresponding corrective actions.

2.6 Product Identification, Trace, Withdrawal and Recall

2.6.1 Product Identification

What the SQF Code says

2.6.1.1 Finished product shall be labeled to the agreed customer, company or corporate requirements.

2.6.1.2 Product changeover procedures shall include quality attributes required to meet finished product specifications and customer requirements.

2.6.1 Implementation Guidance

What does it mean?

To allow for effective trace back (refer 2.6.2), recall (refer 2.6.3) and stock control and rotation, materials and products at all stages of production must be labelled and identified. How the site goes about this is entirely their own choice, as long as product can be identified and tracked at every stage of production.

What do I have to do?

The site must be able to clearly identify product upon receipt, throughout the process and when it is a finished product.

Product that is in-process may be identified in a variety of ways. The facility could use bin tags, pallet tags, colors, product tags, etc. The facility must be able to demonstrate how the product identification system works for incoming materials, work-in-progress and for finished product.

The finished product label needs to contain information that accurately describes the product in accordance to customer specification and/or regulatory requirements in the country of origin and intended country of destination. Product changeover procedures need to consider labels and other attributes that can impact finished product specification and customer requirements.

The site is required to prepare a procedure outlining who is responsible for maintaining the product identification system and include in the procedure the methods used to identify product.

When shipping finished product, the site must ensure the product is clearly identified and that all product identification details are accurately described on dispatch documents or otherwise included with a shipment once it leaves the business.

2.6.1 Auditing Guidance

The product identification procedure shall be reviewed for compliance to this requirement by observation, and interviews with operational staff, and review of records at each facility audit. The facility should expect that the auditor will select product at various stages during the process and ask for the origin of product, raw material site, etc. to test the identification system. Evidence may include:

- There is a documented product identification system in place;
- The product identification system is effectively implemented;
- Product is clearly identified during all stages of the process;
- Finished product is labeled to customer requirements;
- Finished product is labeled to regulatory requirements in the country of origin and country of destination;
- Product changeover procedures consider quality attributes and the impact on finished product labels;
- All operational staff understands and uses the product identification system.

2.6.2 Product Trace

What the SQF Code says

2.6.2.1 Finished product shall be traceable forward to the final customer, such as the retailer, distributor, or manufacturer.

2.6.2.2 All raw materials, ingredients, and packaging materials used in manufacturing a finished product, and processing aids associated with the product, shall be identified with the finished product lot number and traceable back to the site (one back).

2.6.2 Implementation Guidance

What does it mean?

The ability to identify and trace product is an important aspect of any food business. Food regulators, retailers, insurance companies and food manufacturers require that product be traceable. The site must document the method used to trace product, ensuring that it provides a link to all raw inputs used. Raw materials and other inputs shall be traceable through the process to the finished product. Records of product dispatch and destination shall be maintained. The documentation must assign responsibility for product dispatch and include the product name, when it was dispatched (sold), who was the customer (not including direct sales to consumers), the quantity and the production batch dates and details.

What do I have to do?

The site must have a process in place that enables them to trace product to their customer (one up) and back to the material site (one back). A written procedure must be documented to show how this is accomplished. The product trace system must account for raw materials, packaging materials and processing aids used that may impact on food quality.

For the purpose of this section, the site's first customer is the first location where the product is delivered after it leaves direct control. This can be a distribution center, customer location, broker, etc. It is not the requirement of the site to be able to trace past the first customer. However, the site should also check with the requirements of their buyers.

For the purpose of the SQF Code, traceability is a "one up, one back" requirement. The site's procedure must include details of how all raw materials, packaging materials and processing aids are linked through to the finished product; and must outline how the site accounts for the reuse of reworked product. The product trace procedure must outline how the site traces product to a customer and who is responsible for implementing and maintaining the product trace system.

The site must test the effectiveness of the trace system at least annually. The auditor will request to see records of the trace test and any corrective actions taken as a result of this review.

The site is required to retain records of all product dispatched. Both the details of the product and where and to whom it was dispatched must be recorded.

Identifying (refer 2.6.1) and tracing bulk materials can be problematic if there are insufficient bulk bins to store separate deliveries. Where bins/silos are continually refilled, delivery batches must still be recorded and the proportion of each delivery identified when materials are used from bulk. The processed material must, as far as possible, be linked with deliveries of raw materials.

2.6.2 Auditing Guidance

The product trace procedure shall be reviewed for compliance to this requirement by observation, interviews with operational staff, and review of records at each audit. The audit shall include a review of trace back on rework (where applicable) and the auditor may need to verify traceability requirements. Evidence may include:

- There is a product trace procedure that documents all applicable materials, work-in-progress, and finished products;
- The product trace system is effectively implemented;
- The product trace system is one up, one back;
- Finished product can be traced back to material suppliers;

- Rework is traceable back to materials and work-in-progress;
- The product trace system has been tested annually.

2.6.3 Product Withdrawal and Recall

What the SQF Code says

2.6.3.1 The site's recall and withdrawal procedures shall apply to product recalled or withdrawn due to failure to meet customer specifications or corporate quality requirements.

2.6.3 Implementation Guidance

What does it mean?

A product recall applies when a product is found to be unsafe or otherwise in breach of regulatory requirements and is withdrawn from public sale and the consumer market is advised not to use or consume that product. Recalls may be mandatory (i.e., initiated by a regulator), retailer driven, or voluntary (i.e., initiated by the site).

A product withdrawal applies when a dispatched product is found not to meet safety or quality requirements, is deemed not suitable for sale and is withdrawn from the distribution chain before it has reached the consumer.

A product recall and withdrawal procedure must be prepared, implemented and regularly reviewed to ensure everyone involved in the recall process understands their role and their responsibility in the event of a recall or withdrawal.

What do I have to do?

The site must have a management committee in place to coordinate and manage recalls and must prepare a withdrawal and recall procedure describing the methods, responsibilities and procedures they implement in the event of a product withdrawal or recall. There must be senior management involvement in the recall committee, as well as departmental and division managers with the authority to make decisions.

The procedure may contain a description of incidents specific to the site's product that may trigger a withdrawal or recall and must include an up-to-date list of customers, regulators and other essential contacts that need to be notified in the event of a withdrawal or recall. It must also include a provision to initiate the recall or withdrawal due to failure to meet customer specification or internal or company quality requirements.

It is assumed the quality provisions required for this element of the SQF Quality Code will be added to the recall procedure developed and implemented to meet the SQF Food Safety Code.

2.6.3 Auditing Guidance

The recall and withdrawal procedure shall be reviewed for compliance to this requirement by observation, interviews with recall committee, and review of actual/mock recall records at each audit. The SQF auditor shall review the annual test of the recall and withdrawal system, and corrective actions taken as a result of the test. The mock recall should include a test of product withdrawals due to not meeting customer or company specification at least once in a 2 year cycle.

Evidence may include:

- A recall committee is established and all members understand their roles and responsibility;
- The methods and responsibilities for notifying customers, SQFI, the certification body, regulators and other essential bodies are identified;
- The recall/withdrawal system has been tested annually;
- The recall/withdrawal system meets regulatory and customer requirements;
- Communication has been tested during an actual or test recall;

- Investigations into the cause of actual recalls/withdrawals have been conducted;
- Corrective actions have been taken on identified deficiencies in the recall/withdrawal (refer 2.5.3).

2.7 Food Fraud

2.7.1 Food Fraud Vulnerability Assessment

What the SQF Code says

2.7.1.1 The food fraud vulnerability assessment shall include the site's susceptibility to ingredient or product substitution, mislabeling, dilution and counterfeiting that could adversely impact food quality.

2.7.1.2 A food fraud mitigation plan shall be developed and implemented which specifies the methods by which the identified food fraud vulnerabilities that could adversely impact food quality shall be controlled.

2.7.1 Implementation Guidance

What does it mean?

Food fraud is often described as EMA, economically motivated adulteration. However, it is more than that. As well as adulteration, food fraud includes substitution, dilution, addition, misrepresentation or tampering of food ingredients or food products. It is in fact illegal deception for economic gain.

The economic risks of food fraud to the industry are apparent. It is estimated that fraud costs the global food industry between $US40bn -$US50bn every year (Australian Food News, 11th July 2017). Food Fraud commonly affects the quality of the product and is therefore a risk to a site's brand or their customers' brand.

What do I have to do?

For many sites, food fraud is a new consideration and the hardest part is getting started. What is a vulnerability assessment? What is a mitigation strategy?

The food fraud strategy is similar to the HACCP methodology sites are familiar with. In general terms it is:

1. Identify the risks (vulnerabilities)
2. Determine corrective and preventative actions (mitigation strategies)
3. Review and verify
4. Maintain records

The food fraud requirements talk about 'vulnerabilities' rather than 'risk'. A risk (ISO 31000 Risk Management) is something that has occurred frequently before, will occur again, and there is enough data to conduct a statistical assessment. Vulnerability is more a condition that could lead to an incident (Dr John Spink, MSU).

'Vulnerabilities' need to be identified in incoming materials and ingredients, and within the site. Not all materials and ingredients are subject to risk, and the highest risks may be from minor or infrequent ingredients that originate from sensitive geopolitical areas, or suppliers with poor past histories. Ingredients can be prioritised based on perceived risk.

Within the site, vulnerabilities may include the potential for intentional or accidental substitution, dilution, or adulteration. The question that needs to be asked is "who benefits financially from internal food fraud"?

Mitigation strategies will be developed based on the identified vulnerabilities.

Although SQF requires that the food fraud vulnerability assessment and mitigation plan be reviewed and verified at least annually, the site should be constantly aware of their supplier history and changes in the supply chain that could impact the vulnerabilities.

SQFI recommends that suppliers initiating their food fraud strategies seek assistance from one of the many resources that are available on-line. Although SQFI lists these resources, we take no responsibility for the information they provide or the outcomes of the assistance they offer.

SQFI partners with the Food Fraud Initiative at Michigan State University (MSU) http://foodfraud.msu.edu. This group offers free on -line training for sites and auditors on food fraud called Massive Open On-line Courses or MOOCs.

Other resources that could be considered include the PwC food fraud vulnerability assessment, and the USP Food Fraud Database.

2.7.1 Auditing Guidance

As with sites, food fraud is also relatively new to auditors, and SQFI recommends that all SQF auditors seek training in food fraud strategies through the resources outlined above, or through their internal CB training.

The auditor must avoid pre-determining a site's food fraud vulnerabilities or making a quick decision on *2.7.1 Food Fraud*. Food fraud is a new and inexact science, and there is no prescribed methodology for determining vulnerabilities or their mitigating actions. It is based on the information that the site has available at the time.

The auditor will seek evidence of compliance to this requirement by review of documents and records, and interview. Evidence may include:

- There is an awareness within senior management of the need for a food fraud vulnerability assessment and mitigation strategies.
- There is a current, documented vulnerability assessment in place that identifies key ingredient vulnerabilities including justification for their inclusion. The methodology for selecting the key ingredient vulnerabilities shall be available.
- The vulnerability assessment shall include an evaluation of the site vulnerabilities including from staff, contractors, and other associates.
- There are documented mitigation (ie prevention) strategies in place for all identified vulnerabilities, which identify what is to be done and who is responsible.
- The mitigation strategies are active, and are being reviewed for effectiveness.
- The vulnerabilities and mitigation strategies are reviewed at least annually.
- There are records available of review of the food fraud program.

2.8 Identity Preserved Foods

2.8.1 General Requirements for Identity Preserved Foods

What the SQF Code says

2.8.1.1 The methods and responsibility for the identification and processing of food and other products requiring the preservation of their identity preserved status (e.g. Kosher, HALAL, organic, GMO-free, regional provenance, free from, free trade etc.) shall be documented and implemented.

2.8.1.2 Identification shall include a statement of the product's identity preserved status of all ingredients, including additives, preservatives, processing aids and flavorings.

2.8.1.3 Raw material and ingredient specifications to identity preserved foods shall include requirements for their handling, transport, storage and delivery prior to use.

2.8.1.4 Assurances concerning the raw material or ingredient's identity preserved status shall be by agreement with the supplier of the material.

2.8.1.5 The process description shall allow for a product's identity preserved status to be maintained during manufacturing.

2.8.1.6 The processing of identity preserved foods shall be conducted under controlled conditions such that:

i. Ingredients are physically separated from ingredients identified as incompatible with the identity preserved food;

ii. Processing is completed in separate rooms; or scheduled as the first production run; or carried out after the completion of a thorough sanitation of the area and equipment; and

iii. Finished product is stored and transported in separate units or isolated by a physical barrier from non-specialty product.

2.8.1.7 The identity preserved status shall be declared in accordance with legal requirements.

2.8.1.8 Additional customer-specific requirements concerning identity preserved foods shall be included in the finished product specification described in 2.3.5, or label register, and implemented by the site.

2.8.1 Implementation Guidance

What does it mean?

Identity preserved foods are products that make a claim – e.g. religious, ethical or nutritional. This can

include, but is not restricted to organic, Kosher, free range, Genetically Modified Organism (GMO) free, halal, etc.

Identity preserved (IP) food is required to be kept separate from non-IP product at all stages of production and storage. The site must ensure that foods claiming special attributes and raw materials used to achieve those special attributes are handled, stored, transported, segregated and properly labeled to prevent commingling with other foods and raw materials that do not have the same attributes.

What do I have to do?

The site must be aware of regulatory and customer requirements concerning product claims and have written procedures stipulating how it ensures that identity preserved products are not commingled (some retailers have specific requirements for labelling of retailer-branded product). The written procedures must detail how the site will accomplish the prevention of commingling of foods and raw materials claimed to have special attributes.

The site must have appropriate licenses, certification or contracts allowing them to use a specific logo or trademark, such as Kosher or organic certification.

The site must have written procedures detailing how raw materials that are processed in identity-preserved products are separated to prevent commingling with generic raw materials during handling, transport, storage and delivery prior to use.

Assurances concerning raw materials or an ingredient's identity preserved status shall be included in raw material specifications (refer 2.3.2). A product process description shall allow for a product's identity preserved status to be maintained with manufacturing carried out on dedicated equipment or scheduled to avoid cross-contamination. The identity preserved status shall be declared in accordance with regulatory requirements.

Identity preserved products should have their own dedicated Food Quality Plans (refer 2.4.4) with the process risk points for cross-contamination identified and controlled.

Customer requirements concerning identity preserved products shall be included in the finished product specification described in 2.3.5 and implemented by the site.

2.8.1 Auditing Guidance

The procedure for identifying and processing of identity preserved foods shall be reviewed for compliance by observation, interviews with senior management, and review of storage and production records at each audit. Evidence may include:

- Claims made on, or on behalf of the product, requiring identity preserved status;
- Nutritional, religious, or ethical claims made meet regulatory requirements and are correctly certified or otherwise authorized;
- There is a procedure in place that identifies methods to preserve the integrity of identity preserved foods;
- Responsibility for IP integrity is assigned and authorized staff understand their roles and responsibilities;
- Documented methods are adequate to preserve the integrity of identity preserved foods;
- Documented methods are effectively implemented;
- Processing of identify preserved foods are conducted under controlled conditions, e.g., in separate rooms, scheduled as first run, or after a complete sanitation of the process line;
- Ingredients and materials for identity preserved foods are stored separately;
- Finished identity preserved product is stored properly and correctly labeled;
- Customer requirements regarding identity preserved foods are included in finished product specifications (refer 2.3.5).

2.9 Training

2.9.1 Training Requirements

What the SQF Code says

2.9.1.1 Appropriate training shall be provided for personnel carrying out the tasks critical to the effective implementation of the SQF Quality System and the maintenance and improvement of quality requirements.

2.9.1 Implementation Guidance

What does it mean?

What is considered appropriate training? All company employees that are responsible for conducting tasks related to food quality plan, or other plan-associated roles must be trained in the procedures that relate directly to their specific responsibilities, as well as those policies that affect product quality. Training may be completed on the job by qualified technical staff or externally by recognized institutions.

What do I have to do?

A training needs analysis must be conducted to identify the skills required for each role in the SQF Quality System. This will be based on the job descriptions (refer 2.1.2.8), procedures and work instructions (refer 2.1.3). It is important to ensure that all relevant positions are covered and that shift employees and relief employees are included to ensure that there are no gaps in the training requirements. Staff in supervisory, management or technical roles must also be included.

The training needs analysis will form the basis for the training program (refer 2.9.2).

2.9.1 Auditing Guidance

Training requirements will be assessed at each audit by interview and examination of records. Evidence may include:

- Training needs analysis has been conducted;
- Training needs analysis is based on job descriptions required within the SQF Quality System;
- Training needs analysis includes coverage for all shifts and relief.

2.9.2 Training Program

What the SQF Code says

2.9.2.1 The employee training program shall include the necessary competencies for specific duties and the training methods to be applied for those staff carrying out tasks associated with:

i. Process control and monitoring of critical quality points (CQPs);
ii. Steps identified as critical to effective implementation of the food quality plan and the maintenance of food quality, and
iii. Product inspection and testing.

2.9.2.2 The employee training program shall include applicable statistical process control training for line operators, quality inspectors and supervisory staff responsible for operating and inspecting key manufacturing processes.

2.9.2.3 The training program shall include training, calibration and proficiency testing of internal laboratory personnel.

2.9.2 Implementation Guidance

What does it mean?

Once the training requirements are identified (refer 2.9.1), the site must ensure that staff is trained to competently carry out their duties and responsibilities. Employees can carry out these activities if they are given

clear and concise instructions regarding how, when and where to carry out the tasks and to record the information.

What do I have to do?

The following programs are considered the minimum required elements for employee training that can specifically affect the Food Quality Plan or meeting customer requirements. They can be offered as classroom training or on-the-job training by qualified personnel. Sometimes training can be offered through team meetings. Type and depth of training will depend upon the employee's work designation. Requirements may include:

- Job/task performance
- Company quality policies and procedures
- HACCP method overview, and specific roles within the Food Quality Plan
- Product quality and grading
- Statistical Process Control and control chart usage
- Measurement, repeatability and reliability of measure devices
- Lab testing proficiency

2.9.2 Auditing Guidance

The employee training program will be assessed for compliance by interview, observation of tasks and examination of records. Evidence may include:

- The employee training program is based on a training needs analysis (refer 2.9.1);
- The employee training program covers all job descriptions required within the SQF Quality System (refer 2.1.2.8);
- The employee training program includes the use of statistical process control, control chart and other quality tools;
- The employee training program includes quality programs;
- The employee training program includes food regulatory requirements;
- The employee training program includes threat analysis relevant to the employee's role in the food quality plan;
- The employee training program includes maintenance of food quality plan relevant to the employee's role in the food quality plan;
- The employee training program includes requirements to meet customer specifications;
- The employee training program has been effectively implemented and maintained.

2.9.3 Quality Instructions

What the SQF Code says

2.9.3.1 Instructions shall be available explaining how all tasks critical to meeting customer specifications, and quality and process efficiency are to be performed.

2.9.3 Implementation Guidance

What does it mean?

Work instructions shall be available for all employees who carry out tasks that are part of the SQF Quality System, e.g., the quality and process efficiency controls identified in the SQF Quality System and customer specifications.

What do I have to do?

Instructions can be provided in a number of ways such as:

- Written work instructions may be useful when a particular task is complicated (i.e., requiring skilled operators) or repetitious (e.g., mundane work that generally results in a high turnover of staff and requires a constant training effort). These instructions can serve as a valuable training reference when staff needs to check the correct way of doing a task. Written instructions can be in the form of quality programs (refer 2.3.1 i) and will be available (if practical) where the task is performed.
- Photos and diagrams can be particularly useful to overcome language barriers or when a task involves a number of different steps.

Instructions may be included in the quality manual (2.1.3), and must be kept up to date as process or System requirements change.

2.9.3 Auditing Guidance

Work instructions will be assessed for compliance by interview with key personnel, observation of tasks and examination of records. Evidence may include:

- There are specific work instructions for maintenance of food quality plan and associated tasks;
- There are specific work instructions for maintenance of quality programs and other tasks related to the SQF Quality System;
- There are specific work instructions for adherence to customer specifications;
- Work instructions are known and applied by personnel conducting quality tasks;
- Work instructions are updated as changes occur to the process or the SQF Quality System.

2.9.4 HACCP for Quality Training Requirement

What the SQF Code says

2.9.4.1 Training in the application of HACCP principles for the identification and control of quality threats shall be provided to staff involved in development and maintenance of the food quality plan.

2.9.4 Implementation Guidance

What does it mean?

Two-day (or equivalent), examinable HACCP methodology training is required for the SQF quality practitioner (refer 2.1.2.5). However other employees involved in the development of food quality plans must also be trained in the HACCP method. Also, staff involved in maintenance of the food quality plans must have an understanding of HACCP principles and the HACCP process, and their role in the HACCP process

What do I have to do?

HACCP training for the SQF quality practitioner must be external training through a recognized training center. For other staff involved in the SQF Quality System, training can be either/or:

- Also through a recognized external training provider;
- On-line;
- Provided internally through a qualified HACCP trainer or SQF quality practitioner.

Whichever method is used, participants must have a good understanding of the HACCP method and its application within their facility. A record of HACCP training must be retained.

2.9.4 Auditing Guidance

The credentials of the SQF quality practitioner will be confirmed during the audit. HACCP training for other staff members shall be confirmed by interview and review of records at each audit. Evidence may include:

- HACCP training has been provided for all staff associated with the development and maintenance of food quality plans;
- All staff associated with the development and maintenance of food quality plans understand HACCP

principles and the HACCP method;

- All staff associated with the development and maintenance of food quality plans are aware of their roles and responsibilities.

2.9.5 Language

What the SQF Code says

2.9.5.1 Training materials and the delivery of training shall be provided in language understood by staff.

2.9.5 Implementation Guidance

What does it mean?

Where employees do not have as their primary language, the language of the site's business, training materials and work instructions must be provided in a language or form that is understood by those employees. For example, sites in English-speaking countries that employee staff with English as a second language, and/or limited command of English, instruction and training must be available in a language or languages understood by all employees.

What do I have to do?

Sites must:

- Establish the common languages of employees working within the facility;
- Consider the literacy level of all employees;
- Provide instructions (refer 2.9.3) related to the process and food quality in the common languages of employees;
- Provide training (refer 2.9.2) related to the SQF Quality System in the common languages of employees;
- Ensure that the messages delivered through training and work instructions are understood by all employees;
- Ensure training materials and work instructions in other languages are updated as the primary materials are changed.

2.9.5 Auditing Guidance

Compliance to this requirement shall be confirmed by interview, observation and review of training materials and work instructions at each audit. Evidence may include:

- A review of primary languages spoken within the site's staff;
- Review of other language work instructions and training materials available;
- Understanding of foreign language employees of the System and tasks involved.

2.9.6 Refresher Training

What the SQF Code says

2.9.6.1 The training program shall include provision for identifying and implementing the refresher training needs of site personnel.

2.9.6 Implementation Guidance

What does it mean?

This element relates back to 2.9.2 – Training Program. The site must ensure that training is current and provide refresher training as appropriate. This may be on an annual basis, start of a new season, or as changes occur to the product, process or SQF Quality System.

What do I have to do?

The site must identify what refresher training is required and when and how it is to be applied. Refresher training may include:

- Review of the SQF Quality System at the start of a new season for seasonal employees;
- Training for employees involved in a change to the process, product or procedures within the SQF Quality System;
- Regular update training for permanent personnel.

2.9.6 Auditing Guidance

Compliance to this requirement shall be confirmed by interview, observation and review of the training program at each audit. Evidence may include:

- The training program includes refresher training;
- The training program identifies means for achieving refresher training requirements;
- Refresher training is appropriate to the type of business and the SQF Quality System;
- Refresher training is being applied as per training program.

2.9.7 Training Skills Register

What the SQF Code says

2.9.7.1 A training skills register describing who has been trained in relevant skills shall be maintained. The register shall indicate the:

i. Participant name;
ii. Skills description;
iii. Description of the training provided;
iv. Date training completed;
v. Trainer or training provider; and
vi. Supervisor's verification the training was completed and that the trainee is competent to complete the required tasks.

2.9.7 Implementation Guidance

What does it mean?

A training skills register is a file of training records. Training records must identify training applied, skills gained, and the assessment applied to ensure the competency was acquired. The training register must comply with the training program (2.9.2), which meets the requirements of the training needs analysis (2.9.1).

What do I have to do?

The site is required to prepare a staff training skills register and document who is trained and when they were trained to do a particular task. This may be in the form of a formal training file for permanent staff detailing training undertaken and signed and dated by the subject employee, or a training matrix may a be used to keep track of large or rotational labor teams.

Whichever form is used, the training register must identify:

- The trainee participant;
- The skill or knowledge applied;
- The type of training provided;
- Date of training;
- Training provider (e.g., internal or external);
- Competency assessment (generally by the immediate supervisor).

It is also advisable to have an overall summary that links the training register back to the training needs analysis (refer 2.9.1), so that gaps in the training program (2.9.2) can be identified and corrected.

2.9.7 Auditing Guidance

Compliance to this requirement shall be confirmed by interview and review of training records at each audit. Evidence may include:

- The training skills register is available and up to date;
- The training skills register includes participant name, skills description, training provided, date of training, training provider, and verification of competencies;
- Individual training skills records are signed and dated by participants;
- Verification of skills are signed and dated by a supervisor or other competent person.