



ISO 22000:2005 - briefing note and transition requirements for IRCA FSMS auditors

Scope:

This document:

1. Explains the transition CPD requirements that you need to meet in order to maintain your IRCA Food Safety auditor certification.
2. Outlines the broad implications of the ISO 22000:2005 for Food Safety auditors
3. Outlines the detailed changes made to the 2005 revision of ISO 22000

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1. Transitioning your FSMS Auditor Certification

The publication of ISO 22000 is important and we will require you (IRCA certificated FSMS auditors) to demonstrate that you have updated yourselves with the standard and that you understand the implications of these changes in the context of your FSMS auditing activities.

Transition requirement for IRCA certificated FSMS auditors

All IRCA certificated FSMS auditors will need to complete **4 hours of continuing professional development** (CPD) focused on ISO 22000:2005 before completing any acceptable audits to the standard. This CPD and your completed audits will be reviewed during your normal tri-annual renewal of certification. You must include details of your relevant CPD in the CPD log that you submit as part of this process, and clearly note which standard each audit was conducted against in your audit log.

When does this start?

We will accept transition CPD and audits to the new standard from January 2006.

What kind of CPD will IRCA accept?

We do not require FSMS auditors to complete a specific transition CPD, and you may achieve this in a number of ways as is consistent with usual IRCA approach to CPD:

- On the job training
- In-house training and seminars with your company
- Attendance at relevant conferences, seminars and workshops
- Reading (this briefing note and other relevant articles)
- A specific FSMS auditor transition course

IRCA will provide a list of ISO 22000:2005 events and seminars that are acceptable for CPD: this will not be an exhaustive list and other CPD is acceptable. These events are offered by IRCA approved training organizations and OEAs, but are not formally certified by IRCA and, therefore, do not fall under IRCA control even though we accept them for CPD along with other training and events. You will find a list of such courses and events at our website, www.irca.org, as soon as they become available.

2. Introduction – implications of ISO 22000:2005 for auditors

The publication of ISO 22000:2005 represents a major step forward in the harmonization of the requirements for food safety management on a global level. Its relevance to all parts of the food chain implies that auditors working both directly and indirectly in the food sector will likely encounter it at some stage. Although a voluntary standard, its success will lie in its adoption by producers and purchasers throughout the food chain as an acceptable alternative to those individual food safety standards with limited recognition across national boundaries. In any case, the requirements of such standards can usually be incorporated into a food safety management system to ISO 22000 as necessary.

Relationship with ISO 9001 and ISO 15161

Many FSMS auditors will be familiar with ISO 9001:2000 and the associated guidance for the food sector in ISO 15161. The ISO 22000 standard is firmly based on the principles of ISO 9001 as far as they relate to food safety. Note that the only customer requirements addressed by ISO 22000 are those relating to food safety. The new standard also incorporates many of the FSMS issues addressed in ISO 15161 but contains detailed prescriptive requirements which are now auditable. A useful cross-reference between the requirements of ISO 22000 and ISO 9001 is given in the Appendix of ISO 22000. The two standards are not mutually exclusive; an organization associated with the food chain can implement both standards simultaneously.

Statutory and regulatory compliance

ISO 22000 does not, of course, seek to undermine or replace existing statutory requirements pertaining to the food sector in the country of application. It recognizes the salient inputs from the regulatory role of the authorities across the whole food chain and requires demonstration of compliance with applicable legislation. ISO 22000 requires a committed policy of regulatory compliance allied with monitoring and updating regimes to maintain regulatory compliance.

Clearly it is the organization's responsibility to evaluate its own compliance and FSMS auditors are not food safety regulatory inspectors. However, auditors must pay attention to how legal requirements are incorporated into the system and how the organization implements its commitment to comply with legal and agreed customer requirements for food safety.

Pre-requisite programmes

ISO 22000 places a clear emphasis on pre-requisite programmes (PRP's) as part of the range of preventive measures against contamination. It distinguishes between the basic conditions and activities necessary for a hygienic environment and the Operational PRP's identified from the hazard analysis as requiring a specific control scheme. Many of the PRP's will originate from the good practice guides (GMP etc.) associated with the relevant part of the food chain. Auditors are not inspectors of hygiene conditions *per se* but need to ensure that the PRP planning and development processes are robust in giving full consideration to potential threats to food safety and how to prevent or control them, assisted by the accessing of relevant information available to the industry.

HACCP

The principles of HACCP (Hazard Analysis Critical Control Plan) as defined by the Codex Alimentarius Commission are incorporated within ISO 22000, forming the core elements of the management system based on a food safety risk management strategy. HACCP has been used internationally for some years in the food industry and much emphasis has been placed on having an effective HACCP plan. ISO 22000 also places strong emphasis on monitoring and maintenance of CCP's which is traditionally a weak area in HACCP systems. The requirement for verification planning and implementation is designed to ensure that the food safety risks are continually managed with the necessary competence. Auditors do not need to be HACCP experts but need to determine whether the overall risk management process is effective both in preventing the production and/or processing of unsafe food and in dealing with it adequately when that may occur.

3. Detailed summary of ISO 22000:2005 requirements

Below you will see the main requirements by clauses and any specific implications for auditors.

Introduction

In a comprehensive introduction, the standard outlines the reasoning for its emphasis on the issues which are considered to be of prime importance in food safety management. These include the whole range of the food chain, communication along it, the use of management systems, HACCP principles combined with pre-requisite programmes, flexibility and global harmonization. Auditors can benefit from an understanding of how ISO 22000 brings all these factors together in an auditable standard. Further guidance is available in ISO/TS 22004.

Scope – Section 1

This section makes it very clear that ISO 22000 is intended for the widest possible application in the food sector from initial production to final consumption. It applies equally to both large and small organizations which are directly or indirectly involved in the food chain. Any organization which could potentially introduce a food safety hazard into the food chain may implement it. It is designed for flexibility in that a smaller organization could use it to implement a set of externally developed control measures from a customer, for instance.

Normative references – Section 2

ISO 22000 is directly linked with ISO 9000:2000 for its application. This couples the standard with the 8 principles of quality management as well as the terminology used in the ISO 9000 series of standards.

Terms and Definitions – Section 3

- Although definitions are aligned with ISO 9000:2000, new definitions relating to the food sector are introduced. Many are taken directly from the Codex Alimentarius texts. For clarification, several terms are worth noting ;
- *3.3 Food safety hazard* - This includes allergens (note 3) and any ingredients at the animal feed stage which may potentially cause adverse human health (note 4).
- *3.9 operational prerequisite programme* - This term introduces a new stage in hazard control in addition to generic prerequisite programmes and HACPP plans. In this context, it is process specific and is designed to establish the required preventive/control measures suggested by a hazard analysis.
- *3.15 Validation* - The definition is tailored for the food industry through its focus on obtaining evidence of effective HACCP and operational PRP controls.
- *3.17 Updating* - This relates to the application of the latest information used in any part of the FSMS from whatever relevant source. It is not to be confused with improvement which is a separate issue.

General requirements – clause 4.1

The requirement is for an *effective* FSMS, the scope of which is clearly defined and which is based on the management of food safety hazards that may be *reasonably expected* to occur within this scope. The auditor needs to deal with the subjective language used here. Evidence of effectiveness could be obtained from the general level of compliance with ISO 22000 in terms of the number and significance of non-conformances found. Evidence of reasonable expectation could be based on food industry standard practices, the level of access to industry information, the competence of staff and/or the technological resources of the organization. Note that outsourced processes with food safety implications need to be managed within the FSMS.

Documentation requirements - clause 4.2

This section generally mirrors the same section of ISO 9001:2000 which specifies the documentation disciplines necessary for an effective management system. Note that there is no requirement for a FSMS manual but the organization can choose to include documents and procedures it needs in addition to those which are mandatory. These become auditable within the FSMS.

Management commitment - clause 5.1

This clause introduces the first mention of continually improving the effectiveness of the FSMS by requiring a management commitment to this. It also ties the business objectives to food safety. Documented objectives are referenced in clause 4.2 so the auditor can expect to see evidence of management commitment to food safety through setting and reviewing improvement objectives for the FSMS as well as by communicating these throughout the organization.

Food safety policy - clause 5.2

The food safety intentions of top management need to be documented and communicated throughout the organization. The requirement for the policy to be supported by measurable objectives should provide audit evidence of the effectiveness of the policy.

Food safety management system planning – clause 5.3

Planning is a major component in a FSMS and this clause requires the auditor to obtain evidence that the general requirements for a FSMS, as outlined in clause 4.1, are adequately planned. This evidence could take the form of records of the initial setting up of activities as well as records of implementation, monitoring and review. Objective planning is also included. The FSMS needs to be protected throughout changes to the FSMS so planning for change management is required. Change could originate from the introduction of new products, equipment, facilities, procedures and/or staff reorganization.

Responsibility and authority – clause 5.4

This clause introduces the concept of appointing problem handling “champions” in the organization who will deal with reported issues. A problem reporting system needs to be set up to which all personnel in the organization subscribe.

Food safety team leader – clause 5.5

This person performs a similar role in a FSMS to that provided by the management representative in a QMS although the establishment of a food safety team of 2 or more people is also required. The team leader's role should be known throughout the organization.

Communication – clause 5.6

Effective communication, both internally and externally, is an important constituent of a FSMS. Auditors should seek evidence of communication across the organization and beyond, from top management down. This clause provides many examples of the types of information to be communicated.

Emergency preparedness and response – clause 5.7

A risk management approach will normally be taken when implementing this clause, based on the risk of compromising food safety during emergency incidents. Auditors should be familiar with the concepts used to determine risk levels, taking into account such factors as incident severity, duration, likelihood of occurrence and the degree of control already in place. In addition to the identified risk levels, auditors should focus on the process for identifying risks and determining any necessary responses from a food safety standpoint.

Management review – clause 5.8

Closely reflecting the related clause in ISO 9001, the management review process should be a vehicle for an objective assessment by top management of the level of integrity of the FSMS and any improvements which could be made. Auditors should determine that the 7 mandatory inputs and 4 mandatory outputs are adequately addressed by the review.

Provision of resources – clause 6.1

This clause follows through on the earlier need for management commitment to making necessary resources available. Auditors should trace backwards from problems in the system to determine whether there is any link with lack of resources, both human and material. For example, microbiological failure often results from inadequate cleaning resources.

Human resources – clause 6.2

The standard places considerable emphasis on the competence of the food safety team and other relevant staff. Auditors should ensure that any personnel associated with any part of the production/processing/service life cycle for which food safety hazards have been identified are able to demonstrate the necessary ability required by the FSMS. Note that the responsibility and authority of any external experts who are contributing to the FSMS should be documented.

Infrastructure – clause 6.3

As defined in ISO 9000:2000, the infrastructure relating to a FSMS is very wide in scope. Clause 7.2.3 gives some indication of this when covering PRP's. Auditors should track food safety problems backwards to determine any link with infrastructure. Note that this includes the IT and telecommunications systems as far as they are used for food safety.

Work environment – clause 6.4

As well as the physical environment, this clause can relate to issues such as work ethics and information distribution. Any issue in the work environment which can or does compromise food safety is relevant to the auditor.

Planning and realization of safe products – general – clause 7.1

This clause sets up the need for an organization to implement process planning and development for food safety in its production/processing/service activities. Auditors will normally find that any failure in such planning and development will show up against one or more of the subsequent clauses in section 7.

Prerequisite programmes (PRPs) – clause 7.2

The importance placed on PRPs by the standard is evident from the extent of detailed requirements in this section. It specifies a risk based approach to the use of PRPs and includes those related to legislation as well as industry codes of practice. Note that the food safety team requires to approve PRPs and they should be included in verification planning (clause 7.8). Auditors should evaluate the whole process of managing PRPs from the hazard analysis stage to the release of product. Auditors should seek evidence of objectivity in the decision as to whether PRP activities should be employed or not.

Preliminary steps to enable hazard analysis – general – clause 7.3.1

The hazard analysis element of a FSMS is arguably the most important since any failure at this stage can compromise food safety across all processes. This clause requires all information contributing to the hazard analysis to be properly managed and recorded. Auditors should compare the information sources being used with the normal industry practice.

Food safety team – clause 7.3.2

This clause establishes a food safety team of 2 or more personnel with multi-disciplinary skills who meet the competence requirements of clause 6.2. Since the team fulfils an important role in the FSMS, auditors should spend adequate time on the competencies within the team.

Product characteristics – clause 7.3.3

This clause requires the compilation of specification information on all materials, including end products, contributing to the hazard analysis. This includes any regulatory requirements such as labeling and involves updating of the information. Auditors should determine whether such information accurately reflects the processes being audited at the time.

Intended use – clause 7.3.4

The use of subjective language such as *intended use*, *reasonably expected* and *groups known to be especially vulnerable* makes this clause both awkward to implement and audit. Auditors should draw on industry sector knowledge to determine whether adequate cognizance is being taken of the product usage and handling risks to food safety in the hazard analysis. A description of the risk elements involved in post-production product use and handling needs to be kept up-to-date.

Flow diagrams, process steps and control measures – clause 7.3.5

The mandatory use of flow diagrams in describing the input and output steps and activities covered by the FSMS underlines the process approach of the standard. They should be used in a hazard analysis process after checks for accuracy by the food safety team and subsequently maintained under record management. Supplementary information in the form of descriptions and/or procedures for control purposes may also be compiled for hazard analysis. This clause produces an abundance of valuable documentation through which auditors can come to understand the processes involved and the identification of issues for hazard analysis. Process auditing techniques associated with ISO 19011 can align with this approach.

Hazard analysis – clause 7.4

This clause prescribes a detailed series of steps through which a hazard analysis by the food team should proceed, from hazard identification through hazard assessment to determination of hazard control measures. Such methodologies require a level of technical knowledge and experience which is usually beyond that of the auditor. However, the auditor can evaluate the whole process of hazard analysis, considering the inputs and outputs for accuracy through each stage and examining the resulting decisions for objectivity. The auditor needs to determine that the hazard analysis is being conducted with the necessary rigour. The auditor's industry sector experience can be brought to bear, particularly in the areas of hazard identification and control.

Establishing the operational prerequisite programmes (PRPs)

One of the outputs of the hazard analysis is the determination of operational PRPs. This sets up prevention and control measures which deal with food safety risk levels somewhat below those which need to be included in the HACCP plan. Auditors should examine the decision making process at the hazard analysis stage as well as how the necessary control and monitoring activities for operational PRPs are determined.

Establishing the HACCP plan – clause 7.6

On the identification of the highest risks to food safety within the hazard analysis, the HACCP plan becomes the blueprint for their control in the production/processing/service processes being audited. The auditor does not need to be a HACCP expert but can evaluate the process from decision making in the hazard analysis through the determination of control parameters including identification of critical control points (CCPs). Given the importance of this methodology to the FSMS, the auditor should allocate a good proportion of the audit duration to its evaluation. As indicated in the previous section of this briefing note, the monitoring and maintenance of CCPs should be adequately covered as well as the recovery processes on the breaching of critical limits.

Updating of preliminary information and documents specifying the PRPs and the HACCP plan – clause 7.7

This clause sets up a cycle of activity linked to clause 7.3 to assure the currency of the information on which the control elements of the FSMS are based. The auditor can use the document control requirements of the FSMS in determining this.

Verification planning – clause 7.8

This clause sets in place those monitoring arrangements at the process level which are designed to provide assurance that the FSMS is performing effectively on a day to day basis. The food safety team is involved in result evaluation (clause 8.4.2) and failures are to be dealt with through the potentially unsafe product disposition process (clause 7.10.3). As with several other sections of the standard, this clause is best audited as part of a process audit of the verification processes in the FSMS.

Traceability system – clause 7.9

A traceability system is mandatory in ISO 22000 but happens to be a common process in the food industry, often as a result of legislation. The auditor should check the batch and/or lot identification in records maintained throughout the process from material receipt to end product dispatch. Note that the organization needs to define a retention period for traceability records which is related to system assessment and considers the implications for disposition of potentially unsafe products and product withdrawal.

Control of nonconformity – clause 7.10

This clause deals with the processing of end products when their integrity with regard to food safety has been definitely compromised or there is some doubt about it, system parameters having been breached. The auditor should ensure that the process for identifying such a condition is robust and that the correct disposition route of unsafe products is followed, any doubts having been resolved one way or the other during the process. Note that corrective action needs the input of a competent person and its scope includes trend analysis and prevention of recurrence.

Validation, verification and improvement of the FSMS – general – clause 8.1

The food safety team is responsible for the process of validation as well as the processes for verification and improvement of the FSMS. Auditors will need to obtain evidence across most of the FSMS to evaluate the effectiveness of this work by the team.

Validation of control measure combinations – clause 8.2

This clause is intended to create assurance that the control measures in the FSMS, at any level, are effective and reliable. The auditor should check that the validation process itself is effective and reliable and that control measures are not introduced or changed until this assurance is supported by objective evidence.

Control of monitoring and measuring – clause 8.3

This clause addresses the need for known accuracy of measuring equipment and aligns with the corresponding requirement in ISO 9001. Note that it applies only to monitoring and measuring of parameters used in the FSMS in relation to food safety. Standards used for calibration should reflect the way the equipment is used. For example, test pieces used to calibrate a metal detector should equate to the mass and weight of the physical object to be detected.

Food safety management system verification – clause 8.4

This clause links with verification planning (clause 7.8) and defines the methodology for various verification activities including the involvement of the food safety team in result evaluation and analysis. The internal audit process is *de rigueur* for ISO management systems. Note that if the food safety team members are conducting internal audits then another party has to audit the activities of the food safety team.

Continual improvement – clause 8.5.1

This clause requires top management to use the FSMS to continually improve its own effectiveness. Auditors need to take a macro view of this by considering the system performance as a whole when determining the actual trend based on audit evidence.

Updating the food safety management system – clause 8.5.2

This clause involves the food safety team in a pre-planned periodic evaluation of the currency of the information used in the FSMS (refer to definition 3.17). Allied with the lower level updating in clause 7.7, the results of this evaluation feed into the management review (clause 5.8.2). Auditors should check whether the scope of this evaluation covers the whole FSMS starting with the issues which trigger an update through to the successful implementation of the change.

If you have any questions, please contact us as registration@irca.org.

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