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Auditing HACCP-based QA systems

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11.1 Introduction

The food industry today is increasingly under pressure from the outside world. Food legislation is becoming more comprehensive internationally, standards are tightening and inspection authorities are better trained and have a greater understanding of the hazards and their means of control. Similarly, consumers are more aware, have higher expectations and are concerned about food safety and quality, and the media is quick to pick up food-related stories. In order to remain competitive in the marketplace, meat product companies are changing their approach to product safety and quality. They are moving away from systems based on checking the finished product, to a system of assuring safety and quality through design and control of manufacturing and supply chain operations.

In order to facilitate this change in the trading environment, food producers are adopting standardised systems, or frameworks, within which quality systems can be developed and demonstrated to customers and regulatory authorities. The two major systems currently utilised to manage quality systems are Hazard Analysis Critical Control Point (HACCP) and the ISO 9000 series of quality standards. The ISO 9000 system describes 20 elements required to build a quality system (not all elements are required for each of the different standards) (see Table 11.1). The basic premise of the system is that the producer defines systems and procedures, developing a quality system for his whole operation, documents these procedures and demonstrates compliance with his own internal standards. Because of its structured nature the ISO 9000 system offers the added benefit that certification can be gained from third party certifying bodies, to demonstrate to customers that you have a documented quality system in place.

Table 11.1 The 20 elements comprising the ISO 9000 standard

Element	ISO 9001	ISO 9002	ISO 9003
Management Responsibility	✓	✓	✓
Quality System	✓	✓	✓
Contract Review	✓	✓	
Design Control	✓		
Document Control	✓	✓	✓
Purchasing	✓	✓	
Purchaser Supplied Product	✓	✓	
Product Identification and Traceability	✓	✓	✓
Process Control	✓	✓	
Inspection and Testing	✓	✓	✓
Inspection and Test Measuring Equipment	✓	✓	✓
Inspection and Test Status	✓	✓	✓
Control of Non-Conforming Product	✓	✓	✓
Corrective Action	✓	✓	
Handling, Storage, Packaging and Delivery	✓	✓	✓
Quality Records	✓	✓	✓
Internal Quality Audits	✓	✓	
Training	✓	✓	✓
Servicing	✓		
Statistical Techniques	✓	✓	✓

HACCP is a different tool for identifying and controlling product safety hazards, and unlike ISO 9000 is specific to a line and product. HACCP is internationally accepted and is mandatory in many countries. External normalisation companies and agencies are beginning to offer certification services for HACCP, but this is still in its early stages. However, it is likely, through pressures from customers, that HACCP certification will become more of an issue in the future.

A fundamental process within any quality system is auditing. Auditing is not a new concept, but in the past may often have been viewed as a tool for 'checking up' on a company, or policing the company's systems. Auditing is in fact the main tool for driving continuous improvement, by identifying weaknesses in a quality system and recommended changes for improvement. The two major types of audit applicable to safety and quality are the technical audit and the system audit and these will be addressed in this chapter. A common misconception is that anybody can turn up to a company with a blank sheet of paper and audit the company. This is definitely not the case. Audits must be carefully structured and planned, and must be carried out by trained personnel. The major areas of auditing discussed in this chapter are:

- Scope
- Standards
- Preparation
- Format
- Assessment and scoring

- Follow-up
- Frequency

By carefully addressing each of the above areas, a company can develop comprehensive, effective auditing systems for both internal auditing of their own quality systems, and external auditing of suppliers and third party producers.

11.2 HACCP and quality systems

The majority of processors in the meat industry now accept the fact that the traditional approach of testing a product to detect defects, post production, is statistically unsound, gives no assurance that defective or hazardous product is not released onto the market and provides no opportunity for remedial action.[1,2] As a result, many processors have moved away from this traditional 'quality control' approach to more preventative systems based on design and operational control. In order to facilitate this change producers are adopting standard quality systems, such as the ISO 9000 series,[3–7] HACCP[8] and Total Quality Management (TQM)[9] to name but a few. All the above quality systems share a common element, in that they do not provide a company with a ready-made quality system, but define a framework upon which a company can build quality management systems of the required complexity and focus to enable the consistent manufacture of products of a defined quality. The ISO 9000 quality management series offers the additional facility in that the systems and procedures making up the system are formally recorded so that they can be assessed externally and accreditation/certification given if the system meets the requirements of the standards.

There is extensive information in the literature on the quality systems mentioned above, and it would be futile to try to cover all the topics here. However, we should briefly consider the main systems currently favoured.

11.2.1 The ISO 9000 series

The ISO 9000 series of standards for quality systems[3–7] were published in 1987 and were based upon the British Standard BS5750[10] and a similar Canadian standard.[1] The ISO 9000 system is comprised of five separate standards. ISO 9000 'Quality Management and Quality Assurance Standards – Guidelines for Selection and Use', and ISO 9004 'Quality Management and Quality System Elements – Guidelines', offer advice and guidance on selecting the appropriate standard and implementing the guidelines. The standards themselves are encompassed in ISO 9001–9003. ISO 9003 covers the quality system for final inspection and test and is not normally applicable to food processors. ISO 9002 covers the quality system for production and installation and is the standard most commonly sought in the food industry, and ISO 9001 is the quality system for

design/development, production, installation and servicing, and is the most comprehensive of the three standards.

The ISO 9000 standard is composed of 20 requirements (see Table 11.1) which guide a company into the areas which need to be contained within the quality system. Not all the requirements are relevant for all the standards (ISO 9001 uses more than ISO 9003). The standard itself does not define specific criteria for any of the 20 requirements, but the standards do give guidance on what is required in each. It is up to the company to define the specific criteria required in each section.

There are a number of key features which need to be mentioned with regard to ISO 9000.

1. The ISO 9000 system, as a quality system, normally specifies a quality system for the whole company, covering all quality-related activities.
2. The ISO 9000 quality system is based on the contracts and relationships between customers and suppliers.[1]
3. The ISO 9000 system requires companies to define their own standards, systems and procedures, which they believe will result in the production of product of a consistent quality.
4. In order to gain certification in ISO 9001–9003, the company only needs to define their own standards, to document these standards and associated systems and procedures, and to demonstrate to the assessor that they adhere to these internal systems. There is therefore always the chance with ISO 9000 that a company will not have covered all critical elements for product quality or safety within their internal standards, but nevertheless may achieve certification by demonstrating compliance with those set.

The method by which ISO certification is achieved varies, depending on which certifying body is used, but in general the certification processes involves:

- Selection of the appropriate standard and the development of internal standards, systems and procedures covering the 20 elements
- Pre-review of documentation by the third party certification body to identify any early non-conformances, and subsequent remedial action. In a labour-intensive industry this may result in considerable training
- Formal assessment, in house, by the third party certifying agency
- Correction of any non-compliance
- Certification
- Maintenance and reassessment (normally six-monthly maintenance visits and a full review every three years). (This may vary depending on the certifying body used.)

11.2.2 HACCP

Although it is probably fair to say that HACCP predates ISO 9000 (and the BS 5750 series before this), it was not until the publication of HACCP in its current

form, based on the seven principles, in the late 1990s[8] that HACCP has come to the fore as a key safety system utilised in the food industry.

The various features of the HACCP system have already been discussed in this book. However, we can draw a number of comparisons with the ISO 9000 system. The first point to mention is that HACCP is a quality management system, and is similar to ISO 9000 in that it provides a framework on which a system can be built. HACCP does not come 'ready made' and a company implementing HACCP will establish criteria to control hazards, based around the requirements defined in the standards.[8] The HACCP system, however, does have a number of important features, distinct from the ISO 9000 system.

1. HACCP as a quality system focuses on product safety, and is targeted at individual production lines and products. This is unlike ISO 9000 which specifies a quality system for the whole company.
2. Although HACCP provides an empty framework, the safety hazards, limits and in many cases the controls for many of the food processes are very often universally accepted and quantified. This makes it easier for a company to gain information on the hazards and controls relevant to a particular food process. It also has the effect of making it easier for an inspector to assess the completeness and technical accuracy of a HACCP plan.

11.2.3 Total Quality Management (TQM)

TQM is unlike HACCP and ISO 9000 in that it does not provide a rigid framework within which to build up a system. TQM focuses on continuous improvement, through the participation of employees in identifying and implementing improvements, and focuses on 'delighting the customer'. TQM therefore provides a philosophy, culture and discipline within which quality systems such as HACCP and ISO 9000 can be built and operated.[11]

11.3 Establishing benchmarks for auditing

Auditing is a fundamental part of a food safety or quality system, whether it be auditing to certify a supplier or a quality system (such as seen in the ISO 9000 system), or internal auditing to assess compliance to Good Manufacturing Practice (GMP), to verify a HACCP plan or to monitor internal compliance to quality systems and procedures. An audit can be defined as a 'systematic evaluation of a system against a set of defined criteria'. Audits are often viewed as being surreptitious checks on companies' systems, with the auditors being viewed as policemen. This should not be the case, and if an audit is perceived in this way it is not being carried out correctly. An audit is a quality tool which allows an auditor to assess performance against a set of criteria. The main purpose of an audit is to drive continuous improvement by identifying areas of weakness which may pose a risk to product quality or safety (and hence a

business). There are essentially two types of audit, each of which can be further subdivided into a number of types of audit. At the broadest level audits can be defined as:

- Technical audits
- Systems audits.

Technical audits are generally of a limited scope and performed by technical experts in a specific field, such as microbiological safety, hygienic design, or thermal processing. This type of audit will examine a particular process in detail to assess its technical performance against set criteria. In most cases the criteria set for such audits will be defined externally, in either national legislation or industry codes of practice. The technical audit is more often used to assure the manufacturer that the products manufactured, and the processes or unit operations employed, meet a minimum set of requirements to ensure the safety of the end product.

Systems audits are more commonly applied in the food industry and are not necessarily carried out by technical experts. A systems audit is examining compliance with a set of systems or procedures which make up a company's quality system. The systems or procedures covering supply or production procedures may be internationally or nationally defined, but in most cases will be developed internally by the company. The most commonly recognised systems audits in the food industry are those of the ISO 9000 certification system. The key issue with regard to systems audits is that, where the systems are developed internally, they do not necessarily ensure the quality or safety of the product or process. The absence of a 'judgemental element' can be a problem with the ISO 9000 system where the approach of 'say what you do, do what you say, show that you have done it' can get a company certified as ISO 9000 without the company addressing the critical safety or quality issues within the product or process design.

Within the two audit types above, companies will be carrying out, or receiving, audits of different types, the main being:

- Internal audits
- External audits
- Regulatory audits
- Certification audits.

These types of audit will be discussed later in this chapter.

11.3.1 Establishing the ground rules for an audit

Irrespective of the type of audit that will be carried out, there are a number of ground rules which must be followed to ensure that the output of the audit can be used for reporting and improvement. No matter how experienced the auditor, auditing is not simply a case of turning up to the company or department to be audited with a pen and paper to see what you can find. When this approach is used, it inevitably leads to omissions and inconsistencies in the audit process and

Table 11.2 Main elements required in setting up a successful audit system

Element	Rationale
1. Scope	Defines the type and limit of the audit
2. Standards	Define the depth of the audit
3. Preparation	Allows the auditor to develop an understanding of the product, process and standards
4. Format	Determines the method of the audit, e.g. using check lists, questionnaires
5. Assessment and scoring	Describes the method by which the audit will be evaluated
6. Follow-up	Checks progress against an agreed action plan resulting from an audit
7. Frequency	Defines how often audits will take place

assessment. The key elements of an audit, which must be considered, are shown in Table 11.2.

Scope

The scope of an audit is determined by a number of factors, the two most important being the type of audit being undertaken, and the resources available to carry out the audit. The scope of the audit will be made up of a number of different elements. The first element is whether the audit is a technical or systems audit, together with the type of audit (internal, external, etc.). This level will immediately determine the type of auditor required to carry out the audit, as a technical audit will require specialist expertise in the subject area being audited.

The second element should define what the audit will cover. This is always an important question and is more often than not determined by the resources available. HACCP audits will, by the nature of the HACCP study, be product and process line specific. ISO 9000 audits focus on the company's quality system as a whole. The common trap is to focus on in-house operations during the audit, which may result in critical elements which are important for product quality and safety, but which lie outside the core manufacturing process (upstream or downstream from the processing establishment), being missed. As a minimum, a company's quality audit system should include upstream audits as far as the raw material supplier or primary producer (e.g. farmer). These audits should cover how the supplier manages their own upstream and downstream supply chain, but it is often impracticable actually to audit these elements yourself, and downstream audits extend as far as the end user of the product (for retail goods this would normally be down to the retail outlet) or in the case of a further processing plant the inwards goods reception.

Standards

All audits should be carried out against defined standards. Without standards there is no benchmark or frame of reference, and the auditor's personal belief

becomes important in defining what is acceptable and unacceptable. Audits of this nature are rarely satisfactory and can lead to disagreements between the auditor and the company or department being audited over the action points raised. Another consequence of not setting fixed or published auditing standards is that it becomes almost impossible to draw conclusions when trying to evaluate the results of different audits, especially where different auditors are used, because the audits will have been carried out to different standards.

The standards used will depend on the type of audit. For any audit, local legislative requirements which may be agreed with the local veterinary service will be important, but in many cases a company's internal standards may well be stricter than the local legislation. For internal audits, internal procedures and specifications form the basis of the standards against which the audit is carried out. These internal standards should include any published GMPs, and should cover the control, monitoring and corrective actions defined in the HACCP plan. For external audits, e.g. supplier or third party producers, it is more normal to use external standards or industry guidelines. Two good examples are the 'General Principles of Food Hygiene' produced by the Codex Alimentarius[12] or the 'Food and Drink Good Manufacturing Practice Guidelines' produced by the Institute of Food Science and Technology.[13] These are two of many such guidelines which can be useful. When carrying out an external audit, it is important that the auditor takes note of any internal standards being applied by the third party, specifically those defined within the HACCP plan, to assess how well the company is adhering to their own standards.

In all cases the standards to which the audit is being carried out, and its scope, should be mutually agreed in advance of the audit (it is not the objective of the audit to 'catch people out').

Preparation

The key to any successful audit is preparation, whether it is an internal ISO 9000 audit of a department, a HACCP audit of a line or a complex audit of an external supplier. Auditors should familiarise themselves with the scope of the audit and the applicable standards well in advance of the audit. For internal audits they will need to familiarise themselves with the process, products, systems and procedures being audited (it is not good practice to allow auditors to audit within their own department of the plant, and it is good practice to rotate auditors within a company to avoid auditors becoming over familiar with any area or department).[14]

For external audits, the auditor may not be familiar with the product or process in operation because in the meat industry processing covers the scope of processes from slaughter and butchering right through to the preparation of cooked, sliced meats. It is therefore important that the auditor is pre-armed with knowledge of the following:

- The typical hazards associated with such processes and materials
- The controls which should be in place

- The limits within which the process should be capable of working
- The minimum CCPs which should be included in the HACCP plan and GMP requirements
- Product usage
- The process stages and personnel involved, etc.

Format

The audit format determines the method of the audit. There are many different approaches to auditing, each having their own benefits and shortcomings. Whatever approach is used, it should be designed to aid the auditor in covering all the areas defined in the scope of the audit. Some of the more common approaches are:

- Experience based
- Check sheets
- Questionnaires.

Audits based only on experience should generally be avoided, due to possible inconsistencies and the difficulty in interpreting their results. This type of expert audit is more suited to technical audits which are carried out by technical experts and have a very narrow scope. The outcome of this type of audit will be a technical evaluation of a line or process.

Check sheets are the simplest form of 'organised' audit. They normally consist of a series of simple questions designed to cover specific elements of a process or quality system, together with a set of check boxes for each question which can indicate 'Yes' or 'No' at the simplest level to an indication of 'fully compliant', 'partially compliant' or 'non-compliant' in more complex cases. Check sheets often have scores allocated to the individual questions to allow an overall score to be calculated. Scoring is discussed in more detail later in this chapter. Check sheets can be very useful for internal auditing, especially hygiene and GMP auditing, and their relative simplicity enables them to be used by less experienced auditors. The nature of a check sheet is that it is very regimented and guides the auditor in specific directions. This type of audit is less likely to look at areas outside the checklist which in certain situations may provide relevant data for the audit. For example, a check sheet may look at the temperature of a meat slicing operation, it may check that the slicer is clean and that the records of cleaning and disinfection are adequate. However, an auditor using a check sheet is unlikely to pick up whether the slicer is hygienically designed or being operated correctly. Check sheets are therefore more suited to operations where the technical evaluation of suitability has already been performed and the auditor is required to check that systems in place are being adequately performed (verification). Check sheets are therefore particularly suited to the regular auditing of a defined set of specified activities, such as internal hygiene auditing, verification of HACCP systems and ISO 9000 type internal audits.

Check sheets are not well suited to auditing unfamiliar premises (third parties) as their scope is too limited. However, it is often very useful to develop

standard check sheets which can be sent ahead of the audit, with the request that they are completed and returned to the auditor before the audit. These can then be very useful in making an initial assessment as they can often identify areas where attention needs to be focused during the audit.

Audit questionnaires come in many different guises and are widely used for auditing. Audit questionnaires differ from check sheets in that they ask open-ended questions which are a prompt for the auditor to cover a specific (subject) area of the processes or systems in a plant, rather than the specific yes/no type of questions used in a check sheet. Effective use of the open-ended style of audit questionnaires require that auditors are experienced in the topic of the audit and must understand the requirements set out in any standards that are available. A good auditor will use each question in the questionnaire as a starting point for a discussion in a particular subject area with the personnel involved, and will not move on to the next question until they have assured themselves that the personnel involved understand their role in processing and that the company being audited is, or is not, complying with the requirements. When preparing a questionnaire, care must be taken that the questions guide the auditor into all relevant areas, but also that they give the auditor enough freedom to fully investigate issues in sufficient depth. This is illustrated below where we ask the auditor to look at the same subject, traceability (i.e. the ability to trace a particular material from its origin to the retail trade or consumer), but in different ways.

1. Does the company (plant) have a lot traceability system in place?
2. To what extent can a company (plant) trace products in the marketplace?
3. Lot identification on packs, bins or product is an essential tool for product recall and helps effective stock rotation. Each container (primary pack) of food should be permanently marked to identify the producer and lot.[15]

Question 1 is very restrictive and more suited to a check sheet. It leads the auditor to make a yes/no assessment and relies on the experience of the auditor to actually go beyond the simple issue of whether a traceability system is present to look at its suitability and extent.

Question 2 is more balanced and asks the auditor to look into traceability to determine whether a system exists and whether or not it is suitable. This question requires that the auditor knows what the applicable standard or internal requirement for traceability is, and is able to judge the level of compliance.

Question 3 is not in fact a question but a quote from the standard on which the audit is being based. This serves two purposes. It firstly tells the auditor to look into traceability during the audit. However, because the question is a quote from the standard, it also tells the auditor what is required. It is important to note that this does not mean that the auditor need not prepare, or be familiar with, the standards. It does, however, provide a convenient *aide mémoire* for the auditor to use during the audit.

Question 1 is not suitable for use in an audit questionnaire, and it is advised to use the approach given in question 2 or 3 above when developing audit questionnaires.

Assessment and scoring

The information collected by all audits needs to be evaluated. The methods by which the evaluation is done are very dependent on the type of audit carried out. The audit process will generate data which informs an auditor how well the activity in question complies with the given criteria defined in the standards. Criteria have been mentioned several times, but it is at this stage that they become very important. When making recommendations, based on non-compliance to a standard or criterion, these must be based on non-compliance with the agreed criteria, such as a temperature, stock rotation regime or hygiene standard. It is not good practice for the auditor to make recommendations based on personal belief, as these will be open to debate. A non-compliance based on an agreed standard, whether it be an internal standard such as a work procedure, or an internationally agreed standard, is much more likely to be agreed and accepted by the company or department being audited.

There are no fixed rules determining the amount of information handed over to the plant being audited at the end of the audit. For third party or supplier audits, it is common only to give an indication of 'Pass' or 'Fail', rather than a detailed written report. It should be remembered that one of the main purposes of auditing is to drive continuous improvement. The auditor should therefore leave an agreed list of recommendations with the Plant manager or QA manager, whether a third party or internal audit has been done, and if possible the auditor should give advice on how to solve any problems found.

At this stage we need to mention scoring. Many auditors or audit systems utilise a scoring system by which the findings of the audit are converted into a single score, expressed, for example, as percentage compliance or an approval grade (A, B, etc.). There are as many different scoring systems as there are audit methodologies, but each provides a means by which the results of the audit can be quickly and easily interpreted or compared by persons not involved in the audit. Scored audits also have the advantage in that, if the audits are carried out to the same standard, different audits can be compared quickly and easily, simply by using the score.

There are a number of points to remember when developing scoring systems for audits. The first is that, if not developed carefully, scoring systems can hide critical deficiencies. This can often happen if the scoring system allocates points for excellence or above standard. This immediately allows a company to overachieve in a section of the audit and to underachieve in another section, and when the results are averaged at the end they come out with a standard score. For this reason it is not advised to develop scoring systems which increase the score by overachieving; this should be rewarded in other ways.

There are several ways of ensuring that critical issues are accounted for in the overall score of the audit. The first is to have a weighting system, where the score for each question is multiplied by a weighting factor to give the final score for the question. The weight given to each question should reflect its contribution to product safety or quality. Thus, personnel wearing hair covers and overalls, whilst important, would not be weighted the same as having a

calibrated cooking process and strict raw/cooked segregation in an area preparing cooked meats. Where trained auditors are used, it is possible to develop scoring systems where individual questions are not scored, but sections of the audit are scored. The score given to each section represents how well the company or department complies with the given standards, taking into account any critical areas covered in the section. The auditor is therefore looking at the overall picture, placing emphasis on critical issues when giving a score. This can be a very effective system but is obviously more subjective than the method mentioned above. It relies on having well-trained, experienced auditors, good standards and a well-developed audit questionnaire. This approach cannot be used with a check sheet. Where more than one auditor is used to carry out audits of this nature, it is also useful to set up a referee system, either by exchanging reports for discussion between auditors or by having the audit reports refereed by an experienced auditor to ensure consistency between auditors.

Follow-up

The food industry is ever changing. At the external level, new legislation and standards are introduced, new hazards, microbiological or chemical, are discovered which affect the way we work and the risks to our customers, and new process technologies become available. Within a business, new procedures are written, to take account of internal and external pressures, new processes are introduced and new products are manufactured. For this reason auditing cannot be 'one off'. For both internal and external auditing, regular audits are required in order to ensure that the systems and procedures keep pace with the external pressures on the business, and that internally, new procedures are implemented and effective.

Where an audit is part of an audit programme, follow-up is a vital part of ensuring that any actions resulting from a previous audit are being put into place.

Frequency

The frequency at which audits take place is dependent on the nature of the operation being audited. Major suppliers or suppliers of high risk ingredients (i.e. those which may carry pathogens or chemical contaminants) or finished packed product for direct sale will need to be audited more frequently than suppliers of minor ingredients.

11.3.2 Auditing HACCP systems

The principles described above are applicable for all types of audit. In the same way, auditing HACCP systems is no different from auditing other quality assurance systems such as ISO 9000. However, there are a number of points which should be considered. ISO 9000 as a system concentrates on the contractual relationship between supplier and customer, and the conformity to customer specifications.[1] The systems and procedures developed under the ISO 9000 system are therefore derived internally and specify the quality system for

the whole company. HACCP differs from ISO 9000 in that it defines the hazards and controls related to a specific product or process, and a plant will have several different HACCP plans in place, one for each line/product, covering the total manufacturing operation. When auditing HACCP systems, therefore, the scope of the audit is likely to be very different from an ISO 9000-type audit.

Before auditing a HACCP system, it is important that the objective of the audit is very clear. HACCP audits make no check on the technical accuracy of the HACCP plan. This activity is part of the validation process which is discussed elsewhere in this book. A HACCP system audit is used to establish whether or not the controls, monitoring procedures and corrective actions defined in the HACCP plan are being applied correctly, and whether or not they are effective. It is a common misconception that HACCP audits will indicate whether a HACCP system is 'safe' and covers all applicable hazards. This is definitely not the case.

A HACCP systems audit would generally cover the following elements:

1. Have the HACCP studies been carried out according to the seven principles described by the Codex Alimentarius,[7] or an equivalent system?
2. Has a team approach been used to generate the HACCP plan, and what technical expertise has been available to the team?
3. Does that HACCP plan cover all the expected CCPs, together with targets, limits, monitoring systems and corrective actions? (This would normally be a part of validation, and would not be covered in an internal audit.)
4. Is there evidence that the HACCP plan has been validated?
5. Has the HACCP plan been discussed with operators, and do operators have access to work procedures based on HACCP? Have they been sufficiently trained and do they have sufficient tools and authority to carry out their responsibilities?
6. Are monitoring procedures being carried out and recorded on the factory floor? Is there any indication that the control procedures are not effective?
7. Are there clear priorities for action in the event of a process deviation?
8. Has the process changed since the study was carried out?
9. What verification data is available to demonstrate the effectiveness of the HACCP plan?
10. When was the HACCP plan last reviewed?

The above is not an exhaustive list but covers the main elements normally associated with a HACCP audit.

Internal auditing of a HACCP plan

In general there is very little difference in auditing a HACCP system in your own plant and in that of a third party. Both audits will require that the auditor assess the elements described above. However, in an audit 'in house' elements 1–4 above will be assessed initially and then left out of the regular audit system which would focus on elements 5–9. The key to auditing HACCP is not to spend a great deal of time examining the HACCP plan to check its accuracy – this will

have been done when the plan was validated – but to focus on the operational side of HACCP. What we mean here is that the HACCP plan will define a number of controls and monitoring systems associated with each CCP. The aim of the audit is to check that working procedures are available which adequately cover the requirements at the CCP, that the operators have, and understand, these procedures and that any required data collected is being recorded and action taken if the process or material is outside the critical limits.

An important part of the HACCP audit is not only to check that the HACCP plan is implemented and the procedures are in place, but also to check that there have been no changes on the line, to working procedures (e.g. times, temperatures or hygiene) or to product formulation (e.g. preservation system or packaging) which may affect the effectiveness of the HACCP system. Although this is normally associated with the formal review of the HACCP system, it is normally not sensible to leave this type of check for the yearly review but to keep on top of the changes in this more frequent audit system.

External auditing of a HACCP plan

Auditing a third party HACCP plan follows the same principles as defined above. However, although it is not normally necessary to check the content and accuracy of your own HACCP plan, the auditor will need to make a judgement on the content and accuracy of the third party plan, to check its suitability for ensuring the safety of the supplied product. It is very difficult to assess another team's HACCP study, especially if you are not familiar with the product or the processes used by the third party. The way to tackle this problem is to identify the minimum CCPs that you would expect to find for the type of process being audited. This information can often be found in industry guides, or in generic HACCP plans which are produced for different sectors of the food industry. A note of caution here is that by their very nature these guides are generic and can be superficial. However, they should be of use in identifying the minimum number and location of CCPs which you should be able to find in the HACCP plan of the third party. If these minimum CCPs are not present this immediately warns the auditor that this HACCP plan is not likely to be effective at controlling the hazards in the process. As an aside, the Internet is a source of significant information with regard to HACCP, and many food companies post their HACCP plans on the Internet. These can be a useful source of information, but again they must be used carefully as these are individual company plans and have not undergone a peer group review, unlike the industry guides available. The USDA/FSIS provide a number of generic HACCP studies at http://www.inppaz.org.ar/MENUPAL/Bvirtual/FOS/haccp/usda/haccpmod.htm.

If the HACCP plan is acceptable, the auditor will then proceed to determine if the plan has been implemented in the factory and is working as intended.

11.4 What the auditor should look for

In any audit, time plays a crucial factor. The auditor never has sufficient time to cover all the elements they would like to, and good time management is critical to the success of an audit. As an auditor it is therefore important to remember that you will never be able to check everything, and should not try to do so. As a general guide the auditor should carry out following procedures.

- Start with a brief tour of the factory, starting with the raw materials and finishing where the finished goods leave. This tour is not a fact-finding exercise but is intended to give the auditor a general feel of the operation being audited. It will also provide an insight into the management attitude of the company with regard to quality and safety. A clean, tidy, well-organised factory with hand washing, clean operators with suitable protective clothing, notice-boards and signs instructing operators in good practice is always a good indication that the management are committed to quality and safety. On the other hand, an untidy, dirty and haphazardly organised factory gives a clear indication of a general disregard of the management for quality and safety. First impressions are significant, and although it is important that the auditor does not jump to too many conclusions from the initial visit, an experienced auditor will normally be able to tell what the outcome of the audit will be from this visit.
- The auditor should now check whether or not the required systems and procedures are in place to cover the required elements of the HACCP system, and whether they contain the necessary depth of information. The use of a well-designed check sheet or questionnaire is a vital aid to ensuring that all the relevant systems are covered during the audit. Remember that the auditor here is assessing against standards and not making a personal judgement.
- The existence of a well-written procedure is not an indication that the system is implemented in the company. It is the role of the auditor to check that what is written on paper is actually working and is effective. Although the auditor should check whether or not all the required procedures exist, they will not be able to verify that all procedures are in place and working. Therefore he or she should select a number of key elements to check. Selection of the elements to check should not be a random process and the auditor should always check a number of the CCPs defined in the HACCP plan, to assess whether what is described in the HACCP plan is in fact happening on the factory floor. This therefore involves checking that the work instructions for operators cover the work practices and any control measures and that the targets and limits are clearly specified to enable the operator to judge whether the CCP is in control. Monitoring procedures should be available on the line or in a laboratory and records should be meaningful, available and up to date.

- The auditor should also check a selection of other procedures so as to ensure the quality of implementation of the HACCP plan and the background of GMP. It is often useful, during the initial factory visit, to note any activities that do not appear to be in line with a given standard. If a procedure exists which covers the activity observed and which is not in accordance with the standard, clearly there is a problem with implementation.
- It is extremely important to talk to people, especially the operators on the production floor. It is possible to find out more about the current state of implementation of the company's quality system by talking to the operators than in any other way. (Do they know what a CCP is? Have they been told about HACCP?) Ask to see work procedures and line check sheets used for monitoring CCPs and other quality parameters. If the operator does not have the relevant procedure readily available, it is more than likely that the procedure is not being followed.

11.5 Future trends

Food quality and safety is continuously evolving and the foods industry needs to keep abreast of these changes to remain competitive and meet customer requirements. HACCP is here for the immediate future, and future trends in HACCP are discussed earlier in this book. However, one point to note is that many major customers now see HACCP as a key requirement from their suppliers, whereas in the past ISO 9000 was seen as the key requirement. As such, HACCP certification may become a more important feature of the HACCP system. Already many third party accreditation companies are offering HACCP certification services, either as a stand alone, or combined with existing ISO 9000 certification. International standards for assessing and certifying HACCP are being developed[16] with the aim of standardising the certification process. Currently, HACCP certification looks at the approach taken and the standards used for developing the HACCP plan and subsequent implementation of the plan. Technical accuracy of the HACCP plan will not usually be assessed and this may become a weakness of the certification process.

ISO 9000 was the dominant quality system in the early 1990s and is currently under revision (the so-called ISO 9000:2000 standards). This standard will retain the original 9001–9004 standards, but has changed the structure of the elements making up the standards. The ISO 9000:2000 standard has five elements, each with a number of sub-components:

- Quality Management System Requirements (one sub-component)
- Management Responsibility (six sub-components)
- Resource Management (three sub-components)
- Management of Processes (seven sub-components)
- Measurement, Analysis and Improvement (two sub-components).

Many of the sub-components are further subdivided. The 20 elements of the existing ISO 9000 system are covered within the five elements in the new system. However, the new system places more emphasis on validation and will hopefully address the issues associated with the current standard, whereby it is not inconceivable for a company to miss key activities within their internal system but be able to gain accreditation by demonstrating compliance with incorrect or incomplete standards defined internally.

For many companies it is difficult to find the resources, and the necessary skills, within their company for auditing third parties. In addition, many companies are faced with an increasing number of customer audits, which takes valuable resources from the day-to-day activities of the company. Third parties are picking up on these facts and offering third party auditing services, and even accredited auditing services. One such which is operational in the UK is the European Food Safety Inspection Service (EFSIS).[17] The system audits a plant against 35 set criteria in quality, safety and hygiene, and if the audit is acceptable will grant accreditation. Accreditation is a continual process and the frequency of re-accreditation will be determined depending on the type of process and the previous audit score. The rationale behind the EFSIS scheme is that it will reduce the number of third party or customer audits by providing third party auditors who will assess suppliers, and it will allow companies to show they have reached a set of fixed standards defined by EFSIS. Third party auditing and accreditation schemes are becoming seen as a good means of reducing the resource requirements in a company with regard to auditing, and offer independent assessment of a company's safety and quality system. Such systems are dependent upon the skills and professionalism of the auditors who carry out the assessments, but are likely to become more important in the food industry.

Current quality systems, and many of the associated auditing systems, focus on whether or not a system exists, and check that the system is actively implemented within the company. Very few systems require that the subsequent results of the implemented system are evaluated. Within Europe, the European Foundation for Quality Management (EFQM) has developed a model for quality excellence.[18,19] In common with ISO 9000 and HACCP, the EFQM system provides a framework for achieving excellence. This framework is built up of the following nine elements:

1. Leadership
2. People
3. Policy and strategy
4. Partnerships and resources
5. Processes
6. People results
7. Customer results
8. Society results
9. Key performance results.

However, unlike other systems, the EFQM divides these elements into 'enablers' and 'results', elements 1–5 being defined as enablers and elements 6–9 as results. Enablers are those criteria which define what the organisation does, and would be focused on internal policy, systems and procedures making up a quality system. The results are intended to cover what the organisation achieves, the premise being that there cannot be results without enablers. The EFQM website (http://www.efqm.org) describes the system in detail. The EFQM system is not the only system which focuses on results but the future lies with such systems, which look outside the organisation to ensure that what is defined internally has the desired results both internally and externally.

11.6 References

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