

HACCP and ISO 9000: Focus on Community Outcomes

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Background

The existing version of ISO 9000 series Quality Management Standards was first published in 1983, was adopted internationally in 1987, and its philosophical origins can be traced to 1906 with the establishment of the International Electromechanical Commission (IOS, 2001). The origins of third party auditing appear to have begun in 1966 (SGS, 2001) with the publishing of the UK Defence Standards family DEF-STAN 05-21/24/29, which ultimately became British Standard BS 5750 in 1979. It should also be noted that the US Military Standards played a part in this development, eg MIL-Q-9858 A. The intention of the ISO 9000 series is well understood – a management philosophy, structured around twenty elements to enable a systematic process for manufacturing specific products. This standard has been revised, with the release of ISO 9000-2000, with emphasis on continuous improvement and meeting customer needs.

Originally presented publicly in 1971 (HEW, 1972) the Hazard Analysis and Critical Control Point protocol (HACCP) has now established itself as the template for safe food production for the food industry. It needs to be noted that the Seven Principles, as we know them, were not internationalised through the Codex Alimentarius Commission system until 1990, and not finalised until 1996 (Codex, 1997). It is therefore perhaps not surprising that we find ourselves being caught up in an accelerating “HACCP fever” over the past 5 years. With an increasing number of food industry executives now recognising that a soundly developed and implemented HACCP program, that includes the relevant support/ pre-requisite elements, represents an external “insurance policy” for commercial survival. This “insurance policy” also forms part of the food company’s demonstration of due diligence, necessary to protect the health and well being of their consumers, as well as their shareholders. This demonstration of due diligence in the food safety arena is increasingly preoccupying corporate minds, with three key components required to come together:

1. Documented HACCP program = reasonable precautions to be taken,
2. Implementation of the HACCP program, and record keeping = due diligence is being exercised,
and
3. The external audit process = recognition of adequacy/effectiveness of the food safety program.

Clearly, the audit process to provide the security and confidence for the food business and its customers becomes significant – an aspect that will be developed later in this paper.

Integration of HACCP and ISO 9000

If we take Australia as an example, only relatively small proportions of food business are ISO 9001/2 certified:

- 0.07% of all food business (including retail outlets, caterers, restaurants)
- 14.3% of food manufactures and ingredient suppliers

(JAS-ANZ, 2001)

For most of the food businesses that have attempted ISO 9001/2 certification, the integration of HACCP has been a difficult exercise, with most often having their HACCP program separate to their ISO 9001/2 system. This creates a very burdensome QA program to maintain. Food business are questioning the business value of ISO 9000 series, when customer requirements now focus on suppliers being able to demonstrate their food safety control capacity. Sheets of stainless steel, 316L grade can be made consistently by any stainless steel maker around the world, using ISO 9000 as a management tool. Food items however, are often difficult to replicate exactly; even though this is the challenge for the QA Manager at a food manufacturing plant (salt in ham many have a target of 2% w/w, but be given a tolerance of $\pm 0.2\%$ - an allowable variation of 16%,

something that cannot be tolerated in the metal manufacturing). In repetitive manufacturing, the construction of premises and the personal hygiene of operators may only (comparatively) have a small to negligible impact on the accuracy of manufacture of our 316L grade of stainless steel.

The process flows, materials of construction, and personal hygiene practices of operators will therefore have a substantial, and potentially life threatening impact on the food safety of all food products. As a result, companies involved with the handling of food are faced with a challenge: food safety is not negotiable in anyone's mind. By following the "HACCP method" (AgWest, 1997), based on the Codex principles and guidelines, this provides a common sense QA approach to managing identified food safety hazards. But what does ISO 9000 bring to their business' equation? Experience in Australia has shown that for most small and medium food businesses, particularly in the agri-food sector, ISO 9000 does not enhance business performance, but rather adds cost for no commercial benefit. For large food enterprises (100 employees or more), particularly multi-site and multinational enterprises, business discipline together with demonstrated food safety controls can be achieved by integrating ISO 9000 and HACCP. This integration can be achieved through integrating systems such as HACCP-9000 (for details see www.qas.com.au), or through recognition that the HACCP system impacts on a number of ISO elements such as:

- 4.1.1 Quality Policy (production of safe foods)
- 4.2.2 Quality Procedures (HACCP Audit Tables)
- 4.2.3 Quality Planning (HACCP Team + "HACCP Method")
- 4.6 Purchasing (approved supplier program)
- 4.9 Process Control (HACCP Audit Tables + Verification activities)
- 4.10 Inspection and testing (HACCP monitoring & Verification activities)
- 4.11 Control of IMT Equipment (calibration)
- 4.15 HSPPD (HACCP audit tables)
- 4.16 Control of Quality Records (documents control)
- 4.17 Internal Quality audits (verification activities)

This listing is not complete, as there are other minor crossovers with certain HACCP support/ pre-requisite programs, such as training. However a number of major Australian food companies have not pursued or are not renewing their ISO certification, but rather maintaining their HACCP certification through third party food auditing. This trend is reflected in the rise of alternate third party audited standards to ISO in Australia, New Zealand, Asia and the Americas. In Australia alone, there are over 120 food safety certification programs available, mostly industry/commodity specific: one standard that has transcended this pattern is SQF 2000^{CM}, now an internationally recognised third party audited food safety standard (for details see www.sqf.wa.gov.au). Those involved in supermarket retailing in Europe will know of SQF 2000^{CM}, particularly for fresh produce, and will be aware that this standard integrates both food safety and quality into the HACCP-based QA system. SQF 2000^{CM} arose out of difficulties experienced by many business with ISO 9000 – apparent complexity, cost, resources required for maintenance, and the lack of focus on food safety (Peters, 1998). Also, many disappointing anecdotes prevailed relating to the market value of ISO 9000 in the food industry: world class practice (the company has ISO 9001 or 9002), shame about the product (company caused serious pathogen contamination that resulted in substantial numbers of confirmed illness).

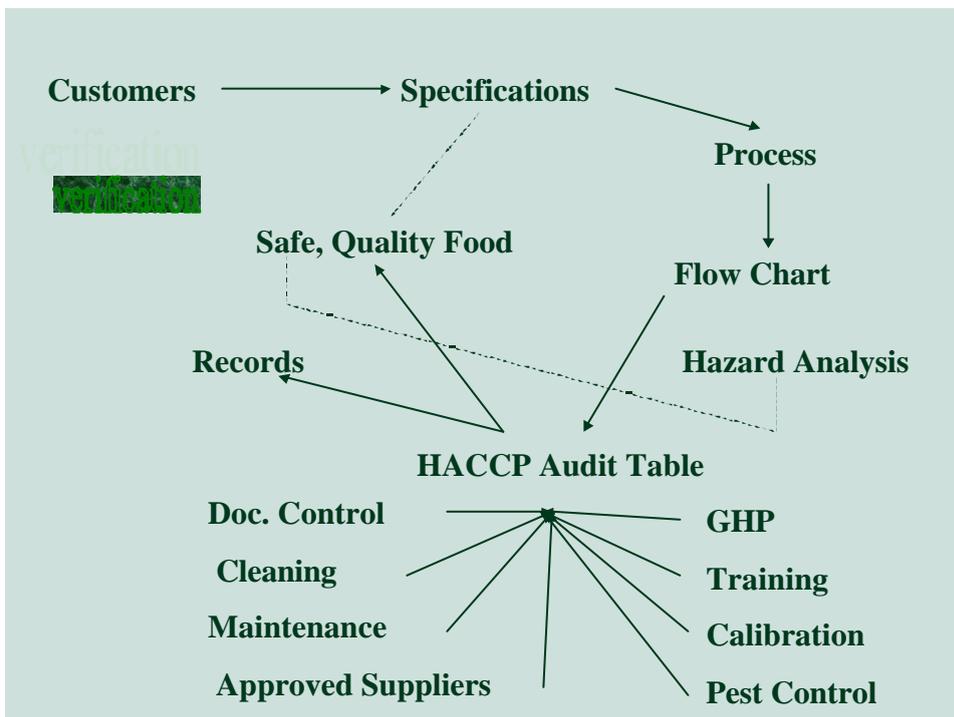
Styles of Auditing

Before I contrast the different styles of auditing that now exist between food safety and quality management systems, certain definitions need to be provided.

What is an Audit ?

- ISO 8402
 - A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives
 - Evaluation of past history, current practices, to give a future projection of performance
 - Inspection is a review of current practices

I also need to explain exactly what a HACCP-based QA program actually looks like as a model:



An immediate difference between ISO and food safety auditing becomes apparent. ISO undertake a sampling of elements over a three-year period, after the initial certification audit, to determine compliance with the twenty elements of the standard. This approach cannot be used for food safety auditing; a sampling of several elements from a food safety program every six months (eg pest control, calibration, and review of monitoring

of one CCP) will not provide any confidence that the business is fully controlling its identified food safety hazards.

A food safety audit must examine all aspects of the HACCP plan (product description and intended use, flow diagrams, hazard analyses, HACCP audit tables, and verification activities) at each audit. Key support programs such as GHP (Good Hygiene Practices), cleaning/sanitation, and pest control as a minimum, need to be included in each audit. As noted above, this differs significantly from the ISO auditing approach, in terms of “core provisions. Food safety auditing has core elements, ISO does not necessarily have the same focus – all twenty elements (where applicable) need to be covered over the three years, noting that there is a particular focus on Management Review (4.1.3) and the Internal Audit process (4.17).

This signals that food safety auditing is a combination of systems auditing and compliance auditing – not only have all the elements of the food safety program been documented and implemented (systems perspective), but their content is appropriate and effective in all aspects (food safety compliance perspective). For many, this is a radical change and a new challenge, because food safety auditing also involves the people element – staff attitudes, staff potential to cross contaminate, staff abilities to recognise new food safety issues, and the effectiveness of staff training. It has always been stated that ISO auditing focuses on the system, not on the individual. Food safety auditing, however, focuses on the individuals as well as the system; the outcome of food safety auditing is external recognition that the practices in place at a food business, as well as the system, will prevent or eliminate identified food safety hazards, or reduce them to acceptable levels.

To further expand the differences between ISO auditing and food safety auditing, we need to look at the approach employed. Food safety auditing requires a thorough evaluation of the product and the process, on the day, by “walking the talk” – following the flow chart, either forward or backwards (depending upon the risk ranking of the process). During this process, it is critical for the food safety auditor to concentrate on the “3 H’s” and the “5 P’s” at each step in the flow chart.

3 Hazards: Biological
Chemical
Physical

5 “P’s”:
Product (including ingredients and packaging introduced at that step)
Premises (the potential hazards from the immediate environment)
Plant (the potential hazards introduced by the equipment and services)
Procedure (the potential hazards introduced by the methods)
People (the potential hazards introduced by the staff themselves)

This is unlike the ISO auditor, who does not have this “now time” responsibility to achieve a community outcome of safe food. This “walk the talk” is essential to confirm, or otherwise, the business identification of the potential hazards, and their assessment of significance to those hazards. This is a pro-active process of hazard confirmation by the food safety auditor.

These differences are further delineated by the focus that the food safety auditor needs to have on the business (auditee) achieving a safe food outcome; to be convinced that a food company’s program is appropriate for the type of food being prepared and the effectiveness in controlling food safety hazards. Unlike an ISO audit process, which seeks evidence of compliance with documented procedures, the food safety auditor needs to ask whether the elements of the food safety program are indeed appropriate for the risk classification of the food

In determining whether the food safety program is effective, the food safety auditor needs to examine five perspectives, in order to have confidence in the business food safety program:

- evidence that all reasonable potential hazards have been identified and assessed;
- current CCP’s are effectively controlling significant hazards;
- critical limits associated with CCP’s have been validated, and therefore will achieve the necessary control of food safety hazards;

- support/pre-requisite programs, together with the documented HACCP plans, are being reviewed and maintained appropriately; and
- evidence that the whole program is and has been delivering safe food – end product microbiological results shelf life validation, reduction in complaints etc.

These five perspectives mirror the QA expectations of the food business, and so it is not surprising that the food safety auditor follows the same logical methodology.

But a significant aspect not yet examined, is the personal attributes of the food safety auditors themselves – the knowledge, skills and experience required to make judgement on the appropriateness and effectiveness of a food safety program. This aspect was formalised in Australia in 1997 by the Quality Society of Australasia, through the recognition that a food safety auditor needed specific qualifications and experience beyond completion of an auditor/lead auditor training course. These can be summarised as follows:

Criteria for Food Safety Auditor

	Associate FSA	FSA	Senior FSA
Tertiary or on-job training	√	√	√
Auditor training	√	√	√
General work experience	4 years	4 years	4 years
Food safety experience	2 years	2 years	2 years
Auditing experience	-	20 days auditing on-site	Auditor requirement + 5 audits as team leader

From “Certification Criteria for Food Safety Auditors”, QSA

Whilst Australia has over 600 registered food auditors (QSA, 2001), we still suffer the traditionalist’s viewpoints:

- I am an auditor (by training), therefore I can audit anything for which there is a published standard (all I need is a checklist)
- I am a government inspector, therefore I am an auditor.

These attitudes have been difficult to shake. But, as the number of class actions against food companies increase (in Australia), these attitudes are changing, with the liability of the food safety auditor now been called into account. The key point at issue is the situation when a business’ food safety program has a serious deficiency – a significant hazard has not been identified (eg raw to cooked cross-contamination), and therefore the food business does not have any control measures in place (eg staff segregation). This becomes the responsibility of the food safety auditor to identify (and the business to then correct). The traditional ISO audit process tends only to examine the stated procedures for compliance, rather than ask the question as to whether the current practices are appropriate (by using the “3 H’s” and the “5 P’s”, as noted earlier). At the centre of this point, is the responsibility that the auditor is expected to assume. For quality management

systems such as ISO 9000, there is little to no responsibility on the business to achieve any defined external objectives. I appreciate that ISO 9000-2000 will have greater business achievement focus than the now out-dated standard, but I doubt whether the style of audit will change, as ISO 9000-2000 has nothing specifically for food safety – so what are the requirements? The business should know, but does the auditor?

Conclusion

In this (perhaps provocative) discussion, I have endeavoured to explain that whilst ISO quality management systems may have a place in a significant number of business sectors, its place is secondary behind *food* business being able to demonstrate that they are controlling significant food safety hazards via the HACCP method. It is very easy for regulators to impose a quality management structure, such as ISO QMS, without recognising the potential issues that may arise. I have focused on one of these issues – the current differences in the audit approach that exists between food safety auditing, and quality management systems auditing. These issues are real, and have serious repercussions for the community at large, who not surprisingly have an expectation that all food sold to them will be safe to eat. Similarly, regulators in the public health arena perceive the introduction of mandatory food safety program development as a necessary strategy to transfer full responsibility for safe food production on to the proprietors of food premises. It is the unique circumstances that each business contributes to its food preparations and production process (due to the “5 P’s”) that makes food safety auditing such a challenge.

As we know, HACCP is a science based, risk management process (Pierson, 1997) and therefore this activity requires particular individuals to determine on behalf on the wider community, that a food business is in fact producing safe foods. But by understanding the perspectives that I have explained, the transition from quality systems auditing to an outcome focussed approach needed for food safety auditing, can be readily achieved. The key is recognition that food safety auditing has a community public health outcome and inherently, a liability on the auditor.

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