A Preliminary Study on On-site Audit of Quality Management of Food Production Enterprises

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Abstract: Food production enterprises should formulate scientific on-site audit procedures and standards. For the key points and difficulties in on-site audits, there must be personnel with professional competence to manage and implement the breakthrough measures. Institutionalized and standardized implementation of scientific on-site audit is the core of improving enterprise quality management.

1. Introduction

In recent years, the breadth and depth of food have significantly changed, from traditional workshop-style processing to modern large-scale production. In the field of modern food production, more refined processing elements have been integrated. The quality of food has become an important factor to determine whether food production enterprises can better gain a foothold in the market. The effect of on-site audit in food quality control is directly related to the efficiency of improving food quality assurance.[5]

2. Various quality standards and certification audits are the keys of on-site audits

Modern food companies are inseparable from quality monitoring. In order to ensure safety, nutrition, health, convenience, diversification and other qualities of food, quality assurance from product quality to enterprise management quality presents a systematic trend, involving the entire food production chain and related aspects. It involves areas such as the cultivation and supply of raw and auxiliary materials, product design, production process, packaging materials, transportation and delivery, and circulation to consumer reviews. [6-7] These areas are interlinked and indispensable.

At present, most of the quality assurance of food production enterprises is completed through strict implementation of standards and certification audits. The quality standards include GB or GB / T, industry standards, enterprise standards, etc. Among them, enterprise standards have the highest requirements, followed by industry standards, and further down the line, GB or GB / T. Certification audits can be divided into two categories: one is product certification, including product safety certification (compulsory certification), product qualification certification (voluntary certification), such as green food certification, organic food certification; the other is management system certification, including four types: Quality Management System (QMS) certification, Hazard Analysis and Critical Control Point (HACCP) certification, environmental management system (EMS) certification, and Occupational Safety & Health Management System (OSHMS) certification. Among them, the first three are often applied by food enterprises, such as ISO9001 quality system certification and ISO/TS16949 quality system certification. [8-9]

In terms of the relationships between standards and certification audits, quality and on-site audits, the author believes, standards and certification audits are the essential part of on-site audits, which is then followed by the quality part. If the standards and certification audits are realized, the quality will be met.

3. Establish scientific on-site audit procedures, analyze key points, and break through the difficulties of on-site audits

On-site audits have always been the key and difficult point of quality management assurance for food enterprises. Taking the on-site audit of ISO9001 quality management system as an example, in the on-site audit of food production enterprises, on-site audit work should be performed according to standard procedures, with a total of 9 steps. This article provides a brief description of the main steps, without listing all of them one by one, it analyzes the key points and difficulties in the on-site audit process, and finds effective measures to break through the difficulties.

3.1 Make an audit plan

The audit plan is a description of the audit activity arrangement. It is the guidance document for the auditor to implement the daily audit activity. [10] It is also an important basis for guiding internal and external audits. It includes purpose, scope, criteria, timescale, and place of on-site audit activities, as well as roles and responsibilities of audit members, and audit resources allocation in key areas, etc.

3.2 Compile a checklist

The checklist can generally be compiled according to the requirements of standard terms, or departments, or processes. In the table below, the author combines personal experience and summarizes the advantages and disadvantages of these three methods in the implementation process.

Table 1. One Comparison of the advantages and disadvantages of the checklists for three different compilation methods

Compilation method	Advantages	Disadvantages	Experience and summary
According to the requirements of standard terms	This kind of checklists take everything into consideration, and therefore is unlikely to miss key points.	The audit meeting of the same requirement will involve multiple departments; the audit of multiple different requirements will result in multiple reviews of one department; the auditor will repeatedly investigate the same department.	1. In the process of on-site audit, the checklist should be used flexibly, neither deviating from the checklist at will, nor scripted, mechanically copied, or in the form of Q & A. 2. According to the on-site audit, the checklist should be flexibly adjusted. Thus, it is not limited to the original scope, nor does it affect the integrity of the audit. 3. If disqualification or valuable clues are found, additional inspection should be made. 4. For experienced auditors, the checklist can be prepared briefly. For inexperienced auditors or when working in new audit areas, however, the checklist should be as detailed as possible.
According to departments	The audit of one department can be completed at a time, and the main processes that each department are responsible for can be covered. Therefore, the audit covers a wide field.	The audit of a department can only get part of the information required. If not paying enough attention to the connection among departments and to the communication among auditors, the audit will be incomplete and the audit depth insufficient.	
According to processes	The PDCA method can conduct a complete review of each process, which is convenient for accurate evaluation of the implementation and effectiveness of the process, and for the evaluation of the quality management system.	The checklists of this kind are similar to those compiled according to the requirements of standard terms.	

3.3 Analysis of key points and breakthroughs of difficulties in the on-site audit process

(1) Meetings. Through the meeting, auditors can announce the purpose, scope, criteria, sampling principles, common methods, and communication methods of the audit. They can also make audit progress report, confirm non-conformance or observation items and so on. Team members can negotiate and deal with disagreement, resolve conflicts, and reach consensus.

(2) On-site audit methods. There are a variety of on-site audit methods. Common ones include consultation to optional information sources, such as documents, records, customer feedback, etc.; interview (follow 5W1H principles); observation; repeat verification; retention of audit records. The difficulties in the on-site audit are as follows. a. Consulting documents. The difficulty of consulting documents lies in the large amount of literature review, wide range of areas, and numerous and miscellaneous information sources. In the process of consulting documents, recording sampling inspection and tracing the operation of the quality management system, it is hard to verify the objectivity of the information, to find non-conformance items, and to look for evidence of the operation of the quality management system. In order to overcome these difficulties, auditors should work in cooperation with a due division of responsibilities, and the audited party should actively cooperate. b. Observing. The difficulty here is to collect comprehensive evidence in a limited time, which is highly professional. Auditors should go deep into the production line to observe and investigate, in order to collect more real audit evidence and verify whether the equipment, facilities and environment of the audited departments meet the requirements. For example, the auditors need to verify whether there is compliance with laws, regulations, and product standards; whether the integrity of equipment is ensured. They also need to check the status identification of raw materials and equipment in the workshop, calibration status of measuring instruments and equipment, warehouse management (financial, card, material stacking and protection) compliance, and product storage, etc. The difficulty of observation can be mitigated under the guidance of food industry experts and the support from professional knowledge and technology, and then the auditors can make an objective evaluation of the compliance of the whole process of food production.

(3) Repeating verification. According to the need, the auditors should carry out necessarily repetitive activities to further trace, analyze and determine some information found in the audit. For instance, re-inspecting the products that have been inspected, repeating a certain reception behavior, verifying the standardization of services, and repeating the calibration and operation of testing instruments.

(4) Audit findings. Findings are the results of evaluating the collected audit evidence against the audit rules. Generally, findings summarize items into three categories, those of non-conformance, those requiring further observation, and those in line with compliance. When the purpose of audit is determined, audit finding can identify opportunities for improvement. The difficulty is the discovery and determination of non-conformance items and observation items. To overcome this, enough attention should be paid to non-conformance or observation items, the auditing party should establish a good communication mechanism with the party under audit, and the two parties should evaluate together to determine the accuracy of the audit evidence. If both parties have disagreement on the audit evidence plan, the dissenting opinions should be resolved and recorded, and finally, auditing party should develop a non-conformance to urge the party under audit to improve. Facts with insufficient evidence to be determined as non-conformance items, but may cause adverse consequences, may be classified within an observation report to remind the trial department to pay attention.

(5) Share of audit results. For large-scale group enterprises, there are situations where multiple production enterprises rely on raw materials provided by a single supplier, so the audit results must be shared within the group to avoid resources waste caused by multiple audits [1].

4. Auditors selection and professional competence

The on-site audit of food production enterprises is a technical, professional and comprehensive

task, and it is necessary to form the audit team with members having strong comprehensive abilities. Auditors must be competent, able to apply flexible audit methods, and have professional production knowledge. The internal audit team involves the management department, procurement department, production department, and sales department, etc., and most of them can be composed of 3 to 5 people. The external expert audit team should contain amphibious experts who understand both food production technology and methodology. Only when equipped the team with sufficient and competent experts, can the efficiency, accuracy, and scientificity of on-site audits be improved.
As internal audit is the cornerstone, this section emphasizes the characteristics of the internal audit team.

4.1 Personnel familiar with inspection and testing

Team members should be able to analyze the completeness of inspection basis and standards, to inspect the integrity and reliability of inspection records, and have relevant qualifications. Besides, they need to determine whether the factory inspection meets the project requirements, whether various products are regularly inspected by third parties in line with national standards, and whether the disposal of unqualified products can be completed within schedule. Furthermore, it is their duty to make sure that the products pass routine quality testing, hygiene index testing, food additives, drug residues, and microbial project testing, etc. [2].

4.2 Personnel familiar with production technology, equipment, and food safety

The product quality highly depends on the effective control of the production process, and the professional competence of relevant personnel should meet modern industrial production requirements. Relevant staff should be able to conduct key analysis of hazards, strictly control key stages, and make accurate assessments of the production process advancement. They should also know how to test the integrity and advancement of the equipment and its maintenance plans. Moreover, they need to develop a complete equipment maintenance system and standardized operation process [3].

Regardless of the size of the enterprise, the additives, disinfectants, and detergents selected in production must meet the requirements of China's laws and regulations, and must be well recorded. Besides, to meet the health management requirements and produce non-toxic, harmless and pollution-free products, relevant personnel are required to resolve all quality problems arising in the product storage and transportation [4].

Conclusion

Overall, the traditional quality audit methods failed to adapt market changes and global development, and the core of quality improvement of food enterprises is on-site audit, which has specific rules and measures. Modern food enterprises should firmly grasp on-site audit as the key of quality management, strengthen the research of on-site audit, and apply scientific methods. During the whole process of planting and purchasing raw materials, product design, manufacture, inspection, sales, and consumption, modern food enterprises should look for quality improvement opportunities. By ways of institutionalized and standardized on-site audits, enterprises should keep improving quality management activities at all stages, and continuously develop overall quality management abilities in order to enhance the products competitiveness, and achieve sustainable development.

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