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Guidelines on the application of ISO 9001:2000 for the food and drink industry

Lignes directrices relatives à l'application de l'ISO 9001:2000 aux industries de l'alimentaire et des boissons

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15161 was prepared by Technical Committee ISO/TC 34, *Food products.*

Annex A of this International Standard is for information only.

A list of standards and other publications related to this International Standard is given in the Bibliography.

Introduction

ISO 9001:2000, Quality management systems — Requirements

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked “NOTE” is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization’s ability to meet customer, regulatory and the organization's own requirements.

The quality management principles stated in ISO 9004:2000 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and fulfilling requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows:

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

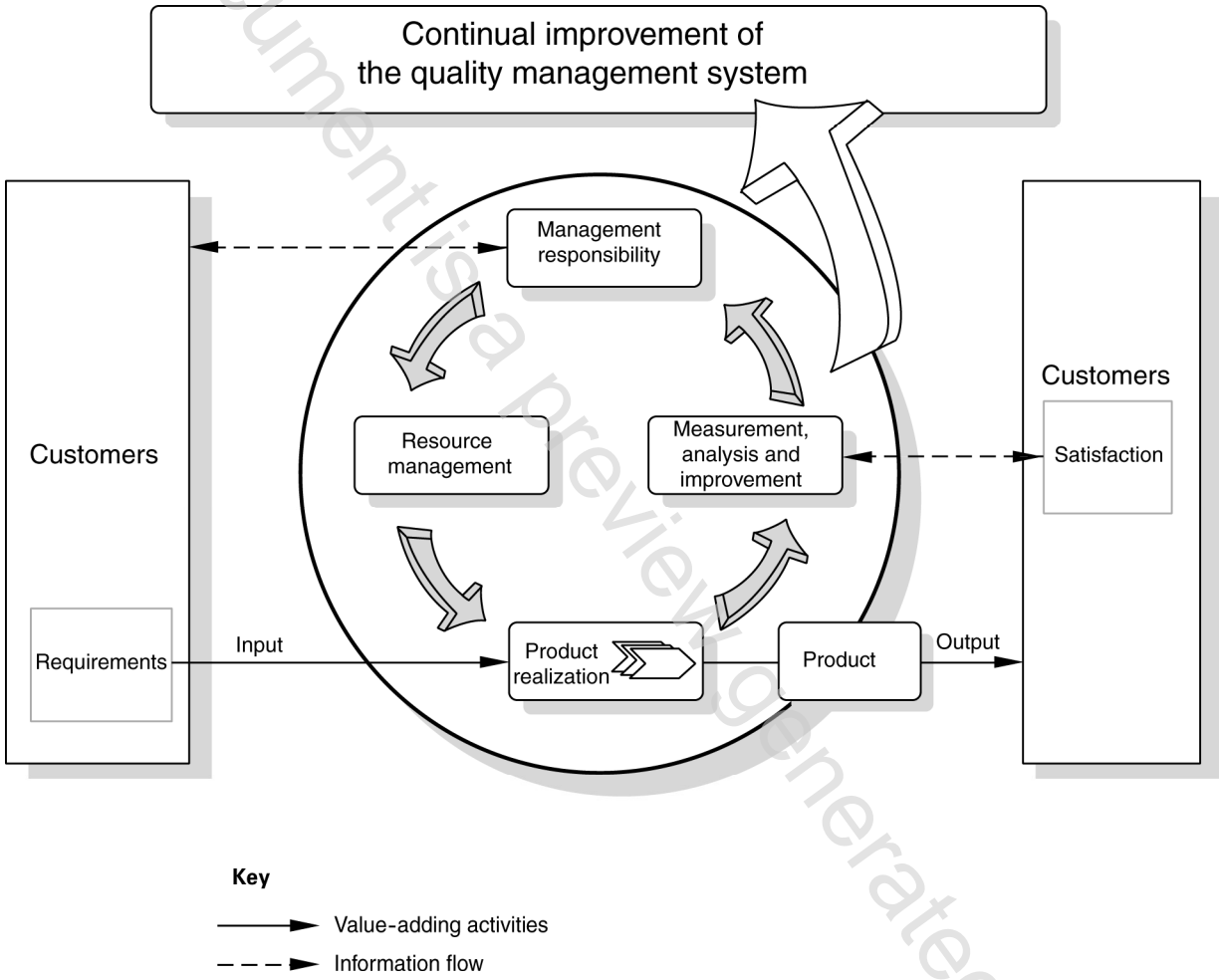

Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently. Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.

0.4 Compatibility with other management systems

This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

There is a need for guidance on implementing the requirements of ISO 9001 for organizations involved in all aspects of the food and drink industry. This includes organizations involved in sourcing, processing and packaging food and drink products. This International Standard aims to encourage the use of the ISO 9000 series of standards within the food and drink industry – the use of these standards alongside other common systems in use in this sector may assist an organization to better address customer satisfaction and organizational effectiveness by the effective implementation of a quality management system.

ISO 9001 also requires organizations to seek to continually improve their quality management systems, an aspect often missing from other models of food safety management commonly used in the food and drink industry.

The adoption of a quality management system needs to be a strategic decision of the organization. The design and the implementation of an organization's quality management system is influenced by varying needs: the particular objectives, the products provided, the processes employed and the size and structure of the organization. It is not the purpose of ISO 9001 to imply uniformity in the structure of quality management systems or uniformity of the documentation. The process-oriented base of ISO 9001 makes it easier to envisage how different systems within a business link together; often it is at the interfaces between internal customers and suppliers or between different systems that problems occur. Any model which clarifies these critical areas for an organization will assist in the smooth running of its business.

ISO 9001 focuses on customers' needs and expectations. One of the most important customer expectations (and often one which is implicit rather than stated directly) is to have safe food products. ISO 9001 allows an organization to integrate its quality management system with the implementation of food safety systems such as HACCP (hazard analysis and critical control point). The internationally recognized principles and steps of HACCP are defined by the Codex Alimentarius Commission in its recommended international code of practice on general principles of food hygiene. Any other accepted food safety system can, of course, also be integrated into the quality management system. However, considering the fact that HACCP is widely used comprehensively, this system was chosen to demonstrate how integration may be achieved.

The application of HACCP within a quality management system conforming to ISO 9001 can result in a food safety system that is more effective than the application of either ISO 9001 or HACCP alone, leading to enhanced customer satisfaction and improved organizational effectiveness. As an example, the application of HACCP for the identification of hazards and control of risks is related to quality planning and preventive actions required by ISO 9001. Once the critical points have been identified, the principles of ISO 9001 can be used for control and monitoring. Procedures for conducting an HACCP study can easily be documented within the quality system.

To assist the user, the requirements of ISO 9001 are given in boxed text in this International Standard, followed by relevant guidance.

Linkages between the basic HACCP principles and specific clauses of ISO 9001 are shown in annex A.

This International Standard represents an attempt to identify the specific issues to be considered when establishing a quality management system in the field of the food and drink industry. Therefore, users of this International Standard are encouraged to gather any experience gained in connection with its application and inform the ISO/TC 34 Secretariat accordingly, so that their views can be taken into account in the first revision.

Guidelines on the application of ISO 9001:2000 for the food and drink industry

1 Scope

This International Standard gives guidance to organizations in applying the requirements of ISO 9001 during the development and implementation of a quality management system in the food and drink industry.

This International Standard gives information on the possible interactions of the ISO 9000 series of standards and the hazard analysis and critical control point (HACCP) system for food safety requirements.

This International Standard is not intended for certification, regulatory or contractual use.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 and the following apply.

3.1
contract
agreed requirements between a supplier and a customer, transmitted by any means

3.2
corrective action
action to eliminate the cause of a detected nonconformity or other undesirable potential situation, including any action to be taken when the results of monitoring at any critical control point indicate a loss of control

NOTE 1 There can be more than one cause for a nonconformity.

NOTE 2 Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

NOTE 3 There is a distinction between correction and corrective action. Correction is the elimination of the nonconformity, while corrective action eliminates its cause.

NOTE 4 Definitions of “nonconformity”, “correction” and “preventive action” can be found in ISO 9000.

NOTE 5 This definition is a combination of the definitions given in ISO 9000 and reference [20].