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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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Contents

Page

Foreword iv
Introduction v
1 Scope 1
2 Normative reference 1
3 Terms and definitions 1
4 Quality management system 3
4.1 General requirements 3
4.2 Documentation requirements 4
5 Management responsibility 7
5.1 Management commitment 7
5.2 Customer focus 7
5.3 Quality policy 8
5.4 Planning 8
5.5 Responsibility, authority and communication 9
5.6 Management review 10
6 Resource management 11
6.1 Provision of resources 11
6.2 Human resources 11
6.3 Infrastructure 12
6.4 Work environment 12
7 Product realization 13
7.1 Planning of product realization 13
7.2 Customer-related processes 15
7.3 Design and development 17
7.4 Purchasing 20
7.5 Production and service provision 22
7.6 Control of monitoring and measuring devices 25
8 Measurement, analysis and improvement 26
8.1 General 26
8.2 Monitoring and measurement 27
8.3 Control of nonconforming product 29
8.4 Analysis of data 30
8.5 Improvement 30
Annex A (informative) Interrelationship between the HACCP and ISO 9001:2000 systems 33
Bibliography 35

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.

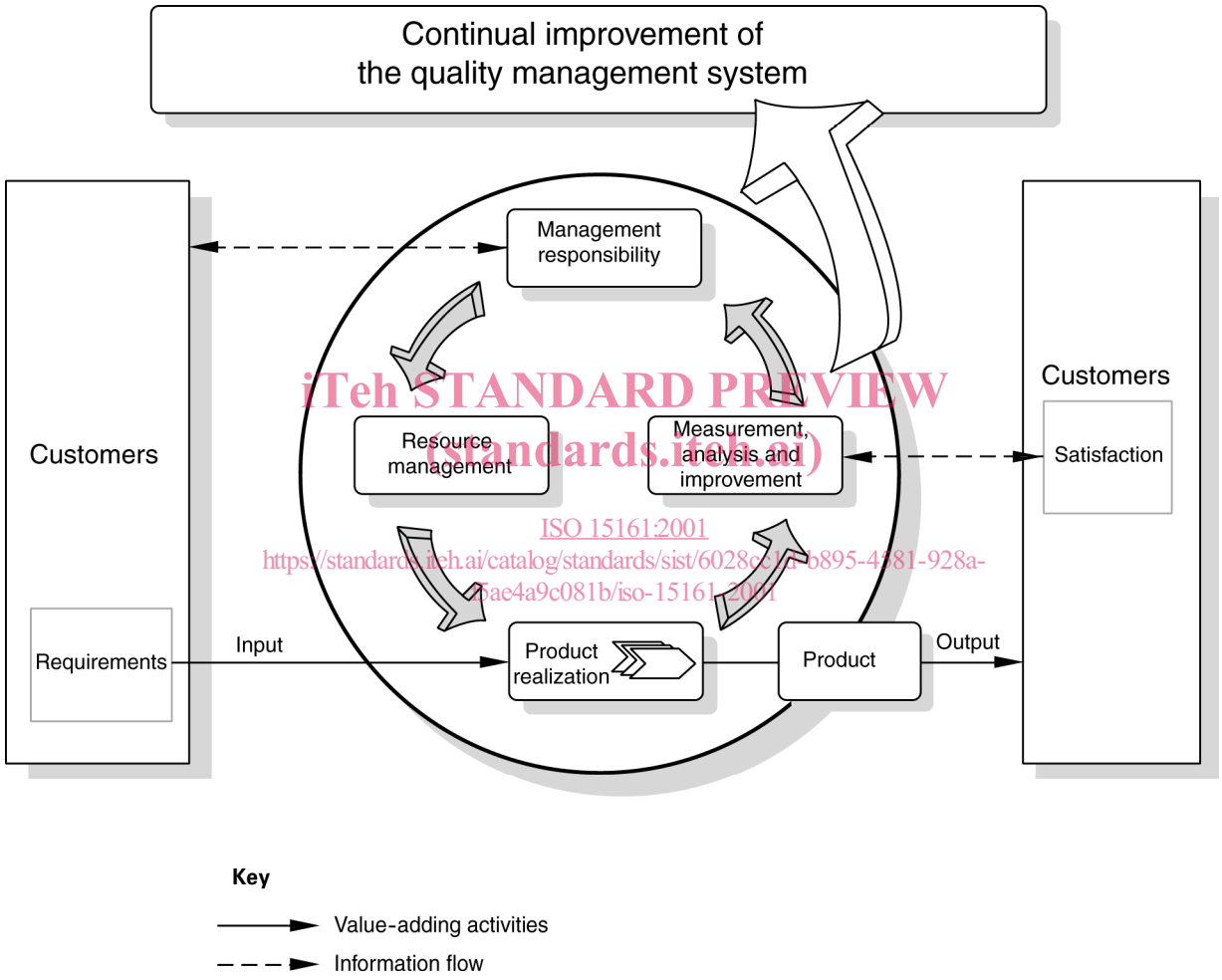

Figure 1 — Model of a process-based quality management system

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].

3.3
critical control point
CCP
step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level

NOTE Taken from reference [20].

3.4
critical limit
criterion which separates acceptability from unacceptability

NOTE Taken from reference [20].

3.5
flow diagram
systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item

NOTE Taken from reference [20].

3.6
good manufacturing practice
combination of manufacturing and quality procedures aimed at ensuring that products are consistently manufactured to their specifications, and to avoid contamination of the product by internal or external sources

3.7
hazard
biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect

NOTE Taken from reference [20].

3.8
hazard analysis
process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan

NOTE Taken from reference [20].

3.9
primary production
those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing

NOTE Taken from reference [20].

3.10
step
point, procedure, operation or stage in the food chain, including raw materials, from primary production to final consumption

NOTE Taken from reference [20].

3.11
validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled, including evidence that the elements of the HACCP plan are effective

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 The conditions of use for validation can be real or simulated.

NOTE 3 Definitions of the terms “objective evidence” and “requirements” can be found in ISO 9000.

NOTE 4 This definition is a combination of the definitions given in ISO 9000 and reference [20].

3.12
verification
confirmation through the provision of objective evidence, that specified requirements have been fulfilled, including the application of methods, procedures, tests and other evaluations, and monitoring to determine compliance with the HACCP plan

NOTE 1 The term “verified” is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as

— performing alternative calculations,

— comparing a new design specification with a similar proven design specification,

— undertaking tests and demonstrations other than mentioned in the definition, and

— reviewing documents prior to issue.

NOTE 3 Definitions of the terms “specification” and “tests” can be found in ISO 9000.

NOTE 4 This definition is a combination of the definitions given in ISO 9000 and reference [20].

4 Quality management system

4.1 General requirements

ISO 9001:2000, Quality management systems — Requirements

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) identify the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, product realization and measurement.

The strong process aspect of this clause should be familiar to organizations operating within the food and drink sector. It is common practice to use process flow charts and other tools to “map” the process of manufacture – indeed the first stage of a HACCP study requires such a definition of the process. The structure of the quality management system should be right for the organization, meeting its needs as much as the organization does for its customers. The quality system should ensure that all those activities within the organization that could impact on the quality and safety of the product are consistently defined (which usually means documented) and effectively implemented. Useful inclusions are relevant codes of practice and legislative requirements, such as weight control, hazard analysis, hygiene, good manufacturing practice (GMP) and good laboratory practice (GLP).

4.2 Documentation requirements

4.2.1 General

ISO 9001:2000, Quality management systems — Requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures required by this International Standard,

d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and

e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

Documents needed by the organization to ensure the effective planning, operation and control of its processes may include the current issue of relevant legislation pertaining to food and drink manufacture. This legislation could cover the following areas:

— safety;

— compositional standards;

— metrology;

— additives;

— lot identification and traceability;

— labelling and packaging information.

There could be other examples, and customer documents may also be included.

4.2.2 Quality manual

ISO 9001:2000, Quality management systems — Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

The requirement to produce a quality manual need not mean a top-level document which stands alone. A quality manual should clearly describe the structure of the quality management system and, ideally, act as a “road-map” through it. All associations and links to other systems or documents, which the organization may be required to operate to, should be detailed within the quality manual. The association with HACCP documentation (such as the HACCP plan) is particularly important and the linkage between the HACCP study and the quality manual should be very clear. It is this document which most clearly shows how the HACCP study is integrated with the quality management system and how the outcomes of the HACCP study are incorporated in the way the organization usually operates.

4.2.3 Control of documents

ISO 9001:2000, Quality management systems — Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Other documentation (in paper or electronic formats) utilized in the food and drink industry, which may be part of the quality management system, could include the following:

a) specifications (e.g. for raw materials, processing, recipes and products);

b) drawings (e.g. artwork for packaging);

c) current legislation and codes of practice;

d) other externally generated documents (e.g. equipment manuals);

e) HACCP plan and HACCP documentation.