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Quality management systems - Guidelines for the application of ISO 9001:2015

Systèmes de management de la qualité -- Lignes directrices pour l'application de l'ISO 9001:2015

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

Introduction

This Technical Specification has been developed to assist users in the implementation of a quality management system based on ISO 9001:2015.

This Technical Specification provides guidance on the requirements in ISO 9001:2015, with a clause by clause correlation to Clauses 4 to 10; however, it does not provide guidance on Annexes A and B.

This Technical Specification gives examples of what an organization can do, but it does not add new requirements to ISO 9001. The examples in this Technical Specification are not definitive and only represent possibilities, not all of which are necessarily suitable for every organization.

ISO 9001:2015 contains requirements that can be objectively audited or assessed. This Technical Specification includes examples, descriptions and options that aid both in the implementation of a quality management system and in strengthening its relation to the overall management of an organization. While the guidelines in this Technical Specification are consistent with the ISO 9001 quality management system model, they are not intended to provide interpretations of the requirements of ISO 9001 or be used for audit or assessment purposes.

This Technical Specification can be used by organizations of all types, sizes, levels of maturity and in all sectors and geographic locations. Implementation can vary based on these factors.

ISO has published a number of other quality management standards and informative resources which can assist the user and provide information on additional implementation methods, including:

— the ISO handbook: *ISO 9001:2015 for Small Businesses – What to do ? Advice from ISO/TC 176*
— the ISO 9001 Auditing Practices Group (APG) papers on website: www.iso.org/tc176/ISO9001AuditingPracticesGroup
— public information on the ISO/TC 176/SC2 website: www.iso.org/tc176/sc02/public
— the ISO handbook: *The Integrated Use of Management System Standards*.

Quality management systems — Guidelines for the application of ISO 9001

1 Scope

This Technical Specification provides guidance on the intent of the requirements in ISO 9001:2015. It is not intended to add to, subtract from, or in any way modify those requirements.

This Technical Specification describes the intent of individual clauses of quality management systems, with possible examples of steps an organization can take to meet the requirements.

This Technical Specification does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9001:2015, Quality management systems — Requirements

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

4 Context of the organization

4.1 Understanding the organization and its context

The intent of this requirement is to establish a good understanding of the relevant internal and external issues that can affect, either positively or negatively, the organization's ability to achieve the intended results of its quality management system. The organization should be aware that internal and external issues can change, and therefore should be monitored and reviewed on a regular basis.

This understanding is necessary to provide the foundation for determining key quality management system elements such as the scope of the quality management system (see 4.3), the processes (see 4.4), the policy (see 5.2), planning, objectives, risks and opportunities (see Clause 6).

Information about internal and external issues can be found from many sources, such as through internal documents and meetings, in the national and international press, websites, publications from national statistics offices and other government departments, professional and technical publications, conferences and meetings with local and state agencies, and professional associations.

Examples of internal and external issues relevant to the organization's context can include, but are not limited to:

a) internal issues:

1) overall performance of the organization, including financial results;

2) resource factors, including infrastructure, environment for the operation of the processes, organizational knowledge;

3) human aspects such as competence of persons, organizational culture, relationships with unions;

4) operational factors such as process, production or delivery capabilities, performance of the quality management system, customer evaluation;

5) factors in the governance of the organization, such as rules and procedures for decision making or organizational structure;

b) external issues:

1) macro-economic factors such as money exchange rates predictions, economic situation, inflation forecast, credit availability;

2) social factors such as local unemployment rates, safety perception, education levels, public holidays and working days;

3) political factors such as political stability, public investments, local infrastructure, international trade agreements;

4) technological factors such as new sector technology, materials and equipment, patent expirations, professional code of ethics;

5) competition, including the organization's market share, similar or substitute products or services, market leader trends, customer growth trends, market stability;

6) factors which affect the work environment such as trade union regulations, legal and statutory requirements, including environmental legislation and codes.

4.2 Understanding the needs and expectations of interested parties

The intent of this requirement is to ensure that the organization considers the requirements of relevant interested parties beyond just those of the contractual customer and end user. The intention is to focus on only those interested parties which are relevant to the quality management system.

a) The following potential interested parties could be considered relevant, if they affect the quality management system:

1) customers;

2) end users or beneficiaries;

3) regulators

4) joint venture partners;

5) franchisors

6) parent and subsidiary organizations;

7) owners, shareholders;

8) bankers;

9) external providers;

10) employees and others working on behalf of the organization;

11) legal and regulatory authorities (local, regional, state/provincial, national or international);

12) trade and professional associations;

13) local community groups;

14) non-governmental organizations;

15) local neighbouring organizations/activities in the locality;

16) competitors;

b) Examples of interested party requirements include:

1) customer requirements regarding conformity, price, availability or delivery;

2) contracts which have been entered into with customer or external providers;

3) industry codes and standards;

4) agreements with community groups or non-governmental organizations;

5) legislation;

6) memoranda of understanding;

7) permits, licences or other forms of authorization;

8) orders issued by regulatory agencies;

9) treaties, conventions and protocols;

10) agreements with public authorities and customers;

11) voluntary principles or codes of practice;

12) voluntary labelling or environmental commitments;

13) obligations arising under contractual arrangements with the organization;

c) To understand the needs and expectations of interested parties, several activities can be carried out:

1) the organization can collect information by, for example, the following methods:

— lobbying and networking;

— participation in relevant associations

— benchmarking;

— active survey;

— market surveillance;

— customer or user surveys;

— monitoring customer needs, expectations and satisfaction;

2) the organization could develop potential relevance criteria for interested parties by examining , for example:

— their possible influence or impact on the organization's performance or decisions;

— their ability to generate risks and opportunities;

— their ability to be affected by the decisions or activities of the organization;

3) the criteria can then be used to determine relevant interest parties and their relevant requirements.

The information resulting from these activities should be considered in planning (see Clause 6).

The organization should be aware that the relevant interested parties and their relevant requirements can be dynamic, and should monitor and review them on a regular basis.

4.3 Determining the scope of the quality management system

The intent of this requirement is to ensure that when the scope is determined, it addresses context-related issues (see 4.1), relevant requirements from relevant interested parties (see 4.2), and the products and services of the organization, without being either too broad or too restricted and that the applicability of each requirement is correctly evaluated.

The scope should also take into account the organization's products and services, considering such issues as:

a) the infrastructure of the quality management system,

b) the organization's different sites and activities;

c) which processes are externally provided;

d) commercial policies and strategies;

e) outsourcing;

f) centralized or externally provided activities, processes, products and services;

g) organizational knowledge.

Examples of activities to process the collected information, in order to determine the quality management system scope, should include:

— assessment of the applicability of the requirements of ISO 9001;

— justification of any non-applicable requirement, taking into account that non-applicable requirements should not affect the ability to achieve conformity of products and services;

— analysis of collected information based on the identified impacts of the organization's capabilities, customer and other relevant interested parties' requirements, and legal requirements;

— determination of the processes, products and services needed to ensure the conformity of its products and services and the enhancement of customer satisfaction.

The outputs of the activities listed above should be available in a documented scope, including justification of any non-applicable requirements.

NOTE The scope of the quality management system can differ from the scope of certification to ISO 9001:2015.

4.4 Quality management system and its processes

4.4.1 The intent of this clause is to determine the processes needed for the quality management system. These include both operational processes (such as those needed for product and service provision) and system processes (such as internal audit and management review).

a) A process:

1) is a set of interrelated or interacting activities;

2) transforms inputs into intended results;

3) has built-in controls and checks of performance and promotes improvement.

b) Inputs and outputs can be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge).

c) Inputs such as the following should be considered:

1) defined quality management system scope;

2) list of products and services;

3) list of sites and production lines processes;

4) capabilities;

5) performance indicators such as:

— service response time; service outage trends;

— throughput rates;

— defect rates; re-work costs; warranty costs;

6) risks and opportunities identified (see 6.1);

7) organization charts;

d) The bullet list in 4.4.1 of ISO 9001, which details activities to process input information, is considered to be clear without further clarification.

e) The organization should refer to 0.3 of ISO 9001 and to the quality management principles in ISO 9000 for further information about the process approach. It is advisable to refer to 0.3.3 and Annex A4 of ISO 9001 for a better understanding of risk-based thinking.

f) When addressing risks and opportunities, the organization should use risk-based thinking to establish, implement, maintain and improve the quality management system and its associated processes, to:

1) decide how risk (positive or negative) is addressed in the design of processes to improve process outputs and prevent undesirable results;

2) improve the effectiveness of the management system;

3) maintain and manage a system that inherently addresses risk and delivers objectives.

g) The outputs of the activities listed above can include, for example:

1) process flow maps (sequences, interrelationships and authorities or responsibilities, risks and defined criteria);

2) quality management system performance data;

3) variation control;

4) indicators.

Further guidance on the process approach and risk-based thinking is available at www.iso.org/tc176/sc02/public.

4.4.2 The intent of this requirement is to ensure that an assessment of documented information is made by the organization to adequately control the operation of its processes and the performance of its quality management system.

It is up to the organization to specify the different types of documented information needed to support the operation of the processes and the quality management system performance. By assessing its own needs and applying risk-based thinking, the organization should consider its size, activity, type of products or services, complexity of its processes, resources etc., as well of the potential consequences of nonconformities.

