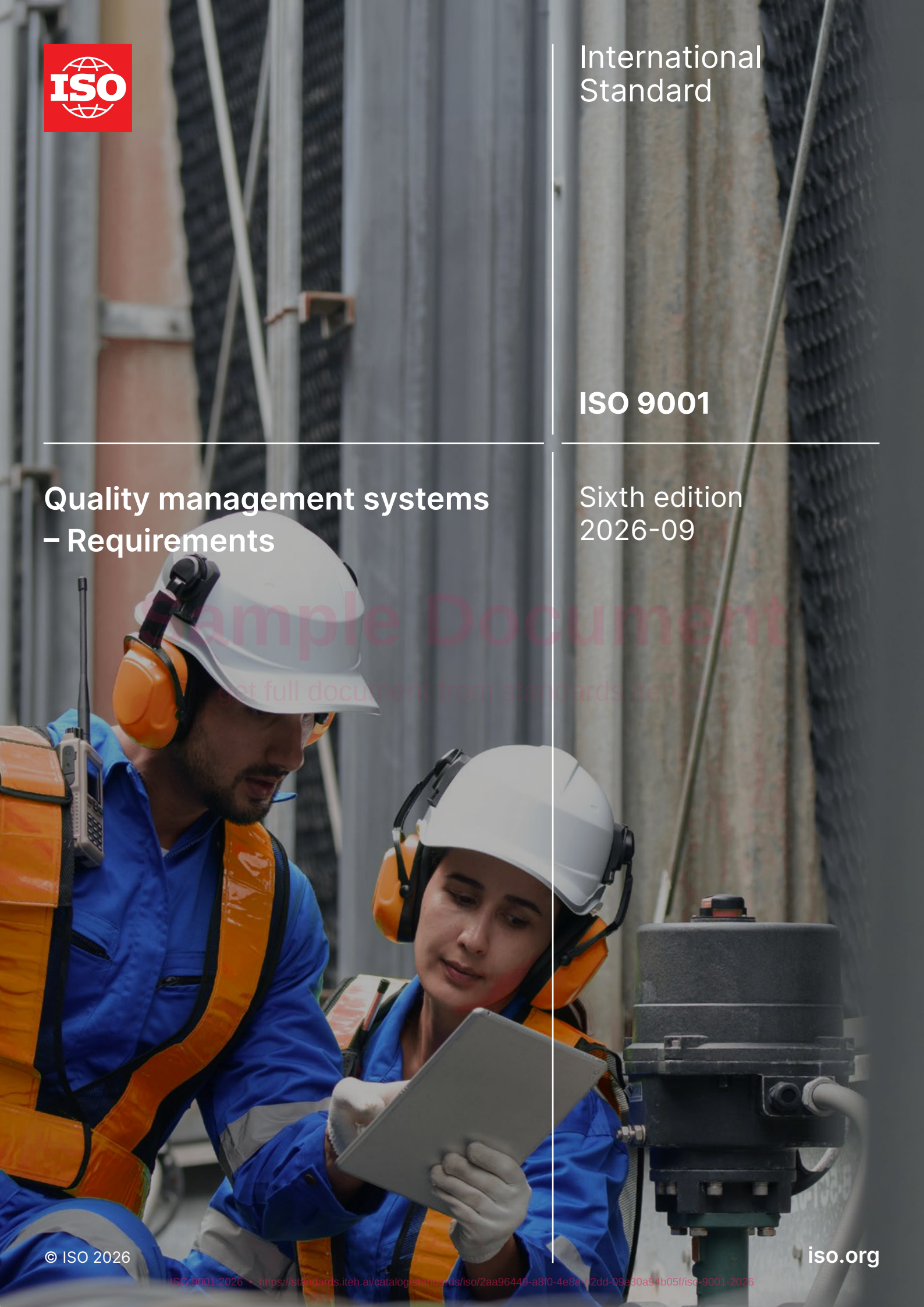
International Standard

ISO 9001

Quality management systems – Requirements

Sixth edition
2026-09



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International Standard

ISO 9001

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*, in collaboration with the European Committee for Standardization (CEN), in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This sixth edition cancels and replaces the fifth edition (ISO 9001:2015), which has been technically revised. It also incorporates the Amendment ISO 9001:2015/Amd 1:2024.

The main changes are as follows:

— Inclusion of core ISO management system terms and definitions: Clause 3 of the document now includes a limited number of terms and definitions. ISO 9000 remains the normative reference for all quality management terms and definitions.

— Introduction of quality culture and ethical behaviour: Quality culture and ethical behaviour are now addressed within the requirements, particularly in relation to leadership, awareness and the environment for the operation of processes.

— Separation of risks and opportunities: Risks and opportunities are more clearly distinguished, with separate consideration of actions to address each.

— Strengthened management of change: Requirements related to changes to the quality management system have been reinforced to support the achievement of intended results.

— Enhanced explanatory content in Annex A: It has been revised to provide enhanced clarification of the structure, terminology and intent of the requirements as informative text, without introducing additional requirements.

— Removal of Annex B: It previously provided information on other ISO/TC 176 standards. References to these standards are now included in Annex A and on the ISO/TC 176 website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

Establishing and implementing a quality management system is a strategic decision for an organization that supports improved performance, enhances customer satisfaction, and provides a foundation for sustained success and sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on the requirements in this document are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to quality management system requirements.

This document can be used by internal and external parties.

This document does not imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this document;

— the use of the specific terminology of this document within the organization.

The quality management system requirements in this document are complementary to requirements for products and services.

Consistently meeting requirements and addressing future needs and expectations of customers and other relevant interested parties poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization can pursue continual improvement in various ways, such as incremental or breakthrough change, innovation or reorganization initiatives.

Annex A provides information and clarifications that can support understanding of the structure, terms and clauses of this document. It does not contain any additional requirements.

For guidance on the application of all clauses in this document, see ISO 9002 [1].

0.2 Quality management principles

This document is based on the quality management principles described in ISO 9000 [2]. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision-making;

— relationship management.

0.3 Process approach

0.3.1 General

This document promotes the adoption of a process approach when establishing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the application of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic determination and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the Plan-Do-Check-Act (PDCA) cycle (see 0.3.2) with an overall focus on risk-based thinking (see A.6.1.2) aimed at preventing undesired results, and opportunity-based thinking (see A.6.1.3) aimed at pursuing desired results by taking advantage of opportunities.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) consideration of processes in terms of risk, opportunity and added value;

c) achievement of effective process performance;

d) improvement of processes based on the results of evaluation of data and information.

Figure 1 gives a schematic representation of any single process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the process steps and related risks.

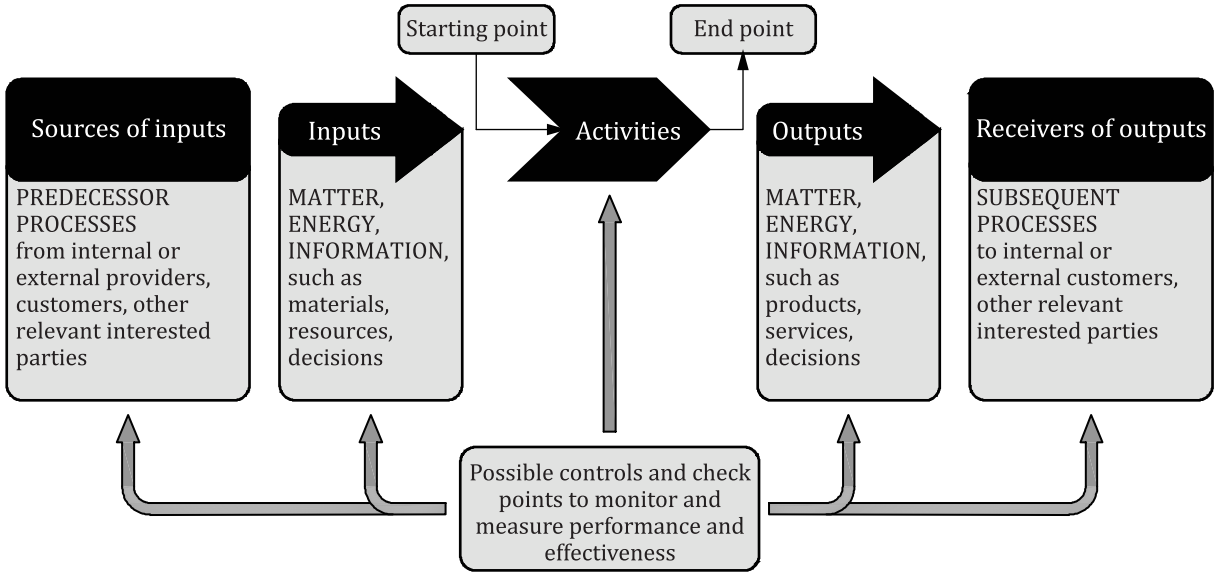


Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be briefly described as follows:

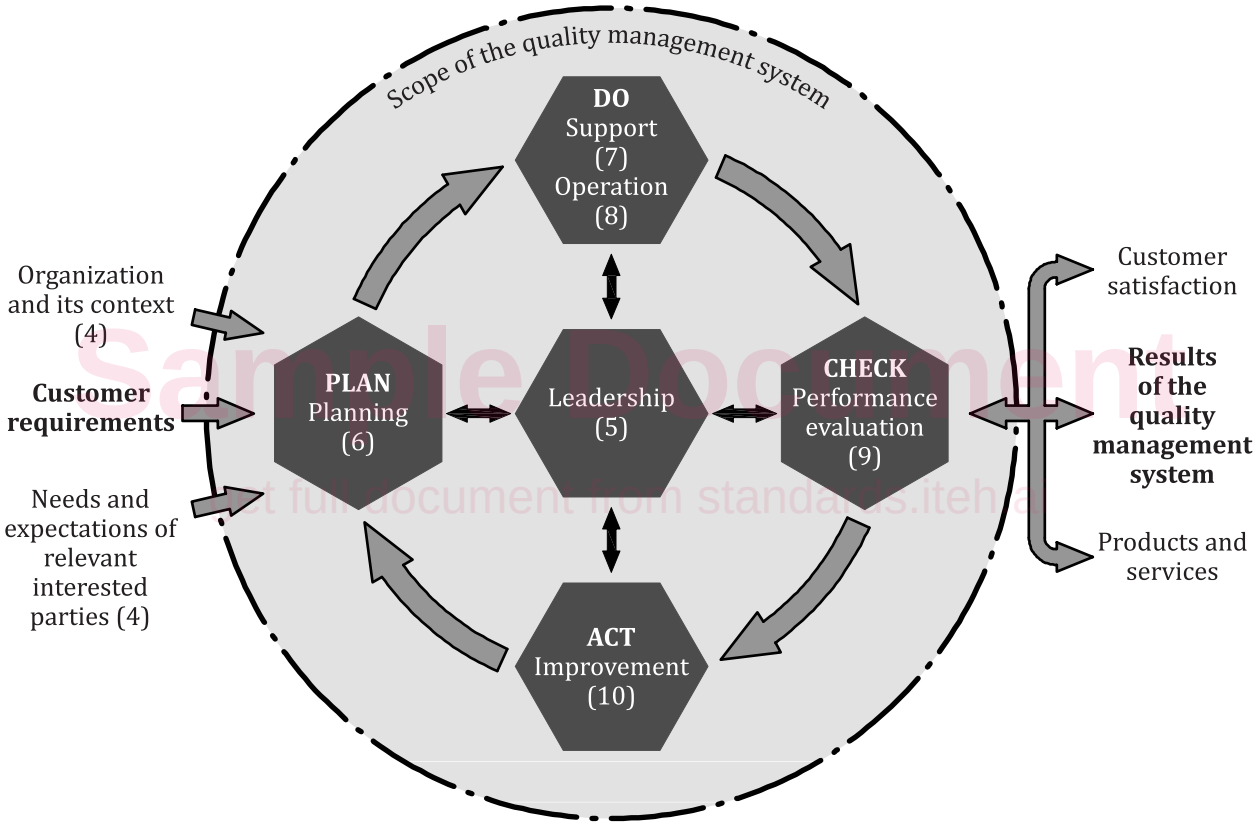
— Plan: Establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customer and other relevant interested party requirements and the organization's policies, and determine and address risks and opportunities.

— Do: Implement what was planned.

— Check: Monitor and, as applicable, measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results.

— Act: Take actions to improve the performance of the quality management system.

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clause 4 to Clause 10 can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this document.

Figure 2 — Representation of the structure of this document in the PDCA cycle

0.4 Relationship with other management system standards

This document applies the harmonized approach as published in the ISO/IEC Directives related to the development of management system standards. The intention is to support alignment and facilitate the integration of the requirements and recommendations of one or more management system standards into an organization's management system.

For more information, see https://www.iso.org/management-system-standards.html.

This document provides a basis for an organization to apply the process approach, coupled with the PDCA cycle, risk-based thinking and opportunity-based thinking, in order to align or integrate its quality management system with the requirements of other management system standards.

This document relates to the following standards:

— ISO 9000 [2] provides the fundamental concepts and vocabulary essential for understanding the requirements of this document;

— ISO 9002 [1] provides guidance on the application of the requirements of this document;

— ISO 9004 [3] provides guidance on enhancing the quality of an organization and its ability to achieve sustained success.

This document does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or asset management.

Sector-specific ISO quality management system standards based on the requirements of this document have been developed. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this document within the particular sector.

Quality management systems — Requirements

1 Scope

This document specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this document are generic.

This document is applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this document, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000, *Quality management — Fundamentals and vocabulary*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org

3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.6)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organization is part of a larger entity, the term "organization" refers only to the part of the larger entity that is within the scope of the *quality management system* (3.4.1).

3.2
interested party
stakeholder
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

EXAMPLE Customers, owners, people in an organization, providers, bankers, regulatory authorities, unions, partners or society that can include competitors or opposing pressure groups.

3.3
top management
person or group of people who directs and controls an *organization* (3.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish *policies* (3.5) and *objectives* (3.6), as well as *processes* (3.8) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The management system elements can include the organization's policies, practices, rules and beliefs.

Note 4 to entry: An organization manages its interrelated elements in an orderly manner to achieve its objectives.

Note 5 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.4.1
quality management system
part of the overall *management system* (3.4) of an *organization* (3.1) related to quality

3.5
policy
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.3)

3.5.1
quality policy
policy (3.5) related to quality

Note 1 to entry: The quality policy:

— is generally consistent with the overall policy of the *organization* (3.1);

— can be aligned with the organization's vision and mission;

— provides a framework for the setting of quality objectives.

Note 2 to entry: The quality management principles presented in ISO 9000 [2] can form a basis for the establishment of a quality policy.

3.6
objective
result to be achieved

Note 1 to entry: An objective can be strategic, tactical or operational.

Note 2 to entry: Objectives can relate to different disciplines (e.g. finance, health and safety, environment). They can be, for example, organization-wide or specific to a project, product, service or *process* (3.8).

Note 3 to entry: An objective can be expressed in other ways, such as an intended result, as a purpose, as an operational criterion, as a *quality objective* (3.6.1) or by the use of other words with similar meaning (e.g. aim, goal, target).

Note 4 to entry: In the context of *quality management systems* (3.4.1), *quality objectives* (3.6.1) are set by the *organization* (3.1), consistent with the *quality policy* (3.5.1), to achieve specific results.

3.6.1
quality objective
objective (3.6) related to quality

Note 1 to entry: Quality objectives are generally based on the *organization's* (3.1) *quality policy* (3.5.1).

Note 2 to entry: Quality objectives are generally specified for relevant functions, levels and *processes* (3.8) in the organization.

3.7
risk
effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events and consequences, or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

Note 5 to entry: The word "risk" is sometimes used when there is the possibility of only negative consequences.

3.8
process
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

Note 1 to entry: Whether the result of a process is called an output, a product or a service depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a "process".

Note 4 to entry: Processes in an *organization* (3.1) are generally planned and carried out under controlled conditions to ensure that intended results can be achieved.

Note 5 to entry: A process where the *conformity* (3.15) of the resulting output cannot be readily or economically validated is frequently referred to as a "special process".

3.9
competence
ability to apply knowledge and skills to achieve intended results

3.10
documented information
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to: