



SLOVENSKI STANDARD SIST EN ISO 9000:2015

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SIST EN ISO 9000:2005

Sistemi vodenja kakovosti - Osnove in slovar (ISO 9000:2015)

Quality management systems - Fundamentals and vocabulary (ISO 9000:2015)

Qualitätsmanagementsysteme - Grundlagen und Begriffe (ISO 9000:2015)

Systèmes de management de la qualité - Principes essentiels et vocabulaire (ISO 9000:2015)

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Quality management systems - Fundamentals and vocabulary (ISO 9000:2015)

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essentiels et vocabulaire (ISO 9000:2015)

Qualitätsmanagementsysteme - Grundlagen und
Begriffe (ISO 9000:2015)

This European Standard was approved by CEN on 14 September 2015.

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European foreword

This document (EN ISO 9000:2015) has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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INTERNATIONAL STANDARD

ISO 9000

Fourth edition
2015-09-15

Quality management systems — Fundamentals and vocabulary

*Systèmes de management de la qualité — Principes essentiels et
vocabulaire*

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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 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 1, *Concepts and terminology*.

This fourth edition cancels and replaces the third edition (ISO 9000:2005), which has been technically revised.

Introduction

This International Standard provides the fundamental concepts, principles and vocabulary for quality management systems (QMS) and provides the foundation for other QMS standards. This International Standard is intended to help the user to understand the fundamental concepts, principles and vocabulary of quality management, in order to be able to effectively and efficiently implement a QMS and realize value from other QMS standards.

This International Standard proposes a well-defined QMS, based on a framework that integrates established fundamental concepts, principles, processes and resources related to quality, in order to help organizations realize their objectives. It is applicable to all organizations, regardless of size, complexity or business model. Its aim is to increase an organization's awareness of its duties and commitment in fulfilling the needs and expectations of its customers and interested parties, and in achieving satisfaction with its products and services.

This International Standard contains seven quality management principles supporting the fundamental concepts described in 2.2. In 2.3, for each quality management principle, there is a "statement" describing each principle, a "rationale" explaining why the organization would address the principle, "key benefits" that are attributed to the principles, and "possible actions" that an organization can take in applying the principle.

This International Standard contains the terms and definitions that apply to all quality management and QMS standards developed by ISO/TC 176, and other sector-specific QMS standards based on those standards, at the time of publication. The terms and definitions are arranged in conceptual order, with an alphabetical index provided at the end of the document. Annex A includes a set of diagrams of the concept systems that form the concept ordering.

NOTE Guidance on some additional frequently-used words in the QMS standards developed by ISO/TC 176, and which have an identified dictionary meaning, is provided in a glossary available at: http://www.iso.org/iso/03_terminology_used_in_iso_9000_family.pdf

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Quality management systems — Fundamentals and vocabulary

1 Scope

This International Standard describes the fundamental concepts and principles of quality management which are universally applicable to the following:

- organizations seeking sustained success through the implementation of a quality management system;
- customers seeking confidence in an organization's ability to consistently provide products and services conforming to their requirements;
- organizations seeking confidence in their supply chain that product and service requirements will be met;
- organizations and interested parties seeking to improve communication through a common understanding of the vocabulary used in quality management;
- organizations performing conformity assessments against the requirements of ISO 9001;
- providers of training, assessment or advice in quality management;
- developers of related standards.

This International Standard specifies the terms and definitions that apply to all quality management and quality management system standards developed by ISO/TC 176.

2 Fundamental concepts and quality management principles

2.1 General

The quality management concepts and principles described in this International Standard give the organization the capacity to meet challenges presented by an environment that is profoundly different from recent decades. The context in which an organization works today is characterized by accelerated change, globalization of markets and the emergence of knowledge as a principal resource. The impact of quality extends beyond customer satisfaction: it can also have a direct impact on the organization's reputation.

Society has become better educated and more demanding, making interested parties increasingly more influential. By providing fundamental concepts and principles to be used in the development of a quality management system (QMS), this International Standard provides a way of thinking about the organization more broadly.

All concepts, principles and their interrelationships should be seen as a whole and not in isolation of each other. No individual concept or principle is more important than another. At any one time, finding the right balance in application is critical.

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2.2 Fundamental concepts

2.2.1 Quality

An organization focused on quality promotes a culture that results in the behaviour, attitudes, activities and processes that deliver value through fulfilling the needs and expectations of customers and other relevant interested parties.

The quality of an organization's products and services is determined by the ability to satisfy customers and the intended and unintended impact on relevant interested parties.

The quality of products and services includes not only their intended function and performance, but also their perceived value and benefit to the customer.

2.2.2 Quality management system

A QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results.

The QMS manages the interacting processes and resources required to provide value and realize results for relevant interested parties.

The QMS enables top management to optimize the use of resources considering the long and short term consequences of their decision.

A QMS provides the means to identify actions to address intended and unintended consequences in providing products and services.

2.2.3 Context of an organization

Understanding the context of the organization is a process. This process determines factors which influence the organization's purpose, objectives and sustainability. It considers internal factors such as values, culture, knowledge and performance of the organization. It also considers external factors such as legal, technological, competitive, market, cultural, social and economic environments.

Examples of the ways in which an organization's purpose can be expressed include its vision, mission, policies and objectives.

2.2.4 Interested parties

The concept of interested parties extends beyond a focus solely on the customer. It is important to consider all relevant interested parties.

Part of the process for understanding the context of the organization is to identify its interested parties. The relevant interested parties are those that provide significant risk to organizational sustainability if their needs and expectations are not met. Organizations define what results are necessary to deliver to those relevant interested parties to reduce that risk.

Organizations attract, capture and retain the support of the relevant interested parties they depend upon for their success.

2.2.5 Support

2.2.5.1 General

Top management support of the QMS and engagement of people enables:

- provision of adequate human and other resources;
- monitoring processes and results;

- determining and evaluating of risks and opportunities;
- implementing appropriate actions.

Responsible acquisition, deployment, maintenance, enhancement and disposal of resources support the organization in achieving its objectives.

2.2.5.2 People

People are essential resources within the organization. The performance of the organization is dependent upon how people behave within the system in which they work.

Within an organization, people become engaged and aligned through a common understanding of the quality policy and the organization's desired results.

2.2.5.3 Competence

A QMS is most effective when all employees understand and apply the skills, training, education and experience needed to perform their roles and responsibilities. It is the responsibility of top management to provide opportunities for people to develop these necessary competencies.

2.2.5.4 Awareness

Awareness is attained when people understand their responsibilities and how their actions contribute to the achievement of the organization's objectives.

2.2.5.5 Communication (standards.iteh.ai)

Planned and effective internal (i.e. throughout the organization) and external (i.e. with relevant interested parties) communication enhances people's engagement and increased understanding of:

- the context of the organization;
- the needs and expectations of customers and other relevant interested parties;
- the QMS.

2.3 Quality management principles

2.3.1 Customer focus

2.3.1.1 Statement

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

2.3.1.2 Rationale

Sustained success is achieved when an organization attracts and retains the confidence of customers and other relevant interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to the sustained success of the organization.

2.3.1.3 Key benefits

Some potential key benefits are:

- increased customer value;