



International Standard

Redline version
compares Fifth edition
to Fourth edition



ISO 9000

Quality management — Fundamentals and vocabulary

Management de la qualité — Principes essentiels et vocabulaire

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This document is a **Redline version** published for information purposes. It is intended to assist users in identifying the changes introduced in comparison with the previous edition of the standard.

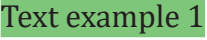




Additions are highlighted in green. Deletions are indicated by red strikethrough.

For graphics, additions are identified by a green frame, and deletions are indicated by a red cross.

Clause and heading numbers that include modifications are highlighted in yellow in the Table of Contents.

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Markup used in this Redline version

 Text example 1	added text (green highlight)
 Text example 2	deleted text (red strike through)
	added graphics (green frame)
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 1.x ...	modified clause and heading numbers (yellow in the Table of Contents)



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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 ~~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).

~~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).~~

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For an explanation ~~on the~~ 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 ~~ISO's~~ adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) ~~see the following URL, see www.iso.org/iso/foreword.html~~.

~~The committee responsible for this document is~~ This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*, in collaboration with the European Committee for Standardization (CEN) Technical Committee, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This ~~fourth~~ fifth edition cancels and replaces the ~~third~~ fourth edition (ISO 9000:2005 2015), which has been technically revised.

The main changes are as follows:

- the title has been changed from “Quality management systems — Fundamentals and vocabulary” to “Quality management — Fundamentals and vocabulary” to better represent the enhanced content;
- the document has been restructured by moving the fundamental concepts and quality management principles from Clause 2 to [Clause 4](#) to align with the structure in the ISO/IEC Directives, Part 2; [Clause 2](#) is now Normative references;
- additions have been made to the fundamentals, dividing them into two congruent groups, “Fundamental quality management concepts” and “Additional concepts relevant to quality management”, to address emerging trends in quality;
- terms have been added and definitions modified to reflect changes to ISO/TC 176 documents;
- the diagrams in [Annex A](#) have been restructured to illustrate the relationship between terms.

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

~~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 document provides the fundamentals of quality management. It provides the foundation and the vocabulary for quality management documents and quality management standards. This document is intended to help the user understand the fundamental principles, concepts and vocabulary of quality management, in order to be able to effectively and efficiently implement a quality management system (QMS) and realize value from quality management documents and QMS standards. This document proposes a well-defined planned QMS, based on a framework that integrates established fundamental concepts, principles, processes and resources related to quality principles and concepts relevant to quality management, 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 aims to increase an organization's awareness of its duties and commitment in fulfilling the needs and expectations of its customers and other interested parties, and in achieving satisfaction with its products and services.

~~This International Standard~~ To gain the most value for their organization's QMS, the user should first seek to understand the quality management principles and their rationale. The quality management principles form the basis of quality management documents. This document contains seven quality management principles supporting the fundamental concepts described in 2.24.2. In For 2.3, for each quality management principle, there is a "Statement" describing each the principle, a "Rationale" explaining why the organization would address the principle, "Key benefits" that are attributed to the principles principle, and "Possible actions" that an organization can take in applying the principle.

The user should then understand the fundamental concepts in 4.3 and additional concepts relevant to quality management in 4.4 to seek insight into how they are used to develop QMS standards. Fundamental concepts are those which are integral to the understanding of quality management in general. Additional concepts are those relevant to the effective application of quality management within an organization.

~~This International Standard~~ The vocabulary in Clause 3 serves as a unified language for quality management documents, ensuring the terms are clearly and accurately defined as used within the quality management documents developed by ISO/TC 176. This document contains the terms and definitions that apply to all quality management documents and QMS standards developed by ISO/TC 176, and other at the time of publication. This document does not contain sector-specific terms and definitions for 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 of the terminological entries provided at the end of the this document. Annex A includes a set of diagrams of the concept systems that form the concept ordering concept diagrams on which the thematic grouping of the terms and definitions in Clause 3 is based.

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 Reference [19].

Quality management — Fundamentals and vocabulary

1 Scope

This ~~International Standard describes~~ document establishes 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 (QMS);
- 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~~ document defines terms that apply to all quality management ~~and quality management system~~ documents and QMS standards developed by ISO/TC 176.

This document is applicable to all organizations, regardless of size, complexity or business model.

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.~~

~~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~~

~~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,~~

- ~~increased customer satisfaction,~~
- ~~improved customer loyalty,~~
- ~~enhanced repeat business,~~
- ~~enhanced reputation of the organization,~~
- ~~expanded customer base,~~
- ~~increased revenue and market share.~~

~~2.3.1.4 Possible actions~~

~~Possible actions include:~~

- ~~recognize direct and indirect customers as those who receive value from the organization,~~
- ~~understand customers' current and future needs and expectations,~~
- ~~link the organization's objectives to customer needs and expectations,~~
- ~~communicate customer needs and expectations throughout the organization,~~
- ~~plan, design, develop, produce, deliver and support products and services to meet customer needs and expectations,~~
- ~~measure and monitor customer satisfaction and take appropriate actions,~~
- ~~determine and take action on relevant interested parties' needs and appropriate expectations that can affect customer satisfaction,~~
- ~~actively manage relationships with customers to achieve sustained success.~~

~~2.3.2 Leadership~~

~~2.3.2.1 Statement~~

~~Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.~~

~~2.3.2.2 Rationale~~

~~Creation of unity of purpose and the direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.~~

~~2.3.2.3 Key benefits~~

~~Some potential key benefits are:~~

- ~~increased effectiveness and efficiency in meeting the organization's quality objectives,~~
- ~~better coordination of the organization's processes,~~
- ~~improved communication between levels and functions of the organization,~~
- ~~development and improvement of the capability of the organization and its people to deliver desired results.~~

~~2.3.2.4 Possible actions~~

~~Possible actions include:~~

- ~~— communicate the organization's mission, vision, strategy, policies and processes throughout the organization,~~
- ~~— create and sustain shared values, fairness and ethical models for behaviour at all levels of the organization,~~
- ~~— establish a culture of trust and integrity,~~
- ~~— encourage an organization-wide commitment to quality,~~
- ~~— ensure that leaders at all levels are positive examples to people in the organization,~~
- ~~— provide people with the required resources, training and authority to act with accountability,~~
- ~~— inspire, encourage and recognize the contribution of people.~~

~~2.3.3 Engagement of people~~

~~2.3.3.1 Statement~~

~~Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.~~

~~2.3.3.2 Rationale~~

~~In order to manage an organization effectively and efficiently, it is important to respect and involve all people at all levels. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives.~~

~~2.3.3.3 Key benefits~~

~~Some potential key benefits are:~~

- ~~— improved understanding of the organization's quality objectives by people in the organization and increased motivation to achieve them,~~
- ~~— enhanced involvement of people in improvement activities,~~
- ~~— enhanced personal development, initiatives and creativity,~~
- ~~— enhanced people satisfaction,~~
- ~~— enhanced trust and collaboration throughout the organization,~~
- ~~— increased attention to shared values and culture throughout the organization.~~

~~2.3.3.4 Possible actions~~

~~Possible actions include:~~

- ~~— communicate with people to promote understanding of the importance of their individual contribution,~~
- ~~— promote collaboration throughout the organization,~~
- ~~— facilitate open discussion and sharing of knowledge and experience,~~
- ~~— empower people to determine constraints to performance and to take initiatives without fear,~~
- ~~— recognize and acknowledge people's contribution, learning and improvement,~~

~~enable self-evaluation of performance against personal objectives,~~

~~conduct surveys to assess people's satisfaction, communicate the results and take appropriate actions.~~

~~2.3.4 Process approach~~

~~2.3.4.1 Statement~~

~~Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.~~

~~2.3.4.2 Rationale~~

~~The QMS consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.~~

~~2.3.4.3 Key benefits~~

~~Some potential key benefits are:~~

~~enhanced ability to focus effort on key processes and opportunities for improvement,~~

~~consistent and predictable outcomes through a system of aligned processes,~~

~~optimized performance through effective process management, efficient use of resources and reduced cross-functional barriers,~~

~~enabling the organization to provide confidence to interested parties related to its consistency, effectiveness and efficiency.~~

~~2.3.4.4 Possible actions~~

~~Possible actions include:~~

~~define objectives of the system and processes necessary to achieve them,~~

~~establish authority, responsibility and accountability for managing processes,~~

~~understand the organization's capabilities and determine resource constraints prior to action,~~

~~determine process interdependencies and analyse the effect of modifications to individual processes on the system as a whole,~~

~~manage processes and their interrelations as a system to achieve the organization's quality objectives effectively and efficiently,~~

~~ensure the necessary information is available to operate and improve the processes and to monitor, analyse and evaluate the performance of the overall system,~~

~~manage risks which can affect outputs of the processes and overall outcomes of the QMS.~~

~~2.3.5 Improvement~~

~~2.3.5.1 Statement~~

~~Successful organizations have an ongoing focus on improvement.~~

~~2.3.5.2 Rationale~~

~~Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.~~

~~2.3.5.3 Key benefits~~

~~Some potential key benefits are:~~

- ~~improved process performance, organizational capability and customer satisfaction;~~
- ~~enhanced focus on root cause investigation and determination, followed by prevention and corrective actions;~~
- ~~enhanced ability to anticipate and react to internal and external risks and opportunities;~~
- ~~enhanced consideration of both incremental and breakthrough improvement;~~
- ~~improved use of learning for improvement;~~
- ~~enhanced drive for innovation.~~

~~2.3.5.4 Possible actions~~

~~Possible actions include:~~

- ~~promote establishment of improvement objectives at all levels of the organization;~~
- ~~educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement objectives;~~
- ~~ensure people are competent to successfully promote and complete improvement projects;~~
- ~~develop and deploy processes to implement improvement projects throughout the organization;~~
- ~~track, review and audit the planning, implementation, completion and results of improvement projects;~~
- ~~integrate improvement consideration into development of new or modified products and services and processes;~~
- ~~recognize and acknowledge improvement.~~

~~2.3.6 Evidence based decision making~~

~~2.3.6.1 Statement~~

~~Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.~~

~~2.3.6.2 Rationale~~

~~Decision making can be a complex process and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making.~~

~~2.3.6.3 Key benefits~~

~~Some potential key benefits are:~~

- ~~improved decision making processes;~~
- ~~improved assessment of process performance and ability to achieve objectives;~~
- ~~improved operational effectiveness and efficiency;~~
- ~~increased ability to review, challenge and change opinions and decisions;~~

~~increased ability to demonstrate the effectiveness of past decisions.~~

~~2.3.6.4 Possible actions~~

~~Possible actions include:~~

~~determine, measure and monitor key indicators to demonstrate the organization's performance,~~

~~make all data needed available to the relevant people,~~

~~ensure that data and information are sufficiently accurate, reliable and secure,~~

~~analyse and evaluate data and information using suitable methods,~~

~~ensure people are competent to analyse and evaluate data as needed,~~

~~make decisions and take actions based on evidence, balanced with experience and intuition.~~

~~2.3.7 Relationship management~~

~~2.3.7.1 Statement~~

~~For sustained success, organizations manage their relationships with relevant interested parties, such as providers.~~

~~2.3.7.2 Rationale~~

~~Relevant interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its provider and partner networks is of particular importance.~~

~~2.3.7.3 Key benefits~~

~~Some potential key benefits are:~~

~~enhanced performance of the organization and its relevant interested parties through responding to the opportunities and constraints related to each interested party,~~

~~common understanding of objectives and values among interested parties,~~

~~increased capability to create value for interested parties by sharing resources and competence and managing quality related risks,~~

~~a well-managed supply chain that provides a stable flow of products and services.~~

~~2.3.7.4 Possible actions~~

~~Possible actions include:~~

~~determine relevant interested parties (such as providers, partners, customers, investors, employees or society as a whole) and their relationship with the organization,~~

~~determine and prioritize interested party relationships that need to be managed,~~

~~establish relationships that balance short term gains with long term considerations,~~

~~gather and share information, expertise and resources with relevant interested parties,~~

~~measure performance and provide performance feedback to interested parties, as appropriate, to enhance improvement initiatives,~~

~~establish collaborative development and improvement activities with providers, partners and other interested parties;~~

~~encourage and recognize improvements and achievements by providers and partners.~~

~~2.4 Developing the QMS using fundamental concepts and principles~~

~~2.4.1 QMS model~~

~~2.4.1.1 General~~

~~Organizations share many characteristics with humans as a living and learning social organism. Both are adaptive and comprise interacting systems, processes and activities. In order to adapt to their varying context, each needs the ability to change. Organizations often innovate to achieve breakthrough improvements. An organization's QMS model recognizes that not all systems, processes and activities can be predetermined, therefore it needs to be flexible and adaptable within the complexities of the organizational context.~~

~~2.4.1.2 System~~

~~Organizations seek to understand the internal and external context to identify the needs and expectations of relevant interested parties. This information is used in the development of the QMS to achieve organizational sustainability. The outputs from one process can be the inputs into other processes and are interlinked into the overall network. Although often appearing to be comprised of similar processes, each organization and its QMS is unique.~~

~~2.4.1.3 Processes~~

~~The organization has processes that can be defined, measured and improved. These processes interact to deliver results consistent with the organization's objectives and cross functional boundaries. Some processes can be critical while others are not. Processes have interrelated activities with inputs to deliver outputs.~~

~~2.4.1.4 Activity~~

~~People collaborate within a process to carry out their daily activities. Some activities are prescribed and depend on an understanding of the objectives of the organization, while others are not and react to external stimuli to determine their nature and execution.~~

~~2.4.2 Development of a QMS~~

~~A QMS is a dynamic system that evolves over time through periods of improvement. Every organization has quality management activities, whether they have been formally planned or not. This International Standard provides guidance on how to develop a formal system to manage these activities. It is necessary to determine activities which already exist in the organization and their suitability regarding the context of the organization. This International Standard, along with ISO 9004 and ISO 9001, can then be used to assist the organization to develop a cohesive QMS.~~

~~A formal QMS provides a framework for planning, executing, monitoring and improving the performance of quality management activities. The QMS does not need to be complicated, rather it needs to accurately reflect the needs of the organization. In developing the QMS, the fundamental concepts and principles given in this International Standard can provide valuable guidance.~~

~~QMS planning is not a singular event, rather it is an ongoing process. Plans evolve as the organization learns and circumstances change. A plan takes into account all quality activities of the organization and ensures that it covers all guidance of this International Standard and requirements of ISO 9001. The plan is implemented upon approval.~~