
**Quality management — Quality of an
organization — Guidance to achieve
sustained success**

*Management de la qualité — Qualité d'un organisme — Lignes
directrices pour obtenir des performances durables*

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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee 2, *Quality systems*.

This fourth edition cancels and replaces the third edition (ISO 9004:2009), which has been technically revised. The main changes compared to the previous edition are as follows:

- alignment with the concepts and terminology of ISO 9000:2015 and ISO 9001:2015;
- focus on the concept of “quality of an organization”;
- focus of the concept of “identity of an organization”.

Introduction

This document provides guidance for organizations to achieve sustained success in a complex, demanding and ever-changing environment, with reference to the quality management principles described in ISO 9000:2015. Where they are applied collectively, quality management principles can provide a unifying basis for an organization's values and strategies.

While ISO 9001:2015 focuses on providing confidence in an organization's products and services, this document focuses on providing confidence in the organization's ability to achieve sustained success.

Top management's focus on the organization's ability to meet the needs and expectations of customers and other relevant interested parties provides confidence in achieving sustained success. This document addresses the systematic improvement of the organization's overall performance. It includes the planning, implementation, analysis, evaluation and improvement of an effective and efficient management system.

Factors affecting an organization's success continually emerge, evolve, increase or diminish over the years, and adapting to these changes is important for sustained success. Examples include social responsibility, environmental and cultural factors, in addition to those that might have been previously considered, such as efficiency, quality and agility; taken together, these factors are part of the organization's context.

The ability to achieve sustained success is enhanced by managers at all levels learning about and understanding the organization's evolving context. Improvement and innovation also support sustained success.

This document promotes self-assessment and provides a self-assessment tool for reviewing the extent to which the organization has adopted the concepts in this document (see [Annex A](#)).

A representation of the structure of this document, incorporating the elements essential to achieve sustained success of an organization as covered in this document, is presented in [Figure 1](#).

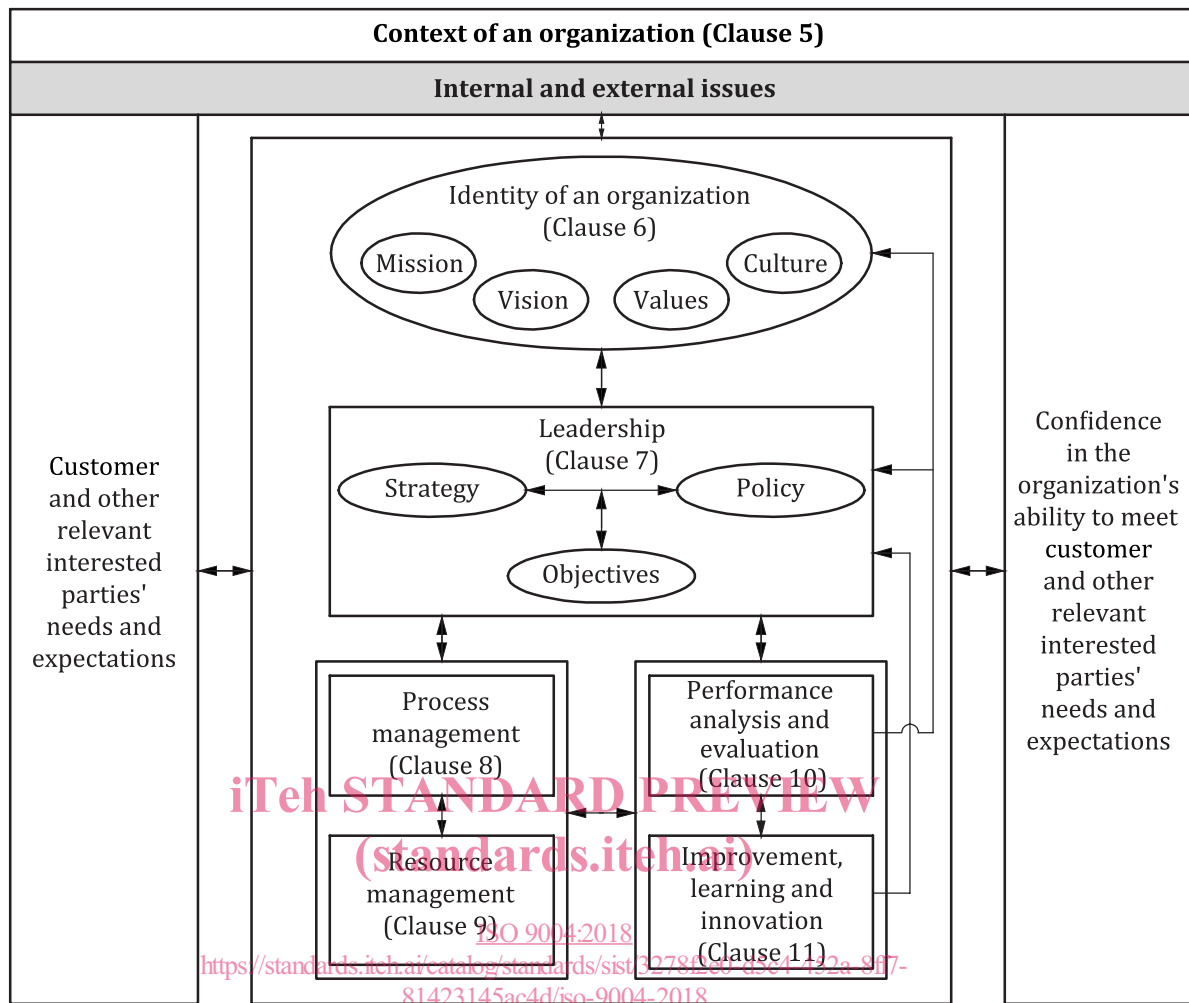


Figure 1 — Representation of the structure of this document

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Quality management — Quality of an organization — Guidance to achieve sustained success

1 Scope

This document gives guidelines for enhancing an organization's ability to achieve sustained success. This guidance is consistent with the quality management principles given in ISO 9000:2015.

This document provides a self-assessment tool to review the extent to which the organization has adopted the concepts in this document.

This document is applicable to any organization, regardless of its size, type and activity.

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

3 Terms and definitions (standards.iteh.ai)

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

4 Quality of an organization and sustained success

4.1 Quality of an organization

The quality of an organization is the degree to which the inherent characteristics of the organization fulfil the needs and expectations of its customers and other interested parties, in order to achieve sustained success. It is up to the organization to determine what is relevant to achieve sustained success.

NOTE 1 The term “quality of an organization” is derived from the definition of “quality” given in ISO 9000:2015, 3.6.2 (“the degree to which a set of inherent characteristics of an object fulfils requirements”), and from the definition of “requirement” given in ISO 9000:2015, 3.6.4, (“needs or expectations that are stated, generally implied or obligatory”). It is distinct from the purpose of ISO 9001, which focuses on the quality of products and services in order to give confidence in the ability of an organization to provide conforming products and services and to enhance its customers' satisfaction.

NOTE 2 All references to “needs and expectations” mean “relevant needs and expectations”.

NOTE 3 All references to “interested parties” mean “relevant interested parties”.

NOTE 4 All references to “interested parties” include customers.

The organization should go beyond the quality of its products and services and the needs and expectations of its customers. To achieve sustained success, the organization should focus on anticipating and meeting the needs and expectations of its interested parties, with the intent of enhancing their satisfaction and overall experience.

The organization should apply all of the quality management principles (see ISO 9000:2015) to achieve sustained success. Particular attention should be given to the principles of “customer focus” and “relationship management” to meet the different needs and expectations of interested parties.

The needs and expectations of individual interested parties can be different, aligned to, or in conflict with those of other interested parties, or can change quickly. The means by which the needs and expectations of interested parties are expressed and met can take a wide variety of forms, for example co-operation, negotiation, outsourcing, or by terminating an activity; consequently, the organization should give consideration to the interrelationships of its interested parties when addressing their needs and expectations.

The composition of interested parties can differ significantly over time and between organizations, industries, cultures and nations; [Figure 2](#) provides examples of interested parties and their needs and expectations.

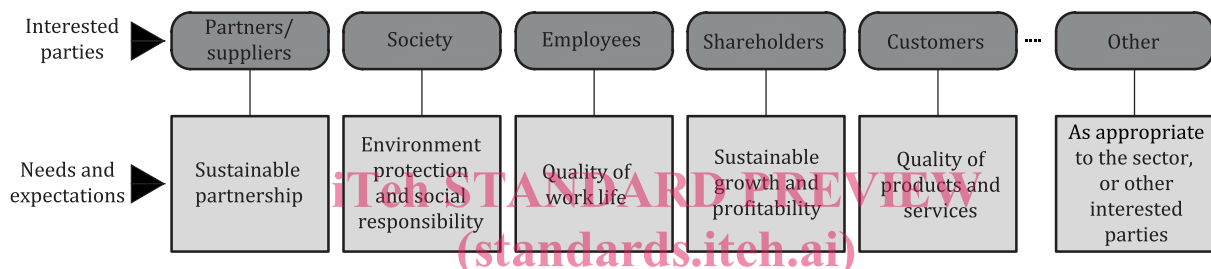


Figure 2 — Examples of interested parties and their needs and expectations

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4.2 Managing for the sustained success of an organization

4.2.1 The quality of an organization is enhanced and sustained success can be achieved by consistently meeting the needs and expectations of its interested parties over the long term. Short- and medium-term objectives should support this long-term strategy.

As the context of an organization will be ever-changing, to achieve sustained success top management should:

- regularly monitor, analyse, evaluate and review the organization’s context in order to identify all interested parties, determine their needs and expectations and their individual potential impacts on the organization’s performance;
- determine, implement and communicate the organization’s mission, vision and values, and promote an aligned culture;
- determine short- and long-term risks and opportunities;
- determine, implement and communicate the organization’s policies, strategy and objectives;
- determine the relevant processes and manage them so that they function within a coherent system;
- manage the organization’s resources to enable its processes to achieve their intended results;
- monitor, analyse, evaluate and review the organization’s performance;
- establish a process for improvement, learning and innovation in order to support the organization’s ability to respond to changes in the context of the organization.

4.2.2 Consideration of the needs and expectations of interested parties can enable the organization:

- a) to achieve objectives effectively and efficiently;
- b) to eliminate conflicting responsibilities and relationships;
- c) to harmonize and optimize practices;
- d) to create consistency;
- e) to improve communication;
- f) to facilitate training, learning and personal development;
- g) to facilitate focus on the most important characteristics of the organization;
- h) to manage risks and opportunities to its brand or reputation;
- i) to acquire and share knowledge.

5 Context of an organization

5.1 General

Understanding the context of an organization is a process that determines factors which influence the organization's ability to achieve sustained success. There are key factors to consider when determining the context of an organization:

- a) interested parties;
- b) external issues;
- c) internal issues.

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5.2 Relevant interested parties

Interested parties are those that can affect, be affected by, or perceive themselves to be affected by a decision or activity of the organization. The organization should determine which interested parties are relevant. These relevant interested parties can be both external and internal, including customers, and can impact the organization's ability to achieve sustained success.

The organization should determine which interested parties:

- a) are a risk to its sustained success if their relevant needs and expectations are not met;
- b) can provide opportunities to enhance its sustained success.

Once the relevant interested parties are determined, the organization should:

- identify their relevant needs and expectations, determining the ones that should be addressed;
- establish the necessary processes to fulfil the needs and expectations of the interested parties.

The organization should consider how to establish ongoing relationships with interested parties for benefits such as improved performance, common understanding of objectives and values, and enhanced stability.

5.3 External and internal issues

5.3.1 External issues are factors that exist outside of the organization that can affect the organization's ability to achieve sustained success, such as:

- a) statutory and regulatory requirements;
- b) sector-specific requirements and agreements;
- c) competition;
- d) globalization;
- e) social, economic, political and cultural factors;
- f) innovations and advances in technology;
- g) natural environment.

5.3.2 Internal issues are factors that exist within the organization itself that can affect the organization's ability to achieve sustained success, such as:

- a) size and complexity;
- b) activities and associated processes;
- c) strategy;
- d) type of products and services;
- e) performance;
- f) resources;
- g) levels of competence and organizational knowledge;
- h) maturity;
- i) innovation.

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5.3.3 When considering external and internal issues, the organization should take into account relevant information from the past, its current situation and its strategic direction.

The organization should determine which external and internal issues could result in risks to its sustained success or opportunities to enhance its sustained success.

Based on the determination of these issues, top management should decide which of these risks and opportunities should be addressed and initiate the establishment, implementation and maintenance of the necessary processes.

The organization should consider how to establish, implement and maintain a process for monitoring, reviewing and evaluating external and internal issues, with consideration of any consequences to be acted on (see [7.2](#)).

6 Identity of an organization

6.1 General

An organization is defined by its identity and context. The identity of an organization is determined by its characteristics, based on its mission, vision, values and culture.

Mission, vision, values and culture are interdependent and the relationship between them should be recognized as dynamic.

6.2 Mission, vision, values and culture

The identity of an organization includes its:

- a) mission: the organization's purpose for existing;
- b) vision: aspiration of what an organization would like to become;
- c) values: principles and/or thinking patterns intended to play a role in shaping the organization's culture and to determine what is important to the organization, in support of the mission and vision;
- d) culture: beliefs, history, ethics, observed behaviour and attitudes that are interrelated with the identity of the organization.

It is essential that the organization's culture aligns with its mission, vision, and values. Top management should ensure that the context of the organization is considered when determining its mission, vision and values. This should include an understanding of its existing culture and assessing the need to change the culture. The strategic direction of the organization and its policy should be aligned with these identity elements.

Top management should review the mission, vision, values and culture at planned intervals and whenever the context of the organization changes. This review should consider external and internal issues that can have an effect on the organization's ability to achieve sustained success. When changes are made to any of the identity elements, they should be communicated within the organization and to interested parties, as appropriate.

7 Leadership

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7.1 General

7.1.1 Top management, through its leadership, should:

- a) promote the adoption of the mission, vision, values and culture in a way that is concise and easy to understand, to achieve unity of purpose;
- b) create an internal environment in which people are engaged and committed to the achievement of the organization's objectives;
- c) encourage and support managers at appropriate levels to promote and maintain the unity of purpose and direction as established by the top management.

7.1.2 To achieve sustained success, top management should demonstrate leadership and commitment within the organization, by:

- a) establishing the organization's identity (see [Clause 6](#));
- b) promoting a culture of trust and integrity;
- c) establishing and maintaining teamwork;
- d) providing people with the necessary resources, training and authority to act with accountability;
- e) promoting shared values, fairness and ethical behaviour so that these are sustained at all levels of the organization;
- f) establishing and maintaining an organizational structure to enhance competitiveness, where applicable;

- g) individually and collectively reinforcing the organization's values;
- h) communicating achieved successes externally and internally, as appropriate;
- i) establishing a basis for effective communication with people in the organization, discussing issues that have general impact, including financial impact, where applicable;
- j) supporting leadership development at all levels of the organization.

7.2 Policy and strategy

Top management should set out the organization's intentions and direction in the form of the organization's policy, to address aspects such as compliance, quality, environment, energy, employment, occupational health and safety, quality of work life, innovation, security, privacy, data protection and customer experience. Policy statements should include commitments to satisfy the needs and expectations of interested parties and to promote improvement.

When establishing the strategy, top management should either apply a recognized and appropriate model available in the market, or design or implement an organization-specific customized model. Once chosen, it is crucial to maintain the stability of the model as the solid foundation and reference for managing the organization.

Strategy should reflect the identity of the organization, its context and long-term perspective. All short- and medium-term objectives should be aligned accordingly (see 7.3).

Top management should make strategic decisions regarding competitive factors (see Table 1).

These policy and strategy decisions should be reviewed for continued suitability. Any changes to the external and internal issues, as well as any new risks and opportunities, should be addressed.

The organization's policies and strategy constitute the basis to establish process management (see Clause 8).

Table 1 — Examples of actions to consider when addressing competitive factors

Competitive factors	Actions to consider
A Products and services	<ul style="list-style-type: none"> — focusing on current and potential customers and potential markets for products and services — offering standard products and services or designs specific to customer requirements — realizing the advantages of being first to market or being a follower — scaling production from one-off to mass production, as appropriate — dealing with short innovation cycles or a stable long-term customer demand — managing quality requirements
B People	<ul style="list-style-type: none"> — recognizing demographic development and changing values — considering diversity — cultivating an image as an attractive employer — determining the desired competence and experience of people to hire — considering appropriate approaches to recruitment, competence development, retention, and leave management — addressing capacity flexibility by considering permanent versus fixed-term contracts — considering full time versus part time or temporary employment, as well as the balance between them

Table 1 (continued)

Competitive factors	Actions to consider
C Organizational knowledge and technology	<ul style="list-style-type: none"> — applying currently available knowledge and technology to new opportunities — identifying the need for new knowledge and technology — determining when this knowledge and technology needs to be available and how to apply it within the organization — determining if this should be developed internally or acquired externally
D Partners	<ul style="list-style-type: none"> — determining potential partners — driving joint technology development with external providers and competitors — developing customized products and services in joint undertakings with customers — co-operating with the local community, academia, public authorities and associations
E Processes	<ul style="list-style-type: none"> — deciding whether process management will be centralized, decentralized, integrated or non-integrated, or a hybrid approach regarding determination, establishment, maintenance, control and improvement of processes, including the assignment of roles and responsibilities — determining necessary information and communications technology (ICT) infrastructure (e.g. proprietary, customized or standard solutions)
F Place	<ul style="list-style-type: none"> — considering local, regional and global presence — considering virtual presence and use of social media — considering the use of virtual decentralized project teams
G Pricing	<ul style="list-style-type: none"> — establishing price position (e.g. low versus premium pricing strategy) — determining prices by using an auction/bidding approach

7.3 Objectives

Top management should demonstrate leadership in the organization by defining and maintaining the organization's objectives based on its policies and strategy, as well as by deploying the objectives at relevant functions, levels and processes.

Objectives should be defined for the short and long term and should be clearly understandable. Objectives should be quantified where possible. When determining the objectives, top management should consider:

- a) to what extent the organization is aiming to be recognized by interested parties as:
 - 1) a leader with respect to competitive factors (see 7.2) emphasizing the organization's capability;
 - 2) having a positive impact on economic, environmental and social conditions around it;
- b) the degree of the organization's and its people's engagement in society beyond immediate business-related topics (e.g. in national and international organizations, such as public administration, associations and standardization bodies).

When deploying the objectives, top management should encourage discussions for alignment between different functions and levels of the organization.

7.4 Communication

The effective communication of policies and strategy, with relevant objectives, is essential to support the sustained success of the organization.