SLOVENSKI STANDARD
oSIST prEN ISO 9004:2017

01-julij-2017

Vodenje kakovosti - Kakovost organizacije - Napotki za doseganje trajne uspešnosti (ISO/DIS 9004:2017)

Quality management - Quality of an organization - Guidance to achieve sustained success (ISO/DIS 9004:2017)

Qualitätsmanagement - Qualität einer Organisation - Anleitung zum Erreichen nachhaltigen Erfolgs (ISO/DIS 9004:2017)

Management de la qualité - Qualité organisationnelle - Guidance pour atteindre performances durables (ISO/DIS 9004:2017)

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

Management de la qualité — Qualité organisationnelle —Guidance pour atteindre performances durables

ICS: 03.120.10; 03.100.70

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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 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.

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

This fourth edition cancels and replaces the third edition (ISO 9004:2009), which has been technically revised.

Introduction

This document provides guidance to managers at all levels to support the achievement of an organization's sustained success in a complex, demanding, and ever-changing environment, with reference to the quality management principles articulated in ISO 9000. Where they are applied collectively, quality management principles can provide a unifying basis for an organization's values and management 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 should focus on the organization's ability to meet the needs and expectations of both its customers and other interested parties, as determined by the organization, to achieve sustained success. This document addresses the needs and expectations of customers and other interested parties and provides guidance for the systematic and continual improvement of the organization's overall performance; this includes the planning, implementation, analysis, evaluation and improvement of an effective and efficient management system.

Factors affecting an organization's success continually emerge, evolve and diminish over the years. Organizations should adapt to changes in these factors. 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".

To achieve sustained success, managers at all levels should be aware of the organization's context. Managers should adapt processes and activities to the evolving context, through learning about and understanding it, as well as by the appropriate application of improvements, innovations, or both.

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).

Representation of the structure of this document, incorporating the elements essential to achieve the sustained success of an organization as covered in this document, is presented in Figure 1.

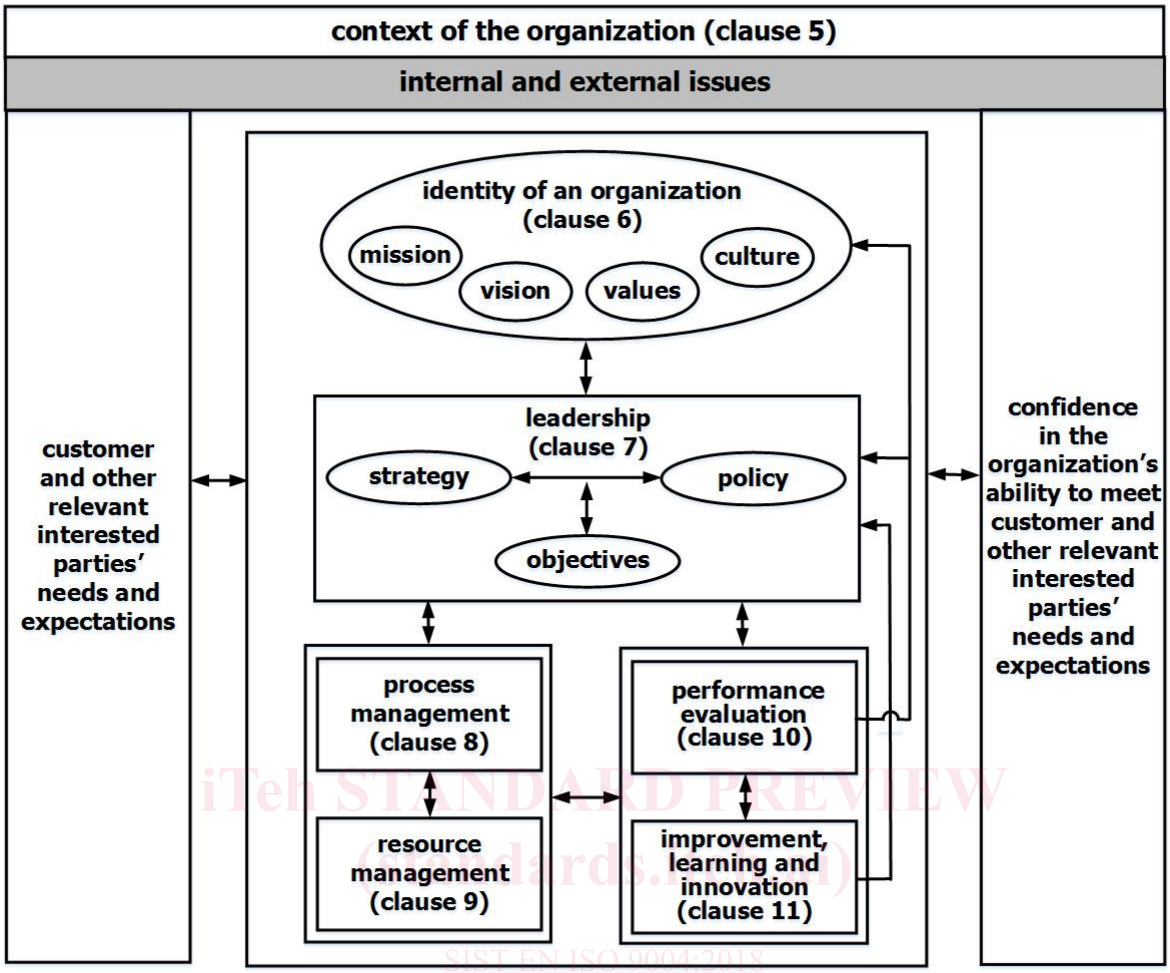
context of the organization (clause 5)
internal and external issues
customer and other relevant interested parties' needs and expectations
identity of an organization (clause 6)
mission
vision
values
culture
leadership (clause 7)
strategy
policy
objectives
process management (clause 8)
resource management (clause 9)
performance evaluation (clause 10)
improvement, learning and innovation (clause 11)
confidence in the organization's ability to meet customer and other relevant interested parties' needs and expectations

Figure 1 — Representation of the structure of this document

DRAFT INTERNATIONAL STANDARD **ISO/DIS 9004**

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

1 Scope

This document provides guidance to managers at all levels to enhance an organization’s ability to achieve sustained success. This guidance is consistent with the quality management principles given in ISO 9000:2015.

This document includes a self-assessment tool for reviewing 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

For the purposes of this document, the terms and definitions given in ISO 9000:2015 *Quality management systems — Fundamentals and vocabulary* apply.

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

- ISO Online browsing platform: available at http://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 interested parties, in order to provide confidence in the organization’s ability to achieve sustained success.

NOTE 1 The term “quality of an organization” is derived from the definition of “quality” given in ISO 9000, 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, 3.6.4, (‘needs or expectations that are stated, generally implied or obligatory’). It is also 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 References to ‘needs and expectations’ and ‘interested parties’ mean ‘*relevant* needs and expectations’ and ‘*relevant* interested parties’ respectively. It is up to the organization to determine what is relevant to achieve sustained success. Similarly, all references to ‘interested parties’ include customers.

To achieve sustained success the organization should go beyond the quality of its products and services and focus on meeting the needs and expectations of its interested parties and not just those of its customers alone, with the intent of enhancing their satisfaction and overall experience.

The organization should apply the quality management 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, including cooperation, negotiation, outsourcing, or by terminating an activity; consequently the organization should give consideration to the inter-relationships 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 below provides examples of interested parties and their needs and expectations.

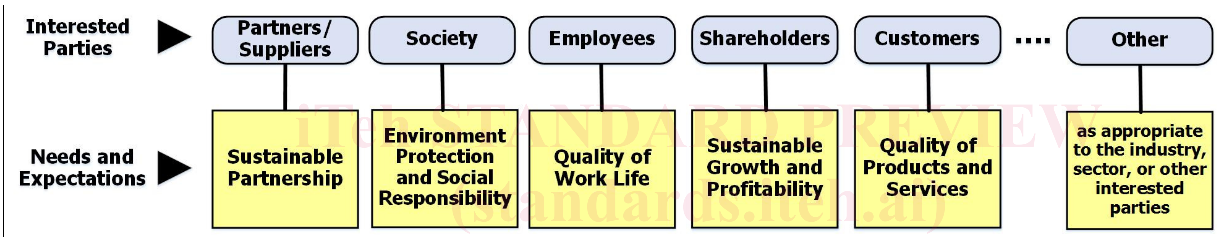
Interested Parties
Partners/ Suppliers
Society
Employees
Shareholders
Customers
....
Other
Needs and Expectations
Sustainable Partnership
Environment Protection and Social Responsibility
Quality of Work Life
Sustainable Growth and Profitability
Quality of Products and Services
as appropriate to the industry, sector, or other interested parties

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

4.2 Managing for the sustained success of an organization

4.2.1 An organization can achieve sustained success by consistently meeting the needs and expectations of its interested parties, over the long term. As the context of the organization will be ever-changing and in order to achieve sustained success, top management should:

a) constantly monitor, regularly analyze and evaluate the organization's context, in order to identify all interested parties, determine their needs and expectations and assess their individual potential impacts on the organization's performance;

b) determine and deploy the organization’s mission, vision, values and culture, which are the basis of the organization’s identity;

c) identify short-term and long-term risks and opportunities;

d) determine, deploy and communicate the organization’s policies, strategy and objectives;

e) determine the relevant processes and manage them so that they function within a coherent system;

f) manage the organization’s resources to enable its processes to achieve their intended objectives;

g) monitor, evaluate and analyze the organization’s performance;

h) establish a process for improvement, learning and promoting 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 will enable the organization to achieve benefits such as:

a) achieving objectives effectively and efficiently;

b) eliminating conflicting responsibilities and relationships;

c) harmonizing and optimizing practices;

d) creating consistency;

e) improving communication;

f) facilitating training and development;

g) facilitating focus on the most important aspects of the organization;

h) managing risks and opportunities to brand or reputation;

i) sharing knowledge.

5 Context of an organization

5.1 General

Understanding the context of the 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 the organization, such as:

a) interested parties;

b) internal issues;

c) external issues.

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 internal and external, 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 sustained success if their relevant needs and expectations are not met;

b) present opportunities to enhance sustained success.

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

- their relevant needs and expectations are determined and the ones that should be addressed are identified;

- the necessary processes to fulfil the needs and expectations of the interested parties are established.

The organization should consider how to establish on-going relationships with relevant 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;

c) competition;

d) globalization;

e) social, economic, political and cultural factors;

f) 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;

b) complexity;

c) activities;

d) strategy;

e) type of products and services;

f) performance;

g) resources;

h) levels of competence and organizational knowledge;

i) maturity;

j) innovation.

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

The organization should determine which internal and external issues could result in:

a) risks to sustained success;

b) opportunities to enhance sustained success.

Once these issues are determined, top management should ensure:

— which of these risks and opportunities should be addressed;

— that the necessary processes are established and implemented.

The organization should consider how to establish, implement and maintain a process for monitoring and evaluating internal and external issues.

6 Identity of an organization

6.1 General

An organization is defined by its identity and context. The identity of an organization is 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 being dynamic.

6.2 Mission, vision, values and culture

The identity of an organization includes its:

a) mission – the organization’s purpose for existing as expressed by top management;

b) vision – aspiration of what an organization would like to become as expressed by top management;

c) values – principles and/or thinking patterns intended to play a role in shaping the organization’s culture and to identify what is important to the organization, in support of the mission and vision;

d) culture – beliefs, history, ethics, observed behaviours and attitudes 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 in alignment with these identity elements and are described in detail in Clause 7.

To ensure sustained success, 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 to the organization and relevant interested parties, as appropriate.

7 Leadership

7.1 General

7.1.1 Top management, through its leadership, should:

a) ensure unity of purpose in the organization by defining, maintaining and communicating (in a way that is concise and easy to understand) its mission, vision and values, following consideration of the context of the organization;