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Vodenje kakovosti - Napotki za razumevanje, vrednotenje in izboljšanje kulture kakovosti organizacije za trajni uspeh

Quality management - Guidance to understand, evaluate and improve organizational quality culture to drive sustained success

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Titre manque

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Quality management — Guidance to understand, evaluate and improve organizational quality culture to drive sustained success

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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 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 3 *Supporting technologies*.

This is the first edition of this standard.

A list of all parts in the ISO 9000 and ISO 10000 series can be found on the ISO 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

The purpose of this document is to assist organizations in understanding, evaluating, and improving their quality culture to improve performance and to achieve sustained success.

ISO 10010 provides guidance on:

- how to determine, define and promote the desired quality culture consistent with the context of the organization;
- the role of leadership and people engagement in achieving a desired quality culture;
- the role of quality culture in the performance of the organization in satisfying its customers and other interested parties;
- using risk-based thinking to support the ongoing identification of risk and opportunities for improvement relevant to quality culture;
- integration of the seven quality management principles (QMPs) in the organization's quality culture.

A representation of the framework for recommended actions is provided in [Figure 1](#).

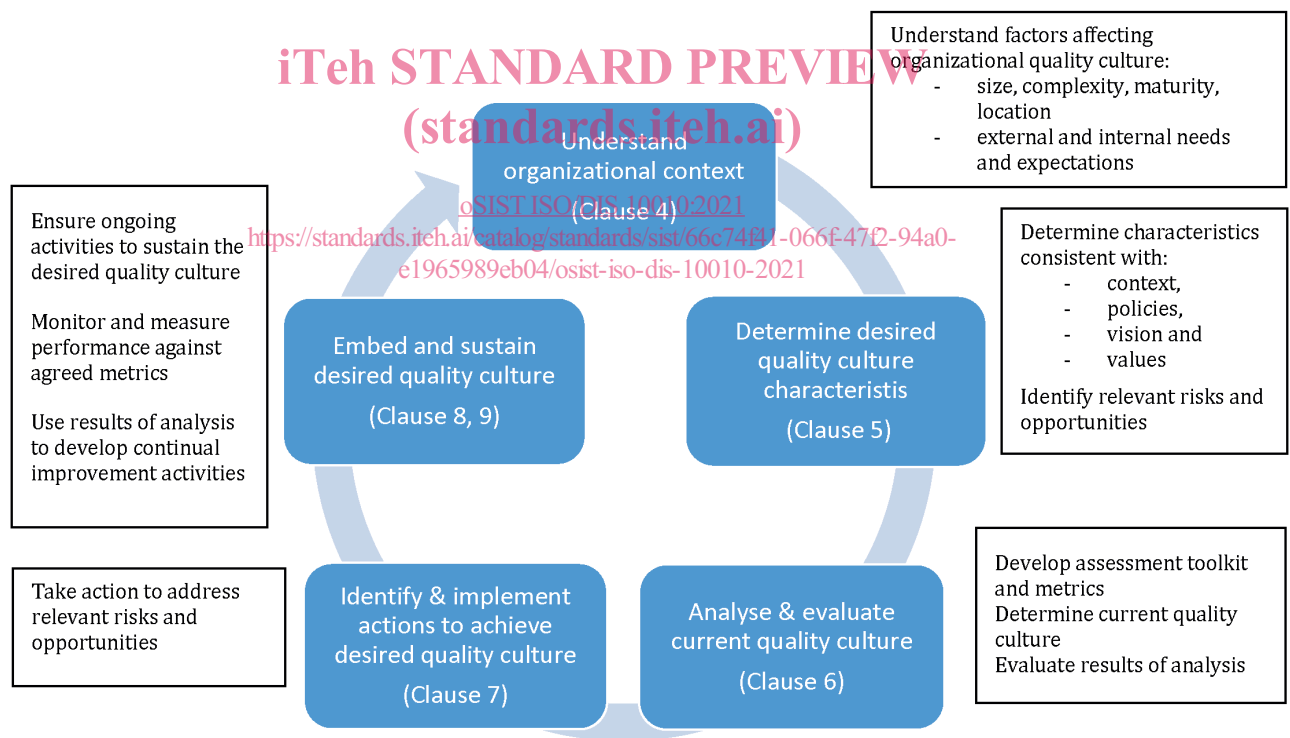


Figure 1 — Framework for actions to understand, evaluate and improve organizational quality culture to drive sustained success

0.2 Quality management principles and fundamental concepts

The quality management principles and fundamental concepts described in ISO 9000:2015 are reflected in this document and can assist the organization in developing a quality culture that helps meet challenges that arise in today's environment of constant change and increasing demands.

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The seven quality management principles listed in ISO 9001:2015 (0.2), to be considered and addressed when developing the desired organization quality culture are:

- customer focus;
- leadership;
- engagement of people;
- process approach;
- improvement;
- evidence-based decision making;
- relationship management.

Note Full descriptions of the quality management principles are provided in ISO 9000:2015 (2.3).

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Quality management — Guidance to understand, evaluate and improve organizational quality culture to drive sustained success

1 Scope

This document provides recommendations for the evaluation, development and improvement of organizational quality culture, including fundamental concepts, quality management principles, people engagement and leadership.

The recommendations in this document are generic and are intended to be applicable to any organization, regardless of its size, industry, location, maturity, or the products and services it provides.

Note This document provides example tools for the evaluation of organizational quality culture by self-assessment to determine quality culture maturity and potential for improvement.

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*

ISO 9001:2015, *Quality management systems — Requirements*
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3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following 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 <https://www.electropedia.org/>

3.1

culture

integrated shared values, attitudes, standards, behaviours, and practices in the organization

3.2

quality culture

culture (3.1) supporting delivery of the quality policy and objectives, and the delivery of products and services that meet the needs and expectations of customers and other relevant interested parties

4 Understand organizational context

4.1 Relationship between quality culture and organizational culture

To understand the relationship between quality culture and organizational culture the organization should consider the guidance provided in ISO 9001:2015 (2.2.1): “An organization focused on quality

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

The organization should consider quality culture as an integral part of the wider organizational culture, whether or not a defined quality management system has not been implemented, and take into account:

- behaviours relevant to product or service quality;
- customer focus;
- risk and opportunity;
- performance evaluation;
- continual improvement.

To determine the maturity of its quality culture the organization should determine the level to which the integration of quality management principles and concepts have been embedded into organizational culture and consider its impact on the establishment, operation and maintenance of organizational processes and procedures.

Figure 2 demonstrates the importance to quality culture of aligning the core mission, vision, and values of the organization to objectives that take into account organizational context and the needs and expectations of relevant interested parties.

Note Sub-cultures can exist in the same organization at different levels, locations, departments etc. and cultural differences across organizations can vary extensively.



Figure 2 — Relationship between quality culture and organizational culture

4.2 Understand the context of the organization

4.2.1 External and internal issues

The organization should take into account external and internal issues relevant to the organization's purpose and strategic direction that can impact its quality culture.

The organization should consider the external and internal issues relevant to the organization's quality culture during the development of the organization's mission, vision, values, and quality objectives.

EXAMPLE 1 An organization that prides itself on independence and being entrepreneurial as a core basis of its culture can run different sites independently. However, the business requires coordination and standard processes, which are identified as an internal issue.

EXAMPLE 2 A start-up organization that has no documented processes before entering a new, highly regulated market, which requires defined levels of documentation and records. This requirement to meet compliance obligations would be identified as an external issue that would impact the desired quality culture.

In both examples, the organizations should analyse their quality culture and identify whether there is a requirement for change.

Historic issues and expectations can also influence quality culture. This can be experienced at various levels such as internationally, within industries or within a single site.

The quality culture should be re-evaluated when there is a major change that impacts the organization. For example, this was experienced in 2020/21 at a global level where many organizations have considered their approach to virtual workplaces and/or workforce, with the associated changes to quality expectations and culture.

There is not a single quality culture that suits all organizations. Just as the impact of context on an organization is very specific, the quality culture will reflect this, and this can be seen in differences even within the same organizations, across different settings such as sites, departments, teams, or job roles.

4.2.1.1 External factors

The organization should consider external factors with the potential to have a major impact on quality culture. These include:

- a) industry and sector (see below). The organization should ensure that it understands quality expectations and requirements in its industry or sector, as these vary and will have an impact on quality culture. The organization should take into account such characteristics as specific quality requirements and expectations; legal, regulatory and statutory requirements; standards and industry requirements; and other industry specific influences. A highly regulated industry is likely to have a different quality culture to industries where price may be more significant factor (e.g. an organization in the highly regulated pharmaceutical industry differs from an organization in the fashion industry);
- b) country and region;
- c) political, economic, social and religious;
- d) legal, statutory and regulatory requirements;
- e) needs and expectations of customers, supply chain and other interested parties;
- f) competitive and market forces;
- g) technological status;
- h) environmental aspects and impacts;