### INTERNATIONAL STANDARD

ISO 10010

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# Quality management — Guidance to understand, evaluate and improve organizational quality culture

Management de la qualité — Recommandations pour comprendre, évaluer et améliorer la culture de la qualité organisationnelle

### iTeh STANDARD PREVIEW (standards.iteh.ai)

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#### **Foreword**

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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 <a href="www.iso.org/directives">www.iso.org/directives</a>).

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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 <a href="https://www.iso.org/iso/foreword.html">www.iso.org/iso/foreword.html</a>.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

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 <a href="https://www.iso.org/members.html">www.iso.org/members.html</a>.

#### Introduction

#### 0.1 General

The purpose of this document is to assist an organization in understanding, evaluating, and improving its quality culture to enhance organizational performance and to help achieve sustained success.

This document provides guidance on how to understand, determine, analyse, evaluate, implement, embed and sustain the desired quality culture consistent with the context of the organization.

#### It also details:

- 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;
- the ongoing determination of risks and opportunities for improvement relevant to quality culture;
- integration of the seven quality management principles (see 0.2) in the organization's quality culture.

A representation of the framework for recommended actions is provided in Figure 1.

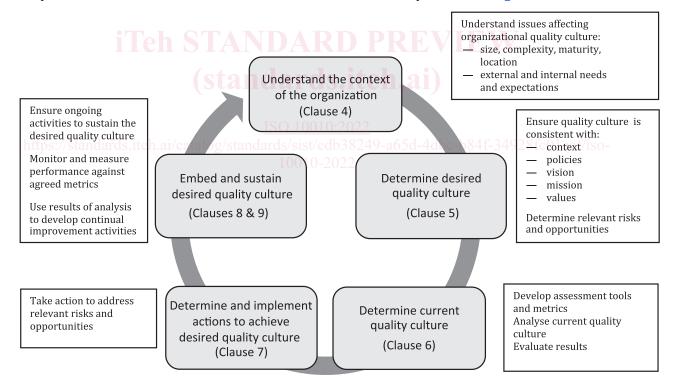


Figure 1 — Quality culture framework

#### 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 as they can assist the organization in developing a quality culture that helps meet challenges that arise in today's environment of change and increasing expectations.

#### ISO 10010:2022(E)

- 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

#### 1 Scope

This document gives guidance on the evaluation, development and improvement of organizational quality culture to help an organization to achieve sustained success. This document takes into account the fundamental concepts and quality management principles, with specific focus on 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

#### **3 Terms and definitions** ISO 10010:20

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

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

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

#### 3.1

#### culture

integrated shared values, beliefs, history, ethics, attitudes and observed behaviours

Note 1 to entry: In this document, "culture" refers to organizational culture.

#### 3.2

#### quality culture

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

#### 3.3

#### process owner

person (or team) responsible for defining and maintaining a process

Note 1 to entry: At the organizational level, the process owner is the person (or team) responsible for the description of a standard process; at the project level, the process owner is the person (or team) responsible for the description of the defined process. A process can therefore have multiple owners at different levels of responsibility.

#### ISO 10010:2022(E)

[SOURCE: ISO/IEC/IEEE 24765:2017, 3.3068]

3.4

#### benchmarking

comparative evaluation and/or analysis of similar operational practices

[SOURCE: ISO 14644-16:2019, 3.3.1]

#### 4 Context of the organization

#### 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 9000:2015, 2.2.1: "An organization focused on quality 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."

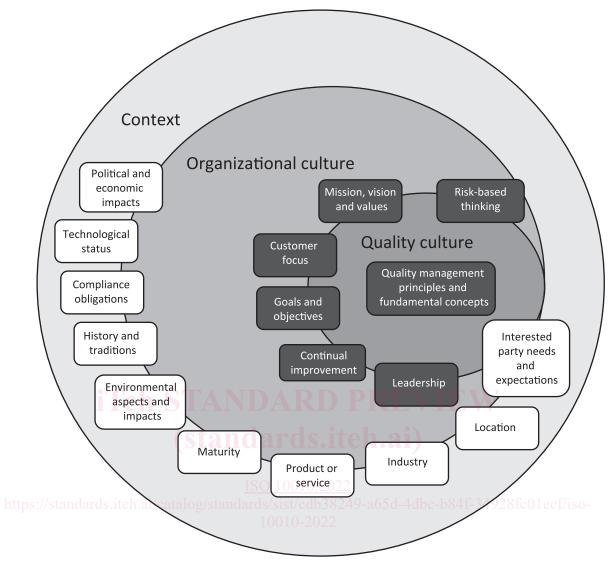
The organization should consider quality culture as an integral part of the wider organizational culture, whether or not a defined quality management system has been implemented, and take into account:

- behaviours that support the provision of product or service quality;
- customer focus;
- risks and opportunities;
   STANDARD PRRVIEW
- 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 fundamental concepts has been embedded into organizational culture and consider its impact on the establishment, operation and maintenance of organizational systems, processes and procedures.

To establish a quality culture, the organization should ensure that its vision, mission and values are aligned to its objectives. The objectives should take into account the context of the organization and the needs and expectations of relevant interested parties. Figure 2 demonstrates this.

 ${\tt NOTE}$  Different cultures can exist within the same organization depending on departments, geographic locations, etc.



NOTE Figure 2 is for illustration only. It includes examples of fundamental concepts, management principles and internal and external issues that contribute to quality culture. For more information on the fundamental concepts and quality management principles, see ISO 9000.

Figure 2 — Example of a relationship between quality culture and organizational culture

#### 4.2 Understand the context of the organization

#### 4.2.1 External and internal issues

#### **4.2.1.1** General

The organization should consider the external and internal issues relevant to the organization's quality culture during the development of the organization's vision, mission, values and 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 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 is identified as an external issue that will impact the desired quality culture.

#### ISO 10010:2022(E)

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

EXAMPLE 3 An organization reconsidered its approach towards virtual workplaces and remote working due to a series of events including a pandemic, a natural disaster and supply chain issues, which impacted its quality 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.

#### 4.2.1.2 External issues

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

- a) industry and sector-specific (see below);
- b) country and region;
- c) political, economic, social and cultural factors and religious beliefs;
- 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;
- https://standards.iteh.ai/catalog/standards/sist/cdb38249-a65d-4dbc-b84f-34928fc01ecf/iso
- h) environmental aspects and impacts;
- i) history and traditions;
- j) local demography.

The organization should ensure that it understands quality expectations and requirements in its industry or sector [see a), above], 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 can be a more significant factor (e.g. an organization in the highly regulated pharmaceutical industry differs from an organization in the fashion industry).

#### 4.2.1.3 Internal issues

The organization should consider internal issues with the potential to have a major impact on quality culture. These include, but are not limited to:

- a) leadership and people (see 4.2.1.4);
- b) product and service offering;
- c) organizational maturity (see below);
- d) approach to risks and opportunities;
- e) resourcing;

- f) training and education;
- g) awareness of the need for quality culture;
- h) available technologies;
- i) earning expectations;
- j) collective agreements and labour representatives;
- k) diversity of workforce;
- l) feedback and complaints.

The organization should consider its development stage and maturity [see c), above] when evaluating its current quality culture and planning for improvement. Development stages can evolve from the initial stage of entrepreneurship, through periods of rapid growth and on reaching established maturity. Quality culture develops as a quality management system becomes more established and embedded, so a start-up business is likely to have a different quality culture to that of an established organization.

The organization should consider where the focus of its quality culture should be according to its level of maturity, taking into account its long-term plans to ensure that focus does not exclude or conflict with other key aspects of quality culture.

EXAMPLE An organization in the initial stages of development can have a quality culture that places greater emphasis on rapidly meeting an emerging need than it does on the quality of its products and services. A more established organization with a secure customer base can have a quality culture that is less agile in meeting changes in the needs and expectations of its interested parties but a good understanding of the quality of its products and services.

#### 4.2.1.4 Leadership and people

The organization should demonstrate top management commitment in the development and improvement of quality culture, as this is potentially the most significant factor. Top management should direct the organization's vision, mission, values and culture, and ensure that desired behaviours are demonstrated and communicated. The organization should also take into account the personalities of key people of influence outside of top management, including (particularly for small organizations) the personality of the owner, as such influence can also be a key factor.

To ensure quality culture is effective, top management should be aware of the importance of people throughout an organization: behaviours, competences, experience and diversity all play an important role in cultural maturity and the achievement of plans for quality improvement.

NOTE Guidance on competence and people development is provided in ISO 10015.

#### 4.2.2 Understanding the needs and expectations of interested parties

ISO 9004:2018, 4.1 states that "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". The organization should therefore take into account the needs and expectations of customers and other relevant interested parties and ensure these are aligned with the organization's vision, mission and values. The organization should ensure objectives are achievable and form the basis for continual improvement (see Figure 1).

NOTE ISO 9004:2018, 4.1, NOTE 1, clarifies the origin of the term "quality of an organization": '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 that meet customer and applicable statutory and regulatory requirements and enhance its customers' satisfaction.'