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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

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Contents

Page

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 www.iso.org/directives).

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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 www.iso.org/members.html.

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.
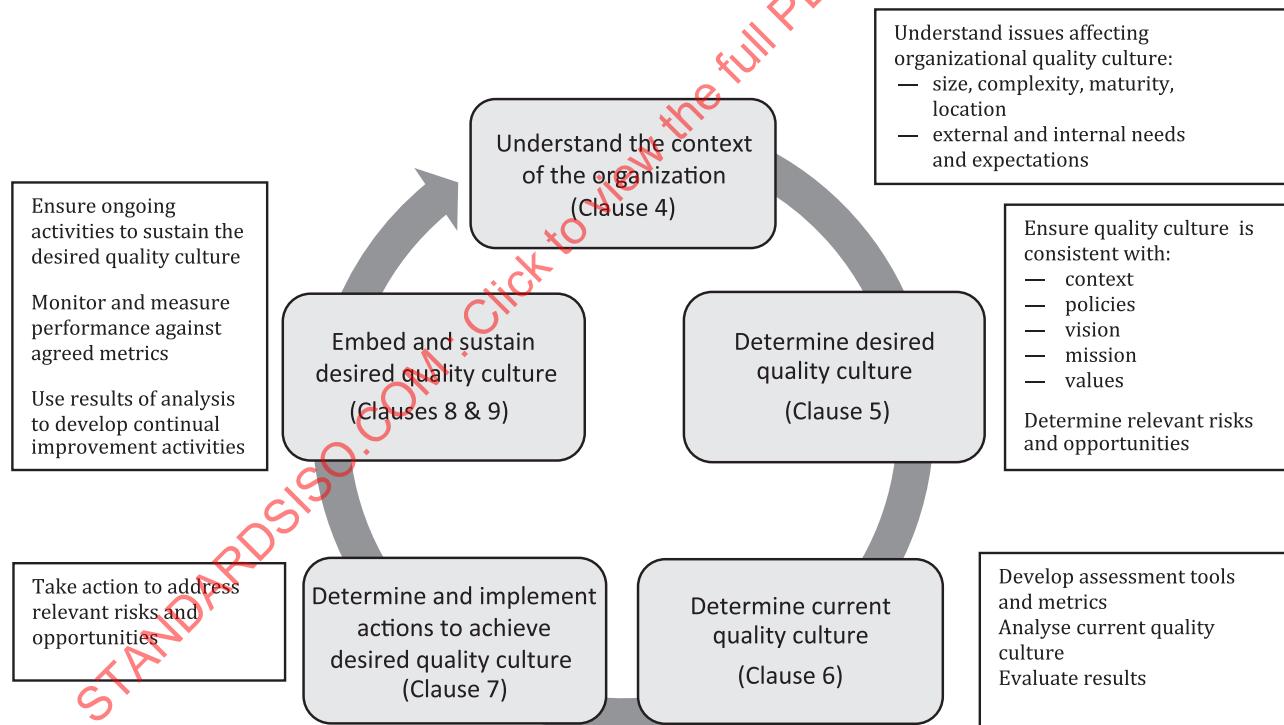
Figure 1 — Quality culture framework

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.

The seven quality management principles 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.

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

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 https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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.

[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;

— 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.

NOTE   Different cultures can exist within the same organization depending on departments, geographic locations, etc.
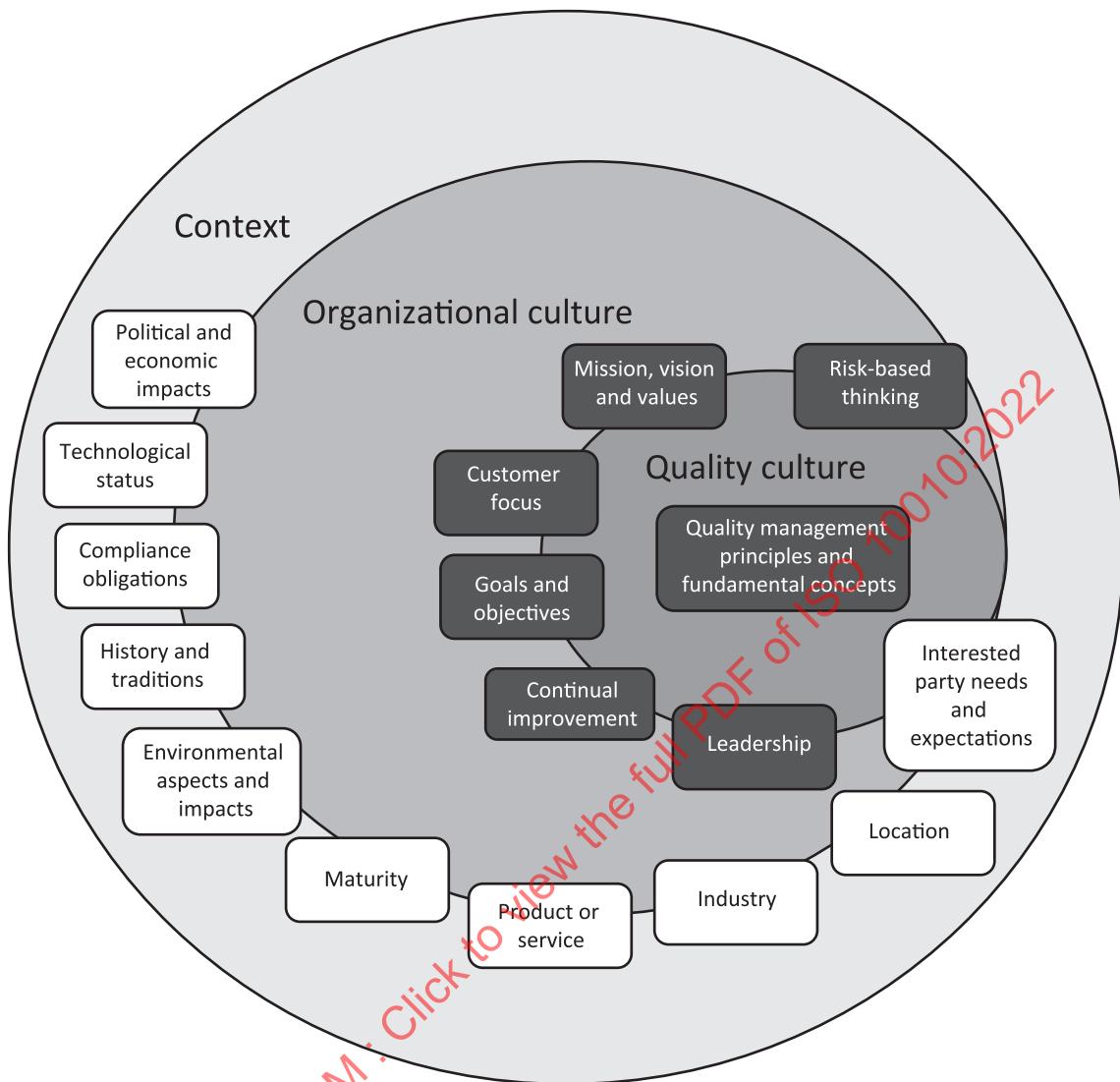
NOTE   Figure 2 is for illustration only. It includes examples of fundamental concepts, management principles and internal and external issues that contribute to quality culture. For more information on the fundamental concepts and quality management principles, see ISO 9000.

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.

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;

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.'

5 Determine desired quality culture

5.1 General

The organization should use its understanding of its context, including external and internal issues (see Clause 4), to determine the desired quality culture. In determining the desired quality culture, the organization should be aware of the interdependency of vision, mission, values and culture and their dynamic relationships.

The desired quality culture should be clearly articulated, accessible and retained as documented information. This can include:

— a quality culture commitment statement, which should be integrated with organizational policies;

— expected behaviours and values to support the desired quality culture.

The organization should provide opportunities for people working at different levels to participate in the determination and implementation of the desired quality culture.

The organization should understand its own business model and where the quality of its product or service fits in with that model to understand what its desired quality culture is or should be. The organization should determine the needs and expectations of customers and other relevant interested parties with respect to deliverables, through processes such as customer feedback.

The type of quality culture the organization desires can be influenced by characteristics of the organization, such as:

a) working directly with customers;

b) mass automated production;

c) custom and/or handmade product;

d) solely service or resource provision;

e) single source supplier or customer.

Once the desired quality culture is identified, the organization should use tools and techniques and other sources of data, such as those described in 6.2, to measure performance and determine if it is meeting the standards for desired quality culture.

5.2 Leadership roles and responsibilities

The organization should recognize that quality culture is an important part of organizational culture and significantly influenced by the attitude, thinking and understanding of top management.

Top management should formulate a quality policy consistent with its vision, mission and values. The quality policy and culture should support the organization's strategic direction and clarify the intention and direction of the organization in terms of quality. The quality policy should be coordinated with the desired quality culture development and integrated with the quality management system.

Top management should:

— establish and communicate the desired quality culture;

— provide relevant policies and resources;

— engage, direct and support quality culture within the organization;

— define expectations and desired behaviours;

— lead by example.

Leadership at all levels should demonstrate the desired quality culture of the organization and communicate that it is a shared responsibility throughout the organization, across all operational and geographic boundaries.

Top management responsibilities include:

a) determining the organization's vision, mission, values and quality policy;

b) integrating requirements for quality culture with management systems through business processes;

c) determining planning, strategic direction, objectives and performance metrics to develop desired quality culture;

d) ensuring the desired quality culture takes into account the capabilities and potential for improvement of the organizational culture;

e) providing adequate resources for the development of quality culture;

f) identifying, appointing and developing quality culture champions;

g) ensuring ongoing commitment to quality culture to support sustained success.

6 Determine current quality culture

6.1 General

Every organization has a quality culture, whether or not they know or measure it. The organization should establish measurable performance criteria, indicators and target values that are used to evaluate the effectiveness of quality culture. The indicators should cover all aspects of the organization. The performance criteria should clearly express the level and status of quality culture that the organization wants to achieve and clarify the quantitative and/or qualitative target of each indicator, clearly describing the status and level required.

6.2 Decide what will be measured and how

The organization should determine the scope of the quality culture evaluation (e.g. total organization, division, site, plant or country). Once this has been determined, the organization should decide the criteria for measuring quality culture (e.g. understanding of the quality policy and objectives, how people working on behalf of the organization comply with management system arrangements, behaviours, mind-sets and attitudes towards quality).

The organization should determine appropriate tools, techniques and sources of data that enable understanding of the organization's quality culture. These include, but are not limited to:

a) interviews or consultations with key interested parties (e.g. customers, employees, suppliers);

b) behavioural and other surveys;

c) assessment of risk;

d) workshops and other meetings;

e) suggestion boxes;

f) quality performance-related data (e.g. nonconformities, customer complaints, design changes, deviations from objectives, recalls, audit reports, accidents, events and incidents).

Top management should determine what will be measured and define management responsibility and accountability at the highest level.

The organization should use a combination of data streams and techniques to ensure a multi-directional view of quality culture. An organization that has not yet determined its desired quality culture can use the results of the data to establish targets and build these targets into quality objectives.

6.3 Monitoring and measuring current quality culture

After determining its desired quality culture (see Clause 5), the organization should evaluate the current quality culture. This can be done by undertaking an analysis of the current culture against the desired culture, and/or assessing desired behaviours and characteristics.

The evaluation should include as a minimum, determining the:

a)   date/time period of evaluation;

b)   scope of evaluation (e.g. location, department, organizational unit, size of assessment sample);

c)   participants and potential need for confidentiality;

d)   desired cultural indicators;

e)   characteristics that demonstrate the desired culture;

f)   maturity level indicators increasing towards the desired culture;

g)   system for scoring to enable subsequent assessments to demonstrate positive or negative changes to maturity levels of the desired culture.

To enable direct comparison of results, consistent question sets should be used for surveys and other measurement tools for agreed periods of time. Documented information related to analysis should be maintained and retained for future benchmarking.

NOTE   An example of a quality culture survey is provided in Table A.1.

6.4 Analyse and evaluate the current quality culture

6.4.1 General

Once all the data from surveys, indicators, workshops, interviews, etc. have been captured, the organization should analyse them to understand what the current quality culture is and evaluate how this compares to what is desired.

6.4.2 Analyse current quality culture

The organization should consider the most effective methods of presenting the data to enable understanding and see gaps. Examples of useful tools include:

—   pareto charts (graph that includes bars);

—   run charts (data plotted over time);

—   pie charts (data segmented visually);

—   radar or spider charts (plotting values with multiple variables);

—   scatter diagrams (using dots to represent values for two variables).

The organization should use the data to generate ideas and actions to address gaps or meet set targets.

The organization should capture as much information as is needed to understand what drives culture to enable it to plan and implement specific actions to build the desired culture and avoid a generic and scattered approach. This work is diagnostic in nature.

The organization should seek to understand the root cause of issues. Root cause analysis requires a qualitative approach; a quantitative approach is rarely enough. The organization should ensure the approach it takes to changing elements of the quality culture is based on understanding the qualitative analysis of root causes.

NOTE   A quantitative approach can reveal a culture where people avoid speaking up. However, the cultural drivers behind a lack of speaking up can be numerous: fear of getting into trouble, fear of reprisals, a desire to respect elders, or because people are disengaged and feel they are never listened to.

The organization can use the following to support analysis:

a)   overall indication of organizational culture based on prevailing external values;

b)   detailed focus on prevailing external values;

c)   overall indication of trends about inclination to improve organizational culture;

d)   detailed indication of people's inclination towards improving quality culture;

e)   overall readiness for acceptance and engagement in systematic improvement of proposed components of quality culture.

Once data are analysed, an action plan should be prepared (see Clause 7) if necessary. The organization should communicate the results of the analysis with relevant interested parties. This should include information on both the current quality culture and the desired quality culture. These actions can form part of the organization's quality objectives and be evaluated through periodic management review.

6.4.3   Evaluate current quality culture

The organization should use root cause analysis to evaluate results derived from data. The following steps can be used:

a)   identify and describe the problem clearly;

b)   identify the possible causes of the problem;

c)   ask "why?" five times to get to the root cause;

d)   establish a timeline from the normal situation up to the time the problem occurred (include feedback from customers and other relevant interested parties);

e)   distinguish between root cause and other causal factors (e.g. event correlation);

f)   establish a causal graph between the root cause and the problem;

g)   address each root cause with an action plan (see Clause 7).

The organization should ensure that root cause analysis considers the broad range of shared organizational beliefs that underpin the way people behave.

NOTE   If there is a common belief that hitting production targets is of primary importance, this can lead to people not reporting issues, because of concerns that this can slow production and it is possible that reporting leads to reprisals. This in turn can directly lead to quality issues and customer dissatisfaction.

7   Determine and implement actions to achieve desired quality culture

7.1   General

The organization should take into account that while quality culture can be seen as intangible, the return on investment can be substantial in terms of improving performance and growth of the organization.

To support achievement of the desired quality culture, the organization should ensure:

a) management at all levels demonstrates ongoing support for quality initiatives, including desired behaviours;

b) top management develops the organization's vision, mission and values, and communicates these to all employees and other relevant interested parties;

c) regular review and, if necessary, updates of, vision, mission and values to reflect changes to external and internal context;

d) quality objectives are established and communicated to all employees and other relevant interested parties;

e) objectives are regularly reviewed and updated, as necessary;

f) employee performance indicators are linked to quality objectives;

g) regular engagement with customers and other relevant interested parties to respond to changing needs and expectations, including when developing products and services, evaluating order fulfilment and considering changes within the marketplace;

h) financial and other incentives are based on organizational policies (employee recognition and reward should be appropriate for the organization and its culture).

7.2 Determine quality culture strategy

7.2.1 Aspects of quality culture

The organization should consider different aspects of quality culture when establishing strategy, such as:

a) intangible culture (related to values);

b) behavioural culture;

c) institutional culture;

d) material culture.

NOTE Intangible and behavioural cultures are internal manifestations of quality culture, which are difficult to form and change. Institutional and material cultures are external manifestations of quality culture and easier to form and change.

7.2.2 Establish quality culture strategy

The organization can adopt different approaches to establish its quality culture strategy. These can include one or more of the following:

a) following: a reactive culture that allows others to lead and innovate while the organization follows;

b) compliance: a basic and steady quality culture, in which quality levels meet legal, statutory and regulatory requirements;

c) innovation: an innovative and inclusive quality culture, requiring research and development, design and other aspects to focus on quality;

d) leading: a constantly improving quality culture, where the organization is expected to be proactive so that its quality level continuously exceeds that of competitors and itself.

Top management should establish a relevant and achievable quality culture strategy, aligned with the organization's strategic plans.

NOTE   Guidance on innovation management is provided in ISO 56002.

7.2.3   Analyse need for quality culture in terms of quality strategy

Based on analysis of the quality culture in terms of the characteristics of the industry, its own development stage and future development objectives, the organization should determine achievable quality values and align these with its vision, mission and values.

Quality values should be in line with social progress, reflect the needs and expectations of customers and other relevant interested parties, and support the organization to carry out quality management activities.

8   Embed desired quality culture

8.1   General

The organization should take action to embed the desired quality culture, addressing weaknesses identified during analysis (see 6.4.2) and evaluation (see 6.4.3) and building on strengths to support development.

The action(s) taken should be appropriate for the results of the assessment and evaluation. Actions can include:

a)   maintaining effective communication to celebrate quality management successes;

b)   training for both top management and the wider workforce;

c)   workforce engagement, formal and informal awareness activities;

d)   identification and appointment of quality culture champions;

e)   setting individual quality culture objectives and commitments;

f)   providing additional resources such as behavioural coaches;

g)   incentivization, recognition and reward campaigns.

NOTE   Guidance on engagement is provided in ISO 10018.

8.2   Enable continual improvement of quality culture

When the organization has determined its current quality culture, evaluated the performance data and implemented an improvement plan, it should periodically review the same data collection processes. The organization should check if actions taken are effective and evaluate if quality culture has improved, stayed the same or declined.

Surveys that are repeated should be reviewed and adapted as necessary.

To enable continual improvement of the quality culture, the organization should monitor changes in the context of the organization (see Clause 4), and take into account factors such as:

a)   changes to top management;

b)   acquisitions and mergers;

c)   changes in business direction;

d)   changes in quality policy;

e)   new products, services or processes;

f)   organizational performance.

The organization should assess if quality culture is, or can be, affected by risks related to changes so that action can be taken to mitigate the risk before quality culture is negatively affected.

9   Sustain desired quality culture

9.1   General

The organization should take action(s) to ensure that the desired quality culture is developed and strengthened over time and is embedded in everything the organization does. Relevant actions for sustaining the desired quality culture include, but are not limited to:

a)   ongoing promotion of desired quality culture;

b)   people engagement (see 9.2);

c)   communication (see 9.3);

d)   management of change (see 9.4);

e)   ongoing assessment and benchmarking (see 9.5).

9.2   People engagement

9.2.1   Quality culture champions

The organization should identify and appoint quality culture champions to take an active role in guiding and encouraging people to adopt the desired quality culture. Quality culture champions can be members of top management but may also be from different levels of the organization.

Quality culture champions should:

a)   take into account the existing quality management system and ensure the desired quality culture is integrated into the system;

b)   organize work and activities related to the desired quality culture;

c)   coordinate and liaise with others, including process owners, to implement various systems and mechanisms to improve quality culture;

d)   guide all people working on behalf of the organization, including those who engage with customers, to adopt and demonstrate desired values and behaviours;

e)   periodically analyse and evaluate the impact of activities to improve the desired quality culture;

f)   report regularly to top management on the enhancement of quality culture and make comments and suggestions.

Top management should support and cooperate with appointed quality culture champions to advance the desired quality culture.

9.2.2 Awareness and training

Top management should take actions to raise awareness of quality culture and desired values and behaviours amongst the people working on behalf of the organization. Actions should support people to:

— learn, understand and demonstrate the quality values and policies of the organization;

— act as role models to new employees;

— internalize and adhere to the values of the quality culture;

— actively participate in activities to develop quality culture.

The organization should recognize the importance of training when developing, embedding and sustaining the desired quality culture and determine training content based on the quality strategy, objectives, external context, and wellbeing of people working on behalf of the organization.

The organization should provide relevant training for anyone working on behalf of the organization, including top management and managers at all levels to improve quality awareness, attitudes, competence, and understanding and to ensure consistency.

Training should demonstrate aspects of quality culture and promote the desired quality culture. Training can include:

a) concept of quality culture;

b) vision, mission, values and policies;

c) quality responsibilities and awareness of traditions;

d) processes, process owners and performance indicators for quality culture;

e) other positive organizational quality culture practices.

9.3 Communication

Top management and other people with responsibility for quality culture should establish regular communication about quality culture and its performance. The organization should communicate about how this relates to the business performance, objectives, and the needs and expectations of interested parties. Communication can be made using multiple methods.

Top management should ensure that a communication plan detailing the types of communication is developed and followed. The communication of information relating to quality culture should relate to planned activities and results. Communication should be inclusive, taking into account the diversity of workers, such as people working remotely, shift workers, volunteers, workers with disabilities and workers with varying levels of literacy.

9.4 Management of change

Changes in the organization and its context, including new product or service offerings, can have an impact on the desired quality culture. To effectively manage potential changes, the impact of changes on the desired quality culture should be discussed on a regular basis as part of the management process. This discussion should include results of any new assessments or benchmarks. When doing this, it is important to identify both positive and negative developments in quality culture. Examples of positive and negative quality culture indicators are provided in Table A.2.

If there is a need for change in the quality culture, top management should develop a clear vision for change. This vision should address the reason for change and its impact on the organization. The reason for change should detail the intended positive outcome of the desired change in quality culture and