



DPC: 25/30483858 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 10 April 2025

Origin: European

Latest date for receipt of comments: 03 June 2025

Project No. 2023/02880

Responsible committee: QS/1/1 Quality Management: Principles, Terminology & Communication

Interested committees:

Title: Draft BS EN ISO 9000 Quality management - Fundamentals and vocabulary.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 03 June 2025

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 9000

Quality management — Fundamentals and vocabulary

ICS: 03.120.10; 01.040.03

ISO/TC 176/SC 1

Secretariat: **ANSI**

Voting begins on:
2025-04-10

Voting terminates on:
2025-07-03

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 9000:2025(en)

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© ISO 2025



Documents

Document Sharing Hub



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Fundamentals of quality management	1
2.1 General	1
2.2 Quality management principles	1
2.2.1 General	1
2.2.2 Customer focus	2
2.2.3 Leadership	2
2.2.4 Engagement of people	3
2.2.5 Process approach	4
2.2.6 Improvement	5
2.2.7 Evidence-based decision making	5
2.2.8 Relationship management	6
2.3 Fundamental quality management concepts	7
2.3.1 Quality	7
2.3.2 Quality management	7
2.3.3 Quality management system	7
2.3.4 Quality assurance	8
2.3.5 Quality control	8
2.3.6 Quality planning	8
2.3.7 Process management	9
2.3.8 Risk-based thinking	9
2.3.9 Organizational quality culture	9
2.3.10 Continual improvement	10
2.4 Additional concepts relevant to quality management	10
2.4.1 Context of an organization	10
2.4.2 Interested parties	10
2.4.3 Integrated management system	10
2.4.4 Circular economy	11
2.4.5 Emerging technologies	11
2.4.6 Innovation	11
2.4.7 Change management	12
2.4.8 Customer experience	12
2.4.9 Knowledge management	12
2.4.10 Information management	13
2.4.11 People aspects	13
2.4.12 Business continuity	13
2.5 Developing the QMS using fundamental concepts and principles	14
2.5.1 Attributes of a QMS	14
2.5.2 Development of a QMS	15
2.5.3 QMS standards, other management systems and organizational excellence models	15
3 Terms and definitions	16
3.1 Terms related to management system	16
3.2 Terms related to organization	19
3.3 Terms related to management	21
3.4 Terms related to process	24
3.5 Terms related to system	26
3.6 Terms related to requirement	27
3.7 Terms related to nonconformity	28
3.8 Terms related to result	30
3.9 Terms related to data, information and document	32
3.10 Terms related to customer	34

ISO/DIS 9000:2025(en)

3.11	Terms related to characteristic	36
3.12	Terms related to determination	38
3.13	Terms related to audit	40
3.14	Terms related to electoral bodies	42
3.15	Terms related to local government	46
Annex A (informative) Concept relationships and their graphical representation		49
Bibliography		68
Alphabetical index of terms		70

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 1, *Concepts and terminology*.

This fifth edition cancels and replaces the fourth edition (ISO 9000:2015), which has been technically revised.

Introduction

This document provides the fundamental concepts, principles and vocabulary for quality management and provides the foundation for quality management and quality management systems (QMS) standards. This document is intended to help the user to understand the fundamental concepts, principles and vocabulary of quality management, in order to be able to effectively and efficiently implement a QMS and realize value from quality management and QMS standards.

This document proposes a well-defined QMS, based on a framework that integrates established fundamental concepts and principles related to quality management, in order to help organizations realize their objectives. It is applicable to all organizations, regardless of size, complexity or business model. Its aim is to increase an organization's awareness of its duties and commitment in fulfilling the needs and expectations of its customers and interested parties, and in achieving satisfaction with its products and services.

This document contains seven quality management principles supporting the fundamental concepts described in [2.2](#). In [2.3](#), for each quality management principle, there is a “statement” describing each principle, a “rationale” explaining why the organization would address the principle, “key benefits” that are attributed to the principles, and “possible actions” that an organization can take in applying the principle.

This document contains the terms and definitions that apply to all quality management and QMS standards developed by ISO/TC 176, at the time of publication. The terms and definitions are arranged in conceptual order, with an alphabetical index of the terminological entries of this document provided in Annex B. [Annex A](#) includes a set of concept diagrams on which the thematic grouping of the terms and definitions in [Clause 3](#) is based.

NOTE Guidance on some additional frequently-used words in the QMS standards developed by ISO/TC 176, and which have an identified dictionary meaning, is provided in a glossary available at: http://www.iso.org/iso/03_terminology_used_in_iso_9000_family.pdf <NEED UPDATED LINK @ PUBLISHING>

Quality management — Fundamentals and vocabulary

1 Scope

This document describes the fundamental concepts and principles of quality management which are universally applicable to the following:

- organizations seeking sustained success through the implementation of a quality management system;
- customers seeking confidence in an organization's ability to consistently provide products and services conforming to their requirements;
- organizations seeking confidence in their supply chain that product and service requirements will be met;
- organizations and interested parties seeking to improve communication through a common understanding of the vocabulary used in quality management;
- organizations performing conformity assessments against the requirements of ISO 9001;
- providers of training, assessment or advice in quality management;
- developers of related standards.

This document specifies the terms and definitions that apply to all quality management and quality management system standards developed by ISO/TC 176.

2 Fundamentals of quality management

2.1 General

The quality management principles and concepts described in [clauses 2.2](#) and [2.3](#) of this document constitute the fundamentals of quality management. They give the organization the ability to meet the challenges on ongoing change in both internal and external issues. The context in which an organization works today is characterized by accelerated change, global markets and supply chains, new technologies, information technology, innovation, and knowledge as a principal resource. The impact of quality management extends beyond customer satisfaction: it can also have a direct impact on the organization's reputation and sustained success.

All concepts, principles and their interrelationships should be seen as a whole and not in isolation of each other. No individual concept or principle is more important than another. At any time, finding the right balance in their application is critical.

2.2 Quality management principles

2.2.1 General

The quality management principles outlined in this document provide organizations with a solid foundation for building or improving their quality management system.

While each principle can be understood individually, they should be viewed as interrelated and interdependent when applied within the organization.

These principles serve as fundamental guidance and are universally applicable to any organization's quality management system.

2.2.2 Customer focus

2.2.2.1 Statement

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

2.2.2.2 Rationale

Understanding current and future needs and expectations of customers and other interested parties contributes to the sustained success of the organization. Every aspect of customer interaction provides an opportunity to build and retain the confidence of customers and other relevant interested parties.

2.2.2.3 Key benefits

Key benefits attributed to each principle are:

- improved customer experience;
- increased customer satisfaction;
- improved customer loyalty;
- enhanced repeat business;
- enhanced reputation of the organization;
- expanded customer base.

2.2.2.4 Possible actions

Possible actions include:

- understand and take action on customers' and relevant interested parties' current and future needs and expectations;
- link the organization's policies and objectives to customer needs and expectations;
- communicate customer needs and expectations throughout the organization;
- plan, design, develop, produce, deliver, support and improve products and services to meet customer needs and expectations;
- measure and monitor customer satisfaction and take appropriate actions;
- determine and address risks and opportunities that can affect customer satisfaction and experience;
- actively manage relationships with customers to achieve sustained success.

2.2.3 Leadership

2.2.3.1 Statement

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives.

2.2.3.2 Rationale

Creation of unity of purpose and the direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.

2.2.3.3 Key benefits

Some potential key benefits are:

- increased effectiveness and efficiency in meeting the organization's quality objectives;
- better coordination of the organization's processes;
- improved communication between levels and functions of the organization;
- development and improvement of the capability of the organization and its people to deliver desired results.

2.2.3.4 Possible actions

Possible actions include:

- communicate the organization's mission, vision, strategy, policies and processes throughout the organization;
- create and sustain shared values, fairness, trust and performance measures at all levels of the organization;
- establish a quality culture and ethical behaviour;
- encourage an organization-wide commitment to quality;
- ensure that leaders at all levels are positive examples to people in the organization;
- encourage a risk approach to proactively address issues to enhance desirable effects;
- provide people with the required resources, training and authority to act with accountability;
- inspire, encourage and recognize the contribution of people.

2.2.4 Engagement of people

2.2.4.1 Statement

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value for customers and other relevant interested parties.

2.2.4.2 Rationale

In order to manage an organization effectively and efficiently, it is important to respect and involve all people at all levels. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives.

2.2.4.3 Key benefits

Some potential key benefits are:

- improved understanding of the organization's quality objectives by people in the organization and increased motivation to achieve them;
- enhanced involvement of people in improvement activities;
- enhanced personal development, initiatives and creativity;
- enhanced people satisfaction;
- enhanced trust and collaboration throughout the organization;

- increased attention to shared values and culture throughout the organization.

2.2.4.4 Possible actions

Possible actions include:

- communicate with people to promote understanding and awareness of the importance of their individual contribution;
- promote collaboration throughout the organization;
- facilitate open discussion and sharing of knowledge and experience;
- empower people to determine constraints to performance and to take initiatives without fear;
- recognize and acknowledge people's motivation, contribution, learning and improvement;
- enable self-evaluation of performance against personal objectives;
- conduct surveys to assess people's satisfaction, communicate the results and take appropriate actions.

2.2.5 Process approach

2.2.5.1 Statement

Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

2.2.5.2 Rationale

The QMS consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.

2.2.5.3 Key benefits

Some potential key benefits are:

- enhanced ability to focus effort on key processes and opportunities for improvement;
- consistent and predictable outcomes through a system of aligned processes;
- optimized performance through effective process management, efficient use of resources and reduced cross-functional barriers;
- enabling the organization to provide confidence to interested parties related to its consistency, effectiveness and efficiency.

2.2.5.4 Possible actions

Possible actions include:

- define objectives of the system and processes necessary to achieve them;
- establish authority, responsibility and accountability for managing processes;
- understand the organization's capabilities and determine resource constraints prior to action;
- determine process interdependencies and analyse the effect of modifications to individual processes on the system as a whole;
- manage processes and their interrelations as a system to achieve the organization's quality objectives effectively and efficiently;

- ensure the necessary information is available to operate and improve the processes and to monitor, analyse and evaluate the performance of the overall system;
- manage risks which can affect outputs of the processes and overall outcomes of the QMS.

2.2.6 Improvement

2.2.6.1 Statement

Successful organizations have an ongoing focus on improvement.

2.2.6.2 Rationale

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

2.2.6.3 Key benefits

Some potential key benefits are:

- improved process performance, organizational capability and customer satisfaction;
- enhanced focus on root cause investigation and determination, followed by prevention and corrective actions;
- enhanced ability to anticipate and react to internal and external risks and opportunities;
- enhanced consideration of both incremental and breakthrough improvement;
- improved use of learning for improvement;
- enhanced drive for innovation.

2.2.6.4 Possible actions

Possible actions include:

- promote establishment of improvement objectives at all levels of the organization;
- educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement objectives;
- ensure people are competent to successfully promote and complete improvement projects;
- develop and deploy processes to implement improvement projects throughout the organization;
- track, review and audit the planning, implementation, completion and results of improvement projects;
- integrate improvement consideration into development of new or modified products and services and processes;
- recognize and acknowledge improvement.

2.2.7 Evidence-based decision making

2.2.7.1 Statement

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results and lead the organization to improve.

2.2.7.2 Rationale

Decision-making can be a complex process and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making for the benefit of all the organization's interested parties.

2.2.7.3 Key benefits

Some potential key benefits are:

- improved decision making processes;
- improved assessment of process performance and ability to achieve objectives;
- improved operational effectiveness and efficiency;
- increased ability to review, challenge and change opinions and decisions;
- increased ability to demonstrate the effectiveness of past decisions.

2.2.7.4 Possible actions

Possible actions include:

- determine, measure and monitor key indicators to demonstrate the organization's performance;
- make all data needed available to the relevant people;
- ensure that data and information are sufficiently accurate, reliable and secure, and available when needed;
- analyse and evaluate data and information using suitable methods;
- ensure people are competent to analyse and evaluate data as needed;
- make decisions and take actions based on evidence, balanced with experience and intuition.

2.2.8 Relationship management

2.2.8.1 Statement

For sustained success, organizations manage their relationships with relevant interested parties.

2.2.8.2 Rationale

Relevant interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its provider and partner networks is of particular importance.

2.2.8.3 Key benefits

Some potential key benefits are:

- enhanced performance of the organization and its relevant interested parties through responding to the opportunities and constraints related to each interested party;
- common understanding of objectives and values among interested parties;
- increased capability to create value for interested parties by sharing resources and competence and managing relevant risks;

- a well-managed supply chain that provides a stable flow of products and services.

2.2.8.4 Possible actions

Possible actions include:

- determine relevant interested parties (such as providers, partners, customers, regulatory agencies, investors, employees, communities or society as a whole) and their relationship with the organization;
- determine and prioritize interested party relationships that need to be managed;
- establish relationships that balance short-term gains with long-term considerations;
- gather and share information, expertise and resources with relevant interested parties;
- measure performance and provide performance feedback to interested parties, as appropriate, to enhance improvement initiatives;
- establish collaborative development and improvement activities with providers, partners and other interested parties;
- encourage and recognize improvements and achievements by providers and partners.

2.3 Fundamental quality management concepts

2.3.1 Quality

The *quality* of an organization's products and services is determined by the extent to which they satisfy customers, and their intended and unintended impacts on relevant interested parties. Users of a product or service may therefore experience good or poor quality, acceptable or unacceptable quality.

The quality of products and services influences not only their intended function and performance, but also their perceived value and benefit to the customer.

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

2.3.2 Quality management

Quality management is the part of overall management of an organization that applies the processes of quality planning, quality control, quality assurance and quality improvement to achieving its intended results. It is about managing the organization so that it meets the needs and expectations of its customers and other relevant interested parties.

Quality management focuses on customers, while at the same time enhances engagement of people in the organization and maintains effective relationships with other relevant interested parties. It supports leadership in the development of policies and practices, as well as maintaining a commitment to evidence-based decision-making. It provides a basis for ongoing development and improvement of processes within a coherent quality management system, so that interrelationships and interactions among processes can be managed effectively and efficiently. The quality management principles when applied together form the foundation of quality management and a quality culture in the organization.

2.3.3 Quality management system

The quality management system (QMS) provides a framework of interacting and interrelated processes and resources required to deliver value and realize results for relevant interested parties. A QMS is used to manage activities by which the organization determines quality objectives, processes, and resources by those whose work affects product and service quality to achieve intended results.

Implementing a QMS enables top management to optimize the use of resources, considering the long- and short-term consequences of their decision. It provides the means to determine risks and opportunities, and actions to address intended and unintended consequences in providing products and services.

Maintaining and continually improving a quality management system enables organisations to improve their performance, while providing confidence in their capabilities to relevant interested parties. This may also provide a competitive advantage.

A QMS can ensure that all activities of an organisation are aligned and make people aware of what is required of them to achieve intended results. This can increase engagement of people and assist in establishing a strong quality culture.

2.3.4 Quality assurance

Quality assurance is the part of quality management that provides customers and other relevant interested parties with a basis for confidence that their needs and expectations will be fulfilled. This can be achieved by providing evidence of the effectiveness of the quality management system, and the processes involved in the delivery of products and services. This can be done by providing results of relevant process monitoring and measurement activities.

Confidence that needs and expectations will be fulfilled is an important aspect of the relationship of organizations with its customers and other relevant interested parties. This applies to both current and future relationships. Consistency between what is promised and what is delivered provides a basis for future customer loyalty and support by relevant interested parties. Effective quality assurance also provides people within the organization with confidence that they are acting with ethics and integrity in the relationship between the organization and its customers and other relevant interested parties.

2.3.5 Quality control

Quality control is the part of quality management that deals with ensuring that the organization consistently meets requirements for products and services. Effective quality control confirms that criteria for processes, products and services are met and that intended outputs are delivered. Information from quality control activities provides inputs to quality assurance and quality improvement.

Quality control activities can be planned to be appropriate to the nature and complexity of processes, products and services. By controlling key aspects of processes, quality control can be consistent with optimising the use of the skills of competent people.

Meeting the needs and expectations of customers and other relevant interested parties is the quality objective that usually has the greatest effect on the success and reputation of an organization. Effective quality control is essential to achieving this quality objective, while preventing or reducing undesired effects for both the organization itself and its relevant interested parties.

Information from quality control activities is important in providing a basis for confidence in the effectiveness of quality management and the ongoing improvement of processes, products, and services.

2.3.6 Quality planning

Quality planning is the building block of subsequent quality management activities aimed at controlling, assuring or improving the quality of an organisation's products or services. In general terms quality planning relates to two different activities:

- Ensuring there are a clear set of requirements for the product or service to be supplied
- Ensuring there is a specified sequence and interaction of processes to realise the product and/or service.

Like in other fundamental concepts, quality planning is scalable, and quality plans can be nested. Quality planning can occur at the system level, as if one were designing the QMS for a new business, or they can occur at the level of an individual process or within a specific project. The detail required in quality plans can vary from industry to industry, as well as the point in the development cycle of a new product or service.

Quality planning is important because it connects quality control arrangements to the needs of the customer or market. ISO quality management standards are primarily concerned with the notion of conformance quality, but conformity to specification is insufficient if the specification is not what the customer wants. Quality planning expresses the voice of the customer into the planned quality management arrangements of a business and is a precursor to an effective QMS. As a result of quality planning an organisation can assure itself that it has produced the right outputs in the right way.

2.3.7 Process management

Process management is a systematic approach and methodology that focusses on activities carried out within processes, rather than within organisational structures. Process management recognises that processes may cross functional boundaries and may have various interactions and interrelationships with other processes.

Process management is the practice of planning, implementing, controlling and improving processes to ensure they achieve the organization's goals and objectives. Process management enables process inputs, activities and outputs to be managed coherently across functional boundaries. Interrelated processes can be managed so that intended results are achieved efficiently and effectively.

Process management can add value by allowing for better resource allocation, monitoring of performance, and continual improvement through analysis and optimization of processes.

2.3.8 Risk-based thinking

Risk-based thinking in quality management takes a preventive approach to potential problems and barriers to achieving planned results. It involves the consideration of the potential benefits and harms of exercising one choice of action over another when faced with a possibility of something not going as intended, including a missed opportunity. Risk-based thinking promotes a commitment in the organization to prioritising and managing the likely effects of uncertainty at all levels of the organization.

Risk-based thinking leads to better informed decision-making when planning and performing activities. Promoting risk-based thinking throughout the organization assists people to focus on improving how work is done. Using risk-based thinking also enables the organization to avoid unnecessary complexity by minimizing the negative consequences of risk and taking advantage of opportunities.

2.3.9 Organizational quality culture

Organizational quality culture refers to the shared values, beliefs, history, attitudes and observed behaviours of people within an organization. This is influenced and consistently reinforced through the behaviours and attitudes of people at any level of the organization. Evidence of top management commitment to quality management concepts and principles, including ethics and integrity, is essential. Many organizations express the aspects of the culture they aspire to through statements such as its mission, vision, and values.

A well-founded organizational quality culture enables people to work together more effectively to meet the needs of customers and other interested parties. A shared commitment to improvement promotes positive relationships within the organization and with external providers, partnering organizations and the community. It is important to note that an organization's quality culture may be heavily influenced and expressed within the context of local customs and cultures.

A quality-focused culture can provide benefits including an improved work environment, a competitive edge, efficient and effective performance, team cohesiveness, high morale, and strong alignment towards goal achievement. Organizational quality culture influences the way people interact with each other and their customers, the context within which knowledge is created, and the way people share (or do not share) it, and the adaptability to change. An organizational quality culture is an important aspect of quality management, including the effective establishment and maintenance of a QMS.

2.3.10 Continual improvement

Continual improvement is a recurring activity to enhance performance which can take place intermittently, frequently or regularly. It is not a one-off activity. Continual improvement can be applied to any aspect of quality management and encompasses all types of improvement methodologies.

A consistent focus on improvement at all levels of an organization promotes commitment to meeting the needs and expectations of customers and other relevant interested parties. Through continual improvement, an organization consistently uses its knowledge of current performance to plan improvement opportunities. This can result in optimising the benefits of achieving objectives and delivering value. An organization that embraces continual improvement demonstrates its commitment to achieving better results.

2.4 Additional concepts relevant to quality management

2.4.1 Context of an organization

Organizations exist within, and are influenced by, the context of the operating environment in which they work. Understanding the context considers internal issues such as values, organizational culture and history, knowledge and performance of the organization. It also considers external issues such as legal, technological, competitive, market, cultural, impact of climate change, social, economic, environmental, and governmental.

By understanding its context, the organization determines issues which influence its ability to achieve the planned quality objectives.. Further, it provides clarity to the organization to manage its risks and opportunities and satisfy relevant interested parties.

2.4.2 Interested parties

Interested parties refer to individuals, groups, or organizations that are affected by or can affect the performance or sustained success of organizations products or services. These parties can, for example, include customers, people in the organization, suppliers, shareholders, regulators, and the community at large. The relevant interested parties are those that can provide a significant opportunity to organizational sustained success if their needs and expectations are met, and a risk if they are not.

Part of the process for understanding the context of the organization is to identify relevant interested parties, their needs and expectations, and their effect on the organization. The concept of interested parties extends the focus of quality management beyond the customer alone.

By engaging and building positive relationships with interested parties, organizations can, for example, improve their overall performance and reputation, anticipate and mitigate potential risks, improve strategic decision-making, support the development of effective organizational strategies and ensure compliance with relevant laws, regulations and standards.

2.4.3 Integrated management system

An integrated management system unifies an organization's functions, processes, and management systems to enable achievement of the objectives of the organization and to meet the needs and expectations of relevant interested parties.

These objectives can include product and service quality, operational efficiency, environmental performance, information security, and health and safety in the workplace.

Having an integrated management system helps organizations improve performance by providing a comprehensive view of the inputs from the various functional disciplines while designing and executing effective processes. It also facilitates a more efficient assignment and prioritization of resources and can help to reduce waste or conflicting information.

Examples of benefits include, aligned objectives and policies, increased efficiency and effectiveness, reduction in costs, and improved communication leading to a strengthened organizational culture.

2.4.4 Circular economy

The circular economy includes a wide variety of topics by decoupling economic activity from the consumption of finite resources. Its objective is to maintain the greatest usefulness and value of existing resources, thus contributing to sustainability and the reduction of waste generated by the system. In this model, products and materials are kept in circulation through processes such as maintenance, reuse, refurbishment, remanufacture, recycling, and composting.

A circular economy involves the design of products that can be used, repaired, re-used or the components recycled thereby minimising the use of raw materials. It also requires a rethinking of design and development, production and service provision, resource traceability, and the incorporation of post-consumer materials. This change requires adjustments in processes throughout the product life cycle.

A circular economy goes beyond the model of “take, make, use and dispose” and focuses on positive benefits for all of society. Effective communication highlighting an organization’s commitment towards sustainability can enhance people engagement within the organization and its reputation with, and accountability to, interested parties.

Using a life cycle perspective, the circular model generates economic, natural and social capital based on three principles: design to eliminate waste and pollution; keep products and materials in use; and regenerate natural systems. This aims to tackle global challenges such as climate change, biodiversity loss, waste, and pollution to reduce the consumption of finite resources.

2.4.5 Emerging technologies

Emerging technologies are the result of the evolution of knowledge based on experience to solve problems more efficiently and effectively.

Emerging technologies are new and innovative technologies or an improvement of an already existing technology. They can have the potential to significantly impact various aspects of society, economic sectors and organizations in the future. These technologies often have the capacity to disrupt traditional methods and create new opportunities for organizations and individuals.

Emerging technologies are characterized by radical innovation either in their application or in their origins, with relatively rapid, coherent growth, with high impact and uncertainty in their application.

Emerging technologies play a crucial role in quality management because they can enable organizations to streamline processes, improve efficiency, and enhance overall performance. These technologies provide advanced methods that can help organizations determine and address quality requirements more effectively, ultimately leading to better processes, products, and services.

Emerging technologies can also help organizations stay ahead of the competition by enabling them to adapt quickly to changing market trends and customer expectations. Regardless of the technologies used, there are issues that must be considered, such as design, dependability, information security, resources, organizational knowledge, competence and change management.

2.4.6 Innovation

Innovation can result in added value for customers and/or other relevant interested parties. The first step toward innovation can be an understanding of needs and expectations (stated or unstated). From there, innovation can be achieved through new or changed products or services, performance, processes, or market position, enabling realization or redistribution of value.

Innovation is changes in technology, products or services, processes, structure of the organization, business models and management systems. It is beneficial to have a systematic approach, rather than random innovation activity.

The opportunity and practicality of innovation can vary depending on various factors such as the organization's size, industry, culture, resources, and market conditions.

Innovation is a way to meet new or anticipated needs and expectations of customers and other relevant interested parties and also can enhance sustainability.

Innovation is a key factor to enhance efficiency and effectiveness, quality, (sustained growth), value to customers and other interested parties, and the ability to address risks and opportunities.

Innovation can provide a competitive advantage by increasing productivity, reducing cost and solving complex business problems.

2.4.7 Change management

Implicit in any organization is the inevitability of change. Change, in and of itself, is neutral. It may have its origins in the action of an external interested party or from an internal decision. However, inherent in changes are either risks or opportunities. A quality management system provides the infrastructure within which organizations may identify both risks and opportunities. Processes should facilitate their ability to address both. These would include implementation of actions to mitigate or avoid risks, and implementation of actions to achieve optimum outcomes from improvement opportunities.

Change management is a process or group of processes that an organization may use to facilitate the implementation and control of change within the organization to improve performance, mitigate or avoid adverse outcomes and achieve intended results. This involves identifying the need for change, developing a strategy for managing the change, engaging and communicating with people in the organization, and providing support and training to implement the change.

Change management can be applied at all levels of the organization. The change can be a result of an internal decision or the response to an external issue from an interested party that affects the organization.

Change management supports the effective control of processes, to adapt to the environment and improve organizational performance, thus mitigating risk and optimizing results. It includes important issues to be considered and managed such as human, social, and cultural aspects along with technological and structural aspects.

Change management helps organizations navigate the complex process of change, minimize resistance, increase engagement of people, ensure continuity, improve communication, and increase the likelihood of successful outcomes.

2.4.8 Customer experience

Customer experience reflects how a customer feels about an organization. It includes the emotional, physical, psychological connection customers have with the product or service provided.

Customer experience extends through the full life cycle of the organization's engagement with the customer, including all interactions, from first discovering and researching a product or service, to its purchase, use and associated follow up.

An organization that focuses on the total interaction with its customers can better understand and identify opportunities for enhancing the entirety of the customer experience. This helps to improve customer satisfaction and loyalty that may not always be achieved by solely fulfilling stated needs and expectations.

For example, putting the customer first, building trust and personal relationships, creating more user-friendly interactions, can enhance the customer experience beyond what can be achieved through product or service performance alone.

2.4.9 Knowledge management

Knowledge is an intangible organizational asset that, like any other asset, needs to be managed. Knowledge management is the process established to acquire, create, retain, use, maintain, protect, and share knowledge within organizations. Knowledge may include experience, expertise and information held by individuals or groups. Knowledge management aids consistent performance over time, despite changing availability of people and their knowledge. To protect loss of knowledge in the organization it is important to obtain,

manage, and share knowledge in a systematic way. It helps the organization achieve its objectives and create value by improving the organization's efficiency, effectiveness and sustainability.

Knowledge management ensures that valuable insights and experiences are not lost but are accessible at the point of use to people in the organization. It supports continual improvement and innovation by enabling organizations to learn from past experiences and adapt to changing environments.

2.4.10 Information management

Information comprises meaningful facts about anything perceivable or conceivable. The accuracy, relevance, timeliness, completeness, and accessibility of information significantly impacts quality management. Information management controls the acquisition, integrity, storage, preservation, and protection of data, and can prevent the misuse of an organization's information. It supports decision-making and operational efficiency by providing reliable and timely information.

Information management ensures the integrity, storage, and protection of data. The adequacy of information management can impact such things as the fulfilment of interested parties' needs and expectations and affect customer satisfaction/loyalty, compliance with legislation, reputation of the organization, etc. Effective management of information is a key performance factor in quality management. Many processes are dependent on the availability of accurate information at the point of use and decision making. Protecting the integrity of information is important for proper and consistent use, especially where there is immediacy between the generation and consumption of information.

Information beyond the immediate control of the organization, such as that generated through external sources, may impact the context of the organization. It is also important to consider and provide safeguards to protect data, including personal data, from malicious entities which may create legal, financial, or performance disruptions.

2.4.11 People aspects

People aspects deal with the provision of necessary supporting personnel resources within an organization and allows the organization to operate a quality management system that will assist it to function efficiently and effectively. Responsible acquisition, deployment, maintenance, enhancement, and disposition of such personnel resources supports the organization in achieving its objectives.

Communication between top management and people enhances their engagement in the QMS. Planned and effective internal (i.e. throughout the organization) and external (i.e. with relevant interested parties) communication increases understanding of the context of the organization, the needs and expectations of customers and other relevant interested parties and the QMS itself.

The engagement of people within the QMS enables the organization to provide the necessary human resources, monitor processes and results, determine and evaluate risks or opportunities and implement appropriate actions. People are essential resources within the organization. The performance of the organization is dependent upon how people understand and behave within the system in which they work.

It is important that people gain the appropriate competence to work within the quality system, and that they understand and apply the skills, training, education and experience needed to perform their roles and responsibilities to the highest degree possible. It is the responsibility of top management to provide opportunities for people to develop these necessary competencies, so that they will understand their responsibilities and how their actions contribute to the achievement of the organization's objectives.

2.4.12 Business continuity

In today's world it is imperative to develop strategies and plans for business continuity in preparation for dealing with natural or man-made disasters that may inflict the company. Businesses can no longer afford long waits to resume operation after such calamities.

In fact, it is prudent for any company to ensure its customers that it has diligently reviewed the risks associated with existing or potential threats present in and around its facilities. Once the impact of such

threats and risks are identified, a plan of action in the form of a business continuity plan can be introduced to eliminate, or at least minimize, the identified risks.

Despite recent trends that have made businesses more reliant on technology, it's important to remember that business continuity management covers a broader spectrum of issues such as risk management, disaster recovery, facilities management, supply chain management, quality management, health & safety, knowledge management, emergency management, security, training, exercises, crisis communications, and public relations.

The need for business continuity planning has been highlighted recently by the continuing rapid increase in the dependency of business on technology and the series of headline-grabbing, thought-provoking disasters witnessed in recent years, caused by and including acts of nature (floods, earthquakes, tornadoes, etc.), man-made events (fire, explosion, sabotage, terrorist acts, etc.), and infrastructure failure (power outages, telecom outages, water/sewage system breakdown, major computer processing disruption, etc.).

Customer satisfaction, and ensuring that the customers succeed, is a key element on any organization's strategy map. Corporate reputation and customer loyalty can be destroyed in a relatively short period of time if a given disaster is allowed to overwhelm the normal operational and management system of a business.

Companies around the world have been put on notice that disasters of various scenarios, be it physical, financial, cyber-based or arising from other natural or man-made sources, are now a matter of fact, and that proactive planning in all facets of business continuity must be a way of life for every corporation.

The need for a well-structured and thoughtful business continuity plan has never been so great as in the time period we live in. Businesses need to pay attention to providing such planning. Buy-in from the most senior level of management is critical. It is no longer a nice thing to have but rather a necessity for any modern business.

There is no doubt that having a business continuity plan is essential. The plan becomes a source of reference at a time of a business continuity event or crisis and the blueprint upon which the strategy and tactics for dealing with a crisis are designed. In particular, it can provide essential guidance on damage limitation in those short windows of opportunity at the beginning of a crisis.

Business continuity plans are strategic in their application, and they aim to keep the facility up and running after it has sustained certain damages.

2.5 Developing the QMS using fundamental concepts and principles

2.5.1 Attributes of a QMS

2.5.1.1 General

Organizations are adaptive and are comprised of systems, processes, and activities as they interact with their environment. To adapt to their varying context, each organization needs the ability to change. Developing a QMS can give people in the organization tools and perspectives to manage complexity and promote innovation and development.

Organizations often innovate to achieve breakthrough improvements. Not all systems, processes and activities can be predetermined; therefore, an organization's QMS needs to be flexible and adaptable within the complexities of the context of the organization.

2.5.1.2 System

Organizations seek to understand the internal and external context to identify the needs and expectations of relevant interested parties. This information is used in the development of the QMS to achieve objectives and sustainability of the organization. The outputs from one process can be the inputs into other processes or can be used as information required for controlling the implementation of other processes and are interlinked into the overall network. Although often appearing to be comprised of similar processes, each organization and its QMS is unique.

2.5.1.3 Processes

The organization has processes within the QMS that can be defined, measured, and improved. These processes interact to deliver results consistent with expectations of relevant interested parties, organizational objectives and cross functional boundaries. Some processes can be critical while others are not. Processes have interrelated activities with inputs to deliver outputs.

2.5.1.4 Activity

People collaborate in a process to carry out their activities. Some activities are prescribed and depend on an understanding of the objectives of the organization and the expectations of interested parties. Some activities are not prescribed but depend on other inputs to determine their nature and execution.

2.5.2 Development of a QMS

A QMS is a dynamic system that evolves over time through periods of improvement. Every organization has policies and practices it uses to manage the quality of its products and services, whether they have been formally planned or not. This document provides information on developing a formal system to manage these activities. It is necessary to determine those which already exist in the organization and their suitability within the context of the organization. This document, along with ISO 9004 and ISO 9001, can then be used to assist the organization to develop a cohesive QMS.

A formal QMS provides a framework for planning, executing, monitoring and improving the performance of quality management activities. The QMS does not need to be complicated; rather it needs to accurately reflect the needs, objectives, and processes of the organization. In developing the QMS, the fundamental concepts and principles given in this document can provide valuable guidance.

QMS planning is not a singular event, rather it is an ongoing process. Plans evolve as the organization learns and circumstances change. A plan takes into account all quality management activities of the organization and ensures that it covers all guidance of this document and requirements of ISO 9001. The plan is implemented upon approval.

It is important for an organization to regularly monitor and evaluate both the implementation of the QMS and its performance. Carefully considered indicators facilitate these monitoring and evaluation activities.

Auditing is a means of evaluating the effectiveness of the QMS and its implementation, in order to identify risks and to determine the fulfilment of requirements. In order for audits to be effective, objective evidence needs to be collected. Actions are taken for correction and improvement based upon analysis of the evidence gathered. The knowledge gained could lead to innovation, taking the organization's performance to higher levels.

2.5.3 QMS standards, other management systems and organizational excellence models

The approaches to a QMS described in QMS standards developed by ISO/TC 176, in other management system standards and in organizational excellence models are based on common principles. They all enable an organization to identify risks and opportunities and contain guidance for improvement. In the current context, many issues such as innovation, ethics, trust and reputation could be regarded as parameters within the QMS. Standards related to quality management (e.g. ISO 9001), environmental management (e.g. ISO 14001) and energy management (e.g. ISO 50001), as well as other management standards and organizational excellence models, have addressed this.

The quality management and QMS standards developed by ISO/TC 176 provide a comprehensive set of requirements and guidelines for a QMS. ISO 9001 specifies requirements for a QMS. ISO 9004 provides guidance on a wide range of objectives of a QMS for sustainable success and improved performance. Requirements for a QMS are also provided in ISO sector-specific standards.

NOTE See <https://www.iso.org/committee/53882.html> for standards with guidelines for components of a QMS and technical subjects in support of a QMS.

The various parts of an organization's management system, including its QMS, can be integrated as a single management system. The objectives, processes and resources related to quality, growth, funding, profitability,

environment, occupational health and safety, energy, security and other aspects of the organization's activities can be more effectively and efficiently achieved and used when the QMS is integrated with other management systems. The organization can perform an integrated audit of its management system against the requirements of multiple International Standards, such as ISO 9001, ISO 14001, ISO/IEC 27001 and ISO 50001. ISO 19011 provides guidance on auditing an organization's management system.

NOTE The ISO handbook "The integrated use of management system standards" can provide useful guidance.

3 Terms and definitions

3.1 Terms related to management system

3.1.1

organization

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.1.6)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, *association* (3.2.6), charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organization is part of a larger entity, the term "organization" refers only to the part of the larger entity that is within the scope of the *quality management system* (3.5.9).

3.1.2

interested party

stakeholder

person or *organization* (3.1.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

EXAMPLE Customers (3.2.12), owners, people in an organization, *providers* (3.2.7), bankers, regulators, unions, partners or society that can include competitors or opposing pressure groups.

3.1.3

top management

person or group of people who directs and controls an *organization* (3.1.1) at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organization.

Note 2 to entry: If the scope of the *management system* (3.1.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.1.4

management system

set of interrelated or interacting elements of an *organization* (3.1.1) to establish *policies* (3.1.5) and *objectives* (3.1.6), and *processes* (3.1.8) to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The management system elements include the organization's structure, roles and responsibilities, planning and operation.

Note 3 to entry: The management system elements can include the organization's policies, practices, rules, and beliefs.

Note 4 to entry: An organization manages its interrelated elements in an orderly manner to achieve its objectives.

Note 5 to entry: The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations.

3.1.5

policy

{organization} intentions and direction of an *organization* (3.1.1) as formally expressed by its *top management* (3.1.4)

3.1.6

objective

result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and environment). They can be, for example, *organization* (3.1.1)-wide, or specific to a *project* (3.4.4), *product* (3.8.8), *service* (3.8.9) or *process* (3.4.1)).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as a *quality objective* (3.8.11) or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of a *quality management system* (3.5.9), *quality objectives* (3.8.11) are set by the *organization* (3.1.1), consistent with the *quality policy* (3.5.6), to achieve specific results.

3.1.7

risk

effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of *information* (3.8.2) related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events (as defined in ISO 31073:2022, 3.3.11) and consequences (as defined in ISO 31073:2022, 3.3.18), or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood (as defined in ISO 31073:2022, 3.3.16) of occurrence.

Note 5 to entry: The word “risk” is sometimes used when there is the possibility of only negative consequences.

3.1.8

process

set of interrelated or interacting activities that use inputs to deliver a result

Note 1 to entry: Whether the “intended result” of a process is called *output* (3.8.7), *product* (3.8.8) or *service* (3.8.9) depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

Note 4 to entry: Processes in an *organization* (3.1.1) are generally planned and carried out under controlled conditions to add value.

Note 5 to entry: A process where the *conformity* (3.1.15) of the resulting output cannot be readily or economically validated is frequently referred to as a “special process”.

3.1.9

competence

ability to apply *knowledge* (3.8.16) and *skills* (3.11.5) to achieve intended results

Note 1 to entry: Demonstrated competence is sometimes referred to as qualification.