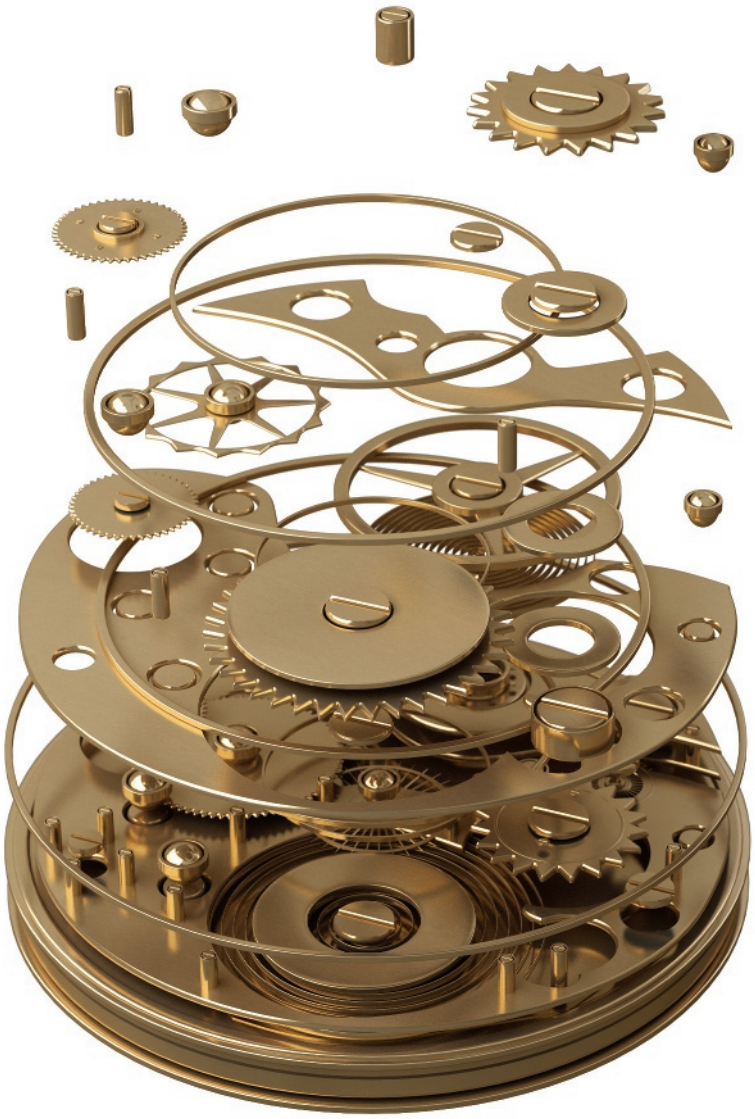
BSI Standards Publication

BS EN ISO 9000:2015

Quality management systems

Fundamentals and vocabulary



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National foreword

This British Standard is the UK implementation of EN ISO 9000:2015. It supersedes BS EN ISO 9000:2005 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee QS/1, Quality management and quality assurance procedures.

A list of organizations represented on this committee can be obtained on request to its secretary.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9000

September 2015

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English Version

Quality management systems - Fundamentals and vocabulary (ISO 9000:2015)

Systèmes de management de la qualité - Principes essentiels et vocabulaire (ISO 9000:2015)

Qualitätsmanagementsysteme - Grundlagen und Begriffe (ISO 9000:2015)

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European foreword

This document (EN ISO 9000:2015) has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2016, and conflicting national standards shall be withdrawn at the latest by March 2016.

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Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Fundamental concepts and quality management principles ... **1**
- 2.1 General ... 1
- 2.2 Fundamental concepts ... 2
  - 2.2.1 Quality ... 2
  - 2.2.2 Quality management system ... 2
  - 2.2.3 Context of an organization ... 2
  - 2.2.4 Interested parties ... 2
  - 2.2.5 Support ... 2
- 2.3 Quality management principles ... 3
  - 2.3.1 Customer focus ... 3
  - 2.3.2 Leadership ... 4
  - 2.3.3 Engagement of people ... 5
  - 2.3.4 Process approach ... 6
  - 2.3.5 Improvement ... 6
  - 2.3.6 Evidence-based decision making ... 7
  - 2.3.7 Relationship management ... 8
- 2.4 Developing the QMS using fundamental concepts and principles ... 9
  - 2.4.1 QMS model ... 9
  - 2.4.2 Development of a QMS ... 9
  - 2.4.3 QMS standards, other management systems and excellence models ... 10

3 Terms and definitions ... **10**
- 3.1 Terms related to person or people ... 10
- 3.2 Terms related to organization ... 11
- 3.3 Terms related to activity ... 13
- 3.4 Terms related to process ... 15
- 3.5 Terms related to system ... 16
- 3.6 Terms related to requirement ... 18
- 3.7 Terms related to result ... 20
- 3.8 Terms related to data, information and document ... 23
- 3.9 Terms related to customer ... 25
- 3.10 Terms related to characteristic ... 26
- 3.11 Terms related to determination ... 27
- 3.12 Terms related to action ... 29
- 3.13 Terms related to audit ... 30

Annex A (informative) **Concept relationships and their graphical representation** ... **33**

Bibliography ... **47**

Alphabetical index of terms ... **49**

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Full document details: BS EN ISO 9000:2015

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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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 fourth edition cancels and replaces the third edition (ISO 9000:2005), which has been technically revised.

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Introduction

This International Standard provides the fundamental concepts, principles and vocabulary for quality management systems (QMS) and provides the foundation for other QMS standards. This International Standard 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 other QMS standards.

This International Standard proposes a well-defined QMS, based on a framework that integrates established fundamental concepts, principles, processes and resources related to quality, 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 International Standard 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 International Standard contains the terms and definitions that apply to all quality management and QMS standards developed by ISO/TC 176, and other sector-specific QMS standards based on those standards, at the time of publication. The terms and definitions are arranged in conceptual order, with an alphabetical index provided at the end of the document. Annex A includes a set of diagrams of the concept systems that form the concept ordering.

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

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Quality management systems — Fundamentals and vocabulary

1 Scope

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

2 Fundamental concepts and quality management principles

2.1 General

The quality management concepts and principles described in this International Standard give the organization the capacity to meet challenges presented by an environment that is profoundly different from recent decades. The context in which an organization works today is characterized by accelerated change, globalization of markets and the emergence of knowledge as a principal resource. The impact of quality extends beyond customer satisfaction: it can also have a direct impact on the organization's reputation.

Society has become better educated and more demanding, making interested parties increasingly more influential. By providing fundamental concepts and principles to be used in the development of a quality management system (QMS), this International Standard provides a way of thinking about the organization more broadly.

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 one time, finding the right balance in application is critical.

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2.2 Fundamental concepts

2.2.1 Quality

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.

The quality of an organization's products and services is determined by the ability to satisfy customers and the intended and unintended impact on relevant interested parties.

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

2.2.2 Quality management system

A QMS comprises activities by which the organization identifies its objectives and determines the processes and resources required to achieve desired results.

The QMS manages the interacting processes and resources required to provide value and realize results for relevant interested parties.

The QMS enables top management to optimize the use of resources considering the long and short term consequences of their decision.

A QMS provides the means to identify actions to address intended and unintended consequences in providing products and services.

2.2.3 Context of an organization

Understanding the context of the organization is a process. This process determines factors which influence the organization's purpose, objectives and sustainability. It considers internal factors such as values, culture, knowledge and performance of the organization. It also considers external factors such as legal, technological, competitive, market, cultural, social and economic environments.

Examples of the ways in which an organization's purpose can be expressed include its vision, mission, policies and objectives.

2.2.4 Interested parties

The concept of interested parties extends beyond a focus solely on the customer. It is important to consider all relevant interested parties.

Part of the process for understanding the context of the organization is to identify its interested parties. The relevant interested parties are those that provide significant risk to organizational sustainability if their needs and expectations are not met. Organizations define what results are necessary to deliver to those relevant interested parties to reduce that risk.

Organizations attract, capture and retain the support of the relevant interested parties they depend upon for their success.

2.2.5 Support

2.2.5.1 General

Top management support of the QMS and engagement of people enables:

— provision of adequate human and other resources;

— monitoring processes and results;

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— determining and evaluating of risks and opportunities;

— implementing appropriate actions.

Responsible acquisition, deployment, maintenance, enhancement and disposal of resources support the organization in achieving its objectives.

2.2.5.2 People

People are essential resources within the organization. The performance of the organization is dependent upon how people behave within the system in which they work.

Within an organization, people become engaged and aligned through a common understanding of the quality policy and the organization's desired results.

2.2.5.3 Competence

A QMS is most effective when all employees understand and apply the skills, training, education and experience needed to perform their roles and responsibilities. It is the responsibility of top management to provide opportunities for people to develop these necessary competencies.

2.2.5.4 Awareness

Awareness is attained when people understand their responsibilities and how their actions contribute to the achievement of the organization's objectives.

2.2.5.5 Communication

Planned and effective internal (i.e. throughout the organization) and external (i.e. with relevant interested parties) communication enhances people's engagement and increased understanding of:

— the context of the organization;

— the needs and expectations of customers and other relevant interested parties;

— the QMS.

2.3 Quality management principles

2.3.1 Customer focus

2.3.1.1 Statement

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

2.3.1.2 Rationale

Sustained success is achieved when an organization attracts and retains the confidence of customers and other relevant interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to the sustained success of the organization.

2.3.1.3 Key benefits

Some potential key benefits are:

— increased customer value;

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— increased customer satisfaction;

— improved customer loyalty;

— enhanced repeat business;

— enhanced reputation of the organization;

— expanded customer base;

— increased revenue and market share.

2.3.1.4 Possible actions

Possible actions include:

— recognize direct and indirect customers as those who receive value from the organization;

— understand customers' current and future needs and expectations;

— link the organization's objectives to customer needs and expectations;

— communicate customer needs and expectations throughout the organization;

— plan, design, develop, produce, deliver and support products and services to meet customer needs and expectations;

— measure and monitor customer satisfaction and take appropriate actions;

— determine and take action on relevant interested parties' needs and appropriate expectations that can affect customer satisfaction;

— actively manage relationships with customers to achieve sustained success.

2.3.2 Leadership

2.3.2.1 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.

2.3.2.2 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.

2.3.2.3 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.

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2.3.2.4 Possible actions

Possible actions include:

— communicate the organization's mission, vision, strategy, policies and processes throughout the organization;

— create and sustain shared values, fairness and ethical models for behaviour at all levels of the organization;

— establish a culture of trust and integrity;

— encourage an organization-wide commitment to quality;

— ensure that leaders at all levels are positive examples to people in the organization;

— provide people with the required resources, training and authority to act with accountability;

— inspire, encourage and recognize the contribution of people.

2.3.3 Engagement of people

2.3.3.1 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.

2.3.3.2 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.

2.3.3.3 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.

2.3.3.4 Possible actions

Possible actions include:

— communicate with people to promote understanding 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;

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— recognize and acknowledge people's 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.

2.3.4 Process approach

2.3.4.1 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.

2.3.4.2 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.

2.3.4.3 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.

2.3.4.4 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.

2.3.5 Improvement

2.3.5.1 Statement

Successful organizations have an ongoing focus on improvement.

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2.3.5.2 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.

2.3.5.3 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.

2.3.5.4 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.

2.3.6 Evidence-based decision making

2.3.6.1 Statement

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

2.3.6.2 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.

2.3.6.3 Key benefits

Some potential key benefits are:

— improved decision making processes;

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— 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.

2.3.6.4 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;

— 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.

2.3.7 Relationship management

2.3.7.1 Statement

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

2.3.7.2 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.

2.3.7.3 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 quality related risks;

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

2.3.7.4 Possible actions

Possible actions include:

— determine relevant interested parties (such as providers, partners, customers, investors, employees or society as a whole) and their relationship with the organization;

— determine and prioritize interested party relationships that need to be managed;

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— 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.

2.4 Developing the QMS using fundamental concepts and principles

2.4.1 QMS model

2.4.1.1 General

Organizations share many characteristics with humans as a living and learning social organism. Both are adaptive and comprise interacting systems, processes and activities. In order to adapt to their varying context, each needs the ability to change. Organizations often innovate to achieve breakthrough improvements. An organization's QMS model recognizes that not all systems, processes and activities can be predetermined; therefore it needs to be flexible and adaptable within the complexities of the organizational context.

2.4.1.2 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 organizational sustainability. The outputs from one process can be the inputs into 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.

2.4.1.3 Processes

The organization has processes that can be defined, measured and improved. These processes interact to deliver results consistent with the organization's objectives and cross functional boundaries. Some processes can be critical while others are not. Processes have interrelated activities with inputs to deliver outputs.

2.4.1.4 Activity

People collaborate within a process to carry out their daily activities. Some activities are prescribed and depend on an understanding of the objectives of the organization, while others are not and react to external stimuli to determine their nature and execution.

2.4.2 Development of a QMS

A QMS is a dynamic system that evolves over time through periods of improvement. Every organization has quality management activities, whether they have been formally planned or not. This International Standard provides guidance on how to develop a formal system to manage these activities. It is necessary to determine activities which already exist in the organization and their suitability regarding the context of the organization. This International Standard, 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

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reflect the needs of the organization. In developing the QMS, the fundamental concepts and principles given in this International Standard 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 activities of the organization and ensures that it covers all guidance of this International Standard 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 plan and the performance of the QMS. Carefully considered indicators facilitate these monitoring and evaluation activities.

Auditing is a means of evaluating the effectiveness of the QMS, in order to identify risks and to determine the fulfilment of requirements. In order for audits to be effective, tangible and intangible 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 QMS performance to higher levels.

2.4.3 QMS standards, other management systems and 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 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. Guidelines for components of a QMS include ISO 10001, ISO 10002, ISO 10003, ISO 10004, ISO 10008, ISO 10012 and ISO 19011. Guidelines for technical subjects in support of a QMS include ISO 10005, ISO 10006, ISO 10007, ISO 10014, ISO 10015, ISO 10018 and ISO 10019. Technical reports in support of a QMS include ISO/TR 10013 and ISO/TR 10017. Requirements for a QMS are also provided in sector-specific standards, such as ISO/TS 16949.

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 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.

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

3 Terms and definitions

3.1 Terms related to person or people

3.1.1
top management
person or group of people who directs and controls an *organization* (3.2.1) at the highest level

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

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Note 2 to entry: If the scope of the *management system* (3.5.3) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

Note 3 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1.

3.1.2
quality management system consultant
person who assists the *organization* (3.2.1) on *quality management system realization* (3.4.3), giving advice or *information* (3.8.2)

Note 1 to entry: The quality management system consultant can also assist in realizing parts of a *quality management system* (3.5.4).

Note 2 to entry: ISO 10019:2005 provides guidance on how to distinguish a competent quality management system consultant from one who is not competent.

[SOURCE: ISO 10019:2005, 3.2, modified]

3.1.3
involvement
taking part in an activity, event or situation

3.1.4
engagement
involvement (3.1.3) in, and contribution to, activities to achieve shared *objectives* (3.7.1)

3.1.5
configuration authority
configuration control board
dispositioning authority
person or a group of persons with assigned responsibility and authority to make decisions on the *configuration* (3.10.6)

Note 1 to entry: Relevant *interested parties* (3.2.3) within and outside the *organization* (3.2.1) should be represented on the configuration authority.

[SOURCE: ISO 10007:2003, 3.8, modified]

3.1.6
dispute resolver
<customer satisfaction> individual person assigned by a *DRP-provider* (3.2.7) to assist the parties in resolving a *dispute* (3.9.6)

EXAMPLE Staff, volunteer, *contract* (3.4.7) personnel.

[SOURCE: ISO 10003:2007, 3.7, modified]

3.2 Terms related to organization

3.2.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.7.1)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, *association* (3.2.8), charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified by modifying Note 1 to entry.

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