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Sixth edition

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Quality management systems — Requirements

COMMITTEE DRAFT 2

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

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Foreword

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

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

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 the 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 2, *Quality systems*.

This sixth edition cancels and replaces the fifth edition (ISO 9001:2015).

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Introduction

0.1 General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this document are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This document can be used by internal and external parties.

It is not the intent of this document to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this document;

— the use of the specific terminology of this document within the organization.

The quality management system requirements specified in this document are complementary to requirements for products and services.

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This document employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise.

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

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— “may” indicates a permission;

— “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

Annex A provides information and clarifications that can support understanding of the requirements of this document. This is an informative annex and does not reflect any additional requirements.

The explanatory information is given only on clauses needing clarification.

For guidance on the application of all clauses see ISO 9002:-

0.2 Quality management principles

This document is based on the quality management principles described in ISO/CD 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

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0.3 Process approach

0.3.1 General

This document promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle

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(see) with an overall focus on risk-based thinking (see A.6.1.2) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring check points, which are necessary for control, are specific to each process and will vary depending on the related risks.

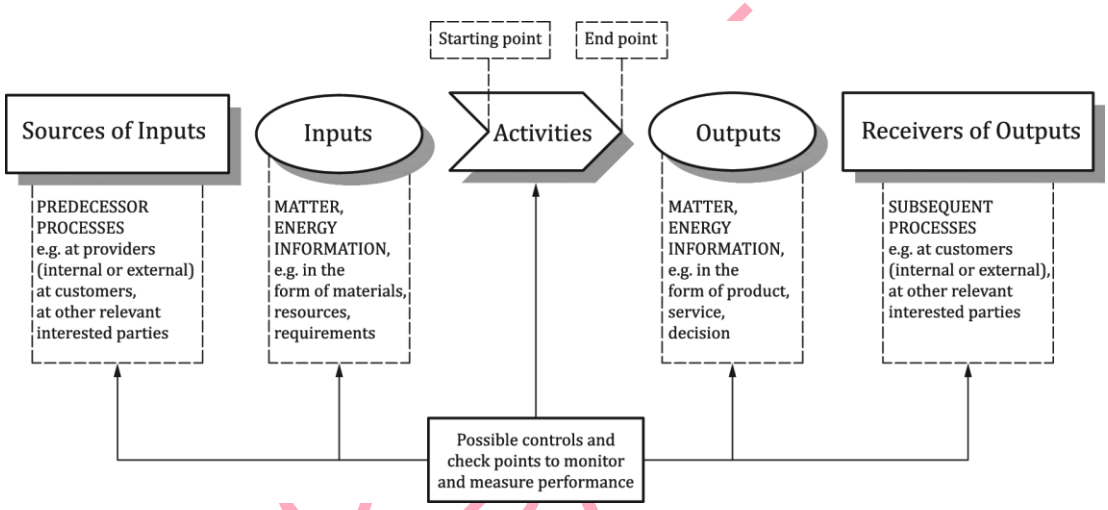
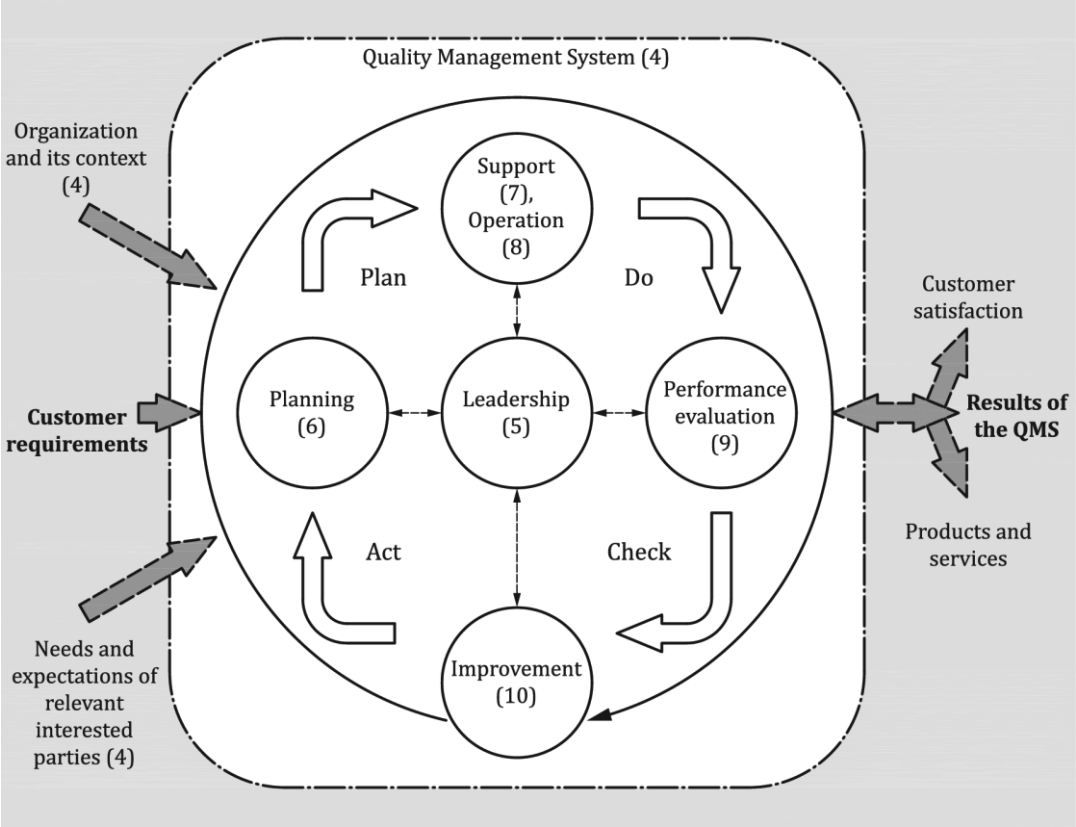


Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clause 4 to Clause 10 of this document can be grouped in relation to the PDCA cycle.

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NOTE Numbers in brackets refer to the clauses in this document.

Figure 2 — Representation of the structure of this document in the PDCA cycle

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The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

0.4 Relationship with other management system standards

This document applies the harmonized structure to improve alignment among its management systems standards.

This document enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This document relates to ISO/CD 9000and ISO 9004 as follows:

— ISO/CD 9000*Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this document;

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— ISO 9004[1] *Quality management – Quality of an organization – Guidance to achieve sustained success* provides guidance for organizations that choose to progress beyond the requirements of this document.

This document does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, or financial management.

Sector-specific quality management system standards based on the requirements of this document have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this document within the particular sector.

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Quality management systems — Requirements

1 Scope

This document specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this document are generic and are intended to be applicable to any organization.

This document is applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this document, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

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2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/CD 9000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/CD 9000 including the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses: • ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its *objectives* (3.6)

Note 1 to entry: The concept of organization includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, 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* (3.4.1).

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3.2
interested party (preferred term)
stakeholder
person or *organization* (3.1) that can affect, be affected by, or perceive itself to be affected by a decision or activity

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

3.3
top management
person or group of people who directs and controls an *organization* (3.1) 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* (3.4) covers only part of an organization, then top management refers to those who direct and control that part of the organization.

3.4
management system
set of interrelated or interacting elements of an *organization* (3.1) to establish policies (3.5) and *objectives* (3.6), as well as *process* (3.8) 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.

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3.4.1
quality management system
part of a *management system* (3.4) with regard to quality

3.5
policy
intentions and direction of an *organization* (3.1) as formally expressed by its *top management* (3.3)

3.5.1
quality policy
policy (3.5) related to quality

Note 1 to entry: Generally the quality policy is consistent with the overall policy of the *organization* (3.1), can be aligned with the organization's vision and mission and provides a framework for the setting of *quality objective* (3.6.1).

Note 2 to entry: Quality management principles presented in ISO/CD 9000 can form a basis for the establishment of a quality policy.

3.6
objective
result to be achieved

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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-wide or specific to a project, product, service, or *process* (3.8).

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* (3.6.1)or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of *quality management system* (3.4.1), *quality objective* (3.6.1) are set by the *organization* (3.1), consistent with the *quality policy* (3.5.1), to achieve specific results.

3.6.1
quality objective
objective (3.6) related to quality

Note 1 to entry: Quality objectives are generally based on the *organization's* (3.1)*quality policy* (3.5.1).

Note 2 to entry: Quality objectives are generally specified for relevant functions, levels and *processes* (3.8) in the organization.

3.7
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 related to, understanding or knowledge of an event, its consequence, or likelihood.

Note 3 to entry: *risk* (3.7) is often characterized by reference to potential events (as defined in ISO 31073:2022[2], 3.3.11) and consequences (as defined in ISO 31073:2022[2], 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[2], 3.3.16) of occurrence.

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

3.8
process
set of interrelated or interacting activities that uses or transforms inputs to deliver a result

Note 1 to entry: Whether the result of a process is called an output, a product or a service 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) are generally planned and carried out under controlled conditions to add value.

Note 5 to entry: A process where the *conformity* (3.15) of the resulting output cannot be readily or economically validated is frequently referred to as a "special process".

3.9
competence
ability to apply knowledge and skills to achieve intended results

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

3.10
documented information
information required to be controlled and maintained by an *organization* (3.1) and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

— the *management system* (3.4), including related *process* (3.8);

— information created in order for the organization to operate (documentation);

— evidence of results achieved (records).

3.11
performance
measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, *processes* (3.8), products, services, systems or *organizations* (3.1).

3.12
continual improvement
recurring activity to enhance *performance* (3.11)

Note 1 to entry: The *process* (3.8) of establishing *objective* (3.6) and finding opportunities for improvement is a continual process through the use of audit findings and audit conclusions, analysis of data, management reviews or other means and generally leads to *corrective action* (3.17) or preventive action.

3.13
effectiveness
extent to which planned activities are realized and planned results are achieved

3.14
requirement
need or expectation that is stated, generally implied or obligatory

Note 1 to entry: "Generally implied" means that it is custom or common practice for the *organization* (3.1) and *interested party (preferred term)* (3.2) that the need or expectation under consideration is implied.

Note 2 to entry: A specified requirement is one that is stated, e.g. in *documented information* (3.10).

Note 3 to entry: A qualifier can be used to denote a specific type of requirement, e.g. product requirement, quality management requirement, customer requirement, quality requirement.

Note 4 to entry: Requirements can be generated by different interested parties or by the organization itself.

Note 5 to entry: It can be necessary for achieving high customer satisfaction to fulfil an expectation of a customer even if it is neither stated nor generally implied or obligatory.

3.15
conformity
fulfilment of a *requirement* (3.14)

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Note 1 to entry: In English the word “conformance” is synonymous but deprecated. In French the word “compliance” is synonymous but deprecated.

3.16
nonconformity
non-fulfilment of a *requirement* (3.14)

3.17
corrective action
action to eliminate the cause(s) of a *nonconformity* (3.16) and to prevent recurrence

Note 1 to entry: There can be more than one cause for a nonconformity.

Note 2 to entry: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence.

3.18
audit
systematic and independent *process* (3.8) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1) itself, or by an external party on its behalf.

Note 3 to entry: “Audit evidence” and “audit criteria” are defined in ISO 19011.

Note 4 to entry: The fundamental elements of an audit include the determination of the *conformity* (3.15) of an object according to a procedure carried out by personnel not being responsible for the object audited.

Note 5 to entry: Internal audits are conducted for management review and other internal purposes and can form the basis for an organization’s declaration of conformity. Independence can be demonstrated by the freedom from responsibility for the activity being audited.

Note 6 to entry: Second party audits are conducted by parties having an interest in the organization, such as customers, or by other persons on their behalf. Third-party audits are conducted by external, independent auditing organizations such as those providing certification/registration of conformity or governmental agencies.

Note 7 to entry: An audit can also be a joint audit carried out at a single auditee by two or more auditing organizations.

3.19
measurement
process (3.8) to determine a value

Note 1 to entry: According to ISO 3534-2, 3.2.1, the value determined is generally the value of a quantity.

3.20
monitoring
determining the status of a system, a *process* (3.8) or an activity

Note 1 to entry: To determine the status, there can be a need to check, supervise or critically observe.

Note 2 to entry: Monitoring can also determine the status of a product or a service.

Note 3 to entry: Monitoring is generally a determination of the status of an object carried out at different stages or at different times.

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4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its quality management system.

The organization shall determine whether climate change is a relevant issue.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to the organization's strategic direction, values, culture, resources, knowledge and performance of the organization.

4.2 Understanding the needs and expectations of interested parties

The organization shall determine:

a) the interested parties that are relevant to the quality management system;

b) the relevant requirements of these interested parties;

c) which of these requirements will be addressed through the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

NOTE Relevant interested parties can have requirements related to climate change.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, the organization shall consider:

a) the external and internal issues referred to in 4.1;

b) the requirements of relevant interested parties referred to in 4.2;

c) the products and services of the organization.

The scope shall be available as documented information.

The scope shall state the types of products and services covered, and provide justification for any requirement of this document that the organization determines is not applicable to its quality management system.

The organization shall apply all the requirements of this document if they are applicable within the determined scope of its quality management system.

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Conformity to this document may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality management system

4.4.1 The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this document.

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

a) determine the inputs required and the outputs expected from these processes;

b) determine the sequence and interaction of these processes;

c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;

d) determine the resources needed for these processes and ensure their availability;

e) assign the responsibilities and authorities for these processes;

f) address the risks and opportunities as determined in accordance with the requirements of 6.1;

g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;

h) improve the processes and the quality management system.

4.4.2 Documented information shall be available to the extent necessary:

a) to support the operation of its processes;

b) as evidence that the processes are being carried out as planned.

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5 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a) ensuring that the quality policy and quality objectives are established and are compatible with the strategic direction of the organization;

b) ensuring the integration of the quality management system requirements into the organization's business processes;

c) ensuring that the resources needed for the quality management system are available;

d) communicating the importance of effective quality management and of conforming to the quality management system requirements;

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e) ensuring that the quality management system achieves its intended results;

f) directing and supporting persons to contribute to the effectiveness of the quality management system;

g) promoting continual improvement;

h) supporting other relevant roles to demonstrate their leadership as it applies to their areas of responsibility;

i) promoting quality culture and ethical behaviour;

j) promoting the use of the process approach and risk-based thinking;

k) taking accountability for the effectiveness of the quality management system.

NOTE 1 Reference to "business" in this document can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence.

NOTE 2 The organization's culture and ethics can be demonstrated through shared values, beliefs, history, attitudes and observed behaviours.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;

b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

c) the focus on enhancing customer satisfaction is maintained.

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5.2 Quality policy

5.2.1 Top management shall establish a quality policy that:

a) is appropriate to the purpose of the organization;

b) provides a framework for setting quality objectives;

c) includes a commitment to meet applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

The quality policy shall be implemented and maintained to take into account the context and strategic direction of the organization.

5.2.2 The quality policy shall:

a) be available as documented information;

b) be communicated within the organization;

c) be available to interested parties, as appropriate.

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5.3 Roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

a) ensuring that the quality management system conforms to the requirements of this document;

b) reporting on the performance of the quality management system to top management;

c) ensuring that the processes are delivering their intended outputs;

d) ensuring the promotion of customer focus throughout the organization;

e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 General

When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

a) give assurance that the quality management system can achieve its intended result(s);

b) prevent, or reduce, undesired effects;

c) achieve continual improvement.

6.1.2 Actions to address risk

The organization shall establish processes to determine, analyse, and evaluate risks that can have an undesirable effect on its ability to continually and consistently provide conforming products and services.

The organization shall plan:

a) actions to address these risks;

b) how to:

— integrate and implement the actions into its quality management system processes ;

— evaluate the effectiveness of these actions.

NOTE Determined risks can include risks related to the ability to provide conforming products and services after a disruption to its operation.

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6.1.3 Actions to address opportunities

The organization shall establish processes to determine the opportunities that can have a desirable effect on its ability to continually and consistently provide conforming products and services.

The organization shall plan:

a) actions to address these opportunities;

b) how to:

— integrate and implement the actions into its quality management system processes ;

— evaluate the effectiveness of these actions.

NOTE Action to address opportunities can include the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions and levels.

The quality objectives shall:

a) be consistent with the quality policy;

b) be measurable (if practicable);

c) take into account applicable requirements;

d) be monitored;

e) be communicated;

f) be updated as appropriate;

g) be available as documented information;

h) be relevant to conformity of products and services and to enhancement of customer satisfaction.

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6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

a) what will be done;

b) what resources will be required;

c) who will be responsible;

d) when it will be completed;

e) how the results will be evaluated.

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6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

To ensure the change is implemented effectively to achieve intended result(s) the organization shall consider:

a) the purpose of the changes and their potential consequences;

b) the integrity of the quality management system;

c) the availability of resources and information;

d) the allocation or reallocation of responsibilities and authorities;

e) how the effectiveness of the change(s) will be monitored and evaluated;

f) how to review the results of the change(s).

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

a) the capabilities of, and constraints on, existing internal resources;

b) what needs to be obtained from external providers.

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7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services including, as applicable, infrastructure for remote and hybrid work.

NOTE Infrastructure can include:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

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7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can include a combination of factors, which can differ substantially depending on the products and services provided. Relevant factors can include;

a) social (e.g. non-discriminatory, calm, non-confrontational);

b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);

c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise);

d) technological (e.g. use of emerging technologies);

e) cultural (e.g. organizational quality culture, ethical behaviour).

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

a) are suitable for the specific type of monitoring and measurement activities being undertaken;

b) are maintained to ensure their continuing fitness for their purpose.

Appropriate documented information shall be available as evidence of fitness for purpose of the monitoring and measurement resources.

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7.1.5.2 Traceability of measurement results

When traceability of measurement results is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, monitoring and measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be available as documented information;

b) identified in order to determine its calibration or verification status;

c) safeguarded from adjustments, damage or deterioration that would invalidate measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve the intended results of its quality management system.

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This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);

b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).

7.2 Competence

The organization shall:

a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;

b) ensure that these persons are competent on the basis of appropriate education, training, or experience;

c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken.

Appropriate documented information shall be available as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

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7.3 Awareness

Persons doing work under the organization's control shall be aware of:

a) the quality policy;

b) their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance;

c) the implications of not conforming with the quality management system requirements;

d) relevant quality objectives.

7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

a) on what it will communicate;

b) when to communicate;

c) with whom to communicate;

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d) how to communicate;

e) who communicates.

7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

a) documented information required by this document;

b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating documented information

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);

b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);

c) review and approval for suitability and adequacy.

7.5.3 Control of documented information

7.5.3.1 Documented information required by the quality management system and by this document shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;

b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;

b) storage and preservation, including preservation of legibility;

c) control of changes (e.g. version control);

d) retention and disposition.

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Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, and controlled.

Documented information available as evidence of conformity shall be protected from unintended alterations.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet requirements and to implement the actions determined in Clause 6, by:

a) establishing criteria for the processes;

b) implementing control of the processes in accordance with the criteria.

Documented information shall be available to the extent necessary to have confidence that the processes have been carried out as planned.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that externally provided processes, products or services that are relevant to the quality management system are controlled.

In order to ensure the control of processes related to the provision of products and services, the organization shall:

— determine the requirements for the products and services;

— determine criteria for the acceptance of products and services

— determine the resources needed to achieve conformity to the product and service requirements;

Documented information shall be available to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organization's operations.

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

a) providing information relating to products and services;

b) handling enquiries, contracts or orders, including changes;

c) obtaining customer feedback relating to products and services, including customer complaints;

d) handling or controlling customer property;

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e) establishing specific requirements for contingency actions, when relevant.

NOTE Customer communication can include training, web site content, publications, social media and Frequently Asked Questions.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

a) the requirements for the products and services are defined, including:

— any applicable statutory and regulatory requirements;

— those considered necessary by the organization;

b) the organization can meet the claims for the products and services it offers.

8.2.3 Review of the requirements for products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities when applicable;

b) requirements not stated by the customer, but necessary for the specified or intended use, when known;

c) requirements specified by the organization;

d) statutory and regulatory requirements applicable to the products and services;

e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as websites or catalogues.

8.2.3.2 Documented information shall be available as applicable, as evidence of:

a) the results of the review;

b) any new or modified requirements for the products and services.

8.2.4 Changes to requirements for products and services

When requirements for products and services are changed, the organization shall ensure that relevant documented information is updated and communicated to relevant persons.

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8.3 Design and development of products and services

8.3.1 General

The organization's design and development process shall be appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

a) the nature, duration and complexity of the design and development activities;

b) the required process stages, including applicable design and development reviews;

c) the required design and development verification and validation activities;

d) the responsibilities and authorities involved in the design and development process;

e) the internal and external resource needs for the design and development of products and services;

f) the need to control interfaces between persons involved in the design and development process;

g) the need for involvement of customers and users in the design and development process;

h) the requirements for subsequent provision of products and services;

i) the level of control expected for the design and development process by customers and other relevant interested parties;

j) the documented information needed as evidence that design and development requirements have been met.

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8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

a) functional and performance requirements;

b) information derived from previous similar design and development activities;

c) statutory and regulatory requirements;

d) standards or codes of practice that the organization has committed to implement;

e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

Documented information shall be available as evidence of design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

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a) the results to be achieved are defined;

b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;

c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;

d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;

e) necessary actions are taken to address problems determined during the reviews, or verification and validation activities;

f) documented information is available as evidence of these activities.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

a) meet the input requirements;

b) are adequate for the subsequent processes for the provision of products and services;

c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;

d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

Documented information shall be available as evidence of design and development outputs.

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8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

Documented information shall be available as evidence of:

a) design and development changes;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

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The organization shall determine the controls to be applied to externally provided processes, products and services when:

a) products and services from external providers are intended for incorporation into the organization's own products and services;

b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;

c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.

Documented information shall be available as evidence of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

a) ensure that externally provided processes remain within the control of its quality management system;

b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;

c) take into consideration:

   1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;

   2) the effectiveness of the controls applied by the external provider;

d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements, as applicable, for:

a) the processes, products and services to be provided;

b) the approval of:

   1) products and services;

   2) methods, processes and equipment;

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3) the release of products and services;

c) competence, including any required qualification of persons;

d) the external providers' interactions with the organization;

e) control and monitoring of the external providers' performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

a) the availability and use of documented information that defines:

1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;

2) the results to be achieved;

b) the availability and use of suitable monitoring and measuring resources;

c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

d) the use of suitable infrastructure and environment for the operation of processes;

e) the appointment of competent persons, including any required qualification;

f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;

g) the implementation of actions to prevent human error;

h) the implementation of release, delivery and post-delivery activities.

NOTE To ensure that the defined requirements are met, organizations can choose to engage in product and service verification or process validation activities, or both, as appropriate. The ability to engage in verification activities does not prevent organizations from choosing validation of a process as a suitable alternative.

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

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The organization shall control the unique identification of the outputs when traceability is a requirement, and shall ensure that documented information necessary to enable traceability is available as evidence.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and ensure that documented information is available as evidence of what has occurred.

NOTE A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

NOTE Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

a) statutory and regulatory requirements;

b) the potential undesired consequences associated with its products and services;

c) the nature, use and intended lifetime of its products and services;

d) customer requirements;

e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Documented information shall be available to describe the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

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8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

Documented information shall be available as evidence on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;

b) traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

a) correction;

b) segregation, containment, return or suspension of provision of products and services;

c) informing the customer;

d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 Documented information shall be available as evidence to:

a) describe the nonconformity;

b) describe the actions taken;

c) describe any concessions obtained;

d) identify the authority deciding the action in respect of the nonconformity.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

a) what needs to be monitored and measured;

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b) the methods for monitoring, measurement, analysis and evaluation, as applicable, needed to ensure valid results;

c) when the monitoring and measuring shall be performed;

d) when the results from monitoring and measurement shall be analysed and evaluated.

Documented information shall be available as evidence of the results.

The organization shall evaluate the performance and the effectiveness of the quality management system.

9.1.2 Customer satisfaction

The organization shall monitor the customers' satisfaction, which is determined by the customers' perception of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Sources of information to support understanding of customer satisfaction can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports, complaints and social media.

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

c) the performance and effectiveness of the quality management system;

d) if planning has been implemented effectively;

e) the effectiveness of actions taken to address risks and opportunities;

f) the performance of external providers;

g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statistical techniques.

9.2 Internal audit

9.2.1 General

The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

a) conforms to:

1. the organization's own requirements for its quality management system;

2. the requirements of this document;

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b) is effectively implemented and maintained.

9.2.2 Internal Audit Programme

The organization shall plan, establish, implement and maintain (an) audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting.

When establishing the internal audit programme(s), the organization shall consider the importance of the processes concerned and the results of previous audits.

The organization shall:

a) define the audit objectives, criteria and scope for each audit;

b) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;

c) ensure that the results of audits are reported to relevant managers;

d) take appropriate correction and corrective actions without undue delay

Documented information shall be available as evidence of the implementation of the audit programme(s) and the audit results.

NOTE See ISO 19011 for guidance.

9.3 Management review

9.3.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of the organization.

9.3.2 Management review inputs

The management review shall include:

a) the status of actions from previous management reviews;

b) changes in external and internal issues that are relevant to the quality management system;

c) changes in needs and expectations of interested parties that are relevant to the quality management system;

d) information on the quality management performance including trends in:

— nonconformities and corrective actions;

— monitoring and measurement results;

— audit results;

— customer satisfaction and feedback from relevant interested parties;

— the extent to which quality objectives have been met;

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— process performance and conformity of products and services;

— the performance of external providers;

e) opportunities for continual improvement.

f) the adequacy of resources;

g) the effectiveness of actions taken to address risks and opportunities (see 6.1);

9.3.3 Management review results

The results of the management review shall include decisions related to continual improvement opportunities and any need for changes to the quality management system.

Decisions shall include

a) opportunities for improvement;

b) any need for changes to the quality management system;

c) resource needs.

Documented information shall be available as evidence of the results of management reviews.

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10 Improvement

10.1 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

The organization shall consider the results of analysis, evaluation of monitoring and measurement data, and the results of management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

Actions shall include:

a) improving processes, products and services;

b) addressing future needs and expectations;

c) correcting, preventing or reducing undesired effects.

NOTE Improvement can be achieved through incremental and breakthrough change, innovation or re-organization initiatives. The use of emerging technologies can support ongoing improvement of the quality management system.

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10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, the organization shall:

a) react to the nonconformity and, as applicable:

— take action to control and correct it;

— deal with the consequences;

b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:

— reviewing the nonconformity;

— determining the causes of the nonconformity;

— determining if similar nonconformities exist, or can potentially occur;

c) implement any action needed;

d) review the effectiveness of any corrective action taken;

e) make changes to the quality management system, if necessary;

f) update risks and opportunities determined during planning, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

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10.2.2 Documented information shall be available as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;

b) the results of any corrective action.

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Annex A
(informative)

Clarification of structure, terminology and clauses

A.1 General

The information given in this annex is intended to provide clarification and to prevent misunderstanding of the requirements contained in this document. While this information addresses and is consistent with these requirements, it is not intended to add to, subtract from, or in any way modify them.

The explanatory information is given only on clauses needing clarification. For guidance on the application of all clauses see ISO 9002.

The requirements in this document are better viewed from a systems perspective and not in isolation, i.e. there can be an interrelationship between the requirements in one clause with the requirements in other clauses.

A.2 Structure and terminology

The clause structure (i.e. clause sequence) and some of the terminology of this document, in comparison with the previous edition (ISO 9001:2015), have been changed to improve alignment with the Harmonized Structure (HS) for Management System Standards (MSS).

There is no requirement in this International Standard for its structure and terminology to be applied to the documented information of an organization's quality management system.

The structure of clauses is intended to provide a coherent presentation of requirements, rather than a model for documenting an organization's policies, objectives and processes. The structure and content of documented information related to a quality management system can often be more relevant to its users if it relates to both the processes operated by the organization and information maintained for other purposes.

To prevent misunderstanding the following terms are clarified:

a) The words “appropriate” and “applicable” are not interchangeable. “Appropriate” means suitable (for, to) and implies some degree of freedom, while “applicable” means relevant or possible to apply and implies that if it can be done, it needs to be done.

b) The word “consider” means it is necessary to think about the topic, but it can be excluded; whereas “take into account” means it is necessary to think about the topic, but it cannot be excluded.

c) “Continual” indicates duration that occurs over a period of time, but with intervals of interruption (unlike “continuous” which indicates duration without interruption). “Continual” is therefore the appropriate word to use when referring to improvement.

d) The word “ensure” means the responsibility can be delegated, but not the accountability.

e) To align the meaning of “documented information” to the Harmonized Structure, two changes have been made. First, the phrase “shall be available as documented information” replaces “maintain documented information” which previously referred to documentation other than records. Second, “documented information shall be available as evidence of” replaces “retain documented information as evidence of” which previously referred to records. It is worth noting that the phrase” as evidence of” is not a requirement to meet legal evidential requirements; its intent is only to indicate objective evidence needs

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to be retained. In the context of documented information, the term “available” means the organization can obtain, use, or provide the information to ensure an effective quality management system.

NOTE For documented information see ISO 10013.

A.3 Applicability

The requirements of this standard for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

A.4 Context of the organization

A.4.1 Understanding the organization and its context

Having a full understanding of the internal and external issues and the relevant requirements of relevant interested parties enables an organization to define the scope of its quality management system and determine the processes needed to ensure that the organization fulfils its purpose, follows its strategic direction and achieves its intended results.

External and internal issues relevant to the organization’s purpose and strategic direction can affect positively or negatively the organization’s ability to achieve the intended results of its quality management system, and it is recommended to monitor and review the changes in the external and internal issues.

In order to determine whether climate change is a relevant issue, it can be considered in relation to the potential impact on the intended results of the quality management system, e.g. the impact on the ability of the organization to consistently provide products and services that meet customer and applicable statutory and regulatory requirements and the enhancement of customer satisfaction. The organization may determine it is either relevant or not relevant. It is not required for an organization to have climate change initiatives unless it has determined it as a relevant issue within the context of the quality management system.

External and internal issues may be determined based on information from different sources such as internal documented information and meetings, publications from national statistics offices and other government departments, professional and technical publications, meetings with customers and relevant interested parties. Determining the external and internal issues that arise from emerging technologies is very important for understanding the context of the organization.

A.4.2 Understanding the needs and expectations of interested parties

Relevant requirements of relevant interested parties can have an effect or potential effect on its ability to provide products and services that meet customer and applicable statutory and regulatory requirements.

It is important that information about these interested parties and their relevant requirements are monitored and reviewed to maintain awareness of any changes that may impact the effectiveness of the quality management system.

Customers are the main (but not the only) interested party for the quality management system. Not all interested party requirements necessarily become requirements for the organization if they are not applicable to the organization or relevant to the quality management system. Others are “mandatory” because they have been incorporated into laws, regulations, permits and licenses, by governmental or court action, or because

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they have been specified by a higher level of the corporate entity to which the organization belongs. There can be others that an organization may decide to adopt voluntarily or by entering into an agreement or contract. Once adopted or agreed to, these become requirements for the organization (see 4.3).

A note in clause 4.2 reminds organizations that relevant interested parties can have requirements related to climate change.

A.4.3 Determining the scope of the quality management system

The scope statement of the quality management system enables an organization to communicate the products and services delivered and covered by the quality management system and its boundaries. In order to avoid confusion and to enable clear identification, the scope can define, the types of activities, products and services covered; related sites where these activities are performed and specific scopes, if relevant. A non-misleading and clear scope reinforces integrity and ethics of the organization.

A.4.4 Quality management system

There is no requirement in this International Standard for its structure and terminology to be applied to an organization's quality management system or documentation.

It is important to establish, implement, maintain and continually improve the structure and content of an organization’s quality management system using the process approach so that it consists of all the processes needed and is relevant to its users.

All processes interact and interrelate to create an aligned quality management system therefore it is important to determine the sequence, interaction and integration of quality management system processes with each other and with other business processes. It is important to define the inputs required and the intended results of each process and to assign the responsibilities and authorities for all processes.

A.5 Leadership

A.5.1 Leadership and commitment

Ethical behaviour is part of the quality culture and is fundamental to the leadership role in supporting the quality management system and the leadership commitment to building trust in the organizations ability to demonstrate its ability to:

a) provide products and services that meet customer and applicable statutory and regulatory requirements,

b) enhance customer satisfaction,

c) protect and improve its reputation.

If decisions, actions and interactions with employees, external providers, customers and other interested parties are not guided by ethical behaviour, all aspects of quality can be undermined.

NOTE See ISO 10010 for further guidance on Quality culture.

A.5.2 Quality policy

The quality policy reflects the organization's quality culture and expectations for ethical behaviour and is communicated to relevant interested parties. Ways to communicate the policy can include training, signage, contracts, meetings, and other reporting channels.

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A.5.3 Roles, responsibilities and authorities

There is no requirement in this International Standard to have one person responsible for the quality management system but that all responsibilities and authorities for relevant roles are assigned to ensure that the quality management system achieves its objectives.

A.6 Planning

A.6.1 Actions to address risks and opportunities

A.6.1.1 General

To determine and address the risks and the opportunities the organization can implement the concepts of risk-based thinking and opportunity-based thinking to enhance its ability to meet the objectives of its quality management system as summarized in the scope of this International Standard. These two concepts are explained in the following two paragraphs.

A.6.1.2 Risk-based thinking

The concept of risk-based thinking has been implicit in previous editions of this International Standard, e.g. through requirements for planning, review and improvement and quality specific requirements that historically have been designed to prevent the delivery of nonconforming products to its clients.

This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Consequently, this International Standard does not have a separate clause or subclause on preventive action. The concept of preventive action is expressed through the use of risk-based thinking in implementing quality management system requirements.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations.

Under the requirements of 6.1, the organization is responsible for the application of risk-based thinking and the actions it takes to address risks, which will determine its processes and the different levels of control that are applied.

Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards.

NOTE See ISO 31000 for further guidance on risk management.

A.6.1.3 Opportunity based thinking

Identifying and managing risks and opportunities are separate processes. Risks are not opportunities. Opportunities result from assessment of the internal and external context including interested parties' needs and expectations, the organization's capability, capacity and competence to leverage its strengths and weaknesses, as well as the results of various monitoring activities and key performance indicators.

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Essentially opportunities can come from many sources. As such it is critical to clearly identify the opportunities, identify the needs and objectives, identify the risk associated with the opportunity itself and formulate a strategy and plan to support the achievement of desired results.

For example, circumstances arise that allow the organization to attract customers, develop new products and services, or improve productivity.

A.6.2 Quality objectives and planning to achieve them

The planning process that includes the establishment of quality objectives and the ways to achieve them ensures that the quality management system can achieve its intended results.

NOTE How to prepare a quality plan is explained in ISO 10005.

A.6.3 Planning of changes

Changes to the organization are inevitable and can affect the organization in different ways, some of which can adversely impact its ability to achieve objectives and some can indicate a potential opportunity that can drive improvements.

Changes can include:

a) an external issue that causes a change to the organization

b) the organization decides to initiate a change

NOTE How to manage change is explained in ISO/TS 10020.

A.7 Support

A.7.1 Resources

A.7.1.1 General

No clarification of the requirement provided.

A.7.1.2 People

No clarification of the requirement provided.

A.7.1.3 Infrastructure

Infrastructure includes all physical resources needed for the operation of the organization's processes.

In service organizations, infrastructure is frequently an important component of the service to which many statutory and regulatory requirements applicable to the service can apply (e.g. healthcare organizations, restaurants, stores)

The actions of "determine", "provide" and "maintain" relate to three different activities that might be performed by different processes or functions of an organization.

A.7.1.4 Environment for the operation of processes

No clarification of the requirement provided.

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A.7.1.5 Monitoring and measuring resources

For many organizations, monitoring and measurement resources are essential to demonstrate conformity of the products and services or to ensure control of the processes to achieve intended results. Requirements in this clause aim to ensure that the resources ensure valid results.

NOTE 1 See ISO 10012 for requirements for measurement processes and measuring equipment.

NOTE 2 See ISO 10009 for guidance for quality tools and their application.

NOTE 3 See ISO 10017 for guidance on statistical techniques for ISO 9001:2015.

A.7.1.6 Organizational knowledge

Requirements regarding organizational knowledge were introduced for the purpose of:

a) safeguarding the organization from loss of knowledge, e.g. through staff turnover; failure to capture and share information;

b) encouraging the organization to acquire knowledge, e.g. learning from experience;

mentoring; benchmarking.

Organizational knowledge combines processes, actions and methodologies to enable creation, maintenance, distribution and access to organizational knowledge. Management of this knowledge is essential for sustainable success.

Having a systematic approach helps to identify, capture, analyse, retrieve, maintain and protect existing knowledge, identify missing knowledge and counter loss of knowledge (e.g. caused by people leaving an organization).

As technology develops it is important to take into account the potential and actual impacts of, for example, big data, machine learning, block chain, and the use of intellectual property.

Deeper consideration of the management of organizational knowledge leads to broader understanding of its impact on quality management, improved efficiency and effectiveness of the Quality Management System and enhancement of quality culture.

NOTE On Knowledge management systems see ISO 30401.

A.7.2 Competence

No clarification of the requirement provided.

NOTE See ISO 19011 for further information on auditor competence.

A.7.3 Awareness

Awareness is attained when persons understand their responsibilities and authorities and how their actions contribute to the achievement of the organization's quality objectives. Organizations can demonstrate initiatives taken to ensure awareness of person and their effectiveness. Persons doing work under the organization's control can demonstrate their awareness in day-to-day activities by distinguishing between what is acceptable and what is not, and by taking appropriate action when processes, products and services do not meet agreed specifications.

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A.7.4 Communication

To be effective, the organization's communication processes provides it and its persons with

the ability to:

— transmit and receive information quickly and to act on it;

— build trust amongst each other;

— transmit the importance of customer satisfaction, process performance, etc.;

— Identify opportunities for improvement

A.7.5 Documented information

See Clause A.2 e) for terminology relevant to 'Documented information'

NOTE How to manage documented information is explained in ISO 10013.

A.8 Operation

A.8.1 Operational planning and control

No clarification of the requirement provided.

A.8.2 Requirements for products and services

No clarification of the requirement provided.

A.8.3 Design and development of products and services

No clarification of the requirement provided.

NOTE See ISO 10007 for guidance on configuration control relevant to 8.3.6 Design and development changes.

A.8.4 Control of externally provided processes, products and services

The organization is responsible for ensuring that externally provided processes, products and services conform to requirements (e.g. through incoming goods inspection, or surveillance of an outsourced service). Therefore, establishing and maintaining proper control of external providers is essential for the organization to meet is quality management system objectives.

Control of externally provided processes, products and services are addressed, e.g. whether through:

a) purchasing from a supplier;

b) an arrangement with an associate company;

c) processes provided externally.

Processes provided externally always have the essential characteristic of a service, since it will have at least one activity necessarily performed at the interface between the provider and the organization.

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The controls required for external provision can vary widely depending on the nature of the processes, products and services. The organization can apply risk-based thinking to determine the type and extent of controls appropriate to particular external providers and externally provided processes, products and services.

NOTE See ISO 37500 for guidance on outsourcing.

A.8.5 Production and service provision

No clarification of the requirement provided.

A.8.6 Release of products and services

No clarification of the requirement provided.

A.8.7 Control of nonconforming outputs

No clarification of the requirement provided.

A.9 Performance evaluation

A.9.1 Monitoring, measurement, analysis and evaluation

No clarification of the requirement provided.

NOTE On measurement processes and measuring equipment see ISO 10012.

A.9.2 Internal audit

No clarification of the requirement provided.

NOTE On quality management systems auditing see ISO 19011.

A.9.3 Management review

No clarification of the requirement provided.

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A.10 Improvement

A.10.1 Continual improvement

The use of emerging technology can facilitate continual improvement. Emerging technologies can include digitization, machine learning, big data, augmented reality and virtual reality, digital twins, cloud computing, internet of things (IoT) and artificial intelligence.

Emerging technologies will impact an organization's quality management system in the future, and the impact will not become fully apparent until such technologies are more mature.

While these technologies are not new to all organizations, their impact is growing, e.g. digitization (developing the processes and business of an organization based on digital technology), within and between organizations and management systems is central to changing ways of working. Digitization includes both the digitization of knowledge and information, and the intelligent networking of machines and processes.

People and products make decisions based on existing data and information. Artificial intelligence makes decisions on a rapidly changing data situation: as a result, decisions are not always comprehensible to people or management systems and can be a challenge.

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Dependency on valid and reliable data is dramatically increasing, so the use of emerging technologies within organizations and society is essential.

When improvement is addressed determining which of the emerging technologies can enhance the improvement needed can have a high added value.

A.10.2 Nonconformity and corrective action

No clarification of the requirement provided.

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