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Quality management systems — Requirements

Systèmes de management de la qualité - Exigences

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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).

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

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

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

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 the requirements in 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.

Consistently meeting requirements and addressing future needs and expectations of customers and relevant interested parties poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization can adopt various forms of improvement in addition to continual improvement, such as breakthrough change, innovation and reorganization.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “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 contain any additional requirements.

The explanatory information is given only on clauses needing clarification.

For guidance on the application of all clauses in this document see ISO/TS 9002^[1].

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.

0.3 Process approach

0.3.1 General

This document promotes the adoption of a process approach when establishing, 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 determination 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 (see [0.3.2](#)) with an overall focus on risk-based thinking (see [A.6.1.2](#)) and opportunity-based thinking (see [A.6.1.3](#)) 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 the results of 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 process steps and related risks.

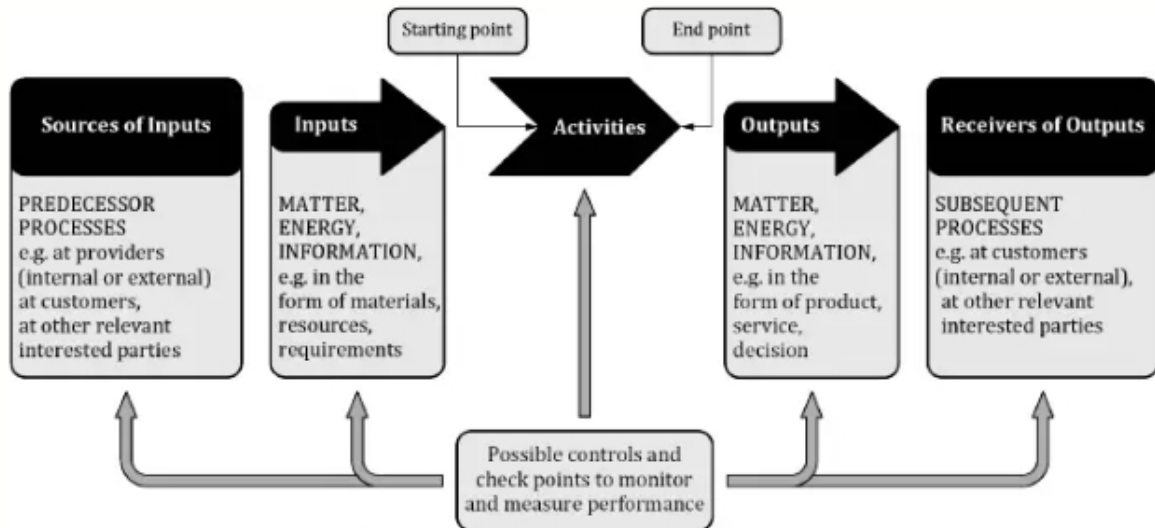
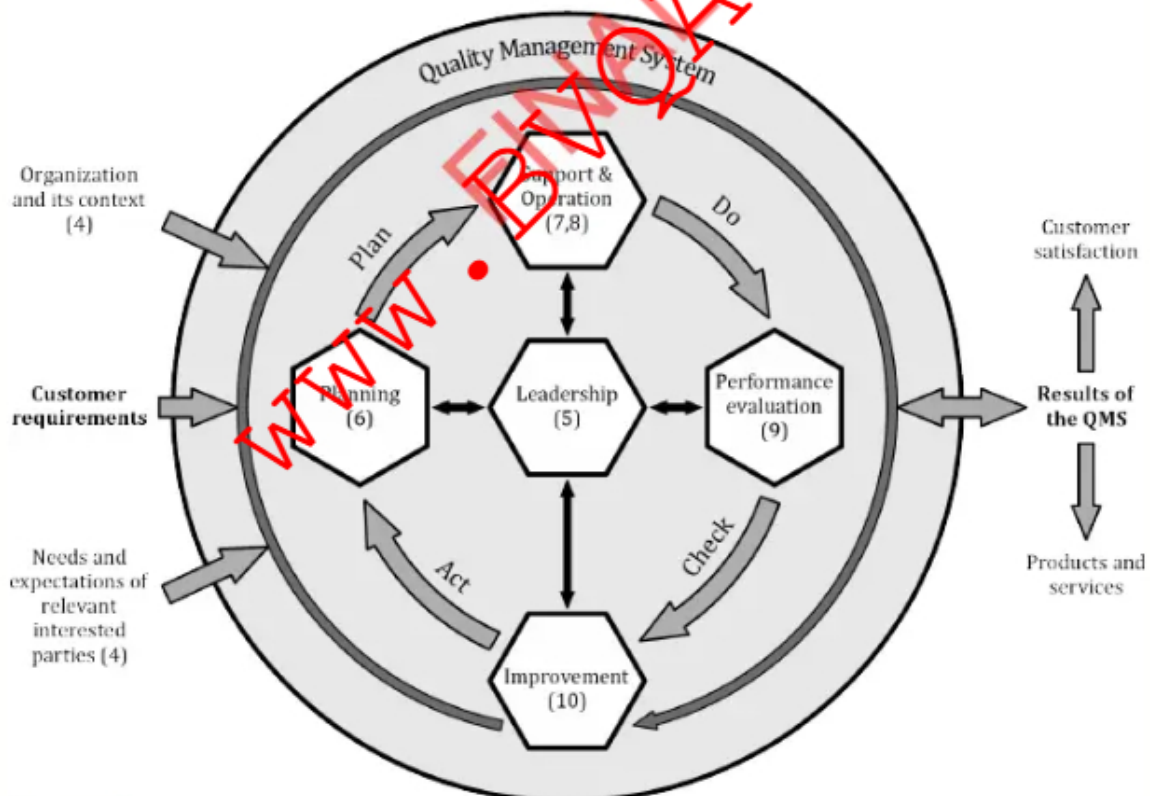


Figure 1 — Schematic representation of the elements of a single process

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.



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

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

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 determine 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 ISO management systems standards.

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

This document relates to :

- ISO/CD 9000 *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this document;
- [ISO 9004 \[2\]](#) *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.
- [ISO/TS 9002 \[1\]](#) *Quality management systems - Guidelines for the application of ISO 9001* provides implementation guidance.

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 ISO quality management system standards based on the requirements of this document have been developed. 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.

NOTE See <https://www.iso.org/management-system-standards-list.html> ^[3] for a list of all management system standards.

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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.

This document is applicable to any organization, regardless of its type or size, for 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.

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 3534-2:2006, *Statistics — Vocabulary and symbols — Part 2: Applied statistics*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

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

EN ISO 9001:2015, *Quality management systems - Requirements (ISO 9001:2015)*

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).

3.2

interested party

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 *processes* (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.

3.4.1

quality management system

part of a *management system* (3.4) related 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: The quality policy is generally 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 objectives* (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

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 objectives* (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 and consequences 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 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 ensure that intended results can be achieved.

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

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 *processes* (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)

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* (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, service 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.

3.15
conformity
fulfilment of a *requirement* (3.14)

Note 1 to entry: In English the word "conformance" is synonymous but deprecated. In French the word "conformité" 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 people selected to ensure impartiality and objectivity of the audit process.

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 by two or more auditing organizations.

3.19 measurement

process (3.8) to determine a value

Note 1 to entry: According to ISO 3534-2:2006, 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.

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 its strategic direction 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 legal, technological, competitive, market, cultural, political, social, economic and environmental issues, 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.

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 referred to in [4.2](#);
- c) the products and services of the organization.

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.

The scope shall be available as documented information.

Conformity to this document can 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.

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;
- 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 An organization's quality culture and ethical behaviour are reflected in its shared values, attitudes, and established practices.

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.

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;
- e) takes into account the context of the organization and supports its strategic direction.

The quality policy shall be implemented and maintained.

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;
- d) be understood and applied within the organization.

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) reporting on opportunities for improvement to top management;
- f) ensuring that the integrity of the quality management system is maintained including when changes to the quality management system are planned and implemented.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 Determining risks and opportunities

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;
- d) enhance desirable effects.

6.1.2 Actions to address risks

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

The organization shall plan:

- a) actions to address these risks;
- b) how to:
 - 1) integrate and implement the actions into its quality management system processes;
 - 2) evaluate the effectiveness of these actions.

Actions taken to address risks shall be proportionate to the potential impact on the conformity of products and services.

NOTE 1 Determined risks can include risks related to the ability to provide conforming products and services during and after a disruption.

NOTE 2 Actions to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

6.1.3 Actions to address opportunities

The organization shall determine, analyse, and evaluate opportunities that can have a desirable effect on its ability to continually and consistently provide conforming products and services and enhance customer satisfaction.

The organization shall plan:

- a) actions to address these opportunities;
- b) how to:
 - 1) integrate and implement the actions into its quality management system processes;
 - 2) evaluate the effectiveness of these actions.

Actions taken to address opportunities shall be proportionate to the potential impact on customer satisfaction and the conformity of products and services.

NOTE Actions to address opportunities can include adopting new practices, launching new products, creating new partnerships, leveraging new technologies, implementing initiatives and other actions to address the current and changing needs and expectations of its customers and other relevant interested parties.

6.2 Quality objectives and planning to achieve them

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

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- 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.

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.

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.

To ensure changes are implemented effectively to achieve intended results the organization shall consider:

- a) the purpose of the changes and 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 changes will be monitored and evaluated;
- f) communication of the changes;
- g) how to review the results of the changes.

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.

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.

NOTE For all types of work (e.g. on site, remote or a combination thereof) infrastructure can include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

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 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).

Some factors are dependent on the organizational quality culture, including 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.

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, 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 can invalidate measurement results.

When measuring equipment is found to be unfit for its intended purpose, the organization shall determine whether the validity of previous measurement results has been adversely affected 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.

This knowledge shall be retained, applied and shared 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 Sources of organizational knowledge can include: experience-based knowledge; lessons learned from failures and successful activities; capturing tacit and undocumented knowledge and experience; the results of improvements in processes, products and services; learning from customers or external providers; standards; research papers; conferences; intellectual property.

7.2 Competence

The organization shall:

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

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

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

- c) the implications of not conforming with the quality management system requirements;
- d) relevant quality objectives;
- e) organizational quality culture and ethical behaviour.

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;
- 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.

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 for products and services, 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;
- c) establishing criteria for the acceptance of products and services;
- d) determining 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.

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 (See [8.4](#)).

Documented information shall be available to the extent necessary to demonstrate the conformity of products and services.

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;
- e) information related to contingency actions, including where relevant to any disruptions in the products or services provided.

NOTE Customer communication can include direct contacts through meetings, electronic mails and document exchange or indirectly through web site content, publications, social media, responses to frequently asked questions, and training.

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:
 - 1) any applicable statutory and regulatory requirements;
 - 2) 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 changed 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 interested parties.

8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

NOTE The design and development process can include cycles of review, verification, validation and feedback, allowing for flexibility throughout the design and development phases.

8.3.2 Design and development planning

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

- a) nature, duration and complexity of the design and development activities;
- b) required process stages, including applicable design and development reviews;
- c) required design and development verification and validation activities;
- d) responsibilities and authorities involved in the design and development process;
- e) internal and external resource needs for the design and development of products and services;
- f) need to control interfaces between persons involved in the design and development process;
- g) need for involvement of customers and users in the design and development process;
- h) requirements for subsequent provision of products and services;
- i) level of control expected for the design and development process by customers and other relevant interested parties;
- j) documented information needed as evidence that design and development requirements have been met.

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 complete, unambiguous, and adequate for design and development purposes.

Conflicting design and development inputs shall be resolved.

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

NOTE Design and development inputs are not always fully defined or known initially. Instead, they can evolve as the design progresses, through repeated cycles of development and validation.

8.3.4 Design and development controls

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

- 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.

8.3.6 Design and development changes

The organization shall determine, 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.

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 customers 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, products or 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 appropriate, for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization and, where applicable, its customers and other relevant interested parties;
- 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 or the services to be provided;
 - 2) the activities to be performed;
 - 3) 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.

8.5.2 Identification and traceability

The organization shall:

- a) use suitable means to identify outputs when it is necessary to ensure the conformity of products and services;
- b) identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision;
- c) 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 as evidence of the results of the review of changes, the person or persons authorizing the change, and any necessary actions arising from the review.

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 or persons 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;
- 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.

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

Documented information shall be available as evidence of the results.

9.1.2 Customer satisfaction

The organization shall monitor the customers' satisfaction. 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 relevant 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;
- 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, and changes affecting the organization.

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 [\[4\]](#) for guidance on auditing management systems.

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 system performance including trends in:
 - 1) nonconformities and corrective actions;
 - 2) monitoring and measurement results;
 - 3) audit results;
 - 4) customer satisfaction and feedback from relevant interested parties;
 - 5) the extent to which quality objectives have been met;
 - 6) process performance and conformity of products and services;
 - 7) the performance of external providers;
- e) opportunities for 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 or resource needs.

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

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 monitoring, measurement, analysis and evaluation of data and information, and the results of management review, to determine 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.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, the organization shall:

- a) react to the nonconformity and, as applicable:
 - 1) take action to control and correct it;
 - 2) 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:
 - 1) reviewing the nonconformity;
 - 2) determining the causes of the nonconformity;
 - 3) determining if similar nonconformities exist, or can potentially occur;
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

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

NOTE Customer complaints can be a source of nonconformities.

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.

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. This information addresses and is consistent with these requirements, and does not add to, subtract from, or in any way modify them.

This annex does not provide guidance for the implementation of requirements; for guidance on the application of requirements see ISO/TS 9002^[1], ISO handbook ISO 9001 for small enterprises - What to do? Advice from ISO/TC176^[2] or the other standards referred to in the notes to the relevant paragraphs of this annex.

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, have been changed in comparison with the previous edition (ISO 9001:2015), to improve alignment with the Harmonized Structure (HS) for management system standards (MSS).

There is no requirement in this document 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 meanings of the following words 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) The word "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 to do an activity can be delegated, but not the accountability for the results of the activity.
- e) To align the use of the term "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 to be retained. In the context of documented information, the term “available” means the organization can obtain, use, or provide the information.

- f) “Strategic direction” refers to the coordinated decisions, plans, and actions an organization undertakes to achieve its objectives and fulfil its intended purpose.

NOTE 1 See ISO 10013^[6] for guidance on documented information.

NOTE 2 See ISO 9000:2015 Glossary - Guidance on selected words used in the ISO 9000 family of standards^[7] for further information on the terminology used in this document.

A.3 Applicability

The requirements of this standard for applicability are addressed in 4.3, which specifies 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.

Applicable statutory and regulatory requirements mentioned in Clause 1 a) are determined by the organization considering those that relate to the organization’s ability to consistently provide conforming products and services and to enhance customer satisfaction through the effective application of the quality management system.

The expression “as applicable” in this document means that the requirement, even if generally determined as applicable according to clause 4.3, can or cannot be applicable in every specific case.

A.4 Context of the organization

A.4.1 Understanding the organization and its context

The concept of “context of the organization” is often referred to by other terms such as “business environment,” “organizational environment” or “ecosystem of an organization”.

Having a full understanding of the internal and external issues and the relevant requirements of relevant interested parties enables an organization to determine 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 positively or negatively affect the organization’s ability to achieve the intended results of its quality management system. They are by their nature changeable, and can change suddenly, just as their effects can be immediate and incisive. For this reason, it is necessary to monitor and review the changes in the external and internal issues.

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 requirements; adhere to applicable statutory and regulatory requirements; enhance customer satisfaction. The organization can determine it is either relevant or not relevant.

Although the application of specific methods or tools is not required, it is important that the external and internal issues relevant to the quality management system are determined using a rational approach and addressed by applying risk-based thinking and opportunity-based thinking.

External and internal issues can 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 affect an organization's ability to provide products and services that meet customer and applicable statutory and regulatory requirements.

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

It is important that information from these interested parties and their relevant requirements are monitored and reviewed to maintain awareness of any changes that can 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. Other requirements are "mandatory" because they have been incorporated into laws, regulations, permits and licenses, by governmental or court action, or because they have been mandated by a higher level of the corporate entity to which the organization belongs. There can be others that an organization can 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).

Expectations relating to sustainability or other external requirements can be expressed by the customer, or other relevant interested parties and when such requirements are determined as relevant by the organization, they fall within the boundaries of the quality management system. Although the application of specific methods or tools is not required, it is important that the interested parties and the requirements and expectations relevant to the quality management system are determined using a rational approach and addressed by applying risk-based thinking and opportunity-based thinking.

A.4.3 Determining the scope of the quality management system

The scope statement of the quality management system enables an organization to communicate which of its products and services are covered by the quality management system and its boundaries. 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.

The scope of this document, the scope of quality management system, and the scope of certification refer to different things, yet they are closely linked. Boundaries define the limits of the quality management system. For many organizations, the quality management system applies to all its products and services. The boundaries of the quality management system can be influenced by specific customer requirements, for example relating to sustainability. If the organization is part of a larger entity, organizational boundaries have to be well defined in the system. These can have an impact on the quality management system.

A.4.4 Quality management system

This clause is closely related to the quality management principle of "process approach". The process approach incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based and opportunity-based thinking. The processes referred to include all processes necessary to meet the requirements of this document.

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.

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.

The evaluation of processes relates to their continuing adequacy and effectiveness. As this depends on contextual factors which are subject to change, such as objectives and new circumstances external and internal to the organization, it is necessary for the organization to be able to modify one or more processes, and their interactions, partially or totally in a timely and controlled manner.

Evidence that processes are being carried out as planned can be provided by available documented information. Documented information is not always necessary to demonstrate conformity to each requirement of this document. It is up to the organization to determine which processes will be supported or accompanied by documented information, and the type and degree of detail of such documented information.

A.5 Leadership

A.5.1 Leadership and commitment

The visible support, involvement, and commitment of the organization's top management is necessary for the effective implementation of the quality management system. Top management is responsible for raising awareness and motivating people to engage in the quality management system. This can assure relevant interested parties that an effective management system is in place.

Ethical behaviour is part of the quality culture and is fundamental to the leadership commitment to support the quality management system and 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.

One of the responsibilities of top management is to lead the organization in maintaining customer focus at all times (5.1.2). This requirement directly refers to the first principle of quality management and the main objective of a quality management system. It is top management's commitment to ensure that conformity is achieved "consistently" i.e. systematically and continually, and that customer satisfaction is enhanced.

NOTE See ISO 10010^[8] for guidance on quality culture.

A.5.2 Quality policy

The quality policy is intended to define the organization's approach to quality and align with the organization's quality culture and expectations for ethical behaviour. .

Interested parties to whom it can be appropriate to communicate the quality policy typically include suppliers of products, processes, and services, to support alignment of behaviour across the entire supply network.

The communication, understanding and application of the quality policy by people at all levels of the organization is one of the methods for ensuring awareness and active involvement.

A.5.3 Roles, responsibilities and authorities

There is no requirement in this document 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.

Top management is required to ensure that responsibilities and authority are assigned as necessary for the requirements of this document to be met. This relates to all people involved in the quality management processes to ensure that it is not considered that the quality management system falls under the responsibility of a few.

It is also required that responsibilities and authority be assigned to report to top management information about the degree to which the quality management system is operating to enable the top management to take action as needed to ensure the integrity of the quality management system in the event of changes. Given the quality management system can require changes (e.g. depending on changes in the internal or

external environment), it is necessary to assign responsibility to prevent any changes related to elements of the quality management system from producing unintended consequences or introducing inconsistencies in the system itself.

In organizations adopting emerging technologies for the management of their quality management system, it is necessary to ensure traceability of quality management system decisions, the responsibility of those who made them, and their accountability.

A.6 Planning

A.6.1 Actions to address risks and opportunities

A.6.1.1 General

To determine and address risks, and opportunities the organization can implement, the fundamental quality concepts of risk-based thinking and opportunity-based thinking are used to enhance the organization's ability to meet the objectives of its quality management system, as summarized in the scope of this document. These two concepts are explained in the following sections.

This document adopts a performance approach to quality management, rather than a prescriptive one. According to this approach, the organization is accountable for the ways in which it decides to apply the requirements of this document, including the extent to which they are applicable, appropriate, and practicable, at all levels of its quality management system: strategic, tactical, and operational. The application of risk-based thinking and opportunity-based thinking can help to demonstrate, to internal and external interested parties, the suitability of such decisions.

A.6.1.2 Risk-based thinking

The concept of risk-based thinking has been implicit in previous editions of this document, for example through requirements for planning, review and improvement, and quality specific requirements that historically have been designed to prevent the delivery of nonconforming products or services to an organization's customers.

This document 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.

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.

Risk-based thinking can ensure that a quality management system continues to achieve its objectives, even in case of disruptive occurrences, i.e. incidents that cause a negative deviation from the planned provision of the products or services, by determining and implementing appropriate countermeasures.

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 to develop a more extensive risk management methodology than is required by this document, for example through the application of other guidance or standards.

NOTE 1 See ISO 31000^[9] for guidance on risk management.

NOTE 2 See ISO 31073^[10] for risk management vocabulary.

A.6.1.3 Opportunity based thinking

Determining 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.

Opportunity-based thinking enables an organization to address the factors that can cause its quality management system to deviate from the planned objectives, to maximize the effect of the opportunities as they arise.

Opportunities can come from many sources. As such it is critical to clearly determine the opportunities, determine the needs and objectives, determine 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

Planning the establishment of quality objectives and the ways to achieve them ensures that the quality management system can achieve its intended results.

Quality objectives are a part of the organization's objectives; they include the degree of product or service quality to be achieved and are derived from the quality policy.

Quality objectives can be related to other types of objectives. When quality objectives are linked to objectives related to other management systems objectives, integration between different management systems can help the organization in decision making.

In general, quality objectives can be defined at the strategic, tactical, and operational levels. It is required that these objectives are measurable as appropriate and necessary to monitor their achievement, but this does not necessarily mean that these objectives should always be expressed in quantitative form.

Communication of the objectives to those who are responsible for them or are otherwise involved in their achievement, including, where appropriate, external interested parties, is a condition for ensuring people's awareness and involvement.

It is required to document the objectives to enable to transfer, disaggregate, and report on them without misunderstandings and errors.

NOTE See ISO 10005 [\[11\]](#) for guidance on how to prepare a quality plan.

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 of which can indicate a potential opportunity that can drive improvements.

The ways in which changes are planned can vary, depending on the circumstances that triggered the need for change and the complexity and severity of the changes to be made.

The reason for changes can include:

- a) an external issue that causes a change to the organization;
- b) the organization decides to initiate a change;
- c) changes that have occurred in other management systems of the organization.

NOTE See ISO/TS 10020 [\[12\]](#) for guidance on how to manage change.

A.7 Support

A.7.1 Resources

A.7.1.1 General

Determining and providing resources means determining what is necessary and appropriate to ensure that the quality management system is effective in achieving the expected results.

Determining the resources needed for the quality management system requires the organization to understand available resources (e.g. economic, structural, organizational) and the conditions that allow or limit their use. Carrying out an activity requires the people who do it, the tools they use, the environment in which people and tools interact, the use of appropriate skills, appropriate measuring and monitoring resources, and the necessary knowledge. All components, and their interactions, should be managed to ensure their continued suitability.

A.7.1.2 People

The organization determines its required resources, represented by people. This means that the necessary workforce should be determined based on the expected workload, making sure that the organization has the necessary people, by number and organizational knowledge. An insufficient number of people, in the relevant roles, is a limitation on the ability of the quality management system to achieve its objectives and can be addressed by risk-based thinking. The people needed can be external to the organization and collaborate with it only temporarily.

Emerging technologies can be used in place of people for some functions. In this case, the risks and opportunities related to such a choice should be carefully evaluated, including the implications on ethical behaviour and accountability of the organization.

NOTE See ISO/DIS 30201 [\[33\]](#) for information on human resource management systems.

A.7.1.3 Infrastructure

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

In service organizations, infrastructure is frequently a key component of the service to which statutory and regulatory requirements can apply.

Infrastructure maintenance helps to ensure that conformity with requirements is achieved on a regular basis. There is no requirement for a specific method or type of maintenance.

The use of hybrid and remote work, as well as the use of innovative technologies, can introduce new risks and opportunities in the infrastructure management and control.

Customers and other interested parties can have specific requirements for infrastructure management, including its disposal or recycling. Infrastructure management can require integration with other management systems, such as with the health and safety management system, or with the environmental management system.

A.7.1.4 Environment for the operation of processes

It is important to consider and manage the various examples of factors that are part of the working environment provided in clause [7.1.4](#) depending on their influence on the ability of the quality management system to ensure conformity with customer and other requirements and to enhance customer satisfaction, for example, psychological factors can be of prevalent importance for those services where quality depends particularly on the psychological well-being of the operators.

The working environment can evolve with technologies, and its management can become more complex when it is not under the direct control of the organization.

in the case of services, the operating environment can be crucial from the organization's customer perspective, and influence customer satisfaction.

Management requirements for the operating environment under quality management system can be strongly related to those found in other management systems, such as that for health and safety. However, this does not mean that a health and safety requirement should be addressed within the scope of the quality management system.

A.7.1.5 Monitoring and measuring resources

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

Monitoring is to determine a status of something which implies observing, supervising, keeping under review; it can involve measuring or testing at intervals, especially for the purpose of regulation or control. Measurement is the process to determine a value, for example a physical quantity, magnitude, or dimension (using measuring resources, especially equipment).

Depending on the specific circumstances, measuring, or monitoring equipment can be used either for indication, monitoring or measuring purposes. In some cases, the same type of equipment can be used for any or all three functions. The level of control required depends on the intended use and determines whether measuring equipment needs to be verified by calibration, at suitable intervals between these activities, using a risk-based approach. The depth and degree of such control can also change, depending on the nature of processes, their outputs, products, services, and related risks.

Traceability of measurement results (7.1.5.2) requires an established calibration hierarchy for measuring equipment. Measurements performed to evaluate products, services or equipment, or measurements performed by their own products, need to be traceable to applicable international or national measurement standards or to an appropriate reference (e.g. certified reference materials).

NOTE 1 See ISO 10012:2013 for requirements for measurement management systems.

NOTE 2 See ISO 10009:2015 for guidance for quality tools and their application.

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

A.7.1.6 Organizational knowledge

Requirements regarding organizational knowledge have been introduced for the purpose of ensuring the organization manages knowledge through:

- a) acquiring or creating new knowledge;
- b) ensuring appropriate application of knowledge;
- c) maintaining knowledge to ensure it is valid and relevant (including retaining knowledge to safeguard the organization from risks associated with the loss of knowledge);
- d) sharing knowledge to support other knowledge-based needs.

Knowledge management facilitates the creation and application of knowledge in a way that benefits the organization and its interested parties and supports the quality management system.

NOTE See ISO 30401:2018 for knowledge management system requirements.

A.7.2 Competence

The competence of personnel needed to ensure the performance and effectiveness of the quality system should be determined and addressed at all levels of the organizational structure, starting with top management.

The necessary competence can be obtained through recruitment, or by assigning different roles, to individuals, through career progression, or various forms of training.

Competence management, including the acquisition and transfer of knowledge and experience, enhances organizational knowledge. When dealing with externally provided processes, products and services, the organization can need to determine and communicate to external providers its requirements for competence, including any required qualifications.

It can be necessary to review competences on a regular basis, or as changes occur, and take subsequent actions to ensure their continued suitability.

NOTE 1 See ISO 10015^[18] for guidance on competence management and people.

NOTE 2 See ISO 10018^[19] for guidance on people engagement.

NOTE 3 See ISO 19011^[4] for further information on auditor competence.

A.7.3 Awareness

Awareness is attained when people 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 people and the effectiveness of those initiatives. 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.

Awareness of the quality management system and the person's role within it is a key component of quality culture and the principles of quality management. Not only is it necessary for people to be aware, but also for them to apply this awareness in their work.

Being aware of the quality policy means aligning that person's day-to-day behaviours, including with relevant interested parties, to the guidelines of top management, concerning the quality management system. Being aware of a person's contribution to the effectiveness of the quality management system also means that person knowing their place in the process of which they are a part and understanding and applying the principle of customer focus. Being aware of the implications of nonconformity means adopting risk-based and opportunity-based thinking appropriately to each person's work, at any level of the organization, staying aligned with established procedures, and knowing what the consequences of nonconformity can be, on subsequent or related activities and on meeting customer requirements. Being aware of quality objectives means knowing what needs to be achieved by each person's work.

A.7.4 Communication

Communication is a process involving objectives, inputs, outputs, tools and content, responsibilities and resources, risks and opportunities and includes internal and external feedback relevant to the quality management system.

To be effective, the organization's communication processes provide it and its persons with the ability to:

- a) transmit and receive information quickly and to act on it;
- b) build trust between relevant parties;
- c) transmit the importance of customer satisfaction, process performance, etc.;
- d) determine opportunities for improvement.

Sometimes communication is established without human intervention, when two or more devices interact with each other.

A.7.5 Documented information

The organization determines the documented information needed to ensure and to demonstrate conformity with the requirements of the quality management system, in addition to that required by this document or required by the customers and other relevant interested parties. The decision to document information can result from the need to control the processes or for other purposes, including the need to provide evidence of conformity to third parties.

Documented information addresses the need to codify procedures, avoid deviations, capitalize knowledge, maintain the history of operations, facilitate and simplify internal and external communications, protect organizational knowledge, etc., The effectiveness of the quality management system does not necessarily depend on the amount of documented information produced.

It is important that documented information be distributed and applied appropriately. Information can be in any medium and be managed by any means. Emerging technologies make it easier to document information and make it readily available, but they introduce new risks, such as that of massive loss of information, as a result of computer failures, or loss of confidentiality, which need to be addressed.

Clause 7.5 addresses the management of documented information so that it is protected and made available as appropriate. This involves controlled distribution, including to external interested parties, and requires that access to documented information be regulated. This includes externally sourced documents when relevant to the quality management system, such as standards and laws, contracts and orders or communications from relevant interested parties.

It is important to prevent unintended use of obsolete documented information by removal or by application of suitable identification or controls if obsolete documented information is kept for any purpose.

This document states that documented information that is available as evidence of conformity has to be protected from unintended alteration. Among other things, this means that it cannot be reasonably possible to inadvertently delete or alter a document.

NOTE 1 See Clause A.2 e) for terminology relevant to 'Documented information'.

NOTE 2 See ISO 10013^[6] for guidance on documented information.

A.8 Operation

A.8.1 Operational planning and control

Product and service realization need to be carried out under controlled conditions to minimize the possibility of nonconformities or other undesirable situations occurring at each stage of the operational processes and that can be reflected in the next stage, eventually resulting in a nonconforming product or service for the customer. These controlled conditions are established by applying risk-based thinking, as outlined in Clause 6 of this document.

"Establishing criteria for processes" means determining how the process is to be performed. Implementing process control "in accordance with the criteria" means verifying that the processes are actually carried out in the intended way. It can be necessary to document processes, for example by describing them in appropriate documented procedures, to ensure that they are carried out in accordance with the established criteria. It can be necessary to document evidence of conformity of product and service processes with requirements by producing appropriate documented information.

NOTE See ISO 10007^[20] for guidance on configuration management.

A.8.2 Requirements for products and services

Sharing adequate information with the customer through an appropriate communication process (8.2.1) ensures the effectiveness of operational activities and for outputs to meet requirements. Such communication is necessary to clarify what products and services are required by customers, and the needs of customers, related to those products and services.

Such communication can be provided in various ways and by different means, and can also include training activities aimed at the customer to enable them to better formulate requests, understand the characteristics of the product or service offered, use the product or service appropriately, maximize the benefits obtainable from the product or service, etc.

Communication with the customer is aimed at obtaining information about any customer's special needs and expectations. Customer information can also include advertising. In addition to complying with the applicable statutory and regulatory requirements, handling such communications with ethical behaviour is important to avoid creating customer expectations that do not correspond to what the organization is actually capable of providing.

The organization determines the requirements for the products and services to be offered to customers in accordance with clause [8.2.2](#). These requirements include those mandatory for the product or service and those attributed to the product or service by the organization.

Before offering a product or service and before committing to its provision, the organization has to ensure that it is capable of delivering what is promised and what is necessary to enhance customer satisfaction ([8.2.3](#)). This requires the organization to make sure it is able to meet all requirements.

NOTE See ISO 10001[121](#) for guidance on codes of conduct for organizations relevant to customer communication ([8.2.1](#)).

A.8.3 Design and development of products and services

Product and service design and development is the set of processes for transforming requirements for the products and services into specified product or service characteristics. This does not only relate to strictly physical or functional characteristics but can also relate to such things as sustainability, ethics and customer experience, if these are relevant to the product or service to be designed or developed, and if determined as necessary to meet customer needs and expectations. For service organizations, the approach to design and development can be different from "traditional" manufacturing organizations. In some cases, organizations can justify the exclusion of certain sub-clauses or individual requirements from their quality management system, without necessarily excluding the entire clause.

Clause [8.3.2](#) specifies what needs to be considered in determining the stages and controls for design and development. "Shall consider" means that the aspects listed in (a) to (j), need to be addressed by the organization, as part of design and development planning, as applicable and appropriate.

The best way to approach design and development is as a process. The applied controls of the design and development process include verification, review, and validation of design and development ([8.3.4](#)). Specifically, verification consists of checking that the design and development, and the results obtained, during and at the end of the design, meet the determined input ([8.3.3](#)) for the design and development process.

Review consists of critically evaluating what was designed, at appropriate stages of design, to be sure that what was designed does not introduce issues that can adversely affect the ability of what was designed, to meet the expected requirements for the product and service.

Validation consists of the practical ascertainment, that the design and development outputs ([8.3.5](#)) meet the input requirements.

Design and development can be aimed at determining innovative solutions for the product or service. In this case, more careful and in-depth design and development control, including verification, review, and validation, can be required.

NOTE See ISO 10007[121](#) for guidance on configuration management relevant to design and development changes ([8.3.6](#)).

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. Therefore, establishing and maintaining proper control of external providers is essential for the organization to meet its quality management system objectives.

Control of externally provided processes, products and services can be addressed 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.

The controls required for external provision can vary widely depending on the nature of the processes, products and services and can include second-party audits, as addressed, for example, in ISO 19011^[4]. 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. Also, opportunity-based thinking can be applied to determine possible improvements of externally provided processes, products, and services through the supply chain.

NOTE See ISO 37500^[23] for guidance on outsourcing.

A.8.5 Production and service provision

This clause concerns realization activities and establishes requirements to ensure that production and service delivery are such that products and services that meet requirements are provided on a regular basis. These are the core processes of an organization, related to the sector in which it operates, and the output of which directly affects customer satisfaction and which sometimes, typically in the case of services, occur at the interface with the customer.

The controlled conditions for production and service delivery depend on the extent to which the other requirements of the quality management system have been met. Conditions for keeping operational processes under control include, where applicable, process validation. Validation should be performed in cases where the result of a process (the product, or service), cannot be fully verified before delivery to the customer, because this is not economically or technically practicable. In this case, detailed documented information of the process and competences are essential to ensure that the actual process is identical to the "validated" one and provide confidence that the output will conform.

In some cases, it is not possible for services to be fully checked for conformity, prior to delivery. Validation can need to be repeated as initial conditions change (for example, after a period of time during which an operator has potentially lost some of their skills). Validation of a process can supplement or replace, in whole or in part, verification of the output: the organization is responsible for determining which combination of verification and validation is best suited for quality assurance purposes.

The organization has to ensure that the product and service, at the different stages of their realization, are determined to indicate their state of control (8.5.2). It is important to know whether the output, intermediate or final, has been submitted to the planned control, and what was the result of that control. Identification and traceability are closely related, since when necessary to trace the previous stages of processing, for example, of a product or service, or to trace it after it has been placed on the market, it is required that it can be uniquely identified. The traceability requirement can be established by the organization, or by its customers, or imposed by statutory or regulatory requirements.

Sometimes, in order to realize the product or service, organizations have to use objects, materials, information, tools, places that belong to the customer or suppliers (8.5.3). The organization is required to determine such property and prevent undesired occurrences. If a problem occurs with customer or supplier property, then this needs to be recorded and promptly communicated to customers or suppliers to resolve

the problem. The above also applies in case the anomaly of the customer or supplier property was not caused by the organization but detected by it.

The conformity of the product or service can be adversely affected by damage occurred at different stages of production or service delivery (8.5.4). Preservation is a way to avoid this. Preservation applies to both tangible and intangible objects, including information.

Since customer satisfaction depends on the performance of the product or service, even after its delivery or provision, for a required or expected period of time, the quality management system also covers, as appropriate, post-delivery activities (8.5.5). Post delivery obligations can derive from:

- a) laws, as in the case of mandatory warranties;
- b) contracts;
- c) customer expectation.

Depending on new circumstances or events, or at the request of interested parties, it can be necessary to introduce changes from what was planned or expected (8.5.6). This is acceptable, as long as the changes are managed in a controlled manner so as not to adversely affect consistent conformity with requirements. Introducing changes from what was planned or expected can result from having determined risks or opportunities, and the change itself can introduce risks and opportunities. Documented information of the ways decisions were made enables the changes established and the related responsibilities to be traced and ensures the appropriate management of any positive and negative consequences of the changes introduced.

A.8.6 Release of products and services

It is important that conformity of products and services is controlled and documented, during their production, release and prior to delivery. These controls can concern the conditions under which the product or service is to be delivered, to verify the adequacy of these conditions, before delivery, and can be applied at different stages of delivery, to enable passage to the next stage.

A.8.7 Control of nonconforming outputs

If all previous steps have been conducted in accordance with the requirements of this document, the possibility of nonconforming output is minimal. The application of continual improvement through the PDCA mechanism serves to further reduce this occurrence over time. However, even by rigorously applying the quality management system, there is a margin of uncertainty, which implies the possibility that the product or service resulting from the operational processes will be non-conforming to the requirements. This can relate as much to the final product, and provided service, as to the intermediate stages of the production and service provision.

Nonconformity can emerge from the controls performed as planned, or accidentally, or, after the delivery, even upon reporting by the customer or other interested parties. In any case, the aim is to prevent the nonconforming product or service, once identified, from being unintentionally used, by taking appropriate action. Correcting a nonconforming product or service can mean reworking or repairing the product or providing the service or parts of it again. In such cases, controls have to be repeated to ensure that conformity has been restored.

NOTE 1 See ISO 10002^[24] for guidance on complaints handling.

NOTE 2 See ISO 10003^[25] for guidance on dispute resolution external to organizations.

A.9 Performance evaluation

A.9.1 Monitoring, measurement, analysis and evaluation

In accordance with the PDCA model, this clause covers the "Check" step. The organization is required to monitor, measure (9.1.1), analyse and evaluate (9.1.3) data related to the status and performance of the

quality management system. This activity refers to a specific observation period, considered by the organization to be adequate to obtain meaningful information.

One of the aspects to monitor and review is customer satisfaction (9.1.2). This can be achieved in multiple ways. To enhance customer satisfaction, obtaining, monitoring, and reviewing of customer satisfaction data is crucial. Customer satisfaction information is the input for improvement actions, as the purpose of the quality management system includes enhancing customer satisfaction.

NOTE 1 See ISO 10004^[26] for guidance on monitoring and measuring customer satisfaction.

NOTE 2 See ISO 10003^[25] for guidance on dispute resolution external to organizations.

NOTE 3 See ISO 10009^[15] for guidance for quality tools and their application.

NOTE 4 See ^[16] for guidance on statistical techniques.

A.9.2 Internal audit

The organization is required to conduct internal audits, based on a programme. An effective internal audit programme is based on an evaluation of the status of processes and their contribution to achieving the objectives of the quality management system, that enables it to determine which processes deserve a more in-depth and detailed audit. All processes of an organization's quality management system need to be audited. It is up to the organization to determine audit frequencies based on their assessment of associated risks. Internal audit is useful for evaluating the ability of the quality management system to adapt to changes and is part of an ongoing process through which aspects of the quality management system that need to be corrected and improved are highlighted. One of the ways to evaluate the effectiveness of the internal audit is to assess its ability to detect the actual state of the system and to provide top management with information useful in making decisions for improvement. Internal audits can also be used to determine opportunities.

NOTE 1 See ISO 19011^[4] for guidance on auditing management systems.

NOTE 2 See <http://www.iso.org/tc176/ISO9001AuditPracticesGroup>^[27] for guidance.

A.9.3 Management review

Management review is one of the most important elements of the quality management system, as it is the way for top management to obtain overall information on the status of the quality management system and make subsequent decisions.

It can be necessary for management to compare the performance and objectives of the quality management system with those of other management systems in the organization, including for the purpose of making decisions and allocating resources taking into account priorities.

Trends in audit results refers to all audits including first, second- and third-party audits of the organization's quality management system.

It is up to the organization to determine the intervals between management reviews, taking into account the risks and opportunities arising from the external and internal context, and related changes.

The status of implementation of decisions arising from the previous management review and changes that have occurred with respect to the context and the needs and expectations of relevant interested parties is an essential topic of a management review.

As a result of the management review, this clause requires making and documenting appropriate decisions and determining what resources will be made available for improvement and necessary changes (9.3.3).

A.10 Improvement

A.10.1 Continual improvement

This clause requires that the quality management system is continually improved. This is a requirement and not merely an option. Therefore, conformity to this document cannot be claimed unless this requirement has been met.

Continual improvement is one type of improvement, but there are other ways to improve the quality management system, which can become necessary in relation to sudden or unexpected changes in the context. Improvement can arise from the need to react to risks, or the ability to take advantage of opportunities. Managing improvement can require more or different skills than those already present in the organization. This is one of the factors to be considered in the context of decisions regarding the resources needed.

The use of emerging technology can facilitate continual improvement and impact an organization's quality management system.

While these technologies are not new to all organizations, their impact is growing, for example, digitalization (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. Digitalization includes both the digitization of knowledge and information, and the intelligent networking of machines and processes.

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

This requirement covers the management of both nonconforming outputs, as addressed in clause 8.7, and any other nonconformities found in the quality management system. Nonconformities can be classified according to their level of severity. The severity of a nonconformity is related to the negative consequences it can generate immediately or over time, on the quality management system and on the organization's ability to provide products and services that consistently meet customer and applicable statutory and regulatory requirements. Appropriate application of risk-based thinking can facilitate the analysis of nonconformity and evaluation of its level of severity.

This clause specifically addresses the actions to be taken once the nonconformity has arisen, in addition to what is stated in clause 8.7. It is not required that corrective action be taken for every nonconformity. It is up to the organization to determine within what limits it can accept that the problem will recur and decide on the need for action to address the cause or causes of the nonconformity. This decision is subject to the need to meet customer needs and expectations and applicable mandatory requirements.

No specific methods or techniques are required for nonconformity management; it is up to the organization to decide. There is no requirement that root cause analysis be done, although the organization can choose to do so, or be required to do so by other bodies.

Bibliography

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