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Quality management systems –

Requirements

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Preface

ISO (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 by an ISO technical committee. Any ISO member body interested in the purpose for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, also take part in the work of ISO. ISO also works closely with the International Electrotechnical Commission (IEC), working together on all matters of electrotechnical standardization.

The procedures used to develop this document and to further support it are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria required for different types of ISO documents shall be specified. This document has been developed in accordance with the rules laid down in the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Particular attention is given to the fact that certain elements of this document may be subject to patent rights. ISO shall not be responsible for identifying any or all such patent rights. Details concerning any patent rights established during the development of the document should be indicated in the Introduction and/or in the ISO Patent Declarations sheet (see www.iso.org/patents).

All trademarks referred to in this document are given for convenience and do not imply recommendation (approval).

For an explanation of the meanings used by ISO of specific terms and expressions related to conformity assessment, as well as information on ISO's compliance with the World Trade Organization (WTO) Technical Barriers to Trade (TBT) agreement, see the following link: www.iso.org/iso/foreword.html.

ISO Technical Committee ISO/TC 176, Quality Management and Quality Assurance, Subcommittee SC 2, Quality Systems, is responsible for this document.

This fifth edition supersedes and replaces the fourth edition (ISO 9001:2008), which underwent a technical revision in which the sequence of sections was revised and revised quality management principles and new concepts were applied. It also supersedes and replaces the Technical Amendments of ISO 9001:2008/Cor.1:2009.

Introduction

0.1 General provisions

Recognizing the necessity of a quality management system is a strategic decision for an organization that can help improve its overall operation and provide a solid foundation for sustainability initiatives.

The potential benefits to the organization from implementing a quality management system based on this International Standard are as follows:

(a) The ability to consistently deliver products and services that meet customer, legal, and other regulatory requirements;

b) Facilitation of opportunities to increase customer satisfaction;

(c) Handling risks and opportunities related to the organization's context and objectives;

(d) The ability to demonstrate compliance with established requirements for the quality management system;

This International Standard can be applied by internal and external parties.

This International Standard is not intended to be used for the following purposes:

- unifying the structure of different quality management systems;

- Alignment of documentation with the structure of the sections of this International Standard;

- use of specific terminology from the International Standard within the organization.

The requirements for quality management systems established in this International Standard are additional to the requirements for products and services.

This International Standard uses a process approach that includes a Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

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

The PDCA cycle allows the organization to ensure that its processes are properly resourced and managed, and that opportunities for improvement are identified and implemented.

Risk-based mindset enables the organization to identify factors that may cause its processes and quality management system to deviate from planned results, put protective mechanisms in place to reduce negative impacts, and ensure that opportunities are maximized when they arise (see Section A.4).

Continuous compliance and identifying future needs and expectations creates challenges for organizations in an increasingly dynamic and complex environment. To achieve these goals, an organization may find it necessary to use various forms of improvement in addition to corrections and continuous improvement, such as radical change, innovation, and reorganization.

The following verb forms are used in this International Standard:

- "shell" (should, should) indicates a requirement;

- "should" indicates a recommendation;

- "may" (may, allowed) indicates permissibility;

- "can" (may, has the ability) indicates the possibility or ability.

Information marked as "NOTE" is provided to improve understanding and clarify the relevant requirement.

0.2 Quality management principles

This International Standard is based on the quality management principles of ISO 9000. The descriptions include a statement of each principle, a rationale for why the principle is important to the organization, a number of examples of benefits associated with the principle and examples of typical actions to improve the organization's performance by following the principle.

Quality management principles:

- customer orientation;

- leadership;

- Involvement of the personnel;

- a process approach;

- improvements;

- fact-based decisions;

- relationship management.

0.3 Process Approach

0.3.1 General provisions

This International Standard aims to promote the use of the process approach to develop, implement and improve the performance of the quality management system, increasing customer satisfaction by meeting customer requirements. Specific requirements essentially related to the adoption of the process approach are included in Section 4.4.

Representation and management of interconnected processes as a system contributes to effective and efficient achievement of organization's planned results. This approach allows the organization to manage the interactions and interconnections of the processes in the system, so that the performance of the organization as a whole can be improved.

The process approach involves the systematic definition and management of processes and their interactions in order to achieve planned results in accordance with the quality policy and strategic directions of the organization. Management of processes and the system as a whole can be achieved using the Plan-Do-Check-Act (PDCA) methodology (see Section 0.3.2) with an overall focus on risk-based thinking (see Section 0.3.3), aimed at realizing positive opportunities and preventing undesirable results.

Application of the process approach within the quality management system ensures:

(a) Understanding and continually meeting requirements;

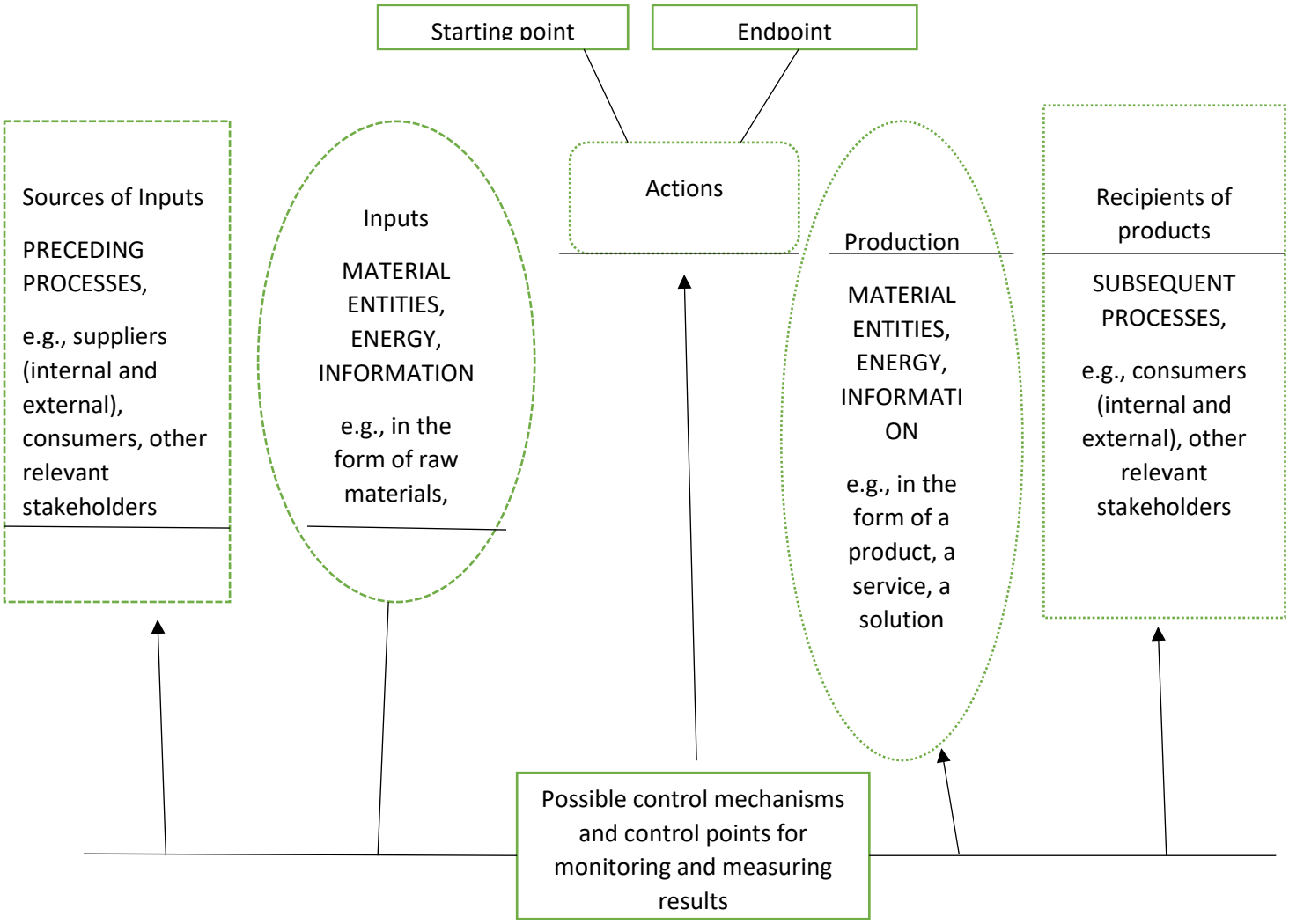
(b) Processes are represented in terms of added value;

(c) The effective execution of the process;

(d) Process improvement based on evaluation of data and information.

0.3.2 Plan-Do-Check-Act cycle

Figure 1 provides a schematic representation of any process and shows the interaction of its elements. The monitoring and measurement points required for control are specific to each process and will vary depending on the risks involved.



Pic. 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 any process and quality management system as a whole. Pic. 2 shows how sections 4 through 10 can be grouped together according to the PDCA methodology.

Quality management system (4)

Picture 2 Representation of the structure of this International Standard in PDCA loop format

The PDCA cycle can be summarized as follows:

Plan: set goals for the system and its constituent processes, identify resources needed to produce results in accordance with customer requirements and organizational policies, and identify and make decisions about risks and opportunities;

Do: execute as planned.

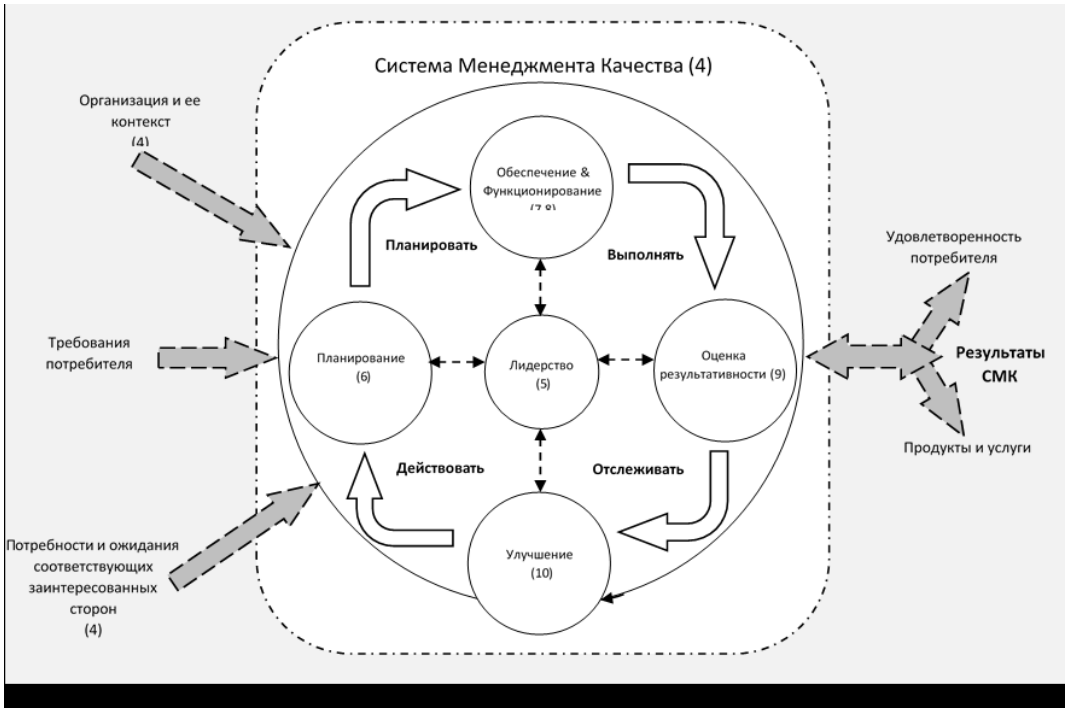
Check: Monitor and (where possible) measure processes, the final product and services against policies, goals, requirements and planned actions, and generate reports on results.

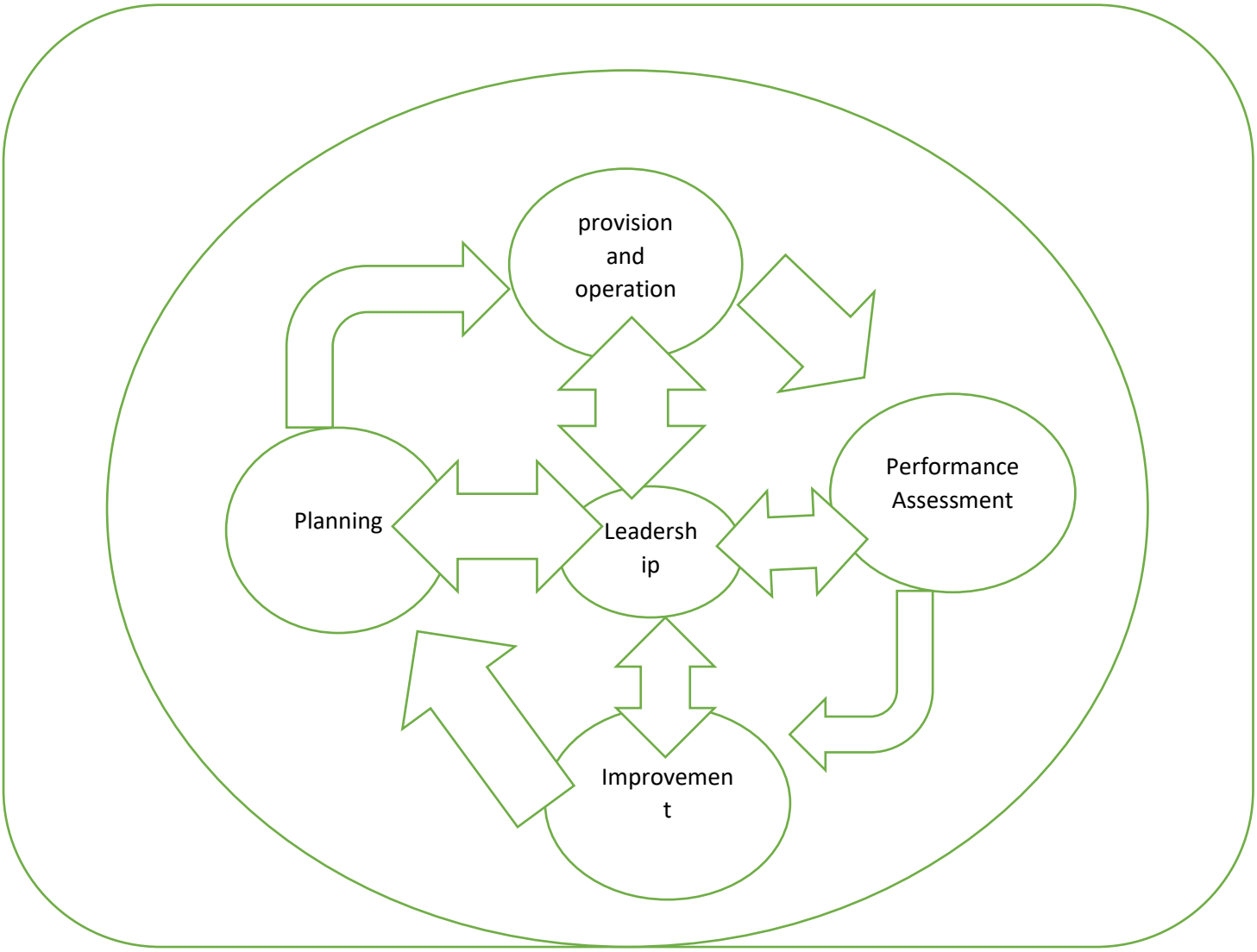
Act: take action as necessary to improve process performance.

0.3.3 Risk-Based Mindset

Risk-based thinking (see Section A.4) is essential to building an effective quality management system. The concept of risk-based thinking was present in previous versions of this International Standard, for example, in taking preventive actions to avoid potential non-conformities, in analyzing any non-conformities before they occur, and in taking actions to prevent recurrence that are consistent with the impact of the non-conformity.

In order to demonstrate compliance with the requirements of this International Standard, the organization shall plan and implement actions to address risks and opportunities. The handling of risks and implementation of opportunities provide the basis for improving the performance of the quality management system, obtaining improved results and preventing negative effects.




provision and operation
Planning
Leadership
Performance Assessment
Improvement

Opportunities may arise as a result of a situation that is conducive to achieving desired outcomes, such as a set of circumstances that enable an organization to attract customers, develop new products or services, reduce losses, or increase productivity. Actions to realize opportunities may also include consideration of the risks involved. Risk is the effect of uncertainty and any such uncertainty can have both positive and negative effects. A favorable deviation caused by risk can lead to opportunities, but not all positive effects of risks turn into opportunities.

0.4 Compatibility with other management system standards

This International Standard follows the framework developed by ISO to improve the compatibility of its issued International Management System Standards (see section A.1.).

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

This International Standard is related to ISO 9000 and ISO 9004 as follows:

- ISO 9000 Quality Management Systems - Essentials and Vocabulary provides the necessary basis for proper understanding and implementation of this International Standard;
- ISO 9004 Managing the Organization for Sustainable Success - A Quality Management Approach provides guidance for organizations that wish to extend the requirements beyond this International Standard.

Annex B contains **a detailed list of other International Standards related to quality management systems** which have been developed by Technical Committee 176.

This International Standard does not include requirements specific to other management systems, those addressing environmental management, occupational health and safety management or financial management.

Industry-specific quality management system standards based on the requirements of this International Standard have been developed for a number of industries. Some of these standards establish additional requirements for quality management systems, while others are limited to recommending the application of this International Standard to a particular industry.

A matrix showing the correspondence between sections of this revision of this International Standard and the previous revision (ISO 9001:2008) can be found on the committee's website www.iso.org/tc176/sc02/public.

Quality management systems - Requirements

1 Area of application

This International Standard specifies the requirements for a quality management system where 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 continual improvement of the system and the assurance of compliance with customer and applicable statutory and regulatory requirements.

All of the requirements of this International Standard are common and are intended to be applied by all organizations regardless of their type or size or the products and services they produce.

NOTE 1 In this International Standard, the terms "product" or "service" refer only to products and services intended for or requested by the consumer.

NOTE 2 Legislative and regulatory requirements may be combined by the term "legal requirements".

2 Normative References

The following documents are - completely or partly - normative references in this International Standard and are mandatory for its application. If a reference document has a date, only the version indicated applies. If the reference document has no date, the latest edition (including any changes) applies.

ISO 9000:2015, Quality Management Systems - Fundamentals and Glossary

3 Terminology and definitions

For the purposes of this document, the terminology and definitions given in ISO 9000:2015 shall apply.

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall identify the external and internal factors that are significant in terms of its objectives and strategic direction and that affect the ability of its quality management system to achieve the expected outcome(s).

The organization shall monitor and analyze information about these external and internal factors.

Note 1 These factors may include positive and negative circumstances as well as conditions to be considered.

Note 2 Understanding the external context can be facilitated by considering factors related to the legal, technological, cultural, social, economic, competitive, and market domains at the international, national, regional, or local level.

Note 3 An understanding of the internal context can be facilitated by considering factors related to the organization's values, culture, knowledge and activities.

4.2 Comprehension of stakeholder requirements and expectations

Because of their influence or potential influence on the organization's ability to consistently deliver products and services that meet customer requirements, applicable legal and regulatory requirements, the organization must establish:

(a) The stakeholders that are significant within the quality management system;

(b) the requirements of those stakeholders that are relevant within the quality management system.

The organization must track and analyze information about these stakeholders and their material requirements.

4.3 Definition of the scope of the quality management system

The organization must define the scope and applicability of the quality management system in order to define its scope.

In defining this scope, the organization should take into account:

(a) the external and internal factors mentioned in 4.1;

(b) The requirements of the relevant stakeholders referred to in 4.2;

(c) the products and services provided by the organization.

The organization shall apply all the requirements of this International Standard if they are applicable within the defined scope of the quality management system.

The scope shall be documented and managed as documented information. The scope shall identify the types of products and services included and provide justification for any requirement of this International Standard that the organization has determined is not applicable within the scope of the quality management system.

Compliance with this International Standard can only be declared if the requirements identified as not applicable do not affect the organization's ability or responsibility to ensure compliance of its products and services and to enhance customer satisfaction.

4.4 The quality management system and its processes

4.4.1 The organization should, in accordance with the requirements of this International Standard, develop, implement, maintain and continuously improve the quality management system, including the necessary processes and their interactions.

The organization shall define the processes required for the quality management system and their application within the organization, and shall:

(a) Define the required inputs and products expected from these processes;

(b) Determine the sequence and interaction of these processes;

(c) Identify and apply the criteria and methods (including monitoring, measurement and relevant performance indicators) necessary to ensure the effective execution and control of these processes;

(d) Identify the resources required for these processes and ensure their availability;

(e) allocate responsibility and authority for those processes;

(f) manage risks and opportunities as required by 6.1;

(g) evaluate these processes and implement any changes necessary to ensure that these processes achieve the expected results;

h) improve the processes and the quality management system.

4.4.2 The organization shall extent necessary to ensure that processes are carried out:

(a) Manage documented information to ensure that its processes are performed;

(b) Retain documented information to have confidence that processes are performed as planned.

5 Leadership

5.1 Leadership and Commitment

5.1.1.1 General.

Senior management should demonstrate leadership and commitment to the quality management system by:

(a) Taking responsibility for the performance of the quality management system;

(b) ensuring that the quality policy and objectives for the quality management system are established and aligned with the context and strategic direction of the organisation;

c) assurance that the requirements of the quality management system are integrated into the business processes of the organization;

(d) Promoting a process approach and risk-based thinking;

(e) Ensuring that the resources required for the quality management system are available,

(f) communicating the importance of effective quality management and meeting the requirements of the quality management system;

g) ensuring that the quality management system achieves the expected results;

(h) Involving, targeting and maintaining the efforts of personnel in ensuring the effectiveness of the quality management system;

(i) Encouraging continuous improvement;

(j) Encouraging the demonstration of leadership at various levels of management within the boundaries of established responsibilities.

NOTE The term "business" in this International Standard may be interpreted broadly to mean those activities that are essential to the existence of an organization, whether public, private, for-profit or not-for-profit.

5.1.2 Customer Orientation

Senior management must demonstrate leadership and commitment to customer orientation by ensuring that:

(a) Consumer requirements and applicable statutory and regulatory requirements are identified, perceived, and consistently met;

(b) Risks and potential opportunities that could affect product and service compliance and the ability to enhance customer satisfaction are identified and acted upon;

(c) A focus on improving customer satisfaction is maintained.

5.2 Policy

5.2.1 Developing a quality policy

Administration should establish, review, and manage a quality policy that:

(a) Is appropriate to the goals and context of the organization and promotes movement in the chosen strategic direction;

(b) Provides a framework for setting quality objectives;

(c) Includes a commitment to meet established requirements;

(d) Includes a commitment to continuous improvement of the quality management system.

5.2.2 Informing about the quality policy

The quality policy shall:

(a) Be formalized as documented information;

(b) Be communicated to the organization's employees, understood by them and applied within the organization;

(c) Be made available to relevant stakeholders wherever possible.

5.3 Organizational Roles, Responsibilities and Authorizations

Administration must ensure that responsibility and authority for the respective roles are established, communicated and understood by the employees of the organization.

Administration shall establish responsibility and authority to:

(a) Ensuring that the quality management system meets the requirements of this International Standard;

(b) Ensuring that processes produce the expected results;

(c) Reporting on the performance of the quality management system and opportunities for improvement (see 10.1), in particular to senior management;

(d) Ensuring that customer orientation is disseminated throughout the organization;

(e) Ensuring that the integrity of the quality management system is maintained in the planning and implementation of changes to it.

6. Planning

6.1 How risks and opportunities are to be handled

6.1.1 In planning the quality management system, the organisation shall take into account the factors mentioned in 4.1 and the requirements mentioned in 4.2 and identify the risks and potential opportunities for which actions should be taken to

(a) Ensure that the quality management system can achieve the expected results,

(b) Enhance positive effects;

(c) Prevent or reduce undesirable effects,

(d) Ensure improvement.

6.1.2 The organization shall plan:

(a) Actions to handle these risks and opportunities;

(b) How:

1) Build these actions into the quality management system processes (see 4.4) and perform them;

2) Evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportional to the potential impact on product and service compliance.

NOTE 1 Possible risk treatment actions may include avoiding risk, accepting risk to realize opportunities, eliminating the source of risk, changing the probability or consequences, transferring risk, or reasonably retaining risk.

NOTE 2 Realizing opportunities may lead to the adoption of new practices, new product launches, new markets, new customers, partnerships, new technologies, and other positive and realistic opportunities to meet the needs of the organization and its customers.

6.2 Quality objectives and planning for their achievement

6.2.1 The organization shall establish quality objectives for the relevant functions, levels and processes required for the quality management system.
The quality objectives shall:

(a) Be consistent with the quality policy;

b) Be measurable;

(c) Take account of established requirements;

d) Be meaningful in terms of compliance of products and services and growth of customer satisfaction;

(e) Be capable of being monitored;

(f) Be communicated;

(g) Be updated as necessary.

The organization shall maintain and manage documented information on quality objectives.

6.2.2 In planning to achieve quality objectives, the organization shall determine:
(a) What will be accomplished;

(b) What resources will be required;

(c) Who will be responsible;

(d) When the objectives will be achieved;

(e) How the results will be evaluated.

6.3 Planning for change

When the organization identifies the need for changes to the quality management system, these changes must be implemented in a planned manner (see 4.4).

The organization shall take into account:

(a) The purpose of the change and its possible consequences;

(b) The integrity of the quality management system;

(c) Availability of resources;

(d) Distribution or redistribution of responsibility and authority.

7. Provision

7.1 Resources

7.1.1 General provisions

The organization shall identify and provide the resources necessary to develop, implement, operate and continually improve the quality management system.

The organization shall take into account:

(a) The capabilities and limitations of available internal resources;

(b) What is needed from external suppliers.

7.1.2 Personnel

The organization shall identify and provide the personnel required for the effective operation of its quality management system and the operation and monitoring of its processes.

7.1.3 Infrastructure

The organization should define, provide and maintain the infrastructure for the operation of its processes in order to achieve conformity of products and services.

NOTE Infrastructure may include

(a) Buildings and related systems;

(b) Facilities, including equipment and software;

(c) Transportation resources;

(d) Information and communication technology.

7.1.4 Process Environment

The organization shall identify, provide and maintain an environment necessary for the operation of its processes and the achievement of product and service compliance.

NOTE A suitable environment can be a combination of physical and human factors, such as:

(a) Social (e.g., nondiscrimination, tranquility, lack of confrontation);

(b) Physiological (e.g., reduction of stress, prevention of overexertion, protection from negative emotions);

(c) Physical (e.g. temperature, heating, humidity, light, airflow, hygiene, noise).

These factors can vary considerably depending on the products and services produced.

7.1.5 Resources for monitoring and measurement

7.1.5.1 General provisions

Where monitoring and measurement is used to provide evidence that products and services meet specified requirements, the organization shall identify the resources necessary to ensure the suitability and validity of the data.

The organization shall ensure that the resources used:

(a) Are suitable for the specific type of monitoring and measurement activities being performed;

(b) Are managed in a manner that ensures they are always fit for purpose.

The organization shall maintain appropriate documented information as evidence of the appropriateness of the monitoring and measurement resources for the purpose of the application.

7.1.5.2 Traceability of measurements

Where traceability of measurements is a requirement; a customer expectation or is considered by the organization to be an integral part of providing confidence in the validity of measurement results, the measuring instruments shall be:

(a) Calibrated or verified, or both, at prescribed intervals, or prior to use against measurement standards corresponding to international or national standards; when such standards are not available, data on the standards used for calibration or verification shall be retained as documented information;

(b) Marked so that their status can be determined;

(c) Protected from adjustment, damage or deterioration due to wear that could invalidate the status and subsequent measurement results.

The organization shall determine whether there is reason to doubt the validity of previous measurement results after a defect in a measuring instrument has been detected and take appropriate action if necessary.

7.1.6 The knowledge base of the organization

The organization shall define the knowledge base necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge base must be kept up to date and be available to the extent necessary.

When dealing with changing needs and trends, the organization should analyze its current knowledge base and find out how to acquire or access the additional information and updates required.

NOTE 1 An organization's knowledge base is knowledge specific to the organization; it is usually sourced from accumulated experience. It is information that is used and shared to achieve the organization's goals.

NOTE 2 An organization's knowledge base can be based on:

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

(b) External sources (e.g., standards; academia; conferences, knowledge from customers or external suppliers).

7.2 Competence

The organization shall:

(a) Identify the necessary competence of the employee(s) performing work under its control that affects the operation and performance of the quality management system;

(b) Ensure that those individuals are competent by virtue of appropriate education, training or experience;

(c) Where possible, take measures to ensure the necessary competence and evaluate the effectiveness of the measures taken;

(d) Maintain appropriate documented information as evidence of competence.

NOTE Possible actions may include, for example, training, mentoring, or relocating current employees; or hiring new or contracted competent personnel.

7.3 Awareness

The organization should ensure that personnel carrying out work within the organization's management system are informed of:

(a) The quality policy;

(b) The relevant quality objectives;

(c) Their contribution to the performance of the quality management system, including the benefits of improvements

d) The consequences of non-conformities with the quality management system.

7.4 Communication

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

(a) On what subject information shall be exchanged;

(b) When to exchange information;

(c) With whom the information is exchanged;

(d) How to exchange information;

(e) Who exchanges the information.

7.5 Documented Information

7.5.1 General provisions

The organization's quality management system shall include:

(a) Documented information required by this International Standard;

(b) The documented information recognized by the organization as necessary to ensure the effectiveness of the quality management system.

NOTE The scope of documented information in the quality management system may vary from organization to organization due to:

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

- The complexity of the processes and their interactions;

- The competence of the personnel.

7.5.2 Creating and updating

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

(a) Identification and output (e.g., title, date, author, or reference number),

(b) Format (e.g., language, software version, graphics) and medium (e.g., paper, electronic form),

(c) Review and approval to maintain suitability and compliance.

7.5.3 Documented Information Management

7.5.3.1 The documented information required by the quality management system and this International Standard shall be managed to ensure:

(a) That it is available and usable where and when it is required;

(b) That it is adequately protected (e.g. against loss of confidentiality, misuse or loss of integrity).

7.5.3.2 To manage documented information, the organization shall do the following, to the extent applicable:
(a) Dispatch, access, release, and application,

(b) Store and retain in proper condition, including maintaining legibility,

(c) Control changes (e.g., version control),

(d) Establish a retention period and methods of destruction.

Documented information of external origin recognized by the organization as necessary for the planning and operation of the quality management system shall be appropriately identified and managed.

Documented information retained as evidence of compliance shall be protected from inadvertent changes.

NOTE The term "access" can refer to a decision regarding permission to view documented information only or permission and authority to view and modify documented information.

8. Functioning

8.1 Operational planning and management

The organization shall plan, implement, and manage the processes (see 4.4) necessary to ensure compliance in the delivery of products and services, and shall perform the actions defined in Section 6 by:

(a) Defining requirements for products and services:

(b) Establishing criteria for,

(1) Processes;

(2) Accepting products and services;

(c) Identifying the resources necessary to achieve compliance with product and service requirements;

(d) Managing processes in accordance with those criteria;

(e) Identifying and maintaining documented information to the extent necessary to:

1) To provide assurance that processes have been performed as planned;

(2) To demonstrate that products and services meet the requirements for them.

The result of such planning should be in a form appropriate to the organization's operations.

The organization must manage planned changes and analyze the effects of unintended changes, taking steps to mitigate any negative effects, if necessary.

The organization must ensure that outsourced processes are performed under manageable conditions (see 8.4).

8.2 Product and service requirements

8.2.1 Communication with customers

Communications with consumers shall include:

(a) Providing information related to products and services;

(b) Managing inquiries, contracts, or orders, including changes;

(c) Receiving consumer opinions and feedback relating to products and services, including consumer complaints;

(d) Handling or managing consumer property;

(e) Establishing special requirements for dealing with unforeseen circumstances, if necessary.

8.2.2 Determining requirements relating to products and services

In determining requirements relating to products and services offered to consumers, the organization shall ensure that

(a) Product and service requirements are identified, including:

1) Any applicable statutory and regulatory requirements;

(2) Those deemed necessary by the organization;

(b) The organization can meet the requirements for the products and services offered.

8.2.3 Analysis of requirements related to products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for the products and services offered to customers. The organization shall conduct an analysis prior to committing to provide products and services to the consumer to consider:

(a) Requirements articulated by the consumer, including requirements for delivery and post-delivery actions;

(b) Requirements not articulated by the consumer but necessary for the specified or intended application, if known;

(c) Requirements established by the organization;

(d) Legislative and regulatory requirements applicable to the products and services.

The organization shall ensure that decisions are made on contract or order requirements that differ from those previously established.

Consumer requirements must be validated by the organization prior to their acceptance if the consumer has not submitted these requirements in a documented manner.

NOTE In some cases, such as Internet sales, it is not practical to conduct a full analysis for each order. Instead, the analysis may address essential product information, such as that contained in catalogs.

8.2.3.2 The organization shall retain documented information, to the extent applicable:

(a) On the results of the analysis;

(b) Any new product and service requirements.

8.2.4 Changes to product and service requirements

The organization shall ensure that appropriate documented information is amended and that appropriate individuals are made aware of the amended requirements when product and service requirements are changed.

8.3 Development and design of products and services

8.3.1 General provisions

The organization shall establish, execute, and maintain a design and development process that ensures the subsequent production of products and services.

8.3.2 Design and Development Planning

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

(a) The nature, duration, and complexity of the design and development work;

(b) The required process steps, including appropriate analysis of design and development results;

(c) The required conformance checks and validation of the suitability of the design and development results;

(d) Responsibilities and authorities associated with the design and development process;

(e) Internal and external resource requirements for the design and development process;

(f) The need to manage the interactions of those involved in the design and development process;

(g) The need to involve consumers and users in the design and development process;

(h) The requirements for subsequent production of products and services;

(i) The expected level of control by consumers and other relevant stakeholders over the design and development process;

(j) Documented information necessary to demonstrate that the requirements for design and development results have been met.

8.3.3 Input data for design and development

The organization shall determine the requirements essential to the specific type of products and services to be designed and developed. The organization shall take into account:

(a) Functional and operational requirements;

(b) Information from previous similar design and development work;

(c) Legislative and regulatory requirements;

(d) Standards or codes of practice to which the organization has committed itself;

(e) The potential consequences of failure due to product and service characteristics.

Baseline data must be consistent with the design and development objectives and be complete and unambiguous.

Inconsistencies in source data must be resolved.

The organization must retain documented information with baseline data for design and development.

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

(a) The results to be achieved are defined;

(b) An analysis has been performed to assess the ability of the design and development results to meet requirements;

(c) Verification was conducted to confirm that the design and development results meet the baseline requirements;

(d) Suitability verification was conducted to confirm that the final products and services meet the requirements associated with the specific application or intended use;

(e) Any necessary action has been taken on problems identified in the analysis, conformance review, or proof of suitability;

(f) Documented information about those actions has been retained.

NOTE. Analysis, conformance testing, and validation of design and development results have clear goals. They may be conducted separately or in any combination as appropriate to the organization's products and services.

8.3.5 Design and development results
The organization shall ensure that design and development results:

(a) Meet the original requirements;

(b) Are suitable for subsequent product and service production processes;

(c) Include directly or make reference to monitoring and measurement requirements, to the extent applicable, and acceptance criteria;

(d) Identify the characteristics of products and services that are essential to their intended use, their safety, and their correct application.

The organization shall retain the results of the design and development process in the form of documented information.

8.3.6 Changes during design and development
The organization shall identify, analyze, and manage changes made during or after the design and development of products and services to the extent that there is no negative impact on compliance.

The organization shall retain documented information on:

(a) Changes made during design and development;

(b) The results of the analysis;

(c) The authorization of changes;

(d) Actions taken to prevent adverse effects.

8.4 Management of externally supplied processes, products and services

8.4.1 General.
The organization shall ensure that externally supplied processes, products, and services are compliant.

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

(a) Externally supplied products and services are intended to be incorporated into the organization's own products and services;

(b) The products and services are provided by an outside supplier directly to the customer on behalf of the organization;

(c) the process or part of the process is performed by an outside supplier as determined by the organization.

The organization shall establish and apply criteria for the evaluation, selection, performance monitoring and reevaluation of external suppliers based on their ability to perform processes or produce products and services as required. The organization must retain documented information on these activities as well as any necessary actions arising from supplier evaluations.

8.4.2 Type and extent of external supply management

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

The organization must:

(a) Ensure that externally supplied processes are under the control of its quality management system;

(b) Identify the controls it expects to apply to both external suppliers and the end result;

(c) Take into account:

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

2) The effectiveness of the controls applied to the external supplier.

(d) Identify conformity assurance activities or other actions necessary to ensure that externally supplied processes, products and services meet requirements.

8.4.3 Information for external suppliers

The organization must ensure the adequacy of the requirements before they are communicated to an external supplier.

The organization shall communicate to external suppliers its requirements for:

(a) The processes, products and services to be delivered;

(b) The approval of:

1) Products and services;

(2) Techniques, processes and equipment;

(3) The release of products and services;

(c) Competence, including any necessary staff qualifications;

(d) The interaction of the external supplier with the organization;

(e) The control and monitoring of the activities of the external supplier to be carried out by the organization,

(f) The conformity or suitability verification activities which the organization, or its customer, intends to perform at the external supplier's premises.

8.5 Production of products and services

8.5.1 Managing the production of products and services

The organization shall produce products and services under manageable conditions.

Managed conditions shall include, to the extent applicable:

(a) The availability of documented information that identifies:

1) The characteristics of the products to be delivered, the services to be rendered, or the actions to be performed;

(2) The results to be obtained;

(b) The availability and application of appropriate resources for monitoring and measurement;

(c) Implementation of monitoring and measurement actions at appropriate stages to confirm that the criteria for monitoring processes or their results and the criteria for acceptance of products and services are met;

(d) Use of appropriate infrastructure and process execution environment,

(e) The appointment of competent personnel, including any required qualifications;

(f) confirming and periodically reaffirming the ability to achieve the planned results of the processes for the production of products and the provision of services in cases where the final result cannot be verified for compliance by subsequent monitoring and measurement;

(g) Implementation of actions to prevent human error;

(h) Implementation of release, delivery and post-delivery actions.

8.5.2 Identification and traceability

The organization shall use appropriate means to identify the results of processes when necessary to ensure product and service compliance.

The organization shall identify the status of process results throughout production, subject to monitoring and measurement requirements.

The organization shall manage the unique identification of process results where traceability is a requirement and retain documented information necessary to ensure traceability.

8.5.3 Property belonging to customers or external suppliers

The organization shall take care of property belonging to customers or external suppliers as long as it is under the organization's control or used by the organization.

The organization shall identify, verify, protect, and preserve property owned by consumers or outside suppliers provided for inclusion in products and services.

If property owned by consumers or external suppliers is lost, damaged, or rendered unusable, the organization must notify the user or external supplier by documenting the occurrence in the form of documented information.

NOTE The property of the user or external supplier may include materials, components, tools and equipment, buildings, intellectual property and personal data.

8.5.4 Preservation of Properties

The organization shall ensure the preservation of process results during the production of products and services to the extent necessary to assure compliance.

NOTE Preservation activities may include identification, processing, contamination control, packaging, storage, transfer or transportation, and protection.

8.5.5 Post-Delivery Activities

The organization shall meet the requirements for post-delivery activities related to products and services.

In determining the required scope of post-delivery activities, the organization shall take into account:

(a) Legal and regulatory requirements.

(b) Possible unintended consequences associated with the products and services;

(c) The nature, use, and anticipated shelf life of the products and the service period;

(d) Consumer requirements;

(e) Consumer feedback data.

NOTE Post-delivery actions may include warranty actions, contractual obligations such as maintenance, and additional services such as disposal or final disposal.

8.5.6 Change Management

The organization shall analyze and manage changes in the production of products and services to the extent necessary to ensure ongoing compliance.

The organization shall retain documented information containing the results of the change analysis, who authorized the change, and any actions resulting from the analysis.

8.6 Release of Products and Services

The organization must implement planned activities at appropriate stages to confirm that product and service requirements have been met.

The release to the customer of products and services shall not occur until the planned activities have been successfully completed or the delivery has been authorized by an authorized person and, where applicable, the customer.

The organization must maintain documented information about the release of products and services. The documented information shall include:

(a) Evidence of compliance with acceptance criteria;

(b) Information that makes it possible to identify the person(s) who authorized the release.

8.7 Management of Nonconforming Process Outcomes

8.7.1 The organization shall ensure that the results of processes that do not conform to identified and managed to prevent their unintended use or delivery.
The organization should take appropriate action based on the nature of the nonconformance and its impact on product and service compliance. This should also apply to nonconforming products and services identified after products are delivered or during or after services are provided.

The organization shall take the following actions (individually or in combination) with respect to nonconforming process results:

(a) Correction,

(b) Isolating, preventing further transfer, returning and suspending the delivery of products and services;

c) Informing the consumer;

(d) Obtaining authority for acceptance with permission to deviate.

Compliance shall be re-checked after correction of non-conforming results.

8.7.2 The organization shall retain documented information that:
(a) Describes the nonconformance;

(b) Records the action taken;

(c) Records details of any approvals received for deviations;

(d) Identifies the authorized person who made the decision to process the non-conformance.

9. Performance Assessment

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General provisions

The organization shall determine:

(a) What requires monitoring and measurement;

(b) The methods of monitoring, measurement, analysis and evaluation necessary to guarantee suitable results;

(c) When monitoring and measurements should be performed;

(d) When the results of monitoring and measurement should be analyzed and evaluated.

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

The organization shall retain the relevant documented information as evidence of the results obtained.

9.1.2 Customer satisfaction

The organization shall track data relating to customer perceptions of the extent to which customer requirements and expectations are met. The organization shall identify methods for obtaining, monitoring, and analyzing this data.

NOTE Examples of monitoring customer perceptions may include customer surveys, customer feedback on the quality of products and services delivered, customer meetings, market share analysis, official positive feedback, warranty claims data, and dealer reports.

9.1.3 Analysis and evaluation

The organization shall analyze and evaluate relevant data and information from monitoring and measurement.

The results of the analysis shall be used to assess:

(a) Compliance of products and services;

(b) The degree of customer satisfaction;

(c) The functioning and performance of the quality management system;

(d) Whether what was planned was successfully completed;

(e) The effectiveness of actions taken to deal with risks and opportunities;

(f) The performance of external suppliers;

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

NOTE. Data analysis methods may include statistical methods.

9.2 Internal audits

9.2.1 The organization shall conduct internal audits at planned intervals to obtain information that the quality management system:

(a) Complies with:

1) The organization's own requirements for its quality management system;

(2) Meets the requirements of this International Standard;

(b) Effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, develop, implement and manage the audit program(s), including their frequency, methods, responsibilities, planning and reporting requirements, which shall take into account the significance of the audited processes, changes affecting the organization and the results of previous audits;

b) Determine the criteria and scope of the audit for each audit;

(c) Select auditors and conduct audits in such a way as to guarantee the objectivity and impartiality of the audit process;

d) Ensure that the results of the audits are communicated to the relevant supervisors;

(e) Take necessary correction and corrective action without undue delay;

(f) Retain documented information as evidence of the implementation of the audit program and its results.

NOTE For guidance, see ISO 19011.

9.3 Management analysis

9.3.1 General points

Senior management should review the organization's quality management system at planned intervals to ensure its continued suitability, compliance and effectiveness, and consistency with the strategic directions of the organization.

9.3.2 Input data for management analysis

The management analysis should be planned and carried out taking into account:

(a) The status of activities in the previous analysis;

(b) Changes in the status of external and internal factors that are important to the quality management system;

(c) Information on the functioning and performance of the quality management system, including trends in:

1) Customer satisfaction and feedback from relevant stakeholders;

2) The extent to which quality objectives are being met;

3) Process performance and conformance of products and services;

4) Nonconformities and corrective actions;

5) Results of monitoring and measurement;

6) Results of audits;

7) Performance of external suppliers;

d) Compliance of resources;

e) Performance of actions taken to address risks and opportunities (see 6.1);

f) Opportunities for improvement.

9.3.3 Results of management analysis

The results of the management review should include decisions and actions related to:

(a) Opportunities for improvement;

(b) Any need for changes to the quality management system;

(c) Need for resources.

The organization shall retain documented information as evidence of the results of the management review.

10. Improvement

10.1 General provisions

The organization must identify and select opportunities for improvement and take any necessary actions to meet customer requirements and increase customer satisfaction.

This should include:

(a) Improving products and services to meet requirements, including consideration of future needs and expectations;

(b) Neutralizing, preventing or reducing undesirable effects;

(c) Improving the functioning and performance of the quality management system.

NOTE Examples of improvements may include correction, corrective action, continuous improvement, fundamental change, innovation, and reorganization.

10.2 Nonconformance and corrective action

10.2.1 When a nonconformity, including any following from a claim, is identified, the organization shall:

(a) Respond to the nonconformity and, to the extent applicable:

1) Take action to manage and correct the non-conformance;

(2) Take action on the consequences;

(b) Assess the need for action to address the cause(s) of the non-conformance so that it does not recur or occur elsewhere, through:

1) Analyzing the nonconformity;

2) Determining the cause of the non-conformance;

(3) Determining whether there are, or could potentially be, similar non-conformances;

(c) Taking any necessary action;

(d) Analyze the effectiveness of any corrective action taken;

e) Update, if necessary, the risks and opportunities identified in the planning phase;

(f) Make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the consequences of the identified non-conformities.

10.2.2 The organization shall retain documented information as evidence of:

(a) The nature of the non-conformities and any subsequent action taken;

(b) The results of any corrective action.

10.3 Continuous Improvement

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

The organization shall take into account the results of the assessment and evaluation and the results of the management review to determine whether there are needs or opportunities for continual improvement.

Annex A
(informational)

Explanation of the new structure, terminology and concept

A.1 Structure and terminology

The structure of sections (i.e., sequence of sections) and some terms have been changed in this edition of the International Standard in comparison to the previous version (ISO 9001:2008) in order to improve compatibility with other management system standards.

There is no requirement in this International Standard applicable to the structure and terminology of the documented information of the organization's quality management system.

The structure of the sections is intended to provide a consistent statement of requirements rather than to serve as a model for documenting the organization's policies, objectives and processes. The structure and content of the documented information relating to the quality management system can often be more suitable for its users if it is related to both the processes carried out in the organisation and the information used for those purposes.

There is no requirement for the terms used by the organization to establish the requirements for the quality management system to be replaced by the terms used in this International Standard. The organization can choose the terminology that is appropriate for its activities (for example: use the terms "record," "documentation," or "protocols" instead of "documented information"; or "supplier," "partner," or "producer" instead of "external supplier").

Table A.1 shows the main differences in terminology between this revision of this International Standard and the previous revision.

Table A.1 - Main differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	**ISO 9001:2015**
Products	Products and services
Management representative	Not used (This kind of responsibility and authority is assigned, but there is no requirement to have one management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measurement equipment	Monitoring and measurement resources
Purchased product	Externally provided products and services
Supplier	External provider
Purchased product	Externally provided products and services
Supplier	External provider

A.2 Products and services

ISO 9001:2008 uses the term "products" to cover all categories of output. This revision of this International Standard uses the term "products and services". The term "products and services" encompasses all categories of produced outputs (hardware, services, information, and consumable/recyclable materials).

The special emphasis on services is intended to emphasize the distinction between products and services in terms of the application of a number of requirements. A characteristic feature of services is that at least some part of it is carried out in interaction with the consumer. This means, for example, that compliance with requirements cannot necessarily be confirmed before the service is provided.

In most cases, the terms "products" and "services" are used together. Most of what organizations supply to consumers or receive from outside suppliers includes both products and services. For example, a tangible or intangible product may have a service associated with it or a service may have a tangible or intangible product associated with it.

A.3 Understanding stakeholder needs and expectations

Section 4.2 establishes the requirements for the organization to identify the stakeholders that are relevant to the quality management system and the requirements of these stakeholders. However, Section 4.2 is not intended to extend the requirements of the quality management system beyond the scope of this International Standard. As defined in the scope, this International Standard applies when an organization needs to demonstrate its ability to consistently deliver products and services that meet customer requirements and applicable statutory and regulatory requirements, and when it aims to improve customer satisfaction.

There is no requirement for the organization in this International Standard to take into account stakeholders that are classified by the organization as insignificant to its quality management system. It is up to the organization to decide whether the specific requirements of the relevant stakeholder are relevant to its quality management system.

A.4 Risk-Based Approach

The concept of risk-based thinking was present in previous versions of this International Standard, for example, in the requirements for planning, analysis and improvement. This International Standard sets out the requirements for an organization to establish its context (see 4.1) and to identify risks as the basis for planning (see 6.1). This reflects the application of risk-based thinking to the planning and execution of quality management system processes (see 4.4) and will be useful in determining the scope of documented information.

One of the key purposes of a quality management system is to act as a preventive tool. Therefore, this International Standard does not contain a separate section or subsection on preventive actions. The concept of preventive action is realized by applying risk-based thinking to the formulation of quality management system requirements.

The risk-based thinking used in this International Standard has contributed to some reduction in the number of prescriptive requirements and replaced them with performance-based requirements. This has increased flexibility over ISO 9001:2008 in the requirements for processes, documented information and responsibilities in the organization.

While 6.1 establishes that the organization must plan risk management activities, there is no requirement to use formal risk management methods or have a documented risk management process. It is up to the organization to decide whether or not to develop a broader risk management methodology than is required by this International Standard, such as the application of other guidelines or standards.

Not all quality management system processes have an equal level of risk in terms of the organization's ability to achieve its objectives and the impact of uncertainty varies from organization to organization. By virtue of the requirements of Section 6.1, the organization is responsible for following risk-based thinking and risk treatment actions, including deciding whether or not to retain documented information as evidence of risk identification.

A.5 Applicability

This International Standard no longer refers to "exceptions" in determining the applicability of its requirements to an organization's quality management system. However, an organization may analyze the applicability of the requirements in relation to its size, its management model, the range of its activities and the nature of the risks and opportunities it faces.

The applicability requirements are established in Section 4.3, which specifies the conditions under which the organization can decide that a requirement cannot be applied to a process within the scope of the quality management system. The organization may make such a determination that a requirement is not applicable only if the determination does not result in a failure to conform products and services.

A.6 Documented information

As part of the harmonization with other management system standards, the general section on "Documented Information" has been adopted without major changes or additions (see 7.5). Where necessary, the text of other sections of this International Standard has been aligned with these requirements. Accordingly, the term "documented information" applies to all documentation requirements.

Where special terms such as "document" or "documented procedures," "quality manual," or "quality plan" were used in ISO 9001:2008, the requirements "manage documented information" are expressed in this International Standard.

Where ISO 9001:2008 used the term "records" to refer to the documents needed to provide evidence of compliance, it is now expressed as the requirement to "maintain documented information." The organization is responsible for determining what documented information must be retained, for what period of time, and on what media it must be retained.

The requirement to "manage" documented information does not preclude the possibility that an organization may also need to "retain" the same documented information for specific purposes, such as retaining previous versions.

Where this International Standard uses the term "information" instead of "documented information" (e.g., in 4.1: "The organization shall track and analyze information about these external and internal factors"), this does not imply a requirement that this information must be documented. In these situations, it is up to the organization to decide whether or not documented information management is necessary or applicable.

A.7 The organization's knowledge base

Section 7.1.6 of this International Standard establishes the need to identify and manage the knowledge available within an organization in order to ensure that its processes are managed and that it can ensure product and service compliance.

Requirements relating to the corporate knowledge base have been introduced to:

(a) Protect the organization from loss of knowledge, such as,

- In the event of a change of personnel;

- When refusing to capture or share information;

(b) To motivate the organization to acquire knowledge, e.g.,

- by learning from experience;

- by training;

- benchmarking.

A.8 Management of externally supplied products and services

Section 8.4 applies to all forms of externally supplied processes, products, and services, e.g., through:

(a) Purchases from a supplier;

(b) Agreements with an associated company;

(c) Outsourcing processes to an external supplier.

Outsourcing always has the essential feature of a service, since it will involve at least one job, the performance of which will require interaction between the supplier and the organization.

The management tools required for outsourcing can vary greatly depending on the nature of the processes, products, and services. The organization can apply risk-based thinking to determine the type and scope of controls applied to specific external suppliers or externally supplied processes, products and services.

Annex B

(Information)

Other International Standards for Management systems and quality management systems developed by ISO/TC 176

The international standards described in this annex have been developed by the technical committee ISO/TC 176 to provide support to organizations that apply this International Standard, and for recommendations to those organizations that have chosen to move beyond the requirements of this standard. The recommendations or requirements contained in these documents specified in this annex do not supplement or modify the requirements of current International Standard.

Table B.1 shows the relationship between these standards and the relevant sections of this International Standard.

This appendix does not include references to standards for quality management systems in specific industries developed by ISO/TC 176.

This International Standard is one of the three main standards developed by ISO/TC 176.

- ISO 9000 Quality Management Systems - The main provisions and vocabulary provide the fundamental basis for the correct understanding and application of this International Standard. The principles of quality management are described in detail in ISO 9000 and taken into account when developing this International Standard. These principles are not requirements in themselves, but they form the basis of the requirements established by this International Standard. ISO 9000 also contains the terms, definitions and concepts used in this International Standard.

- ISO 9001 (this International Standard) establishes requirements aimed primarily at creating trust in the products and services supplied by the organization and, thereby, increasing customer satisfaction. With its proper application, you can also expect the organization to receive other benefits, such as improved internal communications, better understanding and management of the organization's processes.

- ISO 9004 *Managing an organization to achieve sustainable success - an approach from the point of view of quality management* gives recommendations to organizations that have chosen to move beyond the requirements of this International Standard in order to set broader tasks that can lead to improvement of the organization as a whole. ISO 9004 includes recommendations on self-assessment methodology to enable an organization to identify the maturity level of its quality management system.

The international standards listed below can help organizations when they develop their quality management systems or look for improvements in them, their processes or their indicators

- ISO 10001 *Quality management - Customer satisfaction - the ethical standards manual* contains recommendations for organizations to determine that their standards related to customer satisfaction meet the needs and expectations of consumers. The use of the standard can increase consumer confidence in the organization and improve consumer

understanding of what can be expected from the organization, thereby reducing the likelihood of misunderstandings and claims.

- ISO 10002 *Quality management - customer satisfaction - the claims management guide* contains recommendations for managing claims by identifying and meeting the needs and expectations of applicants and resolving any claims received. The ISO 10002 standard provides an open, efficient and easy-to-use process, including staff training. It is also suitable as a guide for small businesses.

- ISO 10003 *Quality management - customer satisfaction - the external dispute resolution guide* contains recommendations for effective and efficient resolution of disputes with external parties on claims related to products. Dispute settlement provides an opportunity to come to an agreement when the organization has not made a satisfactory decision on the claim within itself. Most claims can be resolved successfully within the organization without the need to resort to procedures related to the confrontation of the parties.

- ISO 10004 *Quality management - customer satisfaction - the guidelines for monitoring and measuring customer satisfaction* contain recommendations for activities in the field of improving customer satisfaction and identifying opportunities for improving products, processes and characteristics that are of value to consumers. Such actions can strengthen the loyalty of consumers and help to preserve them.

- ISO 10005 *Quality management systems - guidelines for quality plans* contains recommendations for the creation and use of quality plans as a means of linking requirements for a process, product, project or contract with working procedures that ensure the manufacturing of products. The benefits of developing a quality plan are that there is increased confidence that the requirements will be met, that the processes are in a manageable state, and in the motivation that all this can give to those involved.

- ISO 10006 *quality management systems - guidelines for quality management in projects* are applicable to projects from small to large, from simple to complex, from individual projects to part of the project portfolio. The ISO 10006 standard is intended for use by project managers and who should ensure that their organization applies the methods offered by the ISO family of standards for quality management systems.

- ISO 10007 *Quality management systems - the configuration management guide* serves to assist organizations that apply configuration management in the technical and administrative sphere throughout the product lifecycle. Configuration management can be used to meet the identification and traceability requirements set out in this International Standard.

- ISO 10008 *Quality management - customer satisfaction - the B2C electronic commerce operations manual* provides recommendations on how an organization can implement an effective and efficient system of electronic commerce operations in the B2C sphere and, thereby, lay the foundation for increasing

consumer confidence in the system, increase the ability of organizations to satisfy consumers and help reduce the number of claims and disputes.

- ISO 10012 *Quality management systems - requirements for measurement processes and measuring equipment* provides recommendations for the management of measurement processes and metrological confirmation of the suitability of measuring equipment used to maintain and demonstrate compliance with metrological requirements. The ISO 10012 standard establishes criteria for a measurement management system from the point of view of quality management in order to guarantee the fulfillment of metrological requirements.

- ISO/TR 10013 *the management system documentation manual* contains recommendations for the development and management of documentation required for a quality management system. ISO/TR 10013 can be used for documentation management systems that differ from those specified by ISO standards for quality management systems, for example, for environmental management systems or safety management systems.

- ISO 10014 *Quality Management* - Guidance for achieving financial and economic benefits is addressed to senior management. It contains recommendations for achieving financial and economic benefits through the application of quality management principles. It helps in the application of management principles and in the selection of methods and means that allow the organization to achieve sustainable success

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- ISO 10015 *Quality Management* - Training Guidelines provides training-related recommendations designed to help the organization. ISO 10015 can be applied whenever methodological assistance is needed in interpreting the terms "education" and "training" within the framework of ISO standards for quality management systems. Any mention of "training" includes all types of education and training.

- ISO/TR 10017 *Manual of Statistical Methods for ISO 9001:*2000 describes statistical methods related to the variability that can be observed in the course of processes and in their results, even with obvious constancy of conditions. Statistical methods allow better use of available data in decision-making, and thereby contribute to the continuous improvement of product quality and processes to achieve customer satisfaction.

- ISO 10018 *Quality Management* - the personnel engagement and competence guide contains recommendations that are aimed at staff engagement and competence. The quality management system depends on the degree of interest of competent employees and on how much they are involved in the activities of the organization. It is critically important to identify, develop and evaluate the required knowledge, skills, social and industrial environment.

- ISO 10019 *Guidelines for the selection of consultants on the quality management system and the use of their services* provides recommendations on the selection of

consultants on quality management systems and the use of their services. It contains instructions regarding the process of assessing the competence of consultants in quality management systems and provides confidence that the needs and expectations of the organization related to the services of consultants will be met.

- ISO 19011 *The guidelines for the audit of management systems* contain recommendations on the management of the audit program, planning and conducting audits of management systems, as well as on the competence and evaluation of auditors and audit teams. ISO 19011 is intended for use by auditors, organizations implementing management systems, as well as organizations that need to conduct audits of management systems.

Table B.1 - ratio of sections of other International Standards on quality management and quality management systems and sections of this International Standard

Section ISO 9001	4	5	6	7	8	9	10
ISO 9000	All	All	All	All	All	All	All
ISO 9004	All	All	All	All	All	All	All
ISO 10001					8.2.2, 8.5.1	9.1.2	
ISO 10002					8.2.1	9.1.2	10.2.1
ISO 10003						9.1.2	
ISO 10004						9.1.2, 9.1.3	
ISO 10005		5.3	6.1, 6.2	All	All	9.1	10.2
ISO 10006	All	All	All	All	All	All	All
ISO 10007					8.5.2		
ISO 10008	All	All	All	All	All	All	All
ISO 10012				7.1.5			
ISO/TR 10013				7.5			
ISO 10014	All	All	All	All	All	All	All
ISO 10015				7.2			
ISO/TR 10017			6.1	7.1.5		9.1	
ISO 10018	All	All	All	All	All	All	All
ISO 10019					8.4		
ISO 19011						9.2	
NOTE "All" means that all the sub-paragraphs of this section of current International Standard are related to other International Standards.							

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[1] **ISO 9004,** Managing for the sustained success of an organization - A quality management approach

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[4] **ISO 10003,** Quality management - Customer satisfaction - Guidelines for dispute resolution external to organizations

[5] **ISO 10004,** Quality management - Customer satisfaction - Guidelines for monitoring and measuring

[6] **ISO 10005,** Quality management systems - Guidelines for quality plans

[7] **ISO 10006,** Quality management systems - Guidelines for quality management in projects

[8] **ISO 10007,** Quality management systems - Guidelines for configuration management

[9] **ISO 10008,** Quality management - Customer satisfaction - Guidelines for business-to-consumer electronic commerce transactions

[10] **ISO 10012,** Measurement management systems - Requirements for measurement processes and measuring equipment

[11] **ISO/TR 10013,** Guidelines for quality management system documentation

[12] **ISO 10014,** Quality management - Guidelines for realizing financial and economic benefits

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