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Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organizations

Industries du pétrole, de la pétrochimie et du gaz naturel — Systèmes de management de la qualité spécifiques au secteur — Exigences pour les organismes de fourniture de produits et de services

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Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation 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 67, *Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 12, *Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition cancels and replaces ISO/TS 29001:2010, which has been technically revised. The main changes compared to the previous edition are as follows:

— alignment with ISO 9001:2015.

The boxed text is reproduced from ISO 9001:2015 unaltered and in its entirety. The petroleum, petrochemical and natural gas industry sector-specific supplemental requirements and guidance are provided outside the boxed text.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

ISO 9001:2015, *Quality management systems — Requirements*

0.1 General

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

The potential benefits to an organization of implementing a quality management system based on this International Standard 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 International Standard can be used by internal and external parties.

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

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

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

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

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

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

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

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

In this International Standard, 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.

0.2 Quality management principles

ISO 9001:2015, *Quality management systems — Requirements*

0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 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

ISO 9001:2015, *Quality management systems — Requirements*

0.3.1 General

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

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

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) 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 evaluation of data and information.

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

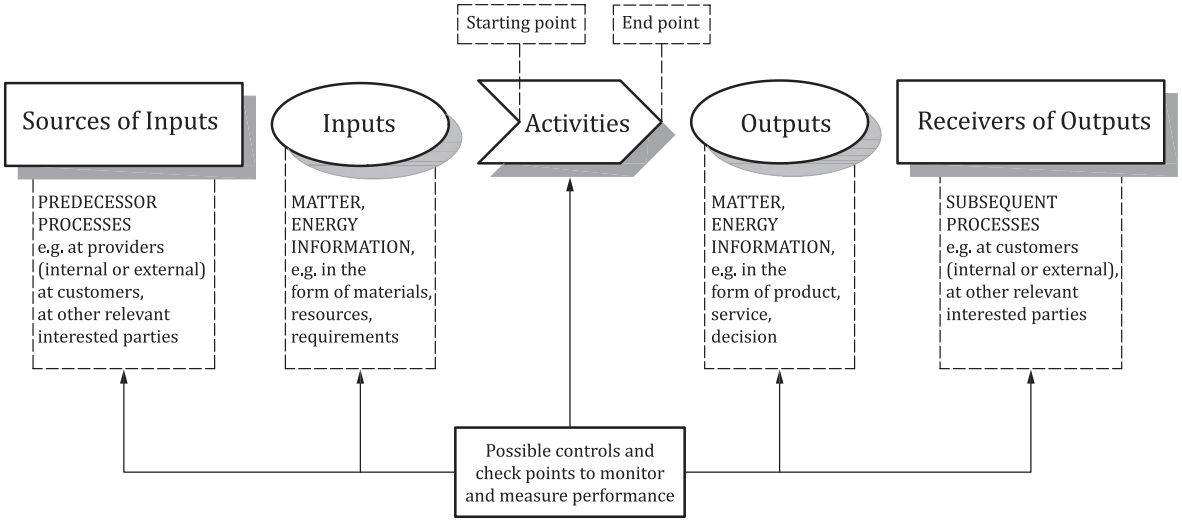


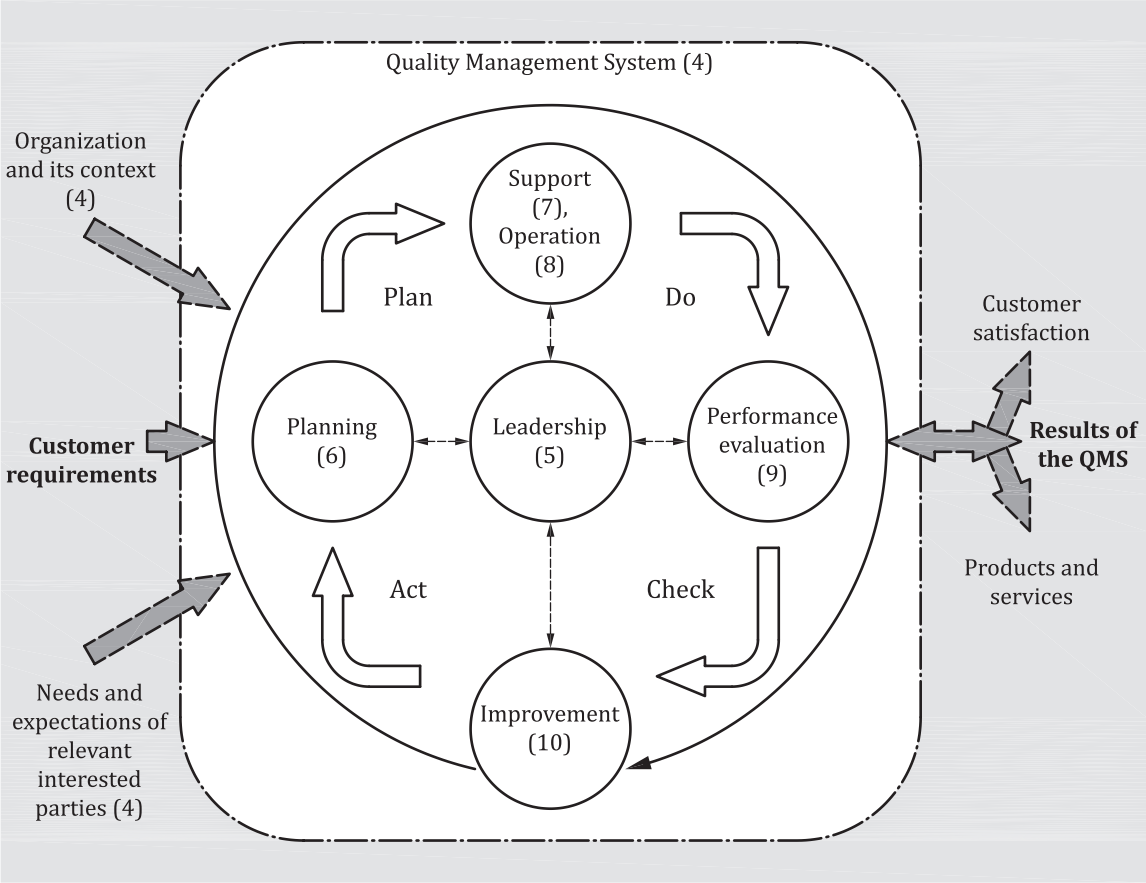
Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

ISO 9001:2015, *Quality management systems — Requirements*

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 Clauses 4 to 10 can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this International Standard.

Figure 2 — Representation of the structure of this International Standard 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 identify and address risks and opportunities;

— **Do**: implement what was planned;

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

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

0.3.3 Risk-based thinking

ISO 9001:2015, *Quality management systems — Requirements*

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformities that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

ISO 9001:2015, *Quality management systems — Requirements*

0.4 Relationship with other management system standards

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

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

This International Standard relates to ISO 9000 and ISO 9004 as follows:

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

— ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

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

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

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

This document also relates to ISO/TS 9002 *Quality management systems — Guidelines for the application of ISO 9001:2015.* ISO/TS 9002 provides guidance on the intent of the requirements in ISO 9001:2015, with examples of possible steps an organization can take to meet the requirements. It does not add to, subtract from, or in any way modify those requirements.

Matrices showing the correlation between the clauses of this edition of this document and the previous edition (ISO/TS 29001:2010) and other international and industry standards dealing with quality management systems requirements can be found on the ISO/TC 67 open access web site at https://committee.iso.org/tc67.

Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organizations

1 Scope

ISO 9001:2015, *Quality management systems — Requirements*

1 Scope

This International Standard 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 International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, 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.

This document defines quality management system requirements for product and service supply organizations to the petroleum, petrochemical and natural gas industries.

This document is written as a supplement to ISO 9001:2015. The supplementary requirements and guidance to ISO 9001:2015 have been developed to manage supply chain risks and opportunities associated with the petroleum, petrochemical and natural gas industries and to provide a framework for aligning requirements with complementary standards employed within the industries.

2 Normative references

ISO 9001:2015, *Quality management systems — Requirements*

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

ISO 9001:2015, *Quality management systems — Requirements*

3 Terms and definitions

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

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
quality specification level
QSL
level defining the extent of control activities, typically including testing, inspection, verification and validation, undertaken by the provider to demonstrate conformance with requirements based on the determination of operational risk and/or obligations

Note 1 to entry: Similar product- or service-specific terms can be used in technical standards to establish the extent of control activities for defined levels of product or service risk, e.g. quality specification level (QSL) in API Spec 6D, product specification level (PSL) in API Spec 6A and API Spec 17D, and exposure level in ISO 19900.

Note 2 to entry: Product or service risk is related to criticality. In this context, 'critical' is defined as that deemed by the organization, product or service specification, or customer as (i) mandatory, indispensable or essential, (ii) needed for a stated purpose or task, and(iii) requiring specific action.

3.2 Competence

3.2.1
competence catalogue
hierarchical structured list of the competences required to perform a task

[SOURCE: ISO/TS 17969:2017, 3.3, modified – 'any task' has been changed to 'a task' and 'competency' and 'competencies' have been changed to 'competence' and 'competences'.]

3.2.2
competence profile
skills and behaviour, each specified at a level of proficiency, required to perform a role or activity in line with the associated risk or opportunity

[SOURCE: ISO/TS 17969:2017, 3.4, modified – 'the role' has been changed to 'a role', 'competency' has been changed to 'competence' and 'or opportunity' has been added.]

3.2.3
proficiency level
level of ability and behaviour attributes within a specific skill

[SOURCE: ISO/TS 17969:2017, 3.8]

3.3
inspection and test plan
tabular presentation of a quality plan, typically used for process or product applications, to define the specific sequence of operational activities, instructions, acceptance criteria, information to be maintained and retained, and associated provider, customer and independent conformity assessment activities

Note 1 to entry: Inspection and test plans may be presented as a single document or as a series of interdependent or supporting documents.

Note 2 to entry: ISO 10005 can be used to inform the development of inspection and test plans for specific processes and products.

4 Context of the organization

4.1 Understanding the organization and its context

ISO 9001:2015, *Quality management systems — Requirements*

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 monitor and review information about these external and internal issues.

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

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

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

The organization shall retain documented information that demonstrates the understanding of its context as described in 4.1 including considerations of Note 1 to Note 3.

4.2 Understanding the needs and expectations of interested parties

ISO 9001:2015, *Quality management systems — Requirements*

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

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

b) the requirements of these interested parties that are relevant to the quality management system.

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

The organization shall retain documented information that demonstrates the understanding of the needs and expectations of interested parties as described in 4.2.

4.3 Determining the scope of the quality management system

ISO 9001:2015, *Quality management systems — Requirements*

4.3 Determining the scope of the quality management system

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

When determining this scope, the organization shall consider:

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

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

c) the products and services of the organization.

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

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

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

If requested, the organization shall advise interested parties of any requirements of this document that the organization determines are not applicable to the scope of its quality management system.

4.4 Quality management system and its processes

ISO 9001:2015, *Quality management systems — Requirements*

4.4 Quality management system and its processes

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 International Standard.

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 To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

4.4.3 The organization shall define the extent of documented information required to meet relevant interested parties' requirements (see 4.2 and 4.3).

5 Leadership

5.1 Leadership and commitment

5.1.1 General

ISO 9001:2015, *Quality management systems — Requirements*

5.1.1 General

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

a) taking accountability for the effectiveness of the quality management system;

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

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

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

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

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

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

h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) promoting improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to “business” in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

5.1.2 Customer focus

ISO 9001:2015, *Quality management systems — Requirements*

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 Policy

5.2.1 Establishing the quality policy

ISO 9001:2015, *Quality management systems — Requirements*

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

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

5.2.2 Communicating the quality policy

ISO 9001:2015, *Quality management systems — Requirements*

5.2.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

b) be communicated, understood and applied within the organization;

c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

ISO 9001:2015, *Quality management systems — Requirements*

5.3 Organizational 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 International Standard;

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

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

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

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

The organization shall define relevant roles. The organization shall maintain and retain documented information covering responsibilities and authorities for these roles.

6 Planning

6.1 Actions to address risks and opportunities

ISO 9001:2015, *Quality management systems — Requirements*

6.1 Actions to address risks and opportunities

6.1.1 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) enhance desirable effects;

c) prevent, or reduce, undesired effects;

d) achieve improvement.

6.1.2 The organization shall plan:

a) actions to address these risks and opportunities;

b) how to:

1) integrate and implement the actions into its quality management system processes (see 4.4);

2) evaluate the effectiveness of these actions.

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

NOTE 1 Options 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.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.1.3 The processes established by the organization for managing risks and opportunities shall:

a) define techniques, tools and their application for identification and assessment of risks and opportunities, and prevention and mitigation of risks;

b) identify relevant interested parties;

c) identify sources of risk and opportunity, areas of impacts, events and their causes, and their potential consequences;

d) analyse potential risk and opportunity by determining consequences and their likelihood;

e) evaluate risk and opportunity and develop controls for them;

f) apply appropriate risk treatments and opportunity realization plans.

The organization shall maintain and retain documented information to support and demonstrate the management of risks and opportunities.

NOTE 1 See 8.1 for supplemental requirements on the management of risks and opportunities in the context of the operations.

NOTE 2 ISO 31000, ISO/TR 31004 and IEC 31010 provide guidance on risk management principles, framework and generic processes, and risk assessment techniques. In these ISO and IEC deliverables, risk includes opportunity.

6.2 Quality objectives and planning to achieve them

ISO 9001:2015, *Quality management systems — Requirements*

6.2 Quality objectives and planning to achieve them

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

The quality objectives shall:

a) be consistent with the quality policy;

b) be measurable;

c) take into account applicable requirements;

d) be relevant to conformity of products and services and to enhancement of customer satisfaction;

e) be monitored;

f) be communicated;

g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

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

ISO 9001:2015, *Quality management systems — Requirements*

6.3 Planning of changes

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

The organization shall consider:

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

b) the integrity of the quality management system;

c) the availability of resources;

d) the allocation or reallocation of responsibilities and authorities.

The organization shall manage risks and opportunities associated with proposed changes (see 6.1).

The organization shall maintain and retain documented information to manage the process of change.

7 Support

7.1 Resources

7.1.1 General

ISO 9001:2015, *Quality management systems — Requirements*

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

ISO 9001:2015, *Quality management systems — Requirements*

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

ISO 9001:2015, *Quality management systems — Requirements*

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 Infrastructure can include:

a) buildings and associated utilities;

b) equipment, including hardware and software;

c) transportation resources;

d) information and communication technology.

7.1.3.1 The organization shall maintain and retain documented information of the processes for the determination and usage of its infrastructure to achieve conformity of products and services. The documented information shall address:

— infrastructure to be maintained;

— method of maintaining the infrastructure, including frequency and monitoring, that ensure infrastructure integrity to performance requirements;

— outcome of maintenance, including applicable testing methods and acceptance criteria;

— responsible personnel.

7.1.3.2 For service-related infrastructure, the documented information shall also address:

— usage history, repairs or redress, modifications, remanufacturing, inspection, and test activities that allow direct verification for reuse of infrastructure;

— list of critical spare parts required by the customer and/or technical requirements including those recommended by the original equipment manufacturer.

7.1.3.3 The organization can apply risk-based maintenance, which typically includes the concepts of:

— preventive and predictive maintenance;

— reliability centred maintenance;

— mean time between failures;

— system, design and process failure mode and effects analysis;

— failure mode and criticality effects analysis;

— process control plans; and

— others that are in context of the organization and its risks.

NOTE IEC 31010 provides general guidance on selection and application of systematic techniques for risk assessment. Sector-specific guidance can be found in ISO 14224, which provides a comprehensive basis for the collection of reliability and maintenance data in a standard format for equipment in all facilities and operations within the petroleum, natural gas and petrochemical industries during the operational life cycle of equipment. Sector-specific guidance can also be found in ISO 20815, which describes the concept of the process of production assurance and reliability management within the systems and operations associated with exploration drilling, exploitation, processing and transport of petroleum, petrochemical and natural gas resources.

7.1.4 Environment for the operation of processes

ISO 9001:2015, *Quality management systems — Requirements*

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 be a combination of human and physical factors, such as:

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).

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

ISO 9001:2015, *Quality management systems — Requirements*

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.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

The organization shall maintain documented information that defines the processes and controls employed to manage monitoring and measurement resources that meet the requirements of 7.1.5.1.

NOTE ISO/IEC 17025 provides general requirements for the competence, impartiality and consistent operation of laboratories. It is applicable to all organizations performing laboratory activities.

7.1.5.2 Measurement traceability

ISO 9001:2015, *Quality management systems — Requirements*

7.1.5.2 Measurement traceability

When measurement traceability 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 retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

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

The organization shall maintain and retain documented information demonstrating the conformance and measurement traceability of the measuring equipment used to determine product conformity to requirements. The documented information shall include a unique identification, specific to each piece of equipment.

NOTE Common practice is to maintain a measuring equipment register.

The organization shall retain documented information of the action taken and of customer notification, if product(s) or services have been delivered.

7.1.6 Organizational knowledge

ISO 9001:2015, *Quality management systems — Requirements*

7.1.6 Organizational knowledge

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

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

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

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

NOTE 2 Organizational knowledge can be based on:

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

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

7.2 Competence

ISO 9001:2015, *Quality management systems — Requirements*

7.2 Competence

The organization shall:

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

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

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

d) retain appropriate documented information 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.

7.2.1 The organization shall validate competence to the risk level associated with the task taking into account the items a) to d).

The organization shall maintain documented information that defines the practices employed to manage competence requirements of personnel whose responsibilities influence the achievement of quality objectives.

NOTE 1 The organization can develop a competence model that defines a competence catalogue, proficiency levels, criteria for attaining and maintaining proficiency, and resulting competence profiles. Options to validate proficiency levels can include technical interviews, assessments and online training.

NOTE 2 ISO/TS 17969 provides competence management guidelines that can be applied to any operation within the petroleum, petrochemical and natural gas industries.

7.3 Awareness

ISO 9001:2015, *Quality management systems — Requirements*

7.3 Awareness

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

a) the quality policy;

b) relevant quality objectives;

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

d) the implications of not conforming with the quality management system requirements.

The organization shall ensure that persons doing work under the organization’s control, including external provider's personnel, are aware of specified regulated and customer quality requirements, risk mitigations and conformity assessment requirements related to their work.

7.4 Communication

ISO 9001:2015, *Quality management systems — Requirements*

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

ISO 9001:2015, *Quality management systems — Requirements*

7.5.1 General

The organization's quality management system shall include:

a) documented information required by this International Standard;

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

ISO 9001:2015, *Quality management systems — Requirements*

7.5.2 Creating and updating

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

ISO 9001:2015, *Quality management systems — Requirements*

7.5.3 Control of documented information

7.5.3.1 Documented information required by the quality management system and by this International Standard 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 be controlled.

Documented information retained 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.

7.5.3.3 The organization shall maintain documented information that defines the processes and controls used to meet the requirements of 7.5.3.2.

When external specification requirements, including addenda, errata, and updates, are used in the design or manufacture of a product or service, the organization shall maintain and retain documented information for the practices employed for the integration of these requirements into the related operating processes.

NOTE When planning the processes and controls to be applied to documented information, ISO/IEC 27000, ISO/IEC 27001, ISO 30301 and ISO 30302 can be considered.

8 Operation

8.1 Operational planning and control

ISO 9001:2015, *Quality management systems — Requirements*

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

a) determining the requirements for the products and services;

b) establishing criteria for:

   1) the processes;

   2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary:

   1) to have confidence that the processes have been carried out as planned;

   2) to demonstrate the conformity of products and services to their requirements.

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

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 outsourced processes are controlled (see 8.4).

The organization shall take into account the customer's scope when determining the requirements for the products and services.

Documented information specifying the processes of the quality management system and the resources to be applied to a specific product, service, project or contract can be referred to as a quality plan, service quality plan or inspection and test plan.

Documented information maintained as the basis for operational process control and retained to demonstrate conformance shall establish the controls required by 8.1 and shall be managed in accordance with 6.1 and 7.5.

The organization shall apply change management processes in respect to risks to the achievement of specified requirements and to the realization of improvement opportunities when planning the operations (see Clause 6).

Where contingency plans are established as a risk treatment, the contingency plan shall at least include:

— roles and responsibility for response;

— communication;

— immediate actions.

NOTE 1 ISO 10005 provides a range of models for documenting and agreeing planning outputs with interested parties.

NOTE 2 Annex C provides additional information for assessing risk to the achievement of specified requirements and to the realization of improvement opportunities, and planning the controls that can be put in place by providers to assure conformance with specified requirements.

8.2 Requirements for products and services

8.2.1 Customer communication

ISO 9001:2015, *Quality management systems — Requirements*

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) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services

ISO 9001:2015, *Quality management systems — Requirements*

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

ISO 9001:2015, *Quality management systems — Requirements*

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;

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 catalogues.

8.2.3.1.1 The organization shall maintain documented information that defines the process for the review of requirements related to the provision of products or services.

NOTE Customer requirements can include conformity assessment requirements (see also Annex C).

ISO 9001:2015, *Quality management systems — Requirements*

8.2.3.2 The organization shall retain documented information, as applicable:

a) on the results of the review;

b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

ISO 9001:2015, *Quality management systems — Requirements*

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General

ISO 9001:2015, *Quality management systems — Requirements*

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.

8.3.2 Design and development planning

ISO 9001:2015, *Quality management systems — Requirements*

8.3.2 Design and development planning

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

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

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

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

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

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

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

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

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

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

j) the documented information needed to demonstrate that design and development requirements have been met.

The organization shall ensure that the required activities for managing risks and opportunities are incorporated in the design development process (see Clause 6 and 8.1).

The organization shall maintain documented information that defines the processes used to plan and control design and development activities of products and/or services.

8.3.3 Design and development inputs

ISO 9001:2015, *Quality management systems — Requirements*

8.3.3 Design and development inputs

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

a) functional and performance requirements;

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

c) statutory and regulatory requirements;

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

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

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

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

Performance requirements can include environmental and safety conditions.

The organization shall also consider outputs of process of managing risks and opportunities.

8.3.4 Design and development controls

ISO 9001:2015, *Quality management systems — Requirements*

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) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;

f) documented information of these activities is retained.

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

ISO 9001:2015, *Quality management systems — Requirements*

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.

The organization shall retain documented information on design and development outputs.

8.3.6 Design and development changes

ISO 9001:2015, *Quality management systems — Requirements*

8.3.6 Design and development changes

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

The organization shall retain documented information on:

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

ISO 9001:2015, *Quality management systems — Requirements*

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 the customer(s) by external providers on behalf of the organization;

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

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

ISO 9001:2015, *Quality management systems — Requirements*

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.

8.4.2.1 The organization shall assess external provider performance at planned intervals, and adjust the type and extent of controls to manage associated risks and opportunities.

The organization shall maintain documented information that defines how the requirements of 8.4.2 are met. The organization shall address the determination of the risks to the achievement of specified requirements and to the realization of improvement opportunities for the products and/or services to conformance to specified requirements of 8.4.2 in accordance with 8.1.

The organization shall retain documented information that demonstrates the effectiveness of the activities identified in 8.4.2 d).

NOTE Annex C provides additional information for assessing risk to the achievement of specified requirements and to the realization of improvement opportunities, and planning the controls that can be put in place by providers to assure conformance with specified requirements.

8.4.3 Information for external providers

ISO 9001:2015, *Quality management systems — 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 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;

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

ISO 9001:2015, *Quality management systems — Requirements*

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 of documented information that defines:

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

   2) the results to be achieved;

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

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

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

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

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

g) the implementation of actions to prevent human error;

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

8.5.1.1 The methods employed in 8.5.1 f) shall consider:

— required equipment;

— competence of personnel;

— use of specific methods, including identified operating parameters;

— identification of acceptance criteria;

— revalidation.

The organization shall maintain documented information that defines the controls used to meet the requirements of 8.5.1 and retain documented information to demonstrate the control effectiveness.

8.5.2 Identification and traceability

ISO 9001:2015, *Quality management systems — Requirements*

8.5.2 Identification and traceability

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

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

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.2.1 The organization shall maintain documented information that defines the processes used to meet the requirements of 8.5.2.

8.5.3 Property belonging to customers or external providers

ISO 9001:2015, *Quality management systems — Requirements*

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 retain documented information on 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.

8.5.3.1 The organization shall maintain documented information that defines the processes that are used to meet the requirements of 8.5.3.

8.5.4 Preservation

ISO 9001:2015, *Quality management systems — Requirements*

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.

The organization shall maintain documented information for risk-based preservation that defines:

a) methods used to preserve products, including environment controls (see 7.1.4), and constituent parts throughout operations, delivery to the intended destination, and/or service delivery, in order to maintain conformity to requirements;

b) storage areas designated to prevent damage or deterioration of product and constituent parts, pending use or delivery;

c) type and frequency of assessment, appropriate to the product being assessed, to detect deterioration;

d) identification and traceability marks, transportation, handling, packaging, and protection requirements, as applicable.

8.5.5 Post-delivery activities

ISO 9001:2015*, Quality management systems — Requirements*

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

ISO 9001:2015*, Quality management systems — Requirements*

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.

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

The areas for production or service provision include changes in:

a) the organizational structure;

b) key or essential personnel;

c) critical providers;

d) design;

e) the management system.

The organization shall notify customers where changes impact product and/or services to be delivered to the customer. The organization shall review changes resulting from assessments of risks and

opportunities and corrective actions. When specified, the organization shall notify the customer of the effect of changes on residual or new risks.

8.6 Release of products and services

ISO 9001:2015, *Quality management systems — Requirements*

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.

The organization shall retain documented information on the release of products and services. The documented information shall include:

a) evidence of conformity with the acceptance criteria;

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

The organization shall maintain documented information that defines the process used to meet the requirements of 8.6.

8.7 Control of nonconforming outputs

ISO 9001:2015, *Quality management systems — Requirements*

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their 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.

8.7.1.1 The organization shall maintain documented information that defines the process used to meet the requirements of 8.7.1.

ISO 9001:2015, *Quality management systems — Requirements*

8.7.2 The organization shall retain documented information that:

a) describes the nonconformity;

b) describes the actions taken;

c) describes any concessions obtained;

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

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

ISO 9001:2015*, Quality management systems — Requirements*

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 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.

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

NOTE ISO 14224 provides a comprehensive basis for the collection of reliability and maintenance data in a standard format for equipment in all facilities and operations within the petroleum, natural gas and petrochemical industries during the operational life cycle of equipment, which can be used for performance measurement.

9.1.2 Customer satisfaction

ISO 9001:2015, *Quality management systems — Requirements*

9.1.2 Customer satisfaction

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

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

The organization shall maintain documented information that defines the process employed to measure customer satisfaction.

9.1.3 Analysis and evaluation

ISO 9001:2015, Quality management systems — Requirements

9.1.3 Analysis and evaluation

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

The results of analysis shall be used to evaluate:

a) conformity of products and services;

b) the degree of customer satisfaction;

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

d) if planning has been implemented effectively;

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

f) the performance of external providers;

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

NOTE Methods to analyse data can include statistical techniques.

The organization shall maintain documented information that defines the process for the identification, collection and analysis of data to demonstrate the suitability and effectiveness of the quality management system. The analysis shall include data generated from monitoring and measurement, internal audits, management reviews, and other relevant sources.

9.2 Internal audit

ISO 9001:2015, *Quality management systems — Requirements*

9.2 Internal audit

9.2.1 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 International Standard;

b) is effectively implemented and maintained.

9.2.2 The organization shall:

a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;

b) define the audit criteria and scope for each audit;

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

d) ensure that the results of the audits are reported to relevant management;

e) take appropriate correction and corrective actions without undue delay;

f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance..

9.2.3 The planned intervals of internal audits shall also take into consideration the risks and opportunities associated with the process (8.1) and the results of performance evaluation (9.1).

NOTE Planned intervals of internal audits can be monthly, quarterly, annually, or according to a schedule that differs for areas or processes over the course of a year.

9.3 Management review

9.3.1 General

ISO 9001:2015, *Quality management systems — Requirements*

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

ISO 9001:2015, *Quality management systems — Requirements*

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

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) information on the performance and effectiveness of the quality management system, including trends in:

   1) customer satisfaction and feedback from relevant interested parties;

   2) the extent to which quality objectives have been met;

   3) process performance and conformity of products and services;

   4) nonconformities and corrective actions;

   5) monitoring and measurement results;

   6) audit results;

   7) the performance of external providers;

d) the adequacy of resources;

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

f) opportunities for improvement.

9.3.3 Management review outputs

ISO 9001:2015, *Quality management systems — Requirements*

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

a) opportunities for improvement;

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

c) resource needs.

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

10 Improvement

10.1 General

ISO 9001:2015*, Quality management systems — Requirements*

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

a) improving products and services to meet requirements as well as to address future needs and expectations;

b) correcting, preventing or reducing undesired effects;

c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

ISO 9001:2015, ***Quality management systems — Requirements***

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, 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 and analysing the nonconformity;

   2) determining the causes of the nonconformity;

   3) determining if similar nonconformities exist, or could 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.

10.2.2 The organization shall retain documented information as evidence of:

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

b) the results of any corrective action.

The organization shall maintain documented information that defines the process that implements the requirements of 10.2.1.

10.3 Continual improvement

ISO 9001:2015, *Quality management systems — Requirements*

10.3 Continual improvement

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

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

10.3.1 The implementation of improvements shall be subject to management of change processes in accordance with 6.3.

The organization shall maintain documented information that defines the process that implements the requirements of 10.3 and retain documented information to demonstrate its effectiveness.

Annex A
(informative)

Clarification of new structure, terminology and concepts

A.1 Structure and terminology

ISO 9001:2015, *Quality management systems — Requirements*

A.1 Structure and terminology

The clause structure (i.e. clause sequence) and some of the terminology of this edition of this International Standard, in comparison with the previous edition (ISO 9001:2008), have been changed to improve alignment with other management systems standards.

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

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

There is no requirement for the terms used by an organization to be replaced by the terms used in this International Standard to specify quality management system requirements. Organizations can choose to use terms which suit their operations (e.g. using “records”, “documentation” or “protocols” rather than “documented information”; or “supplier”, “partner” or “vendor” rather than “external provider”). Table A.1 shows the major differences in terminology between this edition of this International Standard and the previous edition.

Table A.1 — Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See Clause A.5 for clarification of applicability)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider

A.2 Products and services

ISO 9001:2015, *Quality management systems — Requirements*

A.2 Products and services

ISO 9001:2008 used the term "product" to include all output categories. This edition of this International Standard uses "products and services". "Products and services" include all output categories (hardware, services, software and processed materials).

The specific inclusion of "services" is intended to highlight the differences between products and services in the application of some requirements. The characteristic of services is that at least part of the output is realized at the interface with the customer. This means, for example, that conformity to requirements cannot necessarily be confirmed before service delivery.

In most cases, products and services are used together. Most outputs that organizations provide to customers, or are supplied to them by external providers, include both products and services. For example, a tangible or intangible product can have some associated service or a service can have some associated tangible or intangible product.

A.3 Understanding the needs and expectations of interested parties

ISO 9001:2015, *Quality management systems — Requirements*

A.3 Understanding the needs and expectations of interested parties

Subclause 4.2 specifies requirements for the organization to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties. However, 4.2 does not imply extension of quality management system requirements beyond the scope of this International Standard. As stated in the scope, this International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

There is no requirement in this International Standard for the organization to consider interested parties where it has decided that those parties are not relevant to its quality management system. It is for the organization to decide if a particular requirement of a relevant interested party is relevant to its quality management system.

A.4 Risk-based thinking

ISO 9001:2015, *Quality management systems — Requirements*

A.4 Risk-based thinking

The concept of risk-based thinking has been implicit in previous editions of this International Standard, e.g. through requirements for planning, review and improvement. This International Standard specifies requirements for the organization to understand its context (see 4.1) and determine risks as a basis for planning (see 6.1). This represents the application of risk-based thinking to planning and implementing quality management system processes (see 4.4) and will assist in determining the extent of documented information.

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

The risk-based thinking applied in this International Standard has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements. There is greater flexibility than in ISO 9001:2008 in the requirements for processes, documented information and organizational responsibilities.

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

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its objectives, and the effects of uncertainty are not the same for all organizations. Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.

A.5 Applicability

ISO 9001:2015, *Quality management systems — Requirements*

A.5 Applicability

This International Standard does not refer to “exclusions” in relation to the applicability of its requirements to the organization's quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

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

A.6 Documented information

ISO 9001:2015, *Quality management systems — Requirements*

A.6 Documented information

As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it.

Where this International Standard refers to "information" rather than "documented information" (e.g. in 4.1: "The organization shall monitor and review the information about these external and internal issues"), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

A.7 Organizational knowledge

ISO 9001:2015, *Quality management systems — Requirements*

A.7 Organizational knowledge

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure the operation of its processes and that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of:

a) safeguarding the organization from loss of knowledge, e.g.

- through staff turnover;
- failure to capture and share information;

b) encouraging the organization to acquire knowledge, e.g.

- learning from experience;
- mentoring;
- benchmarking.

A.8 Control of externally provided processes, products and services

ISO 9001:2015, *Quality management systems — Requirements*

A.8 Control of externally provided processes, products and services

All forms of externally provided processes, products and services are addressed in 8.4, e.g. whether through:

a) purchasing from a supplier;

b) an arrangement with an associate company;

c) outsourcing processes to an external provider.

Outsourcing always has 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. 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.

Annex B
(informative)

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

ISO 9001:2015, *Quality management systems — Requirements*

The International Standards described in this annex have been developed by ISO/TC 176 to provide supporting information for organizations that apply this International Standard, and to provide guidance for organizations that choose to progress beyond its requirements. Guidance or requirements contained in the documents listed in this annex do not add to, or modify, the requirements of this International Standard.

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

This annex does not include reference to the sector-specific quality management system standards developed by ISO/TC 176.

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

— ISO 9000 *Quality management systems — Fundamentals and vocabulary* provides an essential background for the proper understanding and implementation of this International Standard. The quality management principles are described in detail in ISO 9000 and have been taken into consideration during the development of this International Standard. These principles are not requirements in themselves, but they form the foundation of the requirements specified by this International Standard. ISO 9000 also defines the terms, definitions and concepts used in this International Standard.

— ISO 9001 (this International Standard) specifies requirements aimed primarily at giving confidence in the products and services provided by an organization and thereby enhancing customer satisfaction. Its proper implementation can also be expected to bring other organizational benefits, such as improved internal communication, better understanding and control of the organization's processes.

— ISO 9004 *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard, to address a broader range of topics that can lead to improvement of the organization's overall performance. ISO 9004 includes guidance on a self-assessment methodology for an organization to be able to evaluate the level of maturity of its quality management system.

The International Standards outlined below can provide assistance to organizations when they are establishing or seeking to improve their quality management systems, their processes or their activities.

— ISO 10001 *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations* provides guidance to an organization in determining that its customer satisfaction provisions meet customer needs and expectations. Its use can enhance customer confidence in an organization and improve customer understanding of what to expect from an organization, thereby reducing the likelihood of misunderstandings and complaints.

— ISO 10002 *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations* provides guidance on the process of handling complaints by recognizing and addressing the needs and expectations of complainants and resolving any complaints received. ISO 10002 provides an open, effective and easy-to-use complaints process, including training of people. It also provides guidance for small businesses.

— ISO 10003 *Quality management — Customer satisfaction — Guidelines for dispute resolution external to organizations* provides guidance for effective and efficient external dispute resolution for product-related complaints. Dispute resolution gives an avenue of redress when organizations do not remedy a complaint internally. Most complaints can be resolved successfully within the organization, without adversarial procedures.

— ISO 10004 *Quality management — Customer satisfaction — Guidelines for monitoring and measuring* provides guidelines for actions to enhance customer satisfaction and to determine opportunities for improvement of products, processes and attributes that are valued by customers. Such actions can strengthen customer loyalty and help retain customers.

— ISO 10005 *Quality management systems — Guidelines for quality plans* provides guidance on establishing and using quality plans as a means of relating requirements of the process, product, project or contract, to work methods and practices that support product realization. Benefits of establishing a quality plan are increased confidence that requirements will be met, that processes are in control and the motivation that this can give to those involved.

— ISO 10006 *Quality management systems — Guidelines for quality management in projects* is applicable to projects from the small to large, from simple to complex, from an individual project to being part of a portfolio of projects. ISO 10006 is to be used by personnel managing projects and who need to ensure that their organization is applying the practices contained in the ISO quality management system standards.

— ISO 10007 *Quality management systems — Guidelines for configuration management* is to assist organizations applying configuration management for the technical and administrative direction over the life cycle of a product. Configuration management can be used to meet the product identification and traceability requirements specified in this International Standard.

— ISO 10008 *Quality management — Customer satisfaction — Guidelines for business-to-consumer electronic commerce transactions* gives guidance on how organizations can implement an effective and efficient business-to-consumer electronic commerce transaction (B2C ECT) system, and thereby provide a basis for consumers to have increased confidence in B2C ECTs, enhance the ability of organizations to satisfy consumers and help reduce complaints and disputes.

— ISO 10012 *Measurement management systems — Requirements for measurement processes and measuring equipment* provides guidance for the management of measurement processes and metrological confirmation of measuring equipment used to support and demonstrate compliance with metrological requirements. ISO 10012 provides quality management criteria for a measurement management system to ensure metrological requirements are met.

— ISO/TR 10013 *Guidelines for quality management system documentation* provides guidelines for the development and maintenance of the documentation necessary for a quality management system. ISO/TR 10013 can be used to document management systems other than those of the ISO quality management system standards, e.g. environmental management systems and safety management systems.

— ISO 10014 *Quality management — Guidelines for realizing financial and economic benefits* is addressed to top management. It provides guidelines for realizing financial and economic benefits through the application of quality management principles. It facilitates application of management principles and selection of methods and tools that enable the sustainable success of an organization.

— ISO 10015 *Quality management — Guidelines for training* provides guidelines to assist organizations in addressing issues related to training. ISO 10015 can be applied whenever guidance is required to interpret references to “education” and “training” within the ISO quality management system standards. Any reference to “training” includes all types of education and training.

— ISO/TR 10017 *Guidance on statistical techniques for ISO 9001:2000* explains statistical techniques which follow from the variability that can be observed in the behaviour and results of processes, even under conditions of apparent stability. Statistical techniques allow better use of available data to assist in decision making, and thereby help to continually improve the quality of products and processes to achieve customer satisfaction.

— ISO 10018 *Quality management — Guidelines on people involvement and competence* provides guidelines which influence people involvement and competence. A quality management system depends on the involvement of competent people and the way that they are introduced and integrated into the organization. It is critical to determine, develop and evaluate the knowledge, skills, behaviour and work environment required.

— ISO 10019 *Guidelines for the selection of quality management system consultants and use of their services* provides guidance for the selection of quality management system consultants and the use of their services. It gives guidance on the process for evaluating the competence of a quality management system consultant and provides confidence that the organization's needs and expectations for the consultant's services will be met.

— ISO 19011 *Guidelines for auditing management systems* provides guidance on the management of an audit programme, on the planning and conducting of an audit of a management system, as well as on the competence and evaluation of an auditor and an audit team. ISO 19011 is intended to apply to auditors, organizations implementing management systems, and organizations needing to conduct audits of management systems.

Table B.1 — Relationship between other International Standards on quality management and quality management systems and the clauses of this International Standard

Other International Standard	Clause in this International Standard						
	4	5	6	7	8	9	10
ISO 9000	All	All	All	All	All	All	All
ISO/TS 9002	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" indicates that all the subclasses in the specific clause of this International Standard are related to the other International Standard.							

ISO/TS 9002, *Quality management systems — Guidelines for the application of ISO 9001:2015* provides guidance on the intent of the requirements in ISO 9001:2015, with examples of possible steps an organization can take to meet the requirements. It does not add to, subtract from, or in any way modify those requirements. ISO/TS 9002 does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation. Table B.2 shows the relationship between ISO/TS 9002 and the clauses of this document.

Table B.2 — Relationship between ISO/TS 9002 and the clauses of this document

Other International Standard	Clause in this document						
	4	5	6	7	8	9	10
ISO/TS 9002	All	All	All	All	All	All	All
NOTE "All" indicates that all the subclasses in the specific clause of this International Standard are related to the other International Standard.							

Annex C
(informative)

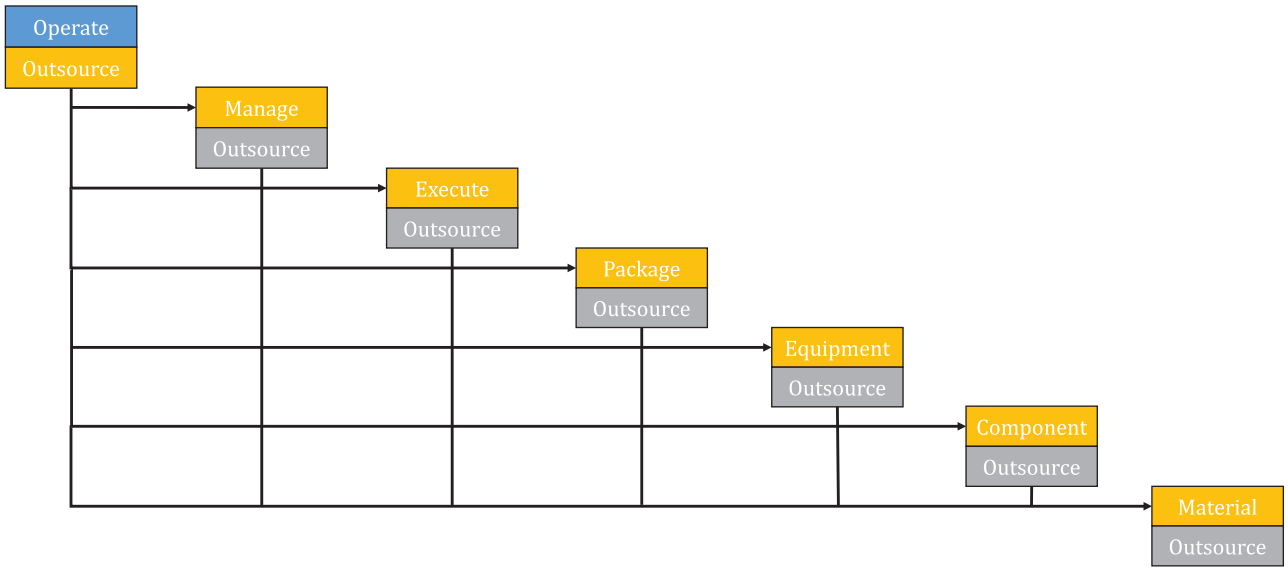
Risk and opportunity management and conformity assessment processes

C.1 General

When an organization wishes to obtain a product or service to be delivered internally or externally, the organization specifies the requirements to be met. It can also specify conformity assessment requirements.

This annex provides methods for assessing risk to the achievement of specified requirements and to the realization of improvement opportunities, and for planning the controls to be put in place by providers to assure conformance with specified requirements, including externally provided products and services in accordance with 8.1 and 8.4.

At any level in the supply chain, the organization can elect to provide products and services using their own processes or to place contracts via a management or execution contractor or directly to package, equipment, component or material providers. Figure C.1 illustrates this cascading contracting model.

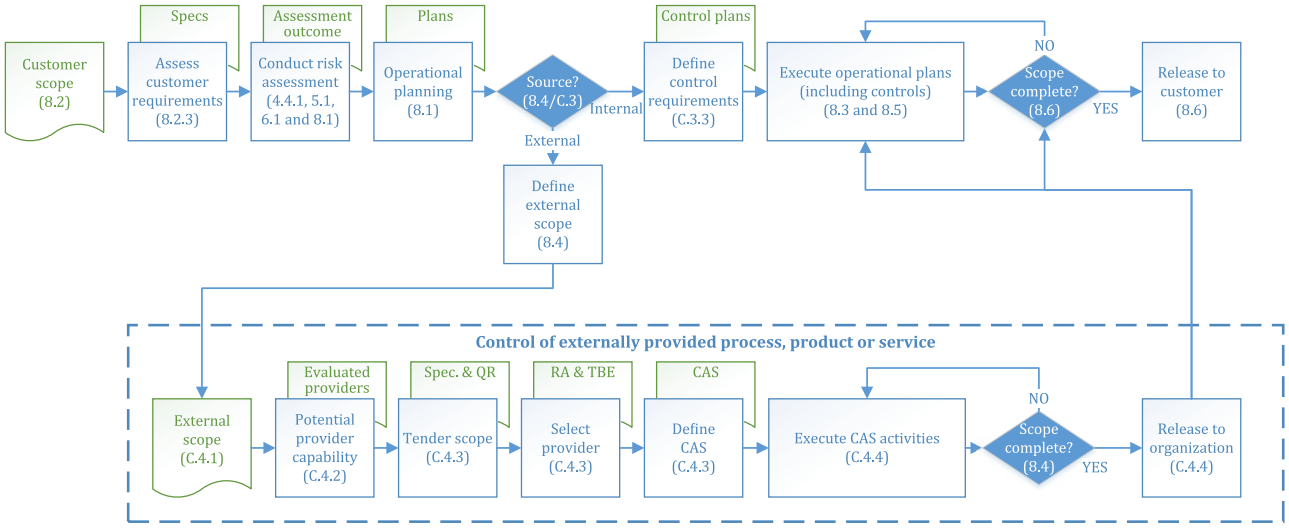


NOTE An operator (blue box) can decide to contract an external provider at any level in the supply chain. Similarly, any other organization in the supply chain (orange boxes) can provide the contracted process, product or service themselves or decide to (partly) outsource these activities.

Figure C.1 — Cascading contracting model

Recognizing that providers of externally provided processes, products and services use their quality management systems to ensure requirements are met and their delivery is assured, the organization should assess and manage the associated risks consistent to the role/scope played by their selected providers of product and/or service in accordance with 8.4.2.

The methodology is designed to be deployed and cascaded down through the supply chain as illustrated in Figure C.2.



NOTE QR is quality requirement, RA is risk assessment, TBE is technical bid evaluation, and CAS is conformity assessment system.

Figure C.2 — Representation of risk management and conformity assessment process

C.2 Risk classification principles

For the purposes of this document, the following risk classification principles apply.

a) Risk classification should be determined taking account of the total life of the product or service, starting with the specified requirements and ending with its product decommissioning and/or service completion.

b) Risk classification should take account of the health, safety and environmental requirements valid for the country or countries in which the product or service is created, used and/or decommissioned/completed.

c) Risk classification should be determined using defined parameters.

d) Risk management should be undertaken by personnel experienced and knowledgeable in the scope of the product or service, including:

— identification and management of failure consequences;

— where relevant, engineering, manufacturing, execution and maturity/complexity;

— previous failures and lessons learnt.

NOTE See 7.1.6 regarding sources of organization knowledge.

C.3 Risk management and conformity assessment process

C.3.1 Customer's scope and context

The customer’s specified requirements for the product and/or service (see 8.2) provide the input for operational planning and control. In planning the delivery and control, the organization should consider:

— the product or service to be evaluated;

— the application in which it will be used;

— the design, production and service delivery processes to be employed;

— those activities to be provided externally;

— any customer or obligatory requirements.

C.3.2 Undertaking risk assessment

The organization should undertake risk assessments in accordance with 6.1 to determine the risks associated with the proposed product or service delivery processes. Risk assessments should consider, as applicable, the following categories of risks to the achievement of specified requirements and to the realization of improvement opportunities:

— obligatory requirements;

— health and personal safety;

— process safety;

— environment;

— capital expenditure (CAPEX);

— operational expenditure (OPEX);

— operations with non-productive time or deferred production;

— competence during use;

— competence during design, manufacturing or execution;

— externally provided processes, products or services.

For special services and for materials and equipment, risk assessments should also consider the following risk categories:

— intended use and reasonably foreseeable misuse;

— field-proven design or configuration;

— reliability and maintainability requirements;

— design/service maturity and complexity;

— past use of the same product, process or service;

— certification and traceability requirements.

The organization should develop a risk assessment process that defines the factors to be considered in evaluating risks and for documenting the assessment outcomes.

Risk assessment should be led by a competent facilitator supported by technical, quality, safety and operational specialists and relevant internal and external stakeholders. Risk assessment may be achieved through facilitated workshops, interviews, studies.

NOTE See IEC 31010 for risk assessment techniques that can be employed.

The output of risk assessment can be a ranking of risk based on:

— consequences of the event;

— likelihood of occurrence;

— failure mode detectability.

Further guidance/tools on risk assessment processes are available in electronic format via https://standards.iso.org/iso/29001/ed-1/en to assist determining conformity levels.

NOTE ISO 31000, ISO 31004 and IEC 31010 also provide guidance/tools for determining conformity levels.

C.3.3 Determination of control and conformity assessment requirements

The organization should review planned product and service delivery processes and the outcomes of risk assessments as the basis for defining control and conformity assessment requirements, to provide the basis for ensuring conformance with requirements.

The control and conformity assessment requirements should address:

a) internal operations as per 8.3, 8.5 and 8.6;

b) externally provided processes, products and services as per 8.4 and C.4;

c) the context under which control and assessment activities are invoked, including:

- first-party conformity assessment activities undertaken by the organization;
- second-party conformity assessment activities undertaken by or on behalf of the customer;
- third-party conformity assessment activities undertaken by an independent body to meet customer or obligatory requirements.

Documented information established to define the control and conformity assessment requirements (see 8.1) should include provisions for customer and independent conformity assessment requirements and obligations.

NOTE The provider remains responsible for operational planning and control and demonstration of the conformity of products and/or services with requirements (see 8.1 and 8.2), regardless of conformity assessment requirements defined by the customer, either by reference to standard/specification requirements or in the scope.

C.4 Control of externally provided processes, products and services

C.4.1 Scope of externally provided activity

The organization should define and manage the delivery of the scope for each externally provided process, product or service in accordance with 8.4.

C.4.2 Potential provider capability evaluation

The organization should evaluate potential providers to determine their capability to meet the scope requirements and that they have the pre-requisite (quality) management system controls to ensure that requirements are met. Considerations may include product or service complexity and the need for the organization's involvement during design, manufacturing and supply chain for the products or services, taking into account:

- design novelty of the products or services (e.g. ranging from modification of proven/tested design to redesign to new design of complex item);
- manufacturing complexity of the products or services (e.g. ranging from mass produced to singular runs that require prototypes, complex assembly and test requirements);
- requisites for preserving goods intended for use in petroleum or natural gas specific activities (e.g. elastomeric components or chemicals);
- supply chain knowledge, risk ownership and accountability, number and type of supply avenues (e.g. multiple layers of subcontracting, complex or unclear sources of component supply);

— providers present resource and proposed facility capabilities.

Evaluation of potential provider capability may be based on prior performance, prequalification or audit.

C.4.3 Conformity assessment requirements for external providers

Conformity assessment requirements specified in information for external providers per 8.4.3 should reflect the outputs of the risk assessment in relation to the scope (see C.3) and include definition of:

— control activities defined by the contract and/or specifications and, where applicable, a defined quality specification level (QSL);

— intended level of assessment of provider's control activities by the customer and when applicable, independent bodies, through nomination of a conformity assessment system (CAS).

The technical bid evaluation (TBE) including evaluation of the providers' capability to conform to the specification and associated QSL should be used to confirm or amend the CAS to be applied to the selected provider and reflected in the contract per 8.4.3.

Examples of approaches to defining conformity assessment requirements are available in electronic format via http://standards.iso.org/iso/29001.

C.4.4 Control of external providers during execution of scope

The organization should undertake planned conformity assessment activities as a prerequisite to release of an externally provided process, product or service for incorporation in its operations as per agreed conformity assessment requirements.

In the context of this document, conformity assessment requirements are typically managed as:

— Hold (H): Point in the chain of activities, defined in agreed documented information, that requires the approval of the customer or designated authority before proceeding.

— Witness (W): Point in the chain of activities, in which the customer or designated authority can witness the operation or process within an agreed timeframe after notification and according to a method, which is defined in agreed documented information.

— Surveillance (S): Point for the periodic observation or monitoring by the customer or its representative or designated authority of an activity, operation, process or documented information at provider's or external provider's premises.

— Review (R): Point for determination of the suitability, adequacy or effectiveness of documented information to verify conformance to agreed requirements and obligations.

Provider performance in meeting the requirements should be routinely assessed during execution of the scope and, where appropriate, corrective action implemented and the level of conformity assessment adjusted consistent with risk.

C.5 Example of conformity assessment activities

Table C.1 provides a matrix for generic conformity assessment activities and their application across four conformity assessment systems or levels of customer intervention based on assessed risk and opportunity.

Table C.1 — Generic conformity assessment activities matrix (adapted from ISO/TR 13881:2000)

CUSTOMER ASSESSMENT ACTIVITIES	CONFORMITY ASSESSMENT SYSTEM (decreasing supply risk)[a] →			
	A	B	C	D
Operational planning and control activities (8.1)				
Post award clarification (8.2)	H	W		
Risk assessment	H	W	R	
Operational planning and processes	H	W	R	
Control planning	H	W		
Design and development activities (8.3)				
Design and development planning (8.3.2)				
Design reviews	H	R		
Design verification	H (3)	R (3)		
Design validation	H (3)	R (3)		
Control of external supply (8.4)				
External supply scope, risk assessment and controls (8.4, C.4)	H	W	R	
Execution of external assessment activities	W	S	S	
Release to organisation	H	W	S	
Production and service provision (8.5)				
Process qualification	H	R	S	
Product, process or service surveillance by:				
— Periodic inspection	H	S	S	S
— Inspection of samples	W	S	S	
— 100 % inspection	W	S		
Release of product or service (8.6)				
Final inspection	H	W		
Providers declaration of conformity	H	W	R	R
Independent certification	H (3)	H	R	

[a] H is hold point, R is review, S is surveillance, and W is witness point.

Suffix "3" indicates third party conformity assessment activities.

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ISO 9001:2015, *Quality management systems — Requirements*

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

[2] ISO 10001, *Quality management — Customer satisfaction — Guidelines for codes of conduct for organizations*

[3] ISO 10002, *Quality management — Customer satisfaction — Guidelines for complaints handling in organizations*

[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*

[13] ISO 10015, *Quality management — Guidelines for training*

[14] ISO/TR 10017, *Guidance on statistical techniques for ISO 9001:2000*

[15] ISO 10018, *Quality management — Guidelines on people involvement and competence*

[16] ISO 10019, *Guidelines for the selection of quality management system consultants and use of their services*

[17] ISO 14001, *Environmental management systems — Requirements with guidance for use*

[18] ISO 19011, *Guidelines for auditing management systems*

[19] ISO 31000, *Risk management — Principles and guidelines*

[20] ISO 37500, *Guidance on outsourcing*

[21] ISO/IEC 90003, *Software engineering — Guidelines for the application of ISO 9001:2008 to computer software*

[22] IEC 60300-1, *Dependability management — Part 1: Guidance for management and application*

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