
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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of document:

- an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;
- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.

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.

ISO/TS 29001 was prepared by Technical Committee ISO/TC 67, *Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries*.

This third edition cancels and replaces the second edition (ISO/TS 29001:2007), of which it constitutes a minor revision.

In this third edition of ISO/TS 29001, the boxed text has been revised in order to ensure that it constitutes the text of ISO 9001:2008 unaltered and in its entirety. No changes other than editorial have been made outside the boxed text.

The fourth edition of ISO 9001 (ISO 9001:2008) cancelled and replaced the third edition (ISO 9001:2000), which was amended to clarify points in the text and to enhance compatibility with ISO 14001:2004.

Since the third edition, the title of ISO 9001 has been revised such that it no longer includes the term "Quality Assurance". This reflects the fact that the quality management system requirements specified in ISO 9001 now also aim to enhance customer satisfaction, in addition to the quality assurance of a product.

Introduction

0.1 General

ISO 9001:2008, Quality management systems — Requirements

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

- a) its organizational environment, changes in that environment, and the risks associated with that environment,
- b) its varying needs,
- c) its particular objectives,
- d) the products it provides,
- e) the processes it employs,
- f) its size and organizational structure.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

NOTE This Technical Specification does not address competitive or commercial matters such as price, warranties, guarantees or clauses intended to sustain commercial objectives.

0.2 Process approach

ISO 9001:2008, Quality management systems — Requirements

0.2 Process approach

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.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the “process approach”.

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

- a) understanding and meeting requirements,
- b) the need to consider processes in terms of added value,
- c) obtaining results of process performance and effectiveness, and
- d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

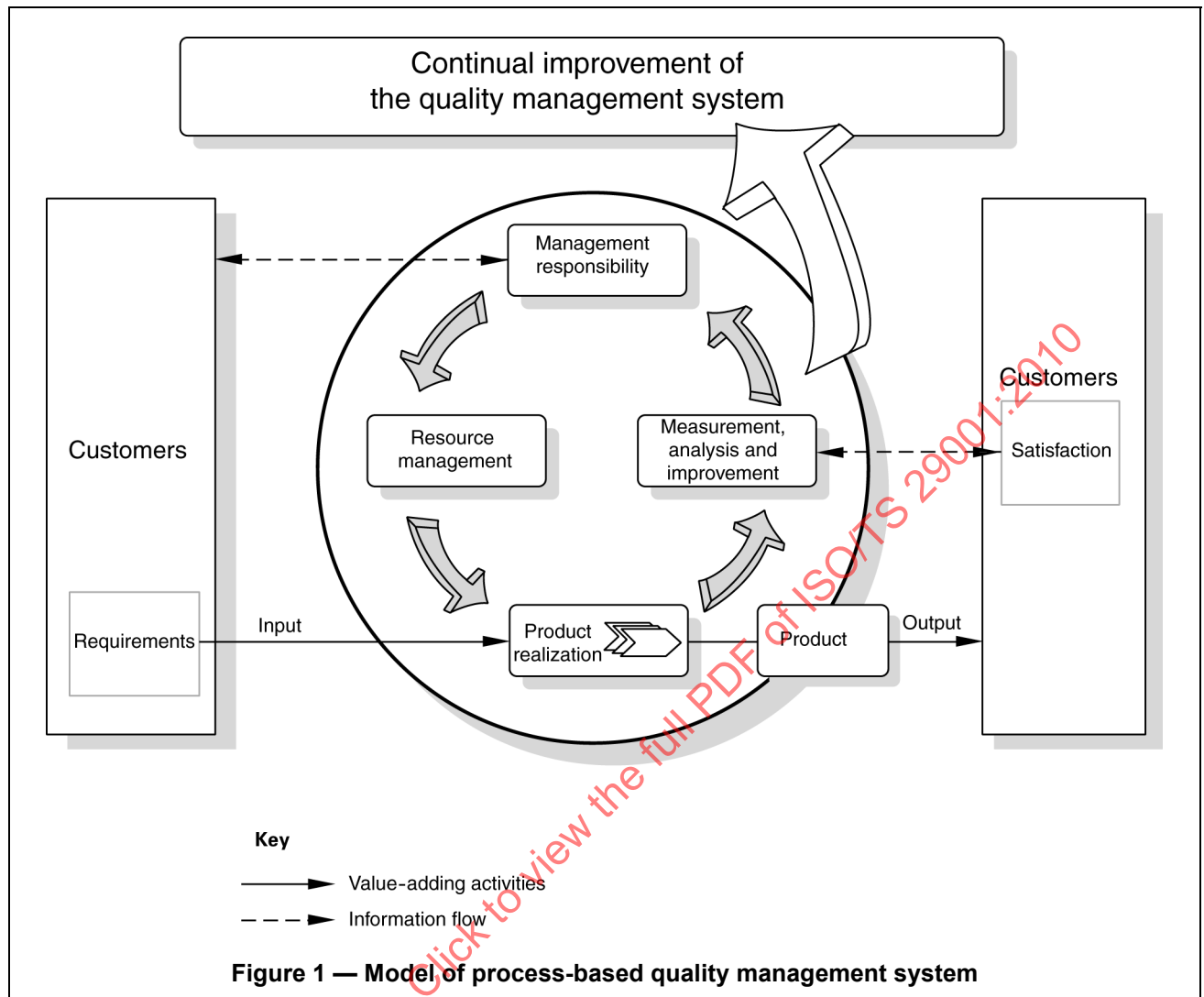
NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.



0.3 Relationship with ISO 9004

ISO 9001:2008, Quality management systems — Requirements

0.3 Relationship with ISO 9004

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

NOTE ISO 9004:2009 has now been published, and has cancelled and replaced ISO 9004:2000.

0.4 Compatibility with other management systems

ISO 9001:2008, Quality management systems — Requirements

0.4 Compatibility with other management systems

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

NOTE For this Technical Specification, Annex A, as described above, is not provided and is not considered part of this Technical Specification. If the comparison of ISO 9001:2008 and ISO 14001:2004 is required, the reader is encouraged to review Annex A of the referenced ISO 9001:2008 document.

0.5 Goal of this Technical Specification

The goal of this Technical Specification is the development of a quality management system that provides for continual improvement, emphasizing defect prevention and the reduction of variation and waste in the supply chain and from service providers.

This Technical Specification, coupled with applicable customer-specific requirements, defines the fundamental quality management system requirements for those subscribing to this Technical Specification.

This Technical Specification is intended to avoid multiple certification audits and provide a common approach to a quality management system for the petroleum, petrochemical and natural gas industries.

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

1 Scope

1.1 General

ISO 9001:2008, Quality management systems — Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

- a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term “product” applies only to

- a) product intended for, or required by, a customer,
- b) any intended output resulting from the product realization process.

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

1.1.1 Field of Application — Supplemental

This Technical Specification defines the quality management system for product and service supply organizations for the petroleum, petrochemical and natural gas industries.

Boxed text is original ISO 9001:2008 text unaltered and in its entirety. The petroleum, petrochemical, and natural gas industry sector-specific supplemental requirements are outside the boxes.

1.2 Application

ISO 9001:2008, Quality management systems — Requirements

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

1.2.1 Application — Supplemental

Where exclusions are made, claims of conformity to this Technical Specification are not acceptable unless these exclusions are limited to requirements within the subclauses listed below in this subclause, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable regulatory requirements:

- 7.3 Design and development;
- 7.5.1 Control of production and service provision;
- 7.5.2 Validation of processes for production and service provision;
- 7.5.4 Customer property.

2 Normative references

2 Normative references

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

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

ISO 9001:2008, Quality management systems — Requirements

3 Terms and definitions

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

Throughout the text of this International Standard, wherever the term “product” occurs, it can also mean “service”.

3.1 Terms and definitions for the petroleum, petrochemical and natural gas industries

For the purposes of this document, the terms and definitions given in ISO 9000:2005 and the following apply.

3.1.1

acceptance criteria

specified limits of acceptability applied to process or product characteristics

3.1.2

acceptance inspection

demonstration through monitoring or measurement that the product complies with specified requirements

3.1.3

calibration

comparison and adjustment to a standard of known accuracy

3.1.4

control feature

organization's documented method for performing an activity under controlled conditions to achieve conformity to specified requirements

3.1.5

delivery

point in time and physical location at which the agreed transfer of ownership takes place

3.1.6

design acceptance criteria

defined limits placed on characteristics of materials, products, or services established by the organization, customer, and/or applicable specifications to achieve conformity to the product design

3.1.7

design validation

process of proving a design by testing to demonstrate conformity of the product to design requirements

3.1.8

design verification

process of examining the result of a given design or development activity to determine conformity with specified requirements

3.1.9

field nonconformity

product nonconformity that is detected after delivery or use has started

3.1.10

manufacturing acceptance criteria

defined limits placed on characteristics of materials, products, and services established by the organization to achieve conformity to the manufacturing or service requirements

3.1.11

tender

offer made by an organization in response to an invitation to provide a product

4 Quality management system

4.1 General requirements

ISO 9001:2008, Quality management systems — Requirements

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

- a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
- b) determine the sequence and interaction of these processes,
- c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) monitor, measure where applicable and analyze these processes, and
- f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2 An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

- a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,
- b) the degree to which the control of the process is shared,
- c) the capability of achieving the necessary control through the application of 7.4.

4.1.1 Outsourced processes and/or services — Supplemental

The organization shall maintain responsibility for product conformance to specified requirements when processes are outsourced.

4.2 Documentation requirements

4.2.1 General

ISO 9001:2008, Quality management systems — Requirements

4.2.1 General

The quality management system documentation shall include

- a) documented statements of a quality policy and quality objectives,
- b) a quality manual,
- c) documented procedures and records required by this International Standard,
- d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

- a) the size of organization and type of activities,
- b) the complexity of processes and their interactions, and
- c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

ISO 9001:2008, Quality management systems — Requirements

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

- a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),
- b) the documented procedures established for the quality management system, or reference to them, and
- c) a description of the interaction between the processes of the quality management system.

4.2.2.1 Quality manual — Supplemental

The quality manual shall identify the manner in which the organization addresses each specific requirement of this Technical Specification, including both the requirements of ISO 9001:2008 and the supplemental requirements.

4.2.3 Control of documents

ISO 9001:2008, Quality management systems — Requirements

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

- a) to approve documents for adequacy prior to issue,
- b) to review and update as necessary and re-approve documents,
- c) to ensure that changes and the current revision status of documents are identified,
- d) to ensure that relevant versions of applicable documents are available at points of use,
- e) to ensure that documents remain legible and readily identifiable,
- f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.3.1 Control of documents — Supplemental

A master list or equivalent control feature shall be used to identify the documents required by the quality management system and their current revision status.

4.2.3.2 Control of document changes — Supplemental

Changes to documents shall be reviewed and approved by the same functions that performed the original review and approval.

4.2.4 Control of records

ISO 9001:2008, Quality management systems — Requirements

4.2.4 Control of documents

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

4.2.4.1 Control of records — Supplemental

The documented procedure shall identify the functions responsible for the collection and maintenance of records.

NOTE Collection is the process of obtaining, assembling and/or organizing applicable documentation with the intent of meeting the requirements of 4.2.4.

Records required by applicable industry product standards shall be retained for not less than the period of time specified by the industry standard or five years, whichever is longer. Records required to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be retained for a minimum of five years.

5 Management responsibility

5.1 Management commitment

ISO 9001:2008, Quality management systems — Requirements

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

- a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,
- b) establishing the quality policy,
- c) ensuring that quality objectives are established,
- d) conducting management reviews, and
- e) ensuring the availability of resources.

5.2 Customer focus

ISO 9001:2008, Quality management systems — Requirements

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy

ISO 9001:2008, Quality management systems — Requirements

5.3 Quality policy

Top management shall ensure that the quality policy

- a) is appropriate to the purpose of the organization,
- b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,
- c) provides a framework for establishing and reviewing quality objectives,
- d) is communicated and understood within the organization, and
- e) is reviewed for continuing suitability.

5.3.1 Quality policy — Supplemental

Top management shall document its approval of the quality policy.

5.4 Planning

5.4.1 Quality objectives

ISO 9001:2008, Quality management systems — Requirements

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

ISO 9001:2008, Quality management systems — Requirements

5.4.2 Quality management system planning

Top management shall ensure that

- a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

NOTE See also 5.6, 7.1, 7.1.1, 7.3.1, 7.5.1, 8.1 and 8.2.2 for other planning requirements.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

ISO 9001:2008, Quality management systems — Requirements

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

ISO 9001:2008, Quality management systems — Requirements

5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

- a) ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) reporting to top management on the performance of the quality management system and any need for improvement, and
- c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

ISO 9001:2008, Quality management systems — Requirements

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

ISO 9001:2008, Quality management systems — Requirements

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.1.1 General — Supplemental

The management review shall be conducted at least annually.

NOTE 5.6.1.1 includes monitoring of quality objectives as part of the management review.

5.6.2 Review input

ISO 9001:2008, Quality management systems — Requirements

5.6.2 Review input

The input to management review shall include information on

- a) results of audits,
- b) customer feedback,
- c) process performance and product conformity,
- d) status of preventive and corrective actions,
- e) follow-up actions from previous management reviews,
- f) changes that could affect the quality management system, and
- g) recommendations for improvement.

NOTE 1 5.6.2 c) in conjunction with 8.4 c) includes trends of product nonconformity.

NOTE 2 5.6.2 f) includes changes to applicable petroleum, petrochemical and natural gas industry standards.

NOTE 3 5.6.2 c) includes reports and analysis of field nonconformities (see 3.1.9), if applicable.

5.6.3 Review output

ISO 9001:2008, Quality management systems — Requirements

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

- a) improvement of the effectiveness of the quality management system and its processes,
- b) improvement of product related to customer requirements, and
- c) resource needs.

6 Resource management

6.1 Provision of resources

ISO 9001:2008, Quality management systems — Requirements

6.1 Provision of resources

The organization shall determine and provide the resources needed

- a) to implement and maintain the quality management system and continually improve its effectiveness, and
- b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

ISO 9001:2008, Quality management systems — Requirements

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, training and awareness

ISO 9001:2008, Quality management systems — Requirements

6.2.2 Competence, training and awareness

The organization shall

- a) determine the necessary competence for personnel performing work affecting conformity to product requirements
- b) where applicable, provide training or take other actions to achieve the necessary competence,
- c) evaluate the effectiveness of the actions taken,
- d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.2.2.1 Training — Supplemental

The organization shall establish control features (see 3.1.4) for identifying training needs and providing for training of personnel who perform activities addressed in the quality management system. The training requirements shall provide for quality management system training and for job training of personnel. The frequency of training shall be defined by the organization.

NOTE 1 6.2.2.1 provides on-the-job training for personnel in any new or modified job affecting product quality, including contract or agency personnel.

NOTE 2 6.2.2.1 includes having a process to measure the extent to which its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives [see 6.2.2 d)]. It is advisable that personnel whose work can affect quality be informed about the consequences brought to bear on the customer of nonconformity to quality requirements.

6.3 Infrastructure

ISO 9001:2008, Quality management systems — Requirements

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

- a) buildings, workspace and associated utilities,
- b) process equipment (both hardware and software), and
- c) supporting services (such as transport or communication or information systems).

6.4 Work environment

ISO 9001:2008, Quality management systems — Requirements

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term “work environment” relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

NOTE 6.4 includes maintaining its premises in a state of order, cleanliness and repair consistent with the product and manufacturing process needs.

7 Product realization

7.1 Planning of product realization

ISO 9001:2008, Quality management systems — Requirements

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

- a) quality objectives and requirements for the product;
- b) the need to establish processes and documents, and to provide resources specific to the product;
- c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
- d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2 A organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.1.1 Planning of product realization — Supplemental

When product requirements are provided from external sources, the organization shall define the methods and shall establish control features (see 3.1.4) used to translate these requirements into the product realization process.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

ISO 9001:2008, Quality management systems — Requirements

7.2.1 Determination of requirements related to the product

The organization shall determine

- 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 specified or intended use, where known,
- c) statutory and regulatory requirements applicable to the product, and
- d) any additional requirements considered necessary by the organization.

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

7.2.2 Review of requirements related to the product

ISO 9001:2008, Quality management systems — Requirements

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

- a) product requirements are defined,
- b) contract or order requirements differing from those previously expressed are resolved, and
- c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed 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 or advertising material.

7.2.2.1 Review of requirements related to the product — Supplemental

The organization shall establish control features (see 3.1.4) to review requirements related to the product.

7.2.3 Customer communication

ISO 9001:2008, Quality management systems — Requirements

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

- a) product information,
- b) enquiries, contracts or order handling, including amendments, and
- c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 Design and development planning

ISO 9001:2008, Quality management systems — Requirements

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

- a) the design and development stages,
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and developmental review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

7.3.1.1 Design and development planning — Supplemental

The organization shall establish control features (see 3.1.4) for the design of the product.

When design and development are outsourced, the organization shall ensure the supplier meets the requirements of 7.3 and provide objective evidence that the supplier has met these requirements.

7.3.1.2 Design documentation — Supplemental

Design documentation shall include the methods, assumptions, formulae and calculations.

7.3.2 Design and development inputs

ISO 9001:2008, Quality management systems — Requirements

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.2.1 Design and development inputs — Supplemental

The organization shall identify, document and review the product design input requirements. Design and development inputs shall include customer-specified requirements (see 7.2.2).

7.3.3 Design and development outputs

ISO 9001:2008, Quality management systems — Requirements

7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

- a) meet the input requirements for design and development,
- b) provide appropriate information for purchasing, production and service provision,
- c) contain or reference product acceptance criteria, and
- d) specify the characteristics of the product that are essential for its safe and proper use.

NOTE Information for production and service provision can include details for the preservation of product.

7.3.3.1 Design and development outputs – Supplemental

Design and development outputs shall be documented.

7.3.4 Design and development review

ISO 9001:2008, Quality management systems — Requirements

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

- a) to evaluate the ability of the results of design and development to meet requirements, and
- b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.4.1 Design and development review — Supplemental

A final design review shall be conducted and documented. Individual(s) other than the person or persons who developed the design shall approve the final design.

7.3.5 Design and development verification

ISO 9001:2008, Quality management systems — Requirements

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

NOTE Design verification activities includes one or more of the following:

- a) confirming the accuracy of design results through the performance of alternative calculations;
- b) review of design output documents independent of activities of 7.3.4;
- c) comparing new designs to similar proven designs.

7.3.6 Design and development validation

ISO 9001:2008, Quality management systems — Requirements

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

NOTE Design validation includes one or more of the following:

- a) prototype tests;
- b) functional and/or operational tests of production products;
- c) tests specified by industry standards and/or regulatory requirements;
- d) field performance tests and reviews.

7.3.7 Control of design and development changes

ISO 9001:2008, Quality management systems — Requirements

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.3.7.1 Control of design and development changes — Supplemental

Design and development changes including changes to design documents shall require the same controls as the original design and development, as well as design documentation.

7.4 Purchasing

7.4.1 Purchasing process

ISO 9001:2008, Quality management systems — Requirements

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.1.1 Purchasing process — Supplemental

The organization shall establish control features (see 3.1.4) for the purchasing process and supplier selection.

NOTE Purchased product includes all products and services that affect compliance with customer requirements.

7.4.1.2 Criteria for supplier selection, evaluation, and re-evaluation — Supplemental

Criteria for the selection, evaluation and re-evaluation of suppliers shall include one or more of the following:

- a) inspection of supplier's final product by the organization at supplier's facility;
- b) inspection of supplier's final product by the organization upon delivery;
- c) surveillance of supplier's conformance to the organization's purchasing requirements;
- d) verification by the organization that the supplier's quality management system conforms to an internationally recognized quality management system standard/technical specification.

NOTE When there are mergers, acquisitions or affiliations associated with suppliers, consideration includes the organization verifying the continuity of the supplier's quality management system and its effectiveness.

7.4.1.3 Supplier-provided processes that require validation — Supplemental

Where an organization chooses to outsource any process that requires validation, the organization shall require that the supplier comply with the requirements of 7.5.2, as applicable (see 4.1).

7.4.2 Purchasing information**ISO 9001:2008, Quality management systems — Requirements****7.4.2 Purchasing information**

Purchasing information shall describe the product to be purchased, including, where appropriate

- a) requirements for approval of product, procedures, processes and equipment,
- b) requirements for qualification of personnel, and
- c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.2.1 Purchasing information — Supplemental

Purchasing information provided to the supplier shall be documented and shall describe the product to be purchased including, where appropriate, the items in 7.4.2, as well as the type, class, grade or other precise identification, the title or other positive identification, and applicable issues of specification, drawings, process requirements, inspection instructions and other relevant technical data.

7.4.3 Verification of purchased product

ISO 9001:2008, Quality management systems — Requirements

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.4.3.1 Verification of purchased product — Supplemental

The organization shall establish control features (see 3.1.4) for the verification of purchased product. The organization shall maintain records of verification activities (see 4.2.4).

7.5 Production and service provision

7.5.1 Control of production and service provision

ISO 9001:2008, Quality management systems — Requirements

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

- a) the availability of information that describes the characteristics of the product,
- b) the availability of work instructions, as necessary,
- c) the use of suitable equipment,
- d) the availability and use of monitoring and measuring equipment,
- e) the implementation of monitoring and measurement, and
- f) the implementation of product release, delivery and post-delivery activities.

7.5.1.1 Control of production and service provision — Supplemental

The organization shall establish control features (see 3.1.4) that describe the control of production and service activities performed.

7.5.1.2 Process controls — Supplemental

Process controls shall be documented in routings, travellers, checklists, process sheets, or other types of control features (see 3.1.4) and shall include requirements for verifying compliance with quality plans, control features and reference standards/codes. The process control documents shall include or reference instructions, workmanship and acceptance criteria for processes, tests, inspections, and customer's inspection hold or witness points.

7.5.2 Validation of processes for production and service provision

ISO 9001:2008, Quality management systems — Requirements

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable,

- a) defined criteria for review and approval of the processes,
- b) approval of equipment and qualification of personnel,
- c) use of specific methods and procedures,
- d) requirements for records (see 4.2.4), and
- e) revalidation.

7.5.2.1 Validation of processes for production and service provision — Supplemental

The organization shall validate those processes identified by the applicable product specification as requiring validation. If these processes are not identified, or there is no product specification involved, the processes requiring validation shall include, as a minimum, non-destructive examination, welding and heat treating, if applicable to the product.

7.5.3 Identification and traceability

ISO 9001:2008, Quality management systems — Requirements

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.3.1 Identification and traceability — Supplemental

The organization shall establish control features (see 3.1.4) for identification and traceability of the product by suitable means from receipt and during all stages of production, delivery and installation, as required by the organization, the customer, and the applicable product specifications.

7.5.3.2 Identification and traceability maintenance and replacement — Supplemental

Control features shall include requirements for maintenance or replacement of identification and traceability marks, and records.

7.5.3.3 Product status — Supplemental

The organization shall establish control features (see 3.1.4) for the identification of product status.

7.5.4 Customer property

ISO 9001:2008, Quality management systems — Requirements

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

7.5.4.1 Customer property — Supplemental

The organization shall establish control features (see 3.1.4) for the verification, storage, maintenance and control of customer property.

7.5.5 Preservation of product

ISO 9001:2008, Quality management systems — Requirements

7.5.5 Preservation of product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.5.5.1 Preservation of product — Supplemental

The organization shall establish control features (see 3.1.4) describing the methods used to preserve the conformity of product for the activities of 7.5.5.

7.5.5.2 Periodic assessment of stock — Supplemental

In order to detect deterioration, the condition of product or constituent parts in stock shall be assessed at specified intervals.

NOTE 7.5.5.2 includes the possible use of an inventory management system to optimize inventory turnover time and ensure stock rotation, such as "first-in-first-out" (FIFO).

7.6 Control of monitoring and measuring equipment

ISO 9001:2008, Quality management systems — Requirements

7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

- a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
- b) be adjusted or re-adjusted as necessary;
- c) have identification in order to determine its calibration status;
- d) be safeguarded from adjustments that would invalidate the measurement result;
- e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

7.6.1 Control of monitoring and measuring equipment — Supplemental

The organization shall establish control features (see 3.1.4) to control, calibrate and maintain monitoring and measuring equipment. Control features shall include equipment type, unique identification, location, frequency of checks, check method, and acceptance criteria.