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English Version

Petroleum, petrochemical and natural gas industries - Sector-specific quality management systems - Requirements for product and service supply organizations (ISO/TS 29001:2010)

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 (ISO/TS 29001:2010)

Erdöl-, petrochemische und Erdgasindustrie -
Sektorspezifische Qualitätsmanagementsysteme -
Anforderungen an Hersteller- und Serviceorganisationen
(ISO/TS 29001:2010)

This Technical Specification (CEN/TS) was approved by CEN on 27 December 2010 for provisional application.

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Foreword

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Endorsement notice

The text of ISO/TS 29001:2010 has been approved by CEN as a CEN ISO/TS 29001:2011 without any modification.

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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.

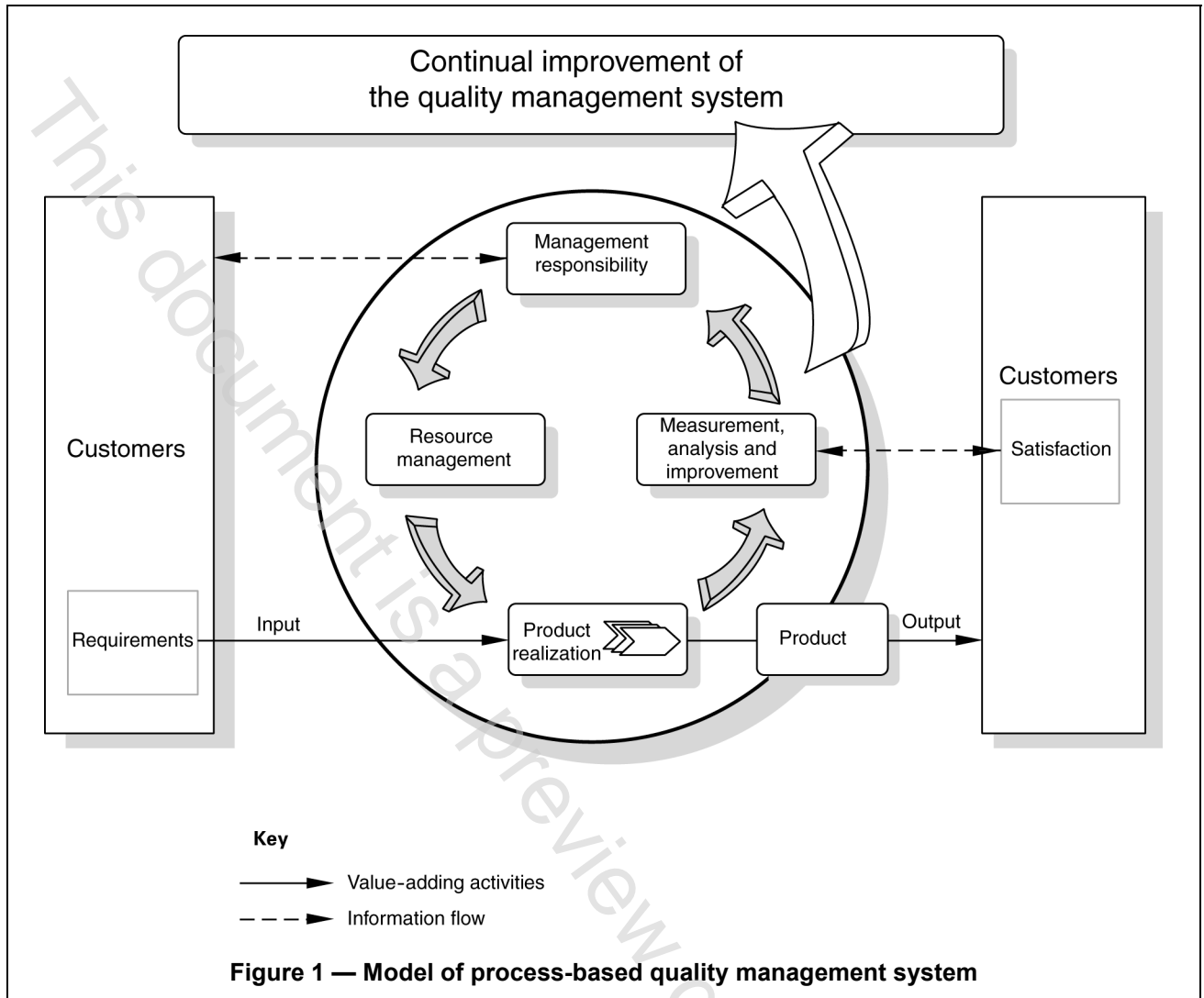
NOTE In addition, the methodology known as “Plan-Do-Check-Act” (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

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”.