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Entwurf

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 DIN CEN ISO/TS 29001
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**Erdöl-, petrochemische und Erdgasindustrie –
 Sektorspezifische Qualitätsmanagementsysteme –
 Anforderungen an Hersteller- und Serviceorganisationen
 (ISO/DIS 29001:2018);
 Englische Fassung prEN ISO 29001:2018**

Petroleum, petrochemical and natural gas industries –
 Sector-specific quality management systems –
 Requirements for product and service supply organizations (ISO/DIS 29001:2018);
 English version prEN ISO 29001:2018

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/DIS 29001:2018);
 Version anglaise prEN ISO 29001:2018

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Gesamtumfang 62 Seiten

DIN-Normenausschuss Erdöl- und Erdgasgewinnung (NÖG)

Nationales Vorwort

Dieses Dokument (prEN ISO 29001:2018) wurde vom Technischen Komitee ISO/TC 67 „Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries“ in Zusammenarbeit mit dem Technischen Komitee CEN/TC 12 „Materialien, Ausrüstungen und Offshore-Bauwerke für die Erdöl-, petrochemische und Erdgasindustrie“ (Sekretariat NEN, Niederlande) erarbeitet.

Für Deutschland hat hieran der Arbeitsausschuss NA 109-00-01 AA „Materialien, Ausrüstungen und Offshore-Bauwerke für die Erdöl-, petrochemische und Erdgasindustrie - Spiegelausschuss zu CEN/TC 12 und ISO/TC 67“ im DIN-Normenausschuss Erdöl- und Erdgasgewinnung (NÖG) mitgearbeitet.

Dieser Europäische Norm-Entwurf enthält unter Berücksichtigung des DIN-Präsidialbeschlusses 1/2004 nur die englische Originalfassung von prEN ISO 29001:2018 und ISO/DIS 29001:2018.

Für die in diesem Dokument zitierten Internationalen Normen wird im Folgenden auf die entsprechenden Deutschen Normen hingewiesen:

ISO 9000 siehe DIN EN ISO 9000

Änderungen

Gegenüber DIN CEN ISO/TS 29001:2011-04 wurden folgende Änderungen vorgenommen:

- a) Veröffentlichung als Norm;
- b) Angleichung an ISO 9001:2015 durch Neustrukturierung der Abschnitte;
- c) Aufnahme neuer Abschnitt 4 „Context of the organization“;
- d) Aufnahme neuer Abschnitt 5 „Leadership“;
- e) Aufnahme neuer Abschnitt 6 „Planning“;
- f) Aufnahme neuer Abschnitt 7 „Support“;
- g) Aufnahme neuer Abschnitt 8 „Operation“;
- h) Aufnahme neuer Abschnitt 9 „Performance evaluation“;
- i) Aufnahme neuer Abschnitt 10 „Improvement“;
- j) Aufnahme neuer informativer Anhang A „Clarification of new structure, terminology and concepts“;
- k) Aufnahme neuer informativer Anhang B „Other International Standards on quality management and quality management systems developed by ISO/TC 176“;
- l) Aufnahme neuer informativer Anhang C „Risk management and conformity assessment processes“.

Nationaler Anhang NA (informativ)

Begriffe

Die Benummerung der folgenden Begriffe ist identisch mit der Benummerung in der englischen Fassung.

3 Begriffe

Für die Anwendung dieses Dokuments gelten die Begriffe nach ISO 9000:2015 und die folgenden Begriffe.

3.1

Konformitätsbewertung

Darlegung, dass festgelegte Anforderungen bezogen auf ein Produkt, einen Prozess, ein System, eine Person oder eine Stelle erfüllt sind

Anmerkung 1 zum Begriff: Konformitätsbewertung schließt Tätigkeiten ein, wie Prüfen, Inspektion, Verifizierung und Zertifizierung.

[QUELLE: ISO 17000:2004, 2.1, modifiziert – Anmerkung 1 zum Begriff wurde geändert und Anmerkung 2 zum Begriff wurde gelöscht.]

3.2

Konformitätsbewertungssystem

CAS

(en: Conformity Assessment System)

System, das verschiedene Stufen der Bewertung von Steuerungstätigkeiten des Anbieters durch den Kunden (zweite Seite) oder eine unabhängige Stelle (dritte Seite) bietet, die auf einer Beurteilung der Fähigkeit des Anbieters beruht, der Produktspezifikation und der zugehörigen Qualitätsspezifikationsstufe zu entsprechen

Anmerkung 1 zum Begriff: Abgeleitet von ISO/TR 13881:2000, Abschnitt 8.

3.3

Kompetenzkatalog

hierarchisch strukturierte Auflistung der zur Ausführung einer beliebigen Aufgabe erforderlichen Kompetenzen

[QUELLE: ISO/TS 17969:2015, 2.2]

3.4

Kompetenzprofil

für ein Leistungsniveau jeweils festgelegte Fertigkeiten und Verhaltensweisen, die entsprechend dem zugehörigen Risiko zur Durchführung der Rolle oder Ausführung der Tätigkeit erforderlich sind

[QUELLE: ISO/TS 17969:2015, 2.4]

3.5

kritisch

wird seitens der Organisation, der Produktspezifikation oder des Kunden als verbindlich, unverzichtbar oder wesentlich angesehen, ist für eine(n) festgelegte(n) Zweck oder Aufgabe notwendig und erfordert besondere Maßnahmen

[QUELLE: API Q1 (9. Ausgabe), 3.1.6]

3.6

Konformitätsbewertung durch eine erste Seite

Tätigkeit, durchgeführt von der Person oder von der Organisation, die den Gegenstand der Konformitätsbewertung anbietet

Anmerkung 1 zum Begriff: Erste Seite (Anbieter), zweite Seite (Anwender) und dritte Seite (unabhängiger Dritter) werden verwendet, um Konformitätsbewertungstätigkeiten in Hinsicht auf einen gegebenen Gegenstand der Konformitätsbewertung zu bezeichnen. Sie sind nicht mit den Bezeichnungen von entsprechenden Seiten (Parteien) im Vertragsrecht zu verwechseln.

[QUELLE: ISO/TS 17000:2004, 2.2]

3.7

Haltepunkt

in einem geeigneten Dokument festgelegter Punkt, über den hinaus eine Tätigkeit ohne die Genehmigung einer bezeichneten Organisation oder Behörde nicht fortschreiten sollte

[QUELLE: ISO/TS 13881:2000, 3.7]

3.8

Leistungsniveau

Niveau der Fähigkeits- und Verhaltensmerkmale innerhalb einer bestimmten Fertigkeit

[QUELLE: ISO/TS 17969:2015, 2.3]

3.9

Qualitätsspezifikationsstufe

QSL

(en: Quality Specification Level)

Stufe, welche den Umfang der Steuerungstätigkeiten definiert, gewöhnlich einschließlich Prüfung, Inspektion und Verifizierung, die vom Anbieter durchzuführen sind, um die Konformität mit den Anforderungen auf der Grundlage der Bestimmung von Dienstleistungsrisiken oder -pflichten nachzuweisen

Anmerkung 1 zum Begriff: Ähnliche produkt- oder dienstleistungsspezifische Benennungen können in technischen Normen verwendet werden, um den Umfang der Steuerungstätigkeiten festzulegen für definierte Stufen von Dienstleistungsrisiken, z. B. Qualitätsspezifikationsstufe (QSL) nach API Spec 6D, Produktspezifikationsstufe (PSL) nach API Spec 6A und API Spec 17D sowie Beanspruchungsklasse nach ISO 19900.

3.10

Bewertung

Verifizieren, ob die Auswahl- und Ermittlungstätigkeiten und deren Ergebnisse hinsichtlich der Erfüllung der festgelegten Anforderungen durch den Gegenstand der Konformitätsbewertung geeignet, angemessen und wirksam sind

[QUELLE: ISO 17000:2004, 5.1]

3.11

Konformitätsbewertung durch eine zweite Seite

Tätigkeit, durchgeführt von einer Person oder einer Organisation, die gegenüber dem Gegenstand der Konformitätsbewertung ein Interesse als Anwender hat

Anmerkung 1 zum Begriff: Personen oder Organisationen, die eine Konformitätsbewertungstätigkeit als zweite Seite durchführen, können z. B. Käufer oder Nutzer eines Produktes oder potentielle Kunden sein, die sich auf ein Managementsystem eines Anbieters verlassen wollen, oder Organisationen, die deren Interessen vertreten.

Anmerkung 2 zum Begriff: Siehe Anmerkung zu 3.6.

[QUELLE: ISO 17000:2004, 2.3]

3.12

Überwachung

systematisch sich wiederholende Konformitätsbewertungstätigkeiten als Grundlage zur Aufrechterhaltung der Gültigkeit einer Konformitätsaussage

[QUELLE: ISO 17000:2004, 6.1]

3.13

Konformitätsbewertung durch eine dritte Seite

Tätigkeit, durchgeführt von einer Person oder einer Stelle, die von der Person oder der Organisation, die den Gegenstand der Konformitätsbewertung anbietet, und von Interessen als Anwender dieses Gegenstandes unabhängig ist

Anmerkung 1 zum Begriff: Kriterien für die Unabhängigkeit von Konformitätsbewertungsstellen und Akkreditierungsstellen sind den auf ihre Tätigkeiten zutreffenden Internationalen Normen und Leitfäden zu entnehmen (siehe Literaturhinweise).

Anmerkung 2 zum Begriff: Siehe Anmerkung zu 3.6.

[QUELLE: ISO 17000:2004, 2.4]

3.14

Kontrollpunkt

Punkt in der Kette der im vereinbarten Qualitäts- oder Kontrollplan festgelegten Tätigkeiten, der von der Konformitätsbewertungsstelle falls für notwendig erachtet zu kontrollieren ist

[QUELLE: ISO/TR 13881:2000, 3.6]

Nationaler Anhang NB
(informativ)

Literaturhinweise

DIN EN ISO 9000, *Qualitätsmanagementsysteme — Grundlagen und Begriffe*

- Entwurf -

Contents

Foreword.....	5
Introduction.....	6
0.0 Field of application	6
0.1 General	6
0.2 Quality management principles	7
0.3 Process approach.....	7
0.3.1 General	7
0.3.2 Plan-Do-Check-Act cycle.....	8
0.3.3 Risk-based thinking	9
0.4 Relationship with other management system standards	10
1 Scope	12
2 Normative references	12
3 Terms and definitions.....	12
4 Context of the organization.....	15
4.1 Understanding the organization and its context.....	15
4.2 Understanding the needs and expectations of interested parties.....	15
4.3 Determining the scope of the quality management system	15
4.4 Quality management system and its processes	16
5 Leadership.....	17
5.1 Leadership and commitment	17
5.1.1 General	17
5.1.2 Customer focus	17
5.2 Policy.....	18
5.2.1 Establishing the quality policy.....	18
5.2.2 Communicating the quality policy.....	18
5.3 Organizational roles, responsibilities and authorities	18
6 Planning	19
6.1 Actions to address risks and opportunities	19
6.2 Quality objectives and planning to achieve them	20
6.3 Planning of changes	20
7 Support.....	21
7.1 Resources	21
7.1.1 General	21
7.1.2 People	21
7.1.3 Infrastructure	21
7.1.4 Environment for the operation of processes	22
7.1.5 Monitoring and measuring resources.....	22
7.1.6 Organizational knowledge	23
7.2 Competence	23
7.3 Awareness	24
7.4 Communication	24
7.5 Documented information	25
7.5.1 General	25
7.5.2 Creating and updating.....	25
7.5.3 Control of documented information	25

8	Operation.....	26
8.1	Operational planning and control	26
8.2	Requirements for products and services.....	27
8.2.1	Customer communication	27
8.2.2	Determining the requirements for products and services.....	27
8.2.3	Review of the requirements for products and services.....	27
8.2.4	Changes to requirements for products and services	28
8.3	Design and development of products and services.....	28
8.3.1	General	28
8.3.2	Design and development planning.....	28
8.3.3	Design and development inputs.....	29
8.3.4	Design and development controls.....	29
8.3.5	Design and development outputs	30
8.3.6	Design and development changes	30
8.4	Control of externally provided processes, products and services.....	30
8.4.1	General	30
8.4.2	Type and extent of control	31
8.4.3	Information for external providers	31
8.5	Production and service provision	32
8.5.1	Control of production and service provision.....	32
8.5.2	Identification and traceability	33
8.5.3	Property belonging to customers or external providers	33
8.5.4	Preservation	33
8.5.5	Post-delivery activities.....	34
8.5.6	Control of changes.....	34
8.6	Release of products and services.....	34
8.7	Control of nonconforming outputs.....	35
9	Performance evaluation.....	35
9.1	Monitoring, measurement, analysis and evaluation	35
9.1.1	General	35
9.1.2	Customer satisfaction.....	36
9.1.3	Analysis and evaluation	36
9.2	Internal audit	37
9.3	Management review	37
9.3.1	General	37
9.3.2	Management review inputs.....	37
9.3.3	Management review outputs.....	38
10	Improvement.....	38
10.1	General	38
10.2	Nonconformity and corrective action	39
10.3	Continual improvement	39
Annex A (informative)	Clarification of new structure, terminology and concepts.....	40
A.1	Structure and terminology.....	40
A.2	Products and services	41
A.3	Understanding the needs and expectations of interested parties.....	41
A.4	Risk-based thinking.....	41
A.5	Applicability	42
A.6	Documented information	42
A.7	Organizational knowledge	43
A.8	Control of externally provided processes, products and services.....	43
Annex B (informative)	Other International Standards on quality management and quality management systems developed by ISO/TC 176.....	44

Annex C (informative) Risk management and conformity assessment processes	48
C.1 General	48
C.2 Risk classification principles.....	48
C.3 Risk management and conformity assessment process.....	49
C.3.1 Customer's scope and context.....	49
C.3.2 Undertaking risk assessment.....	49
C.3.3 Determination of control and verification requirements.....	50
C.4 Control of externally provided processes, products and services.....	50
C.4.1 Scope of externally provided activity	50
C.4.2 Potential provider capability assessment	51
C.4.3 Conformity assessment requirements for external providers	51
C.4.4 Control of external providers during execution of scope	51
Appendix 1 – Examples of conformity assessment activities.....	52
Bibliography	54

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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 67, *Materials, equipment and offshore structures for petroleum, petrochemical and natural gas industries*.

This fourth edition cancels and replaces the third edition (ISO/TS 29001:2010), of which it constitutes a major revision in order to align with ISO 9001:2015.

Introduction

0.0 Field of application

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

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

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.

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:

- understanding and consistency in meeting requirements;
- the consideration of processes in terms of added value;
- the achievement of effective process performance;
- 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.

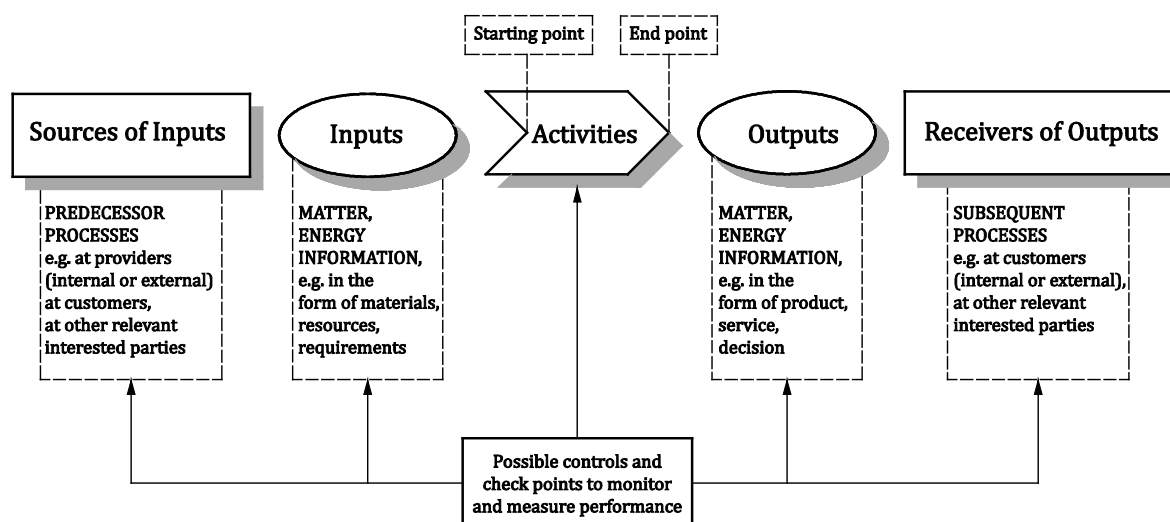


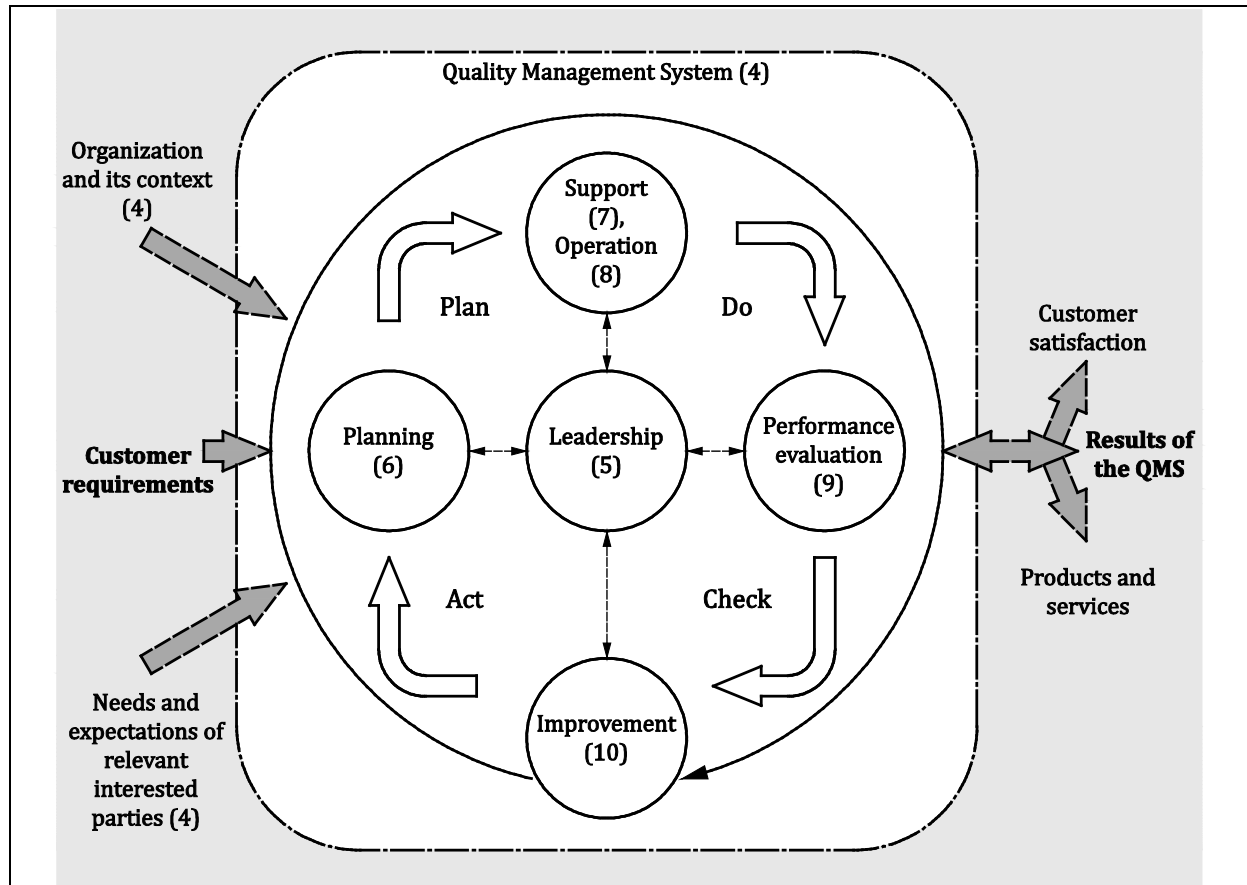
Figure 1 — Schematic representation of the elements of a single process

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 International Standard also relates to ISO/TS 9002, *Quality management systems — Guidelines for the application of ISO 9001:2015*, providing 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 International Standard and the previous edition (ISO/TS 29001:2010) and other industry standards dealing

with quality management systems requirements can be found on ISO/TC 67 open access web site at www.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 International Standard defines quality management system requirements for product and service supply organizations to the petroleum, petrochemical and natural gas industries.

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

The supplementary requirements and guidance have been developed to manage risks associated with the petroleum, petrochemical and natural gas 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.

3.1

conformity assessment

demonstration that specified requirements relating to a product, process, system, person or body are fulfilled

Note 1 to entry: The subject field of conformity assessment includes activities such as testing, inspection, verification and certification.

[SOURCE: ISO 17000:2004, 2.1, modified – Note 1 to entry has been amended and note 2 to entry has been deleted.]

3.2

conformity assessment system

CAS

system providing different levels of assessment of provider's control activities by customer (second-party) or independent body (third-party) based on evaluation of provider's capability to conform to the product specification and associated quality specification level

Note 1 to entry: Derived from ISO/TR 13881:2000, Clause 8.

3.3

competency catalogue

hierarchical structured list of the competencies required to perform any task

[SOURCE: ISO/TS 17969:2015, 2.2]

3.4

competency profile

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

[SOURCE: ISO/TS 17969:2015, 2.4]

3.5

critical

that deemed by the organization, product specification, or customer as mandatory, indispensable or essential, needed for a stated purpose or task, and requiring specific action

[SOURCE: API Q1 (9th edition), 3.1.6]

3.6

first-party conformity assessment activity

conformity assessment activity that is performed by the person or organization that provides the object

Note 1 to entry: The first-, second- and third-party descriptors used to characterize conformity assessment activities with respect to a given object are not to be confused with the legal identification of the relevant parties to a contract.

[SOURCE: ISO 17000:2004, 2.2]

3.7

hold point

point, defined in an appropriate document, beyond which an activity should not proceed without the approval of a designated organization or authority

[SOURCE: ISO/TR 13881:2000, 3.7]

3.8

proficiency level