

Addendum 1  
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# **Specification for Quality Programs for the Petroleum, Petrochemical and Natural Gas Industry**

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**ISO TS 29001:2007 (Identical), Petroleum, petrochemical  
and natural gas industries—Sector specific  
requirements—Requirements for product and service  
supply organizations**



AMERICAN PETROLEUM INSTITUTE





# Specification for Quality Programs for the Petroleum, Petrochemical and Natural Gas Industry

NOTE The amended text appears in italics within the paragraphs.

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*Change the following items to read:*

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## Introduction

### 0.1 General

*Change items a) and f) of the first paragraph to read:*

- a) *Its organizational environment, changes in that environment, and the risks associated with that environment,*
- b) *Its size and organizational structure*

*Change the third paragraph to read:*

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.

### 0.2 Process approach

*Change the second and third paragraphs to read:*

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".

### 0.3 Relationship with ISO 9004

*Change the first paragraph to read:*

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

*Change the third paragraph to read:*

*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.*

*Insert the following NOTE at the end of section 0.3:*

**NOTE** ISO 9004:2009 is published and cancels and replaces the second edition (ISO 9004:2000)

## **0.4 Compatibility with other management systems**

*Change the first paragraph to read:*

*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.*

*Insert the following NOTE at the end of section 0.4:*

**NOTE** For this Technical Specification, Annex A as described above, is not provided and is not considered part of this document. If 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.

## **1.1 General**

*Change items a), b), and the NOTE to read:*

- 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) the 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.*

## **1.2 Application**

*Change the third paragraph to read:*

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 organizations ability, or responsibility, to provide product that meets customer and applicable *statutory and* regulatory requirements.

## **2 Normative reference**

*Change this section to read:*

*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*.

*Delete the NOTE at the end of Section 2.*

### **3 Terms and definitions**

*Delete the second paragraph, the section will read:*

For the purposes of this International Standard, 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”.

#### **4.1 General Requirements**

*Change the second paragraph, item a) to read:*

- a) *determine* the processes needed for the quality management system and their application throughout the organization (see 1.2),

*Change the second paragraph, item e) to read:*

- e) monitor, measure *where applicable* and analyze these processes, and

*Change the last paragraph and NOTE to read:*

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.*

##### **4.2.1 General**

*Change the first paragraph, items c) and d) to read:*

- 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.

*Delete the first paragraph, item e)*

*Change NOTE 1 to read:*

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 documented procedures may be covered by more than one document.*

#### **4.2.2.1 Quality manual — Supplemental**

*Update the ISO 9001 date to 2008, the paragraph should read:*

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**

*Change the second paragraph, item f) to read:*

- 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

#### **4.2.4 Control of records**

*Change the section to read:*

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.

#### **5.5.2 Management representative**

*Change the first paragraph to read:*

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

#### **6.2.1 General**

*Change the section to read:*

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

*Change items a) and b) to read:*

- 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*,

## 6.3 Infrastructure

*Change item c) to read:*

- c) supporting services (such as transport or communication *or information systems*).

## 6.4 Work environment

*Insert this note at the end of the section:*

*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).*

## 7.1 Planning of a product realization

*Change the second paragraph, items b) and c) to read:*

- 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;

### 7.2.1 Determination of requirements related to the product

*Change the first paragraph, items c) and d) to read:*

- c) statutory and regulatory requirements *applicable* to the product, and
- d) any additional requirements *considered necessary* by the organization.

*Insert this note at the end of the section:*

*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.*

### 7.3.1 Design and development planning

*Insert this note at the end of the section:*

*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.*

### 7.3.3 Design and development outputs

*Change the first paragraph to read:*

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.

*Insert this note at the end of the section:*

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

### 7.5.1 Control of production and service provision

*Change items d) and f) to read:*

- d) the availability and use of monitoring and measuring *equipment*,
- f) the implementation of *product* release, delivery and post-delivery activities.

### 7.5.2 Validation of processes for production and service provision

*Change the first paragraph to read:*

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.

### 7.5.3 Identification and traceability

*Change the second and third paragraphs to read:*

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).

### 7.5.4 Customer property

*Change the note to read:*

**NOTE** Customer property can include intellectual property *and personal data*.

### 7.5.5 Preservation of product

*Change the section to read:*

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.

## 7.6 Control of monitoring and measuring devices

*Change the section title to read:*

## 7.6 Control of monitoring and measuring *equipment*

*Change the first paragraph to read:*

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.

*Change the third paragraph, items a) and c) to read:*

- 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);
- c) *have identification in order to determine its calibration status;*

*Change the note to read:*

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 devices — Supplemental

*Change the section title to read:*

### 7.6.1 Control of monitoring and measuring *equipment* — Supplemental

*Change the section to read:*

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.

## 8.1 General

*Change item a) to read:*

- a) to demonstrate conformity *to product requirements*,

### 8.2.1 Customer satisfaction

*Insert this note at the end of the section:*

NOTE *Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.*

## 8.2.2 Internal audit

*Change the second paragraph to read:*

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. *The* selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

*Change the third paragraph to read:*

*A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and recording results.*

*Records of the audits and their results shall be maintained (see 4.2.4)*

*Change the fourth paragraph and the note to read:*

The management responsible for the area being audited shall ensure that *any necessary corrections and corrective* actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

### 8.2.2.2 Response times — Supplemental

*Delete the NOTE at the end of 8.2.2.2.*

## 8.2.3 Monitoring and measurement of processes

*Change the section to read:*

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate *[text deleted]*.

NOTE *When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.*

## 8.2.4 Monitoring and measurement of product

*Change the section to read:*

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

*[text deleted]* Records shall indicate the person(s) authorizing release of product *for delivery to the customer* (see 4.2.4).

The release of product and delivery of service *to the customer* shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

### 8.3 Control of nonconforming product

*Change the section to read:*

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure *shall be established* to define the controls and related responsibilities and authorities for dealing with nonconforming product.

*Where applicable*, the organization shall deal with nonconforming product by one or more of the following ways:

- a) by taking action to eliminate the detected nonconformity;
- b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- c) by taking action to preclude its original intended use or application.
- d) *by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.*

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

*[Text deleted]*

### 8.4 Analysis of data

*Change the second paragraph, items b), c), and d) to read:*

- b) conformity to product requirements (see 8.2.4),
- c) characteristics and trends of processes and products including opportunities for preventive action (see 8.2.3 and 8.2.4), and
- d) suppliers (see 7.4).

*Insert the following NOTE at the end of section 8.4:*

**NOTE** For 8.4 c), also see 8.5.3 relative to preventive action.

#### 8.5.2 Corrective action

*Change the first paragraph to read:*

The organization shall take action to eliminate the *causes* of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

*Change the second paragraph, item f) to read:*

- f) reviewing *the effectiveness of the* corrective action taken.

### **8.5.3 Preventative action**

*Change item e) to read:*

- e) reviewing *the effectiveness of the* preventative action taken.

### **Bibliography**

*Replace the Bibliography page as follows:*

## Bibliography

- [1] ISO 9004:2009, Managing for the sustained success of an organization—A quality management approach
- [2] ISO 10001:2007, Quality management—Customer satisfaction—Guidelines for codes of conduct for organizations
- [3] ISO 10002:2004, Quality management—Customer satisfaction—Guidelines for complaints handling in organizations
- [4] ISO 10003:2007, Quality management—Customer satisfaction—Guidelines for dispute resolution external to organizations
- [5] ISO 10005:2005, Quality management systems—Guidelines for quality plans
- [6] ISO 10006:2003, Quality management systems—Guidelines for quality management in projects
- [7] ISO 10007:2003, Quality management systems—Guidelines for configuration management
- [8] ISO 10012:2003, Measurement management systems—Requirements for measurement processes and measuring equipment
- [9] ISO/TR 10013:2001, Guidelines for quality management system documentation
- [10] ISO10014:2006, Quality management—Guidelines for realizing financial and economic benefits
- [11] ISO 10015:1999, Quality management—Guidelines for training
- [12] ISO/TR 10017:2003, Guidance on statistical techniques for ISO 9001:2000
- [13] ISO 10019:2005, Guidelines for the selection of quality management system consultants and use of their services
- [14] ISO 14001:2004, Environmental management systems—Requirements with guidance for use
- [15] ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing
- [16] IEC 60300-1:2003, Dependability management—Part 1: Dependability management systems
- [17] IEC 61160:2006, Design Review
- [18] ISO/IEC 90003:2004, Software engineering—Guidelines for the application of ISO 9001:2000 to computer software
- [19] Quality management principles <sup>1</sup>, ISO, 2001
- [20] ISO 9000, - Selection and Use <sup>1</sup>, ISO, 2008
- [21] ISO 9001 for Small Businesses—What to do; Advice from ISO/TC 176 <sup>2</sup>, ISO, 2002
- [22] ISO Management Systems <sup>3</sup>
- [23] Reference web sites:
- [24] <http://www.iso.org>  
<http://www.tc176.org>  
<http://www.iso.org/tc176/sc2>  
<http://www.iso.org/tc176/ISO9001AuditingPracticesGroup>

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<sup>1</sup> Available from website: <http://www.iso.org/>

<sup>2</sup> To be updated and aligned with ISO 9001:2008.

<sup>3</sup> A bimonthly publication which provides comprehensive coverage of international developments relating to ISO's management system standards, including news of their implementation by diverse organizations around the world. Available from ISO Central Secretariat ([sales@iso.org](mailto:sales@iso.org))







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