



**DRAFT TECHNICAL  
SPECIFICATION OR  
TECHNICAL REPORT**

<b>Proposed ISO/DTS or ISO/DTR 29001</b>		
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*Title (English)*

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

*Title (French)*

**Industries du pétrole et du gaz naturel - Systèmes de management de la qualité pour des activités sectorielles spécifiques - Exigences pour les activités de production et de services**

Proposed Technical Specification  or Technical Report

Reference language version:  English  French  Russian

Introductory note

Separate ballots are being conducted (1) to confirm TC67 agreement to extending the scope of this document to include "petrochemical" (67N828); (2) to developing a Technical Specification (67N829); and (3) for approval to publish (67N830).

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**Working Group Notes**  
**(To be removed before publication)**

The text outside the boxes denote supplemental requirements in addition to the “base requirements” of ISO 9001:2000.

**Bold Red words** denote Work Group pending actions.

The status of this document as a **Technical Specification** is subject to approval by ISO/TC67.

The potential extension, before publication, of the scope of this document to include "**petrochemical**" is subject to the approval of ISO/TC67.

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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 normative 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 or the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years with a view to deciding whether it should be confirmed for a further three years, revised to become an International Standard, or withdrawn. In the case of a confirmed ISO/PAS or ISO/TS, it is reviewed again after six years at which time it has to be either transposed into an International Standard or withdrawn.

ISO/TS 29001:2003 was prepared by ISO/TC 67, *Materials, equipment and offshore structures for the petroleum, petrochemical and natural gas industries*, and approved for publication as an ISO/TS by ISO/TC 67 to provide additional requirements to ISO 9001:2000 specifically intended for the petroleum and natural gas industries.

**Boxed text is original ISO 9001:2000 text unaltered and in its entirety. The petroleum and natural gas industry sector-specific supplemental requirements are outside the boxes.**

The third edition of ISO 9001 cancelled and replaced the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constituted a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use the third edition of ISO 9001 by excluding certain requirements in accordance with 1.2.

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

# ISO/DTS 29001

## Introduction

### 0.1 General

#### ISO 9001:2000, 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 varying needs, particular objectives, the products involved, the processes employed and the size and structure of the organization. It is not the intent of this International Standard to imply uniformly 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, regulatory 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 9001:2000, 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 identify and manage numerous linked activities. An activity 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, 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 h1 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 the processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

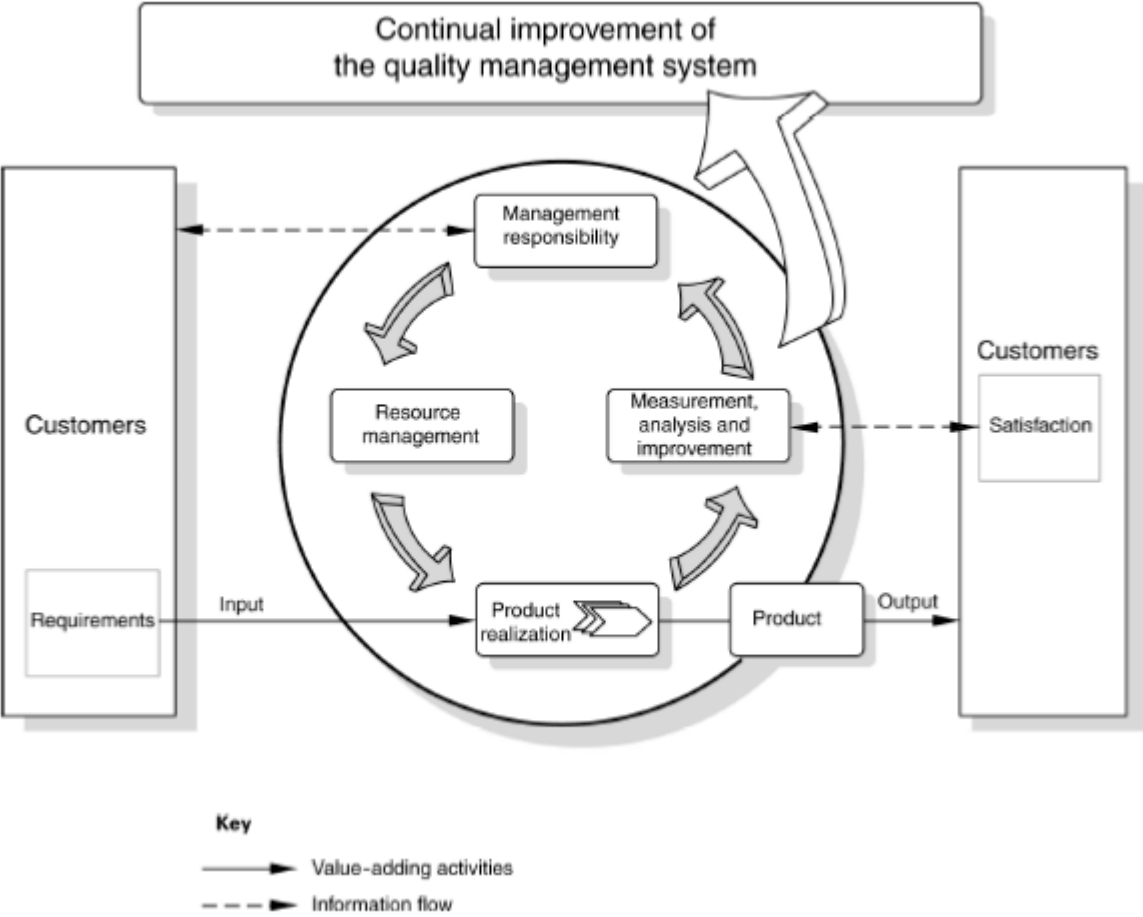


Figure 1 – Model of a process-based quality management system

## 0.3 Relationship with ISO 9004

### ISO 9001:2000, Quality management systems - Requirements

#### 0.3 Relationship with ISO 9004

The present editions of ISO 9001 and ISO 9004 have been developed as a consistent pair of quality management system standards which have been designed to complement each other, but can also be used independently.

Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.

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.

ISO 9004 gives guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement or performance. However, it is not intended for certification or for contractual purposes.

## 0.4 Compatibility with other management systems

### ISO 9001:2000, Quality management systems - Requirements

#### 0.4 Compatibility with other management systems

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.

## 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, emphasising 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 document.

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



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

## 1. Scope

### 1.1 General

**ISO 9001:2000, Quality management systems - Requirements**

**Introduction**

**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 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 regulatory requirements.

NOTE In this International Standard, the term “product” applies only to the product intended for, or required by, a customer.

This **Technical Specification**, defines the quality management system requirements for the design, development, production, installation and service of products for the petroleum and natural gas industries.

### 1.2 Application

**ISO 9001:2000, 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 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:

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

NOTE The exclusion to Section 7.5.2 only applies to the supplemental requirement of 7.5.2.1.

## 2 Normative reference

The following normative document contains provisions, which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*.

## 3 Terms and definitions

### ISO 9001:2000, Quality management systems - Requirements

#### 3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 9000 apply. The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:

supplier → organization → customer

The term “organization” replaces the term “supplier” used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term “supplier” now replaces the term “subcontractor”.

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 and natural gas industries

For the purposes of this **Technical Specification**, the terms and definitions given in ISO 9000:2000 and the following shall apply.

##### 3.1.1

##### **acceptance criteria**

specified limits of acceptability applied to process or product characteristics

##### 3.1.2

##### **calibration**

comparison and adjustment to a standard of known accuracy

##### 3.1.3

##### **control feature**

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

##### 3.1.4

##### **delivery**

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

##### 3.1.5

##### **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

##### 3.1.6

##### **design validation**

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

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### 3.1.7

#### **design verification**

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

### 3.1.8

#### **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

### 3.1.9

#### **special process**

process where the conformity of the resulting product cannot be readily or economically verified by subsequent monitoring or measurement

### 3.1.10

#### **tender**

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

## 4 Quality Management System

### 4.1 General requirements

#### **ISO 9001:2000, 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) identify 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 and analyse 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 with requirements, the organization shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

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

## 4.2 Documentation requirements

### 4.2.1 General

#### ISO 9001:2000, 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 required by this International Standard,
- d) documents needed by the organization to ensure the effective planning, operation and control of its processes, and
- e) records required by this International Standard (see 4.2.4).

NOTE 1 Where the term “documented procedure” appears within this International Standard, this means that the procedure is established, documented, implemented and maintained.

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 9001:2000, 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 9001:2000 and the supplemental requirements.

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## 4.2.3 Control of documents

### ISO 9001:2000, 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 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 9001:2000, Quality management systems - Requirements

#### 4.2.4 Control of records

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

#### 4.2.4.1 Control of records - Supplemental

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

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.

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

## 5 Management responsibility

### 5.1 Management commitment

#### ISO 9001:2000, 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 9001:2000, 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 9001:2000, 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.

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## 5.4 Planning

### 5.4.1 Quality objectives

#### ISO 9001:2000, 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 9001:2000, 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 9001:2000, 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 9001:2000, Quality management systems - Requirements

##### 5.5.2 Management representative

Top management shall appoint a member of 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 9001:2000, 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 9001:2000, Quality management systems - Requirements

## 5.6 Management review

### 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 Part of the management review should include monitoring of quality objectives.

### 5.6.2 Review input

#### ISO 9001:2000, 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,

#### 5.6.2.1 Review input - Supplemental

Input to management reviews shall include reports of and analysis of field nonconformities, if applicable.

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

NOTE 5.6.2.f includes changes to applicable petroleum and natural gas industry standards.

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### 5.6.3 Review output

#### ISO 9001:2000, 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 9001:2000, Quality management systems - Requirements

##### 6 Resource management

##### 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 9001:2000, Quality management systems - Requirements

##### 6.2 Human resources

##### 6.2.1 General

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

#### 6.2.2 Competence, awareness and training

#### ISO 9001:2000, Quality management systems - Requirements

##### 6.2.2 Competence, awareness and training

The organization shall

- a) determine the necessary competence for personnel performing work affecting product quality,
- b) provide training or take other actions to satisfy these needs,
- 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 3.1.3) 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 The organization should provide on-the-job training for personnel in any new or modified job affecting product quality, including contract or agency personnel.

NOTE 2 The organization should have 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). Personnel whose work can affect quality should be informed about the consequences to the customer of nonconformity to quality requirements.

## 6.3 Infrastructure

### ISO 9001:2000, 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).

## 6.4 Work environment

### ISO 9001:2000, 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 organization should maintain 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 9001:2000, Quality management systems - Requirements

#### 7 Product realization

##### 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, documents, and provide resources specific to the product;
- c) required verification, validation, monitoring, 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 The 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, including design and development inputs/outputs, are provided from external sources, the organization shall define the methods and shall establish control features (see 3.1.3) 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 9001:2000, Quality management systems - Requirements**

**7.2 Customer related processes**

**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 related to the product, and
- d) any additional requirements determined by the organization.

**7.2.2 Review of requirements related to the product**

**ISO 9001:2000, 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 3.1.3) to review requirements related to the product.

#### **7.2.3 Customer communication**

#### **ISO 9001:2000, 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 9001:2000, Quality management systems - Requirements**

##### **7.3 Design and development**

##### **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

##### **7.3.1.1 Design and development planning - Supplemental**

The organization shall establish control features (see 3.1.3) 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, formulas, and calculations.

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### 7.3.2 Design and development inputs

#### ISO 9001:2000, 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,

These 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 9001:2000, Quality management systems - Requirements

##### 7.3.3 Design and development outputs

The outputs of design and development shall be provided in a form that enables 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 for 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.

### 7.3.4 Design and development review

#### ISO 9001:2000, 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 9001:2000, 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 can include 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 9001:2000, 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 can include 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 9001:2000, 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, and design documentation.

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## 7.4 Purchasing

### 7.4.1 Purchasing process

#### ISO 9001:2000, Quality management systems - Requirements

### 7.4 Purchasing

#### 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 3.1.3) for the purchasing process and supplier selection.

NOTE Purchased products above include all products and services that affect customer requirements.

#### 7.4.1.2 Criteria for supplier selection, evaluation, and re-evaluation

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, the organization should verify the continuity of the supplier's quality management system and its effectiveness.

#### 7.4.1.3 Supplier provided special processes

Where an organization chooses to outsource any special process, 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 9001:2000, 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:

- a) the type, class, grade or other precise identification, and
- b) the title or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data.

**7.4.3 Verification of purchased product****ISO 9001:2000, 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 3.1.3) for the verification of purchased product.

**7.5 Production and service provision****7.5.1 Control of production and service provision****ISO 9001:2000, Quality management systems - Requirements****7.5 Production and service provision****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 devices,
- e) the implementation of monitoring and measurement, and
- f) the implementation of release, delivery and post-delivery activities.

**7.5.1.1 Control of production and service provision - Supplemental**

The organization shall establish control features (see 3.1.3) that describe the control of production and service activities performed.

**7.5.1.2 Process controls**

Process controls shall be documented in routings, travelers, checklists, process sheets, or other types of control features (see 3.1.3) 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 9001:2000, 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. This includes any processes where 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 establish control features (see 3.1.3) that include activities of 7.5.2 for the qualification and validation of special processes (See 3.1.9) for production and service provision.

## 7.5.3 Identification and traceability

### ISO 9001:2000, 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.

Where traceability is a requirement, the organization shall control and record the unique identification of the product (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 3.1.3) 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

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 3.1.3) for the identification of product status.

#### 7.5.4 Customer property

##### ISO 9001:2000, 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, this shall be reported to the customer and records maintained (see 4.2.4).

NOTE Customer property can include intellectual property.

##### 7.5.4.1 Customer property - Supplemental

The organization shall establish control features (see 3.1.3) for the verification, storage, maintenance and control of customer property.

#### 7.5.5 Preservation of product

##### ISO 9001:2000, Quality management systems - Requirements

#### 7.5.5 Preservation of product

The organization shall preserve the conformity of product during internal processing and delivery to the intended destination. This 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 3.1.3) 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 The organization should use an inventory management system to optimize inventory turns over time and assure stock rotation, such as "first-in-first-out" (FIFO).

#### 7.6 Control of monitoring and measuring devices

##### ISO 9001:2000, Quality management systems - Requirements

#### 7.6 Control of monitoring and measuring devices

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements (see 7.2.1).

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 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;
- b) be adjusted or re-adjusted as necessary;
- c) be identified to enable the calibration status to be determined;

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- 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 See ISO 10012-1 and ISO 10012-2 for guidance.

### 7.6.1 Control of monitoring and measuring devices - Supplemental

The organization shall establish control features (see 3.1.3) to control, calibrate and maintain monitoring and measuring devices. Control features shall include device type, unique identification, location, frequency of checks, check method, and acceptance criteria.

### 7.6.2 Environmental conditions

The organization shall ensure that the environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

NOTE Records of the calibration/verification activity for all gauges, measuring and test equipment, needed to provide evidence of conformity of product to determined requirements, including employee – and customer owned equipment should include

- equipment identification, including the measurement standard against which the equipment is calibrated,
- revisions following engineering changes,
- any out-of-specification readings as received for calibration/verification,
- an assessment of the impact of out-of-specification condition, and
- notification to the customer if suspect product or material has been shipped.

## 8 Measurement, analysis and improvement

### 8.1 General

#### ISO 9001:2000, Quality management systems - Requirements

### 8. Measurement, analysis and improvement

#### 8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

- a) to demonstrate conformity of the product,
- b) to ensure conformity of the quality management system, and
- c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

## 8.2 Monitoring and measurement

### 8.2.1 Customer satisfaction

#### ISO 9001:2000, Quality management systems - Requirements

### 8.2 Monitoring and measurement

#### 8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

### 8.2.2 Internal audit

#### ISO 9001:2000, Quality management systems - Requirements

### 8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

- a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and
- b) is effectively implemented and maintained.

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. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.

The management responsible for the area being audited shall ensure that 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 10011-1, ISO 10011-2 and ISO 10011-3 for guidance.

#### 8.2.2.1 Internal audit - Supplemental

Internal audits shall be scheduled and conducted at least annually by personnel independent of those who performed or directly supervised the activity being audited.

#### 8.2.2.2 Submission of action plans

Response times for submission of an action plan to address detected nonconformities shall be identified.

NOTE ISO 19011 has replaced ISO 10011.

### 8.2.3 Monitoring and measurement of processes

#### ISO 9001:2000, Quality management systems - Requirements

### 8.2.3 Monitoring and measurement of processes

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, to ensure conformity of the product.

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NOTE The organization should maintain records of the effective dates of process changes.

### 8.2.4 Monitoring and measurement of product

#### ISO 9001:2000, Quality management systems - Requirements

#### 8.2.4 Monitoring and measurement of product

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. Records shall indicate the person(s) authorizing release of product (see 4.2.4).

Product release and service delivery 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.

#### 8.2.4.1 Monitoring and measurement of product - Supplemental

The organization shall establish control features (see 3.1.3) to monitor and measure the characteristics of the product.

#### 8.2.4.2 Final acceptance of product

Personnel other than the persons who performed or directly supervised the production of the materials or products shall perform final acceptance and product release.

### 8.3 Control of nonconforming product

#### ISO 9001:2000, Quality management systems - Requirements

#### 8.3 Control of nonconforming product

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

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.

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

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

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity.

#### 8.3.1 Concession - Supplemental

Concession(s) shall be documented.

### 8.3.2 Release or acceptance of nonconforming product under concession

The process of evaluation, release and acceptance of nonconforming product shall include one or more of the following:

- a) Accepting products that do not satisfy manufacturing acceptance criteria provided:
  - i) Products satisfy the design acceptance criteria, or
  - ii) The violated manufacturing acceptance criteria are categorized as unnecessary to satisfy the design acceptance criteria, or
  - iii) Products are repaired or reworked to satisfy the design acceptance criteria or manufacturing acceptance criteria.
- b) Accepting products that do not satisfy the original design acceptance criteria provided:
  - i) The original design acceptance criteria are changed per 7.3.7, and
  - ii) The materials or products satisfy the new design acceptance criteria.

### 8.3.3 Field nonconformity analysis

Nonconforming product that is detected after delivery or use has started is commonly known as a "Field Nonconformity". The documented procedure for nonconforming product shall include requirements for identifying, documenting and reporting incidents of field nonconformities or product failures. The documented procedure shall ensure the analysis of field nonconformities, provided the product or documented evidence supporting the nonconformity is available to facilitate the determination of the cause.

## 8.4 Analysis of data

### ISO 9001:2000, Quality management systems - Requirements

#### 8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

- a) customer satisfaction (see 8.2.1),
- b) conformity to product requirements (see 7.2.1),
- c) characteristics and trends of processes and products including opportunities for preventive action, and
- d) suppliers.

#### 8.4.1 Analysis of data - Supplemental

The organization shall establish control features (see 3.1.3) for the identification and use of the techniques for the analysis of data.

## 8.5 Improvement

### 8.5.1 Continual improvement

### ISO 9001:2000, Quality management systems - Requirements

#### 8.5 Improvement

##### 8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

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### 8.5.1.1 Continual improvement of the organization

The organization shall define a process and establish control features (see 3.1.3) for continual improvement.

NOTE See ISO 9004:2000, Annex B for guidance on continuous improvement.

### 8.5.2 Corrective action

#### ISO 9001:2000, Quality management systems - Requirements

##### 8.5.2 Corrective action

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

A documented procedure shall be established to define requirements for

- a) reviewing nonconformities (including customer complaints),
- b) determining the causes of nonconformities,
- c) evaluating the need for action to ensure that nonconformities do not recur,
- d) determining and implementing action needed,
- e) records of the results of action taken (see 4.2.4), and
- f) reviewing corrective action taken.

#### 8.5.2.1 Corrective action - Supplemental

The organization shall ensure that any corrective action is effective.

#### 8.5.2.2 Corrective action response times

Response times for the submission of an action plan to address corrective action shall be identified.

### 8.5.3 Preventive action

#### ISO 9001:2000, Quality management systems - Requirements

##### 8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

- a) determining potential nonconformities and their causes,
- b) evaluating the need for action to prevent occurrence of nonconformities,
- c) determining and implementing action needed,
- d) records of results of action taken (see 4.2.4), and
- e) reviewing preventive action taken.

#### 8.5.3.1 Preventive action - Supplemental

The organization shall ensure that any preventive action is effective.

## Bibliography

- [1] ISO 9004:2000, *Quality management systems — Guidelines for performance improvements*
- [2] ISO 10012-2:1997, *Quality assurance for measuring equipment — Part 2: Guidelines for control of measurement processes*
- [3] ISO 19011:2002, *Guidelines for quality and/or environmental management system auditing*