

**NEW EDITION**

**The New Version of  
ISO 9001:2015**

**September 2015**



# Principles of Quality Management System

ISO 9001:2008	ISO 9001:2015
Customer focus	Customer focus
Leadership	Leadership
Involvement of people	Engagement of people
Process approach	Process approach
System approach to management	
Continual improvement	Improvement
Factual approach to decision making	Evidence-based decision making
Mutually beneficial supplier relationship	Relationship management

# Terms and definitions

New terms included in the new version of the standard:

## **Risk**

*Effect of uncertainty on an expected result.*

## **Documented information**

*Information required to be controlled and maintained by an organization and the medium on which it is contained.*

## **Context of the organization**

*Combination of internal and external factors and conditions that can have an effect on an organization's approach to its products, services and investments and interested parties.*

*Note: The terminology of the QMS of an organization can be one that is understood by it. There is no requirement to use the terminology of the standard.*

# Standard structure

**The Standard was developed based on the text of Annex SL to ensure compatibility between the different management systems**

## **4. Context of the organization:**

- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs and expectations of interested parties
- 4.3 Determining the scope of the quality management system
- 4.4 Quality management system and its processes

## **5. Leadership:**

- 5.1 Leadership and commitment
- 5.2 Quality policy
- 5.3 Organizational roles, responsibilities and authorities

# Standard structure

## 6. Planning :

6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

6.3 Planning of changes

## 7. Support :

### 7.1 Resources

7.1.1 General

7.1.2 People

7.1.3 Infrastructure

7.1.4 Environment for the operation of processes

7.1.5 Monitoring and measuring resources

7.1.6 Organizational knowledge

# Standard structure

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

7.5.1 General

7.5.2 Creating and updating

7.5.3 Control of documented Information

## **8. Operation :**

8.1 Operational planning and control

8.2 Requirements for products and services

8.2.1 Customer communication

8.2.2 Determining the requirements for products and services

8.2.3 Review of the requirements for products and services

8.2.4 Changes to requirements for products and services

# Standard structure

## **8.3 Design and development of products and services**

8.3.1 General

8.3.2 Design and development planning

8.3.3 Design and development Inputs

8.3.4 Design and development controls

8.3.5 Design and development outputs

8.3.6 Design and development changes

## **8.4 Control of externally provided processes, products and services**

8.4.1 General

8.4.2 Type and extent of control

8.4.3 Information for external providers

# Standard structure

## **8.5 Production and service provision**

8.5.1 Control of production and service provision

8.5.2 Identification and traceability

8.5.3 Property belonging to customers or external providers

8.5.4 Preservation

8.5.5 Post-delivery activities

8.5.6 Control of changes

## **8.6 Release of products and services**

## **8.7 Control of nonconforming outputs**



# Standard structure

## 9. Performance evaluation:

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

9.1.2 Customer satisfaction

9.1.3 Analysis and evaluation

9.2 Internal audit

9.3 Management review outputs

## 10. Improvement :

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual improvement

## Reasonable exception (Annex A.5)

Where a requirement of international standards **can** be applied, then it **MUST** be applied.

Where a requirement of international standards **could not** be applied, **should not** affect the Organization's ability to **ensure** compliance of products / services.

*“This International Standard does not refer to “exclusions” in relation to the applicability of its requirements to the organization’s quality management system. However, an organization can review the applicability of requirements due to the size or complexity of the organization, the management model it adopts, the range of the organization’s activities and the nature of the risks and opportunities it encounters.*

*The requirements for applicability are addressed in 4.3, which defines conditions under which an organization can decide that a requirement cannot be applied to any of the processes within the scope of its quality management system. The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services”*

# Where do we meet requirements related to Risk?

- Identify processes taking into account risk and opportunities (4.4 f)
- The risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed (5.1.2 b)
- The Organization shall identify risk and opportunities when planning the QMS (6.1.1)
- The organization shall plan actions to address these risks and opportunities(6.1.2)
- In determining the type and extent of controls to be applied to the external provision of processes products and services (8.4.2) –  
**Caution! The term “risk” is not mentioned but it is meant**
- In determining the extent of post-delivery activities that are required, the organization shall consider the risks associated with the products and services (8.5.5)
- The management review shall be planned and carried out taking into consideration the effectiveness of actions taken to address risks and opportunities (9.3.1 e)

# Documentation requirements

- The terms "documented procedure" and "file" have been replaced by "documented information"
- Accordingly references to the 2008 version referred to as follows:

*Documented procedure* → **maintain** documented procedure

*Records maintained* → **retain** documented procedure

# Documentation requirements

- **The scope** of the quality management system (4.3)
- The organization shall maintain documented information to the extent necessary **to support the operation of processes** and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned (4.4.2)
- **Quality policy** (5.2.2 a)
- **Quality objectives** (6.2.1)
- The organization shall retain appropriate documented information as **evidence** of fitness for purpose of **monitoring and measurement** resources (7.1.5)
- Where no such standards exist, the basis used for **calibration or verification** shall be retained as documented information (paragraph 7.1.5.2)
- The organization shall retain appropriate documented information as **evidence of competence**(7.2d)

# Documentation requirements

- Retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned and to demonstrate **conformity of products and services** to requirements (8.1 e)
- Documented information describing **the results of the review**, including any new or changed requirements for the products and services (8.2.3.2)
- Changes to requirements for products and services (8.2.4)
- the organization shall consider the necessary documented information to confirm that design and development requirements have been met (8.3.2 j)
- Design and development inputs (8.3.3)
- Design and development controls (8.3.4)
- Design and development outputs (8.3.5)
- Design and development changes (8.3.6)
- The organization shall retain appropriate documented information of the results of the evaluations, monitoring of the performance and re-evaluations of the external providers (8.4.1)
- Controlled conditions shall include, as applicable the availability of documented information that defines the characteristics of the products and services (8.5.1 a)
- Retain any documented information necessary to maintain traceability (paragraph 8.5.2)

# Documentation requirements

- Property belonging to customers or external providers (8.5.3)
- The organization shall retain documented information describing the results of the review of changes, the personnel authorizing the change, and any necessary actions (8.5.6)
- Documented information shall provide traceability to the person(s) authorizing release of products and services for delivery to the customer (8.6)
- The organization shall retain documented information of actions taken on nonconforming process outputs, products and services (8.7.2)
- The organization shall ensure that monitoring and measurement activities are implemented in accordance with the determined requirements and shall retain appropriate documented information as evidence of the results (9.1.1)
- The organization shall retain documented information as evidence of the implementation of the audit program and the audit results (9.2.2 f)
- The organization shall retain documented information as evidence of the results of management reviews (9.3.3)
- The organization shall retain documented information as evidence of :
  - a) the nature of the nonconformities and any subsequent actions taken
  - b) the results of any corrective action (10.2.2)

# Major differences in terminology between ISO 9001:2008 and ISO 9001:2015

ISO 9001:2008	ISO 9001:2015
Products	Products and services
Exclusions	Not used (See <a href="#">Clause A.5</a> for clarification of applicability)
Management representative	Not used (Similar responsibilities and authorities are assigned but no requirement for a single management representative)
Documentation, quality manual, documented procedures, records	Documented information
Work environment	Environment for the operation of processes
Monitoring and measuring equipment	Monitoring and measuring resources
Purchased product	Externally provided products and services
Supplier	External provider



## Changes in requirements

### Most significant changes (only the MAJOR changes are given )

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the quality management system

5.3 Organizational roles, responsibilities and authorities

6.2 Quality objectives and planning to achieve them

7.1.6 Organizational knowledge

8.5.3 Property belonging to customers or external providers

9.1.3 Analysis and evaluation

A.4 Risk-based thinking

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## Changes in requirements

### Abolished Requirements

- Quality Manual (paragraph 4.2.2 of ISO 9001:2008)
- Management representative (5.5.2 of 9001:2008) (position repealed, responsibilities remain, see 5.3)
- Preventive Actions (8.5.3 of 9001:2008)

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**Thank you for your attention**