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ISO 9001:2015 Quality management systems - Requirements (Summary)
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1. Scope

"This International Standard specifies requirements for a quality management system when an organisation:

- a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organisation, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements."

2. Normative reference

3. Terms and definitions

The terms and definitions given in ISO 9000:2015 apply

4. Context of the organisation

- 4.1 Understanding the organisation 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
 - 5.1.1 General
 - 5.1.2 Customer focus
- 5.2 Policy
 - 5.2.1 Establishing the quality policy
 - 5.2.2 Communicating the quality policy
- 5.3 Organisational roles, responsibilities and authorities

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 measurement resources
 - 7.1.5.1 General
 - 7.1.5.2 Measurement traceability
 - 7.1.6 Organisational knowledge

“NOTE 1 Organisational knowledge is knowledge specific to the organisation; is generally gained by experience. It is information that is used and shared to achieve the organisation’s objectives.”

- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented information
 - 7.5.1 General
 - “NOTE 1 The extent of documented information for a quality management system can differ from one organisation to another...”*
 - 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
 - 8.3 Design and development of product 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
 - 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
 - 8.8 Control of nonconforming outputs
- 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
 - 9.3.1 General
 - 9.3.2 Management review inputs
 - 9.3.3 Management review outputs
- 10. Improvement
 - 10.1 General
 - 10.2 Nonconformity and corrective action
 - 10.3 Continual improvement

Reference:

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