

ISO 9001:2000 - Requirement Clauses List

- 4 Quality management system (title only)**
 - 4.1 General requirements
 - 4.2 Documentation requirements (title only)
 - 4.2.1 General
 - * 4.2.2 Quality manual (*written Quality Manual required*)
 - * 4.2.3 Control of documents (*documented Operating Procedure required*)
 - * 4.2.4 Control of records (*documented Operating Procedure required*)
- 5 Management responsibility (title only)**
 - 5.1 Management commitment
 - 5.2 Customer focus
 - * 5.3 Quality policy (*written statement required - must include a commitment to meet requirements and to continual improvement*)
 - 5.4 Planning (title only)
 - * 5.4.1 Quality objectives (*written statement required*)
 - 5.4.2 Quality management system planning
 - 5.5 Responsibility, authority and communication (title only)
 - 5.5.1 Responsibility and authority
 - 5.5.2 Management representative
 - 5.5.3 Internal communication
 - 5.6 Management review (title only)
 - 5.6.1 General
 - 5.6.2 Review input
 - 5.6.3 Review output
- 6 Resource management (title only)**
 - 6.1 Provision of resources
 - 6.2 Human resources (title only)
 - 6.2.1 General
 - 6.2.2 Competence, awareness and training
 - 6.3 Infrastructure
 - 6.4 Work environment
- 7 Product realization (title only) < *** Exclusions allowed only in 7 - 7.6 - see below >**
 - 7.1 Planning of product realization
 - 7.2 Customer-related processes (title only)
 - 7.2.1 Determination of requirements related to the product
 - 7.2.2 Review of requirements related to the product
 - 7.2.3 Customer communication
 - 7.3 Design and development (title only)
 - 7.3.1 Design and development planning
 - 7.3.2 Design and development inputs
 - 7.3.3 Design and development outputs
 - 7.3.4 Design and development review
 - 7.3.5 Design and development verification
 - 7.3.6 Design and development validation
 - 7.3.7 Control of design and development changes
 - 7.4 Purchasing (title only)
 - 7.4.1 Purchasing process
 - 7.4.2 Purchasing information
 - 7.4.3 Verification of purchased product
 - 7.5 Production and service provision (title only)
 - 7.5.1 Control of production and service provision
 - 7.5.2 Validation of processes for production and service provision
 - 7.5.3 Identification and traceability
 - 7.5.4 Customer property
 - 7.5.5 Preservation of product
 - 7.6 Control of monitoring and measuring devices
- 8 Measurement, analysis and improvement (title only)**
 - 8.1 General
 - 8.2 Monitoring and measurement (title only)
 - 8.2.1 Customer satisfaction
 - * 8.2.2 Internal audit (*documented Operating Procedure required*)
 - 8.2.3 Monitoring and measurement of processes
 - 8.2.4 Monitoring and measurement of product
 - * 8.3 Control of nonconforming product (*documented Operating Procedure required*)
 - 8.4 Analysis of data
 - 8.5 Improvement (title only)
 - 8.5.1 Continual improvement
 - * 8.5.2 Corrective action (*documented Operating Procedure required*)
 - * 8.5.3 Preventive action (*documented Operating Procedure required*)

* Clauses that require written documentation

The documentation of the quality management system can differ from one organization to another due to a) the organization's size and type of activities, b) how complex processes and their interactions are, and c) the capabilities of the personnel. Documentation can be in any form or medium.

*** Clause 1.2 states exclusions may only be made within clause 7 and may not affect the ability, or responsibility, to provide product that fulfills customer and applicable regulatory requirements.

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