



QUALITY MANAGEMENT SYSTEM ISO 9001 : 2008

clause 7-8 Requirements



7 - Product Realisation

ISO 9001:2008

7.1 Planning of realization process

“Planning our process management.”

- consistent with the requirements of the QMS



7 - Product Realisation

ISO 9001:2008

7.2 Customer-related processes

“Make sure we understand and can meet our customers’ needs”

7.2.1 Determination of Requirements

7.2.2 Review of Requirements



7 - Product Realisation

ISO 9001:2008

7.2.3 Customer communication
“How do we communicate with
our customers?”

- arrangements
- feedback
(including complaints)



7 - Product Realisation

ISO 9001:2008

7.3 Design and development

7.3.1 Design and development planning

“Providing a disciplined approach.”

7.3.2 Design and development inputs

“What do we need to consider?”

7.3.3 Design and development outputs

“What have we done?”



7 - Product Realisation

ISO 9001:2008

7.3.4 Design and development review
"Are we on track?"

7.3.5 Design and development verification
"Have we got it right?"

7.3.6 Design and development validation
"Does it work?"

7.3.7 Control of design and development changes
"Controlling changes."



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ISO 9001:2008

7.4 Purchasing

7.4.1 Purchasing control

“Who do we get it from?”

- type and extent of control
- evaluate and select (criteria for selection)
- record results of evaluation

7.4.2 Purchasing information

“What do we need?”

7.4.3 Verification of purchased products

“Did we get what we ordered?”



7 - Product Realisation

ISO 9001:2008

7.5 Production and service provision

7.5.1 Control

“Controlling what we do.”

- document processes where necessary
- suitable equipment
- product characteristics
- monitoring and measurement
- release, delivery and post-delivery



7 - Product Realisation

ISO 9001:2008

7.5.2 Validation of processes

“When we cannot measure the results of our process.”

- qualification of processes, equipment, personnel, defined processes
- records, re-validation

7.5.3 Identification and traceability

“Keeping track of what we’re doing.”

7.5.4 Customer property

“Looking after what our customer provides to us.”



7 - Product Realisation

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7.5.5 Preservation of product

“Looking after the product and/or service.”

- preserve product during internal processing and final delivery
- identification, handling, packaging, storage and protection

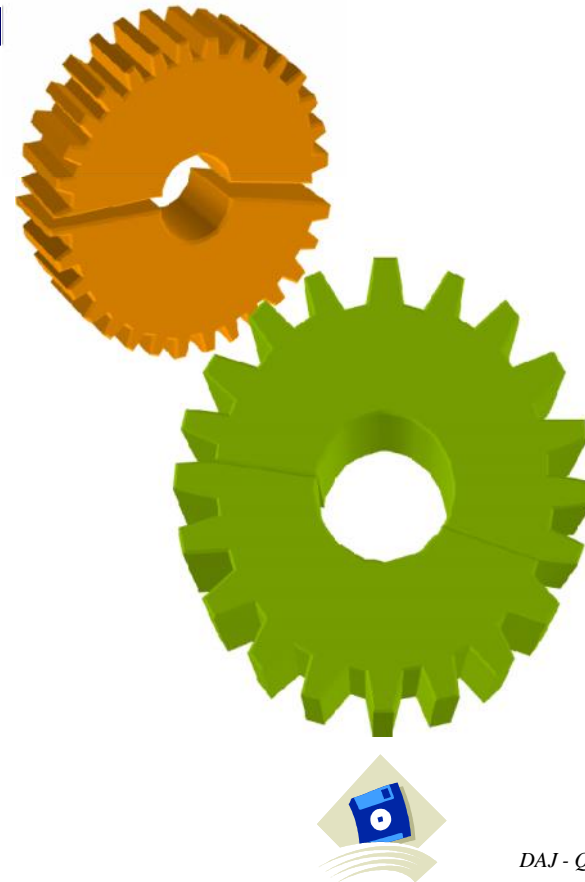


7 - Product Realisation

ISO 9001:2008

7.6 Control of monitoring and measuring devices
“Having confidence in the equipment used to check our work.”

- where conformity is determined through the use of measuring equipment
- calibration processes
- safeguarding from adjustment or damage
- records of calibration
- reviewing previous results



8 - Measurement, Analysis & Improvement

ISO 9001:2008

8.1 General

“Planning the monitoring activities.”

- define, plan and implement monitoring and measurement activities for:
 - conformity
 - improvement



8 - Measurement, Analysis & Improvement

ISO 9001:2008

8.2.1 Customer satisfaction

“How satisfied are our customers?”

monitor information relating to customer perception

8.2.2 Internal audit

“Are we doing what we say, and does it work?”

audit program, status and importance
management responsibility



8 - Measurement, Analysis & Improvement

ISO 9001:2008

8.2.3 Monitoring and measurement of process

8.2.4 Monitoring and measurement of product

“Checking that things are right.”

monitor processes and products

identify potential problems

verified at each key step (product)

maintain records

authorities for acceptance



8 - Measurement, Analysis & Improvement

ISO 9001:2008

8.3 Control of nonconformity

“Sorting out product or service problems.”

Any product or service not fit for use is:

identified

controlled

rectified

customer acceptance if appropriate



8 - Measurement, Analysis & Improvement

ISO 9001:2008

8.4 Analysis of data

“Do the measurements reveal trends?”

- customer satisfaction
- conformance to requirements
- characteristics of process, products and their trends
- suppliers



8 - Measurement, Analysis & Improvement

ISO 9001:2008

8.5 Improvement

8.5.1 Continual improvement

“What improvements do we plan to make?”

8.5.2 Corrective action

“Fixing the cause of known problems.”

8.5.3 Preventive action

“Preventing potential problems.”

