



ISO 9001:2008 – The Changes



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1 Scope

Ensure conformity to “**statutory**” and regulatory requirements.

The word “statutory” has been added throughout the standard.

3 Terms and definitions

Supplier → **organization** → **customer** diagram removed

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4.1 General requirements

para a) the word “**identify**” changed to “**determine**”

para e) “**where applicable**” added

Note 2 added to clarify what “outsourced processes” are

Note 3 added explaining that outsourced processes must be appropriately controlled



It would be a good idea to verify that any existing outsourced processes are appropriately controlled as set out in Note 3.

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4.2.1 Documentation requirements

para d) now includes “records”

para e) deleted

Note 1 amended to explain that requirements can be covered in multiple procedures and that a single procedure can cover multiple requirements



This could be an ideal time for companies who still organize their procedures in line with the standard’s requirements to rethink how they document their processes with a view to reducing the number of QMS documents

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4.2.3 Control of documents

Para f) clarifies external document controls

4.2.4 Control of records

Requirements have been re-worded but no change in intent

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5.5.2 Management representative

Now states that the management representative must be a
“**member of the organization’s management...**”



*A consultant can still be employed to carry out various QMS tasks
e.g. internal audits, document changes etc but in this capacity they
are supporting the nominated management representative*

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6.2.1 Human resources

Minor re-wording of the requirements.

A **Note** added to clarify that competence applies to all staff who directly or indirectly affect product quality

6.2.2 Competence, training and awareness

Title wording rearranged

Para b) “**where applicable**” added and re-worded to clarify training or other action required to achieve necessary competence



Some companies may need to check their systems do address the competence of all staff covered by the QMS

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6.3 Infrastructure

Para c) “**information systems**” added as an example of support services

6.4 Work environment

A **Note** added that gives examples of conditions under which work is performed

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7.1 Planning of product realization

Para c) “**measurement**” added as an activity to be considered during the planning process

7.2.1 Determination of requirements related to the product

A **Note** added to give examples of post-delivery activities



It would be a good idea to check that measuring criteria have been determined and that all post-delivery activities are covered by the QMS

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7.3.1 Design and development planning

A **Note** added that explains that although design, development review, verification and validation have distinct purposes they can be performed and recorded separately, or in any combination as appropriate to the product and organisation

7.3.3 Design and development outputs

A **Note** added that explains that information for production and service provision (design output) can include product preservation details

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7.5.2 Validation of processes

Minor changes to wording but no change to the requirement

7.5.3 Identification and traceability

Para 2 wording changed to ensure that product status is maintained during the entire product realization process



Check that system does ensure product status is identified throughout product realization

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7.5.4 Customer property

Last sentence of this requirement has had slight change of wording but no change to the intention.

Note amended to include “**personal data**” as an example of customer property



Organizations should ensure that all forms of customer property are controlled within their systems

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7.5.5 Preservation of product

Slight wording change. Brings the theme of conformity to requirements and clarifies that preservation methods will be “**as applicable**”

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7.6 Control of monitoring and measuring equipment

Title changed, “**devices**” replaced by “**equipment**”

Minor wording changes to para a) and para c)

References to ISO 10012 deleted

A **Note** added clarifying that calibration of measurement and monitoring software may be by verification and configuration management

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8.2.1 Customer satisfaction

A **Note** added giving examples of methods to obtain customer satisfaction

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8.2.2 Internal audit

Re-structured wording to emphasis requirement to have a documented procedure and to maintain audit records. Additional paragraph added regarding maintenance of audit records.

References to ISO 10011 replaced by ISO 19011

The requirement for “**any necessary corrections**” has been added



Organisations should verify that their audit records are adequate and that audit records include details of any necessary corrections

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8.2.3 Monitoring and measurement of processes

Last sentence of this requirement has deleted “**ensure conformity of product**” from it.

A **Note** added providing some guidance regarding the extent and type of process monitoring and measurement to be undertaken

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8.2.4 Monitoring and measurement of product

Slight changes to paragraph structure and wording but no change in the intention

8.3 Control of nonconforming product

“Where applicable” added to allow flexibility when dealing with nonconforming product (para a – para d). This should help service industries.

Last paragraph has been moved to **para d)** and slightly reworded to become an additional method for dealing with nonconforming product

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8.4 Analysis of data

Clause references in para a) – para d) updated / added. No changes to the requirements

8.5.2 Corrective action

Para f) now includes a requirement to review the “effectiveness” of the action taken, not just a review of the action

8.5.3 Preventive action

Para f) now includes a requirement to review the “effectiveness” of the action taken, not just a review of the action

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Thanks for looking at this presentation which we hope you found useful. If you have any comments please feel free to send them to us. We're always interested to know what others are thinking and any suggestions they may have that can lead to improvement.

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