



ISO 9001:2015 Certified
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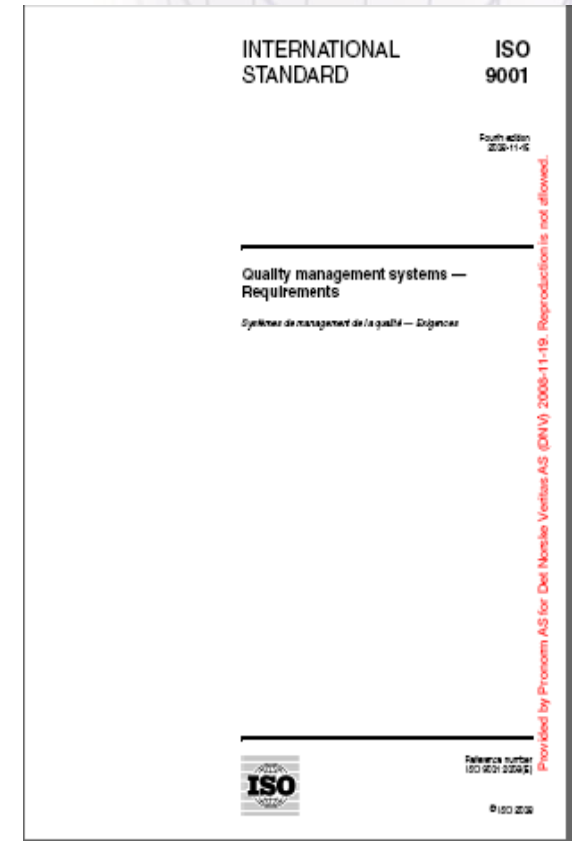
Module VI: QMS Requirements

Clause 8: Operations



Clause 8: Operations

- 8** Operation
 - 8.1** Operational planning and control
 - 8.2** Requirements for products and services
 - 8.3** Design and development of products and services
 - 8.4** Control of externally provided processes, products and services
 - 8.5** Production and service provision
 - 8.6** Release of products and services
 - 8.7** Control of nonconforming outputs





Clause 8: Operations

8.1 Operational Planning and Control

To meet the requirements for the provision of products and services

To implement the actions determined in Clause 6:
(risk and opportunities, quality objectives, changes)

Plan, Implement, Control the process (see 4.4)

- Determine requirements for products/services
- Establish criteria for process and product/service acceptance
- Determine resources needed (5Ms)
- Implement control as per criteria
- Control planned changes and review the consequences of unintended changes (8.5.6), taking action to mitigate any adverse effects, as necessary
- Outsourced processes are controlled

Determine, maintain and retain documented information to the extent necessary



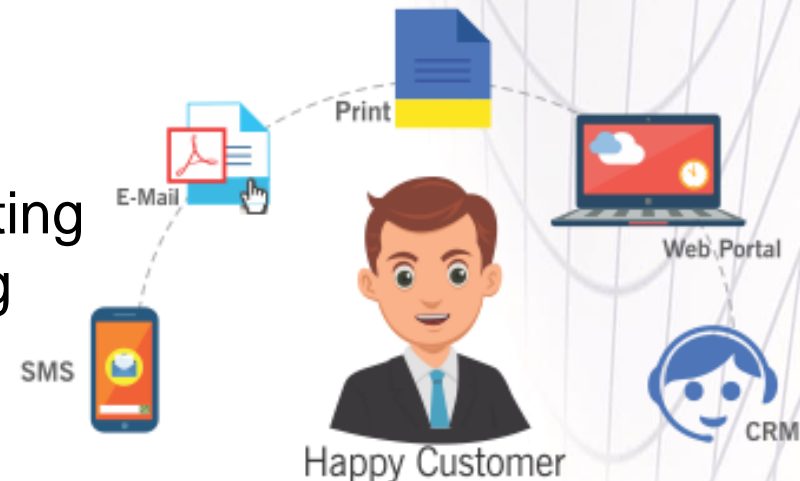
Clause 8: Operations

8.2 Requirements for Products and Services

8.2.1 Customer Communication

Communication with customers SHALL include:

- Providing information relating to products and services
- Handling enquiries, contracts or orders, including changes;
- Obtaining **customer feedback** relating to products and services, including customer **complaints**;
- Handling or controlling customer property;
- Establishing specific requirements for contingency actions, when relevant.





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8.2 Requirements for Products and Services

8.2.2 Determining the requirements for products and services

- Defined legal requirements

- Defined requirements considered to be necessary

- The organization can meet the claims for the products and services it offers



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8.2 Requirements for Products and Services

8.2.3 Review of the requirements for products and services



8.2.3.1 The organization SHALL conduct a review before committing to supply products and services to a customer

Customer requirements (specified and implied), including post delivery activities

Requirements specified by the organization

Legal requirements

Contract of order requirements differing from those previously expressed



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8.2 Requirements for Products and Services

8.2.3 Review of the requirements for products and services

- Contract or order requirements differing from those previously defined are **resolved**
- Where the customer provides no documented statement of requirement, the customer requirements shall be **confirmed** by the organization before acceptance





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8.2 Requirements for Products and Services

8.2.3 Review of the requirements for products and services



8.2.3.2 The organization SHALL retain documented information, as applicable:

- a. On the results of the review;
- b. Or any new requirements for the products and services



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8.2 Requirements for Products and Services

8.2.3 Changes to requirements for products and services



Amend the relevant documented information



Ensure relevant persons are made aware of the requirements changes

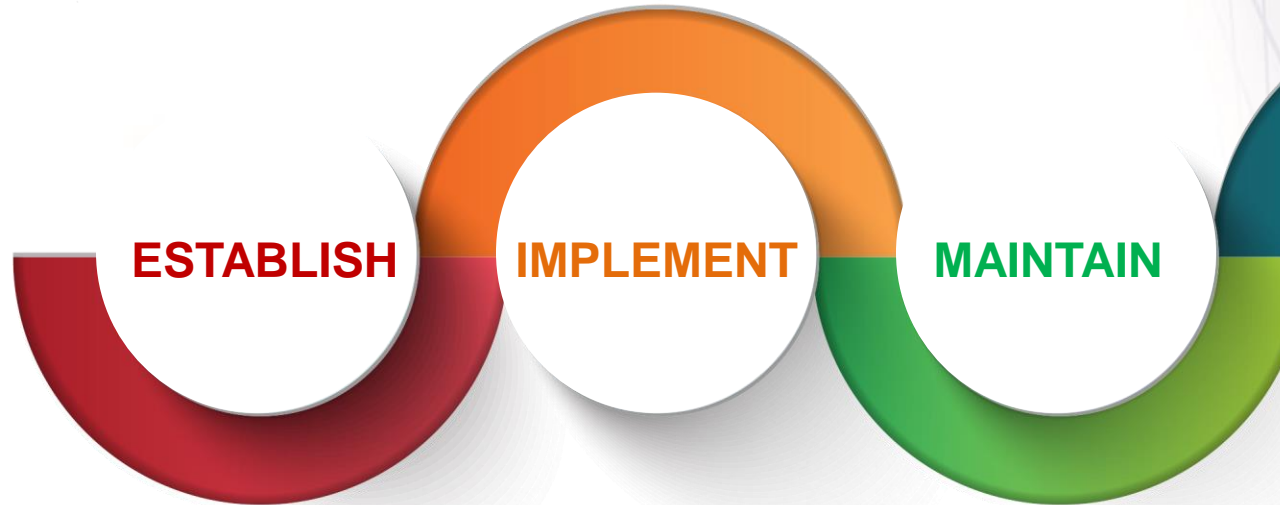


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8.3 Design and development of products and services

8.3.1 General

The organization SHALL



...a design and development process that is **appropriate** to ensure subsequent provision of products and services.

...retain documented information.



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8.3 Design and development of products and services



Plan and control the design and development of the product and service



Determine inputs and maintain documented information



Apply controls to the design and development process



Verify design outputs, if the outputs meet the input requirements, capable of meeting the requirement for the specified application



Conduct reviews at suitable stages, identify changes and maintain documented information



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8.3 Design and development of products and services



Design and development planning

Consider in the design and development process :

Requirements	Nature, activities, duration, stages, reviews, verification, validation, complexities
Expectations	Customers and relevant interested parties
Involvement, interfaces and responsibilities	Authorities, customers, users, interested parties
Documentation resources	Internal and external



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8.3 Design and development of products and services



Design and development inputs

Consider:

- Functional and performance requirements
- Previous and similar activities
- Legal requirements
- Committed standards or code of practice
- Potential consequence of failure

Inputs SHALL be **adequate** for design and development purposes, **complete** and **unambiguous**.



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8.3 Design and development of products and services



Design and development controls

Ensure to:

- Define results to be achieved
- Conduct reviews to evaluate the ability of meeting requirements
- Verify if the outputs meet the input requirements
- Validate of results if it is capable of meeting the requirement for the specified application
- Take necessary actions on problems during the review, verification and validation



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8.3 Design and development of products and services



Design and development outputs

OUTPUTS

Meet inputs requirements

Adequate for subsequent processes

Include acceptance criteria

Include or reference monitoring and measuring requirements

Specific characteristics essential for its their intended purpose

Safe and proper provision of specific characteristics



INPUTS

Adequate for the purpose

Complete Clear

Conflicts are resolved



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8.3 Design and development of products and services



8.3.6

Design and development changes

- Identify, review and control changes during and/or after to ensure that there is no adverse impact on the conformity to requirements



DOCUMENTED INFORMATION

- Design and development changes;*
- Results of reviews;*
- Authorization of the changes;*
- Actions taken to prevent adverse impacts*



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8.4 Control of externally provided processes, products and services

Applied to outsourced products and services that :

- Are intended for incorporation in the organization's products and services
- Are provided directly to customers by external providers on behalf of the organization
- A process, or part of a process , decided upon by the organization





Clause 8: Operations

8.4 Control of externally provided processes, products and services

8.4.2 Types and extent of controls

The organization SHALL:

- Ensure that externally provided processes, products and services do not adversely affect the organization's capability
- Apply criteria for the evaluation, selection, performance monitoring, and re-evaluation of external providers
- Communicate relevant information with external providers e.g. competence, approval, interactions, verification or validation activities etc.



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8.4 Control of externally provided processes, products and services

8.4.2 Types and extent of controls

The organization SHALL **consider**:

- ✓ Potential impact that externally provided processes, products, and services could have on your organization's ability to consistently meet external requirements
- ✓ Controls that external process, product, and service providers have implemented and think about how effective their controls actually are



Clause 8: Operations

8.4 Control of externally provided processes, products and services

8.4.2 Types and extent of controls

The organization SHALL **consider**:

- ✓ Develop and implement controls for external providers, processes, products, and services



Clause 8: Operations

8.4 Control of externally provided processes, products and services

8.4.3 Information for external providers

The organization SHALL **clarify**:

- What is expected from external providers
- Process requirements
- Product requirements
- Service requirements
- Equipment requirements
- Interaction requirements



Clause 8: Operations

8.4 Control of externally provided processes, products and services

8.4.3 Information for external providers

The organization SHALL **clarify**:

- Competence requirements
- Methodological requirements
- Monitoring and control requirements
- Verification or validation requirements

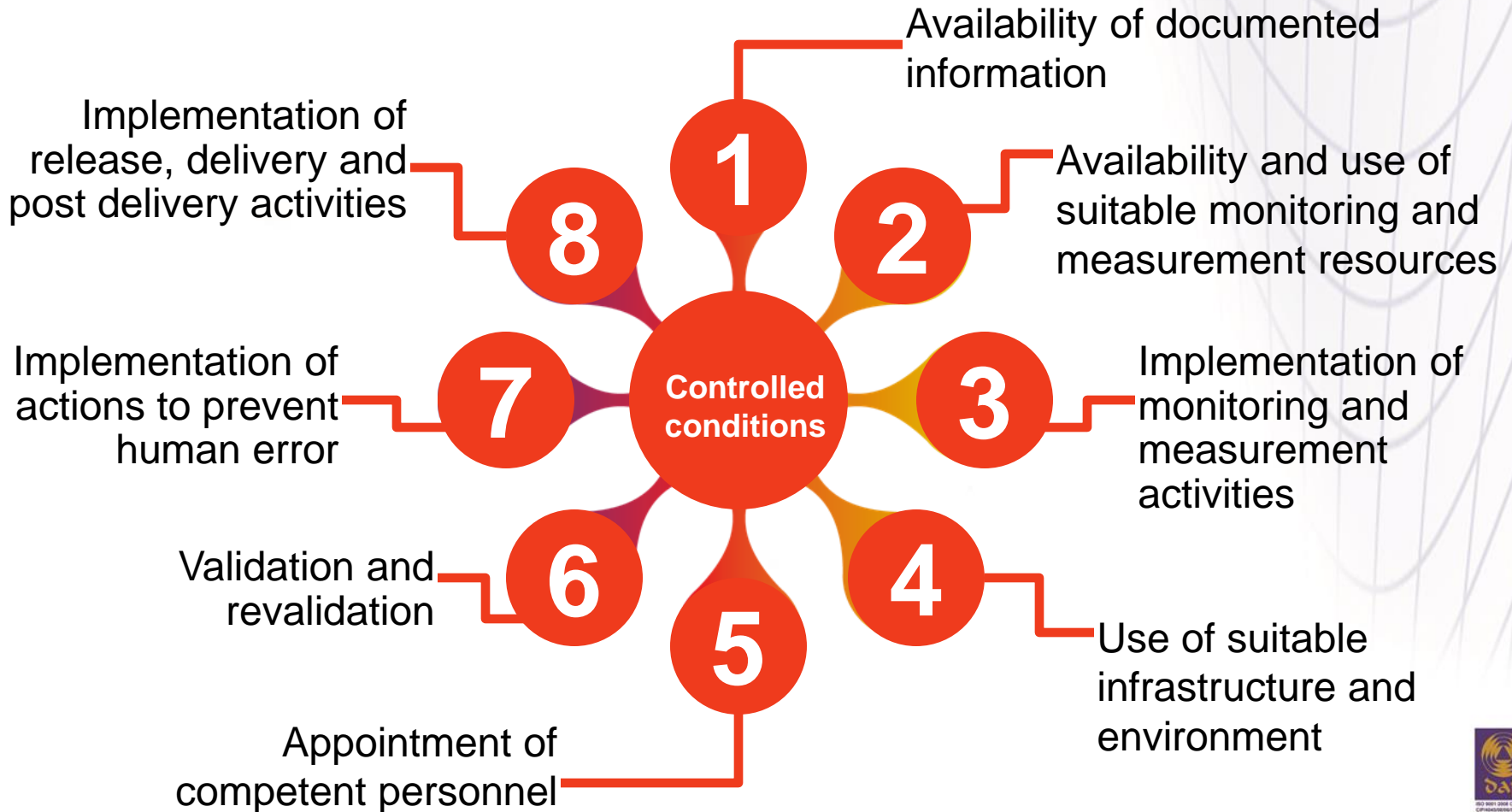
Discuss your organization's requirements with external providers.



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8.5 Production and service provision

8.5.1 Control of production and service provision





Clause 8: Operations

8.5 Production and service provision

8.5.2 Identification and traceability

- **Identify**, where appropriate, the product and service **by suitable means** throughout the service operations.
- **Identify the status of the service** with respect to measurement and monitoring requirements.
- **Control unique identification**, where traceability is a requirement.





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8.5 Production and service provision

8.5.3 Property belonging to customers or external providers

- Exercise care with property while it is under the organization's control or being used by the organization
- Identify, verify, protect and safeguard the property
- If property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported and retain documented information on the occurrence
- *Materials, components, tools and equipment, premises, intellectual property and personal data.*





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8.5 Production and service provision

8.5.4 Preservation

Preserve outputs during operations, to the extent necessary to ensure conformity to requirements



Identification
Handling
Packaging
Storage
Protection



Clause 8: Operations

8.5 Production and service provision

8.5.5 Post delivery activities

Consider:

- Legal requirements
- Potential undesired consequences
- Nature, use and intended lifetime of products and services
- Customer requirements
- Customer feedback





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8.5 Production and service provision

8.5.6 Control of Changes



- Review and control changes for production and services provision to ensure continuing conformity to requirements
- Retain documented information describing the results of review of changes, person authorizing the change, and actions (if any) arising from the review



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8.6 Release of products and services

- Implement planned arrangements on verification against requirements
- Release shall not proceed until planned arrangements have completed, unless approved by relevant authority or the customer
- Retain documented information





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8.7 Control of Nonconforming Outputs

- Ensure that outputs that do not conform to requirements are identified and controlled to prevent unintended use or delivery
- Correct nonconforming outputs and subject to re-verification to demonstrate conformity
- Take action when nonconforming outputs are identified after delivery or use



DEFINING NONCONFORMITY

REQUIREMENT

VS

IMPLEMENTATION

=

REQUIREMENT FULFILLED?

YES

CONFORMITY

NO

NONCONFORMITY



Clause 8: Operations

8.7 Control of Nonconforming Outputs

Deal with nonconforming outputs through any or combination of the following:

A

Correction

B

Segregation,
containment,
return, or
suspension of
provision

C

Obtaining
authorization
for
acceptance
under
concession

D

Informing
the
customer

** Verify nonconforming outputs when corrected*

Concession – *Permission to use or release nonconforming outputs*



Clause 8: Operations

8.7 Control of Nonconforming Outputs

Description of the
NC

*Retain documented
information

Description of the
Actions Taken

Description of any
concession obtained

Deciding Authority
for the action/s taken

- END -

Module II: QMS Requirements

Clause 8: Operations