Module VI: QMS Requirements
Clause 8: Operations
Clause 8: Operations

<table>
<thead>
<tr>
<th>Operation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1</td>
<td>Operational planning and control</td>
</tr>
<tr>
<td>8.2</td>
<td>Requirements for products and services</td>
</tr>
<tr>
<td>8.3</td>
<td>Design and development of products and services</td>
</tr>
<tr>
<td>8.4</td>
<td>Control of externally provided processes, products and services</td>
</tr>
<tr>
<td>8.5</td>
<td>Production and service provision</td>
</tr>
<tr>
<td>8.6</td>
<td>Release of products and services</td>
</tr>
<tr>
<td>8.7</td>
<td>Control of nonconforming outputs</td>
</tr>
</tbody>
</table>
8.1 Operational Planning and Control

**Clause 8: Operations**

**Plan, Implement, Control the process**
(see 4.4)

To meet the requirements for the provision of products and services

- 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

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

Determine, maintain and retain documented information to the extent necessary
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.
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
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
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
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
Clause 8: Operations

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
Clause 8: Operations

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.
8.3 Design and development of products and services

- 8.3.2 Plan and control the design and development of the product and service
- 8.3.3 Determine inputs and maintain documented information
- 8.3.4 Apply controls to the design and development process
- 8.3.5 Verify design outputs, if the outputs meet the input requirements, capable of meeting the requirement for the specified application
- 8.3.6 Conduct reviews at suitable stages, identify changes and maintain documented information
Consider in the design and development process:

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Nature, activities, duration, stages, reviews, verification, validation, complexities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expectations</td>
<td>Customers and relevant interested parties</td>
</tr>
<tr>
<td>Involvement, interfaces and responsibilities</td>
<td>Authorities, customers, users, interested parties</td>
</tr>
<tr>
<td>Documentation resources</td>
<td>Internal and external</td>
</tr>
</tbody>
</table>
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**.
Clause 8: Operations

8.3 Design and development of products and services

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
**Clause 8: Operations**

**8.3 Design and development of products and services**

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**REQUIREMENT**

Adequate for the purpose

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**INPUTS**

Complete  
Clear  
Conflicts are resolved

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**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
8.3 Design and development of products and services

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.
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
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.
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
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
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
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.

In compliance with RA 9184
8.5 Production and service provision

8.5.1 Control of production and service provision

1. Availability of documented information
2. Availability and use of suitable monitoring and measurement resources
3. Implementation of monitoring and measurement activities
4. Use of suitable infrastructure and environment
5. Validation and revalidation
6. Appointment of competent personnel
7. Implementation of actions to prevent human error
8. Implementation of release, delivery and post delivery activities

Controlled conditions
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.
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.
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
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
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
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
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
- Description of the Actions Taken
- Description of any concession obtained
- *Retain documented information
- Deciding Authority for the action(s) taken
Module II: QMS Requirements
Clause 8: Operations