Module V: QMS Requirements
Clause 7: Support

Clause 7: Support

7 **Support**

7.1	**Resources**
7.2	**Competence**
7.3	**Awareness**
7.4	**Communication**
7.5	**Documented Information**

INTERNATIONAL STANDARD

ISO 9001

Fourth edition
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Quality management systems —
Requirements

Systèmes de management de la qualité — Exigences

Reference number
ISO 9001:2008(E)
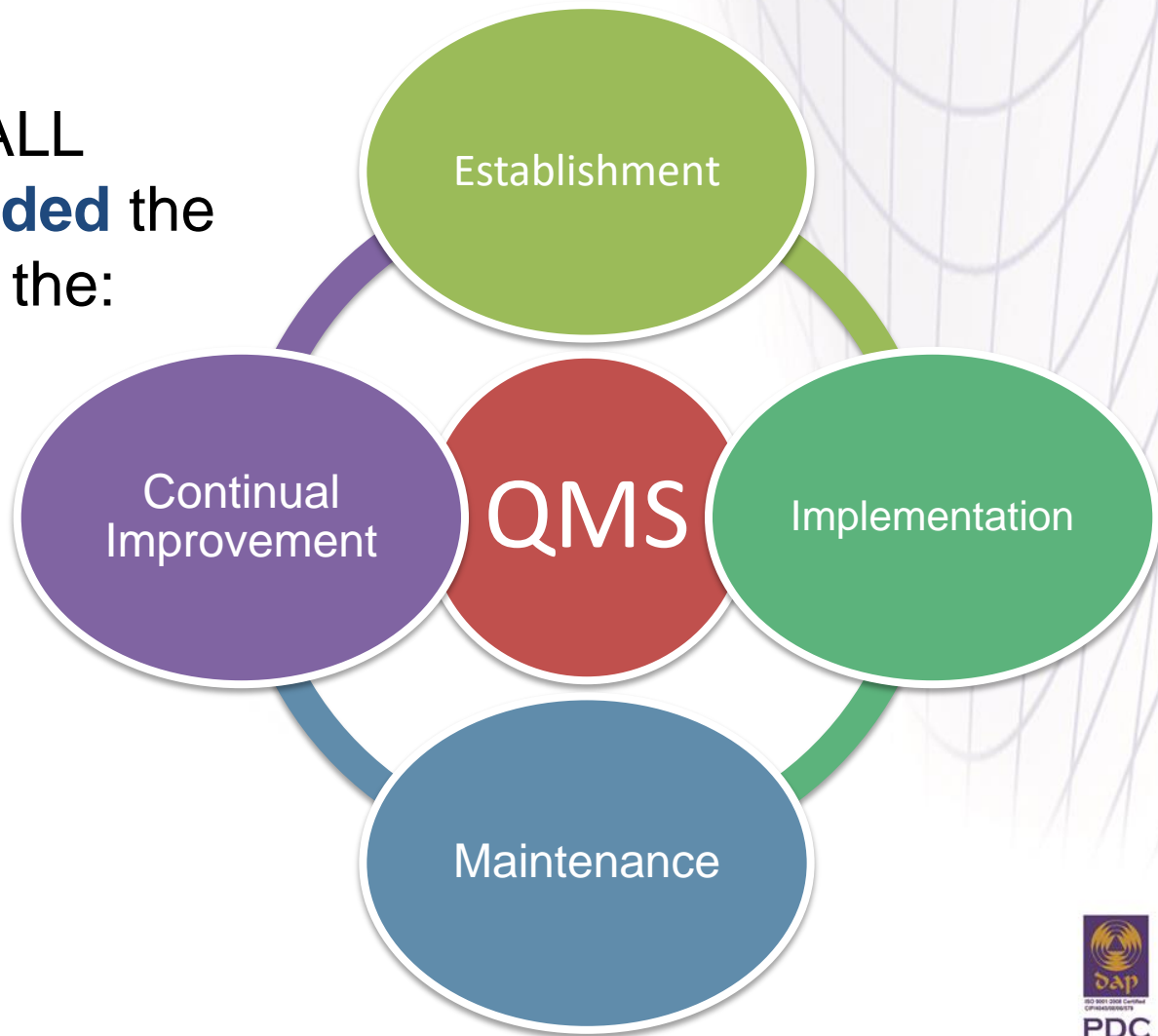
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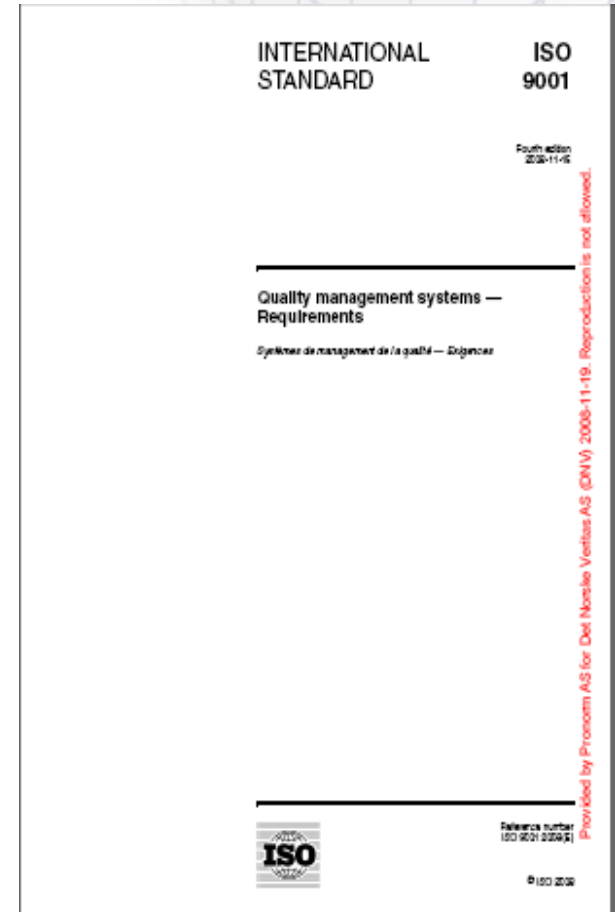
Clause 7: Support
7.1 Resources

7.1.1 General
The organization SHALL **determine and provided** the resources needed for the:

CONSIDER:
A. Capabilities and constraints of internal resources
B. Needs to be obtained from external providers

Establishment

Implementation

QMS

Maintenance

Continual Improvement

Clause 7: Support
7.1 Resources

Clause 7: Support
7.1 Resources

7.1.2 **People**

The organization SHALL

determine and provide the persons necessary for the effective implementation and control of the QMS and for the operation and control of its processes

Note:

 The agency should ensure that existing CSC laws, rules and regulations regarding recruitment, training and developing employee competence are considered in managing people

Clause 7: Support
7.1 Resources

7.1.3 Infrastructure

The organization SHALL **determine, provide and maintain the infrastructure** needed to achieve the conformity to service and necessary for the operation of processes.

Can include:
- Buildings and associated utilities
- Equipment, including hardware and software
- Transportation resources
- Information and communication technology

PDC

Clause 7: Support
7.1 Resources

7.1.4 Environment for the Operation of Processes

The organization SHALL

determine, provide and maintain the environment necessary for the operation of processes and achieve conformity to service requirements

Can be a combination of human and physical factors:
- Social - e.g. calm
- Psychological – e.g. burnout prevention
- Physical – e.g heat, airflow, hygiene

Clause 7: Support
7.1 Resources

7.1.5 **Monitoring and Measuring Resources**

The organization SHALL **determine, provide and maintain the M&M resources** to ensure **valid and reliable results** when used to verify the conformity of products and services to requirements

Clause 7: Support
7.1 Resources

7.1.5 Monitoring and Measuring Resources

The organization SHALL ensure that the resources provided:

- **Suitable** for the activities to be undertaken
- **Maintained** to ensure continuing fitness for use

The organization SHALL **retain documented information** as evidence of fitness for purpose.

Clause 7: Support
7.1 Resources

7.1.5 **Monitoring and Measuring Resources**

Measuring equipment shall be:

- Calibrated or verified, or both, at specified intervals or prior to use

- Identified in order to determine their status

- Safeguarded from adjustments, damage or deterioration

NOTE:
Appropriate action shall be undertaken when previous measurement results has been adversely affected when equipment is found unfit for intended purpose.

Clause 7: Support
7.1 Resources

7.1.6 **Organizational Knowledge**

The organization SHALL:

- **Determine, maintain and ensure availability**
- Consider **current knowledge** in addressing changing needs and trends
- **Determine how to acquire or access** any necessary knowledge and required updates

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Clause 7: Support
7.1 Resources

7.1.6 Organizational Knowledge

❖ Specific to the organization generally gained by experience.

❖ Information that is used and shared to achieve organization's objectives

Clause 7: Support
7.1 Resources

7.1.6 Organizational Knowledge

Internal Sources:
- Intellectual Property
- Experience
- Lessons learned
- Results of improvement

External Sources:
- Standards
- Academe
- Conferences
- Knowledge from customers and external providers

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Clause 7: Support
7.2 Competence

The organization SHALL:

- Determine the necessary competence for personnel performing work affecting conformity to product and service requirements
- Provide training or other **actions** to achieve the necessary competence
- Evaluate the effectiveness of the actions taken
- Maintain records of education, experience, training and qualifications

Applicable Actions:

- Training
- Mentoring
- Re-assignment
- Hiring or contracting of competent persons/providers

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Clause 7: Support
7.3 Awareness

Ensure that persons doing work under the organization's control are aware of:
- Quality Policy
- Quality Objectives
- Employees are aware of the relevance and importance of their activities, how they contribute to achieve the quality objectives
- Implications of Nonconformities

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Clause 7: Support
7.4 Communication

The organization SHALL determine the internal and external communications relevant to the QMS.

- What will be communicated
- When to communicate
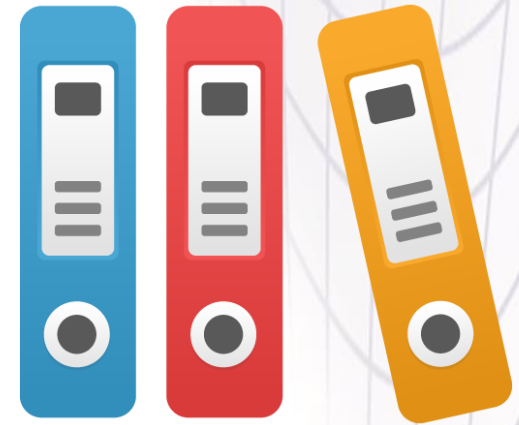- With whom to communicate
- How to communicate
- Who communicates

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Clause 7: Support
7.5 Documented Information

The organization's QMS SHALL include documented information:

    a. Required by the standard
    b. Required by QMS
    c. External origin

Clause 7: Support
7.5 Documented Information

7.5.2 Creating and updating

Appropriate Identification and description (e.g. title, date, author, or ref. no)

Appropriate format (e.g. e.g. language, software version, graphics) and media (e.g. paper, electronic)

Review and approval for suitability and adequacy

7.5.3 Control of Documented Information

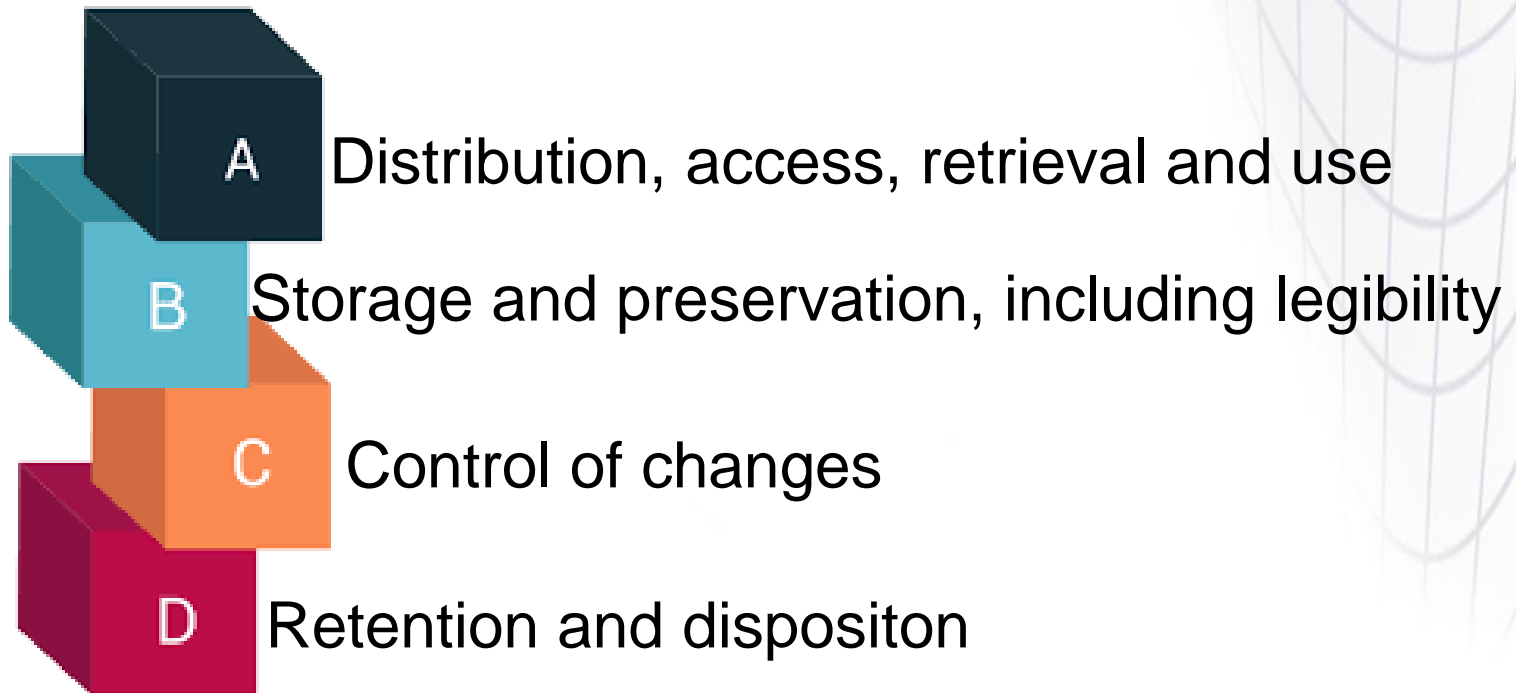Ensure availability and suitability for use where and when it is needed

Adequately protected (e.g. from loss of confidentiality, improper use or loss of integrity)

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Clause 7: Support
7.5 Documented Information

7.5.3.1 Address the following for the control of documented information:

A Distribution, access, retrieval and use

B Storage and preservation, including legibility

C Control of changes

D Retention and dispositon

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Clause 7: Support
7.5 Documented Information

/Identification and controls for documented information of external origin which are necessary for the planning and operation of QMS

/Protection form unintended alterations of retained documented information as evidence of conformity

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Required Documented Information

1. Information to support the operation of its processes, e.g. procedures, work instructions, workflow etc. (4.4.2)

2. Scope of QMS and justification for any ISO 9001:2015 requirement that is not applicable to the scope (4.3)

3. Quality Policy (5.2.2a)

4. Quality Objectives (6.2.1)

5. Characteristics of the product, services and/or activities to be performed (8.5.1a-1)

6. Results to be achieved during production and service provision (8.5.1a-2)

Required Documented Information

7. Information to have confidence that processes are carried out as planned and to demonstrate the conformity of products and services to their requirements (8.1e)

8. Information as evidence of fitness for purpose of the monitoring and measurement resources (7.1.5.1)

9. Information used as basis for calibration or verification of measuring equipment when no int'l or national standards exist (7.1.5.2a)

10. Organizational knowledge necessary for the operation of its processes and to achieve conformity of products and services (7.1.6)

11. Evidence of competence (7.2d)

Required Documented Information

12. Results of the review of requirements for products and services (8.2.3.2a)

13. New requirements for the products and services (8.2.3.2b)

14. Information needed to demonstrate that design and development requirements have been met (8.3.2j)

15. Design and development inputs (8.3.3)

16. Design and development outputs (8.3.5)

17. Design and development changes (8.3.6a), results of review (8.3.6b), authorization of changes (8.3.6c), and actions taken to prevent adverse impacts (8.3.6d)

18. Controls applied to the design and development process

Required Documented Information

19. Evaluation, selection, monitoring of performance, re-evaluation and actions arising from the evaluations of external providers (8.4.1)

20. Information on what occurred when customer or external provider's property is lost, damaged and/or found to be unsuitable for use (8.5.3)

21. Information describing the results of the review of changes during production and service provision, the person/s authorizing the change, and any necessary actions rising from the review (8.5.6)

22. Evidence of conformity with the acceptance criteria during release of products and services (8.6a)

23. Traceability to the person/s authorizing the release of product/service (8.6b)

Required Documented Information

24. Description of Nonconformity (8.7.2a), actions taken (8.7.2b), concessions obtained (8.7.2c), and authority deciding the action/s in respect of the nonconformity (8.7.2d)

25. Results of evaluation on QMS performance and effectiveness (9.1.1)

26. Implementation of the audit programme and audit results (9.2.2f)

27. Results of management reviews (9.3.3)

28. Nature of NCs and any subsequent actions taken (10.2.2a)

29. Results of corrective action to nonconformities (10.2.2b)

- END -

Module II: QMS Requirements
Clause 7: Support