Clause 4
Context of the organization

4.3 Determining the scope of the QMS

~~Exclusions~~ → Non Applicability

- Justify when a requirement can't be applied
- Context helps define scope, or narrow it
- ***Design and development for distributors***

Clause 4
Context of the organization

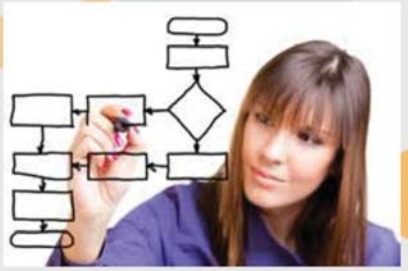
4.4 QMS and its processes

Define the documentation and records "to the extent necessary"

AS explicit requirement for documented information to be maintained with content defined (can be called a quality manual)

Clause 4.
Context of the organization

4.4 QMS and its processes



4.4 QMS and its processes

An AS9120 distributor should have few core processes. Why?

Clause 5. Leadership

5.1 Leadership and commitment

- Top management to demonstrate leadership and commitment to QMS
- Ensure quality policy and quality objectives are compatible with the context and strategic direction
- Integrate QMS into business processes
- Promote process approach and risk based thinking

Clause 6. Planning

6.1 Actions to address risks and opportunities
0.3.3 Risk-based thinking
8.1.1 Operation risk management

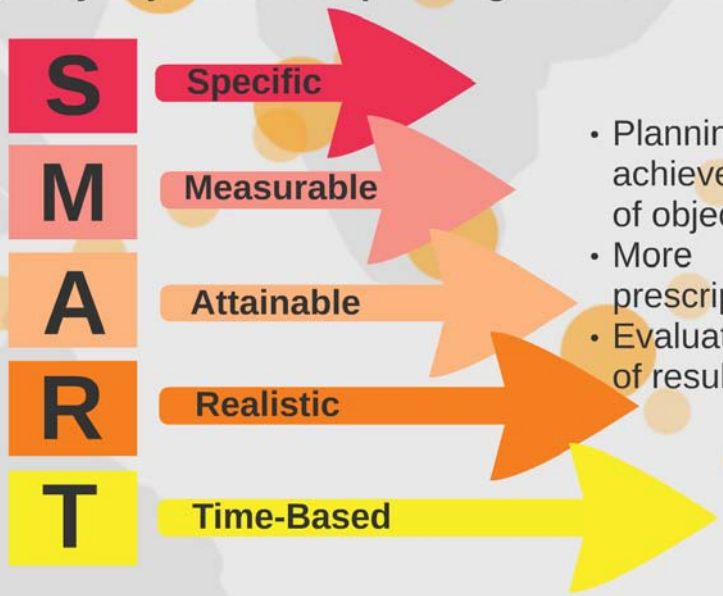
Clause 5. Leadership

5.3 Organizational roles, responsibilities and authorities

- ISO removed management representative
- ***AS adds back management rep as focal point for quality management issues***

Clause 6. Planning

6.2 Quality objectives and planning to achieve them



- Planning the achievement of objectives
- More prescriptive
- Evaluation of results

Change Control

6.3 Planning of changes
- Changes to QMS carried out in a planned manner

7.5.3.2 Control of Documented Information
- Control of document changes (i.e. version control)

8.1 Operational Planning and Control
- Control planned changes and review the consequences of unintended changes & take action, as necessary

8.2.4 Changes to requirements for products & services
- Ensure documentation updated
- Relevant persons aware

8.3.6 Design and development changes
- Identify, review and control changes

8.5.6 Control of changes
- Review and control changes. Records for review of changes, authorizing person(s), and any actions arising from reviews.

Clause 7. Support

7.1.6 Organizational knowledge

- Inherent knowledge the company and its employees should have
- Determine necessary knowledge gained from experience, lessons learned, success, failures, conferences
- Maintained and made available to the extent necessary

Clause 7. Support

7.3 Awareness

AS requires persons to be aware of:
- ***their contribution to product or service conformity***
- ***their contribution to product safety***
- ***the importance of ethical behavior***

Clause 7. Support

7.5 Documented information

- No requirement for 6 mandated procedures or quality manual
- Maintain documented information
- Retain documented information

- ***AS adds the requirement for electronic data protection***

Clause 8. Operation

New requirements:

8.1.3 Product Safety

- ***Consideration throughout the product lifecycle***

8.1.4 Prevention of counterfeit parts

- ***Prevent the use of counterfeit or suspect counterfeit parts (Includes trademark and intellectual property)***

Clause 8. Operation

8.3 Design and development

- ***Distribution AS9120 peculiarity***
- ***Take account of handling obsolescence, where applicable***
- ***For changes, have a process & criteria to notify customers when their requirements are affected***

Clause 8. Operation

8.2.3 Review of the requirements related to products and services

- ***Requirement that review shall be coordinated with applicable functions of the company***
- ***Requirement for actions in case of not meeting some customer requirements***

Clause 8. Operation

8.4 Control of externally provided processes, products and services

- New terminology for suppliers, work transfers, outsourced processes
- ***Explicit requirement for external providers to apply appropriate controls to their direct and sub-tier external providers***
- ***Evaluation of data on test reports - Compliance to requirements***
- ***Validation process of test report accuracy for raw materials identified as a significant operational risk***
- ***More explicit topics to communicate to external providers***

Clause 10. Improvement

10.2 Nonconformity and corrective action

- Requirement to evaluate the need for action based on human factors to ensure nonconformities do not recur

Implementation and Upgrading

TIMELINE

for certification or upgrade

Work with ASA on plans and timing while closing your gaps

Implementation and Upgrading

- ***Needed changes***
- ***Impact of changes***
- ***Resources***
- ***Timing***

Get copy of the requirements

Close the Gaps

Questions?

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simpleque.com

"Documented Information" in ISO 9001:2015

Refer to excerpts from Annex A at the end for explanations of "maintained" and "retained" documented information.

4.3 Determining the scope of the quality management system

The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

4.4.2 Quality management system and its processes

To the extent necessary, the organization shall:

a) maintain documented information to support the operation of its processes;

b) retain documented information to have confidence that the processes are being carried out as planned.

5.5.2 Communicating the quality policy

The quality policy shall:

a) be available and be maintained as documented information;

6.2.1 Quality objectives and planning to achieve them

The organization shall maintain documented information on the quality objectives.

7.1.5.1 Monitoring and measuring resources - General

The organization shall retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;

7.2 Competence

The organization shall:

d) retain appropriate documented information as evidence of competence.

7.5.1 Documented Information - General

The organization's QMS shall include:

a) documented information required by this International Standard;

b) documented information determined by the organization as being necessary for the effectiveness of the QMS.

NOTE: The extent of documented information for a QMS can differ from one organization to another due to:

— the size of organization and its type of activities, processes, products and services;

— the complexity of processes and their interactions;

— the competence of persons.

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

a) identification and description (e.g. a title, date, author, or reference number);
b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
c) review and approval for suitability and adequacy.

7.5.3.1 Control of documented information

Documented information required by the QMS and by this ISO standard shall be controlled to ensure:

a) it is available and suitable for use, where and when it is needed;
b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

a) distribution, access, retrieval and use;
b) storage and preservation, including preservation of legibility;
c) control of changes (e.g. version control);
d) retention and disposition.

Documented information of external origin determined by the organization to be necessary for the planning and operation of the QMS shall be identified as appropriate, and be controlled.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

NOTE: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

8.1 Operational planning and control

The organization shall plan, implement and control the processes needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6 by:

d) determining, maintaining and retaining documented information to the extent necessary:
    1) to have confidence that the processes have been carried out as planned;
    2) to demonstrate the conformity of products and services to their requirements.

8.2.3.2 Review of the requirements for products and services

The organization shall retain documented information, as applicable:

a) on the results of the review;
b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3.3 Design and development inputs

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

f) documented information of these activities is retained.

8.3.5 Design and development outputs

The organization shall retain documented information on design and development outputs.

8.3.6 Design and development changes

The organization shall retain documented information on:
a) design and development changes;
b) the results of reviews;
c) the authorization of the changes;
d) the actions taken to prevent adverse impacts.

8.4.1 Control of externally provided processes, products and services - General

The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.5.1 Control of production and service provision

Controlled conditions shall include, as applicable:
a) the availability of documented information that defines:
   1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
   2) the results to be achieved;

8.5.2 Identification and traceability

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider and retain documented information on what has occurred.

8.5.6 Control of changes

The organization shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

The organization shall retain documented information on the release of products and services. The documented information shall include:
a) evidence of conformity with the acceptance criteria;
b) traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

The organization shall retain documented information that:
a) describes the nonconformity;
b) describes the actions taken;
c) describes any concessions obtained;
d) identifies the authority deciding the action in respect of the nonconformity.

9.1.1 Monitoring, measurement, analysis and evaluation - General

The organization shall evaluate the performance and the effectiveness of the quality management system.
The organization shall retain appropriate documented information as evidence of the results.

9.2.2 Internal audit

The organization shall:

f) retain documented information as evidence of the implementation of the audit program and the audit results.

9.3.3 Management review outputs

The organization shall retain documented information as evidence of the results of management reviews.

10.2.2 Nonconformity and corrective action

The organization shall retain documented information as evidence of:

a) the nature of the nonconformities and any subsequent actions taken;
b) the results of any corrective action.

Annex A (excerpts)

A.6 Documented information

As part of the alignment with other management system standards, a common clause on "documented information" has been adopted without significant change or addition (see 7.5). Where appropriate, text elsewhere in this International Standard has been aligned with its requirements. Consequently, "documented information" is used for all document requirements.

Where ISO 9001:2008 used specific terminology such as "document" or "documented procedures", "quality manual" or "quality plan", this edition of this International Standard defines requirements to "maintain documented information".

Where ISO 9001:2008 used the term "records" to denote documents needed to provide evidence of conformity with requirements, this is now expressed as a requirement to "retain documented information". The organization is responsible for determining what documented information needs to be retained, the period of time for which it is to be retained and the media to be used for its retention.

A requirement to "maintain" documented information does not exclude the possibility that the organization might also need to "retain" that same documented information for a particular purpose, e.g. to retain previous versions of it.

Where this International Standard refers to "information" rather than "documented information" (e.g. in 4.1: "The organization shall monitor and review the information about these external and internal issues"), there is no requirement that this information is to be documented. In such situations, the organization can decide whether or not it is necessary or appropriate to maintain documented information.

New requirement for documentation.