

ISO 9001:2015

(Documentation Requirements)

<u>TERMS</u>	
Shall = indicates a requirement	May = indicates permission
Should = indicates a recommendation	Can = indicates a possibility or a capacity

The mandatory documents: “Maintain”

- Scope of the QMS (clause 4.3) shall be maintained as documented information
- Quality management system and its processes (clause 4.4.2) to support the operation of its processes.
- Quality policy (clause 5.2.1 and 5.2.2) shall maintain a quality policy.
- Quality objectives and plans for achieving them (clause 6.2.1) shall maintain documented information on the quality objectives.
- Organizational knowledge (clause 7.1.6) shall be maintained and made available to the extent necessary.
- Documented information (clause 7.5.1) shall include documented information required.... determined by the organization as being necessary for the effectiveness of the quality management system.
- Control of documented information (clause 7.5.3.1) ... required by the quality management system and by this International Standard ... shall be controlled:
- Control of documented information from external origin (clause 7.5.3.2) shall be identified as appropriate and be controlled.... documented information retained as evidence or conformity shall be protected from unintended alterations.
- Operational planning and control (clause 8.1) determining, *maintaining* and *retaining* documented information to the extent necessary...
- Changes to requirements for products and services.... (clause 8.2.4) The organization shall ensure that relevant documented information is amended....
- Design and development planning (8.3.2) ...shall consider the documented information needed to ...
- Control of production and service provision (8.5.1) ...shall include, as applicable the availability of documented information that defines....

The mandatory records: “Retain”

- Quality Management System and its processes (clause 4.4.2)” retain documented Information to have confidence...”
- Monitoring and measurement (clause 7.1.5.1) shall retain appropriate documented information as evidence of its fitness for purpose of the monitoring and measurement resources.
- Measurement traceability (clause 7.1.5.2) shall be retained as documented information.
- Records of training, skills, experience and qualifications (clause 7.2) shall retain appropriate documented information as evidence of competence.

ISO 9001:2015

(Documentation Requirements)

- Competence (clause 7.2) shall retain appropriate documented information as evidence of competence.
- Evidence of communication (clause 7.4) shall retain documented information as evidence of its communication, as appropriate.
- Operational planning and control (clause 8.1) determining, maintaining and retaining documented information to the extent necessary...
- Review the requirements related to the product (clause 8.2.3.2) shall retain documented information as applicable.
- Changes to requirements for products and services.... (clause 8.2.4) The organization shall ensure that relevant documented information is amended....
- Design and development planning (8.3.2) ...the documented information needed to demonstrate...
- Design and development inputs (8.3.3) ...The organization shall retain documented information on design and development inputs.
- Design and development controls (8.3.4) ... The organization shall apply controls... documented information of these activities is retained.
- Design and development outputs (8.3.5) ... The organization that design and development outputs... shall retain documented information.
- Design and development changes (8.3.6) ... The organization shall identify, review and control changes... The organization shall retain documented information.
- Control of externally provided processes, products and services... (8.4) ... (8.4.1) ... shall retain documented information of these activities... Vender review form 12.0.
- Identification and traceability (8.5.2) ... shall retain the documented information necessary to enable traceability.
- Property belonging to customers or external parties (8.5.3) ... shall report this to the customer or external provider and retain documented information on what has occurred.
- Control of changes (8.5.6) ... shall retain documented information describing the results of the review of changes...
- Release of products and services (8.6) ... shall retain documented information on the release of products and services.
- Control of nonconforming outputs (8.7.2) ... shall retain documented information that ... (a-d)
- Monitoring and measurement results (clause 9.1.1) . . . shall retain appropriate documented information as evidence of the monitoring, measurement, analysis and evaluation results.
- Internal audit program (clause 9.2.2) . . . shall retain documented information as evidence of the implemented audit program and the audit results.
- Management review 9.3 ... Management review outputs (clause 9.3.3) ... shall retain documented information as evidence of the results of management reviews.
- Nonconformity and Corrective actions (clause 10.2.2) . . . shall retain documented information as evidence of.

ISO 9001:2015

(Documentation Requirements)

Non-mandatory documents: “Commonly used”

- Procedure for determining context of the organization and interested parties (clauses 4.1 and 4.2)
- Procedure for identification and evaluation of environmental aspects and risks (clauses 6.1.1 and 6.1.2)
- Competence, training and awareness procedure (clauses 7.2 and 7.3)
- Procedure for communication (clause 7.4)
- Procedure for document and record control (clause 7.5)
- Procedure for internal audit (clause 9.2)
- Procedure for management review (clause 9.3)
- Procedure for management of nonconformities and corrective actions (clause 10.2)