9001 Simplified

List of Required Documents and Records

Documentation is an important part of ISO 9001. The standard includes both explicit and implicit requirements for documentation. Experience has shown that many companies find it difficult to strike a healthy balance between under- and over-documenting.

Though ISO 9001:2015 explicitly requires no more than a couple of documents, the implicit requirements make it clear that generally many more documents are needed. On the other hand, it is neither required nor recommended to document everything.

Let us clarify what's really needed.

Documents

- Documents guide actions and help people make decisions.

- Documents are used to support training, promote standardization, help prevent errors, and help retain corporate knowledge.

- Documents can change.

- When ISO 9001:2015 requires you to "maintain" information, it is referring to mandatory documents.

Mandatory Documents

Scope of your quality management system	Clause 4.3
Quality policy	Clause 5.2
Quality objectives	Clause 6.2
Outputs from design and development activities	Clause 8.3.5

In addition ISO 9001:2015 requires documents to support your operations and to ensure your quality management system is effective. These documents may include:

- ✓ Process maps
- ✓ Process definitions
- ✓ Work instructions
- ✓ Forms
- ✓ Checklists
- ✓ Product and service specifications
- ✓ Position descriptions
- ✓ Training plans
- ✓ Criteria for selecting suppliers

9001Simplified

Recommended Procedures

The following procedures are not mandatory. However, they...

- Help to define how your organization meets the requirements of the ISO 9001 standard
- Define and list the mandatory records
- Clarify responsibilities and authority

Determining the context of the organization and interested parties	Clauses 4.1 and 4.2
Management of risks and opportunities	Clause 6.1
Competence, training and awareness	Clauses 7.1.2, 7.2 and 7.3
Equipment maintenance and measuring equipment	Clauses 7.1.3 and 7.1.5
Document and record control	Clause 7.5
Sales procedures including customer communications	Clause 8.2
Design and development	Clause 8.3
Supplier management	Clause 8.4
Production and service provision	Clause 8.5
Customer and supplier property	Clause 8.5.3
Preservation of products and service outputs	Clause 8.5.4
Nonconforming products and services	Clause 8.7
Corrective action	Clause 10.2
Monitoring customer satisfaction	Clause 9.1.2
Internal audit	Clause 9.2
Management review	Clause 9.3

9001Simplified

Records

- Records provide evidence that an event has occurred or an action completed.
- Records don't change.
- When ISO 9001:2015 requires you to "retain" information, it is referring to mandatory records.

Mandatory Records

Calibration and maintenance of monitoring and measuring equipment	Clause 7.1.5.1
Employee training, skills, experience and qualifications	Clause 7.2
Review of product and service requirements	Clause 8.2.3.2
Design and development inputs	Clause 8.3.3
Design and development controls	Clause 8.3.4
Design and development changes	Clause 8.3.6
Records of supplier selection	Clause 8.4.1
Problems with customer and supplier property	Clause 8.5.3
Control of changes in production and service provision	Clause 8.5.6
Product and service conformity including acceptance criteria	Clause 8.6
Nonconforming outputs	Clause 8.7.2
Monitoring and measurement results	Clause 9.1.1
Implementation of the internal audit program	Clause 9.2
Results of internal audits	Clause 9.2
Results of management reviews	Clause 9.3
Results of corrective action	Clause 10.2

What is "Documented Information"?

The ISO 9001:2015 standard uses the term "documented information" what what is commonly referred to as "documentation". Documented information includes both documents and records.

Are forms documents or records?

Forms play a dual role. Before a form is filled in, it is a document and must be maintained. Blank forms can be revised. Filling in a form or checklist can also guide the user to perform an activity, so forms and checklists can fulfill the function of work instructions.

Once a form is filled in, it becomes a record and is retained. At this point, it can no longer be changed.

9001Simplified