

ISO 9001: 2008 Required Documentation

Quality Documents

- Quality policy (clause 4.2.1.a)
- Quality objectives (clause 4.2.1.a)
- Quality manual (clause 4.2.1.b)

Documented Procedures:

- 4.2.3 Control of documents
- 4.2.4 Control of records
- 8.2.2 Internal audit
- 8.3 Control of nonconforming product
- 8.5.2 Corrective action
- 8.5.3 Preventive action

These documented procedures have to be controlled in accordance with the requirements of clause 4.2.3

Records required by ISO 9001:2008

Clause	Record required
5.6.1	Management reviews
6.2.2 (e)	Education, training, skills and experience Must maintain records of education, training, skills, and experience; there is a procedure
7.1 (d)	Evidence that the realization processes and resulting product fulfill requirements Records needed to provide evidence that the realization (existing) processes and resulting product (service) meet requirements.
7.2.2	Results of the review of requirements related to the product and actions arising from the review. The organization shall review the customer requirements of the service. This review must be conducted prior to commitment to customer. Need records of the results of the review.
7.3.2	Design and development inputs relating to product requirements
7.3.4	Results of design and development reviews and any necessary actions
7.3.5	Results of design and development verification and any necessary actions

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7.3.6	Results of design and development validation and any necessary actions
7.3.7	Results of the review of design and development changes and any necessary actions
7.4.1	Results of supplier evaluations and any necessary actions arising from the evaluations Records of evaluating suppliers must be maintained
7.5.2 (d)	As required by the organization to demonstrate the validation of processes where the resulting output cannot be verified by subsequent monitoring or measurement Need records to validate a process where you cannot monitor or measure easily
7.5.3	The unique identification of the product, where traceability is a requirement
7.5.4	Customer property that is lost, damaged or otherwise found to be unsuitable for use Must maintain records re: customer property issues
7.6 (a)	Basis used for calibration or verification of measuring equipment where no international or national measurement standards exist
7.6	Validity of the previous measuring results when the measuring equipment is found not to conform to requirements
7.6	Results of calibration and verification of measuring equipment
8.2.2	Internal audit results and follow-up actions
8.2.4	Indication of the person(s) authorizing release of product. Need a record of how service gets released (approved). This could include daily inspection records, etc.
8.3	Nature of the product nonconformities and any subsequent actions taken, including concessions obtained
8.5.2	Results of corrective action
8.5.3	Results of preventive action

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Documents which are *not necessarily required* but can be offered as supporting the organization's processes. This documentation should be minimized.

- Process maps, process flow charts and/or process descriptions
- Organization charts
- Specifications
- Work and/or test instructions
- Documents containing internal communications
- Production schedules
- Approved supplier lists
- Test and inspection plans
- Quality plans

STEPS FOR ISO 9000: 2008 Registration Preparation:

1. Perform Gap analysis on required procedures and quality manual, policy, and objectives.
2. Write any procedures which are required
3. Perform gap analysis on required records
4. Work with staff to produce required records as necessary
5. Perform a gap analysis on the process(es)
6. Work with staff to ensure processes and work instructions are in place, up to date, used
7. Work with staff to do an internal audit, and correct non-conformances

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