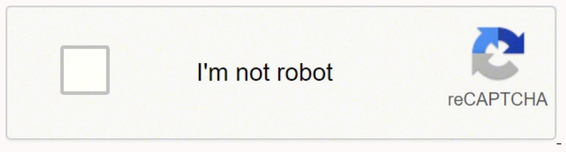

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What documents are required for iso 9001

Documented information is broken up into two types, documents and records. A form is a kind of document. When the form is filled out it becomes a record. Quality manual, policy, procedure or work instructions are other kinds of documents. The specific documents and records you are required to control are listed in the table below. Clause Topic Type of documented information Requirement 4.3 Determining the scope of the QMS Document The scope of the organization's QMS shall be available and be maintained as documented information. 4.4.2 a QMS and its processes Document To the extent necessary, the organization shall maintain documented information to support the operation of its processes. 4.4.2 b QMS and its processes Record To the extent necessary, the organization shall retain documented information to have confidence that the processes are being carried out as planned. 5.2.2 a Communicating the quality policy Document The quality policy shall be available and maintained as documented information. 6.2.1 Quality objectives and planning to achieve them Document The organization shall maintained documented information on the quality objectives. 7.1.5.1 Monitoring and measuring resources Record The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. 7.1.5.2 a Measurement traceability Record Measuring equipment shall be 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 standard exists, the basis for calibration or verification shall be retained as documented information. 7.2 d Competence Record The organization shall retain appropriate documented information as evidence of competence. 7.5.1 b Documented information Document The organization's QMS shall include documented information determined by the organization as being necessary for the effectiveness of the QMS. 8.2.3.2 Review of the requirements for products and services Record The organization shall retain documented information, as applicable, on the results of review and on any new requirements for products and services. 8.3.2 j Design and development planning Record The organization shall consider the documented information needed to demonstrate that design and development requirements have been met. 8.3.3 Design and development inputs Record The organization shall retain documented information on design and development inputs. 8.3.4 f Design and development controls Record The organization shall apply controls to the design and development process to ensure that documented information of these activities is retained. 8.3.5 Design and development outputs Record The organization shall retain documented information on the design and development outputs. 8.3.6 Design and development changes Record The organization shall retain documented information on design and development changes and the results of reviews. 8.4.1 Control of externally provided process, products and services Record The organization shall retain documented information of these activities and any necessary actions arising from the evaluations. 8.5.2 Identification and traceability Record The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain documented information necessary to enable traceability. 8.5.3 Property belonging to customers or external providers Record 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 Record 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 Record The organization shall retain documented information on the release of products and services. The documentation shall include evidence of conformity with the acceptance criteria and traceability to the person(s) authorizing the release. 8.7.2 Control of nonconforming outputs Record The organization shall retain documented information that describes the nonconformity, actions taken, any concessions obtained and identifies the authority deciding the action in respect of the nonconformity. 9.1.1 Monitoring, measurement, analysis and evaluation Record The organization shall retain documented information as evidence of the results [of QMS performance evaluation]. 9.2.2 f Internal audit Record The organization shall retain documented information as evidence of the implementation of the audit program and the audit results. 9.3.3 Management review outputs Record The organization shall retain documented information as evidence of the results of management reviews. 10.2.2 Nonconformity and corrective action Record The organization shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action. The documented information listed above is required because it confirms that your QMS is maintained and effective. Documented information is also used as evidence of conformance, provides consistency in how a process is executed, assists with training and prevents loss of knowledge. All documented information must be controlled. This means that you have a process for identifying, reviewing and approving documents as well as using an appropriate format and media for the contents of the documented information. You need to ensure the documented information is available for those that need to access it, is protected, version controlled and inactive/old versions are disposed of properly. In addition, a retention policy needs to be established for specifying the length of time you will retain your required records. What processes should be documented? If you have a complex or inconsistent process, it is highly recommended that it be documented. Also, consider documenting any process where only one employee knows how to execute. This protects the organization from loss of knowledge in the event that the employee no longer works at the organization. It can be challenging to develop documented information to meet all the requirements. Our Quality Manual and Procedures package is a fully documented QMS used by hundreds of companies worldwide to successfully register to ISO 9001. Use this package as the foundation of your system, tailor the documents for your organization and benefit from the professionally designed processes while saving time. Version 2015 of the ISO 9001 standard has brought some changes, so it's important to know which documents are mandatory in this revision. How many documents are required? So, here is the list of ISO 9001 documentation requirements – below you will see not only mandatory documents, but also the most commonly used documents for ISO 9001 implementation. Mandatory documents and records required by ISO 9001:2015 Here are the documents you need to produce if you want to be compliant with ISO 9001:2015. (Please note that some of the documents will not be mandatory if the company does not perform relevant processes.): Scope of the QMS (clause 4.3) Quality policy (clause 5.2) Quality objectives (clause 6.2) Criteria for evaluation and selection of suppliers (clause 8.4.1) And, here are the mandatory records (note that records marked with * are only mandatory in cases when the relevant clause is not excluded): Monitoring and measuring equipment calibration records* (clause 7.1.5.1) Records of training, skills, experience and qualifications (clause 7.2) Product/service requirements review records (clause 8.2.3.2) Record about design and development outputs review* (clause 8.3.2) Records about design and development inputs* (clause 8.3.3) Records of design and development controls* (clause 8.3.4) Records of design and development outputs *(clause 8.3.5) Design and development changes records* (clause 8.3.6) Characteristics of product to be produced and service to be provided (clause 8.5.1) Records about customer property (clause 8.5.3) Production/service provision change control records (clause 8.5.6) Record of conformity of product/service with acceptance criteria (clause 8.6) Record of nonconforming outputs (clause 8.7.2) Monitoring and measurement results (clause 9.1.1) Internal audit program (clause 9.2) Results of internal audits (clause 9.2) Results of the management review (clause 9.3) Results of corrective actions (clause 10.1) Non-mandatory documents There are numerous non-mandatory documents that can be used for ISO 9001 implementation. However, I find these non-mandatory documents to be most commonly used: Procedure for determining context of the organization and interested parties (clauses 4.1 and 4.2) Procedure for addressing risks and opportunities (clause 6.1) Procedure for competence, training and awareness (clauses 7.1.2, 7.2 and 7.3) Procedure for equipment maintenance and measuring equipment (clause 7.1.5) Procedure for document and record control (clause 7.5) Sales procedure (clause 8.2) Procedure for design and development (clause 8.3) Procedure for production and service provision (clause 8.5) Warehousing procedure (clause 8.5.4) Procedure for management of nonconformities and corrective actions (clauses 8.7 and 10.2) Procedure for monitoring customer satisfaction (clause 9.1.2) Procedure for internal audit (clause 9.2) Procedure for management review (clause 9.3) So, this is it – what do you think? Is this too much to write? Do these documents cover all aspects of quality management? Click here to download a white paper: Checklist of Mandatory Documentation Required by ISO 9001:2015, with more detailed information on the most common ways to structure and implement mandatory documents and records.

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