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# ISO 9001:2015

## Control of Documented Information

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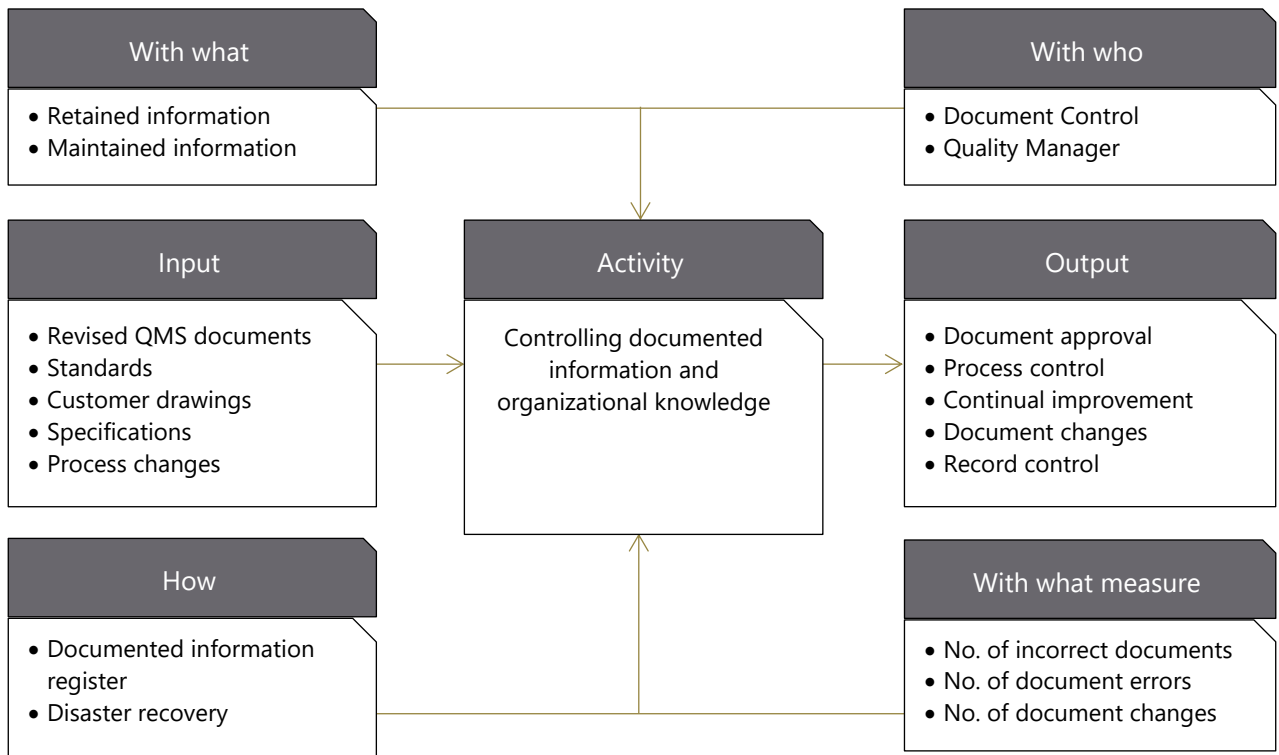
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# 1 Control of Documented Information

## 1.1 Introduction & Purpose

The purpose of this procedure is to ensure that all relevant documented information and organizational knowledge which forms an integral part of our quality management system is managed under controlled conditions and that all documented information is reviewed and approved by authorized personnel prior to issue.

### 1.1.1 Process Activity Map



### 1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9004:2000	Quality management systems	Guidelines for performance improvements
BS EN ISO 19011:2011	Auditing management systems	Guidelines for auditing

### 1.1.3 Terms & Definitions

Term	ISO 9000:2015 Definition
Documented Information	Information (3.8.2) Required to be Controlled and Maintained
Record	Document (3.8.5) Stating Results Achieved or Providing Evidence
Quality Manual	Specification (3.8.7) for the Quality Management System
Specification	Document (3.8.5) Stating Requirements
Objective Evidence	Data (3.8.1) Supporting The Existence or Verity of Something

## 1.2 Application & Scope

Documented information is retained to provide evidence of conformity to the requirements specified by ISO standards, customer requirements and of the effective operation of our management system. **Your Organization** uses standard forms and templates accessed via a local area network computer system. This documented procedure defines the controls for:

1. Approving documents for adequacy prior to issue;
2. Reviewing and revising as necessary and re-approving documents;
3. Ensuring that changes and current revision status of documents are identified;
4. Ensuring that relevant versions of applicable documents are available at points of use;
5. Ensuring that documents remain legible and readily identifiable;
6. Ensuring that documents of external origin are identified and their distribution controlled;
7. Preventing the unintended use of obsolete documents;
8. Ensuring that documents of external origin are identified and their distribution controlled.

This procedure applies to all quality management system documentation and is to be followed by all personnel where appropriate.

## 1.3 Requirements

**Top management** ensures that when we create documented information it is appropriately identified and described (e.g. title, date, author, reference number) and is available in an appropriate format (e.g. language, software version, graphics, etc.) and on appropriate media (e.g. paper, electronic). All documented information is reviewed and approved for suitability and adequacy.

An electronic document management system, which is backed up and updated as required, is used to retain documented information ensuring only the current versions are available to users. Records from process outputs are generated and maintained by the departments responsible for their creation. For electronic records, back up procedures are established, employees are responsible for backing up their data.

## 1.4 Creating, Updating & Controlling Documented Information

**Your Organization** applies the following criteria to all types of 'documented information' in order to assess whether the information is necessary for demonstrating the effectiveness of our QMS, and whether it should be formally controlled.

1. Communicates a message internally or externally;
2. Provides evidence of process and product conformity;
3. Provides evidence that planned outputs were achieved;
4. Provides knowledge sharing.

### 1.4.1 General

All documents and data are reviewed and approved by authorized personnel prior to issue. Each department issues and maintains its own documents. Current revisions of appropriate documents are available at locations where they are used. Documents controlled by this procedure include but are not limited to the following: