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Documented Information

ISO 9001:2015

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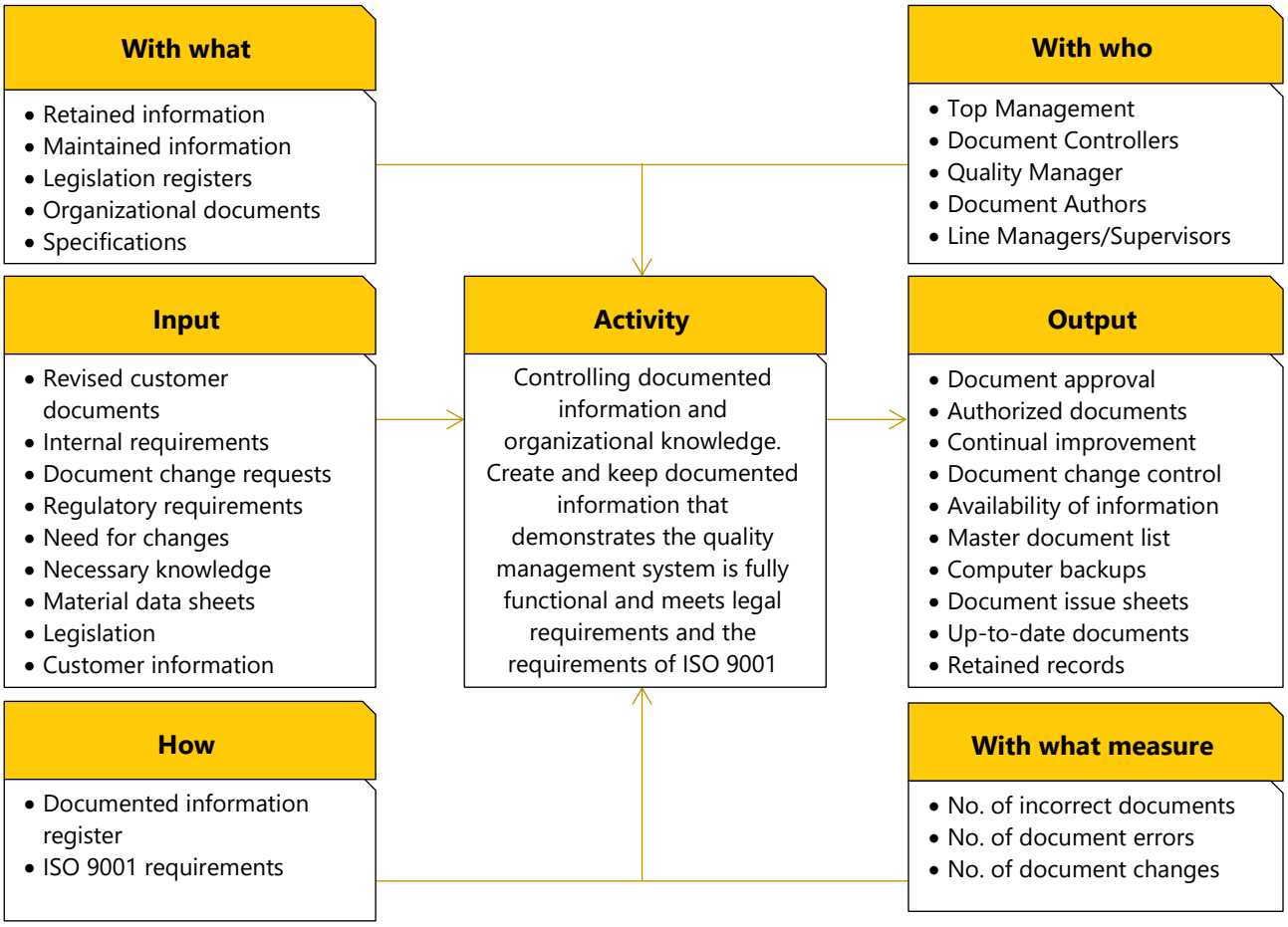
1 Procedure

1.1 Introduction & Purpose

This procedure aims to ensure that all relevant documented information and organizational knowledge that 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 before issue.

1.1.1 Process Overview

The process overview (turtle diagram) provides internal and external auditors, process owners, and participants an overview of the elements that are required by the documented information process:



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 9001:2024	Quality management systems	Amendment 1 Climate action changes 2024-02
BS EN ISO 9004:2018	Quality management	Guidance to achieve sustained success
BS EN ISO 19011:2018	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	Definition
Documented Information	Information (3.8.2) required to be controlled and retained or maintained

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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.

These documents must have revision control as they may be revised and updated during their life cycle. e.g., standards, procedures, policies, etc. All control documents will have the following minimum attributes:

1. Title;
2. Document Reference;
3. Document Revision;
4. Date of Revision;
5. Name/Designation and Signature of Author;
6. Name/Designation and Signature of the Person who approved the Document;
7. Name/Designation and Signature of the Person who Authorized the Document;

1.4.5 Document Hierarchy

Organizational documentation is designed to be an operational aid that fosters a uniform and consistent standard of quality that is based on the following hierarchy:

- Level 1 – Policy;
- Level 2 – Manual;
- Level 3 – Procedures;
- Level 4 – Work instructions;
- Level 5 – Records and forms.

The documents are designed to provide ready answers to common questions and a common standard of practice that facilitates individual, group, or departmental interaction.



1.4.5.1 Quality Policy

The quality policy is the top level of organizational documentation. All lower-level manuals, procedures, and instructions flow from the principles established in written policies.

The quality policy is usually a brief statement of principle that outlines the general philosophy and function of the organization or department. Each principal operation or business area is to be described in a written policy. Senior management is responsible for defining the policy.

1.4.5.2 Quality Manual

Manuals are the second level of organizational documentation. The quality manual contains the policy and objectives, organizational roles and responsibilities, and the requirements of ISO 9001.

The quality manual is the most significant document as it defines your organization's quality management system to satisfy statutory and regulatory requirements as well as stakeholder and consumer needs; and to ensure that all employees are involved in implementing the policy and objectives.

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