

Quality Management System Processes

Module 4



Contents

- Key processes of the quality management system
- Documented processes
- Document control



Key Processes of the QMS

➤ What is a process?



Key Processes of the QMS

➤ Processes not key to the performance of the QMS

❖ The Coffee run



❖ Lunch time orders



❖ Mail



Key Processes of the QMS

The service provider shall identify key processes required for their QMS

Factors to consider

- ❖ Regulatory, Statutory and/or Customer Requirements
- ❖ Effect on Quality
- ❖ Competence of personal
- ❖ Complexity of the processes



Key Processes of the QMS

Examples of key processes

- ❖ Operational/Business Planning
- ❖ Product or Service Requirements
- ❖ Outsourced Activities
- ❖ Management Review
- ❖ Internal Auditing and Corrective Action
- ❖ Training and Competency
- ❖ Monitoring and Measurement
- ❖ Roles and Responsibilities
- ❖ Calibration, if applicable



Documented Processes

Document Hierarchy

➤ Quality Pyramid



QMS Documentation

The quality management system documentation usually includes the following:

- ❖ Quality policy and its objectives
- ❖ Quality manual
- ❖ Documented procedures
- ❖ Work instructions
- ❖ Forms
- ❖ Quality plans
- ❖ Specifications
- ❖ External documents
- ❖ Records



Document Life Cycle

Creation

- ❖ Identify the processes necessary for the effective implementation of the quality management system

Approval

- ❖ The documents should be reviewed by authorized individuals to ensure clarity, accuracy, adequacy and proper structure

Review

- ❖ Periodic reviews are necessary to ensure that documents remain accurate, relevant, and aligned with organisational policies

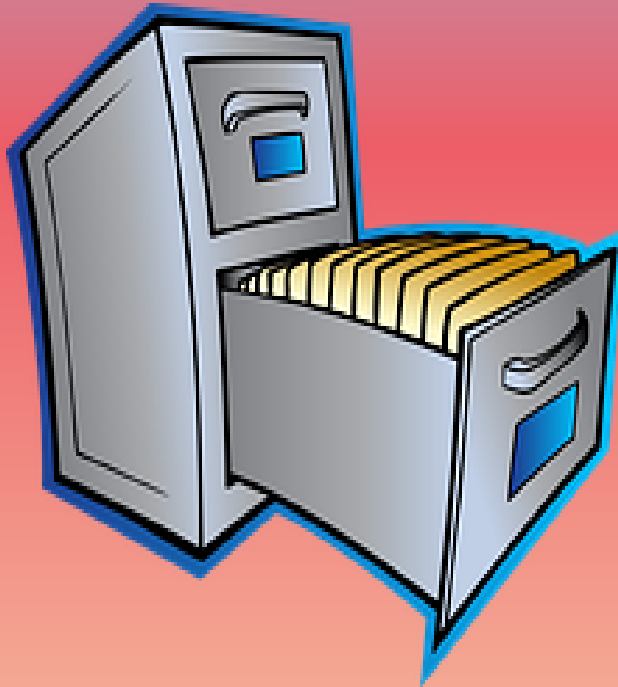
Update

- ❖ Changes in policies, regulations, or operational processes may necessitate updates to existing documents.



Document Control

Whether it is Hard Copies, or Software Accessed, documents must be controlled



Document Control

What is Document Control?



Document Control

The Basics

Document Control manages and oversees all stages of a controlled document's lifecycle,

- ❖ Creation
- ❖ Modification
- ❖ Review cycles
- ❖ Issuance
- ❖ Distribution
- ❖ Accessibility

This practice ensures an organization has easy access to current, accurate, and reliable information



Document Control

Why do documents need to be controlled?

Helps maintain

- ❖ Consistency – Single source of truth
- ❖ Traceability
- ❖ Compliance



Document Control – External

Any document that is created outside of the service provider/organisation

- ❖ Regulations
- ❖ Laws
- ❖ Technical Standards
- ❖ Any other public or private act



Q & A



thank you!