

ISO 9001:2015 Quality Management System (QMS)

Information Leaflet



Quality Management System (QMS)

A Quality Management System (QMS) is a formalized system that documents processes, procedures, and responsibilities for ensuring products or services consistently meet customer and regulatory requirements and for achieving quality policies and objectives. It achieves this by maintaining records of activities, which serve as evidence that quality-related tasks are being systematically performed.

An objective of a QMS is to manage a company's activities to comply with customer and regulatory requirements while continuously improving effectiveness and efficiency through the systematic management of quality-related activities.

ISO 9001:2015- QMS Requirements

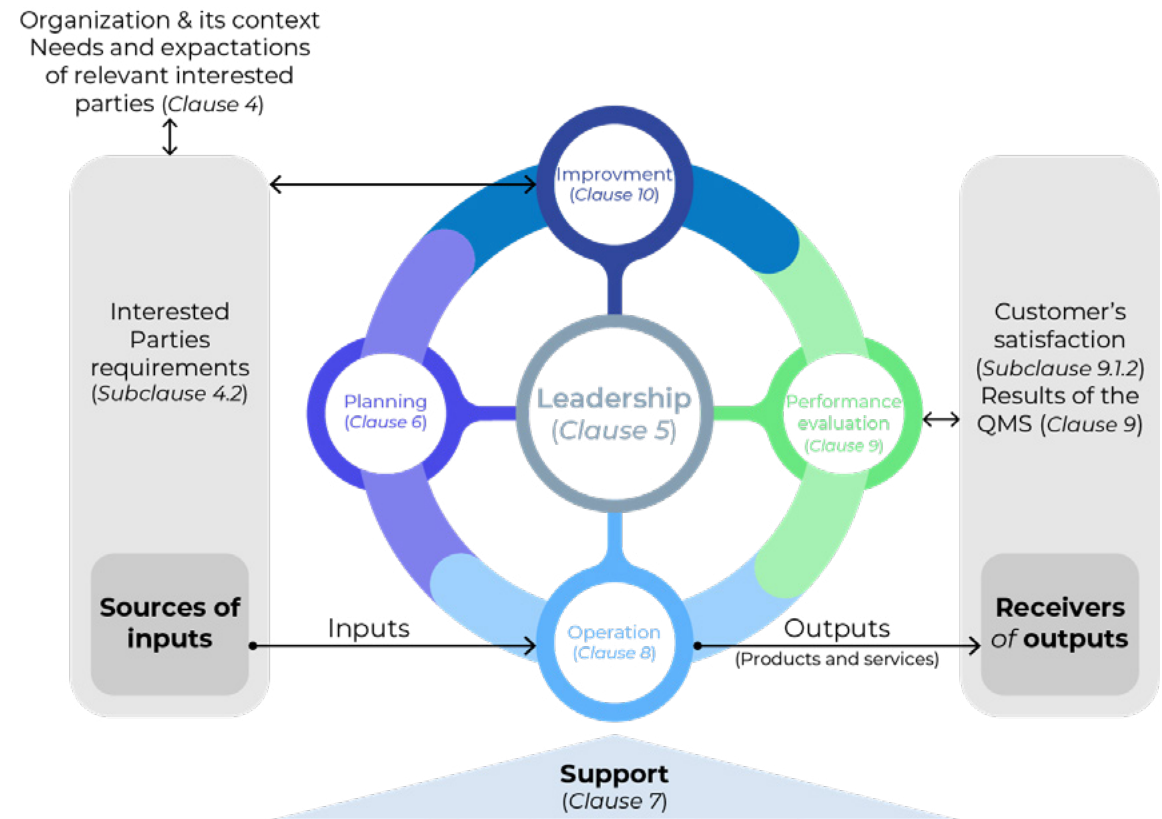
ISO 9001:2015 is an international quality standard published by International Organization for Standardization (ISO). This standard (document) is a set of requirements that affect virtually all aspects of the operations of corporate enterprises, non-profit organizations and government entities.

The standard includes the following summaries/contents,

Clause 0-3: introductory chapters (Scope of ISO 9001:2015, normative references, terms and definitions), and

Clause 4-10: Requirements Chapters

- Clause 4- Context of organization -PLAN
- Clause 5- Leadership -PLAN
- Clause 6- Planning- PLAN
- Clause 7- Support Processes- OPERATION
- Clause 8- Operations- OPERATION
- Clause 9- Performance evaluation - CHECK
- Clause 10- improvement- ACT

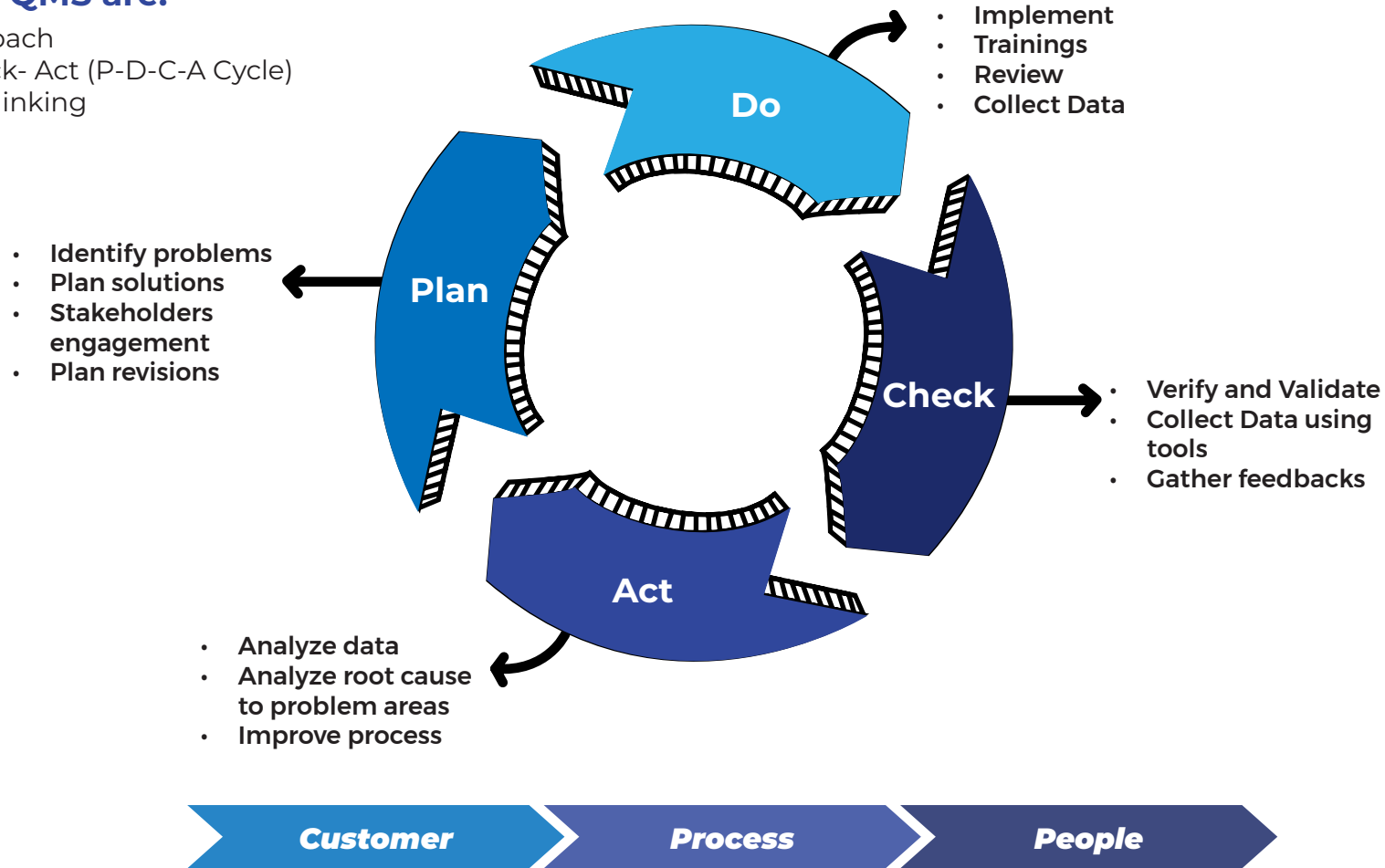


Principles of QMS:



The Pillars of QMS are:

1. Process Approach
2. Plan-Do-Check- Act (P-D-C-A Cycle)
3. Risk-Based Thinking



What are the Benefits of QMS?

The benefits that Quality Management Systems give companies result in more efficient, cost-effective, and safe processes. The main benefits of QMS are listed below.

Improved Regulatory Compliance	Improved Customer Retention and Satisfaction	Promoted Continuous Improvement	Developed Operational Consistency	Enhanced Internal Communications	Streamlined Employee Training	Increased Efficiency and Reduced Waste	Improved Decision-Making	Increased Profits
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What is the QMS Documentation Structure?

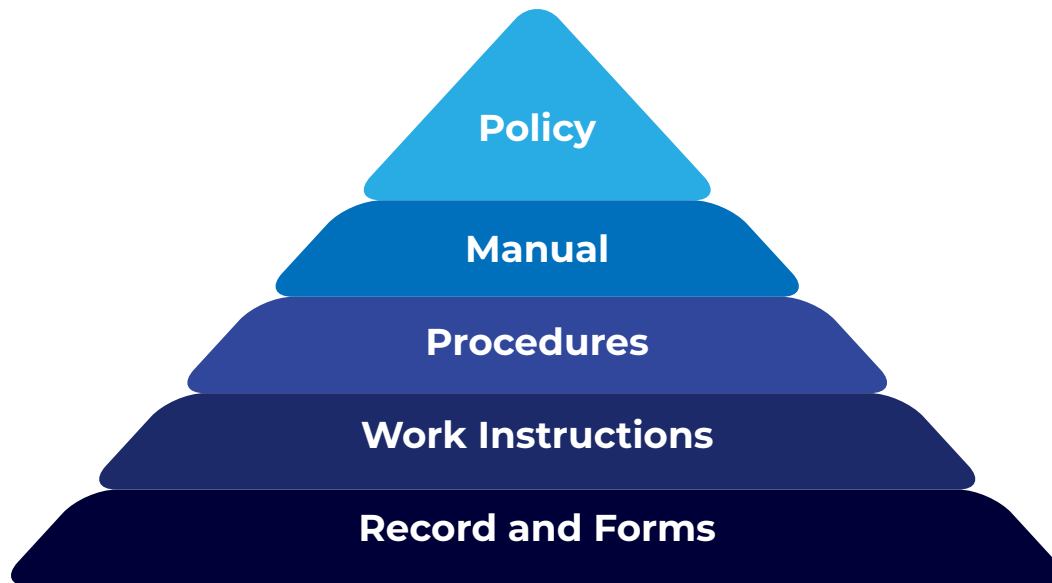
QMS documentation is the Quality Manual that defines a company's quality system. QMS documentation includes policies, procedures, work instructions, records, and other relevant documents. QMS documentation structure is a hierarchical organization of documents. The levels of documents in a QMS pyramid are described below.

Quality Policy: The quality policy is a high-level statement outlining a company's commitment to quality, sets the overall direction for quality efforts and serves as a guiding principle for employees.

Procedures: Procedures outline the step-by-step methods or processes for performing specific tasks or activities and serve to standardize operations, ensure consistency, and facilitate compliance with regulatory requirements.

Work Instructions: Work instructions provide detailed guidelines for completing specific tasks or operations.

Records: Records document the results, activities, or events related to quality management processes, serve as evidence of performance and compliance, enabling traceability and accountability.



Quality Objectives for each processes and levels of the organization have to be developed and communicated with respective Key Performance Indicators (KPIs).