
ORGANIZATION AND LEADERSHIP

ISO 9001:2015 Quality Management System

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OBJECTIVES

- Introduce the ISO 9001:2015 Quality Management System (QMS) standard and its benefits to an organization
- Explain the context of the organization according to ISO 9001
- Discuss who interested parties are, their needs and expectations
- Explain the QMS, its scope and processes
- Leadership and its commitment to the success of ISO 9001 implementation
- Explain how a quality policy is established and communicated

INTRODUCTION

- International Standard?

“An International Standard is a **document containing practical information and best practice**. It often describes **an agreed way of doing something or a solution to a global problem.**”

- Why International Standards?

1. Make products compatible, so they fit and work well with each other.
2. Identify safety issues of products and services.
3. Share good ideas and solutions, technological know-how and best management practices.



INTRODUCTION

Benefits from international standards

1. Increase profits
2. Benefit from the knowledge and best practice
3. More competitive
4. New markets entry
5. Reduce costs

Comparison between ISO 9001:2015 and previous ISO 9001:2008

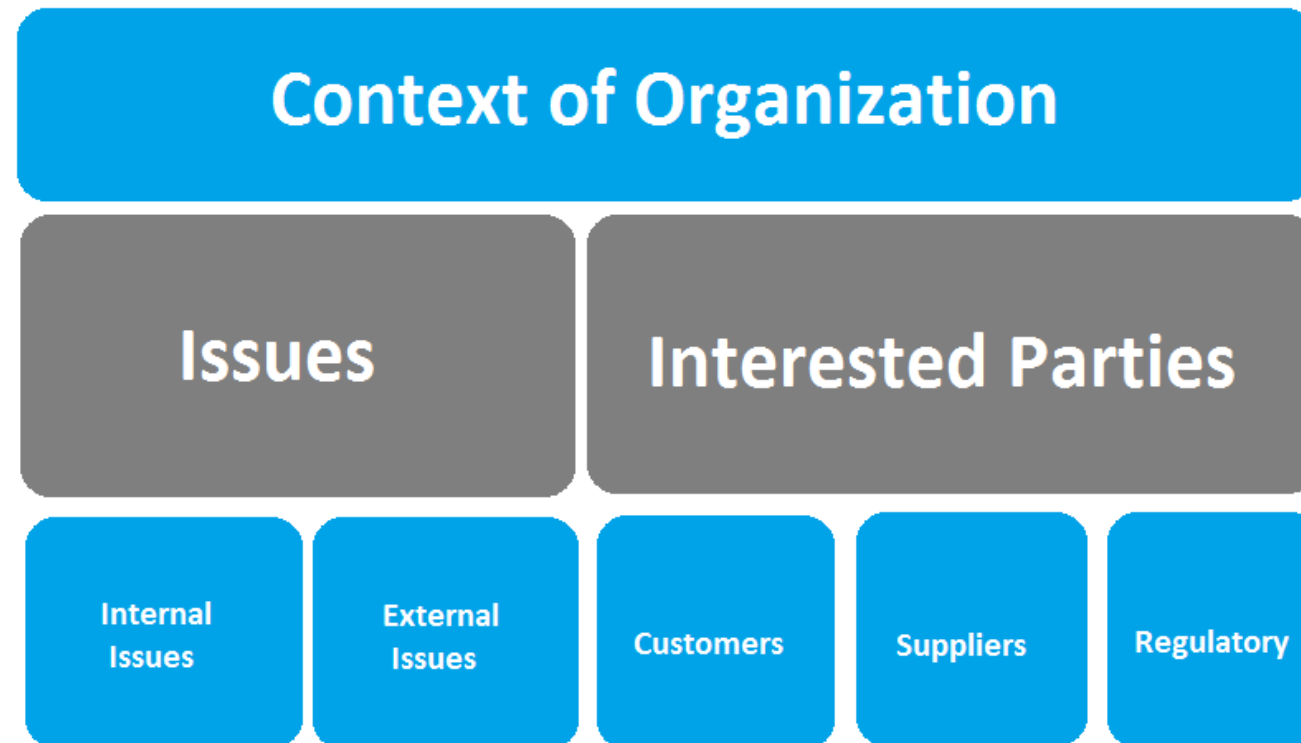
- i. More emphasis on measuring and properly assessing the input and output of processes (Process Approach).
- ii. Risk-based thinking plays very important place in ISO 9001:2015
- iii. More emphasis on leadership and management commitment

I SCOPE OF ISO 9001:2015

Organizations that desire to:

- consistently provide products and services that meet customer and regulatory conditions.
- enhance customer satisfaction

ORGANIZATIONAL CONTEXT



4 Context of the organization

4.1 Understanding the organization and its context

Purpose:

- Understand the external and internal issues that are relevant to the organization's purpose and strategic direction and that can affect, either positively or negatively, the company's ability to achieve the intended results of its quality management system (QMS).
- To **determine context** connotes recognizing the **internal** and **external** elements that can influence strategic business objectives and the QMS planning.

4.1 Understanding the organization and its context

External issues related to:

1. Statutory and regulatory factors
2. Economic factors
3. Market factors
4. Technological factors
5. Political factors
6. Social factors

Internal issues related to:

1. Performance of the organization
2. Resource factors
3. Human aspects
4. Operational factors
5. Factors in the governance of the organization

4.2

Understanding the needs and expectations of interested parties

Purpose:

- Ensure that the company thinks through the relevant requirements of **relevant** interested parties, which can have an impact on the organization's ability to offer products and services that satisfy requirements.
- “**Interested party**” by definition “is a person or organization that can affect, be affected by, or perceive itself to be affected by, a decision or activity”.
- **External** interested parties are those that impose specific legal, regulatory or contractual requirements.
- **Internal** interested parties that may specify conditions.

4.2

Understanding the needs and expectations of interested parties

Criteria for identifying relevant interested parties is by considering their:

- a) possible influence or impact on the organization's performance or decisions;
- b) ability to create risks and opportunities;
- c) possible influences or impact on the market;
- d) ability to affect the organization through their decisions or activities.

4.2

Understanding the needs and expectations of interested parties

Determining the needs and expectations of relevant interested parties

- monitoring customer needs, expectations and satisfaction
- reviewing statutory and regulatory requirements with compliance or legal departments
- conducting customer or user reviews
- market surveillance
- benchmarking
- reviewing requests received
- reviewing supply chain connections

4.3 Determining the scope of the quality management system

Purpose:

- Determine the boundaries of the quality management system so that it is defined in a manner that helps the organization meet requirements and the intended results of the system.

Establishing the scope is based on:

- the external and internal issues
- the relevant requirements of relevant interested parties
- the products and services offered by the organization

4.4 Quality management system and its processes

Process approach

Purpose:

- Ensure that the organization determines the processes needed for its quality management system in accordance with ISO 9001. These include processes for production and service provision, and the processes for the effective implementation of the system.

Process Approach

- “This involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization.”
- Understanding and managing interrelated processes as a system contributes to the organization’s effectiveness and efficiency in achieving its intended results.

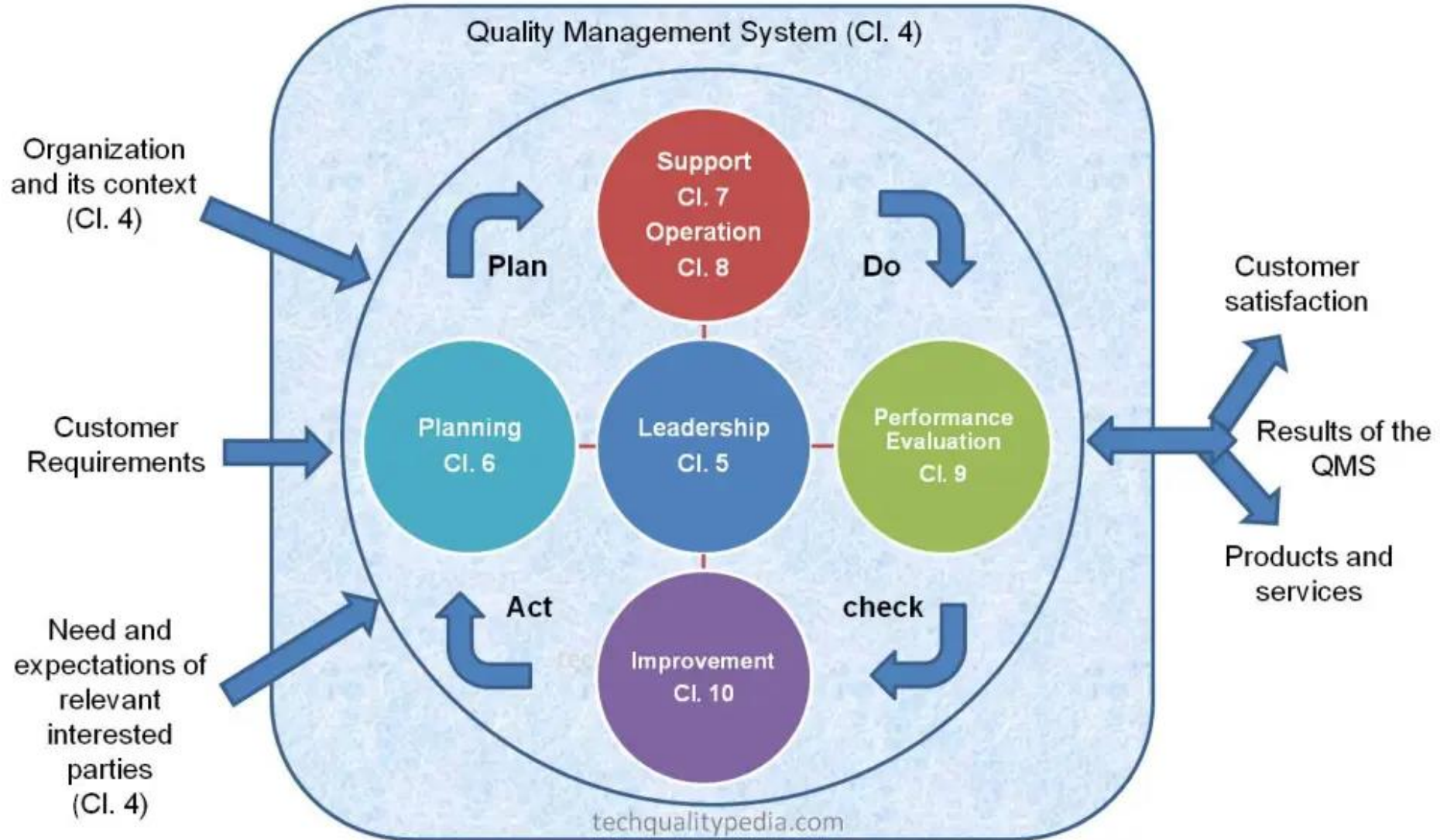
Process approach

Management of the processes and the system

The **PDCA cycle** can be briefly described as follows:

- **Plan:** establish the objectives of the system and its processes, and the resources, and identify and address risks and opportunities;
- **Do:** implement what was planned;
- **Check:** monitor and (where applicable) measure processes and the resulting products and services;
- **Act:** take actions to improve performance, as necessary.

ISO 9001 | Quality Management System | PDCA Approach



Process approach

Risk-based thinking

- ensures risks are identified, considered and controlled throughout the plan and use of the quality management system
- the concept of risk-based thinking was hidden in previous editions of this standard

Application of the process approach enables:

- understanding and consistency in meeting conditions in the standard;
- contemplation of processes in terms of added value;
- the success of effective process performance;
- continual improvement of processes based on evidence-based decision making.

4.4 Quality management system and its processes

Documented information

Purpose:

- Ensure that the organization determines the extent of documented information that is needed.

Documented information?

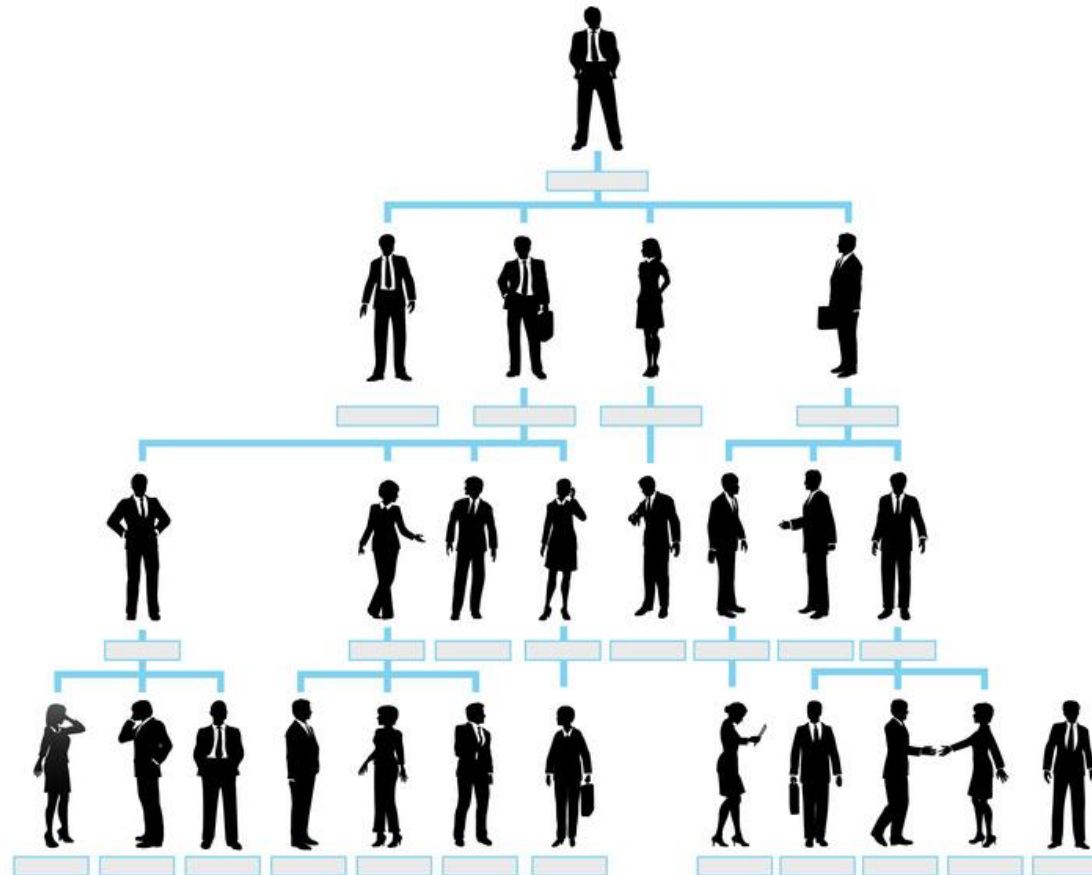
- It is information required to be controlled and maintained by an organization and the medium on which it is contained. The appropriate person reviews what information is used for a process to ensure its results delivery.

Two kinds of documented information

- those maintained to support the operation of its processes such as SOPs, manuals, regulations, forms, software
- those retained in order to have confidence that the processes are being carried out as planned. This type of documented information is frequently referred to as a “record”.

5 LEADERSHIP

5.1 LEADERSHIP AND COMMITMENT



5.1.1 GENERAL

Purpose:

- Ensure that top management demonstrate leadership and commitment by taking an active role in engaging, promoting, and ensuring, communicating and monitoring the performance and effectiveness of the quality management system.
- Top management is defined in ISO 9001:2015 as “the person or group of people who directs and controls an organization at the highest level”.
- Top management has the power to delegate authority and provide resources within the organization.

5.1.1 GENERAL

Demonstration of Leadership's commitment

1. Quality policy and objectives are in place
 2. Responsibilities, roles, and authorities are assigned
 3. Integration of the quality management system requirements ensured.
 4. Resources
 5. Promotion and support for continual improvement.
 6. Recommendations are implemented.
- Top management should ensure that its commitment is well known throughout the organization, and also keep appropriate records to show how this was achieved.

5.1.2 CUSTOMER FOCUS

Purpose:

- Ensure that top management visibly demonstrates leadership and commitment in maintaining the organization's focus on meeting customer and applicable statutory and regulatory requirements, and enhancing customer satisfaction.

Who are the customers?

- “Customers are generally the people or organizations that purchase the organization's products and services; however, it can also mean the individuals or organizations who are the recipients or consumers of the organization's products and services.”
- To accomplish or improve customer satisfaction, focus for on-time delivery performance and on customer complaints.

5.2 Policy

5.2.1 Establishing the quality policy

Purpose:

- Ensure that a quality policy is established which aligns with the strategic direction of the organization, including the organization's overall understanding of what quality means to itself and for its customers.

Quality Policy

- It describes the intentions and direction of the organization as formally expressed by its top management. **Also known as:** Mission statement, Vision, Strategic concept, Charter, or Statement of principles
- A **well written** quality policy statement will ensure **employees understand their job affects** product or service quality and quality control, and therefore the **success of the company**.

5.2.1 Establishing the quality policy

How?

1. clear understanding of the context of the organization
2. the organization's strategic direction
3. the level and type of future improvements needed for the organization to be successful
4. customer satisfaction
5. resources
6. potential contributions of relevant interested parties



- Our vision is to craft the brands and choice of drinks that **people love**, to refresh them in body and spirit while doing so in a manner that ensures that every product is a product they can trust for both quality and safety. It is a trust that must be maintained, enhanced and continue to be earned every day, with 1.9 billion servings a day.
- **Every associate** across our enterprise is responsible for ensuring quality and food safety and in delivering on that brand trust. Whether they work directly in our manufacturing operations, or as part of the delivery and merchandising of our products at the point of purchase – or indirectly in enabling services such as finance, HR, legal, IT, or public affairs – every person plays an important role in “keeping the promise” with our consumers.
- This means that they receive the “perfect product, trusted everywhere” every time. Nothing less than 100% quality and safety is acceptable.

5.2.2 Communicating the quality policy



Purpose:

- Ensure that the quality policy is communicated, understood and applied by persons in the organization so they are able to contribute to the effectiveness of the quality management system, and that it is available to relevant interested parties.
- Quality policy should be readily available and maintain as documented information (review periodically)
- It should be clearly understood throughout the organization via awareness and communication

5.3 Organizational roles, responsibilities and authorities

Purpose:

- For top management to assign the relevant roles in relation to the quality management system, in order to ensure the effectiveness and the achievement of intended results.
- Persons assigned should understand and be aware of their assignments through effective communications activities by management.
- Authority can be delegated, however, the overall responsibility and accountability for the QMS remains with top management.



5.3 Organizational roles, responsibilities and authorities

Assignment of relevant roles with authorities

- ensuring that the quality management system conforms to the requirements of this International Standard;
- ensuring that the processes are delivering their intended outputs;
- reporting on the performance of the quality management system and on opportunities for improvement to top management;
- ensuring the promotion of customer focus throughout the organization;
- ensuring that the integrity of the QMS is maintained even when changes to it are planned and implemented.



Thank
You