



PLANNING AND SUPPORT

ISO 9001:2015 QUALITY MANAGEMENT SYSTEM

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OBJECTIVES

- Discuss organizational roles, responsibilities and authorities
- Discuss actions to address risk and opportunities
- Explain quality objectives and how to plan to achieve them
- Understand the necessary resources and related actions required for achieving good QMS
- Explain the role of communication in successful QMS implementation
- Discuss the document control and its what, who, where and how

6 PLANNING

6.1 Actions to address risks and opportunities

Purpose:

- Ensure that when planning the quality management system processes, the organization determines its risks and opportunities and plans actions to address them.
- Its intent is to prevent nonconformities, and to determine opportunities that might enhance customer satisfaction.
- One of the key changes in the 2015 version of ISO 9001 is to establish a systematic approach to consider risk, by using risk-based thinking.

SWOT Analysis Strategy

	Opportunities (external, positive)	Threats (external, negative)
Strengths (internal, positive)	Strength-Opportunity strategies Which of the company's strengths can be used to maximise the opportunities you identifies?	Strength-Threats strategies How can you use the company's strengths to minimise the threats you identified?
Weaknesses (internal, negative)	Weakness-Opportunity strategies What actions can you take to minimise the company's weaknesses using the opportunities you identified?	Weakness-Threats strategies How can you minimise the company's weaknesses to avoid the threats you identified?

6.1 Actions to address risks and opportunities

Examples of the risks

- failure of processes, products and services to meet their requirements
- the organization not achieving customer satisfaction.

6.1 Actions to address risks and opportunities

Examples of opportunities include the potential

- to identify new customers
- to determine the need for new products or services and to bring them to market
- to determine the need for revising or replacing a process by the introduction of new technology

6.1.2 Actions to address risks and opportunities

Purpose:

- Ensure that the organization plans actions to address its determined risks and opportunities (see ISO 9001:2015, 6.1.1), implements the actions, analyses and evaluates the effectiveness of the actions taken.
- Having **identified** the risks and opportunities, **plan actions** to address these. Incorporated into the processes of both the QMS and the broader business systems, and **evaluate** the effectiveness of these actions.

6.1.2 Actions to address risks and opportunities

Examples of appropriate actions to address risk:

- the assessment, monitoring and evaluation of processes, products and services
- calibration of equipment used in the processes
- corrective actions and their extension to other relevant areas of the organization
- standard and specified methods and work instructions
- training and use of competent personnel

RISK TREATMENT

Actions that can be taken to address risks will depend on the nature of the risk, for instance:

- Avoiding the risk
- Eliminating the risk
- Taking the risk to pursue an opportunity
- Sharing the risk
- Taking no action

6.2 Quality objectives and planning to achieve them

6.2.1

- Quality objectives should be established at relevant functions, levels and processes, as appropriate, to ensure the effective deployment of the organization's strategic direction and its quality policy.

The quality objectives should:

- be consistent with the quality policy
- be measurable

6.2 Quality objectives and planning to achieve them

The quality objectives should:

- take into account applicable requirements
- be relevant to conformity of products and services and to enhancement of customer satisfaction
- be monitored
- be communicated
- be updated as appropriate

6.2 Quality objectives and planning to achieve them

Planning how to achieve its quality objectives, determine the following:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

6.3 Planning of changes

Purpose:

- Determine the need for changes to the organization's quality management system in order to adapt to changes in its business environment, as well as to ensure that any proposed changes are planned, introduced and implemented in a controlled manner.
- The application of risk-based thinking is helpful in planning these changes. Availability of resources and necessary allocation of responsibilities for such change should be considered.

6.3 Planning of changes

Need for a change to the QMS can come from

- management review
- audit results
- reviews of nonconformities
- complaints analysis
- analysis of process performance

7 Support

7.1 Resources

Purpose:

- Ensure that the organization provides the resources necessary for the establishment, implementation, maintenance and continual improvement of the quality management system, and for its effective operation.

Determining the resources needed consider

- the current internal capabilities and any constraints
- analysis of costs versus benefits

7.1 Resources

7.1.2 People

- Ensure that the organization has the right human resources that are needed for the operation and control of its processes and the effective implementation of the quality management system.

7.1.3 Infrastructure

- Make sure that the organization has the facilities, equipment and services needed to consistently provide conforming products and services to its customers.

7.1 Resources

7.1.4 Environment for the operation of processes

- Purpose: to ensure that the organization determines and provides the necessary environment for the operation of its processes, to facilitate provision of conforming products and services.

Environment for the operation of the processes, consider:

- inputs from interested parties
- physical issues
- human factors can be critical in the process

7.1.5 Monitoring and measuring resources

■ 7.1.5.1 General

Make sure that the organization determines and provides suitable resources to ensure valid and reliable monitoring and measuring results, when evaluating the conformity of the organization's products and services.

- **Monitoring** implies critical observation, supervision and checks to determine the quantitative or qualitative status (or both) of an activity, a process, a product, or a service

7.1.5 Monitoring and measuring resources

- **Measurement** considers the determination of a quantity, magnitude, or dimension, by using suitable measuring resources.
- Determine the resources needed for this monitoring and measuring, ensuring its suitability for what is required.
- Documented information should be available to demonstrate the fitness of purpose.

7.1.5.2 Measurement traceability

- Make sure measurement traceability is provided when it is a requirement or when confidence in the validity of the measurement results is necessary.
- Measuring equipment used need to be verified and/or calibrated, controlled, stored, used and maintained.
- The status of calibration/verification should be identifiable.

7.1.5.2 Measurement traceability

- Establish schedules for calibration and maintenance checks for these measuring equipment
- Unfit measuring equipment labeled as such, condition reviewed and necessary actions taken.

7.1.6 Organizational knowledge

- Maintain knowledge determined as necessary for the operation of its processes and to achieve conformity of products and services, as well as to encourage the acquisition of necessary knowledge based on changing needs and trends.
- **Organizational knowledge** is the specific knowledge of the organization coming either from its collective experience or from the individual experience of its persons.

7.1.6 Organizational knowledge

How to determine, maintain and make available knowledge

Internal sources

- failures, near miss situations and successes
- gathering knowledge from customers, external providers
- mentoring, succession planning

External sources

- benchmarking;
- intranet, libraries, awareness sessions, newsletters

7.2 Competence

- Determine the required competence for the jobs or activities in the organization that can affect conformity of products and services or customer satisfaction, and to ensure that the persons are competent to perform them.
- The competence of persons can be based on their education, training, and experience.

7.2 Competence

- Confirmation of competence: job interviews, reviewing resumes, observation, documented information of training or diplomas.
- Competence evaluation by direct observation of performance or by examining the results of assignments.
- Evidence of an employee's competence should be retained.

7.3 Awareness

- Ensure that relevant persons doing work under the organization's control are aware of the quality policy, relevant quality objectives, their contribution to the effectiveness of the system and the implications of not conforming with QMS requirements.
- **Awareness is attained** through understand of responsibilities and authorities and contributions to the organization's success.
- Persons can **demonstrate their awareness** by distinguishing between what is acceptable and what is not

7.4 Communication

- Ensure that the organization establishes the internal and external communications that are needed and which are relevant to the QMS.
- **External relevant interested parties:** reports, specifications, invoices or service level agreements
- **Internal communication:** daily contact, regular department meetings, briefing sessions, email or an intranet, written reports or job specifications

7.4 Communication

How to have effective communication:

- transmit and receive information quickly and to act on it;
- build trust amongst each other;
- transmit the importance of customer satisfaction, process performance
- identify opportunities for improvement.

7.5 Documented information

7.5.1 General

- Ensure that the organization controls the documented information needed for conformity to ISO 9001, as well as the ones needed for the effectiveness of its quality management system.
- ISO 9001 “**maintain documented information**”, means ensuring that information is kept up-to-date
- ISO 9001 “**retain documented information**”, means ensuring that evidence whether or not a requirement has been fulfilled is protected

7.5.2 Creating and updating

- Ensure that, when the organization creates and updates documented information, the appropriate identification, format and media is used, and it is reviewed and approved.

7.5.3 Control of documented information

7.5.3.1

Ensure that documented information is available in a suitable medium whenever needed, and that it is adequately protected.

- Control includes availability, distribution and protection
- Information security issues and data back-up

Example

- Electronic systems with read-only access, password protection or ID

7.5.3 Control of documented information

7.5.3.2

- Ensure that the control of documented information addresses distribution, **access**, retrieval and use, storage and preservation, control of changes, retention and disposition.
- **Version control:** historical documented information are maintained, stored and retrieved accordingly.
- **Storage of obsolete** documents: appropriate medium to ensure its preservation and legibility.

7.5.3 Control of documented information

- **Retention time:** could be a statutory or regulatory requirement, a contractual requirement, or can be determined by the organization. Retained documents should be protected from unintended alterations.
- **Disposal of obsolete** and unnecessary documents: give consideration to the control of sensitive data



THANK YOU