

# Tutorial Sheet 9: Quality Management System and Audit (Part -1)

## Assignment 1: Process Development

**Background of ISO 9000 series** This International Standard describes fundamentals of quality management systems (QMS), which form the subject of the ISO 9000 family, and defines related terms. Quality management systems can assist organizations in enhancing customer satisfaction in particular to meet the customer needs and expectations. Therefore QMS can provide the framework for continual improvement to increase the probability of enhancing customer satisfaction and the satisfaction of other interested parties.

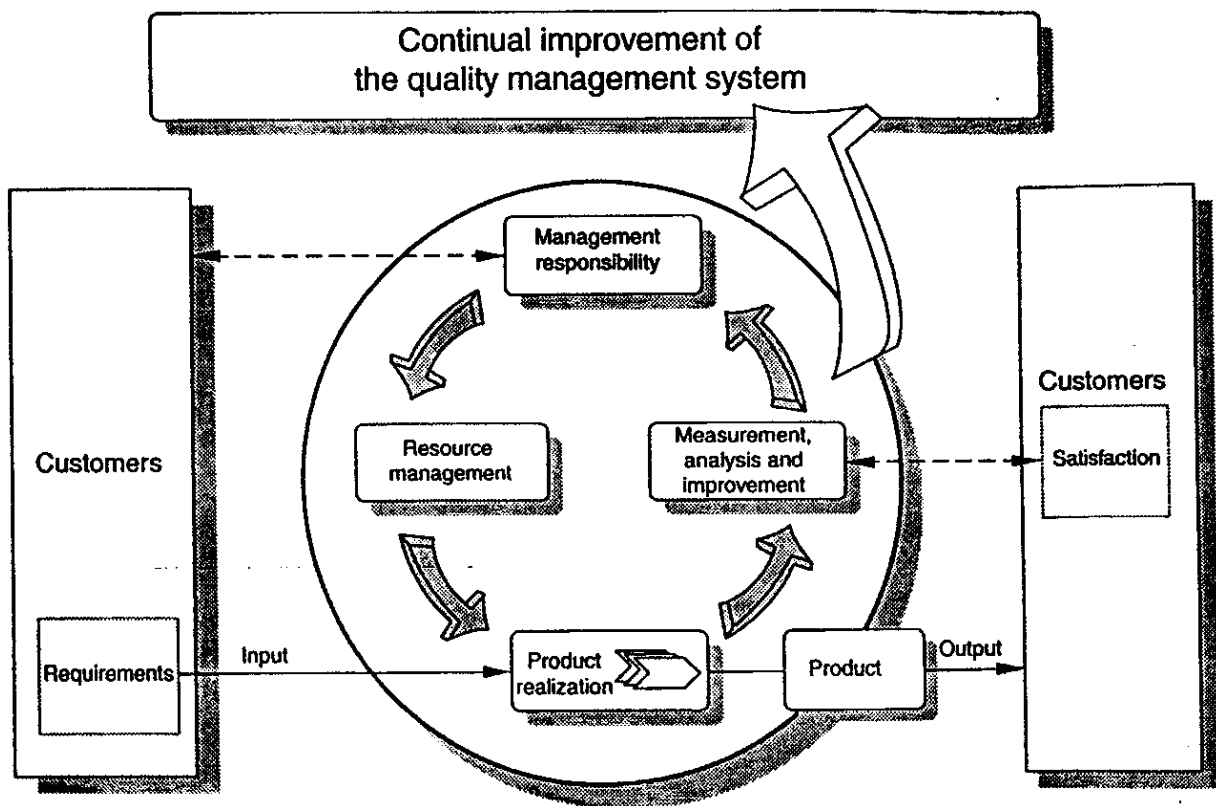
**Quality Management Systems-Fundamentals and Vocabulary (ISO 9000:2005)** Eight quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

- **Customer focus** Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.
- **Leadership** Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.
- **(Involvement of people)** People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.
- **Process approach** A desired result is achieved more efficiently when activities and related resources are managed as a process.
- **System approach to management** Identifying, understanding and managing interrelated processes as a system contributes to the organizations effectiveness and efficiency in achieving its objectives.
- **Continual improvement** Continual improvement of the organization's overall performance should be a permanent objective of the organization.
- **Factual approach to decision making** Effective decisions are based on the analysis of data and information.

- **Mutually beneficial supplier relationships** An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value. These eight quality management principles form the basis for the quality management system standards within the ISO 9000 family.

**Quality Management Systems (ISO 9001:2000)** ISO promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system. This standard aims to enhance customer satisfaction by meeting customer requirements. The below figure shows model of process based quality management system. When used within a quality management system, such an approach emphasizes the importance of

- Understanding and meeting requirements,
- The need to consider processes in terms of added value,
- Obtaining results of process performance and effectiveness,
- Continual improvement of processes based on objective measurement.



**Key**  
 —————> Value-adding activities  
 - - - - -> Information flow

## **Quality Management System Requirements**

**General Requirements** The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard. The organization shall

- identify the processes needed for the quality management system and their application throughout the organization,
- determine the sequence and Interaction of these processes,
- determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- monitor, measure and analyze these processes, and
- implement actions necessary to achieve planned results and continual improvement of these processes.

## **Documentation Requirements**

**General** The quality management system documentation shall include

- documented statements of a quality policy and quality objectives,
- a quality manual,
- documented procedures required by this International Standard,
- documents needed by the organization to ensure the effective planning, operation and control of its processes,
- records required by this International Standard.

**Control of documents** Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in control of records. A documented procedure shall be established to define the controls needed

- to approve documents for adequacy prior to issue,
- to review and update as necessary and re-approve documents,
- to ensure that changes and the current revision status of documents are identified,
- to ensure that relevant versions of applicable documents are available at points of use,
- to ensure that documents remain legible and readily identifiable,
- to ensure that documents of external origin are identified and their distribution controlled,
- to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

## **Control of Records**

Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

**Product Realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. In planning product realization, the organization shall determine the following, as appropriate:

- quality objectives and requirements for the product,
- the need to establish processes, documents, and provide resources specific to the product,
- required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance,
- records needed to provide evidence that the realization processes and resulting product meet requirements as stated in control of records.

**Deliverable:** Write a process for any part of software development life cycle activity.