Total Quality Management

Mechanical Technology Chapter 8 Notes

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Chapter 8

Quality Management System

1. Benefits of ISO Registration

There are various reasons for implementing a quality system that conforms to an ISO standard.

- The primary reason is that customers or marketing are suggesting or demanding compliance to a quality system.
- Other reasons are needed improvement in processes or systems and a desire for global deployment of products and services
- A study of manufacturing firms was undertaken to determine if there was any improvement in performance after registration. Significant improvement was noted in:
  - Internal quality as measured by the percent of scrap, rework, and nonconformities at final inspection.
  - Production reliability as measured by the number of breakdowns per month, percent of time dedicated to emergencies, and percent of downtime per shift.
  - External quality as measured by product accepted by customers without inspection, claims of nonconforming product, and returned product.
  - Time performance as measured by time to market, on-time delivery, and throughput time.
  - Cost of poor quality as measured by external nonconformities, scrap, and rework.

2. ISO 9000 Series of Standards

The ISO 9000 Series of Standards is generic in scope. By design, the series can be tailored to fit any organization's needs, whether it is large or small, a manufacturer or a service organization.

The three standards of the series are:

- ***ISO 9000:2005****—Quality Management Systems (QMS)—fundamentals and vocabulary:* discusses the fundamental concepts related to the QMS and provides the terminology used in the other two standards.
- ***ISO 9001:2008****—Quality Management Systems (QMS)—requirements:* is the standard used for registration by demonstrating conformity of the QMS to customers, regulatory, and the organization's own requirements

- ***ISO 9004:2000****—Quality Management Systems (QMS)—guidelines for performance improvement:* provides guidelines that an organization can use to establish a QMS focused on improving performance.

3. Sector-specific Standards

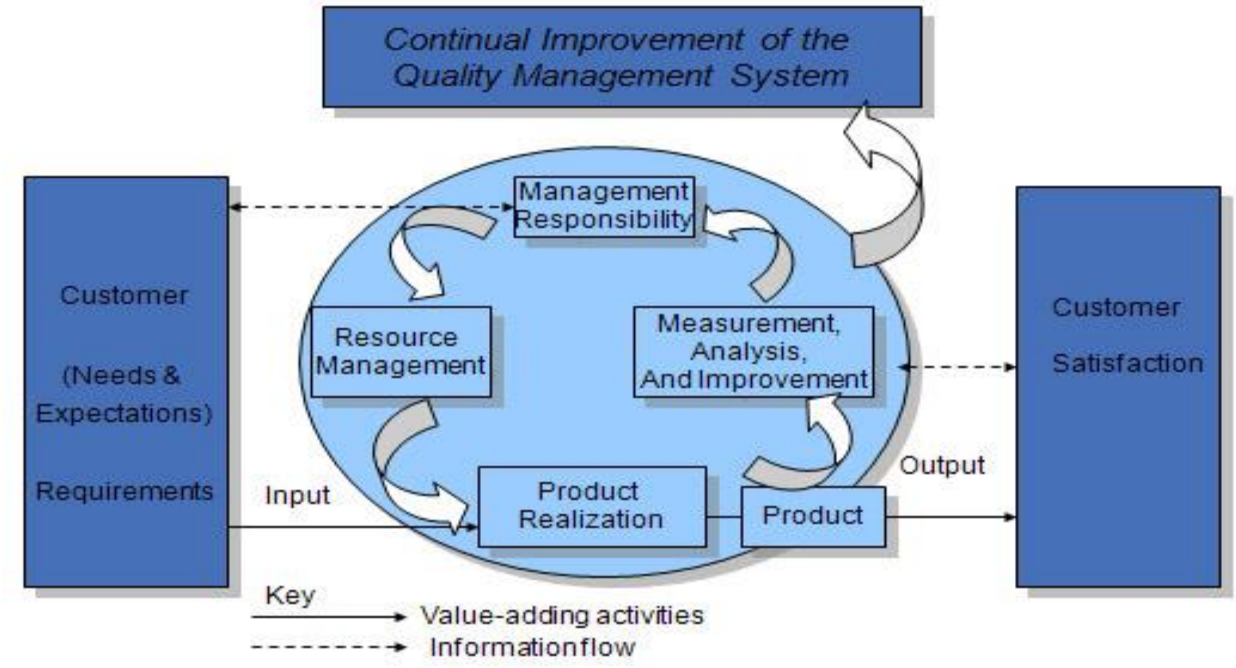
The ISO 9000 system is designed as a simple system that could be used by any industry. Other systems have been developed that are specific to a particular industry. One of the problems with sector-specific standards is the need for suppliers with customers in different industries to set up quality systems to meet each sector's requirements.

- **AS9100:** This aerospace industry quality system was officially released by the Society of Automotive Engineers in May 1997. In March 2001, the International Aerospace Quality Group (IAQG) aligned AS9100 with ISO 9001:2000. Industry-specific interpretations and methodologies are identified in italics and bold type. These additions are accepted aerospace approaches to quality practices and general requirements.
- **ISO/TS 16949:** It harmonizes the supplier quality requirements of the U.S. big three as provided in QS 9000 Third Edition6 with the French, German and Italian automakers. The goal is the development of fundamental quality systems that provide for continuous improvement, emphasizing defect prevention, and the reduction of variation and waste in the supply chain.
- **TL 9000:** It is a specific set of requirements based on ISO 9001 that defines the design, development, production, delivery, installation and maintenance of telecommunications products and services.

4. ISO 9001 Requirements

- **The standard has eight clauses:** Scope, Normative References, Definitions, Quality Management Systems, Management Responsibility, Resource Management, Product and/or Service Realization, and Measurement, Analysis, and Improvement
- The first three clauses are for information while the **last five are requirements that an organization must meet**.
- The application of a system of processes within an organization, together with their identification and interactions and the managing of these processes, is referred to as the **process approach**. This approach emphasizes the importance of:
  - Understanding and fulfilling the requirements.
  - The need to consider processes in terms of value added.
  - Obtaining results of process performance and effectiveness.
  - Continual improvement of processes based on objective measure.

Process Based Quality Management System



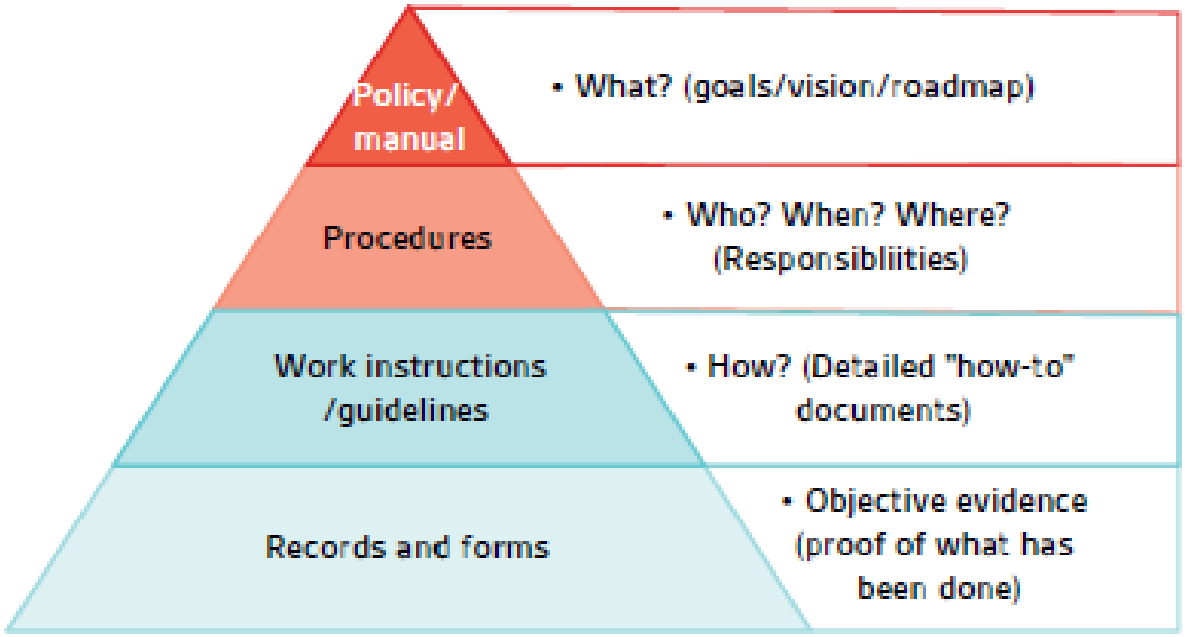
ISO 9001 Requirements

- **Scope:** The requirements of the standard are intended to be applicable to all types and sizes of organizations. Requirements in Clause 7, Product Realization, that are not appropriate to the organization, can be excluded.
- **Quality Management System (QMS):** The organization shall establish, document, implement, and maintain a QMS and continually improve its effectiveness.
- **Management Responsibility:** There are several aspects of management responsibility
  - Management commitment
  - Customer Focus
  - Quality Policy
  - Planning
  - Responsibility, authority and commitment
- **Resource management:** The organization shall determine and provide the resources needed (a) to implement and maintain the QMS and continually improve its effectiveness, and (b) to enhance customer satisfaction by meeting customer requirements. Resources include human resource, infrastructure and work environment.

- **Product Realization:**
  - **Planning:** The organization shall plan and develop the processes needed for product realization.
  - **Customer related processes:** Organization shall determine requirements specified by customer
  - **Design and development:** It shall plan and control design and development of product
  - **Purchasing:** The organization shall ensure that purchased product conforms to specified purchase requirements
  - **Production and service provision:** It shall plan and carry out production and service provision under controlled conditions.
  - **Control of Monitoring and measuring equipment:** It shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements
- **Measurement, Analysis, and Improvement:** The organization shall plan and implement the monitoring, measurement, analysis, and improvement processes needed for its business. Some important aspects are:
  - Monitoring and measurement
  - Control of non-conforming product
  - Analysis of data
  - Improvement
- **Implementation:** There are a number of steps that are necessary to implement a quality management system:
  - Top Management Commitment
  - Appoint the Management Representative
  - Awareness
  - Appoint an Implementation Team
  - Training
  - Time Schedule
  - Select Element Owners
  - Review the Present System

- Write the Documents
- Install the New System
- Internal Audit
- Management Review
- Pre-assessment
- Registration

5. The Documentation Pyramid



6. Internal Audits

After the policies, procedures, and work instructions have been developed and implemented, checks must be made to ensure that the system is being followed and the expected results are being obtained. This activity is accomplished through the internal audit, which is one of the key elements of the ISO 9000 standard.

- **Objectives-** There are 5 objectives namely, (1) Determine that actual performance conforms to the documented QMS. (2) Initiate corrective action activities in response to deficiencies. (3) Follow up on noncompliance items from previous audits. (4) Provide continued improvement in the system through feedback to management. (5) Cause the auditee to think about the process, thereby encouraging possible improvements.

- **Auditor:** Audits should be performed by qualified individuals who have received training in auditing principles and procedures
- **Techniques:** During the actual audit, there are a number of techniques that the auditor should employ. The objective is to collect evidence, and there are three methods: examination of documents, observation of activities, and interviews.
- **Procedure:** Key elements of audit procedure are: plan and checklists, schedules, audit meetings (pre, during audit and post meetings) and audit reports

7. Registration

Quality system registration is the assessment and audit of a quality system by a third party, known as a registrar. There are two parts:

- **Selecting a registrar:** In the United States, Registrar Accreditation Board (RAB) maintains a list of approved registrars. In India, Quality Council of India (QCI), carries out assessment of certification bodies. This is done under the National Accreditation Board for Certification Bodies (NABCB) scheme
- **Registration process:** It has six basic steps: application for registration, document review, pre-assessment, assessment, registration, and follow-up surveillance.

Registrars require a completed application to begin the registration process