



## **ROHINI COLLEGE OF ENGINEERING AND TECHNOLOGY**

**(An Autonomous Institution) | Affiliated to Anna University, Chennai**

**Accredited with A+ Grade by NAAC**

**DEPARTMENT OF MANAGEMENT STUDIES**

**24MG208 – TOTAL QUALITY MANAGEMENT**

**UNIT V**

**QUALITY MANAGEMENT SYSTEMS**

Introduction to IS/ISO 9004:2018- Quality management systems- Guidelines for performance improvements. Environmental Management system, ISO 14000, Quality Audits. TQM culture, Leadership- Quality council, Employee involvement, motivation, empowerment, recognition and reward.

### **Introduction to IS/ISO 9004:2018:**

The International Organization for Standardization (ISO) was officially established on February 23, 1947, in Geneva, Switzerland, to facilitate international coordination and unification of industrial standards. Emerging from the post-WWII merger of the ISA (1926-1942) and the UN Standards Coordinating Committee, ISO grew from 25 countries to a global network covering thousands of standards across technology and business.

### **Meaning Of ISO:**

To maintain a universal standard applicable around the globe, businesses align their QMS with International Organization for Standardization (ISO). An independent NGO by nature, it is the biggest developer of voluntary international standards in the world. The standards laid down by ISO helps in deeming a product or service safe, reliable, and of acceptable quality.

ISO applies to any and every organization, irrespective of its nature, size, or where it is from. The fact that a million different organizations from over 160 countries swear by ISO 9001 standard is a testament to how valuably it is regarded globally.

ISO 9001 provides a framework for an organization to manage their processes in an effective Quality Management System. ISO 9001 Section 10 “Improving the 9001 Quality Management System” discusses ongoing opportunities to enhance customer satisfaction such as improvements to products or services. Ultimately, improving the effectiveness of the QMS will help meet your customers’ requirements.

The ISO 9004 provides guidance for organizations to achieve sustained success in an ever-changing environment, with reference to the seven quality management principles described in ISO 9001:2015.

The newest standard of ISO was revised back in September 2018. Known as the ISO 9004:2018, this certification provides businesses with an even more advanced mechanism of implementing policies, strategies, and objectives to ensure quality products and services. With the ISO certification by your side, you can rest assured that no one can doubt the quality of your product and service.

ISO 9004:2018 offers guidelines for success by considering the quality of an organization, which it defines as the degree to which the characteristics of the organization fulfill the needs and expectations of its customers and other interested parties.

ISO 9004:2018 addresses the improvement of the organization’s overall performance. It includes the planning, implementation, analysis, evaluation, and improvement of an effective and efficient management system.

ISO 9004:2018 recommends the involvement of top management for understanding the context of the organization, and considering external and internal issues. Top management’s focus on the organization’s ability to meet the needs and expectations of customers and other relevant interested parties, and provides confidence in achieving sustained success.

### **Key Aspects of ISO 9004:2018:**

- **Sustained Success Focus:** Aims to help organizations maintain success in complex, changing environments by focusing on the "quality of an organization".
- **Self-Assessment Tool:** Includes a tool with five maturity levels (1 to 5) to evaluate 31 different elements, providing a comprehensive view of current status.
- **Structure & Approach:** Follows the Plan-Do-Check-Act (PDCA) cycle, similar to other management system standards.

- **Relationship to ISO 9001:** While ISO 9001 is for certification, ISO 9004 is for guidance and improvement.
- **Core Elements:** Focuses on leadership, strategy, process management, and resource management.

### **Benefits of ISO**

- Will provide organization with guidance and support to achieve sustained success using a quality management approach. It can be used by any organization, regardless of size, type or industry.
- Promotes self-assessment as an important tool for the review of the maturity level of your organization. It covers leadership, strategy, management system, resources, and processes to identify areas of strength and weakness as well as opportunities for improvement and innovations.
- Provides a wider focus on quality management than ISO 9001. It addresses the needs and expectations of all relevant interested parties. ISO 9004 also provides guidance for the systematic and continual improvement of your organization's overall performance.
- Can be used alongside ISO 9001 and other management system standards, but can also be used independently.
- Is not intended for certification, regulatory or contractual use.

### **Quality Management System:**

A Quality Management System (QMS) is a structured framework that documents processes, procedures, and responsibilities to ensure products or services meet regulatory and customer requirements.

A QMS is tailored to industry-specific needs and requirements, with various QMS types and standards ensuring compliance and continuous improvement through structured approaches.

QMS documentation establishes the framework for consistent quality and compliance by defining policies, procedures, and responsibilities. Building on this foundation, core QMS processes are essential for maintaining product consistency and meeting applicable requirements. Key QMS processes include document control, change control, training, nonconformance management, customer complaints, corrective and preventive actions (CAPA), audits, supplier management, and more.

To establish a QMS, an organization must define its quality objectives, develop documented processes and procedures aligned with applicable requirements, assign roles and responsibilities, and implement systems for monitoring, continuous improvement, and compliance.

**Meaning:**

QMS stands for Quality Management System. A Quality Management System (QMS) is a formalized system that documents processes, procedures, and responsibilities for ensuring that products or services consistently meet customer and regulatory requirements. Consistent products and services are achieved by maintaining records of activities that indicate that quality-related tasks are being systematically performed.

**Definition:**

According to WHO and aligned with international standards, a Quality Management System (QMS) is defined as "coordinated activities to direct and control an organization with regard to quality". It involves a comprehensive, systematic approach encompassing organizational structure, processes, procedures, and resources to ensure quality.

The seven quality management principles are: QMP

- 1 – Customer focus QMP
- 2 – Leadership QMP
- 3 – Engagement of people QMP
- 4 – Process approach QMP
- 5 – Improvement QMP
- 6 – Evidence-based decision making QMP
- 7 – Relationship management

**Customer focus:**

The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations. Rationale Sustained success is achieved when an organization attracts and retains the confidence of customers and other interested parties. Every aspect of customer interaction provides an opportunity to create more value for the customer. Understanding current and future needs of customers and other interested parties contributes to sustained success of the organization.

**Leadership:**

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization's quality objectives. Rationale Creation of unity of purpose and direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives

**Engagement of People:**

Statement Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capability to create and deliver value. Rationale To manage an organization effectively and efficiently, it is important to involve all people at all levels and to respect them as individuals. Recognition, empowerment and enhancement of competence facilitate the engagement of people in achieving the organization's quality objectives.

**Process approach:**

The quality management system consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.

**Improvement:**

Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.

**Evidence-based decision making:**

Decision making can be a complex process, and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause-and-effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making.

**Relationship management**

For sustained success, an organization manages its relationships with interested parties, such as suppliers. Rationale Interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its supplier and partner networks is of particular importance.