



# SNS COLLEGE OF TECHNOLOGY

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## DEPARTMENT OF AEROSPACE ENGINEERING

### 19MEE304 Total Quality Management

Topic: ISO 9001-2015 Quality System

#### 1. Introduction to ISO 9001:2015

ISO 9001:2015 is an **international standard** for **Quality Management Systems (QMS)**, published by the **International Organization for Standardization (ISO)**. It sets requirements for **consistent quality, process efficiency, and customer satisfaction** in organizations.

#### ◆ Key Facts about ISO 9001:2015

- **Latest revision** of ISO 9001, replacing the 2008 version.
- **Applies to all industries**, including manufacturing, services, and IT.
- **Focuses on risk-based thinking, leadership, and continuous improvement.**
- **Process-oriented approach** that enhances operational performance.

#### 2. Need for ISO 9001:2015

- ✓ Improves **product and service quality**.
- ✓ Enhances **customer satisfaction and trust**.
- ✓ Standardizes **business processes** across departments.
- ✓ Helps in **regulatory compliance**.
- ✓ Promotes **risk-based decision-making**.
- ✓ Reduces **waste, defects, and inefficiencies**.
- ✓ Provides a **framework for continuous improvement**.

#### 3. Key Principles of ISO 9001:2015

ISO 9001:2015 is based on **seven quality management principles**:

- 1 **Customer Focus** – Understanding customer needs and exceeding expectations.
- 2 **Leadership** – Strong management commitment to quality.
- 3 **Engagement of People** – Employee involvement in quality initiatives.
- 4 **Process Approach** – Managing activities as interrelated processes.
- 5 **Continuous Improvement** – Enhancing processes and efficiency over time.
- 6 **Evidence-Based Decision Making** – Using data and analysis for decision-making.
- 7 **Relationship Management** – Strengthening supplier and stakeholder relationships.

## 4. ISO 9001:2015 Structure – 10 Clauses

ISO 9001:2015 follows the **High-Level Structure (HLS)** with **10 clauses**:

### ✦ Clauses 1-3: Introduction & Scope

- ① **Scope** – Defines the industries and applications covered.
- ② **Normative References** – Other ISO documents referenced.
- ③ **Terms and Definitions** – Key terminology used in the standard.

### ✦ Clauses 4-10: Requirements of ISO 9001:2015

#### ◆ Clause 4: Context of the Organization

- Identifies **internal and external factors** affecting quality.
- Understands **stakeholder expectations**.
- Defines the **scope of the QMS**.

#### ◆ Clause 5: Leadership

- Top management must **demonstrate leadership and commitment**.
- Establishes **quality policy** and objectives.
- Assigns **roles and responsibilities** for quality management.

#### ◆ Clause 6: Planning

- Implements **risk-based thinking** to address potential issues.
- Defines **quality objectives** and action plans.
- Establishes a **framework for change management**.

#### ◆ Clause 7: Support

- Ensures **availability of resources**, such as personnel and technology.
- Emphasizes **competency, awareness, and communication**.
- Maintains **documented information** for process control.

#### ◆ Clause 8: Operation

- Focuses on **core business processes** to ensure product/service quality.
- Controls production and service delivery.
- Ensures **supplier and subcontractor management**.

#### ◆ Clause 9: Performance Evaluation

- Monitors and measures **QMS effectiveness**.
- Conducts **internal audits and management reviews**.
- Uses **customer feedback and KPIs** for performance analysis.

## ◆ Clause 10: Improvement

- Addresses **nonconformities and corrective actions**.
- Ensures **continuous improvement** of processes and products.
- Promotes **innovation and efficiency**.

## 5. Risk-Based Thinking in ISO 9001:2015

Unlike previous versions, **ISO 9001:2015** emphasizes **risk-based thinking**, which involves:

- ✓ Identifying potential **risks and opportunities**.
- ✓ Implementing **preventive actions** to avoid issues.
- ✓ Using a **proactive approach** instead of reactive problem-solving.
- ✓ Applying risk management to **supplier selection, customer satisfaction, and operational processes**.

✎ *Example:* A **pharmaceutical company** uses risk-based thinking to ensure **drug safety** by analyzing potential risks in raw material sourcing and production.

## 6. ISO 9001:2015 Certification Process

To obtain ISO 9001:2015 certification, an organization must follow these steps:

### Step 1: Gap Analysis

- Identify **current practices vs. ISO 9001:2015 requirements**.
- Develop an **implementation plan**.

### Step 2: QMS Implementation

- Document **policies, processes, and work instructions**.
- Train employees on **quality management principles**.

### Step 3: Internal Audit

- Conduct **internal assessments** to ensure compliance.
- Address any **nonconformities**.

### Step 4: Certification Audit

- Engage an **external certification body** for an audit.
- Certification is issued upon compliance.

### Step 5: Continuous Monitoring and Improvement

- Conduct **annual surveillance audits**.
- Implement **ongoing process improvements**.

✦ *Example:* **Apple Inc.** follows **ISO 9001:2015** to ensure its supply chain maintains **high-quality production standards**.

## 7. Benefits of ISO 9001:2015 Implementation

- ✓ **Enhanced Quality** – Consistent and standardized processes.
- ✓ **Increased Customer Satisfaction** – Improved service and product reliability.
- ✓ **Regulatory Compliance** – Meets industry and legal requirements.
- ✓ **Operational Efficiency** – Reduces rework, waste, and inefficiencies.
- ✓ **Global Market Access** – Recognized in **over 160 countries**.
- ✓ **Stronger Supplier and Stakeholder Relations** – Ensures uniform quality across supply chains.

## 8. Industrial Case Studies of ISO 9001:2015

### ✦ Case Study 1: Toyota

- Implemented ISO 9001:2015 for **lean production and quality control**.
- Reduced **defect rates by 30%**.
- Improved **customer satisfaction scores**.

### ✦ Case Study 2: Infosys

- Adopted ISO 9001:2015 for **software quality management**.
- Improved **client retention by 15%**.
- Reduced **project delivery delays**.

### ✦ Case Study 3: Nestlé

- Applied ISO 9001:2015 in **food safety and quality assurance**.
- Ensured **regulatory compliance in global markets**.
- Enhanced **supply chain transparency**.

## 9. Challenges in Implementing ISO 9001:2015

- ⊖ **Initial Cost & Time-Consuming Process** – Requires investment in training and audits.
- ⊖ **Resistance to Change** – Employees may struggle with new quality requirements.
- ⊖ **Documentation Overload** – Extensive process documentation can be complex.

⊗ **Continuous Monitoring Requirement** – Requires ongoing internal and external audits.

## 10. Conclusion

✦ **ISO 9001:2015** is a globally recognized standard for **quality management**.

✦ **Industries worldwide** use ISO 9001 to enhance efficiency, customer satisfaction, and compliance.

✦ **Risk-based thinking, leadership, and process optimization** are key drivers of ISO 9001:2015.

✦ **Continuous improvement and innovation** ensure long-term business success.