

QUALITY MATTERS - OVERVIEW OF ISO 9001 - QUALITY MANAGEMENT SYSTEM



ISO 9000 Standard

- ISO -Greek word “isos” means “equal”
- pronunciation “eye-soh”

What is ISO 9000?

- **An International Standard and a Set of Guidance Documents Intended for Organizations in all Types of Industries**
- **ISO 9000 Focuses on Managing an Organization's Key Processes**

ISO 9000 Series of Documents

- ISO 9000
- ISO 9001
- ISO 9004
- ISO 10011-1,2,3

- **International Organization for Standardization:**
 - formed in Geneva, Switzerland
 - 300 (+) Countries are members
 - 800 (+) new and revised standards issued annually
- **Technical Committee 176 - responsible for Quality Standard creation - members:**
 - ANSI - American National Standards Institute
 - SCC - Standards Council of Canada
 - BSI - British Standards Institute

Foundation Documents

- MIL 9850
- BSI 3750
- CAN Z299
- EN-29000
- Universal ISO 9000 Adopted (1987)
- Revised: 1994 & 2000 & 2008

Objectives of ISO 9000

- To provide a framework for organizational effectiveness
- To assure consistency in products and services delivered to customers
- Increase customer satisfaction

Intent of ISO 9000

- Provide an effective linkage between an organization's quality management and its “core processes”
- Improve organizational performance
- Increase customer satisfaction

Purpose of ISO 9000

- **Provide a more user friendly Quality Management System that is applicable to all organizations**

Internal Benefits of ISO 9000

- Better management of core business processes
- Increased awareness of quality among staff
- Improved productivity and quality
- Improved internal communications
- Reduced costs of quality

External Benefits of ISO 9000

- Improved customer satisfaction
- Higher perceived quality by market place
- Quicker time to market new products
- Enhanced competitive edge
- Increased market share

8 Management Principles

- Focus on customers
- Leadership
- Involvement of People
- Process Approach
- Systems Approach To Management
- Continual Improvement
- Factual Approach To Decision Making
- Mutually Beneficial Supplier Relationships

Process Approach

- Activities and related resources are managed as a process
- Identification of interfaces of key activities within and between the functions
- Focus on inputs: methods, materials, machinery and resources
- Methodology to evaluate impact on suppliers, customers, and others

Process Approach (con't)

- Considers processes in terms of value added
- Provides results of process performance and effectiveness
- Continual improvement of processes is based on objective measurement

Components of ISO 9001

- **Quality Management System**
- **Management Responsibility**
- **Resource Management**
- **Product Realization**
- **Measurement, Analysis and Improvement**

Quality Management System

- **General Requirements**
- **Documentation Requirements**

Management Responsibility

- **Management Commitment**
- **Quality Policy**
- **Planning**
- **Responsibility Authority and Communication**
- **Management Review**

Resource Management

- **Provision of Resources**
- **Human Resources**
- **Infrastructure**
- **Work Environment**

Product Realization

- **Planning of Product Realization**
- **Customer Related Processes**
- **Design and Development**
- **Purchasing**
- **Production and Service Provision**
- **Control of Monitoring and Measuring Devices**

Measurement Analysis and Improvement

- General Requirements
- Monitoring and Measurement
- Control of Nonconforming Product
- Analysis of Data
- Improvement

Phases of Development/ Maintenance and Costs

- Planning
- Development
- Implementation
- Registration
- Maintenance

Why Obtain Certification?



- **Worldwide Business Requirement**
- **Complete System for Quality Management**
- **Competitive Advantage**
- **Excellent Marketing Tool**

Quality System - Maintenance

- **Processes must be monitored and measured to ensure continued effectiveness and suitability for the organization**

ISO 14000 Environmental Management System

- BS 5750 is considered to be the foundation document
- Places environmental management directly into the hands of management
- Officially released in September of 1996

Why ISO 14000

- Organizations are becoming increasingly concerned to achieve and demonstrate sound environmental performance
- Impacts of environmental loss can tarnish reputable firms and costs associated with legal liabilities can be endless
- ISO 14000 series of standards is intended to specify an internationally recognized system of environmental management

Benefits of ISO 14000

- Fulfill legal and regulatory requirements
- Achieving internal improvements and self regulation
- Satisfy contractual requirements
- Improved Marketing Strategy
- Provide an effective Emergency Preparedness & Response Program
- Reduce risk of liabilities and litigation costs

Integrating ISO 9000/14000

- **Compatibility with terminology and content**
- **Integrated Management Systems:**
 - **Non-Conformance Management**
 - **Corrective Action Management**
 - **Preventive Action Management**
 - **Internal Auditing (ISO 19011)**
 - **Management Review**

Questions?