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# ISO 9000 Quality Systems

## Introduction:

ISO 9000 is a series of standards, developed and published by the International Organization for Standardization (ISO), that define, establish, and maintain an effective quality assurance system for manufacturing and service industries. The standards are available through national standards bodies. ISO 9000 deals with the fundamentals of quality management systems, including the eight management principles upon which the family of standards is based. ISO 9001 deals with the requirements that organizations wishing to meet the standard must fulfill.

The ISO 9000 family addresses various aspects of quality management and contains some of ISO's best known standards. The standards provide guidance and tools for companies and organizations who want to ensure that their products and services consistently meet customer's requirements, and that quality is consistently improved. There are many standards in the ISO 9000 family, including:

- ISO 9001:2008 - sets out the requirements of a quality management system
- ISO 9000:2005 - covers the basic concepts and language
- ISO 9004:2009 - focuses on how to make a quality management system more efficient and effective
- ISO 19011:2011 - sets out guidance on internal and external audits of quality management systems

## Who Should Attend?

Executives, engineers, and supervisors from QA, production, maintenance and engineering, Managers, Supervisors, Engineers, Practitioners in the field of Quality Management, Quality Engineering, Continuous improvement, production & operation and all parties associated with process quality, improvement, production and operation of the company or organization

## Course Objectives:

**By the end of this course delegates will be able to:**

- Demonstrate an understanding of the importance of quality standards
- Explain what the International Organization of Standardizations (ISO) represents
- Exhibit an understanding of the structure of ISO, as an organization
- Explain ISO code of ethics
- Explain the benefits of ISO to organizations
- Identify the hallmarks of the ISO as a brand
- Explain ISO's contribution to world trade
- Exhibit an understanding of the benefits that ISO represents to developing countries
- Recognize ISO standards
- Distinguish between ISO 9000 and ISO 1400
- Determine the elements that constitute the ISO 9000 family
- Explain clients or customers' quality requirements
- Demonstrate an understanding of the general regulatory quality requirements
- Exhibit an understanding of how to enhance client and customer satisfaction
- Exhibit an understanding of the processes involved in continuous quality improvements
- Explain at least five of the eight ISO quality principles
- Name the constituents of ISO 9000:2000 series

- Demonstrate a significant grasp of the ISO 9000 quality standards, as it pertains to different industry sectors
- Explain the ISO/TS 29001:2003 as it pertains to petroleum petrochemical and natural gas industrial sectors
- Explain at least 10 ISO 9000 standards, linking them to their specific standards parameter
- Determine the relationship between performance management and quality improvement in public sector organizations
- Explain how ISO certification might be achieved
- Exhibit an understanding of the marketing opportunity that ISO certification represents
- Suggest the steps that should be taken in preparation for ISO certification assessment
- Explain the progress that the ISO's 2005 to 2010 action plan for developing countries has made, suggesting effort towards its enhancement

### Course Outline:

- Why quality standards matter
- What is the International Organization for Standardization (ISO)
- ISO Structure
- ISO Code of Ethics
- What 'international standardization' means
- How ISO standards benefit society
- The hallmarks of the ISO brand
- ISO and world trade
- ISO and developing countries
- How to recognize an ISO standards

- The ISO Standards: An Introduction
- ISO Standards - ISO 9000 and ISO 1400: An Overview
- The ISO 9000 Family
- Objectives of ISO 9000
- The clients or customers' quality requirements
- General Regulatory Quality Requirements
- Enhancing client and customer satisfaction
- Towards Continuous Quality Improvement
- ISO Quality Principles
- The ISO 9000:2000 series
- ISO 9000:2005 Quality systems - Fundamentals and vocabulary
- ISO 9001:2000 Quality systems - Requirements
- ISO 9004:2000 Quality systems - Guidelines for performance improvements
- ISO 19011:2002 Guidelines for quality and environmental systems auditing
- The ISO 9000 Quality Standards
- IWA 1:2001 to IWA 1:2005
- IWA 2:2003-Quality systems
- IWA 4:2005-Quality systems
- ISO Guide 34:2000-General requirements for the competence of reference material producers
- ISO Guide 34:2000
- ISO 9000:2005-Quality management systems - Fundamentals and vocabulary
- ISO 9001:2000-Quality management systems - Requirements
- ISO 9004:2000-Quality management systems - Guidelines for performance improvements
- ISO 10002:2004-Quality management - Customer satisfaction - Guidelines for complaints handling in organizations

- ISO 10005:2005-Quality management systems - Guidelines for quality plans
- ISO 10006:2003-Quality management systems - Guidelines for quality management in projects
- ISO 10007:2003-Quality management systems -- Guidelines for configuration management
- ISO 10012:2003-Measurement management systems -- Requirements for measurement processes and measuring equipment
- ISO/TR 10013:2001-Guidelines for quality management system documentation
- ISO/TR 10014:1998-Guidelines for managing the economics of quality
- ISO 10015:1999-Quality management
- ISO/TR 10017:2003-Guidance on statistical techniques for ISO 9001:2000
- ISO 10019:2005-Guidelines for the selection of quality management system consultants and use of their services
- ISO/TR 13352
- ISO 13485:1996-Quality systems
- ISO 13485:2003
- ISO 13488:1996-Quality systems
- ISO 14964:2000-Mechanical vibration and shock -- Vibration of stationary structures -- Specific requirements for quality management in measurement and evaluation of vibration
- ISO/TR 14969:2004-Medical devices - Quality management systems -- Guidance on the application of ISO 13485: 2003
- ISO 15161:2001-Guidelines on the application of ISO 9001:2000 for the food and drink industry
- ISO 15189:2003-Medical laboratories - Particular requirements for quality and competence
- ISO/TS 16949:2002-Quality management systems - Particular requirements for the application of ISO 9001:2000 for automotive production and relevant service part organizations
- ISO 19011:2002-Guidelines for quality and/or environmental management systems auditing

- ISO/TS 19218:2005-Medical devices - Coding structure for adverse event type and cause
- ISO 22870:2006-Point-of-care testing (POCT) - Requirements for quality and competence
- ISO/TS 29001:2003-Petroleum, petrochemical and natural gas industries - Sector-specific quality management systems - Requirements for product and service supply organizations
- ISO/IEC 90003:2004
- ISO 9001:2000 Goals
- Identifying goals
- Identifying role expectations
- Applying the ISO 9000 family of standards in your organization
- Establish your current status, determine the gaps between your quality management system and the requirements of ISO 9001:2000
- Determine the processes that are needed to supply products to your customers or clients
- Developing a plan to close the gaps in the processes
- Carrying out your plan
- Undergoing periodic internal assessment
- Demonstrating organizational or departmental conformity to quality standards
- Importance of conformity assessment
- Undergoing independent audit
- Continuous organizational or business improvement
- Maintaining the benefits and continuous improvement
- ISO Certification
- Publicizing ISO Certification
- Preparing for the ISO Certification assessment
- Maintaining Certification
- Performance Management as a Quality Instrument

- **ISO's 2005-2010 Action Plan for developing countries**