ISO 9000:2000 Overview

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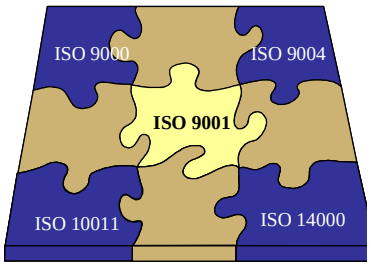

Course Objectives

- ✓ History of ISO 9000 Series of Standards
- ✓ Reasons for & Benefits of the Revision
- ✓ Major Changes to the Standard
- ✓ New ISO 9001 Requirements
- ✓ Quality Management Principles
- ✓ Reasons for / Benefits of Compliance
- ✓ Key Terms & Definitions
- ✓ ISO 9001 Requirements

Course Outline

- Introduction
- Reasons for Revision
- Major Changes
- New 9001 Requirements
- Quality Management Principles
- Reasons for Compliance
- Key Terms & Definitions
- ISO 9001 Requirements

The ISO 9000:2000 Overview module **is a must** for any organization looking to achieve certification to the ISO 9001 standard. The module is also applicable to those companies looking to comply with the ISO 9001 standard's requirements to meet customer requirements, organizational goals, etc.

Management commitment is critical to implementing an effective ISO 9001 compliant quality management system. As a result, the organization's management team is required to show its commitment through its actions as well as its words. Management must be willing to provide the resources needed to implement the system as well as be knowledgeable of the requirements that pertain to their area(s) of responsibility and authority. This module is ideal for communicating those requirements and fulfilling various training requirements mandated by the ISO 9001 standard.

The ISO 9000:2000 Overview module is designed to provide participants with a knowledge and understanding of the International Standards Organization (ISO) 9001 Quality Management System requirements. The module includes an introduction to the ISO 9000 series of standards and discusses some key terms and concept relationships referred to in the standard. The reasons for compliance or benefits associated with implementing and maintaining an ISO 9001 compliant quality management system are also highlighted.

An in-depth review of the ISO 9001 standard requirements is presented in simple, easy to understand language. Additionally, the quality management principles upon which the new standard is based and the "process approach" methodology to continual improvement and the prevention of non-conformity are reviewed.

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Introduction

- The ISO 9000 standards are a set of international quality management standards and guidelines.
- The ISO 9000 standards were initially published in 1987, were revised in 1994 and again in 2000.
- Technical Committee (TC) 176 is responsible for the revision to the standards.
- 53 participating member bodies and 10 observer members were involved in the revision process.

Documentation Requirements 4.2.2 Quality Manual

Establish and maintain a Quality Manual to include:

- Scope of QMS
- Justification for exclusions
- Documented procedures established or reference to them
- Description of the interaction between processes of the QMS

Documentation Requirements 4.2.2 Quality Manual - *Notes*

The scope of the QMS needs to be defined in the Quality Manual. The scope typically includes reference to this standard, other applicable requirements (e.g. industry, statutory, regulatory, etc.) and field of application.

Any justification for exclusions shall be defined and justified. Exclusions are limited to the requirements of Clause 7 of this standard.

Identify the documented procedures the organization has established for the QMS, of refer to them in the manual. If not listed directly or identified in the manual, a supporting document / procedure index is often referenced or included as an appendix.

Describe how QMS processes are connected. This may be addressed by describing the system for initiating and developing process plans. Process plans help to identify the activities and interactions needed to achieve an objective. A process plan may consist of or refer to a flowchart, project plan, quality plan, organization charts, device master record, or combination thereof. A process plan may include identification or reference to procedures, specifications, records, inputs and outputs, required resources such as personnel, equipment, training, skills, suppliers, responsibilities and authority, etc.