

# Understand and Install ISO 9001:2008

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| <b>Location of training:</b> | Your organization location   |
| <b>Duration of training:</b> | 1 day / 8 hours  |
| <b>Fees and Charges:</b>     | \$2,000.00 (plus expenses/if applies)  |
| <b>Number of Attendees:</b>  | Any number up to 20 attendees  |
| <b>Materials:</b>            | Electronic Training; Electronic Reference Manual   |
| <b>Dates:</b>                | To be arranged – suggested dates:  |
| <b>Terms:</b>                | Payment upon completion of course – Company check preferred<br>or Credit Card – Visa, Mastercard, American Express, and Discover |

## Training Topics

### 1. Introduction to ISO 9001 Standard

- The definition and history of Quality Standards
- The difference between ISO 9001:2008 and previous Standards
- The principles and impact of the ISO 9001 Standard
- The requirements of the ISO 9001 Standard

### 2. Understanding the Standard

- Understanding the clause structure
- Review of clause 4.0 Quality Management System
- Review of clause 5.0 Management Responsibility
- Review of clause 6.0 Resource Management
- Review of clause 7.0 Product Realization
- Review of clause 8.0 Measurement, Analysis and Improvement

### 3. Developing and installing the ISO 9001 Quality Management System (QMS)

- Prepare for the System documentation, including:
  - Evaluate current system maturity
  - Create a “To do list” for the installation
  - Understanding the requirements
  - Quality policy manual
  - Six Procedures required by the Standard
  - Additional process descriptions required by the organization for consistent operation
  - Forms and Records
- Strategy for achieving ISO certification
- Create a quality policy statement (clause 5.3)
- Describe the structure of the organization
- Establish departmental responsibilities

### 4. Preparing for certification

- Conduct internal audits
- Hold a management review meeting
- Corrective action management

# Documenting an ISO 9001 System

QRC

## Background

Before 2000, the major criticism of International Standards was that they “created a bureaucracy.” ISO 9001: 2008 provided an opportunity to change that reputation by advising that the extent of documentation should be dependent on:

- ❑ “The size of the organization and type of activities
- ❑ The complexity of processes and their interactions
- ❑ The competence of personnel”

## Training Topics

### 1. Reviewing what the Standard says

- An analysis of the ISO 9001 statements regarding documents and records

### 2. Establishing the present documentation status

- Identifying the present documentation structure
- Determining the accuracy of existing documents
- Discovering documents that exist but are not used
- Identifying documents that are needed but do not exist

### 3. Document Structure

- Creating a document structure that is suitable to the needs of the organization and meets the requirements of ISO 9001 Standards

### 4. Preparing the required documents

- Writing a Quality Manual that meets the requirements of the Standard and is a realistic description of the organization and its policies and goals
- Writing the six Procedures required by the Standard
- Revising existing documents, that are in use, to ISO 9001 compliance
- Working with Departments to develop process descriptions that are needed but do not exist
- Documenting Preventive, Detective and Corrective Controls for the processes
- Insuring that all processes are described at an appropriate level of detail for the users
- Cataloguing existing Forms and Records
- Obtaining approval for prepared documents
- Documents are “installed” when placed in use and any needed training is completed
- An ISO 9001 system is “implemented” when all personnel consistently follow documentation

### 5. Additional understandings

- ISO 9001 compliant Control of Documents Procedures and their implementation
- ISO 9001 compliant Control of Records Procedures and their implementation
- Monitoring the impact of Organic Change on the continued accuracy of the documents
- Controlling changes to the documents

**Return**