

Introduction to ISO 9001

ISO 9001: 2008

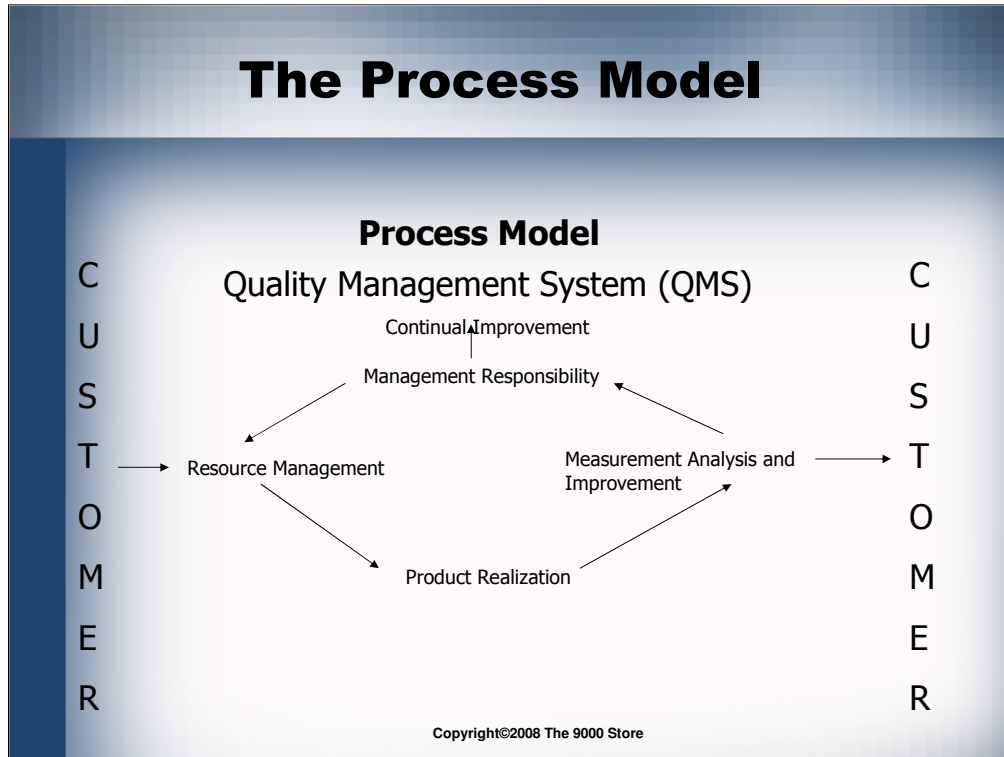
Copyright ©2008 The 9000 Store

Questions we will cover today:

- What is ISO 9001?
- What does a company need to do to Register to ISO 9001?
- What are the requirements?
 - Section 4 – General Requirements
 - Section 5 – Management Responsibility
 - Section 6 – Resource Management
 - Section 7 – Product Realization
 - Section 8 - Measurement, Analysis & Improvement
- What are our next steps?

Copyright©2008 The 9000 Store

The Process Model



This example of the process model is included in the standard.

The five clauses are all found on the process model.

Management Responsibility, Measurement Analysis and Improvement, Product Realization and Resource Management make a cycle.

The most important input to this cycle is customer requirements.

The output of the cycle is customer satisfaction and continual improvement of the quality system.

The standard has been organized around this model.

4.1 General Requirements

The organization will establish, document, implement, maintain and continually improve a Quality Management System (QMS)

- This is where we find the requirement to identify processes that need to be controlled, and determine how they interrelate
- The organization must also determine how to control any outsourced processes

Copyright©2008 The 9000 Store

This is where we find the requirement to:

- identify processes that need to be controlled, and
- determine how they interrelate.

Steps that need to be taken are:

- Identify the processes needed for the QMS
- Determine the sequence and interaction of these processes
- Determine criteria and methods required to ensure the effective operation and control of these processes
- Ensure the availability of information necessary to support the operation and monitoring of these processes
- Measure, monitor and analyze these processes and implement action necessary to achieve planned results and continual improvement

This section does not address the documentation of the processes. It focuses on the development and implementation of the process and goes on to require that they are managed and continually improved.

7.3 Design and Development

- Your procedure must outline your system including:
 - Design and Development planning
 - Design and Development inputs
 - Design and Development outputs
 - Design and Development review
 - Design and Development verification
 - Design and Development validation
 - Control of Design and Development changes

Copyright©2008 The 9000 Store

Your procedure will have a section for each of the items listed on the slide. You will need to state what your process is for each of these sections, and what your records are.

For design, it is good to establish a process where the plan becomes the outline for the project. It will identify responsibilities, what the inputs are, what the timeline is, who needs to be involved in design review, guidelines for when to hold design review meetings, how the verification and validation will take place.

Verification is checking to see if the design output meets design input.

Validation is checking to see if the design performs what it was intended to.

7.4 Purchasing

- Purchasing Information
 - Purchasing documents need to identify all the requirements relevant to what you are purchasing. For example:
 - Quality requirements
 - Identification of the item: specifications, catalogue number or other ID
 - Any required class or grade of product
 - Quantities and delivery dates

Copyright©2008 The 9000 Store

This clause refers to the information that you put on your PO or other purchase documents. The standard is more specific what quality requirements you put on, and asks for the following where appropriate:

- Requirements for approval of product
- Requirements for qualification of personnel
- Quality Management Systems requirements

8.5 Improvement

- Establish a corrective action procedure that includes:
 - Identifying nonconformities with the quality system, product, processes
 - Handling customer complaints
 - Identifying root cause, action to take to prevent reoccurrence
 - Implementing the action and following up to determine effectiveness of the action
 - Record results of corrective action

Copyright©2008 The 9000 Store

Corrective action is for investigating problems that have occurred, and taking action to prevent reoccurrence.

You must investigate root cause, what really made this happen? What can we do to prevent it from happening again?

After you have implemented this idea, follow-up to make sure it worked. Is the problem still happening? Or has it been prevented from happening again.

Record the problem, the root cause, the action taken, the effectiveness of the action, and the actual results of the corrective action.

The results of the corrective action is what actually happened after the corrective or preventive action was implemented. Did the problem occur again? Were you able to see measurable improvement? If so, how much? What date did the problem disappear?

Record the results that you observed when following up on the corrective action to determine effectiveness.

Next Steps

- Determine timeline for implementation
- Perform Gap Analysis Review how your existing quality system fits into ISO 9001:2008 format
- Put together an implementation plan and timeline
- Identify a Registrar

Copyright©2008 The 9000 Store

Each organization will have its own way to approach the implementation

Performing a gap analysis of your current system versus the requirements of the Standard will give you a task list to work from to plan your implementation project.

A good next step would be to identify and process map your key processes. The information you get from your Gap, combined with the process map and list of key processes should give you a good idea of what you will need to do to implement the standard. Then you can build a Gantt chart for the project, outlining the task you need to do and the documents you will need to get into place.