

Questions we will cover today:

- What is ISO 9001?
- Steps to registration
- Benefits of registration
- The Process Model/Process Approach
- What are the requirements of ISO 9001?

Steps to Registration

- A company must first implement the requirements of ISO 9001
 - Evaluate your current quality system
 - Add systems and processes to meet the requirements
 - Document your processes as a Quality Manual, Procedures and Work Instructions
 - Audit the system to ensure it is working as planned

4.2 Documentation Requirements

- Quality management system documentation must include:
 - Documented procedures required by the standard
 - Documents required by the organization for effective operation and process control
 - Quality policy and objectives

7.2 Customer-Related Processes

- Review requirements related to the product and make sure that you can meet them before accepting the contract
 - Find out what the customer expects
 - Document the requirements
 - Don't accept requirements that you cannot meet
 - If there are changes to the contract later, make sure they are communicated to all that they affect

7.5 Production & Service Provision

- Validation of processes for production and service
 - Process validation is required for special processes
 - Special processes are processes where the output or product cannot be tested or inspected to determine if the product conforms
 - The quality is ensured by validating the process, and qualifying the operator

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