ISO 9000:2000

- Quality system standards adopted in 1987 by International Organization for Standardization; revised in 1994 and 2000
- Technical specifications and criteria to be used as rules, guidelines, or definitions of characteristics to ensure that materials, products, processes, and services are fit for their purpose.

Objectives of ISO 9000 Standards

- Achieve, maintain, and improve product quality
- Improve quality of operations to continually meet customers' and stakeholders' needs
- Provide confidence to management, employees, customers, and stakeholders that quality requirements are fulfilled

ISO 9000 Key Characteristics

- Establishes a quality management system (QMS) to facilitates consistency
- It is not prescriptive; does not tell you “how” to do anything; specifies “what” processes need to be in place
- It is not a product standard
- It is not TQM
- It is site specific

ISO 9000:2000 Standards

- ISO 9000:2000, Quality Management Systems – Fundamentals and Vocabulary
- ISO 9001:2000, Quality Management Systems - Requirements
- ISO 9004:2000, Quality Management Systems – Guidelines for Performance Improvement

ISO 9000:2000 Quality Management Principles

1. Customer Focus
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual Approach to Decision Making
8. Mutually Beneficial Supplier Relationships

Structure of ISO 9000 Standards

- 21 elements organized into five major sections:
  - System Requirements
  - Management Responsibility
  - Resource Management
  - Product Realization
  - Measurement, Analysis, and Improvement

See Table 3.7

ISO 9001:2000 Requirements
(1 of 5)

- System Requirements
  - Establish a quality management system
  - Document the quality management system

ISO 9001:2000 Requirements
(2 of 5)

- Management Responsibility
  - Management Commitment
  - Customer Focus
  - Quality Policy
  - Planning
  - Administration
  - Management Review

ISO 9001:2000 Requirements
(3 of 5)

- Resource Management
  - Provision of Resources
  - Human Resources
  - Facilities
  - Work Environment

ISO 9001:2000 Requirements
(4 of 5)

- Product and/or Service Realization
  - Planning of Realization Processes
  - Customer-Related Processes
  - Design and/or Development
  - Purchasing
  - Production and Service Operations
  - Control of Measuring and Monitoring Devices

ISO 9001:2000 Requirements
(5 of 5)

- Measurement, Analysis, and Improvement
  - Planning
  - Measurement and Monitoring
  - Control of Nonconformity
  - Analysis of Data
  - Improvement

Documentation Levels of 9001:2000

- Manual (philosophy, policy, objectives, approach)
- Procedures
- Work instructions (department, product, process)
- Records (proof and objective evidence)
- Ad-hoc, temporary documents

ISO 9000 Certification Process
(1 of 2)

1. The company first implements the control and documentation procedures outlined in the series.
2. It then involves a thorough audit by an independent certification organization (i.e., a Registrar) that is licensed to register quality systems by an accreditation body (e.g., Registrar Accreditation Board in U.S.)

ISO 9000 Certification Process
(2 of 2)

3. Upon compliance, it receives a registration certificate and its name is included in a published directory of registered suppliers.
4. The systems will be continually verified by the registrar in periodic surveillance and full audits are conducted every few years.

ISO 9000 Certifications

- Through Dec. 2002, at least 561,747 ISO 9000 certifications have been issued in 159 countries and economies. In North America, 53,806 certifications were issued. In Europe, 292,970 certifications were issued – The ISO Survey
- Some beginning to question its usefulness

Potential Benefits of Registration *(1 of 2)*

- Documentation of quality management system
- Reduction of variation
- Help develop and expand business
- Reduction or elimination of customer audit
- Increased profitability/reduced costs

Potential Benefits of Registration *(2 of 2)*

- Improved communication, both internal and external
- Greater awareness of quality by employees
- Provision of training to all employees
- Ability to remain or become competitive
- Elimination of duplication of quality systems

Problems with Certification

- Costs - application & maintenance
- Time - application & maintenance
- Level of internal expertise
- Executive commitment
- Selection of registration