



ISO 9001

Quality System Requirements

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ISO 9001 Quality System Requirements

Purpose: This Presentation Describes the ISO 9001 Quality Management System Requirements.

Objectives:

- Overview of the ISO 9001 Series Standard**
- Specific Requirements of the ISO 9001 Series Standard**
- International Trade and the ISO 9001 Series Standard**
- Involvement with the ISO 9001 Series Standard**
- Conclusions**

Definition of Quality

ISO 9000 Definition

“Degree to which a set of inherent characteristics fulfills requirements”

Note: requirements can be stated or implied.

ISO 9001 Standard Used to Assure Quality

What you would get from 99.9% suppliers:

At least 20,000 wrong prescriptions per year.

Unsafe drinking water one hour per month.

No electricity, water or heat for 8.6 hours per year.

No phone service for 10 minutes each week.

Two crashes at each major airport per day.

500 incorrect surgical operations per week.

2,000 lost articles of mail per hour.

Original source unknown

The ISO 9001 Standard

- **Overviews Quality System Guidelines**
- **Internationally Recognized Quality Standards**
- **Applicable to All Organizations in All Industry/Service Areas**
- **Allows for Certification by a Third Party**
- **Identifies Required Quality Policy and Procedures**

ISO 9001

Series Standard assures...

Qualitivity, Inc.

That all business processes are:

Strategically planned and documented

with properly maintained records

with ... immediate corrective action

Benefits of ISO 9001 Standard

- Promotes International Trade
- Prevents Trade Barriers
- Translates to a Common Quality Language
- Establishes Consistent Quality Disciplines
- Minimizes Customer Audits
- Provide Contractual Documents

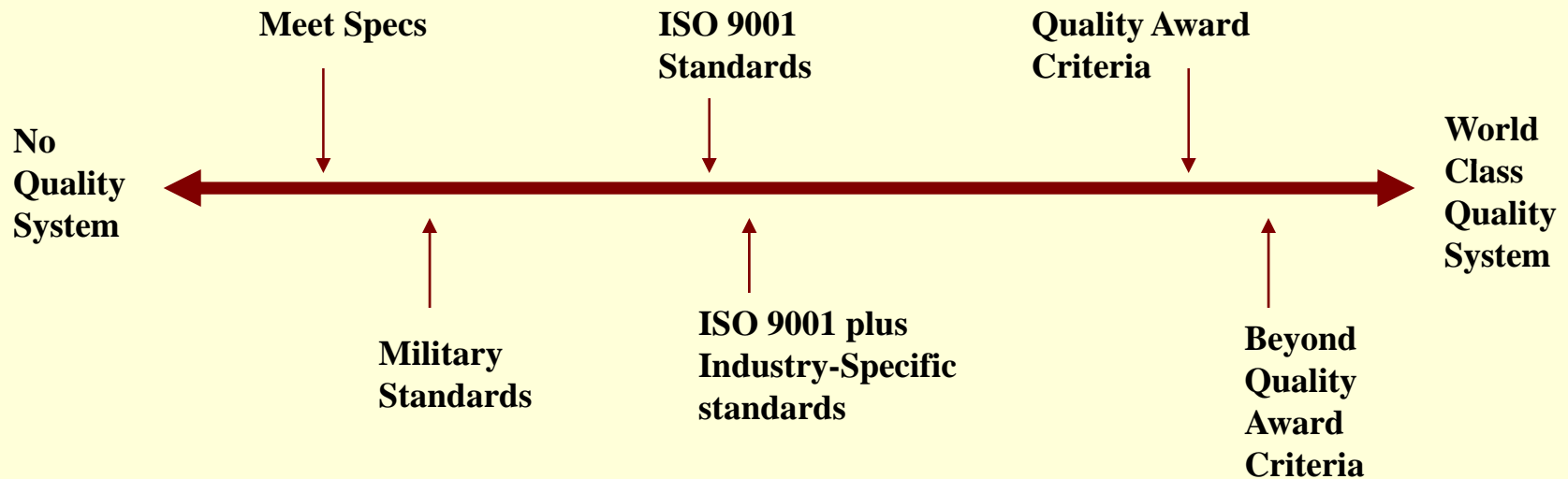
When is ISO 9001 Required?

- **Regulatory Requirements -**
 - International regulations, laws or agreements may require ISO 9001.

- **Customer Requirements -**
 - Prefer to deal only with certified suppliers
 - Must use only certified suppliers to manufacture products to be sold in ISO participating countries.

ISO 9001 Comparison

ISO 9001 and Other Quality System Criteria



ISO 9001 Comparison

From MIL-SPECS to the ISO 9001 Standard

MIL-STD-45208A

MIL-Q-9858

**Management Responsibilities, Continual Improvement,
Installation and Service**

ISO 9001 Comparison

From the ISO 9000 Series Standard to the Malcolm Baldrige National Quality Award

Malcolm Baldrige National Quality Award would be nice to have.

ISO 9000 International Standards for Quality Management is often required to do business.

International Trade

Use the ISO 9001 Standard as a Means to Begin Entry Into International Trade as Well as to Provide Recognition for the Quality System of Your Organization.

Companies Must:

- Understand ISO 9001
- Understand the Internal Situation
- Have a Work Team Strategy
- Have Flow Charts and Required Procedures

What is ISO?

- **International Organization for Standardization**
- **Founded in 1946**
- **Goal to Develop Harmonized Standards in Support of International Trade**
- **Based in Geneva, Switzerland**
- **Who are Members? (aprox. 90 countries)**
- **Member Nations Promote Harmonized Standards**
- **United States Representative is the American National Standards Institute (ANSI)**
- **Greek Prefix (iso) Means Equal**

What is the ISO 9001 Standard?

International Standards for Quality Management and Quality Assurance.

- **Follows a Generic Approach Not Specific to any Product, Service or Industry.**

Specific Requirements of ISO 9001

ISO 9001 Requirements Detail

Qualitivity, Inc.

- 4.0 Quality Management System
 - 4.1 General
 - 4.2 Documentation Requirements
- 5.0 Management Responsibilities
 - 5.1 Management Commitment
 - 5.2 Customer Focus
 - 5.3 Quality Policy
 - 5.4 Planning
 - 5.5 Responsibility, Authority and Communication
 - 5.6 Management Review
- 6.0 Resource Management
 - 6.1 Provision of Resources
 - 6.2 Human Resources
 - 6.3 Infrastructure
 - 6.4 Work Environment
- 7.0 Product Realization
 - 7.1 Planning of Product Realization
 - 7.2 Customer Related Processes
 - 7.3 Design and Development
 - 7.4 Purchasing
 - 7.5 Production and Service Provision
 - 7.6 Control of Monitoring and Measuring Devices
- 8.0 Measurement, Analysis and Improvement
 - 8.1 General
 - 8.2 Monitoring and Measurement
 - 8.3 Control of Nonconforming Product
 - 8.4 Analysis of Data
 - 8.5 Improvement

4.0 Quality Management System

- **General Requirements**
- **Documentation Requirements**
- **Mandatory Procedures**
 - Control of Documents 4.2.3
 - Control of Records 4.2.4
 - Internal Audits 8.2.2
 - Control of Nonconforming Product 8.3
 - Corrective Action 8.5.2
 - Preventive Action 8.5.3

4.1 General Requirements

- **Identify Processes and Applications**
- **Determine Sequence and Interaction**
- **Determine Operation and Control Criteria and Methods**
- **Ensures Availability of Resources**
- **Monitor, Measure and Analyze**
- **Implement Process and Improvements**
- **Manage and Control Outsourced Processes**

4.2 Documentation Requirements

- **Quality Manual**
- **Quality Policy and Objectives**
- **Procedures as Required**
- **Control of Records**

5.0 Management Responsibility

- **Management Commitment**
- **Customer Focus**
- **Quality Policy**
- **Planning**
- **Responsibility, Authority and Communication**
- **Management Review**
- **Management Representative**
- **Internal Communication**

6.0 Resource Management

- **Provision of Resources**
- **Human Resources**
- **Infrastructure and Maintenance**
- **Work Environment**

7.0 Product Realization

- **Planning of Product Realization**
- **Customer-related Processes**
- **Design and Development**
- **Purchasing**
- **Production and Service Provision**
- **Control of Monitoring and Measuring Devices**

SPECIAL NOTE: The requirements listed in Section 7 can be excluded from the audit if justified.

7.1 Planning of Product Realization

- **Requires Determining the Following:**
 - Quality Objectives and Product Requirements
 - Establishment of Processes, Documents and Resources
 - Requirement for Verification, Validation, Monitoring, Inspection and Test Activities
 - Records Required

7.2 Customer-Related Processes

- **Determine Requirement Related to Product**
- **Statutory and Regulatory Requirements**
- **Review Requirements Prior to Quotation**
- **Differences Resolved Before Order Acceptance**
- **Customer Communication**
- **Customer Feedback Including Complaints**
- **Changes to Contract Need Controls**
- **Records**

7.3 Design and Development

- **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**

7.4 Purchasing

- **Purchasing Process**
- **Purchasing Information**
- **Verification of Purchased Product**
- **Supplier Selection and Approval**
- **Records**

7.5 Production and Service Provision

- ***Control of Production and Service***
- ***Validation of Processes and Equipment***
- ***Approval of Equipment and Qualification of Personnel***
- ***Defined Criteria and Workmanship Standards***
- **Identification and Traceability**
- **Customer Property**
- **Preservation of Product**
- **Records**

7.5 Production and Service Provision (continued)

- Control of Production and Service
- Validation of Processes and Equipment
- Approval of Equipment and Qualification of Personnel
- Defined Criteria and Workmanship Standards
- ***Identification and Traceability***
- Customer Property
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7.5 Production and Service Provision (*continued*)

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7.5 Production and Service Provision (*continued*)

- **Control of Production and Service**
- **Validation of Processes and Equipment**
- **Approval of Equipment and Qualification of Personnel**
- **Defined Criteria and Workmanship Standards**
- **Identification and Traceability**
- **Customer Property**
- ***Preservation of Product***
- **Records**

7.6 Control of Monitoring and Measuring Devices

- **Calibration**
- **Identify Calibration Status**
- **Safeguard**
- **Protect From Damage**
- **Record Validity of Measurements If Faulty Gage is Found**
- **Computer Software**
- **Records**

8.0 Measurement Analysis and Improvement

- **General**
- **Monitoring and Measurement**
- **Control of Nonconforming Product**
- **Analysis of Data**
- **Improvement**

8.1 General

- **Demonstrate Product Meets Requirements**
- **Ensure Quality Management System Meets ISO 9001 and Customer Requirements**
- **Continual Improvement of Effectiveness**

8.2 Monitoring and Measurement

- **Customer Satisfaction**
- **Internal Audit**
- **Monitor and Measure Processes**
- **Monitor and Measure Product**
- **Product Cannot Be Released Until Process is Complete**
- **Records**

8.3 Control of Nonconforming Product

- **Identify and Control**
- **Prevent Unintended Use or Delivery**
- **Documented Procedure**
- **Repair and Rework is Re-Inspected**
- **Records**

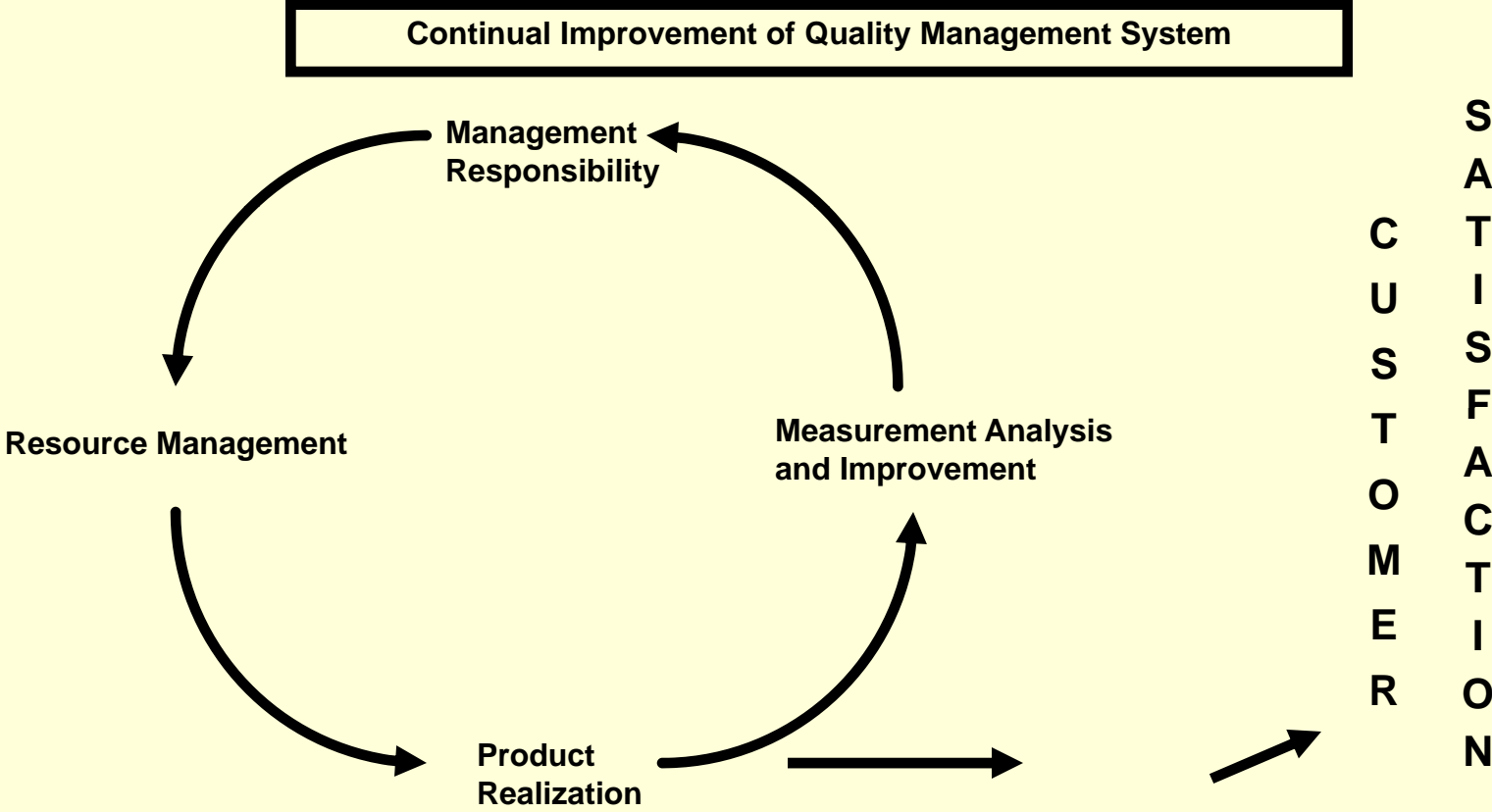
8.4 Analysis of Data

- **Determine, Collect and Analyze Data**
- **Customer Satisfaction**
- **Product Conformity**
- **Trends and Opportunities for Preventive Action**
- **Suppliers**

8.5 Improvement

- **Continual Improvement**
- **Corrective Action**
- **Preventive Action**
- **Documented Procedure**
- **Records**

Process Based Quality Management System



Approach to Implementing an ISO 9000 Series Program:

- **Management Accepts, Acknowledges and Understands ISO 9001 Standard**
- **Management Commits to ISO 9001 Management Responsibilities**
- **Provide Continuous Review and Audit of Quality System**
- **Maintain a Quality Improvement Plan**
- **Adhere to Quality System Requirements in Policy and Procedures**

Implementing ISO 9001 Program (continued)

Management Representative Coordinates Efforts

- Everyone Knows Quality Policy

Auditors of the certifying agency may ask all employees questions regarding their role in the ISO 9001 program.

- Prepare for Semi-annual or Annual Audit
- Everyone Must Have Knowledge of Quality
- ISO Efforts Need to be Company-wide

Why Implement ISO 9001?

- **Market Advantage**
- **Product Quality Improvement**
- **Each Employee Will Benefit**

Implementation of the System

Implementation of the ISO 9001 Series Standard requires trained and experienced personnel empowered to get the job done.

***Even if you are on the right track,
you'll get run over if you just sit there.***

Will Rogers.

Worldwide Recognition

**International Trade
and the ISO 9001 Series
Standard**

What is Driving ISO 9001 Forward?

- **Global Competition**
- **The European Community**
- **Quality Competitive Advantage**
- **Quality Ensured by Third Party Registrar**

ISO 9001 Standard Maintenance

- **Revised Approximately Every Five Years**
- **Comments From Users Encouraged**
- **Future Revision Effective When Published**

Team Participation

Involvement With the ISO 9001 Standard

ISO 9001 Implementation

**Does Your Organization
Want to Become
Certified to ISO 9001?**

ISO 9001 Implementation

ISO 9001

*After the Approval is
Received, Can We Relax?*

- **Quality System Basis is Continual Improvement**
- **Need to Continue to Meet ISO 9001**
- **Approval Agency Comes Back to Verify Compliance**

Statistical Process Control

- **Continual Quality Improvement**
- **Pareto Chart for Corrective Action**
- **Product and Process Quality Index**
- **Six Sigma Quality Methods**

ISO 9001 Implementation

How Do Registrars Work?

- USA
- United Kingdom
- International
- European

ISO 9001 Implementation

Auditor Attributes

- **Auditor Represents Management**
- **Maintain Professional and Positive Attitude**
- **Be Prepared for Audit**
- **Maintain Control of Situation**
- **Ask Questions, Not Statements**
- **Listen Attentively to Responses**

ISO 9001 Implementation

Auditor is a Fact Finder

Relax Person Being Audited

Avoid Arguments

Do Not Offer Opinions

Avoid Suggestions

Gather The Information

ISO 9001 Implementation

Person Being Audited

- **Maintain a Professional and Positive Attitude**
- **Be Prepared for Audit**
- **Know Work Instructions and Quality Policy**
- **Understand Corrective Action**
- **Do Not Volunteer Information**

ISO 9001 Implementation

Conclusions

- **ISO 9001 Standard is Here to Stay**
- **Customers are Demanding it**
- **Understand ISO 9001 International Standards for Quality**

ISO 9001 Overview Test

1. ISO stands for

- a. The International Organization for Standardization.
- b. The International Specifications Organization.
- c. The International Opera.
- d. None of the above.

2. Which of the following are requirements of 7.6 Control of Monitoring and Measuring Devices?

- a. Calibration activities.
- b. Identification of calibration status.
- c. Computer software validation.
- d. All of the above.

Problem Solving Test

3. ISO 9000:2000 defines quality as the degree to which a set of inherent characteristics fulfills

- a. Profitability.
- b. Requirements.
- c. Actions.
- d. Reactions.

4. For which of the following activities does ISO 9001:2000 require a documented procedure?

- a. Control of Documents.
- b. Internal Audits.
- c. Corrective Action.
- d. All of the above.

Problem Solving Test

5. The auditor is a fact finder and during the audit process they should do all of the following except

- a. Relax the person being audited.
- b. Argue aggressively to make sure a point is understood.
- c. Avoid suggestions.
- d. Do not offer opinions.

6. The person being audited is required to

- a. Maintain a positive and professional attitude.
- b. Be prepared for the audit.
- c. Understand corrective action.
- d. All of the above.

Problem Solving Test

7. The ISO 9001 Standard is revised approximately every

- a. 3 years.
- b. 7 years.
- c. year.
- d. 5 years.

8. If justified, requirements of ISO 9001 can be excluded but only from

- a. Section 4.
- b. Section 5.
- c. Section 7.
- d. Section 8.

Problem Solving Test

9. All of the following are good auditor attributes except

- a. Listening attentively to responses.
- b. Maintaining a professional and positive attitude.
- c. Being biased in judgment and becoming opinionated.
- d. Being prepared for the audit.

10. A benefit of the ISO 9001 Quality Management System requirements includes

- a. A common quality language.
- b. Minimizing customer audits.
- c. Consistent quality disciplines.
- d. All of the above.

EMPLAST QUALITY POLICY

QUALITY POLICY (Sample)

"We, the employees of the organization, through continual improvement of our quality management system and objectives, commit ourselves to be quality focused and customer driven by striving to provide defect-free plastic products with the highest level of service, on-time delivery, and customer satisfaction."

Core Management Group

QUALITY OBJECTIVES

To fulfill its internal organizational goals, the company has established quality objectives to:

1. To maintain and continually improve the quality of our products and services.
2. To offer products and services that meets or exceeds our customers' expectations for quality, performance, dependability and overall value.
3. To reduce waste and inefficiency in our operations.
4. To meet the delivery requirements established by our customers.