

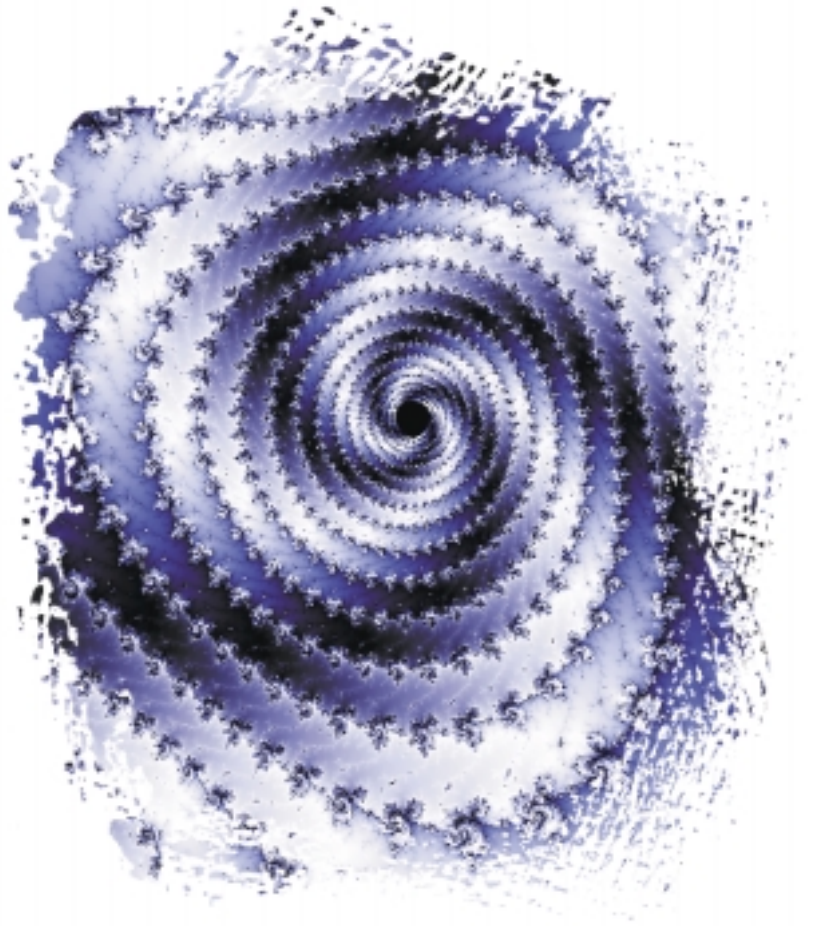
ISO 9001

# The Standard Illustrations

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The International Standard for  
Quality Management Systems



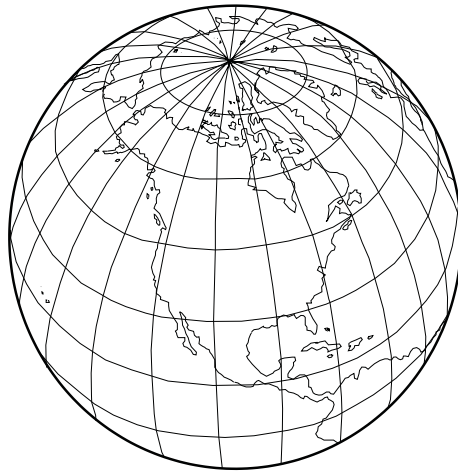
Year 2000 Edition

Leland R. Beaumont

# ISO 9001, The Standard Illustrations

Figures excerpted from  
ISO 9001, The Standard Interpretation  
Third Edition

by Leland R. Beaumont



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# ISO 9001, The Standard Illustrations

The International Standard for  
Quality Management Systems

**By Leland R. Beaumont**

**Published by**  
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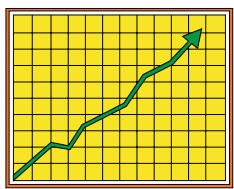
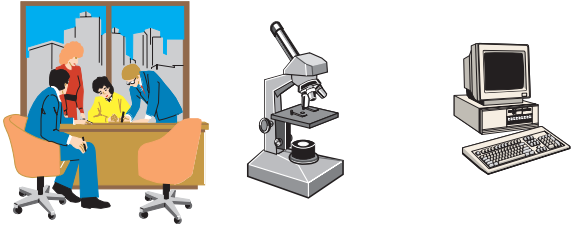
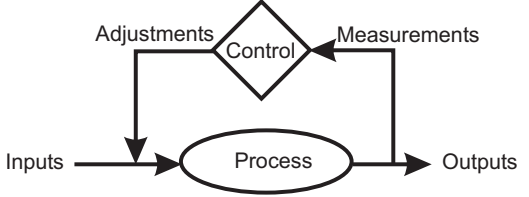
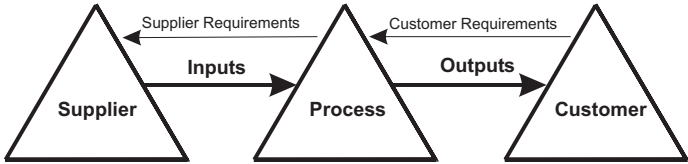
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Printed in the United States of America

Published March 17, 2002

Other books by this author, published by Simply Quality:  
*ISO 9001, The Standard Interpretation*  
*ISO 9001, The Standard Companion*

# 4.1 General Requirements for the Quality Management System

- Establish, document, and implement a quality management system and continually improve its effectiveness.
- Identify the processes needed to perform the work.
- Determine how these processes are applied throughout the organization.
- Determine their sequence and interaction.
- Determine how the effective operation and control of these processes will be ensured.
- Monitor, measure, and analyze these processes.
- Make available the materials, people, skills, equipment, time, and information needed to operate and monitor these processes.
- Work to achieve the planned results from these processes.
- Continually improve the operation of these processes.



## 4.2 Documented Quality System

**This type of document . . .**

**Fulfills these requirements . . .**

### Quality Policy

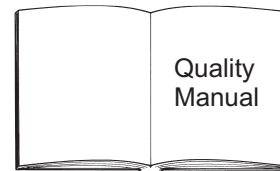
- Defines commitment to quality by top management
- Authorizes the organization to comply with requirements and continually improve



- Is defined and reviewed by top management (5.1)
- Establishes appropriate commitment to quality (5.3a,b)
- Provides framework for setting quality objectives (5.3c)

### Quality Manual

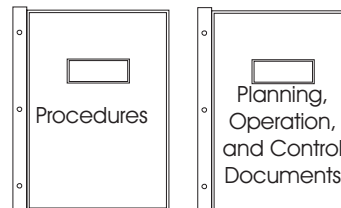
- Defines the scope of the quality management system
- Outlines documentation related to the Standard



- Describes the scope of the quality management system
- Includes or references documented procedures
- Describes how processes interact to form the quality management system

### Documented Procedures

- To meet all the requirements of the Standard
- Others needed for planning, operation and control of processes



- Interact to form an effective quality management system (4.1)
- Referenced by the quality manual (4.2.2)
- Authorized prior to distribution (4.2.3a)

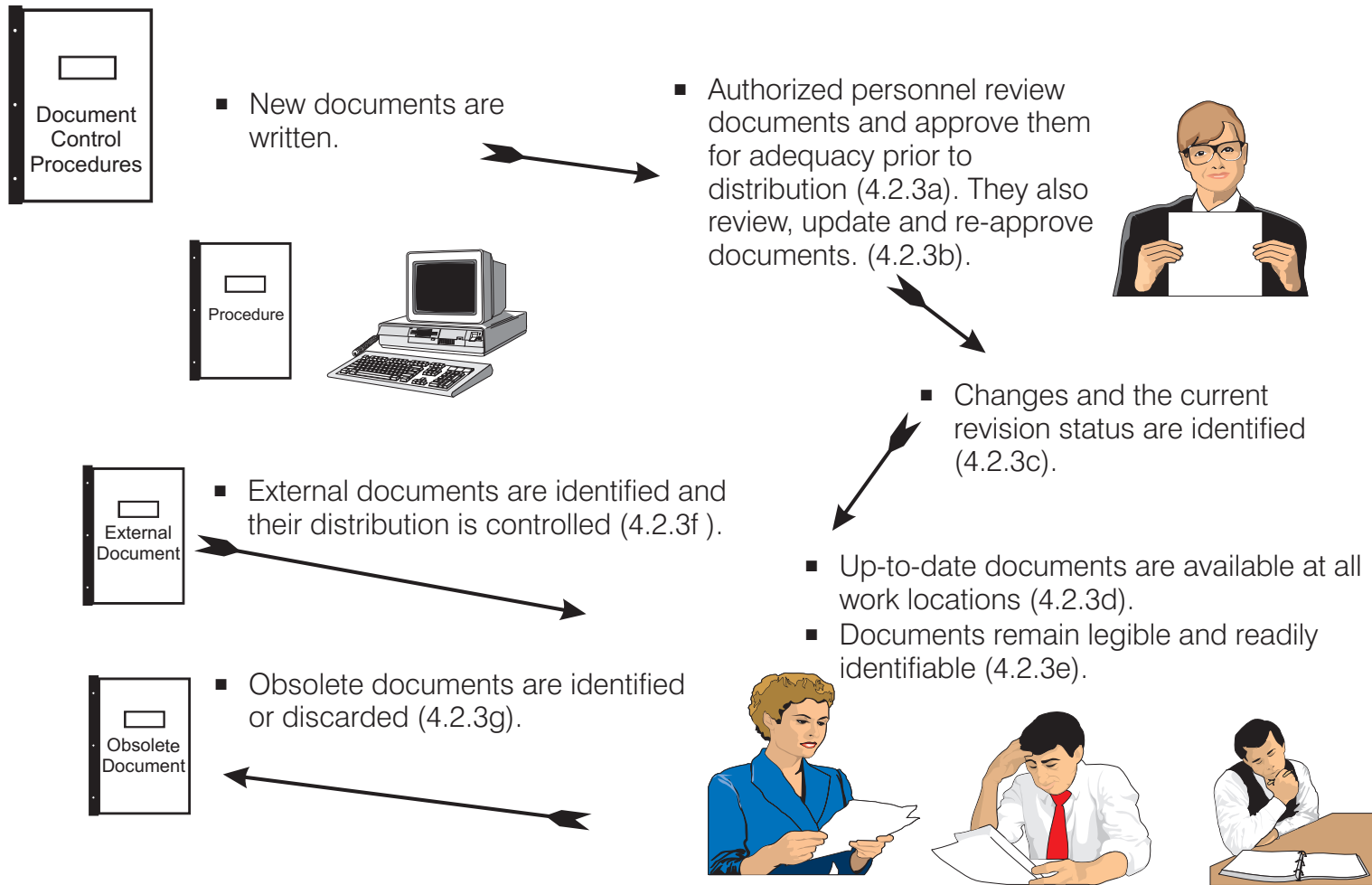
### Records

- Result from use of the system



- Are legible, readily identified, stored, protected, readily retrievable, with defined retention times and disposition (4.2.4)

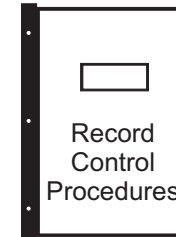
## 4.2.3 Document Control System



## 4.2.4 Records Control System

### Demonstrates

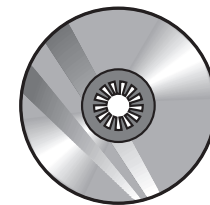
- Conformance to requirements
- Effective operation of the quality management system



- Legible
- Readily identifiable
- Readily retrievable



- Identified
- Stored
- Protected
- Retrievable
- Defined retention time



- May be on electronic media

# 5 Management Responsibility

## 5.1 Management Responsibility

- Communicate the importance of meeting requirements
- Establish the quality policy
- Establish quality objectives
- Conduct management reviews
- Provide adequate resources



## 5.2 Customer Focus

- Understand and meet customer requirements
- Enhance customer satisfaction



## 5.3 Quality Policy

- Appropriate to the purpose of the organization
- Includes a commitment to meet requirements and improve quality system
- Helps establish and review quality objectives
- Is communicated and understood throughout the organization
- Is reviewed and evolves to remain suitable

## 5.4 Planning

## 5.5 Responsibility, Authority and Communication

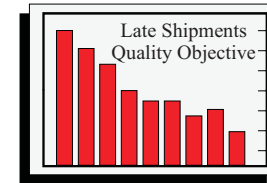
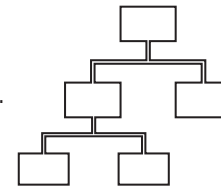
## 5.6 Management Review



## 5.4 Planning

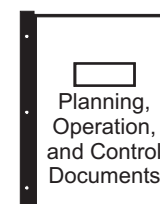
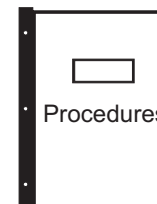
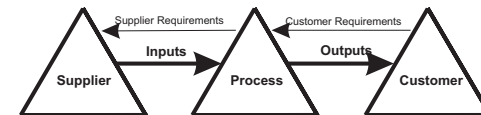
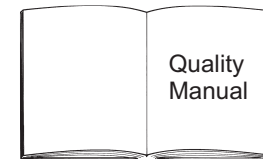
### 5.4.1 Establish Quality Objectives

- Objectives are established for all relevant functions and levels.
- Product objectives are included (see 7.1a).
- Objectives can be measured.
- Objectives are consistent with the quality policy.



### 5.4.2 Plan the Quality System

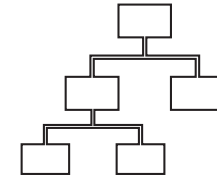
- Top management ensures that the quality management system plans include all the general requirements for the quality management system described in section 4.1.
- Top management also ensures that the current quality management system continues to work effectively while changes and improvements to it are being planned and carried out.



## 5.5 Responsibility, Authority and Communication

### 5.5.1 Responsibility and Authority

- Responsibility and authority is defined for people whose work affects product and service quality.
- This responsibility and authority is communicated within the organization.



### 5.5.2 Management Representative

- Is a manager appointed by top management
- Ensures that quality management processes are established, implemented and maintained
- Reports to top management on the performance of the quality management system
- Identifies and reports to top management on any need to improve the quality management system
- Ensures that members of the organization are aware of customer requirements
- May act as liaison to the registration agency and other external organizations regarding the quality management system



### 5.5.3 Internal Communication

- Appropriate channels of communication are established.
- Communication regarding the effectiveness of the quality management system takes place.



## 5.6 Management Review

### 5.6.1 General Management Review Requirements

Top management reviews the quality management system:

- At planned intervals
- To ensure its continuing suitability, adequacy, and effectiveness
- To assess opportunities for improvement and the need for changes in the quality management system; including the quality policy and quality objectives

### 5.6.2 Review Input

Management reviews Information regarding:

- Audit Results
- Customer Feedback
- Process performance
- Product conformity
- Preventive and corrective action status
- Follow-up actions from previous reviews
- Changes that could affect the quality management system
- Recommendations for improvement



### 5.6.3 Review Output

Results are decisions and actions regarding:

- Improvement of the effectiveness of the quality management system
- Improvement of product to better meet customer requirements
- Needed resources

# 6 Resource Management

## 6.1 Provide Resources

- To implement and maintain the quality management system
- To continually improve effectiveness of the quality management system
- To enhance customer satisfaction by meeting customer requirements



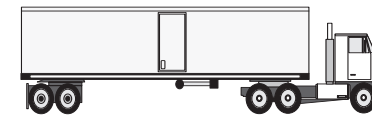
## 6.2 Provide Competent People



## 6.3 Infrastructure

Determine, provide and maintain infrastructure, including:

- Buildings, workspace and associated utilities
- Process equipment, including hardware and software
- Supporting services, such as transport or communication, as needed to conform to product requirements



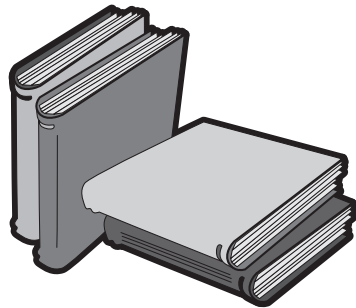
## 6.4 Work Environment

- Determine and manage the work environment needed to meet product requirements.

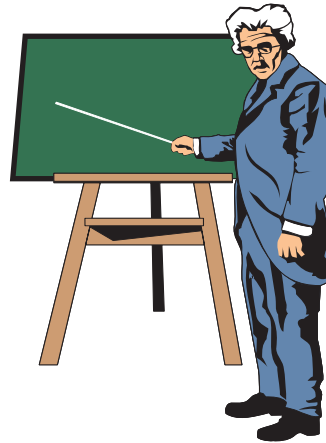


## 6.2 Human Resources

People whose work affects product or service quality must be competent for that work, based on education, training, skills, and experience.



- Identify required competencies, including training needs.



- Satisfy competency requirements through training or other actions.
- Evaluate the effectiveness of these actions.
- Make certain that people understand how their work contributes to quality objectives.



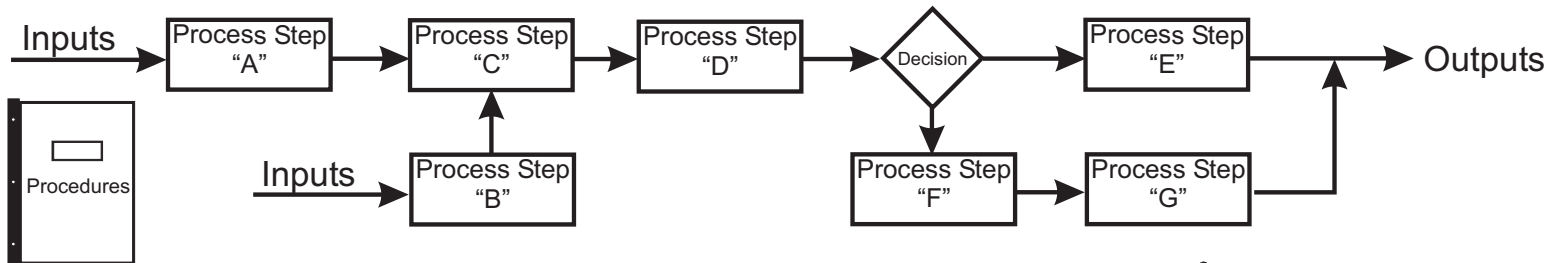
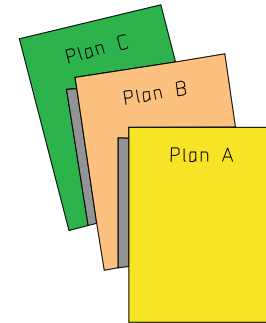
- Maintain records of training, skills and experience.

# 7.1 Planning Production Processes

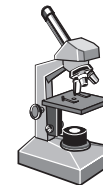
- Plan and develop processes needed to create products and deliver service.
- Plan these processes as part of the quality management system.

Determine:

- Quality objectives
- Processes, documents, and resources



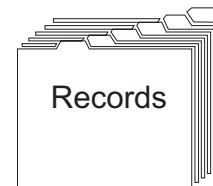
- Verification, validation, monitoring, inspection, and test activities



- Acceptance Criteria



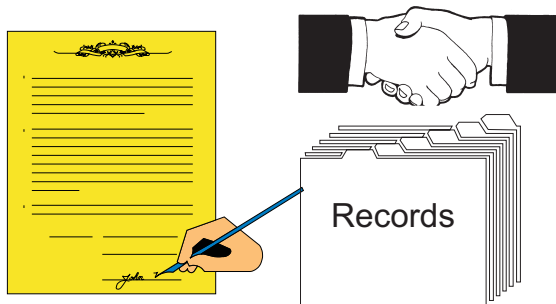
- Records of Conformity



## 7.2 Customer Relationship Processes

### 7.2.1 Identify Product Requirements

- Requirements specified by the customer
- Expected requirements unstated by the customer
- Legal and regulatory requirements
- Any additional requirements



### 7.2.2 Review Product Requirements

Before committing to provide product, ensure that:

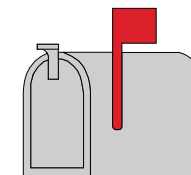
- Product requirements are defined.
- Contract or order changes are understood and resolved.
- The organization has the ability to meet the requirements.

Keep records of the requirements review.

### 7.2.3 Establish Customer Communication

Establish effective communications with the customer regarding:

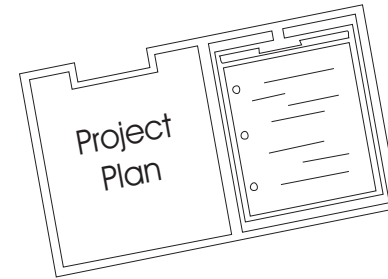
- Product information
- Inquiries, contracts, order handling, job order changes
- Customer feedback and complaints



## 7.3 Design Control System

### 7.3.1 Plan the design and development process

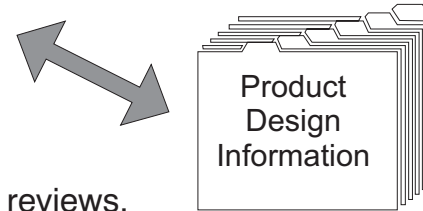
- Development stages, review, verification, and validation activities
- Responsibilities and authorities
- Identification of the organizations involved in design and development
- Description of information flow to carry out the design project
- Transmission of the necessary information among organizations



**7.3.2** Create clear design input requirements — written, complete, clear, reviewed. Include function and performance requirements, as well as statutory, regulatory, and other essential requirements.



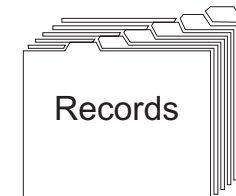
**7.3.3** Create design output that meets design stage input requirements and can be verified against those requirements.



**7.3.4** Review design results with representatives concerned with the design stage. Record these reviews.



**7.3.5** Verify the design to establish that design output meets design input requirements. Record the results.



**7.3.6** Validate that the product meets known user needs and requirements. Record the results.



**7.3.7** Review, evaluate, approve and record all design changes.





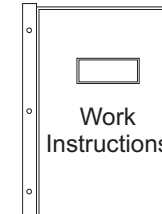
## 7.5.1 Production Process Control

Carry out production and service processes under controlled conditions.

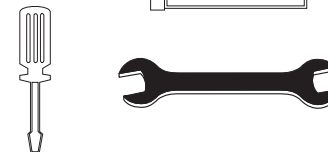
- Information that describes product characteristics is available



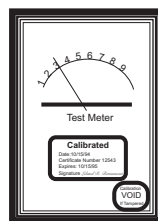
- Documented work instructions define the manner of production, installation, and servicing as needed



- Suitable production, installation, and servicing equipment

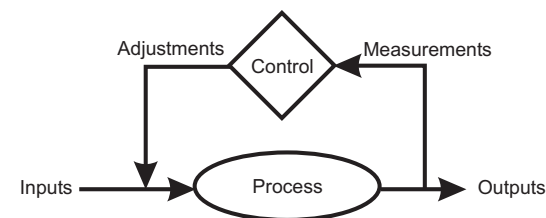


- Availability and proper use of monitoring and measuring devices



- Process parameters and product characteristics are monitored and measured

- Authorization to release the product for shipping
- Follow through on product delivery and post-delivery activities



## 7.5.2 Validate Special Processes

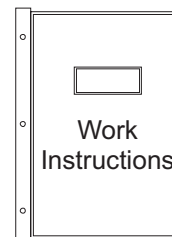
- Identify all “special processes” — where deficiencies become apparent only after delivery or use.
- Validate all of these “special processes” to demonstrate their ability to achieve planned results.
- Establish how each process will be validated, using the following methods as applicable.

- Review and approve process design and implementation.



- Approve equipment and selection of qualified personnel.

- Use specific methods and procedures.
- Establish requirements for record keeping.
- Have criteria for revalidating the process capability.



### 7.5.3 Identify Product Throughout Production

Pending Test    
  Passed    
 Failed    
 27 Pounds

Identify product testing, measurement, and monitoring status if required by:

- The customer
- Regulatory requirements
- Industry practice

Identify the Product from the time it is received and during all stages of production, delivery and installation.



<u>Serial No.</u>	<u>Batch No.</u>	<u>Shift</u>	<u>Operator</u>	<u>Inspector</u>	<u>Shipper</u>	<u>Hospital</u>
123	55872	Third	Jones	Smith	UPS	Doctors
124	55873	Second	Doe	Wesson	UPS	General
125	55874	Second	Doe	Smith	FedEx	Doctors

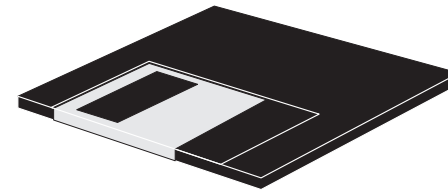
## 7.5.4 Protect Customer-Owned Property



Customer intellectual property



Customer-provided equipment or materials



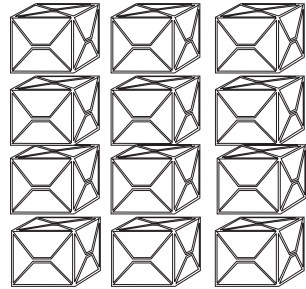
Customer-provided software

Customer-provided shipping systems

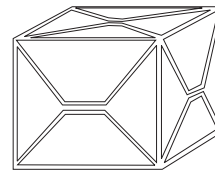


- Identify, verify, protect, and safeguard customer-supplied product for use in the final product.
- Record and report to the customer any lost, damaged, or unsuitable product.

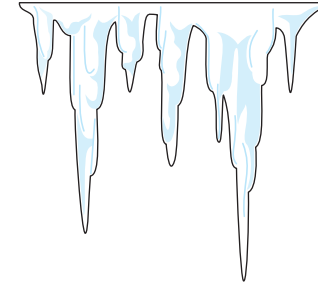
## 7.5.5 Product Preservation



- Prevent damage or deterioration during processing and storage.



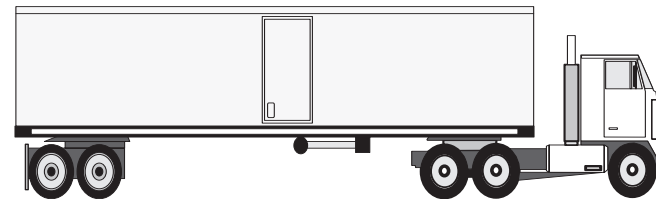
- Control product packaging.



- Preserve the product.

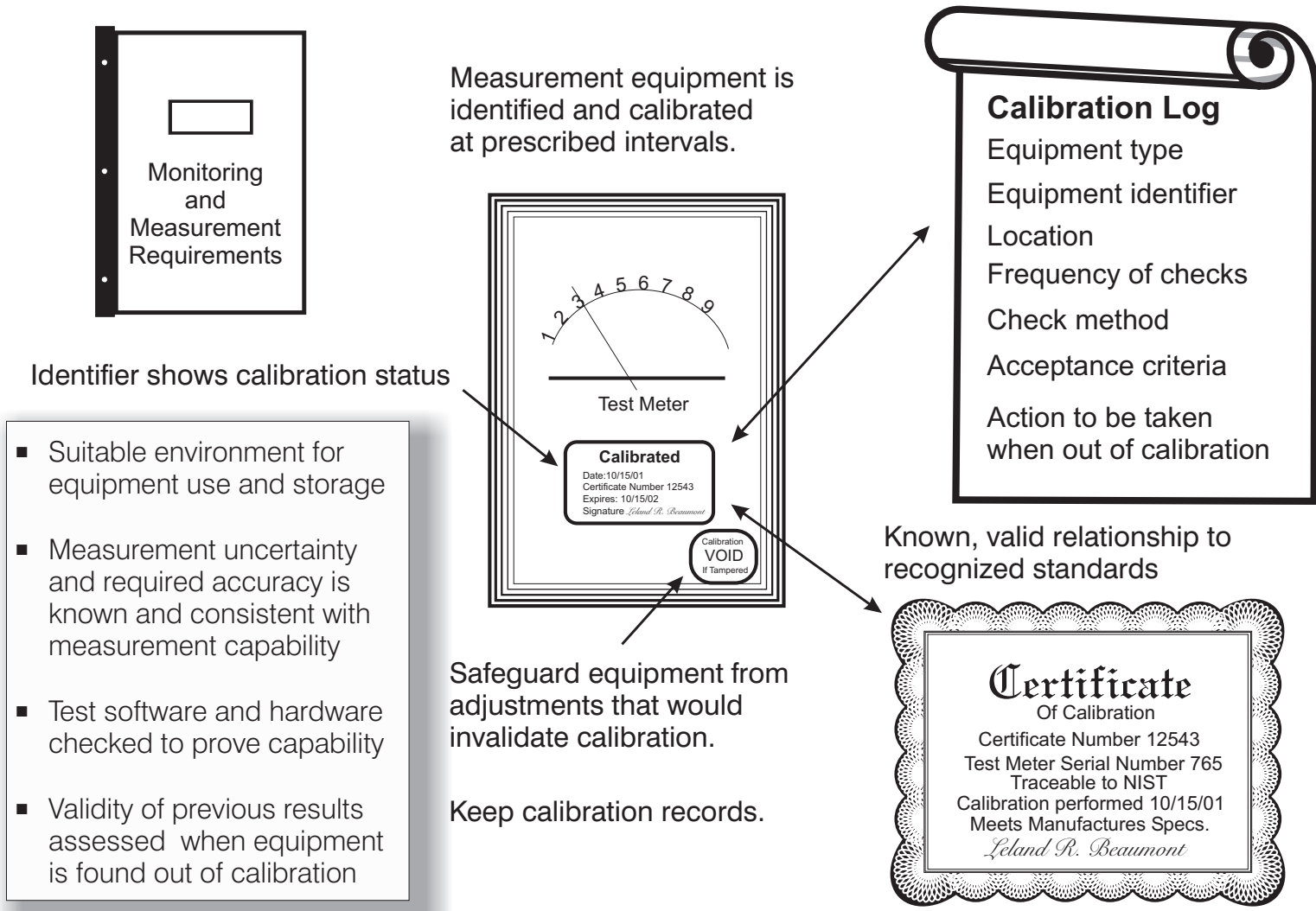


- Prevent damage during product handling.



- Protect product during delivery.

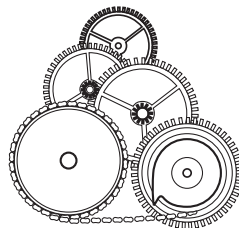
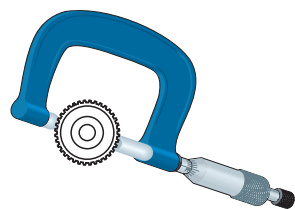
## 7.6 Measurement Control System



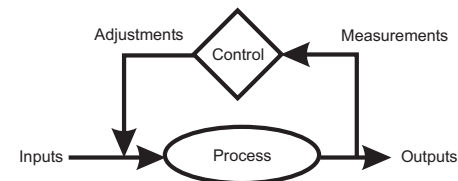
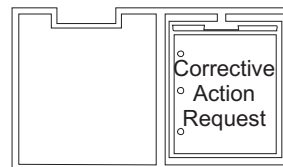
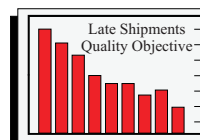
## 8.1 Measure, Understand and Improve

Plan and carry out inspection, testing, measurement, analysis, and improvement processes.

- Demonstrate that products and services meet defined requirements.



- Sustain the effectiveness of the quality management system.
- Continually improve the effectiveness of the quality management system.







## 8.2.2 Internal Audit System

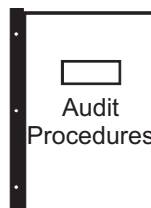
- Determine if quality activities and related results comply with planned arrangements.
- Determine the effectiveness of the quality management system.

January 1995						
Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

- Schedule audits on the basis of status and importance of the activity being audited.
- Consider results of previous audits.
- Define criteria, scope, frequency, and method.

### Auditors:

- Follow a defined procedure.
- Observe work practices.
- Examine records.
- Identify nonconformities.

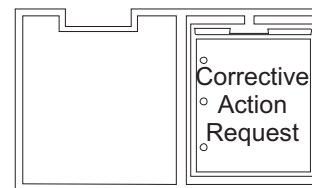


### Audit results are:

- Recorded.
- Brought to the attention of those having responsibility for the area audited.
- Corrective and preventive action is taken promptly.
- Follow-up ensures improvement.

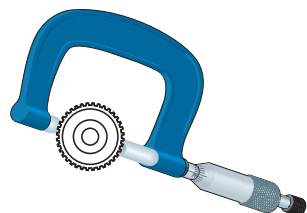
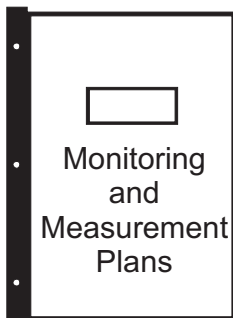


- Top Management reviews the effectiveness of the quality management system (5.6).

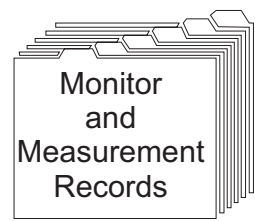


## 8.2.4 Monitoring and Measuring Products

Plan and carry out inspection, test, and measurement of product and service characteristic at all appropriate stages of production.

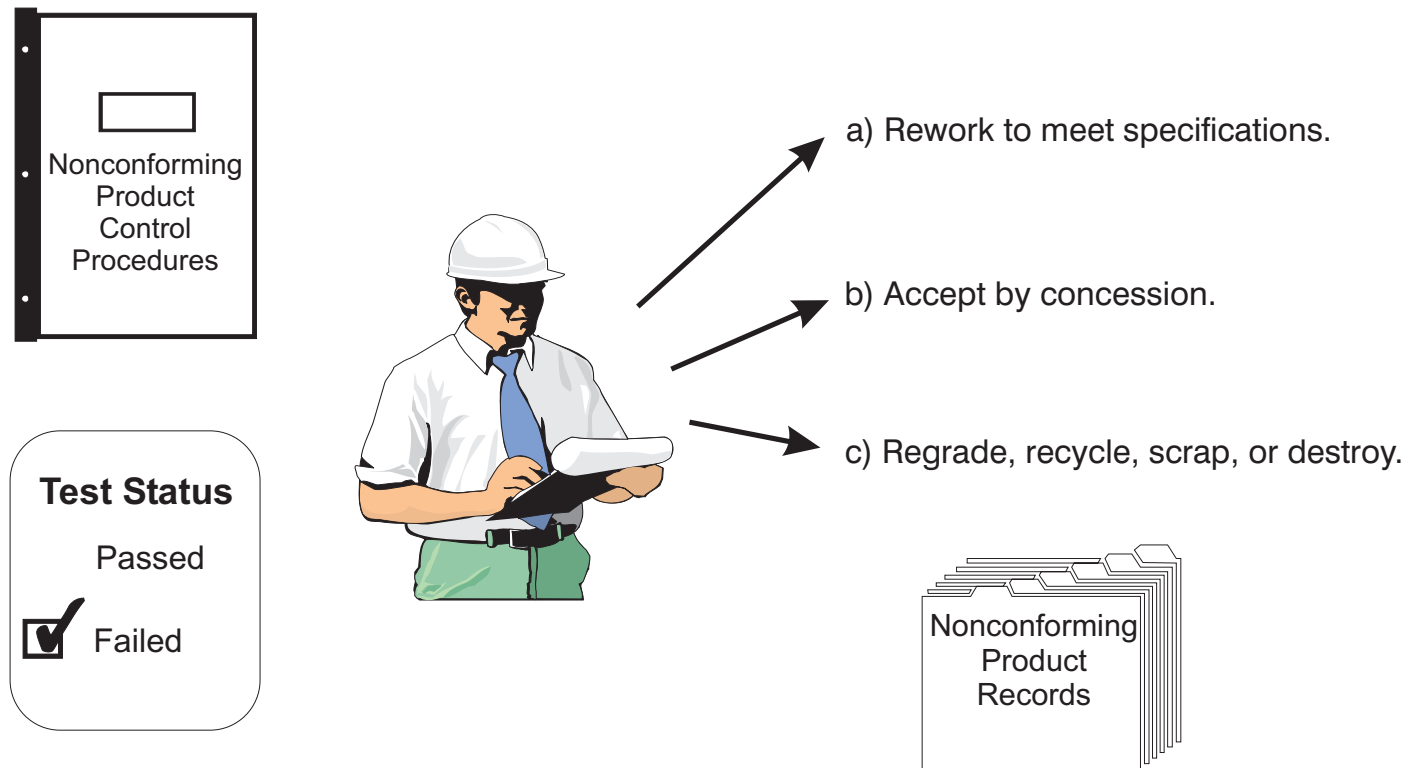


- Retain evidence the products meets the acceptance criteria.
- Maintain inspection, test, and measurement records.
- Record who authorized release of the product.
- Identify and maintain monitoring and measurement status (7.5.3).



- Complete all testing before releasing the product.

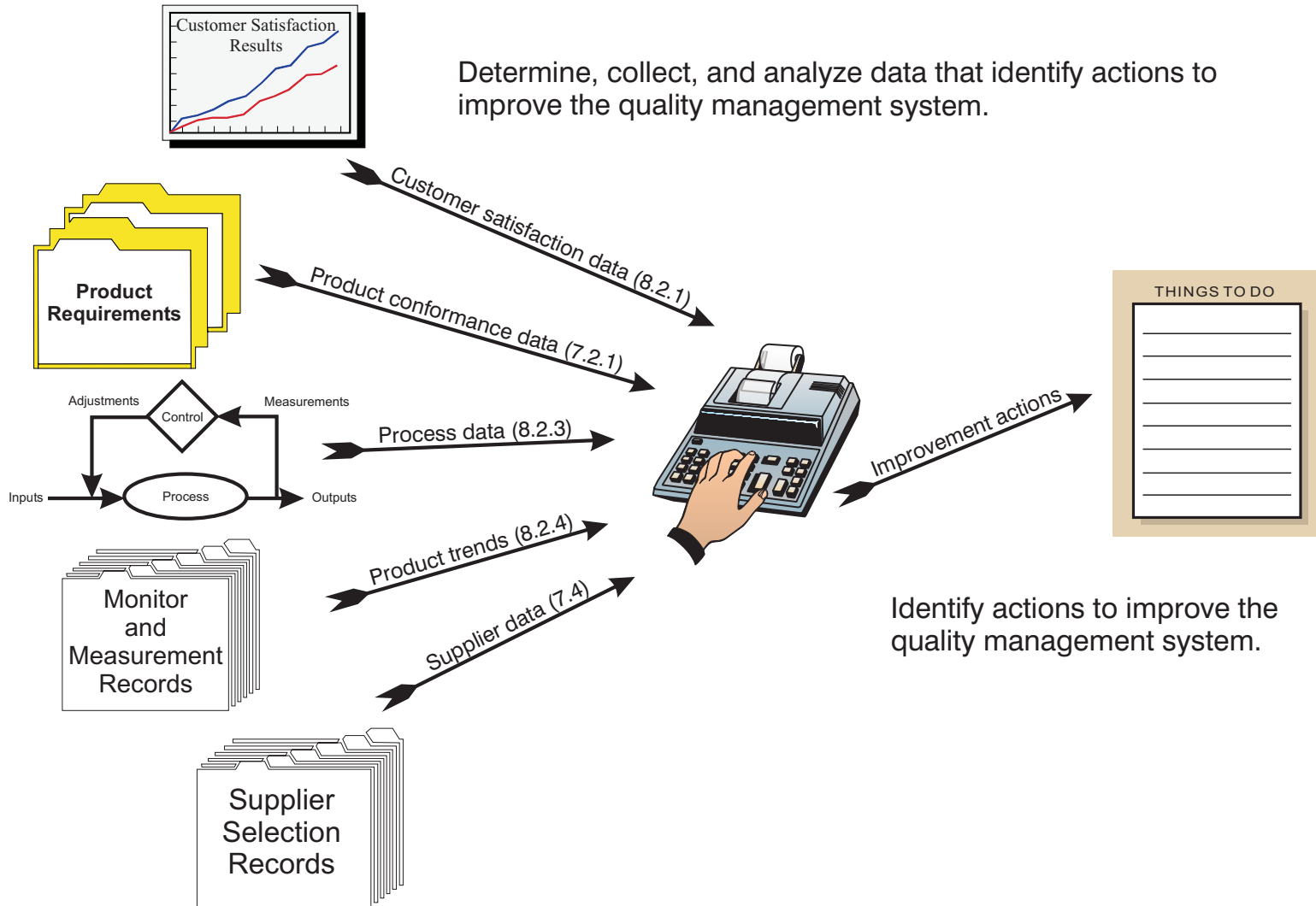
## 8.3 Handling Nonconforming Product



Recall or otherwise reduce the impact of nonconforming product that has been delivered to customers.

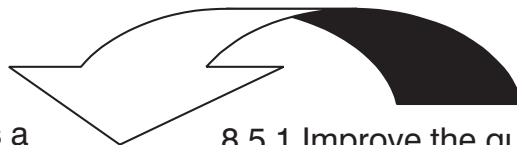
- Reinspect repaired product.
- Report nonconforming product as required by contract.

# 8.4 Data Analysis



## 8.5.1 Continual Improvement

Effectiveness of the quality management system is continually improved upon.



**5.3** The quality policy establishes a commitment to continuous improvement.

**5.4.1** Quality objectives establish measurable goals.

**8.2.2** Audits assess the effectiveness of the quality management system.

**8.4** Information regarding the following is analyzed and understood.

- Customer satisfaction (8.2.1)
- Product conformance (7.2.1)
- Product characteristics and trends (8.2.3)
- Process characteristics and trends (8.2.4)
- Supplier performance (7.4)

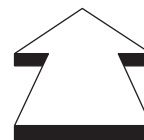
**7.2.3** Customer feedback is gathered and customer complaints are reviewed (8.5.2).

**8.3** Nonconforming product is controlled and recorded.

**4.2.4** Records are kept.

**8.5.1** Improve the quality management system.

- Refine the quality manual, quality policy, and quality objectives (4.2).
- Attended to documented procedures (4.2.1), document controls (4.2.3), and record keeping (4.2.4).
- Clarify responsibility and authority (5.5).
- Increase understanding of human resource needs (6.2).
- Renew the organization's infrastructure (6.3).
- Enrich customer communication (7.2).
- Ensure development meets customer needs (7.3).
- Use more suitable suppliers and specific supplies (7.4).
- Increase effectiveness of production processes (7.5).

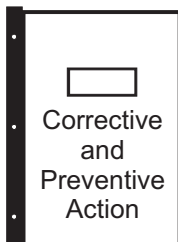


**5.6** Management review identifies improvements.

**8.5.2** Corrective and preventive action eliminates the cause of actual and potential nonconformities.

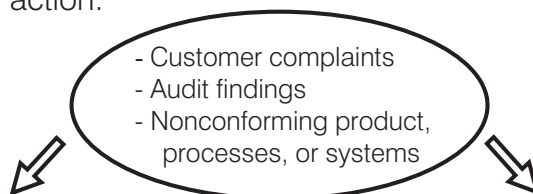


## Corrective and Preventive Action



Procedures describe corrective and preventive action.

- Actions are appropriate to the impacts of the nonconformities.
- Record changes in documented procedures resulting from corrective and preventive action.



Eliminate the cause of *existing* nonconformity.

Eliminate the cause of *potential* nonconformity.

### 8.5.2 Corrective action is taken.

- Resolve complaints and nonconformities.
- Investigate causes of nonconformity.
- Record results of investigations.
- Corrective action is determined, carried out, effective, and reviewed.

### 8.5.3 Preventive action is taken.

- Use information from many sources to detect, analyze, and eliminate potential causes.
- Identify steps needed to prevent problems.
- Carry out the preventive action.
- Ensure preventive action is effective.
- Actions taken are recorded and reviewed.



Top management reviews the effectiveness of the quality management system (5.6).