



ISO 9000

Lesson 3 ISO 9000 Quality System Elements (ISO 9001)

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Student Notes:

20 Quality System Elements



- Management Responsibility
- Quality System
- Contract Review
- Design Control
- Document and Data Control
- Purchasing
- Control of Customer-supplied Product
- Product Identification and Traceability
- Process Control
- Inspection and Testing
- Control of Inspection, Measuring, and Test Equipment
- Inspection and Test Status
- Control of Non-conforming Product
- Corrective and Preventive Action
- Handling, Storage, Packaging, Preservation, and Delivery
- Control of Quality Records
- Internal Quality Audits
- Training
- Servicing
- Statistical Techniques

Student Notes:

Each of these 20 elements will be discussed in this training module.

Obtaining Copies of ISO Standards



- **Since this training is not a substitute for the actual ISO Standards, official copies of relevant documents should be obtained.**
- **Documents are protected by copyright.**
- **Documents may be obtained from ANSI or ASQ.**
- **Copies of the following documents should be obtained:**
 - ISO 9001 (or Equivalent ANSI/ Q Series)
 - ISO 9000-1
 - ISO 9004-1
 - ISO 8402
 - ISO 10011-1
 - ISO 10011-2
 - ISO 10011-3

Student Notes:

ISO standards may be purchased from either ANSI or ASQ. ISO documents may be purchased from ANSI, and the ANSI/ASQ Q series may be purchased from ASQ.

ISO 9001: ANSI/ASQ Q9001



- **Understanding 9001 is tantamount to understanding 9002 and 9003.**
- **Quality system elements are complementary to, not a substitute for, technical requirements.**
- **Elements may be tailored when necessary.**
- **ISO 9001 should be used when a supplier's capability to meet requirements must be demonstrated.**

Student Notes:



**Description and Discussion
of 20 Q9001 Quality
System Elements**

Student Notes:

20 Q9001 Quality System Elements
Management Responsibility



- **4.1 Management Responsibility Defines Those Parts of a Quality System That Only Management has the Authority to Implement.**
 - **4.1.1 Quality Policy**
 - **4.1.2 Organization**
 - Responsibility
 - Resources
 - Management Representative
 - **4.1.3 Management Review**

Student Notes:

While all 20 elements concern managing the quality effort, elements 4.1 through 4.5 are considered the “management core” of the system.

Note that the phrase “documented and maintained” appears over and over throughout the standard.



- **4.2 Quality System**
Addresses the Overall Quality System Structure and Content Needed to Deploy Executive Management's Quality Policy and Management's Delegated Authority and Responsibility for Work Affecting Quality.
 - **4.2.1 General**
 - **Quality Manual**
 - **4.2.2 Quality System Procedures**
 - **4.2.3 Quality Planning**

Student Notes:

The Quality Manual is a very important entity in the quality system.



- **4.3 Contract Review**
Specifies the Necessary Elements in an Enterprise's Process for Establishing/ Reviewing Requirements in Outgoing Proposals and Incoming Orders.
 - **4.3.1 General**
 - **Documentation**
 - **4.3.2 Review**
 - **4.3.3 Amendment to a Contract**
 - **4.3.4 Records**

Student Notes:

“Getting it right” up front is key to “getting it right” downstream. The contract review is a very important step in making certain that “the customer gets what the customer orders. ”



- **4.4 Design Control**
Defines the Major Elements that Each Enterprise's Design and Development Process Must Address.
 - 4.4.1 General
 - Documentation
 - 4.4.2 Design and Development Planning
 - 4.4.3 Organization and Technical Interfaces
 - 4.4.4 Design Input
 - 4.4.5 Design Output
 - 4.4.6 Design Review
 - 4.4.7 Design Verification
 - 4.4.8 Design Validation
 - 4.4.9 Design Changes

Student Notes:

Poor design control can negate the efforts expended in contract review and can lead to frustration in production, installation, and servicing.

20 Q9001 Quality System Elements

4.4 Design Control System



4.4 Design Control System

Establish and maintain procedures for controlling and verifying that the design efforts result in meeting the specified requirements.



Student Notes:

This slide pictorially depicts the interrelation among the various aspects of the design stage.



- **4.5 Document and Data**
Defines the Requirements for Controlling Documents and Data Associated with the Operation of the Enterprise's Quality Management System.
 - **4.5.1 General**
 - **Documented Procedures**
 - **4.5.2 Document and Data Approval and Issue**
 - **4.5.3 Document and Data Changes**

Student Notes:

Among reasons for non-certification, Document Control has consistently been number 1. Failure to document procedures, lack of training on procedures, failure to follow procedures, and failure to control documentation are all contributors to failure of the system.

20 Q9001 Quality System Elements

4.5 Document Control System



4.5 Document Control System

4.5.1 Documented procedures are established and maintained to control documents and data

New documents are written



4.5.2 Authorized personnel review and approve before issue

4.5.2 A master control list is established and maintained

New and revised documents are made available at point of use. Obsolete copies are removed.

Documents may be in any form - paper hardcopy or electronic media

Student Notes:



- **4.6 Purchasing**
Defines the Quality Related Requirements for each Enterprise's Procurement Processes.
 - **4.6.1 General**
 - Documented Procedures
 - **4.6.2 Evaluation of Subcontractors**
 - **4.6.3 Purchasing Data**
 - **4.6.4 Verification of Purchased Product**

Student Notes:

Elements 4.6 through 4.15 follow a more or less logical sequence from purchasing materials and services to delivery of the product or service to the customer.

After poor documentation, poor purchasing practices are the second most frequent reason for non-certification.



- **4.7 Control of Customer-supplied Product
Defines the Requirements for the Management
of Customer-furnished Articles.**
- **4.8 Product Identification and Traceability
Defines the Requirements for Product
Identification and for Unit or Batch Traceability.**

Student Notes:



- **4.9 Process Control**
Defines the Requirements for the Control of Production, Installation, and Servicing Processes that Affect Quality.
 - Documented Procedures
 - Suitable Equipment
 - Compliance with Reference Standards, Plans, Procedures
 - Monitoring of Process Parameters
 - Approval of Processes and Equipment
 - Suitable Maintenance
 - Special Processes

Student Notes:

Alternating with purchasing, a combination of process control, test and measurements, and maintenance of test equipment are the second most frequent reasons for non-certification.



- **4.10 Inspection and Testing**
Defines the requirements for Conducting Inspections and Tests to Verify that Specific Product Requirements Have Been Met.
 - **4.10.1 General**
 - Documented Procedures
 - **4.10.2 Receiving Inspection and Testing**
 - **4.10.3 In-process Inspection and Testing**
 - **4.10.4 Final Inspection and Testing**
 - **4.10.5 Inspection and Test Records**

Student Notes:

20 Q9001 Quality System Elements
Control of Inspection, Measuring,
and Test Equipment



- **4.11 Control of Inspection, Measuring, and Test Equipment**
Defines the Requirements Each Enterprise Must Address for the Selection, Control, Calibration, and Maintenance of Inspection, Measurement, and Test Equipment.
 - **4.11.1 General**
 - **Documented Procedures**
 - **Measurement Uncertainty Must Be Known**
 - **4.11.2 Control Procedure**

Student Notes:

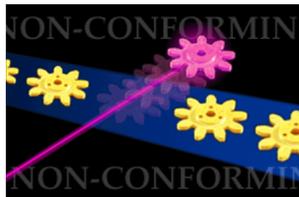


- **4.12 Inspection and Test Status**
Defines the Requirements an Enterprise
Must Address to Adequately Identify
Each Product's Inspection and Test
Acceptance or Rejection Status.

Student Notes:



- **4.13 Control of Non-conforming Product**
Defines the Requirements each Enterprise Must Address to Adequately Control Non-conforming Products.
 - **4.13.1 General**
 - Documented Procedures for Identification, Documentation, Evaluation, Segregation, Disposition, Notification
 - **4.13.2 Review and Disposition of Non-conforming Product**



Student Notes:

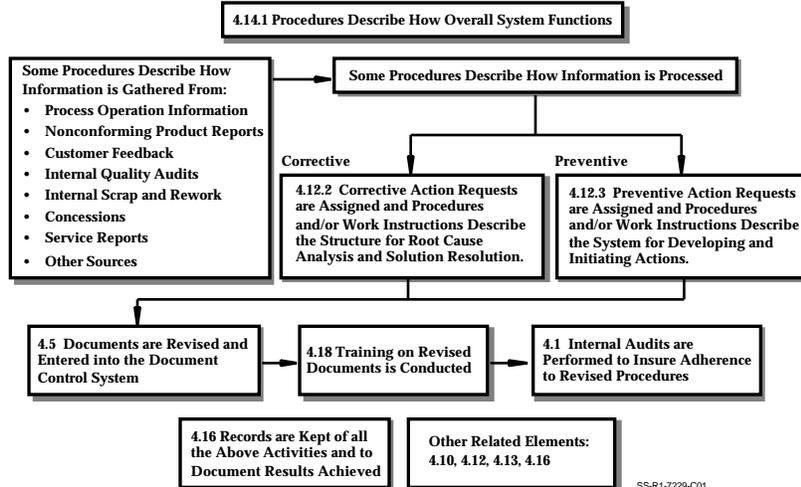


- **4.14 Corrective and Preventive Action**
Specifies the Major Elements that Must Be Present in Each Enterprise's Processes for Corrective Action and for Preventive Action.
 - **4.14.1 General**
 - Documented Procedures
 - Implement and Record any Changes to Documented Procedures Resulting from Corrective/Preventive Action
 - **4.14.2 Corrective Action**
 - **4.14.3 Preventive Action**

Student Notes:

20 Q9001 Quality System Elements

4.14 Corrective and Preventive Action



Student Notes:

Process control, testing and measuring, maintaining test equipment, test status, control of non-conforming product, and corrective and preventive action form the production portion of ISO 9001.

20 Q9001 Quality System Elements
Handling, Storage, Preservation, and Delivery



- **4.15 Handling, Storage, Packaging, Preservation, and Delivery**
Specifies the Requirements that Each Enterprise's Processes for Product Handling, Storage, Packaging, Preservation, and Delivery Must Meet.
 - **4.15.1 General**
 - **Documented Procedures**
 - **4.15.2 Handling**
 - **4.15.3 Storage**
 - **4.15.4 Packaging**
 - **4.15.5 Preservation**
 - **4.15.6 Delivery**

Student Notes:

As is the case of all other quality system elements, documented procedures must be developed and maintained describing how the finished product will be safeguarded until delivered to the customer.



- **4.16 Control of Quality Records**
Defines the Requirements for
Management of Quality Records.

Student Notes:



- **4.17 Internal Quality Audits**
Defines the Requirements for Each
Enterprise's Internal Quality Audit
Process.

Student Notes:

Internal quality audits probably will give more return on investment than any other activity an organization can pursue. Internal audits are the basis for discovering all types of losses that directly affect profit.

20 Q9001 Quality System Elements Internal Audit System



4.17 Internal Audit System

Formal structure for establishment and maintenance of an internal auditing system.

Verify the existence of documentation to comply with all twenty quality system requirements (that apply) (4.2 & 4.5)

Verify that procedures and work instructions are being followed (4.9)



Plan and schedule audits based on status and importance of activities to be audited.



Audit findings are recorded and forwarded to the affected management.



Appropriate corrective action is identified, implemented, and verified.

Student Notes:



- **4.18 Training**
Defines the Requirements for
Managing the Identification and
Delivery of Necessary Training.

Student Notes:

Training must be done if “doing what you say” is to happen.



- **4.19 Servicing**
Defines the Requirements for
Managing Servicing Activities.

Student Notes:

This ISO element deals with any work the supplier must perform after a product or service is delivered.



- **4.20 Statistical Techniques**
Defines the Requirements for Identification and Application of Appropriate Statistical Techniques to the Enterprise's Processes and Products.
 - 4.20.1 Identification of Need
 - 4.20.2 Procedures

Student Notes:

The supplier must evaluate whether statistical techniques are needed in order to adequately establish control or verify process capabilities and product characteristics. If statistical techniques are used, documented procedures must be developed to describe where and how they are to be used.