ISO 9001:2000 Quality System Requirements

Introduction

0.1 General

Establishing a Quality System is a strategic decision by top management. The system must be consistent with the organization's needs, objectives, products, processes, size, and structure.

Conditions that impact organizational performance:
- a) Customer loyalty
- b) Repeat business and referral
- c) Operational results such as revenue and market share
- d) Flexibility and fast response to market opportunities
- e) Costs and cycle time reduction through effective and efficient resource use
- f) Alignment of processes to best achieve desired results
- g) Competitive advantage through improved organizational capabilities
- h) Understanding and motivation of people toward continuous improvement and the organization's goals and objectives
- i) Confidence of interested parties in effectiveness and efficiency
- j) Ability to create value

0.2 Process Approach

ISO 9001 promotes a Process Approach to management. A process is an activity using resources that is managed in order to transform inputs into outputs. The Process Approach is the identification and linking of multiple processes into a system. For an organization to function effectively, these processes and their interactions must be managed.

To improve organizational performance:
- a) Understand and meet customer, regulatory and statutory requirements
- b) Consider the processes in terms of added value
- c) Compile results of process performance and effectiveness
- d) Continually improve processes based on measured objectives
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4.0 Quality Management System

4.1 General Requirements

The organization shall establish, document, implement, and maintain the system and continually improve its effectiveness. To accomplish this:

✓ a) Identify the business systems and processes needed and their application
   b) Determine their sequence and interaction
✓ c) Define effectiveness criteria and methods for their operation and control
   d) Ensure availability of resources and information for operating and monitoring processes
✓ e) Monitor, measure, and analyze processes
   f) Implement actions to achieve planned results and continual improvement
   g) Control any outsourced processes that effect product conformity

4.2 Documentation Requirements

   Documentation shall include:
   ✓ a) Quality Policy and Objectives
   ✓ b) Quality Manual including scope and a description of process interactions
   ✓ c) Documented Procedures
   d) Documents to ensure effective process planning, operation, and control
   e) Records

Document Controls shall consider that documents:
   a) Are approved prior to issue
   b) Are reviewed, updated, and re-approved as necessary
   c) Have changes and revision status identified
   d) Are available at points of use
   e) Remain legible and identifiable
   f) External documents are identified and their distribution controlled
   g) Obsolete documents are removed or identified

Records shall provide evidence of conformity to requirements and effective quality system operation
Records shall be legible, readily identifiable, and retrievable
Procedures shall control record identification, storage, protection, retrieval, retention time, and disposition
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5.0 Management Responsibility

5.1 Management Commitment

Top Management shall provide evidence of its commitment to the Quality Management System and continual improvement of its effectiveness by:
(a) Communicating the importance of meeting customer, statutory, and regulatory requirements
(b) Establishing the Quality Policy
(c) Ensuring that Quality Objectives are established
(d) Conducting Management Reviews
(e) Ensuring availability of resources

5.2 Customer Focus

Assure customer requirements are determined and fulfilled to ensure customer satisfaction.

5.3 Quality Policy

Top Management shall develop a Quality Policy that:
(a) Is appropriate to the purpose of the organization
(b) Contains a commitment to comply with requirements and continual improvement
(c) Provides a framework for establishing and reviewing quality objectives
(d) Is communicated and understood
(e) Is reviewed for continuing suitability

5.4 Planning

Top Management shall ensure that quality system objectives are:
a) Established at relevant functions and levels
b) Measurable and consistent with the Quality Policy

Quality System planning shall be carried out to meet quality requirements and objectives and maintain system integrity when changes are planned and implemented
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5.5 Responsibility, Authority, and Communications

Responsibilities and Authorities are defined and communicated
A Management Representative shall be appointed with the responsibility and authority to:
a) Ensure that system processes are established, implemented, and maintained.
b) Report system performance and need for improvement to top management
c) Promote awareness of customer requirements.

Communication processes shall be established and the effectiveness of the quality management system communicated

5.6 Management Review

Top Management shall review the system at planned intervals to ensure continuing suitability, adequacy, and effectiveness. This review shall assess opportunities for improvement and need for change.

Input to management review shall include:
a) Results of audits
b) Customer feedback
c) Process performance and product conformity
d) Status of preventive and corrective actions
e) Follow-up actions from previous management reviews
f) Changes that could affect the system
g) Recommendations for improvement

Output from management review shall include:
a) Improvement to the effectiveness of the system and processes
b) Product improvements related to customer requirements
c) Resource needs
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6.0 Resource Management

6.1 Provision of Resources
The organization shall determine and provide resources needed to:
   a) Implement and maintain the quality management system and improve its effectiveness
   b) Enhance customer satisfaction by meeting customer requirements

6.2 Human Resources
Personnel performing work affecting product quality shall be competent based upon education, training, skills, & experience. The organization shall:
   a) Determine needed personnel competency
   b) Provide training or other actions
   c) Evaluate the effectiveness of actions taken
   d) Ensure that personnel are aware of the relevance and importance of their activities and contributions to quality objectives
   e) Maintain appropriate records of education, training, skills, and experience

6.3 Infrastructure
The organization shall determine, provide, and maintain buildings, workspace, utilities, process equipment (hardware & software) and support services needed to achieve product conformity.

6.4 Work Environment
The organization shall determine and manage environment for product conformity.
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7.0 Product Realization

7.1 Planning of Product Realization

The organization shall plan and develop product realization processes considering:
   a) Product requirements and quality objectives
   b) Need for processes, documents, and resources for the products
   c) Needs for verification, validation, monitoring, inspection, and test
   d) Defined product acceptance criteria
   e) Records that processes and products meet requirements

Planning output shall be suitable for the organization’s operational method.

7.2 Customer-related Processes

The organization shall determine:
   a) Customer specified requirements including delivery and post-delivery
   b) Other requirements necessary for the product’s intended use
   c) Statutory and regulatory requirements
   d) Other requirements determined by the organization

The organization shall review the product requirements:
   a) Prior to commitment to customer (proposal or order)
   b) To be sure that there is a clear definition of the product
   c) To resolve requirements which have been changed
   d) To determine that the organization can meet all defined requirements
   e) Maintaining records of reviews and resulting actions

Where no documented customer requirements statement exists, requirements shall be confirmed before acceptance

When requirements are changed, documents are amended and personnel notified, customer communications arrangements determined and implemented.
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7.3 Design and Development

Design and Development is planned and controlled though:
a) Definition of design and development phases
b) Review, verification, and validation at appropriate stages
c) Assignment of responsibilities and authorities
d) Management of organizational interfaces

Design inputs that are complete, unambiguous, and not in conflict shall be determined considering:
a) Functional and performance requirements
b) Statutory and regulatory requirements
c) Information from previous designs

Design output that enables verification against input shall:
a) Be approved before release
b) Meet input requirements
c) Provide adequate information for purchasing, production, and servicing
d) Contain or reference acceptance criteria
e) Specify characteristics essential for the product's safe and proper use

Systematic design and development reviews shall be planned and performed at suitable stages. Review participants shall include representatives of concerned functions. Records of reviews and necessary actions shall be maintained.

Verification (Output meets Input) and Validation (Product meets specified application or intended use) shall be performed in accordance with planned arrangements and the results and actions recorded.

Design Changes identified and records maintained. Changes shall be reviewed, verified, and validated before implementation. The effect on constituent parts or delivered products shall be evaluated.
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7.4 Purchasing

The type and extent of supplier control shall depend upon the effect of the purchased part on the product. Evaluate and select suppliers based on their ability to meet requirements. Criteria for selection, evaluation, and re-evaluation shall be established and records of evaluations and necessary actions shall be maintained. Purchasing documents shall clearly describe the item being purchased and be reviewed for adequacy prior to communication to the supplier.

Purchased product shall be verified. If it is verified at the Supplier, the arrangements and method of product release shall be specified in the purchasing documents.

7.5 Production and Service Provision

Production and service shall be carried out under controlled conditions including:

a) Availability of product characteristic information and work instructions
b) Use of suitable equipment
c) Availability and use of monitoring and measuring devices
d) Implementation of monitoring and measurement
e) Implementation of release, delivery, and post-delivery activities
f) Validation of special processes ability to achieve planned results
g) Suitable identification and traceability
h) Suitable identification of product monitoring and measurement status
i) Control of customer property
j) Preservation of product during processing and delivery

7.6 Control of Monitoring and Measuring Devices

The organization shall determine the monitoring and measurements necessary and carry them out. Equipment shall be calibrated and adjusted at specified intervals to traceable standards, identified with the calibration status, and safeguarded from adjustment or damage.

When devices are found out of calibration, effect on product shall be assessed and recorded.

Acceptance Software shall be include in the calibration system.
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8.0 Measurement, Analysis, and Improvement

8.1 General

The organization shall plan and implement monitoring, measurement, analysis, & improvement to:
   a) Demonstrate conformity of product
   b) Ensure conformity of the quality management system
   c) Continually improve effectiveness
   d) Determine applicable methods including statistical techniques

8.2 Monitoring and Measurement

The organization shall measure the performance of the quality management system through such actions as monitoring customer perception to determine their level of satisfaction.

Internal Audits of the quality management system shall:
   a) Be scheduled based on process status and importance
   b) Define audit criteria, scope, frequency, and methods
   c) Be objective and impartial
   d) Have action taken on audit results without undue delay
   e) Verify effectiveness of actions taken and report results

Processes shall be monitored and measured to demonstrate the ability to achieve planned results and have correction & corrective action taken when results are not met. Product shall be monitored and measured at appropriate stages of product realization to determine and record characteristics that verify conformity to requirements. Delivery shall be held until planned arrangements are satisfactorily completed.

8.3 Control of Nonconforming Product

Product that does not conform to requirements shall be identified and controlled as nonconforming product to prevent its use. Controls and related responsibilities and authorities shall be defined. Record the nature of nonconformities and subsequent actions. Corrected product shall be re-verified
8.4 Analysis of Data

The organization shall determine, collect, and analyze data to demonstrate the effectiveness of the Quality Management System and evaluate it for continual improvement. Analysis shall provide information relating to:
   a) Customer satisfaction
   b) Conformity to product requirements
   c) Process and product characteristics and trends including opportunities for preventive action
   d) Suppliers

8.5 Improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

Procedures shall be written to define requirements for:
   a) Reviewing nonconformities (including Customer complaints)
   b) Determining potential or actual nonconformities and their causes
   c) Evaluating the need for preventive action
   d) Determining and implementing actions needed
   e) Recording the results of action taken
   f) Reviewing corrective and preventive actions taken
   g) Preventive actions taken shall be appropriate to the effects of potential problems