

## ISO 9001 2008 QUALITY MANAGEMENT REQUIREMENTS

### 4. GENERAL REQUIREMENTS

#### 4.1 DEVELOP YOUR QUALITY MANAGEMENT SYSTEM (QMS)

- Establish your organization's QMS.
- *Document* your organization's QMS.
- *Implement* your organization's QMS.
- *Maintain* your organization's QMS.
- *Improve* your organization's QMS.

#### 4.2. DOCUMENT YOUR QUALITY MANAGEMENT SYSTEM (QMS)

##### 4.2.1 MANAGE QUALITY MANAGEMENT SYSTEM DOCUMENTS

- Develop documents for your organization's QMS.
- Make sure that your organization's QMS documents respect and reflect what you do and how you do it.

##### 4.2.2 PREPARE QUALITY MANAGEMENT SYSTEM MANUAL

- *Establish* a quality manual for your organization.
- *Maintain* your organization's quality manual.

##### 4.2.3 CONTROL QUALITY MANAGEMENT SYSTEM DOCUMENTS

- Control your organization's QMS documents.
- Control documents that are used as QMS records.

##### 4.2.4 ESTABLISH QUALITY MANAGEMENT SYSTEM RECORDS

- Establish your organization's QMS records.
- Establish a procedure to control your QMS records.

## ISO 9001 2008 QUALITY MANAGEMENT REQUIREMENTS

### 5. MANAGEMENT

#### 5.1 SHOW YOUR COMMITMENT TO QUALITY

## REQUIREMENTS

- Support the *development* of your organization's QMS.
- Support the *implementation* of your organization's QMS.
- Support efforts to continually improve the effectiveness of your organization's QMS.

### 5.2 FOCUS ON YOUR CUSTOMERS

- Enhance customer satisfaction by ensuring that customer requirements are being *identified*.
- Enhance customer satisfaction by ensuring that customer requirements are being *met*.

### 5.3 SUPPORT YOUR QUALITY POLICY

- Ensure that your organization's quality policy serves its overall purpose.
- Ensure that your quality policy makes it clear that requirements must be met.
- Ensure that your quality policy makes a commitment to continually improve the effectiveness of your QMS.
- Ensure that your quality policy supports your organization's quality objectives.
- Ensure that your quality policy is communicated and discussed throughout your organization.
- Ensure that your quality policy is periodically reviewed to make sure that it is still suitable.

### 5.4 CARRY OUT YOUR QMS PLANNING

#### 5.4.1 ESTABLISH QUALITY OBJECTIVES

- Support the establishment of quality objectives.
- Establish quality objectives for your organization.
- Make sure that your quality objectives are effective.

#### 5.4.2 PLAN QUALITY MANAGEMENT SYSTEM (QMS)

- Plan the *establishment* of your QMS.

- Plan the *documentation* of your QMS.
- Plan the *implementation* of your QMS.
- Plan the *maintenance* of your QMS.
- Plan the *continual improvement* of your QMS.

## 5.5 ALLOCATE QMS RESPONSIBILITY AND AUTHORITY

### 5.5.1 DEFINE RESPONSIBILITIES AND AUTHORITIES

- Ensure that QMS responsibilities and authorities are defined.
- Ensure that QMS responsibilities and authorities are communicated throughout your organization.

### 5.5.2 CREATE MANAGEMENT REPRESENTATIVE ROLE

- Appoint a member of your organization's management to oversee your QMS.
- Give your management representative authority over and responsibility for your organization's QMS.

### 5.5.3 SUPPORT INTERNAL COMMUNICATION

- Ensure that appropriate communication processes are established within your organization.
- Ensure that internal communication occurs throughout your organization.

## 5.6 PERFORM QMS MANAGEMENT REVIEWS

### 5.6.1 REVIEW QUALITY MANAGEMENT SYSTEM (QMS)

- Carry out management reviews of your organization's QMS at planned intervals.
- Evaluate improvement opportunities.
- Assess the need to make changes.
- Maintain a record of your management reviews.

### 5.6.2 EXAMINE MANAGEMENT REVIEW INPUTS

- Examine information about your QMS (inputs).

### 5.6.3 GENERATE MANAGEMENT REVIEW OUTPUTS

- Generate management review decisions and

actions (outputs) to improve your organization.

- Generate management review decisions and actions (outputs) to change your general quality orientation.
- Generate management review decisions and actions (outputs) to address resource needs.

## ISO 9001 2008 QUALITY MANAGEMENT REQUIREMENTS

### 6. RESOURCE REQUIREMENTS

#### 6.1 PROVIDE REQUIRED QMS RESOURCES

- *Identify* the resources that your QMS needs.
- *Provide* the resources that your QMS needs.

#### 6.2 PROVIDE COMPETENT QMS PERSONNEL

##### 6.2.1 ENSURE THE COMPETENCE OF WORKERS

- Ensure the competence of anyone within your QMS who could directly or indirectly affect your ability to meet product requirements.

##### 6.2.2 MEET COMPETENCE REQUIREMENTS

- Identify the competence requirements of personnel within your QMS who perform work that could directly or indirectly affect your organization's ability to meet product requirements.
- Provide training, or take other suitable steps, to meet your organization's QMS competence requirements.
- Evaluate the effectiveness of your organization's QMS training and awareness activities.
- Maintain suitable records which show that personnel within your QMS are competent.

#### 6.3 PROVIDE NECESSARY INFRASTRUCTURE

- *Identify* the infrastructure that your organization needs in order to ensure that product requirements are met.
- *Provide* the infrastructure that your organization needs

in order to ensure that product requirements are met.

- ***Maintain*** the infrastructure that your organization needs in order to ensure that product requirements are met.

#### 6.4 PROVIDE SUITABLE WORK ENVIRONMENT

- ***Identify*** the work environment that your organization needs in order to ensure that product requirements are met.
- ***Manage*** the work environment that your organization needs in order to ensure that product requirements are met.

## ISO 9001 2008 QUALITY MANAGEMENT REQUIREMENTS

### 7. REALIZATION REQUIREMENTS

#### 7.1 CONTROL PRODUCT REALIZATION PLANNING

- Establish a product realization planning process.
- Use your product realization planning process to plan the realization of your organization's products.
- Prepare planning outputs that are suitable and consistent with your organization's methods.
- Develop the processes that you will need to use in order to realize products.

#### 7.2 CONTROL CUSTOMER-RELATED PROCESSES

##### 7.2.1 IDENTIFY YOUR UNIQUE PRODUCT REQUIREMENTS

- Identify the requirements that your customers want you to comply with.
- Identify the requirements that are dictated by your product's intended use or purpose.
- Identify the requirements that are imposed on your products by external agencies.
- Identify any additional requirements that are important to your organization and must be met.

##### 7.2.2 REVIEW CUSTOMERS' PRODUCT REQUIREMENTS

- Review your customers' product requirements.
- Maintain a record of your product requirement reviews.
- Control changes in customers' product requirements.

#### 7.2.3 COMMUNICATE WITH YOUR CUSTOMERS

- *Establish* customer communication arrangements.
- *Implement* customer communication arrangements.

### 7.3 CONTROL PRODUCT DESIGN AND DEVELOPMENT

#### 7.3.1 PLAN PRODUCT DESIGN AND DEVELOPMENT

- Plan the design and development of your products.
- Control the design and development of your products.
- Update your planning outputs whenever product design and development progress makes this necessary.

#### 7.3.2 IDENTIFY DESIGN AND DEVELOPMENT INPUTS

- Define product design and development inputs.
- Maintain a record of design and development inputs.
- Review your product design and development inputs.

#### 7.3.3 GENERATE DESIGN AND DEVELOPMENT OUTPUTS

- Produce product design and development outputs.
- Approve product design and development outputs before they are formally released.
- Verify that product design and development outputs meet design and development input requirements.

#### 7.3.4 CARRY OUT DESIGN AND DEVELOPMENT REVIEWS

- Perform systematic design and development reviews throughout the design and development process.
- Maintain a record of design and development reviews.

#### 7.3.5 PERFORM DESIGN AND DEVELOPMENT VERIFICATIONS

- Carry out design and development verifications.
- Maintain a record of design and development verifications.

#### 7.3.6 CONDUCT DESIGN AND DEVELOPMENT VALIDATIONS

- Perform design and development validations.
- Maintain a record of design and development validations.

#### **7.3.7 MANAGE DESIGN AND DEVELOPMENT CHANGES**

- *Identify* changes in design and development.
- *Record* changes in design and development.
- *Review* changes in design and development.
- *Verify* changes in design and development.
- *Validate* changes in design and development.
- *Approve* changes in design and development before you implement these changes.

#### **7.4 CONTROL PURCHASING AND PURCHASED PRODUCTS**

##### **7.4.1 ESTABLISH CONTROL OF YOUR PURCHASING PROCESS**

- Establish criteria that you can use to control suppliers.
- Evaluate your suppliers' ability to supply products that meet your organization's requirements.
- Select suppliers that are capable of supplying products that meet your organization's specified requirements.
- Make sure that purchased products meet specified purchase requirements.

##### **7.4.2 SPECIFY YOUR PURCHASING REQUIREMENTS**

- Describe your purchasing requirements.
- Ensure that purchasing requirements are adequately specified before you discuss them with suppliers.

##### **7.4.3 VERIFY YOUR PURCHASED PRODUCTS**

- *Establish* product verification or inspection methods in order to ensure that purchased products meet purchase requirements.
- *Implement* product verification or inspection methods in order to ensure that purchased products meet purchase requirements.

#### **7.5 CONTROL PRODUCTION AND SERVICE PROVISION**

##### **7.5.1 ESTABLISH CONTROL OF PRODUCTION AND SERVICE**

- Carry out *production* under controlled conditions.
- Carry out *service provision* under controlled conditions.

#### 7.5.2 VALIDATE PRODUCTION AND SERVICE PROVISION

- Validate production and service provision processes whenever process outputs cannot be measured, monitored, or verified until *after* the product is in use or the service has been delivered (such a process is often referred to as a *special process*).
- Establish arrangements to control *special processes*.

#### 7.5.3 IDENTIFY AND TRACK YOUR PRODUCTS

- Establish the unique identity of your organization's products (if appropriate).
- Identify the monitoring and measurement status of your organization's products.

#### 7.5.4 PROTECT PROPERTY SUPPLIED BY CUSTOMERS

- *Identify* property supplied to you by customers.
- *Verify* property supplied to you by customers.
- *Protect* property supplied to you by customers.
- *Safeguard* property supplied to you by customers.

#### 7.5.5 PRESERVE YOUR PRODUCTS AND COMPONENTS

- Make sure that your products and components continue to conform to requirements *while they are being processed internally*.
- Make sure that your products and components continue to conform to requirements *while they are being delivered to the intended destination*.

#### 7.6 CONTROL MONITORING AND MEASURING EQUIPMENT

- Identify your organization's monitoring and measuring needs and requirements.
- Select equipment that can meet your organization's monitoring and measuring needs and requirements.
- Establish monitoring and measuring processes.
- Calibrate your monitoring and measuring equipment whenever necessary to ensure that results are valid.
- Protect your monitoring and measuring equipment.

- Confirm that monitoring and measuring software is capable of doing the job you want it to do.
- Evaluate the validity of previous measurements whenever you discover that your measuring or monitoring equipment is out-of-calibration.

## ISO 9001 2008 QUALITY MANAGEMENT REQUIREMENTS

### 8. REMEDIAL REQUIREMENTS

#### 8.1 ESTABLISH MONITORING AND MEASUREMENT PROCESSES

- *Identify* the monitoring, measurement, and analytical processes that your organization needs to have in order to be able to demonstrate conformity and make improvements.
- *Plan* how monitoring, measurement, and analytical processes will be used to demonstrate conformity and make improvements.
- *Implement* your organization's monitoring, measurement, and analytical processes.

#### 8.2 CARRY OUT MONITORING AND MEASUREMENT ACTIVITIES

##### 8.2.1 MONITOR AND MEASURE CUSTOMER SATISFACTION

- Establish methods that you can use to monitor and measure customer satisfaction (perceptions).
- Monitor and measure customer satisfaction.

##### 8.2.2 PLAN AND PERFORM REGULAR INTERNAL AUDITS

- Establish an internal audit procedure.
- Carry out internal audits of your QMS.
- Take action to address audit results.

##### 8.2.3 MONITOR AND MEASURE YOUR QMS PROCESSES

- Select suitable methods to monitor and measure the processes that make up your organization's QMS.
- Monitor and measure your QMS processes.
- Take appropriate action whenever your QMS processes fail to achieve planned results.

#### 8.2.4 MONITOR AND MEASURE PRODUCT CHARACTERISTICS

- *Monitor* your organization's product characteristics.
- *Measure* your organization's product characteristics.

#### 8.3 IDENTIFY AND CONTROL NONCONFORMING PRODUCTS

- *Establish* a nonconforming products procedure.
- *Document* your nonconforming products procedure.
- *Implement* your nonconforming products procedure.
- *Maintain* your nonconforming products procedure.

#### 8.4 COLLECT AND ANALYZE QUALITY MANAGEMENT DATA

- Figure out what kind of data you need to collect about your organization's QMS.
- Collect data about your organization's QMS.
- Provide information by analyzing your QMS data.

#### 8.5 MAKE IMPROVEMENTS AND TAKE REMEDIAL ACTIONS

##### 8.5.1 IMPROVE THE EFFECTIVENESS OF YOUR QMS

- Continually improve the effectiveness of your QMS.
- Use information to improve the effectiveness of your QMS.

##### 8.5.2 CORRECT NONCONFORMITIES TO PREVENT RECURRENCE

- *Establish* a corrective action procedure.
- *Document* your corrective action procedure.
- *Implement* your corrective action procedure.
- *Maintain* your corrective action procedure.

##### 8.5.3 PREVENT THE OCCURRENCE OF NONCONFORMITIES

- *Establish* a preventive action procedure.
- *Document* your preventive action procedure.

- ***Implement*** your preventive action procedure.
- ***Maintain*** your preventive action procedure.

**ISO 9001 2008 QUALITY MANAGEMENT REQUIREMENTS**