



# QUALITY MANAGEMENT SYSTEM ISO 9001 : 2008

## **Clause 4 – 6 Requirements**



# 4 - Quality Management System

## ISO 9001:2008

### 4.1 General requirements

- establish, document, implement, maintain and continually improve



# 4 - Quality Management System

## ISO 9001:2008

### 4.2 Documentation requirements

“Our documented management system.”

- procedures for: control of documents, control of records, internal audits, corrective action, preventive action, and control of nonconformity
- documents for effective planning, operation and control



# 4 - Quality Management System

## ISO 9001:2008

### 4.2.2 Quality manual

“Write down what we do.”

- justification of exclusions
- documented procedures or reference to them
- details of the interaction between processes of the QMS



# 4 - Quality Management System

## ISO 9001:2008

### 4.2.3 Control of documents

“Provide people with the information they need.”

- document approval, review and update
- currency of documents
- availability
- legibility and readily identifiable
- documents of external origin
- prevent unintended use of obsolete documents



# 4 - Quality Management System

## ISO 9001:2008

### 4.2.4 Control of records

“Managing our records.”

- identification, storage, retrieval, protection, retention, disposition



# 5 - Management Responsibility

## ISO 9001:2008

### 5.1 Management commitment

“Commitment to quality.”

- Top management to provide evidence of commitment

### 5.2 Customer focus

“Do we know what our customers want?”

- Top management to ensure that customer needs and expectations are determined and met
- Enhancing customer satisfaction



# 5 - Management Responsibility

## ISO 9001:2008

### 5.3 Quality policy

- ❖ appropriate
- ❖ commitment to continual improvement
- ❖ framework
- ❖ communicated and understood
- ❖ reviewed for suitability





# 5 - Management Responsibility

## ISO 9001:2008

### 5.4 Planning

“Setting quality objectives.”

- measurable objectives
- process of change is controlled to ensure the integrity of the QMS



# 5 - Management Responsibility

## ISO 9001:2008

### 5.5.1 Responsibility and authority

- what are we expected to do (responsibility)
- what are we allowed to do (authority)

### 5.5.2 Management representative

“Who reports on the QMS?”

- appointed by top management



# 5 - Management Responsibility

## ISO 9001:2008

### 5.5.3 Internal communication

“Keeping our people informed.”

- communicate regarding the effectiveness of the QMS



# 5 - Management Responsibility

## ISO 9001:2008

### 5.6 Management review

“Is the QMS working?”

Inputs: Current performance and  
improvement opportunities

Outputs: Considerations from  
management reviews



# 6 - Resource Management

## ISO 9001:2008

### 6.1 Provision of resources

“What is needed.”

- implement, maintain, and improve QMS
- enhance customer satisfaction

### 6.2 Human resources

#### 6.2.1 General

- education, training, skills, experience



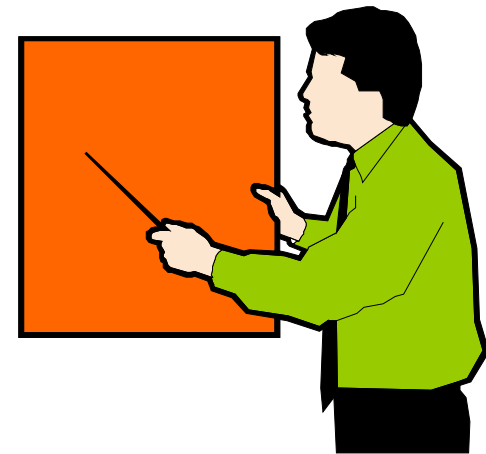
# 6 - Resource Management

## ISO 9001:2008

### 6.2.2 Competency, training and awareness

“Ensuring competence.”

- determine competency
- identify gaps
- provide training or take other action
- evaluate the effectiveness of actions
- awareness of the relevance and importance of activities
- maintain appropriate records



# 6 - Resource Management

## ISO 9001:2008

### 6.3 Infrastructure

“Ensure that working conditions are suitable.”

- workspace
- equipment
- support services

### 6.4 Work environment

- managing the work environment

