

## **INTRODUCTION**

This pocket guide has been created as a quick reference guide to assist personnel to grasp the ISO requirements in simple terms. This guide explains in a basic layout how you need to address the ISO 9001-2008 requirements for the standard.

The intention of this guide to act as a quick reference for ISO 9001-2008 requirements, and has been written in a format that should cater for all facets of an organisation.

We would hope that this guide allows personnel to consider how a clause would be addressed, and what should be done to comply with the standard.

ISO 9001 - 2008 is a culture that needs to be entrenched within an organisation which has adopted the standard. This pocket guide should allow all personnel to have ISO9001-2008 at their fingertips any place, any time, thus allowing ISO9001-2008 to become the standard by which processes are carried out.

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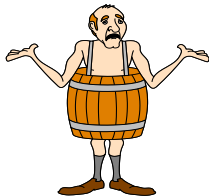
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## UNDERSTANDING QUALITY

Quality is something everyone has to deal with, whether we are at work, at home, day or night, quality has a role to play in our daily lives. Before we can look at quality in the workplace, let us examine some of the definitions or meanings of quality.



### DEFINITION 1.

*Quality is ‘Conforming to Requirements’*

Where ‘Conforming’ means broadly, to **fit or make**.  
Where ‘Requirements’ means, **what is needed?**  
*Now we can say, to fit or make what is needed*

## **How do we achieve Quality**

Quality is achieved by means of the following:-

- Management Commitment to quality.
- Providing required resources and support to all staff.
- Providing adequate training to all staff
- Create a system for control of policies, processes, procedures and instructions that are used in the organisation to produce a quality product or service that meets customer needs.

The best way to control the above points is by means of implementing the ISO 9000 quality standard.

The ISO 9000 quality standard provides a good base on which to build a total quality management system on, since it provides a structured system for implementing new projects and procedures.

By entrenching the ISO 9000 standard your organisation is demonstrating a strong commitment to quality.

Once certification is granted your organisation may display the registered ISO logo which will indicate that your company is committed to quality.

## What is ISO 9000

ISO stands for

# ***INTERNATIONAL STANDARDS ORGANISATION***

The ISO 9000 range consists of the following:-

- **ISO 9000**  
Guidelines for selection and use of the standards on quality management and quality system elements as well as quality assurance.
  
- **ISO 9001**  
Quality assurance in design, development, production, installation and servicing.
  
- **ISO 9004**  
Guidelines for quality management and quality system element



<b>ISO 9001 - 2008</b>	
<b>1.</b>	<b>Scope</b>
<b>1.1</b>	General
<b>1.2</b>	Application
<b>2.</b>	<b>Normative Reference</b>
<b>3.</b>	<b>Terms and Definitions</b>
<b>4.</b>	<b>Quality Management System</b>
<b>4.1</b>	General Requirements
<b>4.2</b>	Documentation Requirements
<b>4.2.1</b>	General
<b>4.2.2</b>	Quality Manual
<b>4.2.3</b>	Control of Documents
<b>4.2.4</b>	Control of Quality Records
<b>5</b>	<b>Management Responsibility</b>
<b>5.1</b>	Management Commitment
<b>5.2</b>	Customer Focus
<b>5.3</b>	Quality Policy
<b>5.4</b>	Planning
<b>5.4.1</b>	Quality objectives
<b>5.4.2</b>	Quality planning
<b>5.5</b>	Responsibility, authority and communication
<b>5.5.1</b>	Responsibility and authority
<b>5.5.2</b>	Management Representative
<b>5.5.3</b>	Internal communication
<b>5.6</b>	Management review
<b>5.6.1</b>	General
<b>5.6.2</b>	Review input
<b>5.6.3</b>	Review output

<b>6.</b>	<b>Resource management</b>
<b>6.1</b>	Provision of resources
<b>6.2</b>	Human resources
<b>6.2.1</b>	General
<b>6.2.2</b>	Training awareness and competency
<b>6.3</b>	Infrastructure
<b>6.4</b>	Work environment
<b>7.</b>	<b>Product Realization</b>
<b>7.1</b>	Planning of realisation process
<b>7.2</b>	Customer- related processes
<b>7.2.1</b>	Determination of product requirements
<b>7.2.2</b>	Review of product requirements
<b>7.2.3</b>	Customer communication
<b>7.3</b>	Design and/or development
<b>7.3.1</b>	Design and Development planning
<b>7.3.2</b>	Design and Development inputs
<b>7.3.3</b>	Design and Development outputs
<b>7.3.4</b>	Design and Development review
<b>7.3.5</b>	Design and Development verification
<b>7.3.6</b>	Design and Development validation
<b>7.3.7</b>	Control of Design and Development changes
<b>7.4</b>	Purchasing
<b>7.4.1</b>	Purchasing Process
<b>7.4.2</b>	Purchasing Information
<b>7.4.3</b>	Verification of purchased product
<b>7.5</b>	Production and service provision
<b>7.5.1</b>	Control of product and service provision

7.5.2	Validation of processes for production and service provision
7.5.3	Identification and traceability
7.5.4	Customer property
7.5.5	Preservation of product
7.6	Control of measuring and monitoring devices
<b>8.</b>	<b>Measurement, analysis and improvement</b>
8.1	General
8.2	Measurement and monitoring
8.2.1	Customer satisfaction
8.2.2	Internal Audit
8.2.3	Measuring and monitoring of processes
8.2.4	Measurement and monitoring of product
8.3	Control of non-conformity
8.4	Analysis of data
8.5	Improvement
8.5.1	Planning for continual improvement
8.5.2	Corrective action
8.5.3	Preventive Action

# ***QUALITY MANAGEMENT SYSTEM***

## ***Requirements***

### **1. SCOPE**

#### **1.1 General**

##### **Standard Requirements**

Specific requirements for a quality management system have been specified by the International Standard for an organisation

- a) The organisation must show that it can always provide products / services that are to customer and regulatory requirements.
- b) Aim to achieve and continually improve on customer satisfaction through the implementation of a quality management system.

#### **1.2 Application**

##### **Standard Requirements**

All requirement of the ISO quality management system are generic and can be implemented into any organisation regardless of the size, type or product / services supplied.

Where any requirements cannot be met this can be considered as a permissible exclusion.

Any exclusions made must not affect the quality of the product, service, customer or regulatory requirements.

## 2. NORMATIVE REFERENCE

### **Standard Requirements**

Members of ISO and IEC have up to date registers of valid International Standards. It is advisable to always apply the most recent addition of the normative document.

ISO 9000:2008 Quality Management Systems -  
Fundamentals and vocabulary

## 3. TERMS AND DEFINITIONS

### **Standard Requirements**

*Examples of a few terms and definitions:-*

*Organisation* = Your company or the company whereby ISO 9001 - 2008 has been implemented

*Customer* = The company that requires a product / service from your organisation.

*Supplier* = A vendor or subcontractor that supplies a product / service to your organisation.

It should be noted were the standard uses the term "*Product*" it could also mean "*Service*"

## **4. QUALITY MANAGEMENT SYSTEM**

### **4.1 General Requirements**

#### **Standard Requirements**

The organisation shall:-

- Establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the documented standard.
- Identify the required processes, evaluate and determine criteria and methods needed to ensure that the standard is continually entrenched in the organisation.
- All outsourced processes are monitored and controlled to ensure they meet legal and customer requirements

### **4.2 Document Requirements**

#### **Standard Requirements**

The quality management system documentation shall include:-

- Documented statements of a quality policy and objectives
- A quality manual
- Documented Standard Operating Procedures / Works Procedures.
- Documents needed by the organisation to ensure the

effective planning, operation and control of its processes

- How external documentation (if they effect the quality management system) need to be controlled, and
- Quality records required by the standard.

#### ***4.2.1 General***

#### ***4.2.2 Quality Manual***

The organisation shall :

- Establish, document and maintain the quality system to ensure that products and services meet specified requirements.
- Provide reference to all manuals and documentation.
- Create quality plans for projects, products and processes used within the quality system.

#### **This Means**

That you must make sure that your quality system meets ISO requirements and that documented procedures are followed.

You must consider a formal planning system.  
Make sure that documents are traceable.

## **What must we do**

You must create a structured system for control of documentation consisting of various structure levels, i.e. Policy Section, Procedures Section

Instruction Section, Data Collection Sheets  
Policy section must be referenced to Procedure Section.  
Procedure Section must be referenced to Instruction Section. Procedures and Instructions must make reference to relevant Data Collection Sheets.

Make sure that all-new processes and projects are recorded on planned data collection sheets and implementation procedures are recorded in management review meetings.

## **Required Records**

- Project Planning Sheets
- Data Collection Sheets for new documents
- Quality Manual

## **Typical Auditors Questions**

- How is new projects, products and processes planned, monitored and carried out?

### **4.2.3 Control of Documents**

The organisation shall:-

- Ensure that all documents and data is controlled.
- Review and approve documents for adequacy prior to issue.
- Required documents should be available when needed.

#### **This Means**

That all documents and data must have unique identification.

That all documents must be traceable in the system.

That documents have been approved and issued under controlled conditions.

That document updates have been reviewed by the approval authority and entered into the quality system under formal conditions.

#### **What must we do**

Develop a document control system for all quality documents allowing for unique document identification, revision status and number of pages.

We must implement an approval process for all new documents and data that are to be used in the quality system.

We must create a system whereby documents that have been issued to employees or departments are recorded for traceability.

Controls of these processes must be clearly recorded in our quality system.

### **Required Records**

- Documents issued.
- Revisions.
- Indexes.
- Document approval.

### **Typical Auditors Questions**

- How are documents issued to relevant staff?
- How are documents updated and approved?
- Who authorises document updates?