



Quality Management Standard

BS EN ISO 9001:2008



The Origin of Quality Standards

- Ministry of Defence
- Marks & Spencer
- Ford Motor Company

- All had their own Quality standards, which they expected their suppliers to adhere to. These standards were supported by teams of supplier auditors.



BS EN ISO 9001

- First published in 1979 as BS 5750 to improve the performance of British manufacturing
- Updated in 1987 and incorporated with ISO and EN standards
- Updated in 1994 as BS EN ISO 9001, 2 & 3
- Updated in 2000 as BS EN ISO 9001:2000
- Updated in 2008 as BS EN ISO 9001:2008

- Now applicable to any type of business



Objectives of BS EN ISO 9001

- The Standard sets out how to *establish, document and maintain* an effective Quality System.
- The Quality System will demonstrate to customers that you are committed to Quality and able to meet their requirements



Why Implement ISO 9001:2008?

- The standard can help you to reduce waste in terms of your procedures, can reduce the amount of paperwork by streamlining your systems.
- Improve the efficiency and productivity of the business.
- Demonstrate to customers that you are committed to Quality and able to meet their requirements.
- Help to secure new business and build on current relationships.
- Help to push the business along and seek new improvements, develop and grow
- Can give you the competitive edge when quoting and marketing.



What is involved in implementing the ISO 9001 Standard?

- Identify the requirements of ISO 9001 and how they apply to your business
- Establish quality objectives and how they fit in to the business
- Produce a documented quality policy and procedures
- Communicate them throughout the business
- Once developed, perform internal audits to ensure the systems and procedures are being adhered to.
- Perform management review meetings to review the business performance and set new targets and action points



What is the Certification Process?

- Introduce procedures in line with the ISO 9001 standard
- Contact a UKAS Accredited Certification Body who will independently audit your systems and approve you to the ISO 9001:2008 Standard.
- Receive your Certificate and Logos and present to your customers to demonstrate your commitment to quality.
- Receive annual audits to ensure that your system remains compliant.



Who is UKAS?

- United Kingdom Accreditation Service
- Government Body who Accredits Certification Bodies to enable them to perform audits to ISO 9001:2008.
- They will audit the Certification Body on a regular basis to ensure that the audits are being performed independently and to a high standard.
- Having a UKAS Accredited Certification Body certify you to ISO 9001:2008 will demonstrate to your customers that you are being independently audited against your systems and procedures.



Does having ISO 9001:2008 mean more paperwork?

- The original standard required a large amount of documentation to be generated but since 2000 the standard has been revised and brought in line with current practices and has made the standard more user friendly.
- There will be documentation generated but this will only be essential items needed to support the business.



BS EN ISO 9001:2008

- Is not a specification
- It does not set levels of performance
- It does not define the absolute quality of the product or service



How is ISO 9001 Different?

- The company decides the level of quality
- It addresses each part of the business
- The company must define responsibilities
- It ensures consistency of performance and conformance to customer requirements



BS EN ISO 9001 Involves:-

- Writing down what you do
- Doing what you have written down
- Auditing and monitoring that you do what you have written down

BS EN ISO 9001:2008

1.2 Application

- where any requirements of the standard cannot be applied due to the nature of the organisation & its product, this can be considered for exclusion
- limited to the requirements within clause 7
- Can't exclude activities that are carried out
- Examples
 - Design & Development
 - Control of Monitoring and Measuring Devices



Requirements of the Standard

4.0 Quality Management System

4.1 General Requirements

4.2 Documentation Requirements



Requirements of the Standard

5.0 Management Responsibility

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Planning and Objectives

5.5 Responsibility, authority & communication

5.6 Management Review



Requirements of the Standard

6.0 Resource Management

6.1 Provision of Resources

6.2 Human Resources

6.3 Infrastructure

6.4 Work Environment



Requirements of the Standard

7.0 Product Realisation

7.1 Planning of Product Realisation

7.2 Customer-related processes

7.3 Design & Development

7.4 Purchasing

7.5 Production & Service provision

7.6 Control of Monitoring & Measuring
Equipment



Requirements of the Standard

8.0 Measurement, Analysis & Improvement

8.1 General

8.2 Monitoring & Measurement

8.3 Control of Nonconforming Product

8.4 Analysis of Data

8.5 Improvement



Quality Manual

- Describes the ‘scope’ of the quality system, including details of & justification for any exclusions
- Addresses all the requirements of the Standard
- Contains or refers to the documented procedures
- Describes the interaction of the processes of the QMS
- Contains the Quality Policy and Statement of Objectives



Quality Procedures

- Quality Procedures define **responsibility** for a process, and how the process interacts with other processes within the organisation.
- Quality Procedures define ‘HOW’ the Company will satisfy the requirements of the customer, Standard, own system requirements and any Applicable Legislation.



Quality Procedures

- There are 6 Mandated Documented Procedures
 - Control of Documents
 - Control of Records
 - Internal Audit
 - Control of Nonconformities
 - Corrective Action
 - Preventive Action

You will also require documented procedures for any process that requires one to maintain system conformance



Work Instructions

- Work Instructions can be used to document how specific tasks are performed, maybe a client specific requirement for processing their order.
- Work Instructions provide detailed methods of operation in support of Procedures
- Same level of document control required



ISO 9000 Work Programme

- Gap Analysis (where you are now?)
- Draft Quality Manual and Procedures (where you need to be)
- Staff Awareness training
- Review and Amend Manual and Procedures
- Verify & implement Procedures
- Compile the Audit Schedule
- Perform Internal Audits and Management Review