

# ISO 9001:2008 Quality Manual

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## COMPANY PROPRIETARY INFORMATION

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## Approvals

The signatures below certify that this quality manual has been reviewed and accepted, and demonstrates that the signatories are aware of all the requirements contained herein and are committed to ensuring their provision.

	Name	Signature	Position	Date
Prepared by				
Reviewed by				
Approved by				

## Amendment Record

This quality manual is reviewed to ensure its continuing relevance to the systems and process that it describes. A record of contextual additions or omissions is given below:

Page No.	Context	Revision	Date

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# Introduction

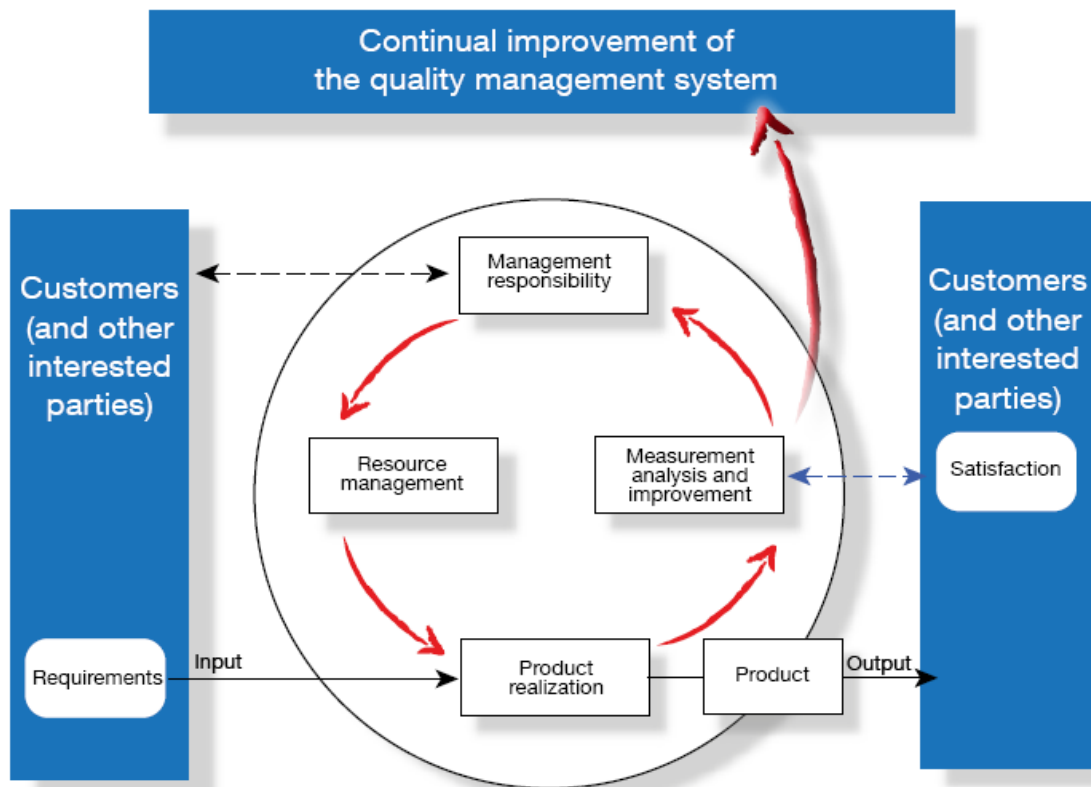
Your Company has developed and implemented a quality management system in order to document the company's best business practices, better satisfy the requirements and expectations of its customers and to improve the overall management of the company.

The quality management system of Your Company meets the requirements of the international standard ISO 9001: 2008. This system addresses the design, development, production, installation and servicing of the company's products.

This manual describes the quality management system, delineates authorities, inter relationships and responsibilities of personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the quality management system to ensure compliance to the necessary requirements of the standard.

This manual is also used externally to introduce our quality management system to our customers and other external organizations or individuals. The manual is used to familiarise them with the controls that have been implemented and to assure them that the integrity of our quality management system is maintained and focused on customer satisfaction and continuous improvement.

Quality Management System Process Approach



The model above illustrates that effectiveness and improvement can be represented as a cyclical process that uses components of the quality management system to analyze data and then direct changes and initiatives that ensure the system's continual improvement. This ensures a proactive approach to meeting the quality management system objectives and customer requirements.

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# 1. Scope

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The International Organization Standard ISO 9001:2008 describes the requirements for a quality management system by addressing the principles and processes surrounding the design development and delivery of a general product or service. The activity covered by **Your Company** is for the provision of and/or **[amend as appropriate]** supply of **[specify business/industry/sector]**.

The quality management system complies with all applicable requirements contained in ISO 9001:2008, covers the design and provision of all products and/or services, and encompasses all operations at our facility located at **[insert address of your facilities here]**.

The following table identifies ISO 9001:2008 requirements not applicable to **Your Company** and provides a brief narrative justifying their exclusion from the scope of the quality management system:

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Clause	Justification
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## 2. References

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In addition to ISO 9001:2008, the company will also make reference to relevant British and or international standards as well as customer specifications appropriate to the product and its market.

Standard	Title	Title & Description
ISO 9000:2005	Quality management systems	Fundamentals and vocabulary
ISO 9001:2008	Quality management systems	Requirements
ISO 9004:2000	Quality management systems	Guidelines for performance improvements

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## 3. Terms & Definitions

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Our quality management system uses the same internationally recognised terms, vocabulary and definitions given in ISO 9000:2005. Acronyms, terms, vocabulary and definitions unique to our organization, customers, industry and region are referenced throughout our quality manual and are contained in Appendix A.1.

The following terms and definitions are taken from ISO 9000:2005:

Term	ISO Clause	Definition
Document	3.7.2	Information and its supporting medium
Procedure	3.4.5	Specified way to carry out an activity or a process
Quality Manual	3.7.4	Document specifying the quality management system of an organization
Quality Plan	3.7.5	Document specifying how procedures and resources shall be applied
Record	3.7.6	Document stating results achieved or evidence of activities performed
Specification	3.7.3	Document stating requirements

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## 4. Quality Management System

### 4.1 Introduction

Your Company has implemented a quality management system that exists as part of a larger, overall management system which has established, documented and implemented our quality policy and related processes for providing products and services which meet or exceed customer requirements, whilst satisfying the requirements of ISO 9001:2008.

Your Company has adopted the process approach advocated by ISO 9000:2005, by defining and managing process inputs, controls and outputs to ensure the desired results are achieved and by managing the interfaces between interrelated processes to ensure system effectiveness is maintained.

Your Company monitors, measures and analyzes relevant processes and takes action to achieve planned results and ensures the continual improvement of our quality management system. Any outsourced process or activity is controlled as per applicable ISO 9001 requirements.

Specific responsibilities for, and the sequence and interaction of key quality management system processes are detailed in the quality procedures, some of which contain or reference deployment flow charts depicting the process or which is also described in the narrative of the procedure. Appendix A.2 describes the sequence and interaction of our organizational processes.

### 4.2 Documentation Requirements

#### 4.2.1 General

This quality manual contains documented statements of our quality policy and quality objectives and references the documented procedures required by ISO 9001:2008 and other documents needed to ensure effective planning, operation and control of our key processes.

The level and type of quality management system documentation established for our business is continually reviewed to ensure it remains appropriate for the complexity of the interactions of our core processes and the competence of our employees. Quality management system documents and data exist in hard copy and electronic format.

The quality management system documentation includes this quality manual, quality procedures, forms and other internal and external documents and data needed to manage, perform or verify work affecting product quality. Any quality management system documentation which is utilized or generated is categorised into the following hierarchy:

#### Quality Management System Documentation Hierarchy:

Tier	Document Type	Purpose
1	Policy	Key system driver of process inputs and objectives; statement of corporate vision
2	Quality manual	Describes corporate approach and responsibilities for achieving quality
3	Procedures	Describe the methods required for process implementation
4	Work instructions	Describe the operating practices and controls of each process
5	Forms	Key system outputs; data, records, proof of conformance and evidence of verification

#### 4.2.2 Quality Manual

This manual has been prepared to describe Your Company's quality management system; its associated procedures, and the processes needed to implement our quality policy in order to achieve our quality objectives. Each section of the manual makes reference to various procedures, forms and process maps relating to the requirements outlined in that section.

### 4.2.3 Document Control

All quality management system documents are controlled according to the Document Control Procedure (P001) which defines the process for:

- Approving documents for adequacy prior to issue
- Reviewing and revising as necessary and re-approving documents
- Ensuring that changes and current revision status of documents are identified
- Ensuring that relevant versions of applicable documents are available at points of use
- Ensuring that documents remain legible and readily identifiable
- Ensuring that documents of external origin are identified and their distribution controlled
- Preventing the unintended use of obsolete documents
- Ensuring that documents of external origin are identified and their distribution controlled

The company uses standard forms and a local area network computer system with an electronic document management system which are updated as required.

Documents which are controlled include but are not limited to the followings examples:

- Quality manual
- Procedures
- Records

Controlled documents are identified with a document name and document number:

- Procedures are prefixed P
- Forms are prefixed F
- Work instructions are prefixed W

A list of key quality management system documents; including all quality procedures, forms and other key quality management system documents is located in Appendix A.3.

Supporting documentation:

Ref	Title & Description
P001	Document Control Procedure

### 4.2.4 Control of Records

Records are established to provide evidence of conformity to the requirements specified by the standard, customer requirements and of the effective operation of the quality management system are formally controlled through the application of the Control of Records Procedure (P002).

Records which are controlled include but are not limited to:

- Corrective Action Reports
- Management Review Reports
- Customer Complaints
- Calibration Records

Supporting documentation:

Ref	Title & Description
P002	Control of Records Procedure