

QM 001 – Scope of the Quality Management system

Introduction

The company has established, documented and implemented a quality management system for the site, which is maintained in order to continually improve its effectiveness in accordance with legislation, international standards and best industry practice. The processes that contribute to meeting the requirements of these standards have been determined.

Scope

The scope of the Quality Management System includes all products, including intermediate products, manufactured on site and activities conducted on site.

These requirements are aligned with the policies and objectives of the site and include those of the international standard ISO 9001:2008.

Should the site be required to outsource any process that may affect product conformity to the defined standards of the Quality Management System then the site will assume control over this process. This is further defined in the Control of Sub-Contract Processes.

Procedure

These processes and their interaction are documented within this manual and its procedures.

The top level procedures of the Quality Management System Procedures are pre-fixed QM and are as follows:

- QM 001 - Quality Management System
- QM 002 - QMS Manual Summary
- QM 003 - Document Control
- QM 004 - Customer, Statutory and Regulatory Conformance
- QM 005 - Record Control
- QM 006 - Management Commitment
- QM 007 - Quality Policy

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- QM 008 - Responsibility and Authority
- QM 009 - Management Review
- QM 010 - Resources and Training
- QM 011 - Infrastructure and Work Environment
- QM 012 - Contract Review
- QM 013 - Design and Development
- QM 014 - Purchasing, Orders and Verification of Purchased Materials
- QM 015 - Production
- QM 016 - Identification and Traceability
- QM 017 - Customer Property
- QM 018 - Preservation of Product
- QM 019 - Despatch and Distribution
- QM 020 - Maintenance
- QM 021 - Waste Management
- QM 022 - Calibration
- QM 023 - Measurement and Monitoring
- QM 024 - Customer Satisfaction
- QM 025 - Internal Audit
- QM 026 - Monitoring and Measuring QMS, Analysis of Data
- QM 027 - Control of Non-Conforming Product
- QM 028 - Corrective Action, Preventive Action and Improvement
- QM 029 - Crisis Management
- QM 030 - Product Recall

The controlled records of the Quality Management System are pre-fixed QMR and are as follows:

- QMR 001 Management Review Minutes
- QMR 002 Training Record
- QMR 003 Product Release Record
- QMR 004 Design and Development Records
- QMR 005 Supplier Assessment Record
- QMR 006 Validation Record
- QMR 007 Identification and Traceability Record
- QMR 008 Register of Customer Property
- QMR 009 Calibration Record
- QMR 010 Internal Audit Record
- QMR 011 Records of Non-conforming Product
- QMR 012 Corrective Action Request Form

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QMR 013 Preventative Action Request Form
QMR 014 Supplier Self Assessment and Approval Form

The Criteria and Methods required to ensure that the operation and control of these processes are effective are documented in these procedures.

These procedures are supported by second tier documents specific to each area including:

- Work instructions
- Specifications
- Testing schedules
- Risk assessments
- Job Descriptions
- Control Point Monitoring Procedures

Measurement, monitoring and review are carried out by analysis of data in key areas:

- Control Point monitoring
- Analytical testing
- Complaints analysis
- Key Quality performance indicators
- Standard Exception Reporting
- Results of Inspections
- Results of Internal audits
- Results of External Audits

The company has assessed the resources required to implement, maintain, and improve the Quality Management System and these resources have been provided including:

- Skilled Personnel
- Suitable materials

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- Suitable equipment
- Appropriate Hardware and Software
- Infrastructure
- Information
- Finances
- Audit resource
- Training resource

Action is taken in response to results in order to correct and prevent deficiencies and to improve the probability of achieving company objectives.

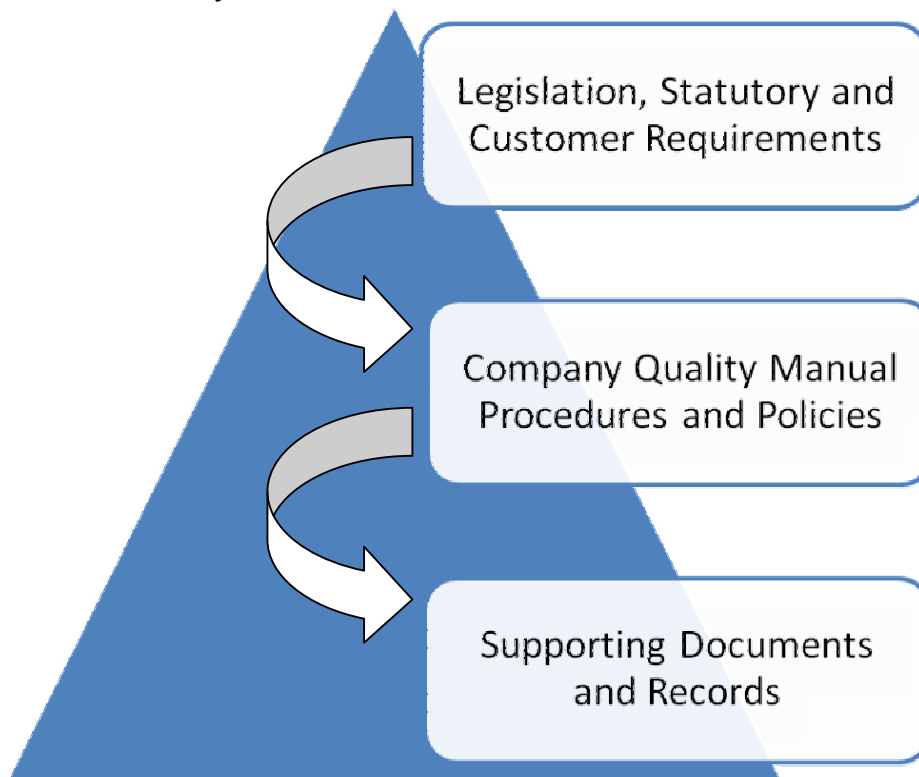
Regular management reviews are conducted by the Senior Management team to ensure performance is monitored and analysed. Review outputs include site quality objectives which are published and communicated to all staff to ensure focus is maintained both on meeting these objectives and on continuous improvement.

Responsibility

Senior Management is responsible for implementing, maintaining, reviewing and improving the Quality Management System. The Technical Manager is a member of the Senior Management team and has been appointed the Management Representative.

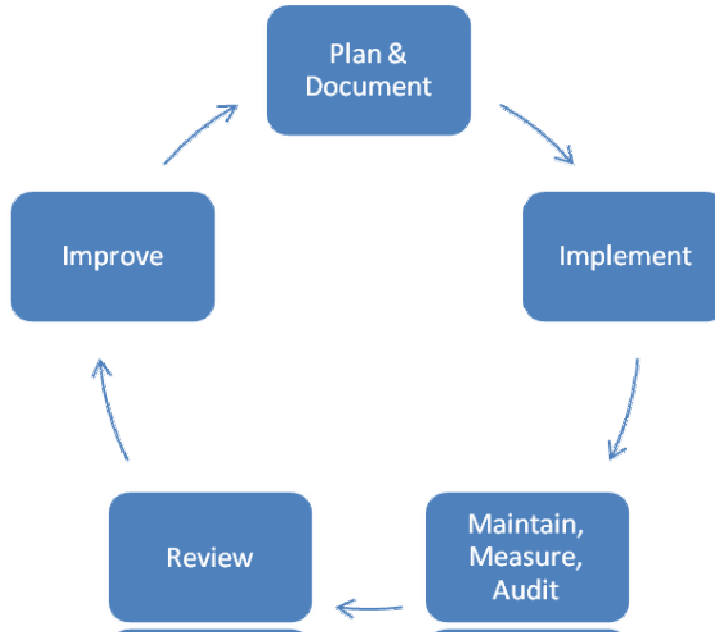
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Document Hierarchy



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Quality System Process Diagram



Revision Number	Summary of Changes made from previous revision	Requested By:	Authorised By:
2	Update to meet the requirements of ISO 9001:2008	Quality Manager	Site Director