

Signatrol.com

Data Logging Solutions

Quality Manual

for

Signatrol Ltd.

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This manual is issued on the authority of the Managing Director. Its purpose is to define the policies and responsibilities adopted within the company in order to deliver its quality objectives.

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1 The Quality Management System

1.1 Company Introduction

Signatrol Ltd. was formed in 2004 to design, manufacture and sell electronic data loggers.

The company operates from a single site in Tewkesbury UK.

1.2 Scope of Supply

Design, manufacture and supply of data loggers and data logging systems.

1.3 Structure and purpose

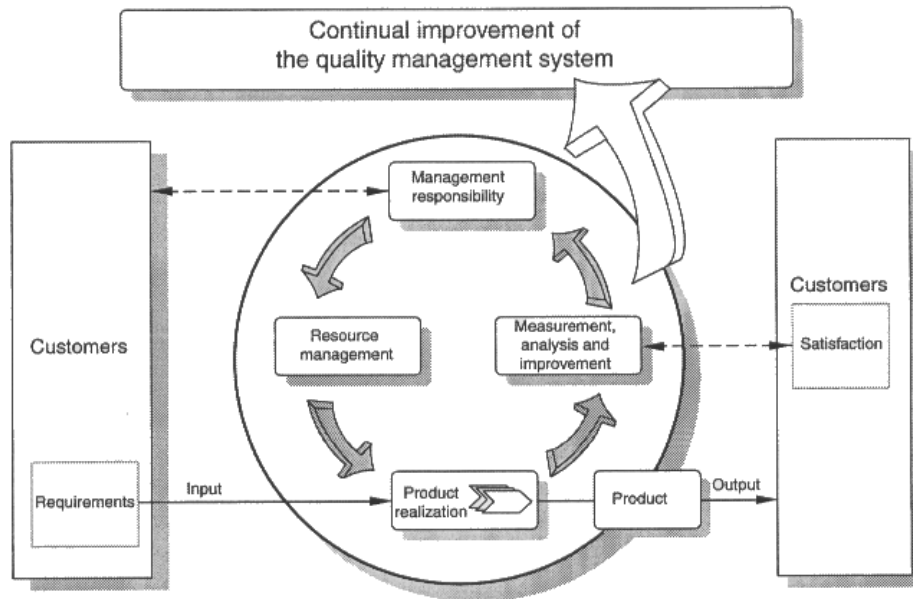
The Quality system complies with the requirements of ISO9001:2000 and is maintained and monitored by the Managing Director. A cross reference is contained in the appendix 10.1. There are no exclusions.

The Quality Assurance function is designed to achieve the following aims

- The continued development and application of the quality control system and quality procedures.
- The maintenance of the Quality Manual and Quality Procedures.
- Helping with the assessment and audits of suppliers and sub-contractors.
- Ensuring that the management review is carried out bi-annually ensuring that the quality system is both suitable and effective and achieving the goals of the quality policy.
- To ensure that records are kept of the findings.

The purpose of the quality system is :

- To establish the objectives and processes necessary to deliver results in accordance with customer requirements and the company's policies.
- To monitor and measure the processes against policies, objectives and requirements for the product and to report on the results.
- To define, monitor and control the interaction between the processes.
- To define, monitor and control any outsourced processes in order to achieve the quality objectives.
- To take action to continually improve the process performance.



1.4 Document Hierarchy

Documents are organised as a three level structure:

- **Quality Manual:** Top level document designed for senior managers detailing policy and structure for the effective control and monitoring of the system
- **Procedures:** Intended for managers and supervisors detailing the individual methods used to control and monitor the various processes
- **Work Instructions:** Detailed instructions on how to perform particular tasks and intended for people who are actually performing the task.

1.5 Control of Documents

Procedures are in place to ensure that all documents are effectively controlled to:

- Approve for adequacy prior to issue.
- Review, update and re-issue.
- Ensure that changes and current revision status are identified.
- Ensure that the relevant versions of applicable documents are available at points of use.
- Ensure that documents remain legible and readily identified.
- Ensure that documents of external origin are identified and their distribution controlled.
- To prevent the unintended use of obsolete documents and to ensure that they are suitably identified if they are retained for any purpose.

1.6 Records

Records are kept to establish conformity to requirements (both internal and external) and to verify the effective operation of the quality system. Records can be 'paper' or electronic and are stored in a variety of methods and for differing times depending upon the nature of the record and any requirements that are placed on us by external bodies.

Procedures are in place to ensure that:

- Records are established that provide evidence of conformity to requirements and of the effective operation of the quality system.
- Records remain legible and are readily identifiable and retrievable.
- Relevant storage periods that comply with the requirement of the Quality System or, where appropriate, external bodies, are established and that records are maintained for that period.

2 Management Responsibility

2.1 Commitment to Quality

Managers are required to demonstrate their commitment to the development and implementation of the quality system by:

- Communicating to staff the importance of meeting customer, statutory and regulatory requirements.
- Establishing and implementing the quality policy
- Ensuring that the quality objectives are attained.
- Taking part in the Management Reviews
- Ensuring the availability of adequate resources.

2.2 Customer Focus

Managers should take all necessary steps to ensure that customers requirements are accurately determined and meet with the aim of enhancing customer satisfaction, by monitoring information relating to customer perception to whether the organisation has met the customers requirements. Results of which are analysed and presented and the Quality Management Review.

2.3 Quality Policy

Signatrol Ltd. has a policy of continuous development and improvement of its products together with its manufacturing and quality systems with the following objectives.

- To monitor and enhance customer satisfaction.
- To monitor and improve the efficiency of our manufacturing operations.
- To develop the skills and abilities of our employees through appropriate education and training.
- To ensure that all our products comply with relevant current legislation and EU directives.

The organisation and structures laid down in this manual are designed to meet these objectives and all personnel are expected to enthusiastically and energetically support them and to assist with their implementation.

The quality policy is reviewed bi-annually at the Management Quality Review Meeting to ensure its continued suitability and is placed on the company notice board.

2.4 Statement of Objectives

Quality objectives are reviewed bi-annually at the Quality Review Meeting and measurable and achievable quality improvement targets are established as goals for the next period.

2.5 Responsibility and Authority

All relevant responsibilities and levels of authority are defined within each procedure. It is departmental managers responsibility to ensure that staff within their department are sufficiently well trained and have all the necessary documentation and resources to work to the relevant procedures and work instructions.

2.6 Internal Communications

The results and findings from the Management review are published so that all staff are

aware of the effectiveness of the quality system.

Managers relay information, where appropriate, to the staff under their responsibility following briefings regular at Management Meetings.

3 Management Quality Review

A Management Quality Review is held at approximately six monthly intervals where the quality system, quality policy and quality objectives are assessed for their suitability, adequacy and effectiveness.

Performance against previously established targets is evaluated and new quality improvement targets are agreed.

Records of the meeting are maintained

3.1 Review Input

Data relating to the following are presented and analysed:

- Results of Audits
- Customer Feedback
- Process performance and product conformity
- Status of preventative and corrective actions
- Follow up actions relating to previous reviews
- Changes in operating practices that could affect the QMS
- Recommendations for improvements and agreement revised quality targets.

3.2 Review Output

The review meeting shall consider and take any decisions it may think necessary to:

- Improve the effectiveness of the QMS and its processes
- Improve product related customer requirements
- Identify and provide adequate resources

4 Resource Management

4.1 General

It is the responsibility of each manager to ensure the provision of adequate resources, Human, Physical and Infrastructure, to ensure that staff under their control are able to:

- Do their job effectively and efficiently
- Implement, maintain and continually improve the QMS
- Enhance customer satisfaction by meeting customer requirements

4.2 Human Resources

Procedures are established to:

- Ensure that all staff, by virtue of appropriate education, training, acquired skills and experience, shall be competent to do the work they are required to do.
- Determine the level of competence required for staff to do their job
- Provide appropriate training or other action to satisfy any needs
- Evaluate the effectiveness of any action taken
- Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievements of the Quality Objectives
- Maintain appropriate records of education, training, skills and experience.

4.3 Infrastructure and Work Environment

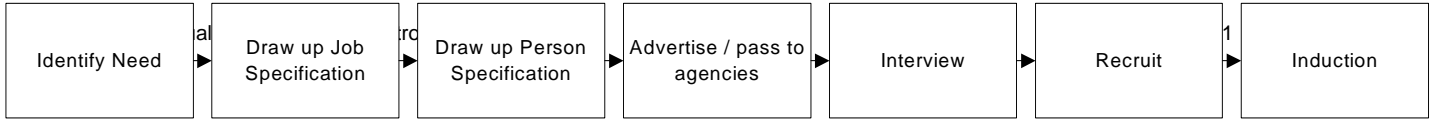
The organisation undertakes to review the requirements to provide and maintain the infrastructure and work environment necessary to manufacture the product and achieve the quality objectives.

4.4 Resource Management Processes

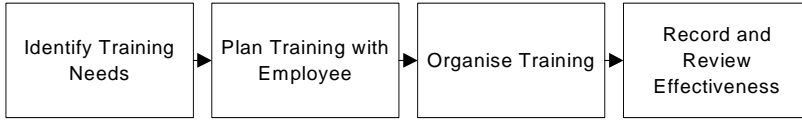
The following block diagram is an abridged resource management flow chart. Click on ' In Detail' to see the process in more detail and on 'Procedures' to view related procedures.

Resource Management

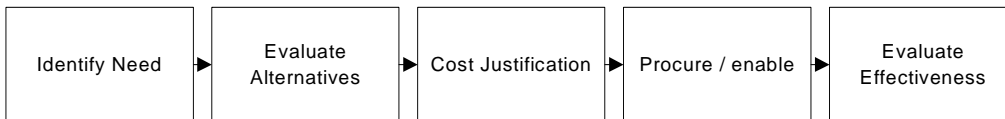
Recruitment



Training and Staff Development



Capex / Infrastructure



5 Product Realisation

5.1 Planning of Product Realisation

Prior to starting any new project, a project plan is produced which establishes, amongst other things, the following:

- Quality Objectives
- Product requirements
- Resource Needs
- Records to provide evidence that the resulting product meets the requirements including verification and validation criteria.

5.2 Customer Related Processes

5.2.1 Determination of requirements

It is the responsibility of the sales department to accurately determine the customer's requirements. Which includes the following:

- Delivery and post delivery activities
- Requirements not stated but necessary for the intended use, where known.
- Statutory and regulatory requirements related to the product.
- Any additional requirements as defined by the company

5.2.2 Review of requirements related to the product

The sales department is responsible, seeking additional advice where necessary, for reviewing the customer requirements to establish:

- That product requirements are defined
- Any deviation from standard product specifications and/or changes from previous expressed requirements are resolved
- The company has the ability to fulfil the contract.
- Where no documented statement of requirements from the customer exists, confirming the details to the customer either before acceptance of the order or as a condition of acceptance.
- That any changes to a contract are reviewed and effectively communicated to the appropriate staff.

5.2.3 Customer Communication

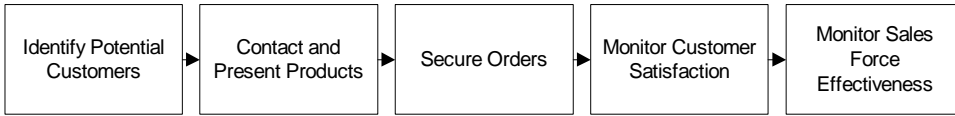
Procedures are implemented to adequately control the following aspects of Customer Communications:

- Product Information
- Enquiries, Contracts, order handling
- Customer Feedback, including complaints

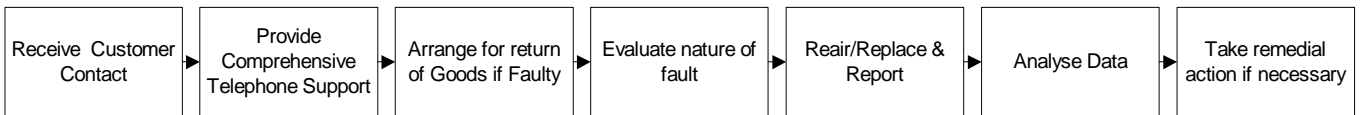
5.2.4 Sales and After Sales processes

The following block diagram is an abridged product realisation flow chart. Click on 'In Detail' to see the process in more detail and on 'Procedures' to view related procedures.

Sales: Group 1



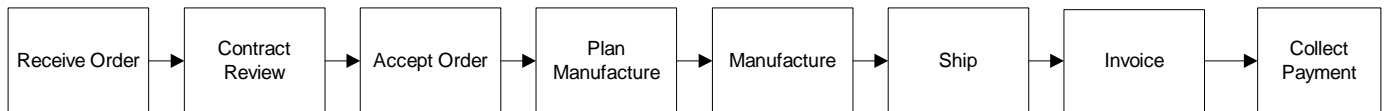
After Sales: Group 2



6 Operations

6.1 The Operations Process

The following block diagram is an abridged product realisation flow chart. Click on 'In Detail' to see the process in more detail and on 'Procedures' to view related procedures.



From the point of accepting the order onwards, the system bureaucracy is handled and controlled by the companies ICAPS computer system, the operation of which is defined in the systems internal help file.

A summary of the system operation is as follows:

- Raises order acknowledgement
- Maintains customer data base
- Provides sales data history
- Provides delivery schedules and historical information
- Identifies component shortages
- Raises purchase orders and provides historical data for analysis
- Calculates product manufactured costs and produces reports
- Prints Dispatch Notes
- Generates Invoices
- Produces management reports

The Sage system provides a rigid structure that controls most aspects of the operations process.

6.2 Control of Production

The production activity is carried out under controlled conditions which ensure that:

- The correct information is available
- The correct work instructions are available
- The correct Monitoring and measuring devices are available
- The necessary information is measured and recorded
- Release, Delivery and past delivery instructions are correctly adhered to

6.3 Process Validation

Processes that are employed in the manufacturing phase that cannot be verified by subsequent testing have procedures to control and record their validation to ensure that they achieve the planned result(s). Such procedures may be carried out internally or externally and should:

- Define the criteria for review and approval of the process(es)
- Approve the equipment and qualification and training of the personnel
- Define the methods
- Define the criteria for re-validation

6.4 Purchasing

The Purchasing activity is under the control and supervision of the Sales Manager and it is his responsibility to ensure that purchased product conforms to the specified purchase

requirements.

Purchase orders are placed on suppliers who are on the computer system and an official order raised which will contain as a minimum:

- Latest drawing issue for material or part (where relevant)
- Delivery dates and instructions
- Prices and quantities agreed

And where appropriate:

- Requirements for approvals, procedures, processes and equipment
- Requirements for qualification of personnel.
- Certificate of Conformity.
- Any relevant Inspection Instructions.

6.4.1 Verification of Purchased Product

When goods arrive, checks are made to ensure that they conform to requirements of the order in terms of price, quantity and description and are accompanied by the appropriate paperwork. In addition, any special requirements or goods inwards inspections that are required carried out.

Records are maintained on the computer system of all orders so that past supplier performance can be examined and reports obtained.

6.4.2 Control of Suppliers

Suppliers are selected in accordance with the company's requirements for product to be supplied to the right quality, at the right price and to agreed time-scales. The company approves suppliers prior to the placement of the first order and monitors their performance against the defined criteria on a regular basis.

Unless there is an overwhelming reason to continue to source from a particular supplier, those who do not meet minimum acceptable standards will be removed from the list of approved suppliers and no further orders will be placed until such time as the reason for the unacceptable performance can be shown to have been rectified.

Records of the results of supplier analysis are maintained.

6.4.3 Control of Sub-contractors

Controls for sub-contractors are similar to those applied to Suppliers but the difference being that Sub contractors manufacture to drawings supplied by the company and therefore are subject to a higher level of inspection.

Subcontractors, in addition to the normal supplier assessments must also demonstrate that they operate a quality system that:

- Ensures that they are working to the appropriate drawing(s) and issue(s)
- Ensures adequate control and supervision is exercised over their own suppliers and Sub-contractors
- Have sufficient inspection resources to ensure that the product is manufactured in accordance with the drawing(s) supplied.
- Provides for identifying and reporting any non-conformancies
- Ensures staff are fully competent to carry out the work.
- They have and continue to maintain any third party approvals that may be required.

Sub-contractors shall be audited by the company at appropriate intervals to ensure the correct operation of the quality system.

The company approves sub-contractors prior to the placement of the first order and monitors their performance against the defined criteria on a regular basis. Unless there is an overwhelming reason to continue to source from a particular supplier, those who do not meet our minimum acceptable standards will be removed from the list of approved suppliers and no further orders will be placed until such time as the reason for the unacceptable performance can be shown to have been rectified

Records of the results of sub-contractor analysis are maintained.

6.5 Identification and Control

6.5.1 Product

The product is clearly identified at all stages of the realisation process

6.5.2 Stock

Stock is clearly identified and stored in such a way as to maintain it's quality. Stock which has a shelf-life is rotated to use the oldest stock first and monitored to establish that it is not beyond its shelf life when used.

Component and batch identification ensures traceability of components through the stock control and purchase record system.

6.5.3 Customer Supplied Product

Customer supplied product is clearly identified and segregated to ensure that it is reserved for the project for which it was intended and records of such material are maintained.

The company has a duty care to ensure the integrity of customer supplier product and undertakes to keep it under conditions appropriate to the nature of the product or as defined by the customer. Title to the product and the intellectual property therein remains with the Customer unless they are the subject of a special agreement.

6.5.4 Non Conforming Product

Non-conforming product is clearly identified and segregated until either:

- A concession to use the product is raised and the product is subsequently used
- The product is re-worked to comply with requirements
- The product is returned to the supplier for credit or replacement
- The product is scrapped and disposed off.

6.6 Preservation of the Product

The conformity of the product, or parts of the product, is preserved during processing and transportation to its intended destination by ensuring :

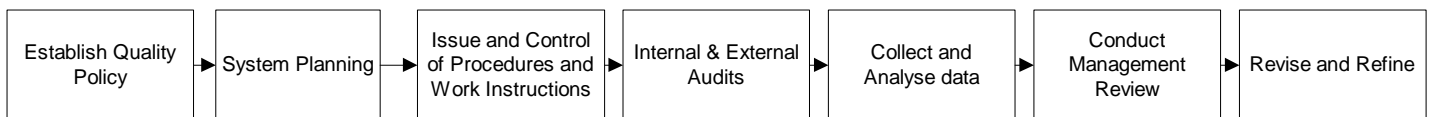
- Clear and accurate identification
- Adequate Packaging appropriate to the nature of the product and its intended shipping method
- Appropriate handling and storage

7 Quality Assurance & Control

7.1 The QA Process

The following block diagram is an abridged product realisation flow chart. Click on 'In Detail' to see the process in more detail and on 'Procedures' to view related procedures.

Quality Assurance



7.1.1 Inspection

The company has procedures in place to ensure that the measuring devices and processes needed to provide evidence of the conformity of the product to the determined requirements are available.

7.1.2 Control of Inspection of measuring Equipment

Devices used for inspection and validation are:

- Calibrated or verified at specific intervals prior to use. Such checks being traceable to national standards and recorded.
- Adjusted or re-adjusted as necessary, such re-calibrations are recorded and periodically reviewed.
- Clearly identified so that calibration status can be easily established.
- Safeguarded against un-authorized adjustment.
- Protected from damage and deterioration during handling, maintenance and storage.

7.1.3 Test and Inspection software

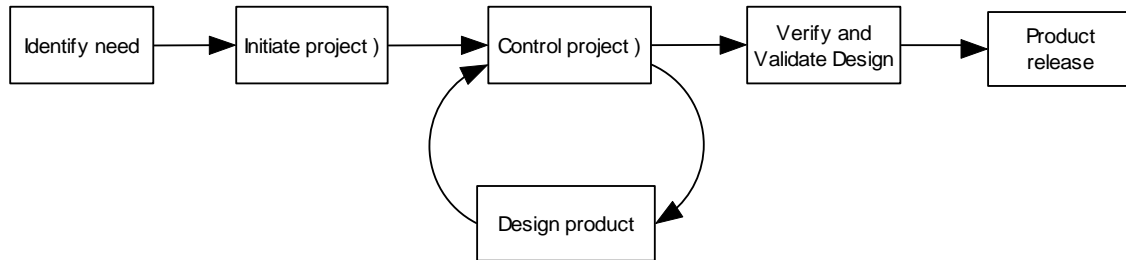
Where applicable, controls are in place to ensure that any software used for inspection or validation:

- Is the correct software for the inspection process
- Is the latest Issue
- Is installed on the correct hardware.

8 Product Development

8.1 Product Development Processes

The following block diagram is an abridged Design/development flow chart.



8.2 Design and Development Planning

Prior to the commencement of a design and development project a quality plan is generated that outlines:

- The various stages in the design process
- The review, verification and validations that are appropriate at each stage
- The responsibilities and authorities for the individual elements of the design

8.3 Design and Development Inputs

The design input takes the form of a 'Statement of Requirements' which includes the following:

- Functionality and mandatory performance criteria
- Statutory and regulatory requirements.
- Any relevant information from previous designs etc.
- Any other requirements deemed necessary
- The criteria for the verification and validation of the design

Design Inputs form part of the quality records.

8.4 Design and development Outputs

Design and development outputs are documented and reviewed to provide evidence of the following:

- The design meets the input requirements
- The design provides the appropriate information for purchasing, production and service.
- The design meets product acceptance criteria
- The design specifies the characteristics essential for its safe and proper use
- The design meets any special conditions for use to ensure compliance with relevant standards.

8.5 Design and Development Review

Project reviews are held at various stages as defined in the quality plan to ensure that:

- The design as envisaged is capable of meeting the input requirements.
- Any potential problems are identified and appropriate action is taken.

8.6 Design and Development Verification

Tests on the product are performed, prior to release, to ensure that the design meets the

design input requirements.

The results of these tests are recorded and retained as part of the quality records.

8.7 Design and Development Validation

Tests on the product are performed, prior to release, to ensure that the design is capable of meeting the requirements for its intended use.

The results of these tests are recorded and retained as part of the quality records.

8.7.1 Software Validation

Software reliability is ensured by:

- Following good design practice
- Breaking the design down into functional modules.
- Verifying the module where appropriate
- Ensuring that the code is well commented so that it could be easily understood by another professional programmer

The software is finally validated running on the intended target hardware. The company recognises that it is virtually impossible to totally validate the software but such tests are performed to ensure that:

- It does what it was specifically designed to do
- It does not do what it was specifically designed not to do.

8.8 Control of Design and Development changes

After the initial design input information has been accepted, any change to the requirements are identified at the design review meeting and the effects of the change on the product, its intended use and any product already delivered are evaluated prior to acceptance.

All such changes are documented and form part of the quality records.

9 Measurement Analysis and Improvement

9.1 General

The company embraces the general principle of continual improvement and has procedures to for the monitoring, measurement, analysing and improving processes.

These procedures are designed to:

- Demonstrate the conformity of the product
- Ensure the conformity of the QMS
- Continually improve the effectiveness of the QMS
- Continually improve the various processes within the Company
- Take appropriate corrective and preventative action when non-conformities are identified.

Where appropriate, statistical techniques are used to monitor parameters where 100% checking would be impracticable but the determination of applicable methods and extent of use is regulated by the QA department.

9.2 Customer Satisfaction

Procedures are implemented to monitor customer satisfaction in a number of key areas as determined by the management review and suitable targets for improvement are adopted and monitored.

9.3 Internal Audits

Internal audits are carried out periodically by the QA department as determined by the audit programme. The audit programme contains the audit criteria, scope, frequency and methods and is derived by taking into account:

- The status and importance of the processes and areas to be audited.
- The results of past audits

Discrepancies or non conformities identified at the audits are actioned by the departmental managers responsible in a timely manner with the minimum of delay. The QA department follows up all such actions to ensure their timely implementation.

9.4 Monitoring of Processes

Key aspects of all process are monitored and analysed and the results presented to the Management Review.

9.5 Analysis of Data

Data relating to the effectiveness of the QMS, the effectiveness of the processes and conformity of product to requirements, Customer Satisfaction, Suppliers & Sub-contractors and any identifiable trends are presented to the Management Review where they are analysed and decisions regarding opportunities for process improvements or preventative actions are taken.

9.6 Improvement

9.6.1 Corrective Action

When non-conformities are identified the following actions are taken:

- Review of Non Conformance (Including customer complaints)
- Determination of the cause
- Evaluation of the need for action.
- Determining the appropriate course of action

- Recording the results and reviewing the effectiveness of the action taken.

9.6.2 Preventative Action

In addition to the corrective actions, the Company investigates mechanisms by which the non conformance was allowed to happen and implements such changes to the QMS, procedures and work instructions as deemed necessary to prevent future occurrences of a similar nature.

The results of all such changes are recorded and form part of the quality records.

10 Appendix

10.1 Cross Reference to ISO9001:2000

B.S REFERENCE	DESCRIPTION	QUALITY MANUAL REF:
1	Scope	
1.1	General	
1.2	Application	
2	Normative Ref:	
3	Terms and Definitions	
4	Quality Management System	
4.1	General Requirements	1.2
4.2	Documentation Requirements	1.3
4.2	Quality Manual	
4.2.3	Control of Documents	1.4
4.2.4	Control of Records	1.5
5	Management Responsibility	
5.1	Management Commitment	2.1
5.2	Customer Focus	2.2
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5.5		
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8.2.4	Monitoring and Measurement of Product	9.4
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8.4	Analysis of data	9.5
8.5	Improvement	9.6
8.5.1	Continual Improvement	
8.5.2	Corrective Action	9.6.1
8.5.3	Preventative Action	9.6.2