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.***

**Issue and Revision History**

| Issue | Comment | Date | Originators Signature |
|---|---|---|---|
| 01 | Initial Issue | 13/06/17 | B Turner |
| 02 | Minor Corrections | 05/06/2018 | B Turner |
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## CONTENTS

## 3. 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. This Quality Manual described the processes that Signatrol Ltd use to conform to ISO 9001 2015.

## 4. Scope

This Quality Manual is designed to establish the principles and procedures to:

a) Demonstrate the Company's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
b) Enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

## 5. The Organisation and its context

The organisation is a SME operating in the data logging market. It supplies a variety of products, some of which are the Company's own design and some are third party products, for recording data. It meets the needs and regulatory requirements of a number of markets, primarily Pharmaceutical and Food.

It recognises that these markets require high accuracy and reliability and that the Company has a number of strong competitors.

Data integrity is a prime requirement for these specialist markets and is the overriding requirement for all products.

In addition, the Company offers a calibration/recalibration service.

## 6. Needs and Expectations of Interested Parties

The needs and expectations of interested parties are monitored on a regular on-going basis at the sales and management meetings.

# 7. The Quality Management System and Processes

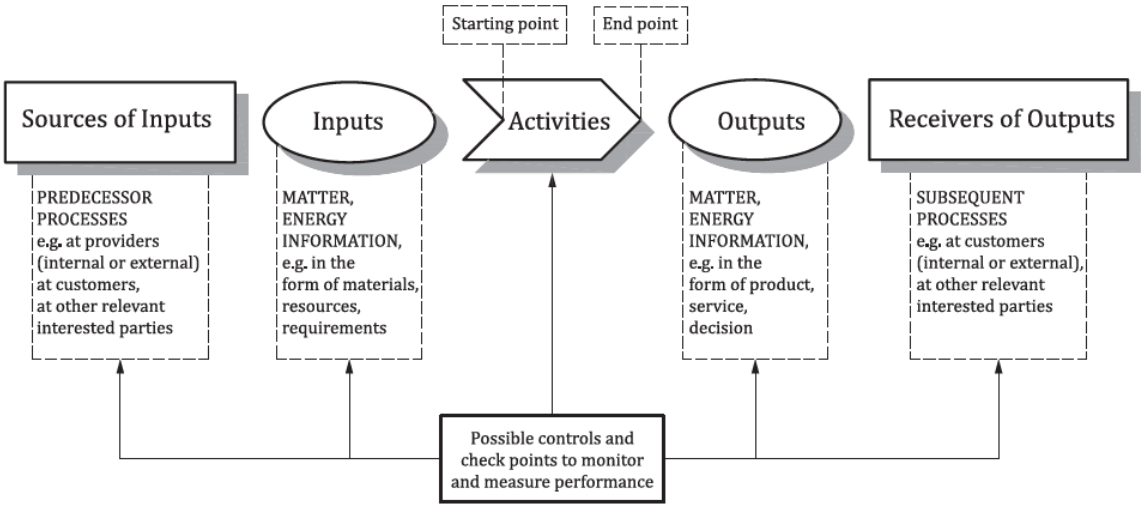



**Figure 1 — Schematic representation of the elements of a single process**

## 7.1 General Requirements

Procedures are implemented to establish, document and maintain the quality system with the aim of improving the quality in line with the requirements of ISO9001 2015.

**a) Determining Processes**

All processes that are needed for the quality management system and their application throughout the organisation are determined and Inputs and Outputs clearly defined.

**b) Interaction and Sequences**

The sequence and interaction of these processes are determined.

**c) Effectiveness**

An annual Quality Management Review monitor the effectiveness of the processes. Managers are encouraged to immediately report and significant deviations from established procedures or any loss of effectiveness.

**d) Resources**

The Managing Director ensures that sufficient information and resources are available to implement these processes. Any requirement is identified at either the regular management meetings or at the Quality Management Review. Managers are encouraged to immediately report any issues arising from lack of resources. Staff are encourages to raise and recourses issues at the annual performance review. It is the Managing Director's responsibility to

endure that sufficient funds are available to provide the required recourses.

**e) Risks and Opportunities**

There is an on-going evaluation of Risks and Opportunities and the regular management meetings and appropriate actions are discussed and implemented.

**f) Analysis**

Monthly audits together with the Annual Management Review continuously monitors, measures and analyses the processes. Modifications to the processes are implemented where appropriate.

**g) Responsibilities and Resources**

All responsibilities and resources are defined in the relevant procedure or work instruction.

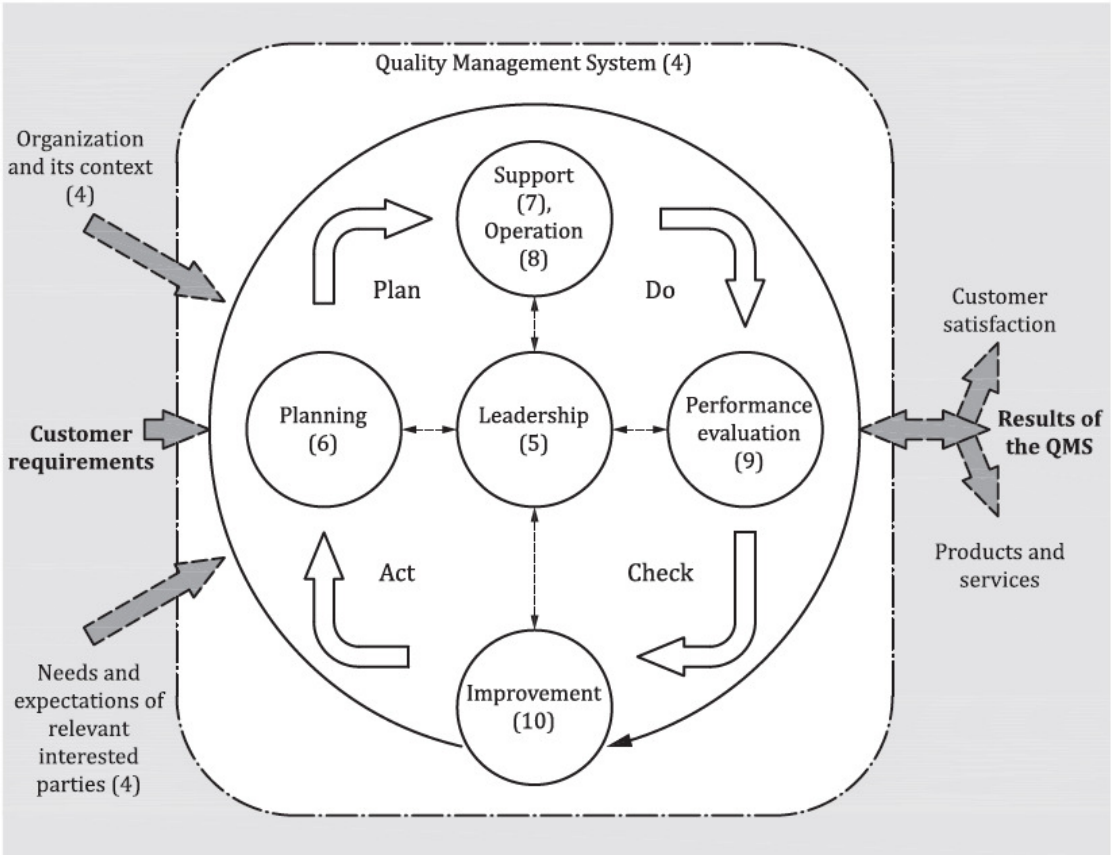
**h) Corrective Actions**

Actions to achieve planned results and to achieve continual improvement of the processes are identified during the monthly audits together with the annual Quality Management Review and are implemented as soon as practicable. Managers are encouraged to immediately report and significant issues arising during the course of business which are addressed as soon as is practicable.

The overriding principle is that all processes are managed by the organisation to ensure complained with ISI 9001 2015

# 8. Plan-Do-Check-Act cycle

The plan-Do-Check Cycle can be applied to all process and the Quality Management as a whole.




The numbers in brackets refer to the clauses in the International Standard

## 8.1 Documentation Requirements

### 8.1.1 General

**a) Quality Policy**

Signatrol Ltd. design, manufacture and supply data loggers and data logging systems to a variety of markets and 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.

- Evaluate Risk and Opportunity

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 annually at the Management Quality Review Meeting to ensure its continued suitability and is placed on the company notice board.

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

**i) Quality Manual**
The Quality Manual is maintained by the Managing Director who has ultimate responsibility for quality matters.

**j) Procedures**
Procedures are available to ensure that the company meets ISO9001 2015 and which define the records to be maintained

**k) Documents**
All documents necessary for the organisation to ensure effective planning, operation and control of processes are generated and maintained.

**8.1.2 Quality Manual**

This Quality Manual is maintained by the Managing Director and contains the following:

**a) Scope of Supply**
Design, manufacture and supply of data loggers and data logging systems.

Structure and purpose

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.

**b) 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.

- There are no exclusions.
- To take action to continually improve the process performance.

**c) Procedures**

Procedures are referenced but not included in the manual there is a document hierarchy as follows:

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.

**d) Description of Interaction between processes**

These are detailed and referenced where appropriate within the procedures.

### 8.1.3 Control Of Documents

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

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

### 8.1.4 Control of 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.

# 9. Management Responsibility

## 9.1 Management Leadership and Commitment

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 the effectiveness of the Quality System
- Promoting the use of the process approach and risk-based thinking
- Ensuring that the quality objectives are attained.
- Taking part in the Management Reviews
- Ensuring the availability of adequate resources.

## 9.2 Customer Focus

Managers should take all necessary steps to ensure that customer's 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.

## 9.3 Quality Policy

Signatrol Ltd. design, manufacture and supply data loggers and data logging systems to a variety of markets and has a policy of continuous development and improvement of its products together with its manufacturing and quality systems with the following objectives.

- To ensure that any customer and applicable statutory and regulatory requirements are determined, understood and consistently met.
- To monitor and enhance customer satisfaction.
- To monitor and improve the efficiency of our manufacturing operations.
- To ensure that any risks and opportunities that can affect conformity of products are determined and addressed.
- 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 annually at the Management Quality Review Meeting to ensure its continued suitability and is placed on the company notice board.

## 9.4 Planning

**9.4.1 Statement of Quality 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.

**9.4.2 Quality Management System Planning**

The initial planning of the system was carried out by the Managing Director to conform to ISI 9001 2015 and subsequently verified by external audit. (QMS)

Changes to the Management System require authorisation by the Managing Director who will confirm that the integrity of the system is not compromised.
This will be checked by external audit annually.

## 9.5 Responsibility Authority and Communication

**9.5.1 Responsibility and Authority**

The Managing Director is directly responsible for all quality matters and ensuring that the requirements of this manual are met.

All relevant departmental responsibilities and levels of authority are defined within each procedure. It is departmental manager's 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.

### 9.5.2 Management Representative

The Managing Director shall have responsibility and authority for:

a) Ensuring that the processes needed for the QMS are established, implemented and maintained
b) Reporting to the Board of Directors on the performance of the QMS and any need for improvement
**c)** Ensuring the promotion of the awareness of customer requirements throughout the organisation.

### 9.5.3 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.

## 9.6 Management Review

Regular management meetings are held (normally Monthly) and records of the meeting are maintained.

The scope of these meetings is to:

a) Evaluate current financial performance.
b) Address any new Risks and opportunities.
c) Evaluate the effectiveness of current strategies.
d) Formulate any new or revised strategies.

Management Quality Review is held annually where the quality system, quality policy and quality objectives are assessed for their suitability, adequacy and effectiveness and revised as necessary

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

Records of the meeting are maintained

## 9.7 Review Input

Data relating to the following are presented and analysed:

a. Results of Audits
b. Customer Feedback
c. Process performance and product conformity
d. Status of preventative and corrective actions
e. Follow up actions relating to previous reviews
f. Changes in operating practices that could affect the QMS
g. Recommendations for improvements and agreement revised quality targets.
h. Analysis of Risks and Opportunities

## 9.8 Review Output

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

a) Improve the effectiveness of the QMS and its processes
b) Improve product related customer requirements
c) Identify and provide adequate resources
d) Assess if there is a need to modify the Quality Policy.

# 10. Resource Management

## 10.1 Provision of Resources.

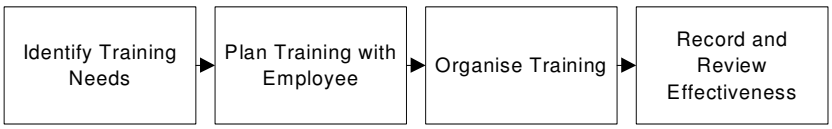
It is the responsibility of each manager to ensure the provision of adequate resources, Human, Physical and Infrastructure, to ensure that staff under their control are able to:

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

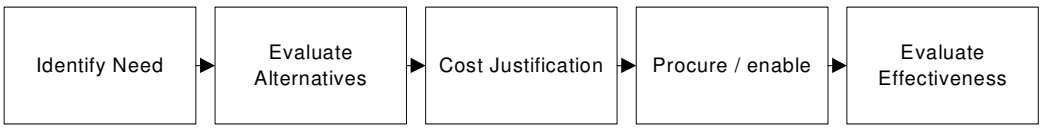
**Resource Management**

Recruitment


Training and Staff Development




Capex / Infrastructure




## 10.2 Human Resources

### 10.2.1 General

Personnel performing work shall be deemed competent on the basis of education, trainings skills and experience.

### 10.2.2 Competence, training and Awareness

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.

### 10.3 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.

## 11. Product Realisation

### 11.1 Planning of Product Realisation

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

a) Quality Objectives and Product requirements
b) The need to establish resource needs and any special process and documents
c) Required verification, validation, monitoring, measuring, inspection and test specific to the product and the criteria for product acceptance.
d) Records needed to provide evidence that the resulting product meets the requirements including verification and validation criteria.

### 11.2 Customer Related Processes

#### 11.2.1 Determination of requirements

It is the responsibility of the sales department to accurately determine the customer's requirements. Which must, amongst other things, include the following:

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

#### 11.2.2 Review of requirements related to the product

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

a) That product requirements are defined
b) Any deviation from standard product specifications and/or changes from previous expressed requirements are resolved
c) The company has the ability to fulfil the contract.
d) 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.

e) That any changes to a contract are reviewed and effectively communicated to the appropriate staff.

**11.2.3 Customer Communication**

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

a) Product Information
b) Enquiries, Contracts, order handling
c) Customer Feedback, including complaints

## 11.3 Design and Development

**11.3.1 Design and Development Planning**

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

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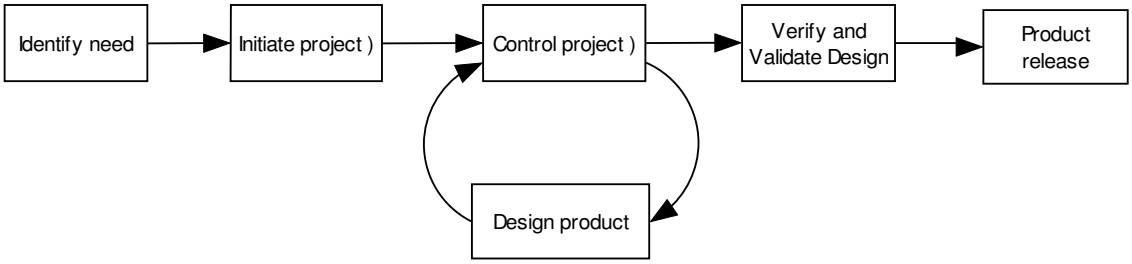



Prior to the commencement of a design and development project a quality plan is generated that outlines:

a) The Nature, Duration and Complexity
b) The required process stages
c) The various stages in the design process
d) The review, verification and validations that are appropriate at each stage
e) The responsibilities and authorities for the individual elements of the design
f) The internal and external resource needs
g) The need for customer involvement in the design
h) The documentary requirements to demonstrate that the design and development criteria have been met.
i) The adequacy of the requirements to be communicated to any external suppliers.

**11.3.2 Design and Development Inputs**

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

a) Functionality and mandatory performance criteria
b) Statutory and regulatory requirements.
c) Any relevant information from previous designs etc.
d) Any other requirements deemed necessary

It should also define the criteria for the verification and validation of the design.

Design Inputs form part of the quality records.

**11.3.3 Design and development Outputs**

Design and development outputs are documented and reviewed to provide evidence of the following and are in a form suitable for verification against the design inputs.

a) The design meets the input requirements
b) The design provides the appropriate information for purchasing, production and service.
c) The design meets product acceptance criteria
d) The design specifies the characteristics essential for its safe and proper use

**11.3.4 Design and Development Review**

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

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

**11.3.5 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.

**11.3.6 Design and Development Validation**

Tests on the product are performed in accordance with the planned arrangements, 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.

Software Validation

Software, by its very nature is complex and prone to error and so it requires its own validation controls.

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.

### 11.3.7 Control of Design and Development changes

After the initial design input information has been accepted, any change to the requirements shall be reviewed, verified and validates as appropriate at a design review meeting. The review shall, amongst other things, evaluate the effects of the change on the product, its intended use, any constituent parts and any product already delivered are evaluated prior to acceptance.

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

## 11.4 Purchasing

### 11.4.1 Purchasing Process

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.

### 11.4.2 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.

### 11.4.3 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.

### 11.4.4 Purchasing Information

Purchasing information is contained either in drawings, or as stated on the purchase order and, where appropriate, includes the following:

**c) Requirements or approval of product, procedures, processes and equipment**

a) Requirements for qualification of personnel
b) QMS requirements.

### 11.4.5 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.

## 11.5 Production and Service Provision

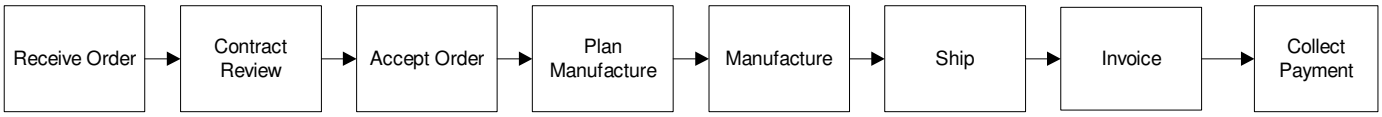
### 11.5.1 Control of Production and Service Provision

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

a) The correct information is available
b) The correct work instructions are available
c) Suitable equipment is available and used correctly
d) The correct Monitoring and measuring devices are available
e) The necessary information is monitored, measured and recorded
f) Release, Delivery and past delivery instructions are correctly adhered to

**11.5.2 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 computer system, the operation of which is defined in the systems internal help file.

A summary of the system operation is a s 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.

**11.5.3 Validation of Processes for Production and Service Provision.**

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:

a) Define the criteria for review and approval of the process(es)
b) Approve the equipment and qualification and training of the personnel
c) Define the methods
d) Maintain appropriate records
e) Define the criteria for re-validation

### 11.5.4 Identification and Traceability

All items are clearly identified and, where required, traceable as follows:

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

Stock
Stock is clearly identified and stored in such a way as to maintain its 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.

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.

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.

### 11.5.5 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

## 11.6 Control of Monitoring and Measuring Resources

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.

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.

### 11.7 Measurement Traceability

All measurement critical equipment used for inspection and validation must be:

a) Calibrated or verified at specific intervals prior to use. Such checks being traceable to national standards and recorded
b) Adjusted or re-adjusted as necessary, such re-calibrations are recorded and periodically reviewed.
c) Safeguarded against un-authorised adjustment.
d) Protected from damage and deterioration during handling, maintenance and storage.
e) Records of Calibration and Verification equipment are maintained together with records to demonstrate the validity of previous measuring results.
f) Clearly identified so that calibration status can be easily established

## 12. Measurement, Analysis and Improvement

### 12.1 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:

a) Demonstrate the conformity of the product
b) Ensure the conformity of the QMS
c) Continually improve the effectiveness of the QMS through
   i) Continually improving the various processes within the Company
   ii) Taking 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.

### 12.2 Monitoring and Measurement

#### 12.2.1 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.

#### 12.2.2 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

Normally, each procedure is audited at least annually

The audits ensure that the QMS:

a) Conforms to planned arrangements, to the requirements of the standard and the requirements of the QMS
b) Is effectively implemented and maintained

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.

**12.2.3 Monitoring and Measurement of Processes**

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

**12.2.4 Monitoring and Measurement of Product**

The company monitors the performance of its products to ensure that they conform to specification. This may be performed on a sample basis. Results are maintained and, in the event of non-conformance either:

- The specification is amended or
- Changes to the product are implemented.

No product or service shall be released for sale until it has been approved by the appropriate person.

## 12.3 Control of Non-Conforming Product.

When non-conformities are identified a review of the non-conformance (Including customer complaints) is undertaken and the following actions are taken:

a) Action to eliminate the cause
b) Authorise its use, release or acceptance under Concession
c) Action to preclude its original intended use
d) Take action to appropriate the effects or potential effects of the non-conformity if it is detected after delivery or use has started.

Records of the nature of the non-conformity and the actions taken will be maintained.

## 12.4 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.

Analysis shall provide information on the following:

a) Customer Satisfaction
b) Conformity to product requirements
c) Characteristics and trends of processes and products
d) Supplier performance

## 12.5 Improvement

### 12.5.1 Continual Improvement

The organisation continually strives to improve its quality through its Quality Policy, Quality Objectives, Audit Results, Analysis of data, corrective and preventative actions and management review.

### 12.5.2 Corrective Actions

The company takes action to eliminate the cause of non-conformities as follows:

a. The non-conformities are reviewed (Including Customer Complaints)
b. The cause(s) of the non conformity are established
c. The need for action is evaluated to ensure the non-conformities do not re-occur.
d. The corrective action is determined and implemented
e. Records of the results of the actions are maintained.
f. A review of the effectiveness of the action is performed.

### 12.5.3 Preventive actions

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.

a) Potential non-conformities and their causes are identified. The cause(s) of the non conformity are established
b) The need for action is evaluated to ensure the non-conformities do not occur.
c) The preventive action is determined and implemented
d) Records of the results of the actions are maintained.
e) A review of the effectiveness of the action is performed.