PLASMOTEC

Quality Manual

CONTENTS

APPENDIX

1.0 Quality policy and objectives

- To consistently provide customers with mouldings or products that meet or exceed their requirements:
    - That are fit for purpose and entirely consistent with specification.
    - Within any applicable statutory or regulatory framework.
    - On time and in full.
- To provide an effective QMS that satisfies or exceeds the needs and requirements of stakeholders and interested parties:
    - That is appropriate in the overall context of the business.
    - That takes account of and addresses the risks and opportunities in the context of the business.
- A QMS designed to encourage and enhance customer focus, customer satisfaction, and continuous improvement and excellence throughout the business.
- A QMS demonstrably capable of proving conformity with ISO 9001:2015.

The scope of the QMS is Plastic Injection Moulding and the design and manufacture of plastic injection mould tooling.

The quality policy is determined by the Managing Director and is an output of the Strategic Review and Management review and continuous improvement.

The quality policy is distributed to all employees via the Company's Intranet and disseminated through mandated training.

The quality policy is available to relevant interested parties as appropriate subject to the written approval of a director.

2.0 Quality management principles

The QMS is built upon and incorporates the following foundation principles. These can be thought of as being: philosophies, standards, ideologies or doctrines. These Quality Management Principles (QMP's) should underlie the QMS. The QMP's are described in ISO 9000:2015 Quality management systems Fundamentals and vocabulary and fully endorsed by the Company.

The Quality Management Principles are:

Customer focus
Leadership
Engagement of people
Process Approach
Improvement
Evidence based decision making
Relationship management

Relevant flow charts and / or training documents [1]

- BS EN ISO 9000:2015 Quality management systems Fundamentals and vocabulary PL 933

3.0 Context of the organisation

The interested parties relevant to the QMS are:

- Customers
- Government and other regulatory bodies
- Shareholders
- Employees
- Suppliers

The parties considered to be interested parties is determined and reviewed at each strategic review undertaken by the Board.

At the same review the Board will consider key strategic threats, weaknesses, risks and opportunities in the context of the Company and its interested parties.

The Board will evaluate internal and external issues that are relevant to its purpose and strategic direction and the impact they may have on the QMS and the sufficiency and achievement of the Quality Objectives.

To the extent necessary the Quality Objectives and QMS will be endorsed or modified in line with changes as they arise or resulting from the strategic review.

External and internal issues that are relevant to the QMS and the sufficiency of the QMS will also be considered at the monthly QMS review meetings.

[1] *Note re documents identified under each section of this Quality Manual*

Flow charts, training documents and other controlled documents and organisational knowledge are retained, stored and maintained within the document's index held in the PDMS. Any documents detailed against any section of this quality manual are intended to identify the main documents and resources considered to be directly applicable and associated with the subject area. See also QMS documentation and organisational knowledge section.

3.1 **Interested parties – customers**

Customers are important and critical to any business. It is a fundamental requirement of the QMS that it properly factors in the needs of the customer and how those needs are satisfied. It is further essential that the QMS properly provides continuous satisfaction of those needs and mechanisms that can be used to monitor performance and facilitate continuous improvement.

3.2 **Interested parties - government and other regulatory bodies**

One of the interested parties identified above is the Government and other regulatory bodies. The Company has a responsibility to satisfy requirements placed upon it by the government and any relevant legal obligations. Such obligation or requirements fall into the following categories:

- Obligations to HMRC re Income Tax, National Insurance, Corporation Tax, VAT and other taxes
- Payroll and Auto enrolment requirements and generally any, and all, employment related obligations.
- Food Safety re contact of plastic products with food.
- Packaging waste and certain other compliance requirements regarding waste disposal.
- Health and Safety requirements.

3.3 **Interested parties – shareholders**

The Company's shareholders are interested parties and their interests are aligned with those of the directors and the Company. They are one and the same. Shareholders fully endorse the QMS and its objectives

3.4 **Interested parties – employees**

The Company believes its strategy and objectives should take account of legitimate employee interests. Legitimate employee interests and needs are aligned with those of the Company.

3.5 **Interested parties – suppliers**

Even though we are the clients of our suppliers, we need to consider what our suppliers want from us. Ensuring that we have a solid value chain up-stream, would ensure that we are able to deliver our product down-stream. Requirements of suppliers include receiving regular orders, working in a safe environment, and favourable payment terms.

3.6 Delivering the requirements of the interested parties

To a very significant degree the interests and needs of the interested parties are common and satisfied by adherence with the following controls employed by the Company:

- Strong financial control designed to facilitate and deliver the Company's financial goals and compliance with certain regulatory requirements. Compliance with many such requirements is predicated upon strong financial control and understanding. Specifically, the use of the following financial control techniques or practices are used to provide assurance that the Company satisfies those obligation:
    - Detailed monthly management accounts produced to a high standard and on a timely basis.
    - Budgetary control techniques and the regular construction of detailed financial budgets and monthly comparison to actual performance.
    - A fully developed integrated costing system.
    - Financial control and techniques designed to ensure accuracy and control and to meet statutory and regulatory obligations.

- The quality management principles (QMPS's) detailed in this document and training are proactively employed to encourage a culture directed at employee competence, development, progression, job satisfaction and a sound, stable, healthy and profitable business compliant with the obligations placed upon it. And one that is customer focused and wants to continuously improve.

- Training systems and the use of the training control panel is a key element of how we deliver the QMP's and the QMS generally. Training is designed to deliver and encourage the acquisition of knowledge, new skills and expertise and to demonstrate competence. To encourage development and progression. To promote customer satisfaction and efficiency.

- A systematic approach to the management of quality to enhance customer satisfaction and ensure product conformity tailored to the demands of the product and customer and the business we are in.

- A strong focus on what exactly is the specification for each product we sell that takes account of the risks inherent in the process and the specific risks applicable to the product.

- A QMS designed to address and control the generic risk and specific risks associated with the manufacture of each plastic product we sell.

- A QMS that is demonstrably capable of proving conformity with ISO 9001:2015.

- A system of control that ensures we know the "food status" of each material we use and the requirements of each product and each customer such that we can ensure the integrity of the use of materials. The system extends to provision of technical compliance data to the customer and a system for managing the same.

4.0 The scope of the Quality Management System

The Company provides plastic injection moulded products. This accounts for greater than 95% of gross revenue. Whilst the Company may well supply products to customers from a broad range of industry sectors, the primary target market sector is packaging, albeit very loosely defined. Customers may from time to time require certain products to be pad printed and/or entail some light assembly work. Such post moulding work generally represents a very small percentage of gross revenue and is deemed non-core to the business. The manufacture of plastic mouldings requires a mould tool as an integral part of the moulding process. From time to time customers will contribute to the cost of tool origination. The vast bulk of tools used are built in-house and all tools are built with the expectation of being used in-house. Tools built in-house necessitate and incorporate tool design.

The QMS applies to the Company without any constraint.

The QMS scope is therefore: Plastic Injection Moulding and the design and manufacture of plastic injection mould tooling.

5.0 The QMS and its processes

The QMS is defined by the following:

- This document
    - Pulls together and describes the QMS and provides a mechanism to demonstrate consistency with the standard.
- The various flow charts that exist and which are summarised within the overall master flow chart FC OO1
    - Defines system or process objectives, inputs and outputs and graphically describes processes.
    - Details dependency between processes.
- The PDMS and the various control panels that exist
    - Enables the relevant process to be used and managed to make the system work effectively.
    - Encourages and facilitates control and the management of risk.
    - Establish practical responsibility, authority and accountability.
    - Understand resource availability and process interdependencies.
    - Provides for the provision of information to any authorised user to “get the job done” and to ensure information is available to provide evidence-based decision making and a basis for analysis.
    - Ensure information is available to improve and evaluate performance and provide traceability.

- The application of the 4 pillars of effective production control
    - A practical application of process control to injection moulding developed by the Company that is fully integrated into the PDMS and supported by detailed training.

- Training Material
    - Designed to deliver and encourage the acquisition of knowledge and best practise, develop employees, teach new skills and expertise and to demonstrate and confirm competence and application. To encourage development and progression. To motivate and to provide transparency. To deliver the QMS, monitor performance and encourage customer focus and efficiency.

6.0 Commitment and customer focus

The QMS and its application within the Company is of paramount importance and its maintenance, design and content is a continual focus point for all.

The design of the QMS is additionally predicated on securing lasting improvement in the ability of the Company to enhance efficient and productive practices that complement continuous improvement in the entire customer experience.

Initiatives often involve the use of the PDMS and its use or extension with suitable attention given to the provision of systems that take account of the need to gather and use data. Securing greater efficiency in data capture and emphasis on good data analysis to aid and improve decision making and to assist addressing risk.

QMS improvement initiatives are planned and their roll out co-ordinated and tested. Where applicable and desirable initiatives and changes to the QMS are supported via:

- Planning including system design, execution and testing.
- Training material.
- Validation of training.
- Use of different formats to deliver initiatives including video, shadowing, buddying up, questions and answers, performing the task successively subject to scrutiny and evaluation.
- Use of the off-line test PDMS designed and built to facilitate real “mirror” simulation of improvement initiatives to afford validation of the system changes and enable training.
- Management Review – QMS meetings
- Internal Audit

A key objective of the above is to encourage and enhance customer focus, customer satisfaction and continuous improvement.

The Company utilises a Quality Assurance Control Panel and specifically the mechanism of a Specification Check score to help manage product quality and risk.

This systematic approach to applying a score to the sufficiency of the specification of the products we sell provides a simple approach designed:

- To encourage a comprehensive and complete understanding of the product specification.
- To provide a risk-based approach to the determination of what we need to do to assure quality and facilitate improvement.
- To give a simple measure that communicates the extent to which we know the precise specification for each product we sell and how comprehensively we have addressed the specific risk associated with the manufacture and sale of those products.
- To provide a simple standard measure that is relatively easy to understand, to derive and use as a control tool.

The specification score is therefore a key performance indicator (KPI) which is precisely correlated with the crucial demand of knowing what the specification is for each product we sell. And one that can be used to calibrate the risk associated with the manufacture of a given product. The specification check score KPI can be applied to a single product or any grouping of products. We use it in the context of a single product and to provide an aggregate percentage score based upon all products that are in "progress" or "outstanding" at any given point in time.

The specification check score KPI is therefore a key measure that is entirely consistent and appropriate to the Company's QMS, comparable, easily understood and calculated and published by the PDMS.

Other KPI's are in use that are targeted at the QMS and its performance.

In addition, the proper use of the Sales Order Control panel is integral to ensuring focus. Here delivery performance expressed in a calculation that considers the extent to which a delivery is affected On Time and In Full (OTIF) is a KPI captured by the PDMS.

Amongst other things KPI's are used to help interpret performance, to communicate key gaols, to promote excellence, encourage customer focus and to encourage continuous improvement.

In many instances KPI's are a built-in feature of the PDMS

Customer focus, obtaining customer feedback and understanding customer needs is a focus of telesales activity and collated and disseminated via sales meetings.

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- PL 852 The Training Protocols and Systems we employ
- PL 924 QA KPI's
- PL 934 Sales Training Part 8 - The Sales Meeting
- PL 943 KPI - On Time In Full
- PL 946 Strategic review
- PL 947 The QMS Meeting
- PL 957 Internal Auditing

7.0 Organisational roles, responsibilities and authorities

Overall responsibility for the QMS rests with the Managing Director. Elements of the system will impact upon all employees. Specific relevant roles, responsibilities and authorities are assigned, communicated and understood via the following:

- The organisation chart (see Appendix 1).
- Training, training review meetings & training practices.
- The construction of the PDMS and the application of access rights, edit rights and authorities.
- The use of key Performance Indicators (KPI's).
- Job descriptions.
- Meetings.
- The intranet.

Relevant flow charts and / or training documents

- PL 852 The Training Protocols and Systems we employ
- PL 924 QA KPI's
- PL 934 Sales Training Part 8 - The Sales Meeting
- PL 943 KPI - On Time In Full
- PL 947 The QMS Meeting

8.0 Monitoring and measuring

Measurement is an important element in the manufacture of both mould tools and products. And it is critical to ensuring product conformity. The company uses primarily physical dimension measurement and the measurement of weight as control tools extensively within the QMS.

Accuracy of measuring equipment used is essential to ensure valid and reliable results when measuring equipment is used.

The task of measuring product is complicated because of potential shrinkage. All injection moulded products will shrink to some degree once they start to cool. The rate of cooling and the extent of cooling will vary according to the material used and many other factors or variables. Some products may be susceptible to significant shrinkage such that there is a need to fully evaluate the extent and speed the product shrinks and the impact that has on how product conformity can be assured.

Relevant flow charts and / or training documents

- FC 010 Drawings
- FC 013 Initial Sample Inspection report
- FC 021 First Offs
- FC 023 Last Offs

- FC 041 Measuring Devices: Gauges and CMM Requirements, Production & Calibration
- BOTR 39 Gauges
- BOTR 47 Gauge Usage
- PL761 CMM Training Part 1
- PL847 Engineering Drawing Training
- PL851 Product Specification
- PL911 Measuring Devices

9.0 QMS documentation and organisational knowledge

QMS documentation consists of:

- This document.
- The various flow charts that document various processes, protocols, procedures, controls and the objectives of those processes.
- The Plasmotec Database Management System (PDMS) and the various programs and data held therein and specifically.
    - The documents held in the documents index in the PDMS.
    - The control panels held therein.
    - Training documentation and material held in the PDMS.

The PDMS contains the various documented elements of the QMS. It is through the various control panels, flow charts, training documentation and programs integral to the PDMS that the Company establishes, implements, maintains, documents and continually improves the QMS including the processes needed and their interactions.

The PDMS design and functionality is fundamental and integral to:

- The roll out of QMS objectives and requirements, their integration with systems and processes and their achievement.
- Promoting a process approach and risk-based thinking.
- Facilitating and ensuring the availability of key resources.
- Communicating KPI's, goals and requirements.
- Assisting and supporting activity.
- Providing feedback to assist securing goals and to promote improvement.
- The storage and availability and use of organisational knowledge.

The Quality Manual and Flow Charts and other Quality documentation are maintained in electronic format in the computerised Quality Document Index in the PDMS. Access is controlled by means of user permissions that may only be set or changed by authorised personnel. Documents are reviewed and if considered acceptable incorporated into the documents index by the Managing Director or under his direct instruction.

All employees are given easy access to the documentation that is relevant to them. All documents are given unique identification references that include revision or version numbers. All documents are dated to show the date of issue or when last amended as

appropriate. Obsolete documents which have been subject to changes are marked "superseded" and flagged accordingly in the documents index.

Physical copies of the quality manual should not generally be made and are only issued in "uncontrolled" status.

Maintenance of Quality documentation is the responsibility of the Managing Director.

When revisions are implemented, the revision number of the complete affected document is updated.

Relevant documentation received from external organisations is incorporated as appropriate into the Quality Document Index.

Computer Data is backed up regularly in a manner designed to mitigate and largely eliminate the risk of data loss. The back-up policy is maintained by the Company's external computer supplier who monitor equipment performance and backup integrity.

All records electronic or otherwise must be maintained for a minimum of 5 years. Physical copies of job cards and In Process Inspection Records should be retained for a period of 8 years. Certain accounting books and records need to be retained for a period of 12 years.

Relevant flow charts and / or training documents

- PL 465 Plasmotec Electronic Data Backup Policy
- The PDMS Documents Index

10.0 Competence of those that affect the performance and effectiveness of the QMS

The following resources are used as appropriate to determine, evaluate, ensure and demonstrate competency of those that affect the performance and effectiveness of the QMS.

- Training material, training review meetings & training practices
- The construction of the PDMS and the application of access rights, edit rights and authorities.
- The use of key Performance Indicators (KPI's)
- The use of the Quality Control Panel and the PDMS
- Job descriptions
- The QMS review meeting

Relevant flow charts and / or training documents

- PL 852 The Training Protocols and Systems we employ
- PL 924 QA KPI's
- PL 943 KPI - On Time In Full
- PL 947 The QMS Meeting

11.0 Awareness of the Quality Policy, Quality Objectives and the contribution an individual makes

Awareness of the following is proactively promoted by the Company to all those that impact the QMS:

- The Quality Policy and objectives.
- The Quality Manual.
- The contribution of an individual to the effectiveness of the QMS's performance.
- The contribution that can be made to the effectiveness of the QMS through improved performance.
- The implications of not conforming to the QMS requirements.

The following resources are used as appropriate to communicate and promote awareness:

- Publication of the Quality Policy and objectives.
- The training control panel.
- Job descriptions.
- Training material.
- Training review meetings.
- Induction training.
- The Company's intranet.
- Specific KPI's and their review.
- The snag system.

Relevant flow charts and / or training documents

- FC 001 The overall flow chart
- FC 055 Snags
- PL 852 The Training Protocols and Systems we employ
- PL 924 QA KPI's
- PL 934 Sales Training Part 8 - The Sales Meeting
- PL 943 KPI - On Time In Full
- PL 947 The QMS Meeting
- The Intranet

12.0 Operational planning and control

The various processes making up the QMS are summarised in the Overall Flow Chart. This overview shows each key process undertaken by the Company and the relationships between them. Each individual process is then supported by its own Flow Chart.

The Flow Charts show:

- Process objectives
- Responsibilities
- Resources required as applicable
- Key elements of each process and key decision points
- Key control techniques
- Process inputs and outputs

The PDMS and the deployment of Control Panels within the PDMS provide control points or screens focused on functional areas.

The design objective of any control panel and the PDMS generally is to:

- To promote accuracy, efficiency, customer service, competitiveness, excellence, risk-based thinking, data capture, evidence-based decision making, control of the process and compliance with the QMS.

The Quality Assurance Control Panel (QACP) and the Specification is, in addition to the above, expressly designed to provide:

- A comprehensive repository or mechanism for documenting, maintaining and using the specification for each product including details that are product risk specific and
- To detail any product regulatory requirements.
- A record of the product's characteristics.
- The requirements to assure conformity with the product specification.
- A conduit for the "real time" presentation and communication of the Spec check score KPI.

The Orders Control Panel is, in addition, to the design objective of any control panel designed to:

- Hold all details relating to all product orders.
- Provide a conduit through which deliveries, invoices and job cards are raised and stored and validated.
- A mechanism for managing the customer interface.
- A means by which the Company can identify and deal with order requirements differing from those previously defined.
- A structure through which the On-Time-In-Full (OTIF) KPI can be determined and managed.

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- PL 347 Afterwork Control Panel
- PL 366 Orders Control Panel

- PL 851 Product Specification
- PL 852 The Training Protocols and Systems we employ
- PL 859 Quality Assurance Control Panel
- PL 924 QA KPI's
- PL 930 EU food regulations and compliance
- PL 934 Sales Training Part 8 - The Sales Meeting
- PL 943 KPI - On Time In Full
- PL 947 The QMS Meeting

13.0 Design and development of products and services

The Company is involved to a varying degree with the design of new tooling and new products.

Depending on the specific complexity of the project the following will be used to control the design and development process:

- Customer sign off of detailed product drawing and design brief.
- 3 drawing.
- Moldflow simulation.
- Provision of 3 d model.
- Prototype tooling.
- Pre and post tool build meetings.
- Validation and optimisation of the moulded product.
- Customer sign off the finished product
- Application of the 4 pillars of effective production control.

The design of any new tooling and product needs to take account of:

- Functional and performance requirements
- Information derived from similar design and development activities
- Any statutory and regulatory requirements
- The Company's tool build standards
- The intended material(s) to be used and their characteristics
- The expected volumes
- OPTIMISATION

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- FC 003 Quotations
- FC 005 Tooling Orders
- FC 006 Printing New Artwork
- FC 007 Tool Identification & Part Number Allocation

- FC 010 Drawings
- FC 011 Tool Build Process
- FC 012 Tool Sample and Approval Procedure
- FC 013 Initial Sample Inspection Report
- FC 014 Concessions
- FC 016 Tool Close Out Meeting
- FC 018 Setting Card Origination and Authorisation and Usage
- FC 020 Overview of the 4 pillars
- FC 032 Product Standard Forms
- FC 042 Tooling Attributes
- BOTR 54 Tool validation and setting optimisation
- BOTR 55 Tool validation approval SICA and ISIR's

14.0 Control of externally provided processes, products and services

Products sold by the Company are manufactured and supplied by the Company.

The Company's policy is to only use materials or products of an acceptable quality in the production process. All materials and products purchased are subject to Goods Inwards protocols.

All significant supplier issues are logged on the Computer Snag Report System for actioning and reviewed.

Material and masterbatch requirements are identified through the PDMS Materials and Colours Control Panels.

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- FC 055 Snags
- FC 060 Supplier Approvals
- FC 061 Purchase Orders
- FC 062 Goods Inwards
- FC 065 Returns

15.0 Identification and traceability

All materials and master batches are allocated unique reference numbers that identify them.

Material and colour reference numbers are used throughout the Company’s purchasing processes, stores areas and processes and to identify what materials can be used to produce any given product.

Job Cards pull together the resources required including the specific materials and colours that may be used to make a product.

The batch number of the raw material and the masterbatch used during the manufacturing process is recorded in the box allocated on the physical job card.

During the printing/assembly process the job card reference of the product being processed must be transferred to and shown on the printed job card.

Job cards are retained in both physical and computer format for traceability at a future date.

Material and masterbatch batch numbers for each delivery are posted to the PDMS computer purchase order on receipt. Batch numbers are assigned to materials reprocessed internally at the processing point.

All finished product is labelled as part of the weigh counting process to enable identification and traceability to the originating job card.

Unique meaningful numbers are assigned to each product the company manufactures.

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- FC 007 Tool Identification & Part Number Allocation
- FC 026 Quality Control Final Audit
- FC 027 Moving Product to and Undertaking Afterwork
- FC 029 Weighing Product and Booking In
- FC 030 Invoicing
- FC 031 Despatch
- FC 062 Goods Inwards
- FC 070 Chipped Material Control
- PL347 Afterwork Control Panel
- PL366 Orders Control Panel

16.0 Property belonging to customers or external providers

Material may on occasion be supplied by the customer. This is referred to as free issue material. Free issue material supplied by the customer is allocated a unique material reference number and dealt with in the same way as purchased materials.

Tooling may be supplied by the customer and the customer may contribute to the cost of manufacture. All tools are uniquely identified. Unique identifying numbers are stamped on all tools and a corresponding tool record established in the PDMS.

Relevant flow charts and / or training documents

- FC 061 Purchase Orders

- FC 062 Goods Inwards
- PL354 BOTR 18 Material Numbering
- PL 384 BOTR 20 Tool numbering, attributes, locations and inserts

17.0 Preservation

The products made by the Company do not generally have a limited life span. However, products must be suitably identified and protected so that they are free of contamination and not exposed to excessive forces that would compromise the integrity of the products and render them inconsistent with specification. Suspect product must also be clearly segregated and identified so that it does not get mixed with good product.

Products once moulded are identified with shift labels showing the operator, date, shift and job card number.

All finished mouldings are identified with a label showing, amongst other things, the job card, part number and product description and stored appropriately if not for immediate despatch.

All products are packaged using approved packaging materials in accordance with the product packaging specification.

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- FC 007 Tool Identification & Part Number Allocation
- FC 027 Moving Product to and Undertaking Afterwork
- FC 029 Weighing Product and Booking In
- FC 040 QA Defect Product Containment
- PL 352 Part numbers
- PL 501 Quarantine Training Document
- PL 558 Lifting, Moving and keep Clear Areas Training
- BOTR 01 Labelling
- BOTR 03 All level work 1 work to a high standard feedback
- BOTR 40 Product Problem Containment

18.0 Post-delivery activities

Servicing of products supplied by the Company is not applicable given the nature of the products supplied.

Post-delivery activities are not relevant except insofar as any obligation may exist to meet regulatory obligations.

19.0 Control of Changes

To ensure changes to a product are properly controlled to ensure on-going conformity with the product's specification:

- New product numbers are up-issued or re-assigned whenever a "significant" modification to the form of a product results. This includes whenever a modification to the tool required to make a product takes place.
  - A consequence of raising a new product number is that it forces the creation of a new product specification. The new specification will be given a specification check score of zero by the PDMS. This in turn will frustrate manufacture of the product until the specification is updated and validated.
  - The structure of the PDMS is such that a new product requires further action to associate the new product with a schedule. Job cards are created, and invoicing is affected through the conduit of a schedule.

- The Specification screen and Schedule are maintained to ensure they are complete and up to date and fully reflect the up to date specification for the product.

- The Spec check KPI is consistently monitored to encourage both focus on the sufficiency of the specification and continuous improvement.

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- FC 007 Tool Identification & Part Number Allocation
- FC 008 Moulding Orders
- FC 009 Create schedule / Add New Part to Schedule
- FC 015 Raising Job Cards
- PL 352 Part numbers
- PL 384 BOTR 20 Tool numbering, attributes, locations and inserts
- PL 390 BOTR 41 Part Numbering
- PL 851 Product Specification
- PL 859 Quality Assurance Control Panel
- PL 924 QA KPI's
- PL957 Internal Auditing

20.0 Release of products

The following activities are used to verify that product requirements have been met

- First Off and where applicable Midd offs
- Last offs
- Production and Quality In Process Inspections
- Final Audit
- As appropriate other measures as detailed in the product specification

First off, last off and final audit work is recorded in the PDMS and visible via the QACP and Orders Control panel and the afterwork control panel and generally via the PDMS. The sequencing and prioritisation of verification work is assisted by the PDMS and certain control utilities embedded in the system to promote the timely completion of all critical product verification work prior to despatch.

The timeliness of first off and last off activity and final audit work are KPI's.

Relevant flow charts and / or training documents

- FC 001 Overall Flow Chart
- FC 021 First Offs
- FC 022 In Process Inspection
- FC 023 Last Offs
- FC 026 Quality Control Final Audit
- FC 030 Invoicing
- PL 366 Orders Control Panel
- PL 851 Product Specification
- PL 859 Quality Assurance Control Panel
- PL 924 QA KPI's

21.0 Control of non-conforming outputs

Processes exist to ensure that products that do not conform to specification are identified and controlled to prevent their unintended use or delivery. BOTR 40 provides for the containment of non-conforming product.

Products may be quarantined if considered appropriate for a short while prior to final determination as to whether they are in fact acceptable and consistent with specification. Products may be sorted to identify conforming product from bad. Rework may also take place where appropriate to bring the product to a conforming acceptable standard. In exceptional circumstance Quality Assurance may seek customer authorisation for acceptance under a concession where the products are not entirely consistent with specification

Non-conformances identified in any process deemed sufficiently significant and material should be escalated and recorded as a snag. Snags may be raised to address issues of process improvement or customer complaints or areas where improvement is required. There is no exclusion to what may constitute a Snag.

Relevant flow charts and / or training documents

- FC 014 Concessions
- FC 040 QA Defect Product Containment
- FC 055 Snags
- FC 065 Returns
- BOTR 01 Labelling
- BOTR 15 Mouldings Quarantined because of a set tolerance infringement
- BOTR 38 Identification of Moulding Quality Issues
- BOTR 40 Product Problem Containment
- BOTR 44 Rework
- PL 501 Quarantine Training Document
- PL 550 Creating Concessions and ISIRs
- PL 851 Product Specification
- PL 859 Quality Assurance Control Panel
- PL 871 Concessions
- PL 945 Moulding Quarantined because of a set tolerance infringement - QA

22.0 Performance evaluation, monitoring, measuring, analysis and evaluation

The Directors, as appropriate, determine what should be monitored and measured and the methodology to be employed. They also determine, in conjunction with the QA team, when measuring should be performed and how results should be analysed and used.

Wherever practicable such measurements should be classified and utilised as KPI's and their capture and usage automated as much as possible.

The Company uses KPI's throughout to:

- Provide unambiguous focus on key areas and targets.
- Assist the communication of key goals.
- Assist with the delegation of tasks.
- Promote goal congruency.
- Incentivise.
- Provide a tool that can assist with the allocation of resources.
- Promote customer care.
- Promote the importance of the product specification as the foundation of effective quality assurance.
- Help provide feedback as to the success or otherwise of initiatives and actions to address areas of concerns or exploit opportunities.
- Monitor customer satisfaction.
- Provide feedback concerning product conformity.
- Help promote consideration of risk into the assessment of the sufficiency of quality measures and protocols as they apply to any product.

Relevant flow charts and / or training documents

- FC 055 Snags
- PL 605 Monthly Management Accounts Checklist
- PL 851 Product Specification
- PL 924 QA KPI's
- PL 859 Quality Assurance Control Panel
- PL 934 Sales Training Part 8 - The Sales Meeting KPI
- PL 943 KPI - On Time In Full
- PL 947 The QMS Meeting

23.0 Internal audit

Internal audits are planned, controlled and administered by the Managing Director. The audit programme is planned to take into consideration the priorities and importance of each element of the QMS. The objective is to provide information on whether the QMS conforms to the Company's requirements and the requirements of the ISO standard.

The Managing Director ensures that all necessary audits are performed over a rolling twelve-month period covering:

- key areas
- Areas that have been subject to change
- The results of previous audits

Audit programmes are used to:

- Plan
- Control
- Record
- Evidence work done.

Although not always practicable internal audits are undertaken where possible by personnel independent of the function being audited. The extent to which trained individuals are used is flexed according to the level of supervision provided.

On completion of the audit a formal Snag is completed. This is to:

- Evidence the audit.
- To properly record any non-conformities found and to assess their significance and their risk to the efficacy of QMS.
- Record any areas that may warrant further investigation.
- Facilitate appropriate investigation into the detail of any issues found as considered appropriate based on the above.
- Highlight and record correction and preventative actions necessary.
- Provide a repository for work undertaken.

Relevant flow charts and / or training documents

- FC055 Snags
- PL 947 The QMS Meeting
- PL 953 Internal Audit Programme

24.0 Management review

A QMS meeting takes place on a regular basis and with no greater than 3 months between any two meetings. The objectives of the meeting are to:

- Review the QMS to ensure its continuing suitability, adequacy, effectiveness and continuing alignment with the strategic direction of the Company.
- Review relevant KPI's.

The meeting content should be planned such that at each meeting KPI's are considered and reviewed. In addition, the following "topics" are considered and included on a planned and rotational basis, apart from the review of brought forward items which should be undertaken at each meeting. All topics should be considered at least once during any rolling twelve months.

- Status of actions from previous management reviews
- Changes in external and internal issues that are relevant to the QMS
- Information on the performance and effectiveness of the QMS, including trends in:
    - Customer satisfaction and feedback from relevant interested parties
    - The extent to which the quality objectives have been met
    - Process performance and conformity of products and services
    - Nonconformities and corrective actions
    - Monitoring and measurement results
    - Audit Results
    - The performance of external providers
- The adequacy of resources.
- The effectiveness of actions taken to address risks and opportunities
- Opportunities for improvement.

ISO 9001:2015 provides that "outputs" of the management review shall include decisions and actions related to:

- Opportunities for improvement.
- Any need for changes to the quality management system.

The minutes are then circulated to all attendees and a copy stored in the documents index.

Relevant flow charts and / or training documents

- FC055 Snags
- PL 859 Quality Assurance Control Panel
- PL 924 QA KPI's
- PL 934 Sales Training Part 8 - The Sales Meeting
- PL 943 KPI - On Time In Full
- PL 945 Strategic review
- PL 947 The QMS Meeting

25.0 Non-conformity and corrective action

Non-conformances identified in any process deemed sufficiently significant and material should be escalated and recorded as a snag. Snags may be raised to address issues of process improvement, customer complaints or areas where improvement is required. There is no exclusion to what may constitute a Snag.

The objectives of the snag system are to:

- Provide a repository to hold all relevant information.
- To ensure the issue is properly escalated.
- To ascertain and record the pertinent facts.
- to ensure the root cause or causes are properly considered and identified
- To ensure both corrective and preventative actions as appropriate are identified and implemented.
- To assess the implications and risks the snag infers of similar non-conformities occurring.
- The risk posed to the effectiveness of the QMS.
- The risk a snag constitutes if it is not properly addressed on the Company's ability to achieve the Quality objectives.
- To ensure the disposition of the snag factors in consideration of all of the above.
- To facilitate a review of snags and control over the actions identified.
- To facilitate a review of the effectiveness of the actions taken.

Snags are recorded using the PDMS Snag system and monitored by Quality Assurance and the Directors.

Relevant flow charts and / or training documents

- FC055 Snags
- PL 924 QA KPI's
- PL 934 Sales Training Part 8 - The Sales Meeting
- PL 943 KPI - On Time In Full
- PL 947 The QMS Meeting

26.0 Continuous Improvement

The Company seeks to exploit opportunities to secure improvement throughout. Improvements sought are without restriction and hence can be fall into any of the following categories. The categories are detailed to illustrate the scope of opportunity to improve and not to indicate any constraint upon where improvement may be sought:

1. Customer service
2. Reduce variability in products made
3. Correct or prevent or eliminate undesired effects
4. The quality and effectiveness of the Company's systems
5. The quality and effectiveness of the Company's QMS
6. The quality and effectiveness of training
7. The quality and effectiveness of communication within the Company
8. The quality and effectiveness of communication with customers
9. Reducing downtime
10. Identification of the root cause of issues
11. The timely and effective disposition of snags
12. Technical knowledge and application
13. Productivity
14. The application of the 4 pillars of effective production control
15. The quality of supervision and the application of strong management

All improvement should be sought. Often the greatest improvement is to be gained by securing lots of small changes.

Opportunities to improve should be exploited whenever they arise and should be encouraged. Notwithstanding a forum for improvement discussion is: the QMS meeting, the sales meeting and the production meeting.

Relevant flow charts and / or training documents

- FC055 Snags
- PL 859 Quality Assurance Control Panel
- PL 924 QA KPI's
- PL 934 Sales Training Part 8 - The Sales Meeting
- PL 943 KPI - On Time In Full
- PL 945 Strategic review
- PL 947 The QMS Meeting

End