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INTRODUCTION

This document describes the organisation, responsibilities for, databases and documentation used in the control of product and service quality by Chamberlain Plastics International Limited. Its purpose is to enable personnel, customers, suppliers and other parties to understand the essential processes required to maintain the appropriate quality standards, which are necessary to ensure that the organisation's products and services conform to customer requirements.

It is the responsibility of all employees to make the procedures and processes described in this document and other quality system documentation effective.

4. QUALITY MANAGEMENT SYSTEM

4.1 UNDERSTANDING THE ORGANISATION AND ITS CONTEXT

The company has determined the external and internal issues that are relevant to its purpose and strategic direction and that effect its ability to achieve the intended results of the quality management system. These issues include:

Issue	Internal/External	Bias
Changes in technology.	External/Internal	Opportunity
Competition.	External	Neutral
Corporate image and values.	Internal	Opportunity
Currency exchange rates.	External	Neutral
Customer base.	External	Opportunity
Enquiries from interested parties	External	Opportunity
Financial status.	External	Neutral
Industrial relations.	External/Internal	Neutral
International politics and conflicts.	External	Neutral
International time zones.	External	Neutral
Language differences.	External	Risk
Legislation, regulations and international standards.	External	Neutral
Litigation	External	Risk
National and international holidays, festivals and cultures.	External	Risk
Natural disasters.	External	Risk
Supplier/provider base.	Internal	Opportunity
The company's quality management system, its requirements, knowledge base, product performance and resources etc.	Internal	Opportunity
Trade agreements.	External	Opportunity
Weather and climate.	External	Risk

The company defines the bias terminology as follows:

Risk – Negative effect of uncertainty
Opportunity – Positive effect of uncertainty
Uncertainty – A deficiency of information related to understanding or knowledge of an event, its consequence, or likelihood. (Not to be confused with measurement uncertainty.)

The company monitors and reviews these issues during its management review, contract review and relevant processes.

4.2 UNDERSTANDING THE NEEDS AND EXPECTATIONS OF INTERESTED PARTIES

The company has determined the interested parties that are relevant to the quality management system and the requirements of these interested parties.

INTERESTED PARTY	INTERNAL/EXTERNAL	NEEDS AND EXPECTATIONS
Agents; Customers; End Users.	External	Accurate information; Consistency; Delivery; Good communication; Health and safety; Pricing; Quality/product performance; Reliability.
Director; Owner. Shareholder.	Internal/External	Accurate information; Compliance to regulations and legislation; Market growth; Operation efficiency and effectiveness; Return on investment; Sales and profitability.
Employees; Management.	Internal	Accurate information; Good communication; Good work environment; Health and safety; Job security; Market growth; Operation efficiency and effectiveness; Promotion, recognition and reward; Sales and profitability.
Solicitor	External	Legal requirements/representation
Subcontractors; Suppliers.	External	Accurate information; Good communication; Delivery schedules; Future product requirements/insight; Long term supply; Market growth; Operation efficiency and effectiveness; Quality/product performance.
Regulatory bodies.	External	Compliance to standards, regulations and legislation; Submission of required reports on time.
Government.	External	Growth in taxable revenue; Increased local employment.
Local community.	External	Environmental protection; Ethical behaviour; Local employment.

The company monitors and reviews these needs and expectations during its management review and contract review and relevant processes.

4.3 DETERMINING THE SCOPE OF THE QUALITY MANAGEMENT SYSTEM

Chamberlain Plastics International Limited was founded in 1963 and operates from a single site based in Higham Ferrers, Northamptonshire, England. The company is privately owned by the Managing Director.

The company manufacture filmic and cloth laminates, under the trade name of Metalon, supplying product for automotive, furniture, label stock and decals, insulation and display applications, and sells to national and international markets.

The scope of the company is coating, laminating, conversion, and supply of thin gauge polymer film/fabric laminates. Departmental activities include:

- accounts and finance;
- sales and marketing;
- purchasing and goods inwards;
- production activities involving solvent based coating/in-line laminating operation, dry laminating operations, and conversion activities involving blocking, slitting, bobbin winding and guillotining operations;
- technical and quality control;
- packing and despatch.

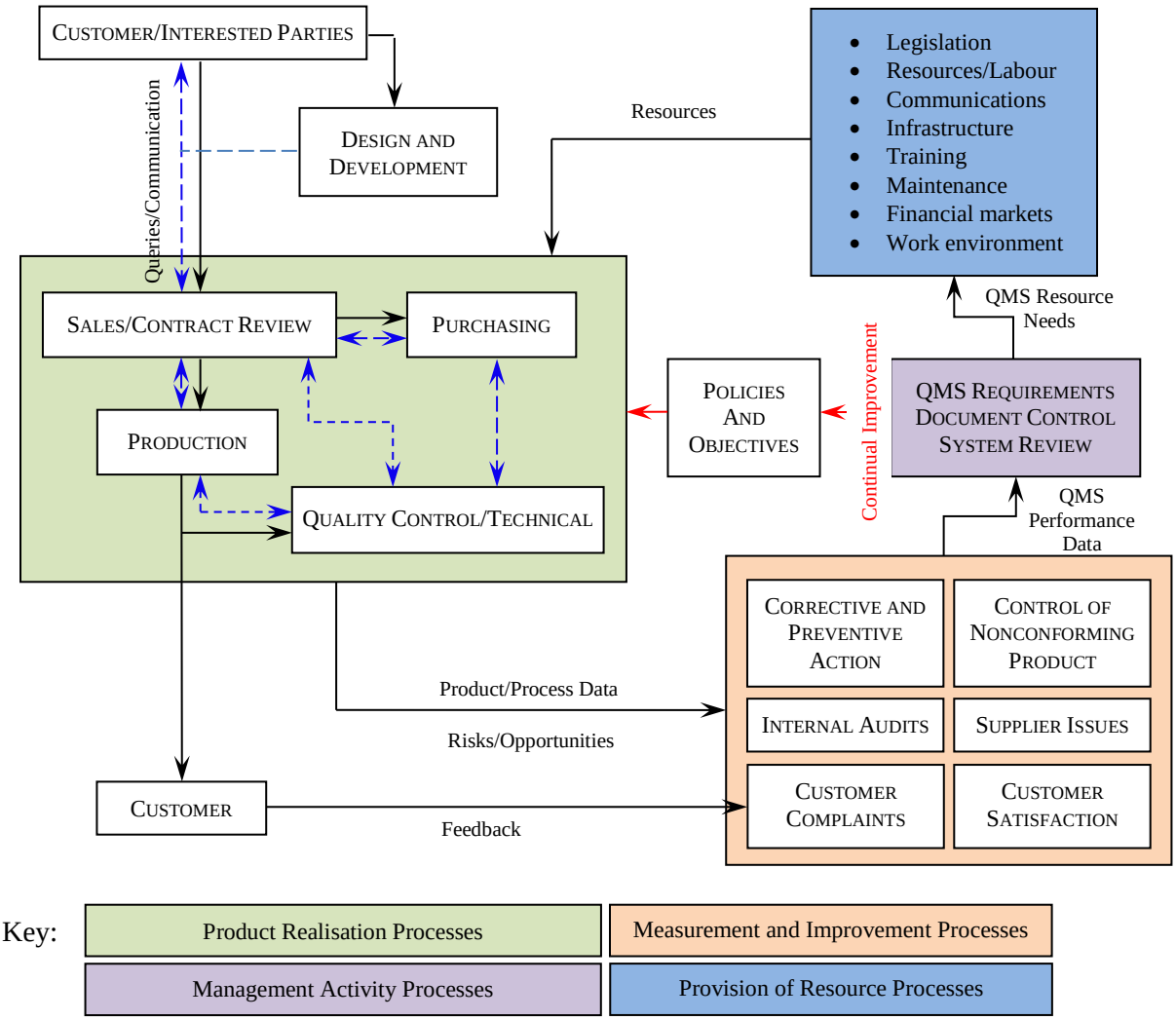
This document describes the scope of the company's quality management system, which is in accordance with the requirements of the international Quality Management System standard, ISO 9001: 2015.

Chamberlain Plastics International Limited excludes paragraph f of clause 8.5.1 of ISO9001: 2015 relating to Control of Production and Service Provision as there are no processes, the output of which, cannot be checked by suitable inspection and testing.

4.4 THE QUALITY MANAGEMENT SYSTEM AND ITS PROCESSES

The company has established and continually improves operational and QMS databases to control, maintain and review the quality management system including the processes needed and their interactions.

The processes needed for the quality managements system and their application throughout the organisation have been determined:



This evaluation is detailed in relevant process flow charts, control plans, process failure mode analysis charts and quality plans. These plans determine the inputs required and outputs expected, apply criteria and methods needed for the effective operation and control of these processes, determine the resources required, assign responsibilities and authorities, and address the risks and opportunities where relevant.

Processes are monitored and analysed and appropriate actions taken to ensure that processes are effective and to make continual improvement.

5 LEADERSHIP

5.1 LEADERSHIP AND COMMITMENT

5.1.1 GENERAL

For the purpose of administrating the quality management system, top management is defined as the Managing Director and departmental managers. The company top management is committed to the development and implementation of the quality management system and to its continually improved effectiveness.

This is demonstrated by:

- establishing the quality policy and quality objectives for the quality management system and ensuring that they are compatible with the context and strategic direction of the organisation;
- integrating the quality management system requirements into the organisation's business processes;
- promoting the use of the process approach and risk-based thinking;
- ensuring that the resources needed for the quality management system are available;
- communicating the importance of effective quality management and of conforming to the quality management system requirements;
- ensuring that the quality management system achieves its intended results;
- engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- promoting improvement;
- supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 CUSTOMER FOCUS

Top management ensure that, through the quality management system, customer requirements are determined, understood and met, with the aim of maintaining and enhancing customer satisfaction.

Specific customer requirements, including applicable statutory and regulatory requirements, are identified and documented by the sales department during the contract review process, allowing these requirements to be communicated and achieved, ensuring satisfaction of all customer declared needs.

Information about customer needs, expectations, risks and opportunities that can affect conformity of products and services, and the ability to enhance customer satisfaction is also extracted from customer feedback, complaints, benchmarking against competitive products and customer satisfaction data.

Quality system processes that most directly contribute to achieving this objective are those related to the control of product realisation processes and to monitoring and measuring of product.

5.2 POLICY

5.2.1 ESTABLISHING THE QUALITY POLICY

The company quality policy is established, approved, and reviewed by the Managing Director, and:

- is appropriate for the organisation;
- provides a framework for setting quality objectives for the purpose of continuous improvement of the quality management system;
- includes a commitment to meet the requirements of the defined quality system and improve its effectiveness;
- is reviewed periodically following the system review processes.

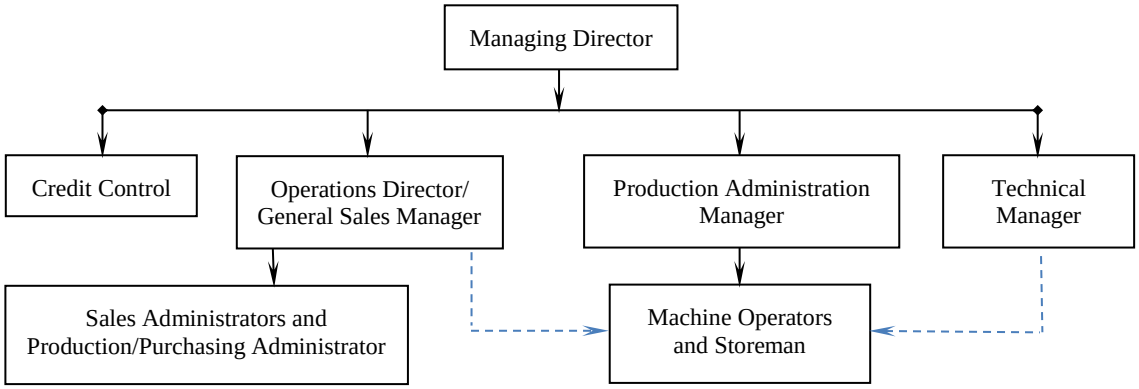
5.2.2 COMMUNICATING THE QUALITY POLICY

Management ensure that the quality policy is:

- available and maintained as documented information;
- understood and communicated throughout the organisation;
- available to relevant interested parties.

5.3 ORGANISATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES

The responsibilities and authorities for relevant roles throughout the company are defined as follows:



All staff are allocated with authority to perform their allocated responsibilities and deliver their intended outputs.

All staff share the authority and responsibility of identifying non-compliances or possible improvements, and recording these instances such that corrective action can be taken, both to rectify the immediate situation and to prevent recurrence.

Top management continually reviews the company's resources to ensure that adequate staff, equipment, and materials are available to meet customer requirements.

The following provides a summary of the principal responsibilities of each job role, and these are clarified in greater detail within the system.

Managing Director

- contract management and control;
- control of communications;
- control of finance and accounts;
- infrastructure;
- management review;
- quality policy and objectives;
- resources;
- training;
- work environment.

Operations Director/General Sales Manager

- contract review;
- control of contract documentation;
- customer communication/liaison, including development items;
- customer requirements;
- management and co-ordination of operations, sales, purchasing and support functions;
- production planning and organisation;
- quotations/pricing;
- sales order processing;
- sales quality objectives;
- supplier selection, communication and purchasing;
- training.

Production Administration Manager

- administration of production and ancillary personnel;
- health and safety policies, regulations and records;
- infrastructure;
- management and co-ordination of maintenance and production support functions;
- resources;
- training.

Technical Manager

- control and maintenance of the quality management system;
- control of nonconforming product;
- design and development;
- document issue and change control;
- environmental Permitting Regulations;
- inspection and testing;
- maintaining the QMS, QC and operation databases;
- management and co-ordination of quality control, technical and support functions;
- measuring equipment control and calibration;
- product quality objectives;
- quality audits;
- training.

Credit Control

- control and recovery of outstanding moneys;
- credit worthiness of customers and potential customers;
- export agents commission payments;
- payment schedules for supplier accounts;
- training.

Sales Administrator

- consignment collection, despatch and invoicing;
- contract review;
- control of contract documentation;
- customer communication/liaison;
- customer complaint processing;
- customer requirements;
- liaise with Banks, Chamber of Commerce and agents;
- quotations;
- sales order processing;
- training.

Production/Purchasing Administrator

- computer system data backup;
- despatch and invoicing;
- issue, control and maintain production documentation;
- plan product manufacturing;
- purchasing and supplier communication;
- stock records;
- training.

Machine Operators

- completed works order documentation;
- inspection and testing;
- packing;
- product identification;
- product planning, organisation;
- set up, operation and control of relevant machine and materials;
- stock control, verification, storage and preservation;
- training.

Storeman

- goods received verification and preservation;
- packing and despatch;
- product identification;
- stock control, storage and preservation;
- training.

The Technical Manager is appointed by the Managing Director to represent the company on all matters relating to the quality management system. Duties in this respect include:

- ensuring that the quality management system, including its processes, are established, implemented and maintained, and conforms to the requirements of this standard;
- reporting on the performance of the quality management system and on opportunities for improvement to top management;
- liaising with external bodies on matters relating to the quality management system;
- promoting the awareness of the quality management system and the requirements of customers throughout the organisation.

6. PLANNING

6.1 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES

The company considers risks and opportunities when taking actions within the management system, as well as when implementing or improving the management system and has established a system of quality plans that are available at all relevant levels within the company. Where relevant, these plans determine quality objectives, risks and opportunities, actions and responsibilities associated with the issues detailed in item 4.1 and the requirements of interested parties referred to in item 4.2 above.

Opportunities may present themselves in the form of:

- customer enquiries for non-standard products;
- evaluation and adoption of alternative materials and processes;
- modifications and improvements in technology and/or existing equipment;
- production trials.

The company's quality management system, as described in this document, is used to prevent defects, customer dissatisfaction, and enhance desirable effects. The Corrective Action procedure, PROC05 defines how risks are managed in order to minimize their likelihood and impact, and how opportunities are managed to improve their likelihood and benefit.

Any member of staff may propose a course of action to his/her manager who will consider the benefits in taking such action. A factor for consideration is the likely effect of an opportunity, or a potential problem that the action is intended to address related to the costs of taking the action, and whether it is proportionate to the benefits returned.

In addition, actions may be decided as a result of problems or non-conformities in other areas, recommended opportunities for improvement and decisions taken at management review, or error-prevention studies such as failure modes and effects analysis.

In each case, the manager has the responsibility and authority to:

- determine the potential opportunity, or non-conformity and its cause(s);
- evaluate the need for preventive action;
- determine the appropriate action and ensure it is implemented;
- review the action taken for its effectiveness and re-evaluate the risk of the potential non-conformity.

Records are maintained of all preventive actions raised and their outcomes. Sales opportunities, modifications, alternative materials and processes, production trials and the status of preventive actions are presented at management reviews.

6.2 QUALITY OBJECTIVES AND PLANNING TO ACHIEVE THEM

A system of quality objectives, consistent with the quality policy, is established by top management at all relevant levels within the company and are communicated to all relevant points within the organisation. These objectives are measured, monitored, recorded and regularly reviewed, and the performance against them monitored with the aim of making continuous improvement. The specific quality objectives for each process are defined in the Management Review report.

Where relevant, records established from setting and reviewing quality objectives include the scope of the objective, resources required, responsibility, time scale or frequency, and method of evaluation.

6.3 PLANNING OF CHANGES

In addition to the setting, measuring, monitoring, recording and review of the quality objectives, the top management ensure that the quality management system is developed in accordance with the planned requirements, and its integrity, availability of resources, and the allocation or reallocation of responsibilities is maintained when changes to the company and its systems are planned and implemented. Records of major changes to the QMS and/or processes are maintained.

7 SUPPORT

7.1 RESOURCES

7.1.1 GENERAL

Top management ensure that the resources needed to implement, maintain and continually improve the quality management system, and meet the requirements of the customers, and interested parties are identified, and provided.

7.1.2 PEOPLE

Top management ensure that the labour force needed to effectively implement the company's quality management system and operate, maintain and control its processes are identified, and provided.

7.1.3 INFRASTRUCTURE

The company determines, provides, and maintains the appropriate buildings, workspace, equipment, computer hardware and software, utilities and supporting services (transport and communications) necessary to ensure that its products and service meet the defined requirements. The Production Administration Manager controls and maintains support contractors and subsequent records.

Departmental managers are responsible for identifying the need and requirements for new, and/or modification of existing infrastructure, work environment, equipment and facilities in their departments. Requests for significant changes and/or expansions of facilities are submitted to the Managing Director for review and approval.

7.1.4 ENVIRONMENT FOR THE OPERATION OF PROCESSES

The company ensures that the working environment, both human and physical factors, is appropriate for the requirements of products and services to be met.

7.1.5 MONITORING AND MEASURING RESOURCES

The company identifies the resources required to ensure conformity of its products and the processes by which monitoring and measurement takes place, including the provision of suitable equipment, which is, as appropriate:

- calibrated and/or checked at defined intervals against standards traceable to national and international standards. If no such standards exist, the basis for calibration is recorded;
- adjusted as necessary;
- identifiable as to its calibration status;
- protected against damage and deterioration, and unqualified adjustment which would render its calibration invalid.

When equipment is found to be out of calibration, the results of measurements made with that equipment since it was last known to be in calibration are analysed and corrective action taken as appropriate.

Software used for product monitoring and/or measurement is verified prior to reliance on its results.

Records of calibrations, and any actions taken as a result of equipment being out of calibration, are maintained.

7.1.6 ORGANISATIONAL KNOWLEDGE

Top management have determined the knowledge necessary for the operation of its processes and to achieve conformity of its products and services. This knowledge takes the form of job specifications, flow charts and training matrix, and have been established for all relevant personnel.

The company operates an 'on the job training' approach where experienced personnel pass on their knowledge and experience to the trainee, including lessons learned from successful and failed practices, techniques, results of modifications, improvements and trials. Operators are free to make their own notes on unusual jobs and set-ups, and where appropriate, these are transcribed into formal instructions and issued accordingly.

In addition, knowledge may be obtained from external sources such as the internet, provider knowledge, professional bodies, technical libraries, conferences, exhibitions, competitive samples and information from customers and other interested parties.

7.2 COMPETENCE

The company recognises that the workforce is fundamental in enabling the quality system to be effective. All staff performing work affecting product and service quality is in possession of the appropriate competency and skills by virtue of appropriate knowledge, education, training, and experience. Where these skills are found to be deficient action is taken to acquire the necessary competency.

The company top management ensures that the requirements for skills and competence for all activities affecting quality are determined, and that staff performing these activities are trained accordingly. In addition, the effectiveness of training is reviewed and additional training provided as necessary.

7.3 AWARENESS

All staff is made aware of the relevance and importance of their roles in the contribution to the effectiveness of the company's quality policy and relevant quality objectives. The quality policy is provided and explained to each employee by the top management.

The company has established and maintains an environment which encourages employee awareness and fulfilment of customer requirements, and commitment to meeting quality requirements and continual improvement at all levels throughout the organisation.

The company provides the following categories of training and awareness programs:

- company induction;
- computer systems;
- Environmental Permitting Regulations;
- equipment operation;
- fire awareness;
- first aid;
- fork lift truck operation/lifting equipment;
- health and safety;
- inspection and testing;
- product induction;
- QMS induction;
- quality audits;
- relevant department/area activities and duties.

Records of all training and experience are maintained for all individuals.

7.4 COMMUNICATIONS

Internal information relating to the quality management system and its performance and effectiveness is communicated to all staff when required by departmental managers using the following methods:

- the management review process report;
- the Intranet;
- manuals, procedures, instructions, specifications, quality records, reports and training;
- notice boards;
- meetings and verbal communication.

Methods of external communications include:

- sales brochures/samples and product data sheets;
- telephone, web site, letter, facsimile and e-mail;
- on site visits to the company by the interested party, or visits to the interested party by company representatives.

7.5 DOCUMENTED INFORMATION

7.5.1 GENERAL

The documentation and records associated with appropriate clauses of the standard and the needs of the business are issued, controlled and maintained using one of the following databases:

- Accounting and salary software.
- Operations database, which holds electronic records associated with:
  - company control;
  - product/stock control;
  - purchasing details;
  - sales order details;
  - works order details.
- QC database, which holds electronic records of test results.
- QMS database, which holds electronic records associated with:
  - control of measuring and test equipment;
  - control of non-conforming product;
  - document and data control;
  - quality system audits;
  - training.

The company's quality system documentation is summarised in Appendix A of this document and includes:

- this quality document;
- the company quality policy, (see 5.2);
- documentation relating to the planning, operation and control of the company processes, including quality objectives, (see 6.2) are available at the applicable point of use. These are in the form of:
  - control plans;
  - failure mode analysis;
  - laboratory test methods;
  - process flow charts;
  - process instructions;
- quality plans and associated documentation;

- procedures, including:
  - Document Control PROC01;
  - Quality Records PROC02;
  - Quality Audits PROC03;
  - Control of Non-conforming Product PROC04;
  - Corrective Action PROC05;
  - Preventive Action PROC06.
- sales documentation;
- works documentation.

7.5.2 CREATING AND UPDATING

Where appropriate, documents comprising this quality management system are controlled and stored on electronic media by the Technical Manager, who in co-operation with the relevant departmental personnel is responsible for the preparation and issue of procedures.

The Managing Director signs the Policy Statement and other documents are authorised by the Technical Manager, or departmental managers. The complete manual is published in hard copy form and held by the Technical Manager.

Documents comprising this quality management system, whether of internal or external origin, and whether paper, and where practical, electronic or other media, are:

- approved by the relevant person(s) prior to issue, and following amendment;
- identifiable as to their revision status;
- available at points of use;
- identifiable and legible;
- removed from use when obsolete, and if not destroyed, suitably identified.

The Technical Manager, in co-operation with members of the quality organisation who are engaged in the day-to-day working of instructions, produce draft for each instruction. The agreed drafts are approved by the Technical Manager who publishes them in the relevant format, and distributes them to the appropriate point of use in the quality organisation. The Technical Manager holds and maintains a database of documents and instructions with hard copies held by relevant machine operators.

7.5.3 CONTROL OF DOCUMENTED INFORMATION

All quality records are stored in a manner to prevent damage, deterioration and loss. At the end of the minimum retention period documents, including those stored on electronic media, are disposed of at the discretion of the department manager. The company ensures that records are collected, maintained, and remain legible, identifiable and retrievable when required,

In addition, the history of the documents is maintained where appropriate and details of changes notified to relevant personnel on issue/reissue.

8 OPERATION

8.1 OPERATIONAL PLANNING AND CONTROL

The company plans and develops the processes needed to ensure that its products and services, including outsourced products, meet the specified requirements, consistent with the overall requirements of the quality management system.

Product realisation plans are established in collaboration between Sales, Production, and Technical Managers. The plans are in the form of various production documents, such as instruction documents, specifications, reference standards, samples, control plans, regulatory requirements, test methods and flow charts, and includes where applicable:

- the specific quality requirements for the product;
- the need to establish processes, new documentation, and additional resources;

- the need for inspection and testing, or other activities to ensure conformance with requirements, and the criteria for product acceptance;
- responsibilities and authorities;
- resource management relating to work force, employee competence, infrastructure and work environment;
- the needs for records to demonstrate product conformance;
- control planned changes and review the consequence of unintended changes.

Product verification and validation plans determine the inspection and testing program for a product, and for materials and components incorporated into the product. This includes:

- inspection and testing scope, frequency, and method,
- acceptance criteria, and
- requirements for records necessary to demonstrate product conformity.

The Technical Manager is responsible for identifying product quality objectives and requirements. This may be integrated with the process of determining customer and product requirements.

8.2 REQUIREMENTS FOR PRODUCT AND SERVICES

8.2.1 CUSTOMER COMMUNICATION

The company has defined arrangements for communicating with customers with respect to product information, the handling of enquiries and orders (including amendments and customer property), customer feedback and complaints.

Sales/sales support is responsible for receiving and processing customer feedback and complaints. All received customer communication is recorded in the relevant customer correspondence file. Every complaint is communicated to relevant functions within the organisation. Appropriate top management decide how to respond to the customer and, when appropriate, what corrective or preventive actions should be implemented internally.

8.2.2 DETERMINING THE REQUIREMENTS FOR PRODUCTS AND SERVICES

The company ensures that the customers' requirements for product and service quality are known and understood, including those unspecified but necessary for the products' intended use, and statutory and/or regulatory requirements. These are in addition the company-related requirements for the products.

8.2.3 REVIEW OF THE REQUIREMENTS FOR PRODUCTS AND SERVICES

Before making a firm offer or accepting a contract, the company reviews the proposed offer or contract to ensure that:

- the product is within the company's capabilities;
- statutory, regulatory, product and delivery requirements are clearly defined;
- the company has the ability to meet the requirements;
- any differences or queries are resolved;

Records of such reviews are maintained.

Where there is no documented requirement (e.g. a verbal order) or incomplete, ambiguous or conflicting requirements, the sales department confirms the requirements before acceptance of the contract. Accepted orders are confirmed with a Sales Order Acknowledgement.

In the case of non–standard enquiries, product characteristics are determined and reviewed with regard to requirements specified by the customer, or if these are not known, to relevant existing standard product requirements, where applicable. A production trial sample is provided for customer approval before accepting the contract.

8.2.4 CHANGES TO REQUIREMENTS FOR PRODUCTS AND SERVICES

In the case of a change to a contract after acceptance, the sales department ensures that documentation is amended accordingly and relevant personnel informed of the changes.

8.3 DESIGN AND DEVELOPMENT OF PRODUCTS AND SERVICES

8.3.1 GENERAL

The company has established, implemented and maintains a design and development process to ensure the subsequent provision of products and services. Where a customer enquiry has been identified as non-standard the General Sales Manager, if necessary in co-operation with the Technical Manager, and Managing Director accepts, or rejects the enquiry as a viable development item after considering the following:

- the commercial aspects;
- design and development complexities and requirements, including time scales;
- expected financial achievements of the proposal;
- internal/external resources;
- process feasibility and capability;
- purchasing requirements;
- statutory and regulatory requirements.

8.3.2 DESIGN AND DEVELOPMENT PLANNING

The Technical Manager determines and plans the design and process stages, including test methods required to achieve product approval by the customer, and maintains records of the development review, verification and validation activities, design changes including responsibilities for these activities.

The General Sales Manager resolves incomplete, ambiguous or conflicting requirements, and controls the need for the involvement of customers and interfaces between persons associated with the development process, including the level of control expected by customers and other interested parties.

Where necessary, The Technical Manager, programmes the required production trials and issues the relevant documentation and records the resulting test results on the appropriate database.

8.3.3 DESIGN AND DEVELOPMENT INPUTS

The company obtains defined standards or codes of practice, statutory and regulatory requirements, functional and performance specifications from the customer, or where these are not known, or unavailable, the Technical Manager establishes the performance criterion from a reference sample provided by the customer or, existing product knowledge, including the outcome of previous similar development projects and the risks associated with these projects, whether they be successful, or otherwise. The Technical Manager retains relevant information on design and development inputs.

8.3.4 DESIGN AND DEVELOPMENT CONTROLS

The Technical Manager defines the validation activities and results to be achieved, and reviews the ability of the results to meet specified requirements. Where test results are considered acceptable and verified against specified requirements, the General Sales Manager offers the customer a trial production sample for validation and approval in their process. Where test results are considered unacceptable the Technical Manager determines the cause of failure and takes appropriate corrective action and updates the necessary records and interested parties.

8.3.5 DESIGN AND DEVELOPMENT OUTPUTS

The Technical Manager maintains records of design and development outputs. Customer validated and approved products and associated product components and relevant external providers are added to the appropriate modules of the operations database. Where applicable, the Technical Manager establishes the relevant product data sheets, process instructions, reference standards and associated production documentation.

8.3.6 DESIGN AND DEVELOPMENT CHANGES

The company identifies, reviews and controls changes made during, or subsequent to the design and development of products and services to ensure that there is no adverse impact on conformity to requirements. The Technical Manager maintains and controls records of changes to development projects, including the review and authorisation of the changes, and actions taken to prevent adverse impacts.

8.4 CONTROL OF EXTERNALLY PROVIDED PROCESSES, PRODUCTS AND SERVICES

8.4.1 GENERAL

The company uses appropriate methods to ensure that all purchased and outsourced materials, or services meet the specified requirements. The methods employed and the levels of control over suppliers depend on the significance of the purchased product or service in the quality of the finished product.

Suppliers are evaluated on their ability to supply goods and/or services that meet the company's requirements. Criteria for the selection and monitoring of suppliers and providers are:

- historical performance in supplying to Chamberlain Plastics International Limited;
- demonstrating their capability to supply by providing a successful trial sample and subsequent trial order to specification;
- supplier survey questionnaires.

Records of the evaluations, any resulting actions and relevant interactions are maintained.

8.4.2 TYPE AND EXTENT OF CONTROL

Purchased items are received by Goods In and are verified against documentation to ensure conformance with the requirements specified in the purchasing information, and inspected for delivery condition.

The Technical Manager is responsible for selecting appropriate methods for purchased product verification and acceptance, and the degree and frequency of testing is defined by the importance of the material incorporated in the product, level of confidence in the effectiveness of the controls applied by the supplier, and the supplier's quality performance history.

Any requirement for the company or its customer to inspect, or verify the product at the supplier's premises prior to release is agreed and specified in the purchasing information.

8.4.3 INFORMATION FOR EXTERNAL PROVIDERS

Information for external providers is detailed on Purchase orders and are issued by the Purchasing department. The company ensures that purchasing information provided to suppliers and providers is adequate prior to its issue, and includes product descriptions and codes, quantity, requirements for products (including applicable statutory and regulatory requirements), procedures, processes, equipment, delivery, and qualification of personnel and/or quality management systems, as appropriate.

8.5 PRODUCTION AND SERVICE PROVISION

8.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

The production of the company's products and services is planned and controlled, including the provision of, as applicable:

- specifications and product information;
- quality plans, procedures and work instructions;
- suitable equipment, including monitoring and measuring resources;
- competent personnel;
- the implementation of monitoring and measurement;
- release, delivery, and post-delivery activities.

8.5.2 IDENTIFICATION AND TRACEABILITY

All products (including purchased material) within the control of the company are identifiable with unique codes and product descriptions, and their status with regard to any inspection and/or monitoring to which they are subjected. In addition, where traceability is a specific requirement, product is identified throughout all stages of procurement, production, and delivery phases, and is identifiable to Sales Order, Purchase Order, and/or QA reference.

The origins of a product and its component films, including coating and associated mix ingredients used in the product make up can be traced using one of the following:

- the customer purchase order number;
- sales order number;
- QA reference number;
- despatch note number, or;
- invoice number.

The number provided allows retrieval of the works order(s) applicable to the production process and contains information allowing reference to:

- inspection and test records and sample retainers;
- component material identification;
- raw material purchase orders and supplier batch numbers.

The inspection and test status of all conforming product is identified by storage in dedicated areas appropriate to the relevant process.

8.5.3 PROPERTY BELONGING TO CUSTOMERS AND EXTERNAL PROVIDERS

The company takes great care of any customer and supplier property, including materials, documentation, and/or intellectual property, used in its processes. Its use is governed in the same way as the company's own property with the additional feature that records are made and the customer is informed of any loss, defects, damage or other unsuitability.

8.5.4 PRESERVATION

The company ensures that the conformity of its products and their constituents, including the identification, labelling, packaging etc. as appropriate, are preserved during all processing and delivery to the intended destination.

8.5.5 POST-DELIVERY ACTIVITIES

The company provides relevant technical and sales support covering the product description, intended use, construction, attributes, presentation, performance, storage, shelf life and disposal of its products. These may take the form of:

- external communications as detailed in 7.4 above;
- product data sheets, including health and safety information;
- certification to relevant international standards, regulations and legislation, and customer requirements;
- customer feedback.

8.5.6 CONTROL OF CHANGES

In addition to changes implemented following items 7.5.2 and 8.2.3 above, any discrepancies away from the day to day running of the quality management system is verbally communicated by the user to the Technical Manager, or designee, who makes the necessary amendment and where applicable, issues copies to relevant interested parties. Urgent changes are reported verbally to the Technical Manager who makes the changes in manuscript, signs and dates the amendment, and issues copies of the page to relevant users. In the absence of the Technical Manager, the Manager supervising the process approves and distributes the amendments.

Revisions and amendments to the quality managements system arising from the operation of the review and audit procedures are published in accordance with item 7.5.2 above. All superseded documentation is withdrawn and destroyed except that which the Technical Manager retains copies for reference purposes in a manner which indicates its obsolete status.

The Technical Manager establishes and maintains files of national and customer standards relevant to the needs of the business. Where required, the Technical Manager checks the review status of the national standard and amends the company copy accordingly.

When customer standards are used in contract conditions, the Technical Manager checks that the review status given in the contract documents corresponds to the review status of the file copy, if not, he obtains the applicable amendments from the customer, and adds them to the file copy.

Files held on the company network server are copied automatically onto DAT tape at the end of each working day, and retained off the premises until the following working day. In addition, relevant operations databases are copied to the C:\ drive on the computer of the last user to close the database, and the user's identification is automatically recorded.

Electronic mailing systems, web site and associated software including internet security and virus protection are controlled by an external IT provider. Virus definitions are automatically updated by the relevant software. Documents comprising the company web site is controlled and maintained by the Technical Manager.

The Technical Manager holds and maintains a database of documents and instructions with hard copies held by relevant machine operators. The database controls and maintains the review status, document details and issue history of documents and databases used in the quality management system.

8.6 RELEASE OF PRODUCTS AND SERVICES

The company quality plans and test methods identify the requirements for measurement and monitoring of products in order to demonstrate conformity with requirements, which is carried out at appropriate stages of production.

Evidence of measurements and monitoring results is maintained, which includes the identity of the person authorising release of the product. Release of the product to the next stage of processing, or to the customer, is not permitted by the operator, or Quality Control until conformance with the requirements can be demonstrated, unless otherwise approved by a relevant authority and, where applicable, the customer.

8.7 CONTROL OF NONCONFORMING OUTPUTS

The company ensures that any product/service that fails to meet the defined requirements is identified and controlled to prevent its unintended use and/or delivery to the customer. The responsibility and authority for dealing with non-conforming product and making decisions about its eventual disposition is with the Technical Manager.

Any non-conforming product is reported to the Technical Manager immediately on discovery and, if practical, is labelled accordingly, segregated from conforming production and/or moved to a quarantine area.

The Technical Manager:

- decides on the fate of the product, which may include scrap, rework, return to supplier, or use under concession, or reassigned to an alternative application, or other, and ensures that this action is taken;
- ensures that the non-conforming product is not used for further processing or supplied to the customer unless it has been confirmed as conforming or a concession to supply has been approved;
- instigates and following up action to prevent recurrence of the non-conformity;
- documents the product details, non-conformity and the resultant corrective actions and responsibilities.

In the case of non-conformity in product detected after delivery, the Technical Manager ensures that appropriate steps are taken to minimise any effects of the non-conformity.

9 PERFORMANCE EVALUATION

9.1 MONITORING, MEASUREMENT, ANALYSIS AND EVALUATION

9.1.1 GENERAL

The company uses appropriate methods to monitor, measure, analyse, and improve the processes in the quality management system to:

- demonstrate product conformity;
- ensure conformance to the quality management system;
- make continual improvement.

The methods are determined in the quality plans for each process. These include:

- Coating Control Plan;
- Conversion/Outsourced/Packing Control Plan;
- Laminating Control Plan;
- QC Process Control Plan;
- Quality Control Testing Plan;
- Sales/Contract Review Control Plan;
- Thermoforming Control Plan.

The effectiveness of the quality system is monitored by internal audits and by measuring quality performance and customer satisfaction. Results of these activities are reported to top management and are used to identify opportunities for improvement.

9.1.2 CUSTOMER SATISFACTION

The company monitors customer satisfaction and uses the results to make improvements to its products and services. In addition to customer complaints, feedback information is obtained from time to time relating to product conformance and company response to the needs and aspirations of its customers. The methods for obtaining feedback include:

- visits, either to, or from the customer;
- Customer Satisfaction Questionnaire is included with each consignment;
- telephone calls, emails, vendor rating;
- analysis of repeat business.

9.1.3 ANALYSIS AND EVALUATION

The company generates relevant data and uses it to confirm the suitability and effectiveness of the quality management system, and to identify opportunities for continual improvement. This data is collected from:

- monitoring and measuring systems;
- customer satisfaction analysis;
- supplier performance measurement;
- characteristics and performance of processes and products;
- training;
- internal audits.

In particular the company management are looking for trends that indicate improvement or deterioration in performance and opportunities for preventive action.

9.2 INTERNAL AUDIT

The company has a planned system of internal quality system audits to determine:

- conformance to the company quality management system and the current issue of international quality management system standard, ISO 9001;
- that the quality management system is effectively implemented and maintained.

The preparation and update of the audit programme is the responsibility of the Technical Manager, who ensures that audits are planned on the basis of the risk to the business and importance of the process being audited, and the performance history of the area during previous audits. The scope of the audit is defined at the planning stage, and auditors assigned who are competent following sign off by the Technical Manager, and are independent of the work being audited.

On identifying non-conformities at audit, the auditor brings them to the attention of the management of the area under audit, who in turn is responsible for corrective action to eliminate the non-conformity and its cause within an agreed time scale.

The auditor is responsible for follow-up action to ensure satisfactory closure of non-conformities and for documenting the audit results.

9.3 MANAGEMENT REVIEW

9.3.1 GENERAL

Top management reviews the quality management system, its continued suitability, adequacy, and effectiveness. The purpose of management reviews is to:

- evaluate the suitability, adequacy and effectiveness of the quality system;
- consider changes to the quality management system and to the quality policy and quality objectives; and
- identify opportunities for improvement of the quality system, processes, and products.

When management review meetings are held the meetings are chaired by the Managing Director and are attended by departmental managers.

Management reviews are conducted at least once a year. More frequent reviews are scheduled as the need arises, or where circumstances require increased attention and input from the top management.

9.3.2 MANAGEMENT REVIEW INPUTS

The following topics will always be on the agenda:

- the status of actions from previous management reviews;
- changes in external and internal issues that are relevant to the quality management system;
- information on the performance and effectiveness of the quality management system including trends in:
    - customer satisfaction and feedback from relevant interested parties;
    - the extent to which 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;
- adequacy of resources;
- the effectiveness of actions taken to address risks and opportunities;
- opportunities for improvement.

Any company data may be used as input for management review.

9.3.3 MANAGEMENT REVIEW OUTPUT

The output of management review of the quality management system includes a summary report addressing the topics listed on the control plan and any additional data. The report includes associated data analysis, and action points of the management review processes. Action points are identified to individual persons, and the report is communicated throughout the organisation.

10 IMPROVEMENT

10.1 GENERAL

The quality policy with its quality objectives, analysis and evaluation of data, quality audits, corrective and preventive actions and the management reviews, are all used by the company as the basis for continual improvement to the quality management system and its effectiveness.

Opportunities and priorities for improvement are identified by comparing present quality performance to objectives defined in the quality policy and quality objectives.

10.2 NONCONFORMITY AND CORRECTIVE ACTION

In addition to item 8.7 above, the company implements and reviews corrective action to control and put right non-conformities to products, raw materials, systems and customer complaints, and to take further action to eliminate the causes to prevent recurrence.

This includes:

- identifying, investigating and reviewing non-conformities from the respective source;
- determining the risk and opportunity to the business, customer and future production;
- determining the cause of the non-conformity and establishing problems that have a common source;
- ensuring that all corrective actions are taken and recorded, including the disposition of the affected material;
- review the corrective actions for their effectiveness.

Records of the nonconformity and all corrective actions raised and their outcomes are controlled and maintained by the Technical Manager.

10.3 CONTINUAL IMPROVEMENT

Quality performance is evaluated by management reviews of the quality system. Where quality performance is found to be deficient of a defined objective, the management review identifies specific improvement actions to reach the objective. When a quality objective is reached, the management review may set a new, higher objective in this area and specify new improvement actions.

APPENDIX A: ASSOCIATED DOCUMENTS

Associated Documents relevant to this Quality Manual are listed below:

- Procedures
  - PROC01 Document Control
  - PROC02 Quality Records
  - PROC03 Quality Audits
  - PROC04 Control of Non-conforming Product
  - PROC05 Corrective Action
  - PROC06 Preventive Action
- Failure Mode Analysis
  - Production process activities
    - Coating
    - Conversion and Packing
    - Laminating
    - Thermoforming
  - Purchasing process
  - Quality Control process
  - Sales/Contract Review process
- Control Plans
  - Management Review process
  - Production process activities
    - Coating
    - Conversion/Outsourced/Packing
    - Laminating
    - Thermoforming
  - Quality Control process
  - Quality Control Testing Plan
  - Sales/Contract Review process
- Flow Charts
  - Coating
  - Control of Monitoring and Measuring Equipment
  - Conversion/Outsourced Product
  - Customer Complaints
  - Design and Development Review
  - Goods In
  - Guillotine
  - Identification and Traceability
  - Laminating
  - Maintenance
  - Mixing
  - Packing and Despatch
  - Purchasing
  - Quality Control
  - Sales/Contract Review
  - Training
- Planning of Changes
  - Planning of Changes
- Training Records
  - Employee Appraisal & Personal Development Plan
  - Training Matrix

Quality Control Test Methods, including A4 sample retainers and reference standards
- TM01 Accelerated Ageing Tests
- TM02 Laminate Adhesion
- TM03 Coating Weights/Mix Solids Determination
- TM05 Emboss Retention
- TM06 Coating Adhesion
- TM08 A4 Sample Retainer
- TM09 Calibration of Measuring Equipment
- TM10 Visual Inspection
- TM11 Q-U-V Exposure
- TM12 CP123 Visual Inspection
- TM13 Dry Wipe Properties

Process Instructions
- Production processes
  - Coating
  - Conversion
  - Laminating

Survey Questionnaires
- Customer Survey Questionnaire
- Supplier Survey Questionnaire

APPENDIX B: LEGAL COMPLIANCE

Chamberlain Plastics International Limited comply with the following legal and statutory regulations:

The Health and Safety at Work Act
Data Protection Act
Factories Act
UK Tax Regulations
Environmental Permitting Regulations
REACH
COSHH
ISO9001:2015
Environmental Protection Act