Quality Policy Manual

"Packaging Quality, Efficiency & Customer Satisfaction into Every Order"

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1.1 POLICY

Merlin Packaging Technologies has established, documented, and implemented a Quality system which conforms to the requirements of ISO 9001:2008 and has built in policies and procedures to ensure continual improvement and effectiveness of the Quality Management System. The Quality system is documented in the Quality Manual. Additional procedures and forms and other documents complement the Quality Manual. Procedures are referenced in the Quality Manual. The Quality Manual and referenced Procedures are our Quality Policy. Our Quality Policy Statement is ***"Packaging Quality, Efficiency & Customer Satisfaction into Every Order".***

1.2 EXECUTIVE MANAGEMENT'S COMMITMENT

We, the **Management Team**, are committed in meeting Customer requirements, needs and expectations on a continuous basis. Continual improvements to this quality policy, objectives, procedures and documentation, processes, services and product will be a top priority of our **Management Team** and employees.

Rob Kirkpatrick
President/Management Representative

1.3 QUALITY SYSTEM SCOPE

The scope of this Quality Management System covers the operations of **Merlin Packaging Technologies** located in Columbus, Ohio, USA. **Merlin Packaging Technologies** provides custom filling and packaging of adhesives, epoxy, sealants, coatings, lubricants, resins and other liquid products. We package products in cartridges (including universal cartridges), syringes, bottles, jars, tubes and many other types of containers. Businesses using our service range from electronics and aerospace to construction and general industrial.

Merlin Packaging Technologies will provide services and products according to established written procedures complying with ISO 9001:2008 requirements; as well as government, regulatory, where applicable; and/or to specific Customer contract requirements.

@**Merlin Packaging Technologies** has the following permissible Quality Management System (QMS) exclusions: **All of Section 7.3** because Merlin Packaging Technologies does not design & develop products. **Merlin Packaging Technologies provides custom filling and packaging processing and does not manufacture &/or service products and therefore portions of Section 7.5 relating to production and servicing are exclusions.**

Non-applicability and/or Limited Applicability statements, where applicable, are documented in this Quality Policy Manual and its Supporting Procedures.

1.4 DEFINITIONS

Definitions defined in the ISO 9001:2008 Standard applies to the **Merlin Packaging Technologies** Quality Management System.

1.5 RESPONSIBILITY

The **Management Team,** consisting of the **President, Management Representative, Plant Manager & Customer Service**, have the responsibility and authority to maintain the Quality system compliant to ISO 9001:2008 and other requirements and to continually improve its effectiveness. Through the use of Quality audits, Quality Assurance is able to verify the implementation of the procedures described in the Quality Manual. The ***Internal Audit Procedure Process Map*** describes the internal auditing program.

The policies, objectives and procedures defined in this manual, its supporting procedures and documentation, apply to all operations and processes performed by **Merlin Packaging Technologies** employees (full, part, temporary and/or contract).

2.1 DOCUMENTATION TIERS

Merlin Packaging Technologies's documented Quality system is in three tiers based on the requirements of ISO 9001:2008. These standards are available from Customer Service.

Tier One is this Quality Manual. It contains procedures describing the implementation of Quality systems.

Tier Two is comprised of the MASTER Procedure Process Map, Key Procedure Process Maps (those required by the ISO 9001:2008 standard) and other Procedure Process Maps. The MASTER & Key Procedure Process Maps are designated in ***BLUE*** when referred to in this document. Other Procedure Process Maps are designated in ***GREEN*** when referred to in this document.

Tier Three is comprised of forms and other documents that are used to fulfill the requirements of this Quality Manual and its supporting Procedure Process Maps.

2.2 QUALITY MANUAL

This manual is the Tier One documentation that the employees of and those doing business with the company should refer to in order to understand **Merlin Packaging Technologies's** Quality Management System. The manual contains an index that contains the manual section number, the **Merlin Packaging Technologies** document(s) that address the requirements in the standards, the ISO 9001:2008 Clause. Hyperlinks are used whenever possible which enable easy movement back and forth between the Quality Manual to the documents addressing standard requirements. The Quality Manual distribution is controlled by having a READ ONLY MASTER located on the **Merlin Packaging Technologies** intranet (for accessibility by employees) and website (for accessibility by Customers & other Stakeholders). Only copies located at these sites are to be considered current and valid. Changes to this manual shall be made in accordance with the ***Document Control Procedure Process Map***.

3.1 OUTSOURCING

When **Merlin Packaging Technologies** chooses to outsource any process that affects product conformity to requirements, it will still be **Merlin Packaging Technologies's** responsibility to ensure that the process is in control, and **Merlin Packaging Technologies** remains ultimately responsible for the product.

ISO 9001:2008 Standard Clause	Merlin Packaging Technologies Manual Section	Evidence of Compliance
4.0 QUALITY MANAGEMENT SYSTEM		
4.1 General Requirements	4.1 A Quality Management System (QMS) has been established, documented, implemented & is maintained. QMS effectiveness is maintained in accordance with the requirements of ISO 9001:2000.	• **This *Manual* & its supporting *Procedure Process Maps*** • ***Effectiveness Reviews***
a-f	a) Processes needed for the QMS & their application are identified; b) Sequence and interaction of these processes are identified; c) Criteria & methods needed to ensure that both the operation & control of these processes are effective; d) Ensure the availability of resources & information necessary to support the operation & monitoring of these processes; e) Monitor, measure & analyze these processes; and f) Implement actions necessary to achieve planned results & continual improvement of these processes.	• **This *Manual* & its supporting *Procedure Process Maps*** • ***MASTER Procedure Process Map*** • ***Product & Process Work Instructions*** • ***Quality Plans (Job Packages)*** • ***Effectiveness Reviews*** • ***Quality Objective Measurables*** • ***Continual Improvement Projects***
Outsourcing	Outsourced work will be controlled and controls will be identified in the QMS.	**VERY LIMITED APPLICABILITY – Currently only applies to internal audit and external audit subcontractors.**
4.2.1 Documentation Requirements (General)	4.2.1 The QMS will contain the minimum: a) Quality Policy Statement; b) Manual; c) Procedure Process Maps; d) Product & Process Work Instructions, Forms, Control Plans & etc.; and e) Records.	• **This *Manual* & its supporting *Procedure Process Maps*** • ***Quality Policy Statement*** • ***MASTER Procedure Process Map*** • ***Product & Process Work Instructions*** • ***Quality Plans (Job Package)*** • ***Forms & Other Documents*** • ***Effectiveness Reviews***
4.2.2 Quality Manual	4.2.2 This Quality Manual contains the minimum: a) QMS Scope, permissible exclusions & justifications, permissible non-applicability statements & justifications; b) Reference to Procedure Process Maps; and c) A description of the interaction between the QMS & Procedure Process Maps.	• ***Section 3.0 of this Manual*** • ***This Table (interactions& references)*** • ***Procedure Process Maps***
4.2.3 Document Control	4.2.3 Documents will be: a) Approved & reviewed for adequacy prior to issue; b) Reviewed and updated as necessary and re-approved; c) Controlled to ensure changes & the current revision status are identified; d) Controlled to ensure that relevant versions of applicable documents are available at points of use; e) Controlled to ensure that documents remain legible & readily identifiable; f) Controlled to ensure that documents of external origin are identified & their distribution controlled; and g) Controlled to prevent the unintended use of obsolete documents, & to apply suitable identification to them if they are retained for any purpose.	• ***Document Control Procedure Process Map***
4.2.4 Record Control	4.2.4 QMS records will be established & maintained to demonstrate compliance to ISO 9001:2000.	• ***Record Control Procedure Process Map***
	Records will be: a) Legible; b) Readily identifiable; c) Readily retrievable; d) Ensure controls for identification, storage, protection, retrieval, retention times, & disposition.	• ***Record Control Procedure Process Map*** • ***Cross Reference of Records Matrix***

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5.0 MANAGEMENT RESPONSIBILITIES		
5.1 Management Commitment	5.1 Evidence of Management Commitment to the implementation & continually improving the effectiveness includes: Communicating the importance of meeting customer, statutory & regulatory requirements to all employees; a) Establishing a Quality Policy; c) Establishing Quality Objective Measurables; d) Conducting Management Reviews; and e) Ensuring availability of resources.	• **This *Manual* & its supporting *Procedure Process Maps*** • ***Communications via bulletin boards, emails, meetings, etc.*** • ***Product & Process Work Instructions*** • ***Quality Plans (Job Packages)*** • ***Forms & Other Documents*** • ***Effectiveness Reviews*** • ***Management Reviews***
5.2 Customer Focus	5.2 The President and the Management Team will ensure Customer requirements are determined & met with the aim of improving Customer Satisfaction.	• ***Quality Plans (Job Packages)*** • ***Communications with Customer*** • ***Customer Satisfaction/Dissatisfaction Procedure Process Map***
5.3 Quality Policy	5.3 The President and the Management Team have ensured that the Quality Policy is: a) Relevant to the company & our business.; b) Evidence of Management commitment to meeting requirements & continually improving the QMS effectiveness; b) Is the framework for establishing & reviewing Quality Objective Measurables; c) Is communicated & understood throughout the company; d) Is reviewed for continued suitability.	• ***Quality Policy Statement*** • **This *Manual* & its supporting *Procedure Process Maps*** • ***Communications via bulletin boards, emails, meetings, etc.*** • ***Product & Process Work Instructions*** • ***Quality Plans (Job Packages)*** • ***Effectiveness Reviews*** • ***Management Reviews***
5.4.1 Quality Objectives	5.4.1 Quality Objective Measurables have been established & are monitored & tracked for effectiveness.	• ***Quality Objective Measurables*** • ***Effectiveness Reviews***
5.4.2 Quality Planning	5.4.2 Quality Plans are established & maintained. When changes are made in the QMS or to the Objectives, Management ensures integrity is maintained.	• ***Quality Plans (Job Packages)*** • ***Configuration Control Program*** • ***Document Control Procedure Process Map***
5.5.1 Responsibility & Authority	5.5.1 Responsibilities & authorities are defined & communicated via job descriptions, organizational charts, & product/process work instructions (This includes personnel who manage, perform & verify work affecting quality).	• ***Job Descriptions*** • ***Organizational Charts*** • ***Product/Process Work Instructions***
5.5.2 Management Representative	5.5.2 The Quality Manager has been appointed as the Management Representative. The Management Representative duties, responsibilities & authorities are defined in a job description & in the organizational chart.	• ***Appointment Letter*** • ***Job Descriptions*** • ***Organizational Chart***
5.5.3 Internal Communication	5.5.3 The President & Management Representative ensure that QMS related communications take place & are understood. Communications are via bulletin boards, meetings, emails, etc.	• ***Quality Memo*** • ***Quality Objective Measurables***
5.6.1 Management Review	5.6.1 The President and the Management Team reviews the QMS to ensure its continuing suitability, adequacy & effectiveness. Management Reviews include assessing opportunities for Improvement & the need for changes to the QMS, quality policy & quality objectives measurables. Records from Management Reviews will be maintained.	• ***Management Review Procedure Process Map*** • ***Management Review Minutes***
5.6.2 Review Input	5.6.2 Review inputs are: a) Results of internal, external (Registrar, Regulatory, Customer Audits; b) Customer Feedback; c) Process performance; d) Product conformity; e) Corrective Actions; f) Preventive Actions; g) Past Management Review Issues; h) Changes to the QMS, Quality Policy & Quality Objective Measurables; i) Recommendations for improvements.	• ***Management Review Procedure Process Map*** • ***Corrective Action Procedure Process Map*** • ***Preventive Action Procedure Process Map*** • ***Internal Audit Procedure Process Map*** • ***Customer Satisfaction/Dissatisfaction Procedure Process Map*** • ***Management Review Minutes*** • ***Regulatory & Customer Requirements*** • ***External Audit Results (Registrar, Regulatory or Customer)***

ISO 9001:2008 Standard Clause	Merlin Packaging Technologies Manual Section	Evidence of Compliance
5.6.3 Review Output	5.6.3 Review Outputs are: a) Improvements on the effectiveness of the QMS & its processes; b) Improvements to products as related to Regulatory & Customer Requirements; and c) Identification of resource needs.	• ***Management Review Procedure Process Map*** • ***Corrective Action Procedure Process Map*** • ***Preventive Action Procedure Process Map*** • ***Management Review Minutes*** • ***Regulatory & Customer Requirements*** • ***Resource Plan*** • ***Effectiveness Reviews***
6.0 RESOURCE MANAGEMENT		
6.1 Provision of Resources	6.1 Resources will be provided to: a) Implement & continually improve the effectiveness of the QMS; and b) Meet Regulatory & Customer requirements.	• ***Training Procedure Process Map*** • ***Management Review Minutes*** • ***Regulatory & Customer Requirements*** • ***Resource Plan*** • ***Effectiveness Reviews***
6.2.1 Human Resources	6.2.1 Personnel competency will be based on appropriate education, training, skills and experience requirements.	• ***Training Procedure Process Map*** ***Training Matrix*** • ***Job Descriptions***
6.2.2 Competence, Awareness & Training	6.2.2 Management will: a) Determine the necessary competence for personnel; b) Provide training or take other actions; c) Evaluate effectiveness of training, and/or other actions taken; d) Ensure personnel are aware of the relevance & importance of their activities & how they contribute to to achieving quality objective measurables; e) Maintain records of training, education, skills & experience.	• ***Training Procedure Process Map*** • ***Training Matrix*** • ***Job Descriptions*** • ***Organizational Chart*** • ***Performance Reviews*** • ***Training Effectiveness Surveys*** • ***Training Plans (Outlines)*** • ***Quality Objective Measurables***
6.3 Infrastructure	6.3 Management will determine, provide, and maintain infrastructure needed to achieve product conformity. Infrastructure includes, **as applicable**; a) Buildings, workspace, and associated utilities; b) Process equipment (both hardware & software); c) Supporting services (such as transport or communication); and Preventive Maintenance will be scheduled & recorded.	• ***Safeguarding Computer Data Procedure Process Map*** • ***Housekeeping Activities, as needed*** • ***Preventive Maintenance Activities***
6.4 Work Environment	6.4 **As applicable,** work environments needed to achieve product & process conformity will be determined & maintained.	• ***Housekeeping Activities, as needed***
7.0 PRODUCT REALIZATION		
7.1 Planning of Product Realization	7.1 Processes will be developed & planned. Plans will determine the following, as applicable; a) Quality objective measurables & product/process requirements; b) The need to establish processes, documents, & provide resources; a) Required verification, validation & test activities; b) Criteria for product acceptance; and c) Records needed to provide evidence that products meet Requirements.	• ***Work Instructions*** • ***Job Package*** • ***Regulatory & Customer Requirements***
7.2.1 Determination of Requirements Related to the Product	**7.2.1** Management will ensure that the following are determined for each product: a) Product requirements specified by the customer, including the requirements for delivery and post-delivery activities; b) Product requirements not stated by the customer but necessary for specified or intended use, where known; c) Statutory and regulatory requirements related to the product, and d) Any additional requirements.	• ***Quote Review Procedure Process Map*** • ***Contract & Purchase Order Review Procedure Process Map*** • ***Quote Review Records*** • ***Contract Review Records*** • ***Job Package*** • ***Regulatory & Customer Requirement***

ISO 9001:2008 Standard Clause	Merlin Packaging Technologies Manual Section	Evidence of Compliance
7.2.2 Determination of Requirements Related to the Product	**7.2.2** Management will ensure the following for each product: a) Reviews will be conducted & documented at quotation stage & prior to committing to manufacturing a product; b) Customer requirements are defined, c) Contract or order requirements differing from those previously expressed are resolved, and d) A review to ensure capability & feasibility exists to meet defined requirements. Review records will be maintained. Where the customer provides no documented statement of requirements, customer requirements will be confirmed before acceptance. Where product requirements are changed, relevant documents are amended & relevant personnel will be made aware of the changed requirements.	• ***Quote Review Procedure Process Map*** • ***Contract & Purchase Order Review Procedure Process Map*** • ***Quote Review Records*** • ***Contract Review Records*** • ***Job Package*** • ***Regulatory & Customer Requirement***
7.2.3 Customer Communications	7.2.3 Effective arrangements for communicating with customers will be established in relation to: a) Product information, b) Quotes, contracts or order handling, including amendments, and c) Customer feedback, including customer complaints.	• ***Quote Review Procedure Process Map*** • ***Contract & Purchase Order Review Procedure Process Map*** • ***Customer Satisfaction/Dissatisfaction Procedure Process Map*** • ***Safeguarding Computer Data Procedure Process Map*** • ***Quote& Contract Review Records***
EXCLUSION - 7.3 DESIGN & DEVELOPMENT – Section is excluded because Merlin Packaging Technologies does not have a proprietary product and is not design responsible for customer products.		
7.4.1 Purchasing Process	7.4.1 Purchased product will be verified upon receipt to ensure conformance to purchase order requirements. The type & extent of control applied to the supplier & purchased product will be dependent upon the effect of the purchased product on production processes. Suppliers will be evaluated & selected based on their ability to supply the production process. Criteria for selection, evaluation and re-evaluation will be established. Records of the results of evaluations & any necessary actions arising from the evaluation will be maintained.	• ***Purchasing Procedure Process Map*** • ***Supplier Approval Procedure Process Map*** • ***Customer Requirements*** • ***Government/Regulatory Requirements*** • ***Purchase Order (issued to suppliers) Requirements***
7.4.2 Purchasing Information	7.4.2 Purchasing information (POs) will describe the product to be purchased, including **where appropriate**: a) Requirements for approval of product, procedures, processes & equipment; b) Requirements for qualification of personnel; and c) QMS requirements. Purchase Order requirements will be reviewed prior to their communication to the supplier. Purchasing Records will be maintained for traceability purposes.	• ***Purchasing Procedure Process Map*** • ***Supplier Approval Procedure Process Map*** • ***Customer Requirements*** • ***Government/Regulatory Requirements*** • ***Purchase Order (issued to suppliers) Requirements***
7.4.3 Verification of Purchased Product	7.4.3 Inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements will be implemented as needed. @ Where **MERLIN** or its customer intends to perform verification at the supplier's premises, **MERLIN.** will state the intended verification arrangements & method of product release in the Purchase Order. Records of inspection & other activities will be maintained.	• ***Purchasing Procedure Process Map*** • ***Supplier Approval Procedure Process Map*** • ***Customer Requirements*** • ***Government/Regulatory Requirements*** • ***Purchase Order (issued to suppliers) Requirements***

ISO 9001:2008 Standard Clause	Merlin Packaging Technologies Manual Section	Evidence of Compliance
7.5.1 Control of Production & Service Provision	Production & service will be planned & carried out under controlled conditions. Controlled conditions will include, as applicable: a) Availability of information that describes the characteristics of the product; b) Availability of work instructions, as necessary; c) Use of suitable equipment; d) Availability & use of monitoring & measuring devices; e) Implementation of monitoring & measurement; and f) Implementation of release, delivery & post-delivery activities.	• ***Job Package*** • ***Work Instructions*** • ***Inspection Instructions***
7.5.2 Validation of Processes for Production & Service Provision	Production and service processes will be validated where output results cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Validation will demonstrate the ability of these processes to achieve planned results. Arrangements for these processes will be established including, as applicable: a) Defined criteria for review and approval of the processes; b) Approval of equipment and qualification of personnel; c) Use of specific methods and procedures; d) Requirements for records; and e) Revalidation.	• ***Job Package*** • ***Work Instructions*** • ***Inspection Instructions***
7.5.3 Identification & Traceability	Where appropriate, product will be identified by suitable means throughout production & processing. Product status will be identified with respect to monitoring and measurement requirements. Where traceability is a requirement, traceability control & records will be maintained throughout production & processing.	• ***Job Package*** • ***Work Instructions*** • ***Inspection Instructions***
7.5.4 Customer Property	Care will be exercised with customer property while it is under our control or being used. Customer Property will be identified, verified, protected and Safeguarded. Customer property that is lost, damaged or otherwise found to be unsuitable for use will be reported to the customer and records maintained.	• ***Customer Supplied Product Procedure Process Map*** • ***Job Package*** • ***Work Instructions*** • ***Inspection Instructions***
7.5.5 Preservation of Product	Product conformity will be preserved during internal processing & delivery to the intended destination. This includes identification, handling, packaging, storage and protection. Preservation also applies to the assemblies, sub-assemblies & component levels.	• ***Job Package*** • ***Work Instructions*** • ***Inspection Instructions***
7.6 Control of Monitoring & Measuring Devices	Monitoring &Measurement needed to provide evidence of conformity of product to determined requirements will be determined & controlled. Monitoring & Measurement Processes will be carried out in a manner that is consistent with applicable requirements. Where necessary to ensure valid results, measuring equipment will be: a) Calibrated or verified at specified intervals, or prior to use, against standards that are traceable to international or national measurement standards. Where no standards exist, the basis for calibration/verification will be recorded; b) Adjusted or re-adjusted as necessary; c) Have calibration status identified; d) Safeguarded from adjustments that would invalidate the measurement result; e) Protected from damage & deterioration during handling, maintenance and storage. The validity of previous measuring results will be assessed & recorded when the equipment is found nonconforming. Appropriate action on the equipment & any product affected will be taken. Records of the results of calibration and verification will be maintained. Applicable computer software will be confirmed & reconfirmed as necessary.	• ***@Calibration Activities*** • ***Preventive Maintenance Procedure Process Map*** • ***Calibration Records*** • ***Preventive Maintenance Records***

ISO 9001:2008 Standard Clause	Merlin Packaging Technologies Manual Section	Evidence of Compliance
8.0 MEASUREMENT, ANALYSIS & IMPROVEMENT		
8.1 General	8.1 Monitoring, measurement, analysis & improvement processes will be planned & implemented as needed: a) To demonstrate product conformity; b) To ensure conformity of the QMS; and c) To continually improve the effectiveness of the QMS. This will include determination of applicable methods, including statistical techniques, & the extent of their use.	• ***Quality Objective Measurables*** • ***Job Package***
@8.2.1 Customer Satisfaction	8.2.1 Customer satisfaction will be measured & monitored to determine if customer requirements have been met. The methods for obtaining & using this information will be determined & will result in an early warning customer feedback system. Feedback will be reviewed for possible incorporation into the Corrective and/or Preventive Action Systems.	• ***Customer Satisfaction/Dissatisfaction Procedure Process Map*** • ***Corrective Action Procedure Process Map*** • ***Preventive Action Procedure Process Map*** • ***Management Review Procedure Process Map*** • ***Quality Objective Measurables*** • ***Job Package***
8.2.2 Internal Audit	8.2.2 Internal audits will be performed at planned intervals to determine whether the QMS: a) Conforms to the planned arrangements & to ISO 9001:2000: b) Conforms to the QMS established; and c) Is effectively implemented and maintained. • An audit program will be planned, taking into consideration the status and importance of the processes & areas to be audited, as well as the results of previous audits. • Audit criteria, scope, frequency & methods will be defined. • Selection of auditors and conduct of audits will ensure objectivity & impartiality of the audit process. • Auditors will not audit their own work. • Responsibilities & requirements for planning & conducting audits, & for reporting results and maintaining records. • Management responsible for the area being audited will ensure that actions are taken without undue delay to eliminate detected nonconformities & their causes. • Follow-up activities will include the verification of the actions taken & the reporting of verification results.	• ***Internal Audit Procedure Process Map*** • ***Annual Internal Audit Plan & Schedule*** • ***Auditor Qualification Records***
8.2.3 Monitoring &Measuring of Processes	8.2.3 Suitable methods for monitoring and, where applicable, measurement of the QMS processes will be employed. These methods will demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction & corrective action will be taken, as appropriate, to ensure conformity of the product.	• ***Job Package*** • ***Quality Objective Measurables*** • ***Effectiveness Reviews***
8.2.4 Monitoring & Measuring of Product	8.2.4 Product characteristics will be monitored and measured to verify that product input requirements have been met. This will be carried out at appropriate stages of the product realization process in accordance with planned arrangements. Evidence of conformity with acceptance criteria will be maintained. These Records shall indicate the person(s) authorizing release of product. All tests, verifications & validations will be traceable to the personnel performing the process and the results of the process will be clearly stated.	• ***Job Package*** • ***Quality Objective Measurables*** • ***Effectiveness Reviews***

ISO 9001:2008 Standard Clause	Merlin Packaging Technologies Manual Section	Evidence of Compliance
8.3 Control of Nonconforming Product	8.3 Product, systems & processes which do not conform to requirements will be identified & controlled to prevent unintended implementation, use or delivery. Nonconformities will be controlled by one or more of the following ways: a) Taking action to eliminate the detected nonconformity; b) Authorizing its use, release or acceptance under concession only if it meets regulatory and/or customer requirements, by a relevant authority &, where applicable, by the customer; d) Taking action to preclude its original intended use or Application; e) Reviewed after the concessions are made to ensure requirements are still being met. Records of the nature of nonconformities & any subsequent actions taken, including concessions obtained, will be maintained. Records will be traceable to the personnel making the concessions.	• ***Control of Nonconformities Procedure Process Map*** • ***Job Package***
8.4 Analysis of Data	8.4 Data will be collected, tracked, monitored & analyzed to demonstrate the suitability & effectiveness of the QMS & to evaluate if improvement of the effectiveness of the QMS can be made. This includes data generated as a result of monitoring & measurement from other relevant sources. The analysis of data will provide information relating to: a) Customer feedback; b) Conformity to product requirements; c) Characteristics and trends of processes & products including opportunities for preventive action; and d) Suppliers. Records of the results of analysis will be maintained.	• ***Management Review Procedure Process Map*** • ***Quality Objective Measurables*** • ***Effectiveness Reviews***
8.5.1 Improvement - General	8.5.1 Changes will be identified & implemented to ensure the suitability & effectiveness of the QMS is continually improved. This will be performed through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions & management review.	• ***Continual Improvement Procedure Process Map*** • ***Corrective Action Procedure Process Map*** • ***Preventive Action Procedure Process Map*** • ***Management Review Procedure Process Map***
8.5.2 Corrective Action	8.5.2 Actions to eliminate the cause of nonconformities in order to prevent recurrence will be taken. Corrective actions will be appropriate to the effects of the nonconformities encountered. Procedures will be established to define requirements for: a) Reviewing nonconformities (including customer complaints; b) Determining the causes of nonconformities; c) Evaluating the need for action to ensure that nonconformities do not recur;, d) Determining and implementing action needed; e) Updating documentation, if needed; f) Records of the results of any investigations &/or action taken; and f) Reviewing corrective action taken & its effectiveness.	• ***Corrective Action Procedure Process Map*** • ***Control of Nonconformity Procedure Process Map*** • ***Management Review Procedure Process Map*** • ***Customer Satisfaction/ Dissatisfaction Procedure Process Map*** • ***Effectiveness Review***
8.5.3 Preventive Action	8.5.3 Actions to eliminate the causes of potential nonconformities in order to prevent their occurrence will be taken. Preventive actions will be appropriate to the effects of the potential problems. Procedures will be established to define requirements for: a) Determining potential nonconformities and their causes; b) Evaluating the need for action to prevent occurrence of nonconformities; c) Determining and implementing action needed; d) Records of the results of any investigations &/or action taken; and e) Reviewing preventive action taken & its effectiveness.	• ***Preventive Action Procedure Process Map*** • ***Management Review Procedure Process Map*** • ***Customer Satisfaction/ Dissatisfaction Procedure Process Map*** • ***Effectiveness Review***

MANUAL REVISION HISTORY

This manual has been revised as follows:

Clause	Date	Revision Details	Revision Level	Approval
ALL	03/01/06	Release of ISO9001:2000 Quality Policy Manual	03/01/06	RK
Scope	05/01/06	Changed wording to reflect actual QMS exclusions	05/01/06	RK
Section 7.4	05/01/06	Added	05/01/06	RK
Section 7.6	05/01/06	Added	05/01/06	RK
Section 7.4	05/09/06	Removed “ITCN” references and replaced with “MERLIN”	05/09/06	RK
Section 7.6	05/09/06	Removed Calibration Procedure Process Map Reference because is not required or needed.	05/09/06	RK
Section 8.2.1	05/09/06	Removed the repeat of Section 8.2.1	05/09/06	RK