ISO 9001:2000 Quality Management System

(mo/yr)

Revisions		Rev:	Orig
Letter	E.O. Number - Description	Date	

Used On	Contract#:		**Your Co Name**				
Prepared By:							
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Your Dept:			Size:	**A**	CAGE:		Your Form# (mo/yr) 1 of 17

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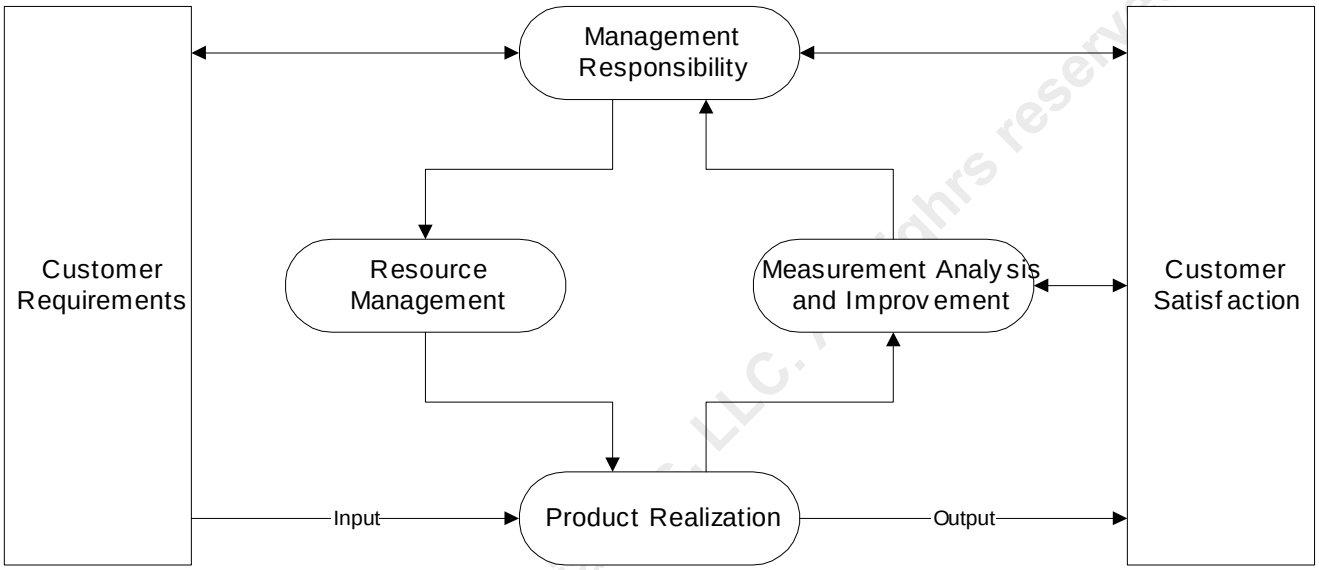
TABLE OF CONTENTS

This quality manual complies with the requirements of ISO 9001:2000

4.0 Quality Management System

4.1, 4.2, 4.2.1, 4.2.2 General Requirements of the QMS, Documentation Requirements-General, Quality Manual

This quality management system (QMS) is established, documented, implemented and maintained as described herein and by the supporting documents referenced in Appendix I. This QMS ensures that necessary procedures and instructions are in place as a documented part of the work process. The QMS process sequences and interactions are as follows:



This quality manual defines the QMS, policy, objectives, organization, responsibilities and procedures used to ensure the effective planning, operation and control of processes that affect the quality, reliability and safety of products and services. Quality improvements that are expected to increase the effectiveness of the QMS and satisfy business needs are derived from measuring and monitoring of QMS processes. Information from the analysis of QMS records is included in on-going planning at appropriate intervals during each calendar year to ensure that QMS processes achieve planned results. Records of QMS activities are maintained according to Section 4.2.4. Functions of the QMS that are subcontracted are controlled according to Section 7.4.1. The following exclusions and their justifications apply to the QMS: None

4.2.3 Control of Documents

The Document Control Center (DCC) is the custodian and source for controlled copies of released documentation masters and external documents that affect the form, fit or function of a product or service. Some documents are received, retained without change and distributed under control by DCC. Documents are approved by designated authorities prior to release and distribution by DCC. Approvals may be accomplished by actual signatures or initials on hard

copy documents or electronic signatures with authorization information provided by and maintained in electronic files. All QMS documents are identified by number and exhibit the latest change and current revision level. QMS documents are available at all points of use in hardcopy or electronic format. Masters and area specific documents, department procedures and standards that do not affect form fit or function of a product or service may be controlled and authorized by designated authorities and may be retained in the originating department or area. Some types of data are maintained within system databases which limit write access where appropriate. Other types of data are held within local areas and controlled by local teams. See Section 7.3.7 for Change Control information.

4.2.4 Control of Records

Information created during the operation of the QMS is retained in hardcopy format, microfiche or computer files. Records and reports are controlled to maintain their legibility, identification, storage, protection, retrieval, retention time and disposition. The record retention period is seven (7) years unless otherwise specified by designated authorities.

5.0 Management Responsibility

5.1, 5.2, 5.3, 5.4, 5.4.1, 5.4.2 Management Commitment, Customer Focus, Quality Policy, Planning, Quality Objectives, QMS Planning

All relevant functions and levels of organization within the Company are guided by Customer product requirements and quality objectives of this QMS. Designated authorities regularly review and work to continuously improve perceived Customer satisfaction and the effectiveness of the QMS using processes that include management reviews, resource allocation, product realization and measurement activities. The QMS, policy and objectives are continuously maintained and communicated regardless of the implementation status of planned changes.

5.5, 5.5.1 Responsibility, Authority and Communication

The Management Team is responsible for defining the objectives and strategy of the business operation. The Team is comprised of managers that perform the functions of Accounting, Manufacturing, Facilities, Machine-Shop, Quality, Business, Purchasing, EHS and Engineering. Product and service management includes the following departments:
Manufacturing, Engineering, Purchasing and Quality

- Manufacturing is responsible for the following functions:
  Corrective action, production processing and indication of inspection status, completed item testing and statistical quality control and analysis
- Engineering is responsible for the following functions:
  Design, drawings, documentation and changes, handling, storage and delivery
- Purchasing is responsible for the following functions:
  Purchasing, materials and purchasing data

5.5.2 Management Representative

- Quality is responsible for the following functions:
  Facilitation, implementation, establishment and maintenance of processes for the QMS, quality policies and procedures and the quality organization; initial quality planning, communication of Customer requirements, records, flowdown of requirements to Supplier(s), nonconforming material, work instructions, measuring and test equipment, production tooling used as a media of inspection, use of Supplier's inspection equipment by the Customer, standard and advanced metrology requirements, materials control, completed item inspection, internal audits, communication of QMS concerns with external organizations, Customer/Government source inspection at Suppliers and Customer/Government property control.

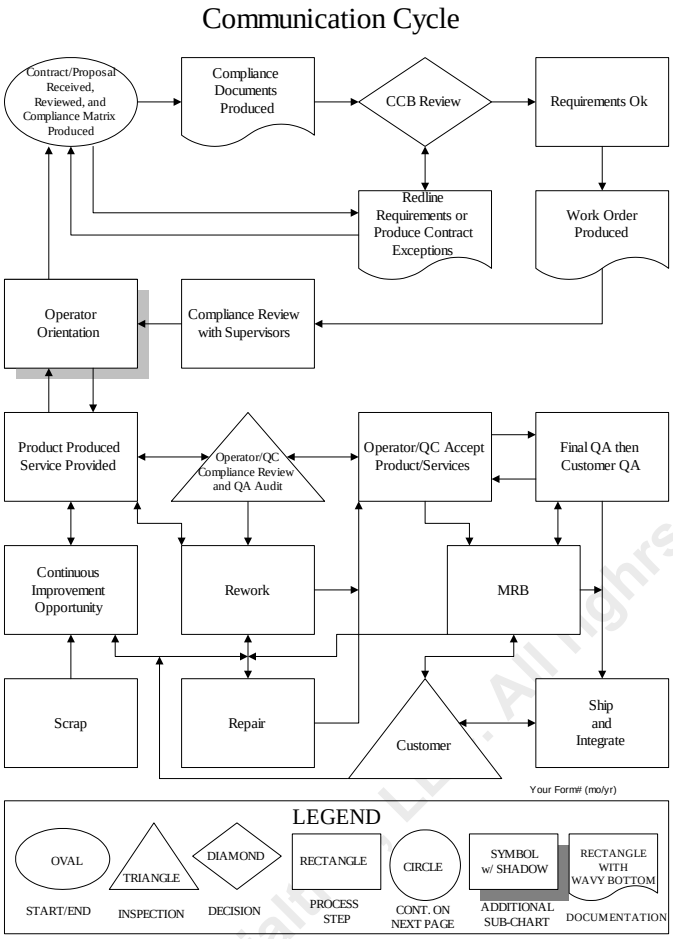
All direct management efforts are accomplished using cross-functional personnel or teams selected on the basis of meeting Quality, Cost and Schedule objectives.

Supporting management departments include:
Accounting, Business, Environmental, Health and Safety and Facilities

- Accounting is responsible for the following functions:
  Money management, credit and collections, accounting, data processing, employment and employee benefits and labor relations
- Business is responsible for the following functions:
  Market research, sales, contracts, customer relations, advertising and promotions
- Environmental, Health and Safety is responsible for the following functions:
  Community relations, health and safety, waste treatment, EPA regulatory compliance and drug free workplace compliance
- Facilities is responsible for the following functions:
  Security, facilities engineering and plant maintenance

Managers of each department are responsible for identifying staff and maintaining adequate personnel, equipment and other applicable resources. Managers have authority to support their responsibility and to continually promote improvement.

5.5.3 Internal Communication



5.6, 5.6.1 Management Review, General

Review meetings are held by all managers two times each year to assess…
1) the need for changes to the QMS and the quality policy and objectives, 2) improvement opportunities, 3) the status, adequacy, effectiveness and continuing suitability of the QMS, and 4) internal audits of the QMS. Reviews are reported and records are controlled according to Section 4.2.4.

5.6.2 Review Input

The bi-annual management review meetings are conducted according to the following list of Agenda items: results of audits, Customer feedback, process performance and product conformity, status of preventive and corrective actions, follow-up actions from previous management reviews, changes that affect the QMS and recommendations for improvement.

5.6.3 Review Output

The results of the bi-annual management review meetings are documented and released with the following content: improvement of the effectiveness of the QMS and its processes, improvement of product related to Customer requirements and resource needs.

6.0 Resource Management

6.1, 6.2, 6.2.1 Providing Resources, Human Resources, General

The resources needed to implement and maintain the QMS, continuously improve its effectiveness and enhance Customer satisfaction are achieved by practicing Total Quality Management (TQM), a system based on the fact that all business activities are processes rather than discrete events. Scientific methods of data collection and analysis are used where applicable to continually monitor and improve the processes. The responsibility for process improvement rests directly on the employee responsible for each process to encourage employees to practice Continuous Improvement. TQM is a long-term philosophy and methodology that enables the achievement of continuous quality improvement and fulfillment of Customer needs as well as satisfying employee needs to operate in a challenging environment that requires their best efforts. Employees that perform work that affects product quality are qualified according to their education, training, skills and experience.

6.2.2 Competence, Awareness and Training

Employees are selected according to job descriptions that define the general skill level and qualifications needed to meet the basic requirements of the job. New employees receive general orientation from the Human Resources and EHS Departments and specific orientation from their manager that includes communication of the relevance and importance of their work activities and their contribution to established quality objectives. Managers have a direct responsibility for determining the learning needs of their employees and for ensuring that those needs are met. As part of the employee performance evaluation and development planning process, the manager and employee document specific needs and evaluate the effectiveness of the training process. This document is retained as part of the employee's personnel record in the Human Resources Department according to Section 4.2.4. The responsibility for designing and delivering specific training programs rests with the area of expertise, for example; the EHS Department assures safety training and the Quality Department offers TQC methodology. The majority of task specific training is conducted “on-the-job” under the direction of local management. The EHS Department maintains a computer database of sponsored and externally taught credit and non-credit courses that are completed by employees. Other evidence of training is maintained by department managers.

6.3, 6.4 Infrastructure, Work Environment

Buildings, work environment, workspace and associated utilities, hardware and software controlled process equipment and support equipment used for transport or communication that is necessary to achieve conformance to product requirements are determined, provided and maintained according to the requirements of this QMS and established quality policy and objectives.

7.0 Product Realization

7.1 Planning of Product Realization

The product realization process (PRP) determines the quality objectives and requirements for a product or service. A quality plan or other suitable document is prepared that defines the sequence and interaction of the PRP, exclusions and applicable processes of the QMS and appropriate production processes and documentation requirements. The plan controls out-sourced activities and the necessary monitoring, measurement and analyses to ensure the PRP is continuously improved and achieves planned results. The PRP includes management activities that define the criteria necessary to effectively operate the process and the resources for monitoring its operation. During the production process the product or service is verified, validated, monitored, inspected and tested. Records are produced during the PRP that provides objective evidence that the resulting product or service meets requirements. Records are controlled according to Section 4.2.4 herein.

7.2, 7.2.1, 7.2.2, 7.2.3 Customer Related Processes, Determination of Requirements Related to Product, Review of Requirements Related to the Product, Customer Communication

Incoming orders are reviewed prior to their acknowledgement for acceptability, validity, changes to requirements from previous contracts and special instructions. Orders are reviewed to determine the Company's capability to deliver items that are in compliance with contract, statutory, regulatory and organizational requirements. Special attention is given to delivery and post-delivery activities and where known, necessary but unstated or undocumented Customer requirements. Customers are oriented to communicate their product information, feedback, inquiries, order handling, amendments and complaints to the Contracts Department.
All managers are responsible for developing organizations and systems that accommodate the goal of achieving Customer satisfaction. Managers need to recognize and support Employees charged with the responsibility of interacting with Customers. Employees that are authorized to interact with Customers need to carefully listen to Customers and fully understand their requirements and expectations. Employees need to be as responsive as possible to Customer needs within the province and spirit of good business practices. Managers need to monitor Customer satisfaction on a continuing basis to make appropriate adjustments and corrections.
The Engineering Department is responsible for new product development, which begins with product definition and progresses in a systematic fashion through the various stages of the development cycle. Products that are designed to meet a Customer contract are developed by a team that remains involved until the Customer accepts the item. Each project is evaluated periodically to determine its status and applicability to the original concept. Projects advance according to established procedures, including product documentation, retention of records and communication of changes to affected Employees when relevant documents are revised.
Contract, product and performance records are controlled according to contract requirements and/or Section 4.2.4 herein.

7.3, 7.3.1 Design and Development, Planning

Each project is guided by a project team that is led by a responsible authority. The team defines design inputs, technical and economic goals and the responsibility and authority for design and development stages with appropriate review, verification and validation of each stage. The team identifies and assigns activities and resources and between-group design and development interfaces to ensure effective communication and clear assignments. The team also documents appropriate updates of planning outputs and release of the completed design to production according to organizational and technical requirements. Records are controlled according to Section 4.2.4.

7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6 Design and Development Inputs, Outputs, Review, Verification and Validation

A product or service specification is established for each design that enables verification of design and development inputs and is refined until compatible with the final product.
The specification defines the requirements for essential design and development requirements, function and performance, similar design information where applicable, product or service acceptance criteria and purchasing, production and servicing requirements. Design reviews are performed with participation from contributing groups throughout the design and development stages with appropriate review, verification and validation of each stage. Reviews identify problems and propose necessary actions and ensure the design is complete, unambiguous and does not conflict with organizational and technical requirements - results are communicated to affected personnel. Prototype items may be built using production processes and procedures to verify manufacturing capability. Product and service evaluations are performed to ensure conformance to statutory and regulatory agency controls. The design is validated to ensure conformance to the original concept and application. Prior to release of a product or service to production the project team ensures that the design contains characteristics essential for safe and proper use and achieves intended performance and application goals. Once in production, products and services are manufactured or performed with superior workmanship at a competitive cost. Careful attention to quality enables the product or service to meet or exceed Customer expectations and applicable statutory and regulatory requirements. Doing a job properly the first time and doing it consistently contributes significantly to higher productivity. Records for design and development reviews and necessary actions are produced and controlled according to Section 4.2.4.

7.3.7 Control of Design and Development Changes

Requests for changes are reviewed, verified, validated and approved by designated authorities prior to implementation as needed during the early stages of product or service development. An Engineering Order is required to implement a change after approval by the Customer or release to production from the project team. New documents are issued upon approval and authorization of the Originator and the document control center representative (DCC). Changes to released documents that are retained in DCC are created and authorized by an approved

change process which identifies the nature of the change and the affect the change has on constituent parts and delivered products or applicable services. An approved change process is also used to make authorized changes to training documentation. All processes defined by a DCC controlled document that requires an immediate change to the process may be temporarily revised using a controlled temporary process followed by an approved change process. Updated copies of documents such as drawings, lists and procedures are reviewed and signed by designated authorities. Product and service operating information is updated using information supplied through an approved change process. Controls are in place to ensure the use of current documentation. QMS documents that are stamped or exhibit the term “Obsolete” may not be used unless approved in writing by designated authorities. Some documents may be held by technicians and others that are considered aids may not be current or correct - such documents are identified and segregated from production documentation and are not used to manufacture products or perform service activities. Records are maintained according to Section 4.2.4.

7.4, 7.4.1, 7.4.2 Purchasing, Purchasing Process, Purchasing Information

The quality of products and services is related to the quality of purchased items and Suppliers, which makes it essential to cultivate competent Suppliers. Effective interaction with Suppliers helps to ensure that the highest quality materials are received on time to meet production schedules. The technical and commercial activity related to Suppliers, components and materials is the Purchasing Department. The department works according to procedures, guidelines and strategies that provides criteria for Supplier selection, evaluation and re-evaluation to ensure the supply of material that conforms to requirements. The extent of Supplier control is dependent on an item’s affect on the design and development process and/or the performance requirements of a product or service. A Supplier evaluation and the use of a performance model for Supplier selection is applied at the discretion of the Purchasing Department. The Performance Model (PM) examines Supplier attributes for Quality, Capability, Responsiveness, Delivery, Cost, Business and the affect of their product or service on the Environment. Records of Supplier evaluations and necessary actions are controlled according to Section 4.2.4. Buyers in the Department purchase products, services, components and materials only from approved Suppliers. Chemical purchasing requires additional consideration to ensure the safety of products and personnel. All chemicals are purchased according to the defined and documented direction of the Environmental Safety and Health Department. Where appropriate, Suppliers (subcontractors) of purchased parts and services are assessed and approved collectively by the Purchasing Department. Approval of each component type is determined individually based on the acceptability of initial deliveries followed by continued conformance to specified requirements. The selection of Suppliers, parts and services is aimed at maximizing the use of material of known quality and performance from Suppliers with proven ability to continually meet PM requirements. Conformance to these requirements is assessed by performance in all areas of PM. Performance reviews are held with key Suppliers as determined by the Purchasing Department. Materials, components and products are identified using a part numbering system that uniquely identifies each part used to produce, ship or

support the products and services. All purchase orders use part number references and documentation cross-references to provide appropriate criteria for acceptance, procedures, processes, equipment and special processes that require qualified or certified Operators. Purchase orders include a reference to a quality management system that is applicable to the product or service and the Supplier. Where appropriate, the purchase order contains reference to source inspection at the Supplier's facility and the requirements for release of an acceptable product or service. Designated authorities review and approve purchase orders prior to their release. The history of past purchases is retained according to Section 4.2.4.

7.4.3 Verification of Purchased Product

Deliveries are verified for conformance to purchase order requirements according to documented inspection instructions. If specified in the Customer's purchase contract, the Customer Representative is afforded the opportunity to perform source inspection at any stage of product manufacture or shipment prior to acceptance. Acceptance will not relieve the Company of the responsibility or commitment to provide acceptable product quality.
The applicable policy to repair or replace defective products shall apply. Incoming supplies are source controlled. If materials are designated for further inspection they are assigned to a test department that verifies conformance of the supplies to the written specifications according to an inspection plan and other documented procedures. Defective supplies are clearly identified as nonconforming and segregated from good material. Nonconforming supplies are reviewed to determine the appropriate corrective action by the designated department(s).

7.5, 7.5.1, 7.5.2 Production and Service, Control and Validation

Systems are in place to control, verify and correct activities and equipment within manufacturing and service operations to ensure that events occur as planned. To assist the production process, information that describes characteristics of the product or service is available at appropriate points in the form of workmanship standards, instructions and/or procedures. Applicable documents define the approvals required to release a product or process to production and the necessary delivery and post-delivery activities to ensure consistent quality. The documents define the equipment and Employee qualifications that are necessary to perform the approved process and achieve planned results. The performance of finished products and services is verified by using measurement devices with valid calibration status, controlled software programs or by physical inspection. Processes are controlled to the extent necessary to minimize process variability and to ensure conformance when a product or service cannot be verified by monitoring or measurement devices. This may include a method of continuous monitoring or may involve taking regular samples or readings. The results are recorded and measured against established limits. Corrective action is initiated when results indicate a defective condition. Processes are re-validated when latent defects are discovered. Records are controlled according to Section 4.2.4.

7.5.3 Identification and Traceability

Parts are identified using a part numbering system that uniquely identifies each item used in a product or service. Part number identification is maintained throughout the production process. The status of service operations or manufactured products is maintained by monitoring and/or measurement activities that indicate the successful completion of a process step, assembly and test or inspection operation. Subsequent to manufacture when products are stored or shipped and installed a handling system tracks Customer purchase order numbers, product numbers, event dates and serial numbers where applicable. Products sold are allocated a unique product number, where a product is a marketed unit. Products, systems and instruments generally have a serial number that uniquely identifies the unit when combined with the product number. Products considered as accessories, components or software may or may not be allocated a serial number. Products sold as services do not have serial number identification. Records are controlled according to Section 4.2.4.

7.5.4 Customer Property

A negotiated agreement to identify, verify, protect, store and maintain Customer supplies is established and any product that is lost or damaged or is otherwise unsuitable for use is recorded and reported to the Customer. Records are controlled according to Section 4.2.4.

7.5.5 Preservation of Product

Procedures are established that promote safe handling methods, preservation of product conformity during internal processing and to prevent deterioration while in storage or delivery to the intended destination. Products and constituent parts that are ready for shipment are packaged in appropriately secure containers. Preservation, packaging, packing and marking activities are carried out according to the current requirements of International, U.S. and independent carriers. Delivery is arranged according to the instructions received directly from the Customer or via relevant contract requirements. When supplies require special handling or storage, action is taken to ensure that adequate instructions concerning their handling and storage are identified. The handling of devices sensitive to electrostatic discharge (ESD) or contamination limits is performed according to the procedure listed in Appendix I. To maximize the effectiveness of ESD handling and contamination control, a system of static and contamination protection is enforced in areas of prime sensitivity. Applicable production areas are ESD and contamination controlled and handling techniques are closely monitored.
The techniques are maintained in a current state and kept prominent in people's minds in all relevant areas throughout the plant. Regular audits are carried out in all areas of prime sensitivity for static handling and contamination control.

7.6 Control of Monitoring and Measuring Devices

Inspection, measuring and test equipment is purchased and installed according to Customer and organizational requirements. Consideration includes statutory and regulatory requirements, delivery and post-delivery activities and where known, unstated Customer requirements.

A tracking number is assigned and equipment is performance tested prior to its use to verify conformance to specifications. Software used to perform automated tests or inspections is verified prior to release and routinely checked to ensure acceptable performance. Equipment of known measurement traceability is used to determine compliance with specifications and where no standard exists, the justification of calibration or verification is recorded. Measurement uncertainty has been established and is consistent with the required measurement capability. Managers ensure that personnel receive training so that proper handling, preservation, storage and use of measuring and test equipment is understood and practiced. The manager of each equipment user area ensures that all measuring and test equipment used within the area bears a valid calibration status label. Equipment overdue for calibration or with damaged calibration integrity seals is not used. Environmental conditions suitable for calibrations, inspections, measurements and tests are maintained. Electrical and mechanical measuring and test equipment is calibrated by the Metrology Department (MD). MD determines the need for and interval of periodic calibration of equipment, considering the manufacturer's specification, results of prior calibration and methods and extent of its use. MD operates a calibration recall system to assist managers in identifying and scheduling equipment due for calibration. Procedures and methods of calibration are assessed, documented and maintained as appropriate by MD. Measuring equipment is adjusted or re-adjusted as necessary to maintain its accuracy and precision. Electrical and mechanical reference standards have traceability maintained to nationally recognized standards through a scheduled system of recertification operated by the MD. The sources of calibration services are selected by MD based on the sources' ability to provide the required service. Results of calibrations are recorded in a recall database.
All equipment subject to scheduled calibration has a valid calibration status label affixed to the item indicating who performed the calibration, when it was calibrated and when the next calibration is due. Calibration integrity seals are applied to strategic points on the equipment to provide a safeguard from adjustments which would invalidate the calibration. When equipment received for normal calibration is found out of tolerance, an 'Out of Tolerance' notification is sent to the equipment user's manager for assessment of appropriate corrective action. Previous test results, the scope of application and the extent of the nonconformity are assessed when considering subsequent action. Equipment considered faulty by a user is reported to MD for fault diagnosis and repair with the details recorded in the recall database. If the calibration has been compromised in any way, the equipment is performance tested prior to reuse. Some equipment requires a routine preventive maintenance process. In such cases, personnel independent of MD are assigned to carry out those responsibilities and record results which include evidence of completion. Records are controlled according to Section 4.2.4.

8.0 Measurement, Analysis and Improvement

8.1 General

The Company plans, implements and determines the applicable methods and extent of their use for monitoring, measurement, analysis and improvement processes to demonstrate product or

service conformance, ensure QMS conformance and continuously improve the effectiveness of the QMS.

8.2, 8.2.1 Monitoring and Measurement, Customer Satisfaction

Customer perception surveys are conducted and personnel assigned to interact with Customer Representatives are tasked with recording their perception of Customer satisfaction. Records are forwarded to the internal audit process for review and disposition by Senior Management at least twice each year. Support of products after delivery to the Customer is normally provided by a Service Representative; however, in order to meet unusual Customer requirements, special management between the Customer and the Service Representative may take place. Customer support provides a comprehensive calibration and repair service together with replacement and exchange parts and consumable supplies. Specialized product support is provided to each Service Representative, including a supply of current information and a source for replacement parts throughout the planned support life of the product. Special arrangements may occasionally be made with Customer support for special product service, e.g., factory-only installed options whereby Customer units are returned for modification or repair. Delivered items are provided continuing support throughout their life cycle.

8.2.2, 8.2.3 Internal Audit, Monitoring and Measurement of Processes

The quality of every process is the direct responsibility of each person performing the work. QMS system processes are monitored and measured where applicable to demonstrate the QMS processes achieve planned results and appropriate corrective and preventive actions are taken when results are not achieved to ensure product conformance. A process of internal quality audits is operated to determine the effectiveness of the QMS. The audit process is managed by the Quality Management Representative. The system involves establishing a quality audit plan with appropriate quality objectives and requirements for the audit. Areas that perform activities within the QMS are scheduled for regular audits at appropriate time intervals. The plan includes Customer perception surveys and complaints and appropriate verification, validation, monitoring, inspection and test and criteria for audit acceptance. Suitably qualified Auditors that are independent of the area being audited are assigned to individual audits. Auditors visit areas at assigned times to verify whether activities comply with planned arrangements and to determine the overall effectiveness of the QMS relating to the area being audited. The result of an audit and a comparison to previous audit results is discussed with local area management. A report is generated shortly afterwards that summarizes the scope of the audit and the extent, if any, of nonconformities and corrective actions requested. The report that is authorized by the Quality Management Representative is sent to the local area manager with specified requirements to communicate audit results to their staff and to take corrective action on nonconformities without undue delay. A written response that provides detailed information on the affected area's plan to correct all discrepancies including a time schedule is sent to the Quality Management Representative. Follow-up audit activities include the review of actions taken to eliminate the cause of the nonconformance, prevent its recurrence and to determine that

the corrective action is appropriate to the affect of the nonconformance. Overall results of the QMS audits are shared with senior management at least twice each year. Records are controlled according to Section 4.2.4.

8.2.4 Monitoring and Measurement of Product

Appropriate product or service characteristics are monitored and inspected as required to determine their conformance to requirements. Electrical and mechanical verifications are conducted with calibrated equipment. Inspection and test results are collected at various monitoring points. Records of verification, monitoring, inspection or test are maintained with traceability to the individual that is responsible for accepting the product or service. Completed items that meet planned requirements are delivered to stores or delivered to the next stage in the process. Assemblies are inspected or otherwise verified for quality fitness at each stage prior to progressing to the next stage. Statistical methods are used to analyze data and present information where appropriate. Statistical sampling techniques are used for monitoring quality levels. Control charts are used to monitor failures and help identify failure reasons. Products are shipped only after completion of production, test, inspection or software verifications whose records indicate that planned operations have been successfully completed. Items or services that are needed before their completion are accepted for release by the Customer or designated authorities. Any product identified as requiring Customer source inspection is held until released by the Customer for shipment. Recording of software on media is systematically verified prior to acceptance. Records are controlled according to Section 4.2.4.

8.3 Control of Nonconforming Product

Any assembly, component or process that is considered discrepant according to a planned requirement will be corrected or categorized as nonconforming material. If corrected, it is re-inspected to ensure compliance to requirements. Nonconforming material is identified, segregated from good material to the extent practicable or removed from the production process to prevent its unintended use or delivery. Nonconforming supplies or processes detected prior to and after delivery or use are reviewed and dispositioned according to work area documentation that defines the control, authority and responsibilities for disposition. Records identify the root cause of the nonconformance, actions taken to eliminate and prevent recurrence and the responsible authority for acceptance. Records are controlled according to Section 4.2.4.

8.4 Analysis of Data

Appropriate data from monitoring and measuring activities is defined, collected and analyzed to demonstrate the suitability of the QMS and to identify opportunities to improve the effectiveness of the QMS. Data analysis includes characteristics and trends from Suppliers, Customer perception surveys, product conformance including delivery and post-delivery activities, necessary but unstated Customer requirements where known, statutory and regulatory product requirements and organizational requirements. Records are controlled according to Section 4.2.4.

8.5, 8.5.1, 8.5.2, 8.5.3 Improvement, Continuous Improvement, Corrective and Preventive Action

The effectiveness of the QMS is continuously improved using the quality policy and objectives, audit results, analysis of data, corrective and preventive actions and management reviews.
A nonconformance procedure is used as the foundation for continuous improvement action and to identify and correct incidents of nonconformances related to materials, processes, products, services and Customer complaints. Designated authorities have responsibilities concerning defect analysis and/or identification of nonconformities to eliminate the cause of the nonconformance and to prevent recurrence. Corrective and preventive action is taken when it is consistent with findings from analysis or investigation of incidents and when it is determined to be appropriate to the affect or potential affect of the nonconformance. Corrective and preventive actions are communicated to appropriate levels of management. Individuals or teams are empowered to initiate corrective action, implement preventive measures in processes and procedures and monitor the effectiveness of the corrective and preventive actions.

Appendix I – Supporting Documents

Section	Title	Supporting Document Title	Doc/Section #
4.1	QMS General		
4.2.1	Documentation Requirements, General		
4.2.2	Quality Manual		
4.2.3	Control of Documents		
4.2.4	Control of Records		
5.1	Management Commitment		
5,2	Customer Focus		
5.3	Quality Policy		
5.4.1	Planning Quality Objectives		
5.4.2	QMA Planning		
5.5.1	Responsibility and Authority		
5.5.2	Management Representative		
5.5.3	Internal Communication		
5.6.1	Management Review General		
5.6.2	Review Input		
5.6.3	Review Output		
6.1	Resources		
6.2.1	Resource Mgmt General		
6.2.2	Competence, Awareness, Training		
6.3	Infrastructure		
6.4	Work Environment		
7.1	Planning of Product Realization		
7.2.1	Determination of Requirements		
7.2.2	Review of Requirements		
7.2.3	Customer Communication		
7.3.1	Design & Development Planning		
7.3.2	Design & Development Inputs		
7.3.3	Design & Development Outputs		
7.3.4	Design & Development Review		
7.3.5	Design & Development Verification		
7.3.6	Design & Development Validation		
7.3.7	Design & Development Changes		
7.4.1	Purchasing Process		
7.4.2	Purchasing Information		
7.4.3	Verification of Purchased Product		
7.5.1	Control of Production and Service		

Section	Title	Supporting Document Title	Doc/Section #
7.5.2	Validation of Processes		
7.5.3	Identification and Traceability		
7.5.4	Customer Property		
7.5.5	Preservation of Product	ESD – Contamination Control: XXX	
7.6	Control of Monitoring and Measuring Devices		
8.1	Measurement, Analysis and Improvement, General		
8.2.1	Customer Satisfaction		
8.2.2	Internal Audit		
8.2.3	Process Monitoring and Measurement		
8.2.4	Product Monitoring and Measurement		
8.3	Control of Nonconforming Product		
8.4	Analysis of Data		
8.5.1	Continuous Improvement		
8.5.2	Corrective Action		
8.5.3	Preventive Action		