Document Title: QUALITY POLICY MANUAL

Document No: QA-040 Revision: BB

Rev	ECO No.	Originator	Date
See Agile For Previous Revision Information			
AY	13-0584	Stacy Irwin	06/06/2013
AY	MC13-0217	Lisa Kaiser	06/10/2013
AZ	16-0123	Neelam Singh	03/03/2016
BA	17-0263	Peter Henrich	04/20/2017
BB	17-0890	Peter Henrich	06/05/2017
BB	MC17-0225	Peter Henrich	06/12/2017

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1.0 SCOPE

Crane Aerospace & Electronics has developed and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2008, ISO 13485:2003, AS9100C, and MIL-PRF-38534 for Interpoint Brand products. The Company resolves its commitment in continuous maintenance for effectiveness and process improvements. This Manual is the top-level document of Crane Aerospace & Electronics QMS.

For the AS9100C standard, section 7.5.1.4 Post-Delivery Support is excluded because Crane Aerospace & Electronics does not offer post-delivery support.

For the ISO 13485, Sections 7.3, 7.5.1.2.2, 7.5.1.2.3, 7.5.1.3 and 7.5.2.2 are excluded.

Crane Aerospace & Electronics does not manufacture sterile medical devices.

This Manual defines and describes the quality system, delineates authorities and responsibilities of the management personnel involved in the operation of the system, and provides general procedures for all activities comprising the quality system. For our customers and other interested parties, it presents the quality system, informing them of what specific controls are implemented at our Company to assure quality.

This Manual applies to the activities of Crane Aerospace & Electronics in the following two locations for AS9100C/ISO 9001:2008 and the Redmond location for ISO13485:2003 as well:

10301 Willows Road NE
Mail: P.O. Box 97005
Redmond, Washington 98052

4F, 5 South 6th Road,
K.E.P.Z.,
Kaohsiung, Taiwan

This Manual also applies to the activities of Crane Aerospace & Electronics in the following two locations for ISO 9001:2008 elements only:

8 Forge Court; Reading Road
Yateley Hampshire; GU46 7RX
United Kingdom (UK)

2-4 Boulevard de la gare
Saint Gratien; 95210
France

2.0 REFERENCE DOCUMENTS

The following documents were used to develop this procedure:

ISO 9001:2008	Quality Management Systems, Requirements, International Standard
ISO 13485:2003	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
AS9100C	Quality Management Systems – Requirements for Aviation, Space and Defense Organizations
MIL-PRF-38534	General Specification for Hybrid Microcircuits
GEN-047	Records Retention Matrix

2.0 MANUAL ISSUANCE AND MAINTENANCE

The Quality Manual shall be initiated and maintained by the Crane Aerospace & Electronics (CAE) Quality Assurance Department. The initial issue and any major updates of the manual shall be reviewed for concurrence and approved by management representatives with executive responsibility for quality prior to updated releases.

The Quality Manual is available to employees via the internal Configuration Management System. All Crane Aerospace & Electronics Sales Offices outside the Redmond facility will have access to the latest revision of the Quality Manual through the Interpoint Brand product website.

The Quality Manual shall be reviewed at least annually for updating to reflect current practices, policies, and organizational structure.

4.0 QUALITY MANAGEMENT SYSTEM REQUIREMENTS

4.1 General Requirements

Crane Aerospace & Electronics primary concern is for the quality of our Interpoint Brand products and services. In order to assure our success we must offer products and services that meet our customer's needs and requirements. These products or services must also satisfy or exceed our customer's expectations. Our products and services shall comply with laws and ethical standards of conduct in society. We shall also strive through continuous quality improvement and close cooperation with our suppliers to provide products and services that are competitive while assuring the financial well-being of Crane Aerospace & Electronics

Crane Aerospace & Electronics has established, documented, implemented and maintains a Quality Management System (QMS) aligned to the ISO 13485:2003, ISO 9001:2008, AS9100C standards, and MIL-PRF-38534. The System, where applicable, incorporates the requirements from each of these standards and any other appropriate requirements. The quality manual, procedures, work instructions and forms define organizational structure, responsibilities, processes, procedures, and resources available for quality management.

Crane Aerospace & Electronics has identified and documented processes necessary to establish and maintain an effective QMS throughout the organization (see FIGURES 3 - 6). Where appropriate the sequence and interaction of the processes has been determined and ensures that the operation and control of these processes are effective in maintaining the overall quality of the goods and services delivered by Crane Aerospace & Electronics (see FIGURE 2). Outplant services for production processes are controlled by the purchasing process.

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Crane Aerospace & Electronics shall ensure that sufficient resources are made available to: implement, monitor, maintain and continually improve upon processes, in order to assure the continued effectiveness of the QMS.

The effectiveness of the QMS is monitored against objectives established by the management using Business Unit Reviews, Key Process Indicators (KPI), and Internal Audits.

Outsourced processes include Residual Gas Analysis, Destructive Physical Analysis, Ionic Chromotography, Parylene Coating, and Laser Welding. These processes are controlled according to MIL-STD-883, customer requirements or CAE requirements through MATL-011 Outplant Processing procedure.

4.2 Documentation Requirements

4.2.1 General

Crane Aerospace & Electronics QMS documentation includes:

- Quality Policy and Quality Objectives
- Quality Manual
- Documented procedures required by ISO 9001:2008
- Documented procedures required by AS9100C
- Documented procedures required by ISO 13485:2003
- Documented procedures required by MIL-PRF-38534
- Documents required by Crane Aerospace & Electronics to ensure the effective planning, operation and control of its processes
- Records required by ISO 9001:2008, AS9100C and ISO13485:2003.
- Quality System requirements imposed by the applicable regulatory authorities.

Documented procedures and processes established for the Quality Management System are referenced herein. The matrix in QA-093 details the QMS procedures.The use of industry-standard guidelines may also be used to ensure conformity of product to requirements as well as ensure the integrity and efficiency of the appropriate QMS.

Crane Aerospace & Electronics shall ensure that personnel have access to Quality Management System documentation and are aware of relevant procedures. Customer and/or regulatory authority representatives shall have access to QMS documentation.

For each Interpoint Brand product, including all medical devices, a Bill of Materials (BOM) shall be established identifying raw materials and documents defining product specifications and quality management system requirements. These documents shall define the complete manufacturing process. The BOM links the product to applicable documents including but not limited to the Schematic, Automated Test Procedure (ATP), Product Traveler, and Customer specific documents. The Traveler identifies all manufacturing process steps for the product and associated manufacturing and quality procedures.

4.2.2 Quality Manual

This manual was written to meet the requirements of ISO9001:2008, ISO13485:2003, AS9100C and MIL-PRF-38534.

4.2.3 Control of Documents

Crane Aerospace & Electronics has established and maintains documented procedures to control documents and data that relate to our quality system and the requirements of ISO9001, ISO13485, AS9100C standards and MIL-PRF-38534. These shall include, internal

procedures/work instructions/forms, documents of external origin such as drawings, specifications, manufacturer test reports and certificates of conformity, and internal documents such as sales/purchase orders, calibration and training records, audits and corrective actions.

GEN-002 (Documentation Change Control Procedure) provides a formal process for the initial release, revision, and approvals of Crane Aerospace & Electronics documents and records governing product configuration and quality management system.

Documents and data shall be maintained in hardcopy and/or electronic formats in such a manner as to maintain their legibility and fitness for use.

All documents such as procedures shall be reviewed for accuracy and approved prior to release by authorized personnel as defined in Crane Aerospace & Electronics released procedures. This shall pertain to initial document releases as well as future revisions. Furthermore, a master list of documents shall be maintained and readily available to identify the current revision of documents, so as to preclude the use of invalid or obsolete documents. Document revisions are reviewed and approved by the original approving functional group(s) or by another designated functional group(s) that has access to pertinent background information.

Document revisions to procedures shall be noted on the individual documents as well as in the Configuration Control database.

The Configuration Control System shall ensure that essential documents, contract or data change information, contract instructions, specifications or any other documents are available at the point of use.

The issue, control and recall of documents shall be under the jurisdiction of the Configuration Control Manager and the QA Manager. Requests for changes to controlled documents shall be submitted to Quality Assurance at a minimum for review and initiation.

Where required due to contract or regulatory requirements, Crane Aerospace & Electronics shall coordinate appropriate document changes with customers or regulatory agencies.

Crane Aerospace & Electronics has defined the period for which one copy of obsolete controlled documents is retained which is documented in GEN-047 (Records Retention Matrix). This period ensures that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device, but not less than the retention period of any resulting record, or as specified by relevant regulatory requirements.

Changes to this Quality Manual are reviewed and approved by Senior Management.

See Figure 6 for the Outline of the Documentation Structure.

4.2.4 Control of Records

Records have been established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. All records are legible, readily identifiable and retrievable. A Records Retentions Matrix (GEN-047) has been established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

For medical devices, records are maintained for a period of time at least equivalent to the lifetime of the medical device as defined by the organization, but not less than two years from the date of product release or as specified by relevant regulatory requirements.

Records are available for review by customers and regulatory authorities in accordance with contract or regulatory requirements.

Quality records will include as defined in GEN-047 (Records Retention Matrix):

- Management reviews;
- Employee certifications and training records;
- Design planning, development, and testing activities;
- Customer contract and / or purchase order reviews;
- Purchase orders;
- Design inputs and outputs;
- Design reviews and resulting actions;
- Results of verification and validation testing, including any necessary actions;
- Changes during the development process;
- Supplier records and verification of purchased product;
- Qualified processes, equipment, and personnel as appropriate;
- Device master file (Bill of Material) and production batch records;
- Process and software validation;
- Unique identification of the individual product or lot – when traceability is a specific requirement;
- Product Traceability Records
- Notification to the customer when customer property is lost, damaged, or is otherwise unsuitable for use;
- Equipment Maintenance, Calibration records and test software verifications;
- Quality system audits;
- Inspection plans / control plans and results, including, as applicable, receiving, in–process, and final;
- Advisory notices and product recalls
- Risk Management
- Customer Feedback
- Analysis of data
- Monitoring of Special Storage conditions
- Records of rework and nonconforming material transactions, including: inspection rejections, internal rejections, deviations, customer complaints, and return material;
- Corrective and preventive actions;
- Other records as specified by the customer.

Safeguards shall be maintained for records on any media that protects against disaster, system obsolescence, and loss.

5.0 MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Senior management is actively involved in maintaining the QMS. It provides the vision and strategic direction for growth of the QMS, and establishes quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement and maintenance of the QMS, senior management communicates the importance of fulfilling customer, legal and regulatory requirements through the periodic communication meetings as well as by conducting management reviews to ensure the availability of resources.

Senior management identifies measurements for product conformity and on-time delivery performance, setting performance goals and ensuring that appropriate action is taken if planned results are not achieved.

5.2 Customer Focus

Crane Aerospace & Electronics strives to meet or exceed the needs of its customers. Much of our ability to provide customer satisfaction will come from our review of customer purchase order documents and our effectiveness in complying with them, along with any other appropriate regulatory requirements. In addition it is our intention to develop clear channels of communication with customers, both pre and post-delivery, so that issues relating to order expediting/delivery /quality can be discussed. Crane Aerospace & Electronics will review customer generated feedback on our performance and will utilize the data during QMS reviews to help identify process improvements that will allow us to better server customer needs.

5.3 Quality Policy

Our guiding principle is to anticipate and exceed the requirements of our internal and external customers.

We will provide superior products and services that always satisfy the customer by continually improving processes.

Our ultimate goal is 100% quality, delivery and performance every time.

Responsibility for upholding this policy applies to all sites under the leadership of the President of Crane Aerospace & Electronics and the guidance of the Director of Quality who encourage the personal commitment of all co-workers to address quality as part of their skills.

Our guiding principle is to anticipate and exceed the requirements of our internal and external customers. Crane Aerospace & Electronics is on a continual journey dedicated to anticipating and exceeding the requirements of internal and external customers. All employees are committed to build the best products, which meet or exceed requirements, and to provide the best services of any company in our industry.

We will provide superior products and services that always satisfy the customer by continually improving processes, Crane Aerospace & Electronics recognizes that the disciplines of quality, environmental management, health, and safety are integral parts of its management function. We view these as a primary responsibility, and fundamental to the best business practice of operating under the control of a Quality Management System in compliance with ISO 9001:2008, ISO13485:2003 and AS9100C standards. Crane Aerospace & Electronics implements continual improvement initiatives focused on Safety, Quality, Delivery, and Cost by taking action to:

- Communicate the Quality policy and objectives, as well as performance in achieving these objectives, throughout the Company and to interested parties to ensure they are understood;
- Take due care to ensure that activities are safe for employees, associates and others who come into contact with its products, work and other activity;
- Work closely with Customers and Suppliers in seeking to establish the highest Quality standards;
- Adopt a forward-looking view on future business decisions which may have an impact on Quality;
- Train all members of staff in the needs and responsibilities of Quality Management;
- Constantly strive to meet, and where possible exceed, our customer's expectations.
- Maintain the effectiveness of the quality management system and ensure it is reviewed for suitability.

Our ultimate goal is 100% quality, delivery and performance every time.

We are committed to 100% accurate, on time delivery of our products and services.

5.4 Planning

5.4.1 Quality Objectives

Crane Aerospace & Electronics has established that relevant functions and levels within the organization have clear, measurable quality objectives that are consistent with the company policies and product requirements. These are represented under the Key Process Indicators (KPI) of Safety, Quality, Delivery and Cost. Adequate resources are available and output is planned in a controlled manner as is required by the QMS, being mindful of the process, the impact of change, and the need for continual improvement.

5.4.2 Quality Management System Planning

Quality planning at the company level shall consist of implementation, updating, and maintenance of this Quality Manual and the supporting quality specifications. Customer and supplier feedback as supplied through formal reports, through performance reviews, during audits or through surveys shall be considered during the update reviews of this document.

The approach and deployment of quality planning within the Business Unit shall include, as appropriate:

- Design / Development Assurance Plans;
- Short and long term plans, including Continuous Improvement Projects, with goals for improving quality and customer satisfaction. Performance to these goals shall be monitored and reported.
- Product quality
- Cycle time
- Customer service
- Training
- Cost
- Delivery commitments
- Process capability
- Product reliability
- Maintaining methods for disaster recovery;
- Cross–functional teams;
- Subcontractor / supplier input;
- Feasibility reviews;
- Failure Mode and Effects Analysis (FMEA);
- Control plans, inspection and testing techniques;
- Identification of customer special characteristics;
- Consideration and awareness of product safety issues relative to design and process control;
- Utilization of mistake proofing methodologies when planning processes, facilities, equipment and tooling;

Business Plan:

Each Business Unit shall have the authority and responsibility for ensuring compliance to the company's Business Plan requirements. As appropriate, the Business Plan shall be communicated throughout the organization. Comprehensive continual improvement activities shall be included in the plan. These activities shall address opportunities in quality and productivity. Business Plan results shall be tracked, reviewed, and revised by management at appropriate intervals. Records of such reviews shall be maintained. Senior management of the Business Unit shall define quality objectives that address customer expectations and measurements that shall be included in the Business Plan and used to deploy the Quality Policy.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

As part of the QMS, a hierarchical organizational chart has been created which defines the management authority structure within the company including the interrelation of all personnel who manage, perform and verify work affecting quality. This chart shall be

maintained by the Human Resources Department and made available for reference to interested parties. Senior management ensures the independence and authority necessary to manage, perform, and verify work affecting quality. They also ensure that responsibilities and authorities are defined, documented and communicated within the organization.

Due to the small number of people at the UK and France locations, these locations do not have a dedicated quality manager. The director of sales for the Standard Power solution will designate a member of the UK office and a member of the France office to establish quality objectives, maintain quality certifications, and execute the quality management system at their respective locations.

The quality manager assigned to the Kaohsiung location is responsible for establishing quality objectives, maintaining quality certifications, and executing the quality management system at the Kaohsiung location.

The quality manager assigned to the Redmond location is responsible for establishing quality objectives, maintaining quality certifications, and executing the quality management system at the Redmond location. For products and manufacturing processes that are subject to MIL-PRF-38534, the Redmond quality manager will coordinate with the Land and Maritime division of the Defense Logistics Agency and provide oversight of product and process qualifications at both the Redmond and Kaohsiung locations. The Redmond quality manager will provide advice and assistance, as appropriate, on administering the quality management system to the Kaohsiung, UK, and France locations.

5.5.2 Management Representative

To ensure the integrity and overall suitability of the QMS, a member of management has been appointed who will have the responsibility and authority to implement, modify or amend the QMS, as necessary, to assure that the requirements imposed on the quality system are maintained and the quality principles of the company adhered to. In addition, the management representative shall have the responsibility and authority to resolve matters related to quality and product conformity.

The management representative is responsible for reporting to senior management on the performance of the quality management system and any need for improvement. This is primarily done during the Quality Management Review. The management representative also ensures the promotion of awareness of regulatory and customer requirements throughout the organization (typically achieved through the development and maintenance of group level policies).

5.5.3 Internal Communication

The appointed management representative shall further be responsible for raising employee awareness and acceptance of the QMS through effective communication (e.g., memo's, meetings, etc) and training. As part of the awareness effort, employees shall be made aware of appropriate customer imposed requirements (e.g., as highlighted on orders, included in special messages, references in procedures, verbal/written notifications, etc…) that could affect the quality level of delivered goods and services.

5.6 Management Review

5.6.1 General

The management representative shall be responsible for reviewing Crane Aerospace & Electronics quality system on an annual basis at a minimum and reporting to senior management on its performance and any areas that require improvement (e.g., procedures, work instructions, policies or quality objectives). This will be done to ensure the QMS continued suitability and effectiveness in satisfying the requirements of AS9100C, ISO9001:2008, ISO13485:2003, customer needs/requirements and/or the stated quality policy and objectives of Crane Aerospace & Electronics management. Any other relevant supporting documentation from the reviews shall be maintained on file, as appropriate (e.g. ., corrective actions, recommendations for improvement, requests for resources, meeting minutes, etc). At a minimum, the members of senior management in attendance during the review are the Director of Quality, the Solution Leaders, Supply Chain Manager and Operations Manager (or respective designates for each).

5.6.2 Review Input

The Management Review input includes:

- Result of internal and external audits
- Customer feedback
- Processes performance and product conformity (Balanced Scorecards)
- Status of preventive and corrective actions
- Follow-up actions from previous Management Review
- Strategic or operational changes that could affect the QMS
- Improvement recommendations
- New or revised regulatory requirements

5.6.3 Review Output

The Management Review Output comprises the minutes of the meeting and the resulting action items regarding:

- Improvements needed to maintain the effectiveness of the QMS and its processes
- Improvement of the product related to customer requirements
- Resources needed

6.0 RESOURCE MANAGEMENT

6.1 Provision of Resources

Crane Aerospace & Electronics goal is to provide all of its customers with the highest quality goods and services. To this end, the company's QMS shall be provided, by management, sufficient human, material and financial resources to ensure that it is effectively implemented, maintained, improved upon and meets regulatory and customer requirements. Through planned and efficient use of: technology, resources, customer participation, supplier

participation, and quality management techniques, Crane Aerospace & Electronics shall ensure that customer needs are met now and into the future.

6.2 Human Resources

6.2.1 General Competence Awareness and Training

Anyone in Crane Aerospace & Electronics having an assignment associated with any of the processes of the QMS is competent through education, skill, training and experience as necessary. Requirements for education, skills, training and experience are found in the job descriptions maintained by the Human Resources department.

6.2.2 Competence, Training and Awareness

The needs for training of personnel are established and documented in training procedures. Training requirements are outlined and maintained in certification lists that are managed manually or through the Electronic Training Record (ETR) system. Training records are retained as defined in GEN-047 (Record Retention Matrix). Appropriate training is provided to all levels of personnel within Crane Aerospace & Electronics. performing activities affecting product quality. All employees are aware of the importance of their activities and how they contribute to achieving quality objectives. The qualifications of personnel performing specialized operations, processes, tests or inspections are evaluated and documented. The employee's performance review is also used to identify specific individual training as well as evaluate effectiveness of actions taken to satisfy competency needs. Formal training records are maintained by the Quality Assurance Training Coordinator. These include proof of certification for special processes, as applicable. Additional documented education and experience records are maintained in the employee personnel files. It is the responsibility of the Senior Management to ensure that their employees are aware of the quality objectives and of the importance of their activities in achieving these objectives.

To ensure that CEI facilities have the necessary competencies to maintain and continuously improve the quality management system, at least one member of the Redmond quality department and one member of the Kaohsiung quality department will have successfully completed a certified course on the AS9100 quality standard. If there are no course graduates due to personnel turnover or transfers, a member of the quality department will be scheduled to complete an AS9100 course within 90 days of the transfer.

6.3 Infrastructure

Crane Aerospace & Electronics has developed and continues to improve upon an infrastructure that it believes enhances operational effectiveness, maintains product conformity/fitness for use and promotes employee teamwork. To ensure product integrity, Interpoint Brand products are maintained in a controlled environment as required by MIL-PRF-38534. To allow for proper material tracking within the facility, material routing is used to identify both materials and storage locations. In addition, designated areas have been established to ensure proper segregation of accepted, un-accepted, bonded and scrap materials; so as to prevent the inadvertent use of unapproved or unacceptable materials.

To ensure efficient use of human resources, sufficient technological and material resources are made available to employees, to enable them to safely and effectively carry out their job responsibilities.

Crane Aerospace & Electronics has established documented procedure GEN-037 for preventative maintenance (PM) activities including frequency of required PMs and reaction requirements if PM results or missed PMs are found to affect product quality. Maintenance records are maintained per the GEN-047 Record Retention Matrix.

6.4 Work Environment

Facilities, including workstations and associated equipment, shall be maintained in a state of order, cleanliness, and repair appropriate to the product(s) manufactured. All work areas must comply with established safety, regulatory and environmental standards and codes.

Crane Aerospace & Electronics has established documented procedures outlining Electrostatic Discharge (ESD) control, health, cleanliness, and clothing requirements for permanent and temporary personnel working in or entering the manufacturing work areas, including training/supervision of visitors. These documents also outline environmental condition requirements and the monitoring of such conditions to prevent any adverse effect to the quality of the product(s) manufactured. Control of contaminated or potentially contaminated product is handled through the documented procedure for handling of nonconforming material.

7.0 PRODUCT REALIZATION

7.1 Planning of Product Realization

Crane Aerospace & Electronics QMS has been developed to ensure that all customers receive the highest quality products and services; as exemplified in the company's overall quality objectives. Through the establishment of documented procedures and processes relating, but not limited to: risk management, customer contract review, material inspection, equipment, calibration, purchasing and order processing, Crane Aerospace & Electronics shall ensure that all applicable requirements for material and contract conformances are consistently met. Records associated with these procedures and processes shall be maintained.

While the products supplied by Crane Aerospace & Electronics are not considered to be serviceable and do not require maintenance, Crane Aerospace & Electronics shall make appropriate resources available to its customers for the purpose of verifying product conformance and/or with questions relating to specifications, installation and use. If the staff of Crane Aerospace & Electronics is not immediately able to assist the customer, the material manufacturer shall be consulted for support and/or clarification.

7.1.1 Project Management

Crane Aerospace & Electronics plans and manages product realization through the ENG-013 Product Development Procedure, taking into account acceptable risk, resource and schedule constraints.

ISO 10006:2003, "*Quality management systems - Guidelines for quality management in projects"* provides additional guidelines as a project management standard.

7.1.2 Risk Management

Crane Aerospace & Electronics incorporates risk management throughout the design and development (ENG-026 FMEA procedure), supply chain (QA-053 Supplier Evaluation Process) and product realization (QA-015 Corrective Action, Preventive Action and Risk Management procedure) phases of the production cycle.

7.1.3 Configuration Management

Crane Electronics follows ISO 10007:2003, *"Quality management systems – Guidelines for configuration management"* which provides industry-standard best practices and guidelines for configuration management.

7.1.4 Control of Work Transfers

Crane Aerospace & Electronics routinely transfers work outside the company, and has defined the process to control the quality of work through the MATL-011 Outplant Processing procedure.

7.2 Customer Related Processes

7.2.1 Determination of Requirements Related to the Product

Crane Aerospace & Electronics has a documented review process for all purchase orders and contracts received to ensure that our customer's requirements (e.g., product type, quantities, delivery, revision, etc) are adequately defined and documented; so that potential problem issues can be identified and resolved prior to final acceptance.

7.2.2 Review of Requirements Related to the Product

The appropriate functions responsible for verifying that the customer request can be satisfied shall include review the purchase order, request for quote, drawing or specification. Appropriate action shall be initiated to resolve differences to ensure satisfaction of contractual requirements before acceptance of the order. This verification shall include a consideration of verbal and electronic ordering methods as well as a means to convey changes to existing order requirements. Amendments to contracts shall be reviewed and appropriate actions shall be initiated to resolve any differences.

The review of customer specifications shall include as appropriate:

- The Development / Product Engineering function shall be responsible for determining product compliance with the customer's requirements, ensuring all product requirements are defined and documented, determining associated risks and for the initiation of the cross–reference process;
- The Quality function shall be responsible for determining compliance to those quality requirements that include measurement data, performance criteria, verification and/or validation requirements, customer special requirements, audit parameters and compliance to special labeling and packaging requirements;
- The Materials function shall be responsible for determining compliance to the delivery requirements;
- The Manufacturing Engineering function shall investigate, confirm and document the manufacturing feasibility of the proposed products, including risk analysis.

7.2.3 Customer Communication

Formal communication channels are established and maintained between the Crane Aerospace & Electronics and the customer to ensure that customer requirements are properly addressed. Communication with customers regarding complaints and advisory notices/recalls are outlined in documented procedure MKT-001.

Internal communication channels are established and maintained between the Program Manager and all of the program employees to ensure that the customer requirements are known and understood at all times, and that cost, schedule, technical performance and quality objectives are being achieved.

7.3 Design and Development

For the ISO13485:2003 standard, this section for requirements for Design and Development is not applicable. Crane Aerospace & Electronics does not perform design and development of medical devices.

7.3.1 Design and Development Planning

Product/Program Management coordinates the development of project plans with the functional units. These plans may include an Engineering Development Plan, Configuration Management Plan, Software Development Plan and/or Quality Assurance Plan depending on the size and scope of the specific project.

These plans define the organization and responsibility, the resources, the task sequences and all the mandatory steps and phases required by the project including review, verification, validation and design transfer activities. Project plans are reviewed and updated as required during the design and development process. Updates or changes to these plans may require customer approval when defined by the contract. Periodic project design reviews as defined in the project plans and project phase reviews as mandated by the Phase Review Process are conducted by the responsible Product/Program Manager to evaluate the progress of the project.

The design and development process is outlined in documented procedure ENG-013. Planning output is documented and updated as the design and development process progresses.

7.3.2 Design and Development Inputs

The design input requirements are defined either by the customer's Statement of Work, the customer's product specification, military and other governing specifications, and internal product specifications in the case of development projects, and/or the contract. The documents identify characteristics such as function, performance, reliability, physical constraints, spare capacity, safety, and outputs of risk management. Requirements are defined so that their achievement can be verified to ensure customer satisfaction. Any conflicting, incomplete, or ambiguous requirements are escalated to the Product/Program Manager for resolution and, where necessary, discussed with the customer. All inputs are reviewed for adequacy and approved.

7.3.3 Design and Development Outputs

The design output is a product definition that meets the design input requirements and satisfies the acceptance criteria. This definition is contained in design specifications, drawings, parts lists and test procedures, which are all reviewed before release. As appropriate, the product data package specifies the characteristics that are essential to the safe and proper functioning of the product and identify key characteristics, when applicable, in accordance with the design or contract requirements:

- All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained are defined;
- Drawings, part lists, specifications;
- A list of those drawings, part lists and specifications necessary to define the configuration and the design feature of the product;
- Information on material, processes, type of manufacturing and assembly of the product necessary to ensure conformity of the product.

All records of the design and development outputs shall be maintained.

7.3.4 Design and Development Review

Project team meetings, peer reviews, and formal design reviews are conducted as defined in the Project Management Plan throughout the design, development, and qualification phases of product development in order to control, coordinate, and track the project status. Participants include representatives of the functions concerned with the design and development stage being reviewed as well as any other specialist personnel.

Product/Program Management ensures that formal hardware and/or software design reviews are conducted for each program. Reviews are supported by independent design review expertise as required to ensure adequacy of the design to satisfy the contractual, quality and productivity requirements of the end product. The design reviews identify problems and proposed necessary actions, and authorize progression to the next stage.

7.3.5 Design and Development Verification

Designs are verified to meet product/program (input) requirements through the design output documents preparation and approval process. The approval and release of the documents is the record that the design meets the requirements of the specification. As an integral part of design verification, designs are verified through analysis, alternative calculations, test, demonstration, and design similarity analysis. Records of the results of the verification are reviewed before being released and are maintained as quality records.

7.3.6 Design and Development Validation

Product function and performance are validated in accordance with the customer or internal SOW or product specification. These activities typically include standard and environmental condition tests, reliability and maintainability demonstrations, formal qualification testing and acceptance testing, and ensures the product is capable of meeting the requirements of the specified application or intended use.

Design and/or development validation follows successful design and/or verification:

- Validation is normally performed under defined operating conditions.
- Validation is normally performed on the final product, but may be necessary in earlier stages prior to production completion.
- Multiple validations may be performed if there are different intended uses.
- For medical product, validation is performed prior to the delivery or implementation of the product and will include clinical evaluations and/or evaluation of the performance of the medical device as required by national or regional regulations.

7.3.6.1 Design and Development Verification and Validation Testing

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following:

- Test plans or specifications identify the product being tested and the resources being used defined test objectives and conditions, parameters to be recorded, and relevant acceptance criteria;
- Test procedures describe the method of operation, the performance of the test, and the recording of the results;
- The correct configuration standard of the product is submitted for the test;
- The requirement of the test plan and the test procedures are observed;
- The acceptance criteria are met.

7.3.6.2 Design and Development Verification and Validation Documentation

Crane Aerospace & Electronics shall ensure that reports, calculations, test results, etc., demonstrate that the product definition meets the specification requirements for all identified operational conditions.

7.3.7 Control of Design and Development Changes

Design changes can result in a change to existing documentation or the generation of new documentation. Design change documentation is reviewed, approved, controlled, recorded and issued in accordance with established configuration management procedures by the same functions involved in the original issue. Controlled documents, which include drawings, test procedures, engineering change orders (ECOs), etc., are reviewed and approved prior to their initial release or revision. The review of design and development changes shall include the evaluation of the effect of the changes on constituent parts and product already delivered.

Changes to controlled documents are approved by the same authorized functions/organizations that reviewed and approved the original document, unless specifically authorized otherwise by those functions/organizations.

The change control process provides for customer and/or regulatory authority approval of changes, when required by contract or regulatory requirement.

7.4 Purchasing

7.4.1 Purchasing Process:

Crane Aerospace & Electronics has established a documented set of procedures, including MATL-017, and work instructions to insure that purchased products conform to specified requirements including conformance to: print specifications, established quality standards and any applicable customer requirement.

7.4.2 Purchasing Information:

Crane Aerospace & Electronics shall evaluate and select suppliers on the basis of their ability to: meet Crane Aerospace & Electronics contract requirements, supply desired products, meet quality requirements, and adhere to delivery schedules. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained. The extent of control exercised by Crane Aerospace & Electronics over suppliers shall include subsequent quality audits and monitoring of supplier's facility. This control shall be dependent upon the type of product, the impact of the suppliers product on Crane Aerospace & Electronics customers and, where applicable, on the quality audit reports and/or records of previous supplier performance. Both Crane Aerospace & Electronics and its suppliers shall provide "right of access" during normal business hours to customers/regulatory authorities for the purposes of verifying product and/or order records.

Purchasing information shall describe the product to be purchased, including where appropriate:

- requirements for approval of product, procedures, processes and equipment,
- requirements for qualification of personnel, and
- Quality management system requirements.

Crane Aerospace & Electronics shall ensure the adequacy of specified purchase requirements prior to communication to the supplier.

Relevant purchasing information is maintained to the extent required for traceability given in section 7.5.3.2.

7.4.3 Verification of Purchased Product

Sources selected by the purchasing authority for procurement of materials or services shall by evaluated and approved by Quality Assurance, prior to including them on the list of approved sources. The Quality Assurance Manager shall have the right to remove any supplier from the approved supplier list, based on its failure to meet Crane Aerospace & Electronics order requirements or for any other reason that could adversely affect the quality of the product Crane Aerospace & Electronics supplies to its customers. The purchasing authority will be the final authority on which bidder shall receive a purchase order.

Crane Aerospace & Electronics shall only purchase materials from original equipment manufacturers or reputable distributors whose quality system meet or exceed Crane Aerospace & Electronics and/or customer specified requirements. When applicable, procured materials shall be accepted if accompanied by documentation clearly tracing the material lots to the original manufacturer (e.g., test reports/certificates of conformity). When

applicable, all materials upon receipt shall be inspected to verify conformance with issued purchase order requirements; using in house or manufacturer supplied print specifications. Records of such verification shall be maintained.

A list shall be maintained by Quality Assurance of suppliers who, based on quality performance, have been approved to supply Crane Aerospace & Electronics with goods and services. The list shall include the scope of the approval and relevant contact information.

The Quality Department maintains quality reports on all primary product suppliers and provides copies to suppliers informing them of their quality status and if applicable corrective actions need to be taken to address deficiencies. These documents shall serve as the basis for determining the continued suitability of suppliers.

Records demonstrating supplier performance and product conformance shall be maintained on file. In addition, a random sample from each of the manufactures Crane Aerospace & Electronics is an authorized distributor for, shall be sent out for independent raw materials test report validation. Crane Aerospace & Electronics shall, as part of its audit of suppliers, provide them with copies of standard terms and conditions clauses that are applicable to all orders, unless specifically stated otherwise on submitted purchase orders. If verification is intended to be performed at the supplier's premises, the purchasing documentation shall state the intended verification arrangements and the method of product release.

7.5 Production and service provisions

7.5.1 Control of Production and Service Provision

Processes for the manufacturing, inspection and testing of products are identified, planned and carried out under controlled conditions, in order to ensure the quality of those products.

Documented procedures defining those processes are provided by means of drawings, specifications, workmanship standards and work instructions. Workmanship, including accept and reject criteria, is specified in written standards or by means of representative samples. Planned inspections and tests are performed at specific points during the manufacturing cycle.

Manufacturing travelers are used as evidence that all manufacturing and inspection operations have been completed as planned or otherwise documented and authorized. Where key characteristics have been identified, appropriated process control is planned to ensure that all necessary tools are available to perform the controls. The manufacturing, inspection and testing, of the products are performed in a suitable working environment, with the use of suitable production equipment. The precision of the equipment selected is consistent with the process capability. A schedule for preventive maintenance is maintained to provide evidence of the maintenance performed on the equipment.

Controlled conditions also include as applicable:

- The implementation of release, delivery and post-delivery activities;
- The implementation of defined operations for labeling and packaging;
- Accountability for all product during manufacturing (e.g., parts quantities, split orders, non-conforming product);
- Provision for the prevention, detection, and removal of foreign objects;

- Monitoring and control of utilities and supplies and chemical products to the extent they affect product quality; and
- The requirements for the control of processes are as prescribed in contracts and as defined in the applicable manufacturing, inspection, and test work instructions.

Production operations are carried out using approved data. This data contains as necessary:

- Drawing, parts list, traveler, work instructions, test specifications, etc.
- A list of tools, ATP, and associated software with the applicable revision, etc.

7.5.1.1 Production process verification

When required by customer or regulatory agency, first article inspection is performed to verify all documentation, testing, engineering, production, qualification and quality meets all aspects of the customer and regulatory agency documentation (i.e. PO, SOW, SCD, Regulatory Specifications). First Article Inspection is performed initially and after subsequent changes provided by the customer.

For medical devices, the identity of personnel performing any inspection and testing is recorded. Certified personnel for these functions is recorded in the training database and product travelers and process logs are used to record inspection and testing performed by those employees.

7.5.1.2 Control of Production Process Changes

Production process changes are documented and approved by the Quality and Manufacturing Engineering departments, and when applicable by the regulatory authority or the customer.

Results of these changes are assessed to confirm that the desired effect has been achieved without adverse effect to product quality.

7.5.1.2.1 Cleanliness of Product and Contamination Control (ISO 13485:2003)

Crane Aerospace & Electronics has established documented requirements for cleanliness of product during manufacture and prior to shipment for use by end customers.

7.5.1.2.2 Installation Activities (ISO 13485:2003)

This section is not applicable. Crane Aerospace & Electronics does not perform the installation of medical devices.

7.5.1.2.3 Servicing Activities (ISO 13485:2003)

This section is not applicable. Crane Aerospace & Electronics is not required to provide servicing of medical devices.

7.5.1.3 Control of Production Equipment

Documented procedures are established and maintained to assure adequate control of Production Equipment used in the manufacture of product. The procedures address the design, production, release for production, identification and control, verification of accuracy, revisions and modifications, storage, maintenance and required records. Production Equipment and programs are validated prior to use, maintained and inspected periodically

according to documented procedures. Validation prior to production use includes verification of the first article produced to the design data/specification. .

For the ISO13485:2003 standard, this section for requirements for sterile medical devices is not applicable. Crane Aerospace & Electronics does not manufacture sterile medical devices.

7.5.1.4 Post-delivery Support

This section is not applicable as Crane Aerospace & Electronics does not offer post-delivery support.

7.5.2 Validation of Processes for Production and Service Provision

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product, the processes are carried out by certified operators and/or require continuous monitoring and control of process parameters to assure that the specified requirements are met. This includes any processes where deficiencies become apparent only after the product is in use or the service has been delivered. Special processes to be implemented are identified and qualified and/or validated and approved prior to use.

The qualification and/or validation demonstrates the ability of these processes to achieve the planned results. Crane Aerospace & Electronics has defined criteria for the review and approval of these processes. Applicable aspects of special processes are controlled, as defined by the process specification, including special process changes. The significant process operations and parameters to be controlled during production are defined in documented procedures. Documented procedures are established and maintained to assure the requirements for qualification and/or validation of process operations, including associated equipment and personnel are specified. Records are maintained for qualified processes, equipment, and personnel, as appropriate. Personnel responsible for the performance and control of special processes are trained and certified. Crane Aerospace & Electronics has established provisions for the revalidation of these processes, as applicable.

Crane Aerospace & Electronics has established documented procedures for the validation of the application of computer software (and changes to such software and/or its application) for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.

7.5.2.2 Requirements for Sterile Devices (ISO 13485:2003)

This section for requirements for sterile medical devices is not applicable. Crane Aerospace & Electronics does not manufacture sterile medical devices.

7.5.3 Identification and Traceability

7.5.3.1 Identification

Documented procedures are established and maintained to identify product undergoing fabrication or assembly from receipt and during all stages of production and delivery to the extent required by contract.

When specified by requirement, the procedures allow for unique identification of individual product or batches for traceability, which is recorded.

Documented procedure QA-007 has been established to ensure that product returned to Crane Aerospace & Electronics is distinguished from conforming product.

7.5.3.2 Traceability

Documented procedures are established for traceability of the product including the extent of product traceability and records required. Records shall include traceability of all components, materials and work environment conditions, if these could cause a medical device not to satisfy its specified requirements. Crane Aerospace & Electronics does not utilize agents or distributors for the distribution of medical devices.

When traceability is required, loss of traceability is considered a nonconformance. When required by contract, regulatory or other established requirement, provisions are made for identification to be maintained throughout the product life, for traceability of all product manufactured from the same batch of raw material or from the same manufacturing batch to destination (delivery, scrap, etc.), for traceability of an assembly to its components and to the next higher assembly, for retrieval of the sequential production record (manufacture, assembly, inspection) of a given product, and for maintenance of identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

7.5.3.3 Status Identification

Product status is identified with respect to monitoring and measurement requirements. A procedure establishes and controls acceptance authority media used (e.g., stamps, electronic signatures, passwords). The identification of product status shall be maintained throughout production, storage, and installation of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized deviation/waiver) is dispatched, used or installed.

7.5.4 Customer Property

Customer furnished property is processed in the same manner as other products within Crane Electronics, Inc When specified in a contract, special handling instructions for Customer furnished property shall take precedent over Crane Aerospace & Electronics standard procedures. Loss, damage, or unsuitability of a customer's material is documented and reported to the customer. Verification by Crane Aerospace & Electronics does not, however, absolve the customer of the responsibility to provide an acceptable product.

7.5.5 Preservation of product

Crane Aerospace & Electronics preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage
and protection. Preservation also applies to the constituent parts of a product.

Preservation of product includes, where applicable in accordance with product specifications and/or applicable regulations, provisions for:

- Cleaning;

- Prevention, detection and removal of foreign objects;
- Special handling for sensitive products;
- Marking and labeling including safety warnings;
- Shelf life and stock rotation;
- Special handling for hazardous materials;
- Special storage conditions.

Crane Aerospace & Electronics ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

Products, including incoming materials, materials in process, and finished goods (deliverable/returned), are handled in a manner that prevents abuse, misuse, damage or deterioration. This includes protection from Electrostatic Discharge (ESD) and physical damage and exercising safety precautions in labeling hazardous materials in accordance with regulations. Secure storage facilities or stock rooms are provided as necessary for storage of material and products pending use or shipment, to prevent damage or deterioration. Those areas are limited to authorized personnel only. An ESD control program is established for storing of ESD sensitive material.

Hazardous material is stored in accordance with its specific handling requirement in accordance with regulations. Shelf life expiration dates are recorded and monitored. Where applicable, special preservation methods are used to protect material during storage. Special storage conditions will be controlled and monitored.

Packaging methods are documented to ensure the protection of the product for delivery and transportation. These documents shall include specified packing, preservation and marking (including materials used) in accordance with contractual requirements.

Delivery methods and carriers are selected to ensure damage free shipments and on-time delivery per contract specifications.

7.6 Control of Monitoring and Measurement Devices

Documented procedure QA-050 has been established to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. Inspection, measurement, and test equipment is selected which assures sufficient accuracy and precision to determine product compliance. All equipment covered by the calibration program is calibrated or verified at defined intervals against standards that are traceable to an internationally recognized standard. Where no such standards exist, the basis used is documented.

A list of all monitoring and measuring equipment used for acceptance of product is maintained, and a process is defined for the calibration of this equipment.

The following are defined for each piece of equipment:

- Equipment type and unique identification
- Location

- Calibration method
- Calibration frequency
- Acceptance criteria

The calibration process defines action to be taken when results are unsatisfactory, including assessing and documenting the validity of previous inspection and test results. Documented procedures for out of tolerance conditions have been established to ensure appropriate action on the equipment and any product affected is taken when equipment is found not to conform to requirements.

Inspection, measurement, and test equipment storage, usage, and calibration are in a controlled in-door environment, where there is no exposure to adverse environmental conditions that would affect accuracy and fitness for use.

A system is defined to recall equipment when required. Calibrations are rechecked if equipment is dropped, damaged, or otherwise suspected of no longer being within calibration.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Crane Electronics, Inc has established and maintains detailed, documented procedures and work instructions for the performance and monitoring of inspection and testing activities, in order to verify that the specified requirements for products, customers and the QMS are met. Where appropriate, Crane Aerospace & Electronics shall identify the need for statistical techniques required for establishing and verifying product characteristics. The types of techniques chosen for use shall be such that they fulfill the customer's and/or CEI's requirements for product specification verification.

The QMS itself shall be audited at scheduled intervals to verify its effectiveness and ability to meet the needs of our customers achieve established quality objectives and adhere to the requirements of AS9100C. Based on auditing results, areas of improvement will be explored and enhancements to the system implemented, where appropriate.

Crane Electronics, Inc has established and maintains documented procedures for the monitoring, measurement, analysis and improvement processes needed to maintain the effectiveness of the quality management system.

8.2 Monitoring and Measurement of Product

8.2.1 Customer Satisfaction

Crane Aerospace & Electronics shall review: customer complaints, returns, feed back and performance evaluation reports, to try and obtain a sense of the perceived quality and satisfaction levels it is providing to its customers as a whole. A documented procedure MKT-001 has been established identifying all modes of customer feedback used to provide early warning of quality problems and the process for determining corrective or preventive actions needed. If national or regional regulations require Crane Aerospace & Electronics to gain experience from the post-production phase, the review of this experience will form part of the feedback system.

When possible, Crane Aerospace & Electronics will take appropriate measures to enhance its operations where actual or perceived customer satisfaction levels could be improved upon (e.g., have customer requirements been fully met and if not what measures can be implemented to ensure future compliance).

8.2.2 Internal audits

Crane Aerospace & Electronics has established and maintains a documented procedure governing the planning and implementation of internal quality audits. These audits are designed to determine the effectiveness of Crane Aerospace & Electronics quality system and to verify its ability to meet the needs of our customers, adhere to company quality objectives and satisfy the requirements of ISO 9001:2008, ISO13485:2003, AS9100C, and to supplement the requirements of the self-audit program as defined in MIL-PRF-38534.

To satisfy auditing requirements, Crane Aerospace & Electronics conducts periodic audits of its activities to verify their effectiveness to the quality system. Activities found to be of greater importance to the quality system shall be audited on a more frequent basis, if deemed necessary by the QA Manager. Qualified personnel, who are not directly responsible for the activity being audited, shall conduct internal audits to ensure an objective evaluation.

The specific procedure that applies to Crane-Redmond is QA-017, "*Internal Quality Audit Procedure.*"

8.2.3 Monitoring and Measurement of Processes

Crane Aerospace & Electronics monitors and measures various processes used within the quality system using suitable methods. These performance measurements ensure that our processes are sufficient to meet the quality requirements. If a process is deemed to be in an out of control situation we will take action as appropriate in order to ensure product quality.

Crane Business System tools are leveraged to monitor and improve processes throughout the company, from cell level through strategic objectives. These tools may include the 3-in-1 analytical tool, A3 projects, and kaizen activities. If process nonconformities are identified, they are evaluated to determine the effects on products, potential effects on other processes and products, and to control nonconforming product. Control of Nonconforming product is referenced in QA-016 (Nonconforming Material procedure).

8.2.4 Monitoring and Measurement of Product

Crane Aerospace & Electronics. inspects and tests products to ensure all requirements are in accordance with the applicable specifications at various points in the process. When key characteristics are called out for the product (via SCD, assembly drawing, traveler, test procedure), the characteristic is inspected and/or tested and is documented.

Crane Aerospace & Electronics performs sampling and 100% inspection based on the critical nature of the test in accordance with regulatory specifications. If sampling inspections or tests exhibit non-conformance, then increase sampling and/or 100% inspection/test will be performed. When a 100% inspection or test is reduced to a sample plan, the plan shall be submitted to customer or regulatory agency for approval (e.g. alternate method).

All products are inspected and tested to meet all requirements prior to ship. If product requires additional testing upon completion of the production process then the product may be held or released with customer approval under positive recall.

Crane Aerospace & Electronics records the results of the inspection and the identity of the person authorizing release of product. Product is not released until it has passed all required inspections, unless allowed by Crane Aerospace & Electronics procedures with positive recall traceability (i.e. Crane Aerospace & Electronics may ship product prior to completion of Life Test with customer approval per MIL-PRF-38534 allowances).

Documented procedures are established and maintained for inspection and testing activities in order to verify that the specified requirements for the product are met and to require that records be maintained. The inspection and test procedures specify the resources and methods to be used and the methods of recording the results. Personnel authorized to perform inspection and test are identified, the limits of authorization are defined, and training and qualification requirements are specified.

Conformance Criteria - Quality Assurance assures that adequate inspection instructions and acceptance criteria, as applicable, are available at each point of inspection and test. These documents provide workmanship standards and conformance criteria, as required, to determine the acceptance or rejection of all articles, as defined by individual contract requirements. Inspection and Test Procedures - Quality Engineering initiates and/or approve inspection and test procedures for all areas of Quality Assurance.
These procedures are readily available to all inspection and test personnel and include reference to the applicable drawings or specifications.

Inspection and test procedures include, as applicable:

- Identification of the article to be inspected or tested.
- Inspection, measuring and test equipment to be used.
- Preliminary operations to be performed such as calibration, operational checks, adjustments, etc.
- Conditions to be maintained during the inspection or test such as cleanliness, temperature, humidity and any special precautions.
- Step by step method of performing each inspection and test operation, including magnification conditions, input characteristics and test sequences.
- Criteria for determining acceptance or rejection of the article, such as test limits, tolerance conditions and workmanship standards.
- Details of any sampling plans to be used.
- Workmanship Inspection Standards - Samples of acceptable workmanship are provided by Quality Assurance in areas where workmanship standards are necessary, and where such standards cannot be properly defined pictorially or verbally. Quality Assurance and the customer when required by contract jointly select such samples.

8.3 Control of nonconforming product

Crane Aerospace & Electronics has established a documented procedure QA-016 for the control of nonconforming product. All product – whether production materials, components, assemblies, final product, or other types of work – detected or suspected as not conforming to requirements shall become the responsibility of the Quality function for:

- Controlling further movement of the material to prevent material from unintended use or delivery;

- Documenting and reviewing material;
- Coordinating the disposition action;
- Notifying appropriate personnel;
- Initiating and verifying corrective action and effectiveness;
- Establishing and tracking a prioritized defect reduction plan;
- Trend analysis and providing input for corrective and preventive action.
- Coordinating the actions appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or customer use has started.

Nonconforming or suspect nonconforming material, including unidentified material, shall immediately be visually identified as nonconforming, and shall be prevented from inadvertent further processing, where practicable, by storage in an area that is visually identified and segregated for this purpose.

Review and disposition of nonconforming or suspect nonconforming material shall be coordinated by Quality with the appropriate operations / manufacturing and engineering functions. The material may be sorted, reworked, returned to the supplier, scrapped, or deviated. Nonconforming product shall be accepted by deviation/waiver only if regulatory requirements are met. Records of the nature of nonconformities and any subsequent actions taken, including deviations/waivers obtained and the identity of persons(s) authorizing the deviations/waivers, shall be maintained.

Nonconforming product may be released for use when a deviation has been processed and approved. All deviations shall clearly specify the temporary limits of acceptability, state the definitive corrective action and be approved by the appropriate engineering functions. If the affected dimension, feature, or characteristic is a specified customer requirement; no deviation shall be issued unless the customer approval has been granted. This applies equally to product or services purchased from suppliers.

The Business Unit shall concur with any requests by a supplier before submission to the customer. The Business Unit shall also ensure compliance with the original or superseding specification and requirements when the deviation expires.

If the nonconforming material is accepted for rework / repair, rework instructions shall be provided and the material shall be reinspected to an approved quality plan before it returns to the process. The documented rework procedures and work instructions shall undergo the same authorization and approval process as the original procedures and work instructions. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

8.4 Analysis of data

Crane Aerospace & Electronics has a continuous focus on quality and maintains an operational excellence program. The OPEX program utilizes numeric metrics of operations and materials to drive continued improvement in quality and financial performance.

Documented procedures have been established to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:
a) customer feedback;
b) conformity to product requirements;
c) characteristics and trends of processes and products including opportunities for preventive action, and,
d) suppliers.

Records of the results of the analysis of data shall be maintained.

8.5 Improvement

8.5.1 Continual Improvement

Crane Aerospace & Electronics is committed to continuous improvement to ensure and maintain the continued suitability and effectiveness of the quality management system. Continuous improvement is:

- A part of the quality policy
- Reflected in the quality objective
- A part of the actions taken upon audit results
- Driven by opportunities surfacing from data analysis
- A result of corrective action when the action taken corrects a new problem
- Always a result of preventive action
- A required output from management review

Documented procedure MKT-001 has been established which outlines the process for the issue and implementation of advisory notices and recall and the handling of customer complaints. The procedure is capable of being implemented at any time. All records of customer complaint investigations shall be maintained. If investigation determines that the activities outside the company contributed to the customer complaint, relevant information shall be exchanged between the organizations involved. If corrective and/or preventive action is not taken for a customer complaint related to medical devices, the reason shall be authorized and recorded using the documented nonconforming material process.

8.5.2 Corrective Action

Crane Aerospace & Electronics has established and maintains documented procedures that define who will be responsible and have the authority for initiating corrective and preventive actions. The degree to which corrective and preventive actions will be taken shall be appropriate to the magnitude of the problem. When these actions are initiated, controls shall be used to ensure that the specified actions have been taken and are effective.

Crane Aerospace & Electronics has developed the *Corrective and Preventive Action Procedure*, QA-015, which defines the process of initiating corrective action measures and subsequent effectiveness verification. Elements of the corrective action program include:

- Documenting and processing customer complaints, customer returns internal and external audits and/or reports of product non-conformities.
- Investigating the root causes of non -conformities relating to: the product, process, quality system, and recording the findings.
- Preparing and implementing a list of corrective actions designed to eliminate the non –conformity problems, based on the findings from the root cause analysis.
- Evaluating the need for action to ensure that nonconformities do not recur.
- Establishing procedures for the review of initiated corrective actions to ensure that the non-conformity issues have been effectively dealt with.
- Provisions for relaying corrective action requests to our suppliers; in those cases where non-conformity root causes have been determined to come from the supplier or original material manufacturer.
- Procedures to be followed if corrective action requests have not been addressed in a timely manner and/or have been found to not have adequately resolved the source of the non-conformity.

8.5.3 Preventive Action

Crane Aerospace & Electronics has developed documented procedure QA-015, which define measures taken within the company, as part of a preventive action initiative, to identify potential problem areas that could result in non-conformities. The preventive action initiative shall:

- Analyze information derived from product documentation (e.g., test reports, inspection results), customer complaints and product audits to join with our suppliers in developing effective preventive actions designed to address potential causes of non - conformities.
- Conduct periodic reviews of our procedures to help identify potential problems, which could impact on the quality of the products and services we provide our customers.
- Upon the identification of a potential problem area, it shall be submitted to management for review and consideration for corrective action initiation.
- Analyze customer feedback either from direct comments or through performance reports to determine areas where improvements could be made to improve our ratings with the customer or where overall customer satisfaction could be enhanced.
- Eliminate the causes of potential non-conformances in order to prevent their occurrence by assessing the risk of potential non-conformances and their causes, evaluating and implementing appropriate improvement actions to prevent occurrence, documenting the results of those actions, and verifying the effectiveness of those actions taken.

Crane Electronics, Inc. Sequence and Interaction of Key Processes

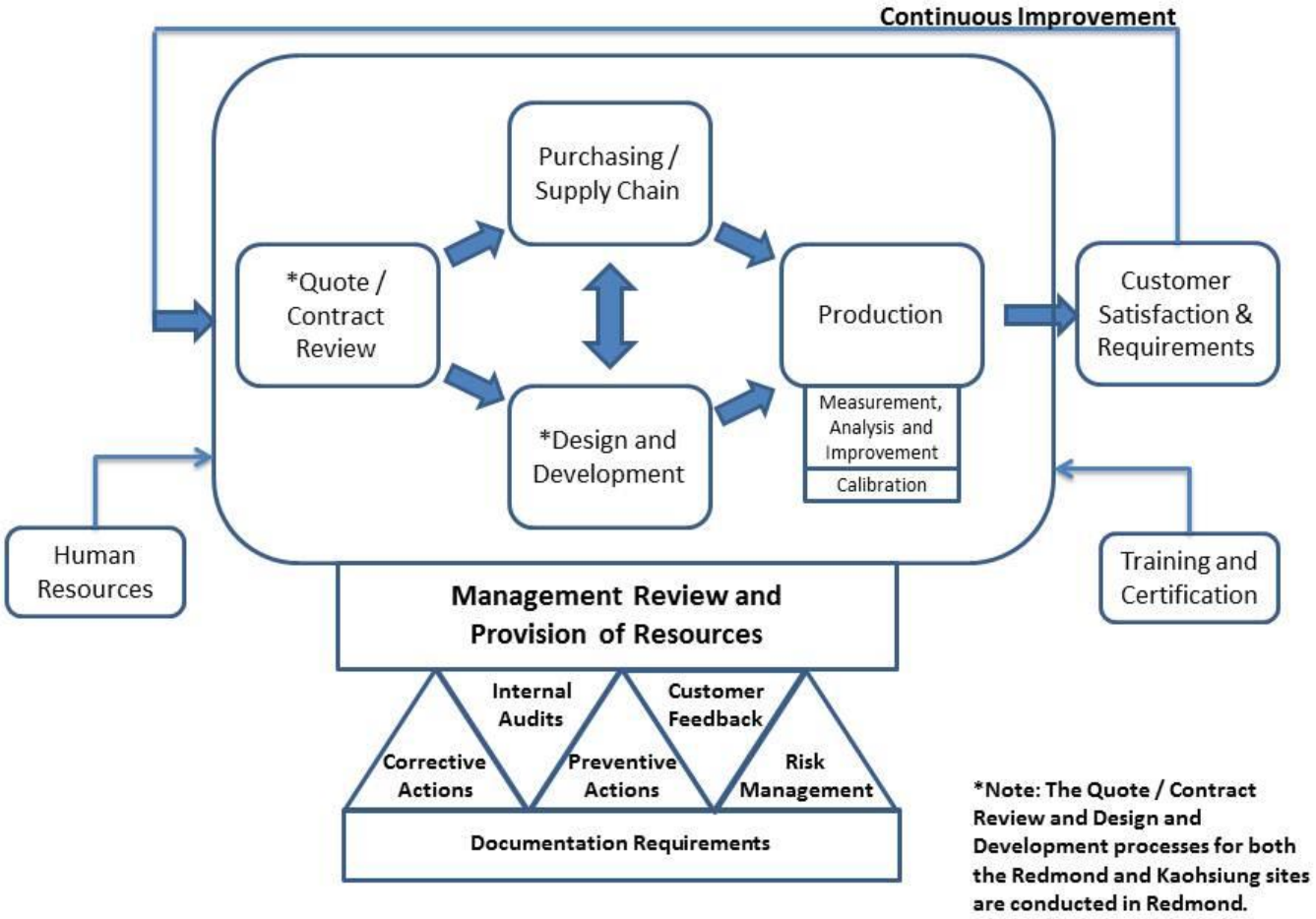

FIGURE 1

AS9100C, ISO13485:2003 Element Applicability Matrix (Redmond Site)

Instructions: This matrix is a controlled document and is used to define the specific ISO9001:2008, AS9100C & ISO 13485:2003 requirements that apply to each QMS Process / Area in the company. It is used to inform each process owner of the requirements that they must comply with. It is also used to guide internal auditors on what should be covered during QMS audits.

Enter **XX** if the element has primary applicability in the process (i.e. this process is directly responsible for / manages conformance to this element). Enter an **X** if the element has secondary applicability in the process (i.e. requirements somewhat apply here but there is not direct responsibility for conformance). An example is Document Control (4.2.3). Every process has some responsibility but the Quality Assurance department normally manages document control and has primary responsibility.

		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES	DESIGN CONTROL	DOCUMENTATION CONTROL	MANUFACTURING	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTION
4.1	General Requirements	XX	X	X	X	X	X	X	X	X	X
4.2	General Documentation Requirements	XX	X	X	X	X	X	X	X	X	X
4.2.2	Quality Manual	X	X	X	X	X	XX	X	X	X	
4.2.3	Control of Documents	X	X	X	XX	X	X	X	X	X	X
4.2.4	Control of Records	X	X	X	XX	X	X	X	X	X	X
5.1	Management Commitment	XX	X	X	X	X	X	X	X	X	X
5.2	Customer Focus	X	XX	X	X	X	X	X	X	X	X
5.3	Quality policy	X	X	X	X		XX	X	X	X	
5.4.1	Quality Objectives (Planning)	XX	X	X	X		X	X	X	X	
5.4.2	Quality Management System Planning	XX		X			X		X		
5.5	Responsibility, Authority and Communication	XX	X	X	X	X	X	X	X	X	X
5.6	Management Review	X	X	X	X	X	XX	X	X	X	X
6.1	Provision of Resources	XX							X		
6.2	Human Resources	X	X	X	X		X	X	XX	X	X
6.2.2	Competence, Awareness and Training	X			X	X	X	X	XX		
6.3	Infrastructure	XX	X	X	X		X	X	X	X	X
6.4	Work environment	X		X		XX		X			
7.1	Planning of Product Realization	X		XX		X	X			X	X
7.2	Customer-Related Processes		XX	X		X	X			X	X
7.3	Design and Development *			XX	X	X	X		X		

*Note: The requirement is not applicable to medical device components and parts.

FIGURE 2

		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES	DESIGN CONTROL	DOCUMENTATION CONTROL	MANUFACTURING	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTION
7.4	Purchasing						X		X	XX	X
7.5.1	Control of Production and Service				X	XX	X	X			
7.5.2	Validation of Processes for Production and Service				X	XX	X	X			
7.5.3	Identification and Traceability				X	XX	X	X		X	
7.5.4	Customer Property			X			XX				
7.5.5	Preservation of Product					XX	X	X		X	
7.6	Control of Monitoring and Measuring Devices	X				X	XX	X			
8.1	General	XX					X				X
8.2.1	Customer Satisfaction	X	X				X				XX
8.2.2	Internal Audit	X	X	X	X	X	XX	X	X	X	X
8.2.3	Monitoring and Measurement of Processes	X	X	X	X	XX	X	X	X	X	X
8.2.4	Monitoring and Measurement of Product	X				X	XX	X	X		
8.3	Control of Nonconforming Product				X	X	XX	X	X	X	
8.4	Analysis of Data	X	X	X	X	X	XX	X	X	X	X
8.5.1	Continual Improvement	XX	X	X	X	X	X	X	X	X	X
8.5.2	Corrective Action	X	X	X	X	X	XX	X	X	X	X
8.5.3	Preventive Action	X	X	X	X	X	XX	X	X	X	X

FIGURE 2 (continued)

ISO9001:2008, AS9100C Element Applicability Matrix (Kaohsiung Site)

Instructions: This matrix is a controlled document and is used to define the specific ISO9001:2008 and AS9100C requirements that apply to each QMS Process / Area in the company. It is used to inform each process owner of the requirements that they must comply with. It is also used to guide internal auditors on what should be covered during QMS audits.

Enter **XX** if the element has primary applicability in the process (i.e. this process is directly responsible for / manages conformance to this element). Enter an **X** if the element has secondary applicability in the process (i.e. requirements somewhat apply here but there is not direct responsibility for conformance). An example is Document Control (4.2.3). Every process has some responsibility but the Quality Assurance department normally manages document control and has primary responsibility.

		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES**	DESIGN CONTROL**	DOCUMENTATION CONTROL	MANUFACTURING	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTION
4.1	General Requirements	X			X	X	X	X	X	X	X
4.2	General Documentation Requirements	X			X	X	X	X	X	X	X
4.2.2	Quality Manual	X			X	X	X	X	X	X	
4.2.3	Control of Documents	X			X	X	X	X	X	X	X
4.2.4	Control of Records	X			X	X	X	X	X	X	X
5.1	Management Commitment	X			X	X	X	X	X	X	X
5.2	Customer Focus	X			X	X	X	X	X	X	X
5.3	Quality policy	X			X		X	X	X	X	
5.4.1	Quality Objectives (Planning)	X			X		X	X	X		
5.4.2	Quality Management System Planning	X							X		
5.5	Responsibility, Authority and	X			X	X	X	X	X	X	X
5.6	Management Review	X			X	X	X	X	X	X	X
6.1	Provision of Resources	X							X		
6.2	Human Resources	X			X		X	X	X	X	X
6.2.2	Competence, Awareness and Training	X			X	X	X	X	X		
6.3	Infrastructure	X			X		X	X	X	X	X
6.4	Work environment	X				X		X			
7.1	Planning of Product Realization					X	X			X	X
7.2	Customer-Related Processes					X	X			X	X
7.3	Design and Development (N/A)*										

*Note: Clause 7.3 Design and Development is a process centralized out of the Redmond Site. It is not applicable to the Kaohsiung site.

**Note: These process areas are not applicable to this site.

FIGURE 3

		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES**	DESIGN CONTROL**	DOCUMENTATION CONTROL	MANUFACTURING	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTIONN
7.4	Purchasing						X			XX	X
7.4.3	Verification of Purchased Products				X	X	X	X			
7.5.1	Control of Production and Service				X	X	X	X			
7,5,2	Validation of Processes for Production and Service				X	X	X	X			
7.5.3	Identification and Traceability				X	X	X	X		X	
7.5.4	Customer Property						X				
7.5.5	Preservation of Product					X	X	X		X	
7.6	Control of Monitoring and Measuring Devices	X			X	X	X	X			
8.1	General	X					X				X
8.2.1	Customer Satisfaction	X					X				X
8.2.2	Internal Audit	X			X	X	X	X	X	X	X
8.2.3	Monitoring and Measurement of Processes	X			X	X	X	X	X	X	X
8.2.4	Monitoring and Measurement of Product	X				X	X	X	X		
8.3	Control of Nonconforming Product	X			X	X	X	X	X	X	
8.4	Analysis of Data	X			X	X	X	X	X	X	X
8.5.1	Continual Improvement	X			X	X	X	X	X	X	X
8.5.2	Corrective Action	X			X	X	X	X	X	X	X
8.5.3	Preventive Action	X			X	X	X	X	X	X	X

**Note: These process areas are not applicable to this site.

FIGURE 3 (continued)

ISO9001 :2008 Element Applicability Matrix (France Site)

Instructions: This matrix is a controlled document and is used to define the specific ISO9001:2008 requirements that apply to each QMS Process / Area in the company. It is used to inform each process owner of the requirements that they must comply with. It is also used to guide internal auditors on what should be covered during QMS audits.

Enter **XX** if the element has primary applicability in the process (i.e. this process is directly responsible for / manages conformance to this element). Enter an **X** if the element has secondary applicability in the process (i.e. requirements somewhat apply here but there is not direct responsibility for conformance). An example is Document Control (4.2.3). Every process has some responsibility but the Quality Assurance department normally manages document control and has primary responsibility.

		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES	DESIGN CONTROL**	DOCUMENTATION CONTROL**	MANUFACTURING**	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES**	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTION
4.1	General Requirements	X	X				X	X		X	X
4.2	General Documentation Requirements	X	X				X	X		X	X
4.2.2	Quality Manual	X	X				X	X		X	
4.2.3	Control of Documents	X	X				X	X		X	X
4.2.4	Control of Records	X	X				X	X		X	X
5.1	Management Commitment	X	X				X	X		X	X
5.2	Customer Focus	X	X				X	X		X	X
5.3	Quality policy	X	X				X	X		X	
5.4.1	Quality Objectives (Planning)	X	X				X	X		X	
5.4.2	Quality Management System Planning	X					X				
5.5	Responsibility, Authority and Communication	X	X				X	X		X	X
5.6	Management Review	X	X				X	X		X	X
6.1	Provision of Resources	X									
6.2	Human Resources	X	X				X	X		X	X
6.2.2	Competence, Awareness and Training	X					X	X			
6.3	Infrastructure	X	X				X	X		X	X
6.4	Work environment	X					X	X			
7.1	Planning of Product Realization	X					X			X	X
7.2	Customer-Related Processes		X				X			X	X
7.3	Design and Development (N/A)*										

*Note: Clause 7.3 Design and Development is a process centralized out of the Redmond Site. It is not applicable to the France site.

**Note: These processes areas are not applicable to this site.

FIGURE 4		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES	DESIGN CONTROL**	DOCUMENTATION CONTROL**	MANUFACTURING**	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES**	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTION
7.4	Purchasing (N/A)*										
7.5.1	Control of Production and Service						X	X			
7.5.2	Validation of Processes for Production and Service						X	X			
7.5.3	Identification and Traceability						X	X		X	
7.5.4	Customer Property						X				
7.5.5	Preservation of Product						X	X		X	
7.6	Control of Monitoring and Measuring Devices	X					X	X			
8.1	General	X					X				X
8.2.1	Customer Satisfaction	X	X				X				X
8.2.2	Internal Audit	X	X				X	X		X	X
8.2.3	Monitoring and Measurement of Processes	X	X				X	X		X	X
8.2.4	Monitoring and Measurement of Product	X					X	X			
8.3	Control of Nonconforming Product	X	X				X	X		X	
8.4	Analysis of Data	X					X	X		X	X
8.5.1	Continual Improvement	X	X				X	X		X	X
8.5.2	Corrective Action	X	X				X	X		X	X
8.5.3	Preventive Action	X	X				X	X		X	X

*Note: Clause 7.4 Purchasing is a process centralized out of the Redmond Site. It is not applicable to the France site.

**Note: These process areas are not applicable to this site.

FIGURE 4 continued

ISO9001:2008 Element Applicability Matrix (UK Site)

Instructions: This matrix is a controlled document and is used to define the specific ISO9001:2008 requirements that apply to each QMS Process / Area in the company. It is used to inform each process owner of the requirements that they must comply with. It is also used to guide internal auditors on what should be covered during QMS audits.

Enter **XX** if the element has primary applicability in the process (i.e. this process is directly responsible for / manages conformance to this element). Enter an **X** if the element has secondary applicability in the process (i.e. requirements somewhat apply here but there is not direct responsibility for conformance). An example is Document Control (4.2.3). Every process has some responsibility but the Quality Assurance department normally manages document control and has primary responsibility.

		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES	DESIGN CONTROL**	DOCUMENTATION CONTROL**	MANUFACTURING**	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES**	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTION
4.1	General Requirements	X	X				X	X		X	X
4.2	General Documentation Requirements	X	X				X	X		X	X
4.2.2	Quality Manual	X	X				X	X		X	
4.2.3	Control of Documents	X	X				X	X		X	X
4.2.4	Control of Records	X	X				X	X		X	X
5.1	Management Commitment	X	X				X	X		X	X
5.2	Customer Focus	X	X				X	X		X	X
5.3	Quality policy	X	X				X	X		X	
5.4.1	Quality Objectives (Planning)	X	X				X	X		X	
5.4.2	Quality Management System Planning	X					X				
5.5	Responsibility, Authority and Communication	X	X				X	X		X	X
5.6	Management Review	X	X				X	X		X	X
6.1	Provision of Resources	X									
6.2	Human Resources	X	X				X	X		X	X
6.2.2	Competence, Awareness and Training	X					X	X			
6.3	Infrastructure	X	X				X	X		X	X
6.4	Work environment	X					X	X			
7.1	Planning of Product Realization	X					X			X	X
7.2	Customer-Related Processes		X				X			X	X
7.3	Design and Development (N/A)*										

*Note: Clause 7.3 Design and Development is a process centralized out of the Redmond Site. It is not applicable to the UK site.

**Note: These process areas are not applicable to this site.

FIGURE 5

		Processes									
		A	B	C	D	E	F	G	H	I	J
		MANAGEMENT	INSIDE SALES	DESIGN CONTROL **	DOCUMENTATION CONTROL **	MANUFACTURING**	QUALITY ASSURANCE	TRAINING AND CERTIFICATION	HUMAN RESOURCES**	SUPPLY CHAIN	CUSTOMER FOCUS/ SATISFACTION
7.4	Purchasing (N/A)*										
7.5.1	Control of Production and Service						X	X			
7.5.2	Validation of Processes for Production and Service						X	X			
7.5.3	Identification and Traceability						X	X		X	
7.5.4	Customer Property						X				
7.5.5	Preservation of Product						X	X		X	
7.6	Control of Monitoring and Measuring Devices	X					X	X			
8.1	General	X					X				X
8.2.1	Customer Satisfaction	X	X				X				X
8.2.2	Internal Audit	X	X				X	X		X	X
8.2.3	Monitoring and Measurement of Processes	X	X				X	X		X	X
8.2.4	Monitoring and Measurement of Product	X					X	X			
8.3	Control of Nonconforming Product	X	X				X	X		X	
8.4	Analysis of Data	X					X	X		X	X
8.5.1	Continual Improvement	X	X				X	X		X	X
8.5.2	Corrective Action	X	X				X	X		X	X
8.5.3	Preventive Action	X	X				X	X		X	X

*Note: Clause 7.4 Purchasing is a process centralized out of the Redmond Site. It is not applicable to the UK site.
**Note: These process areas are not applicable to this site.

FIGURE 5 continued

Structure of Documentation Used in the QMS

FIGURE 6