Cygnus Manufacturing Co.
Saxonburg, Pennsylvania
Quality Management System Manual

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1 Scope

This section is intended to describe the scope of the quality management system (QMS). Subsequent sections describe the QMS and the elements of the system and set policies to be met by the organization.

The quality manual is intended to meet the needs of the organization and external parties. It is written as a directive to the organization including statements of things that "shall" be done by the organization. For readers outside the organization, these "shalls" should be read as actions that "will" be done (or are being done) by the organization.

This quality management system and this quality manual apply to the operations of Cygnus Manufacturing Company LLC (CMC), located at 491 Chantler Drive, Victory Road Business Park; Saxonburg, PA.

The quality management system shall comply with the organization's quality policy and with all applicable statutory and regulatory requirements, standards, and guidelines, including, but not limited to, the following:

- ISO 9001:2008, Quality management systems – Requirements
- ISO 13485:2003, Medical devices - Quality management systems - Requirements for regulatory purposes
- AS 9100C:2009, Aerospace - Quality management systems - Requirements
- Exclusions:
  - 7.3 Design and Development
  - 7.5.1.4 (AS 9100C) Post Delivery Support - items a, c, d & e
- Not Applicable:
  - 7.5.1.2.2 (ISO 13485) Installation activities
  - 7.5.1.2.3 (ISO 13485) Servicing activities
  - 7.5.1.3 (ISO 13485) Particular requirements for sterile medical devices
  - 7.5.2.2 (ISO 13485) Particular requirements for sterile medical devices
  - 7.5.3.2.2 (ISO 13485) Particular requirements for active implantable medical devices and implantable medical devices
  - 8.2.4.2 (ISO 13485) Particular requirements for active implantable medical devices and implantable medical devices

2 Normative References

ISO 9000:2005, Quality Management Systems - fundamentals and vocabulary

3 Terms and Definitions

For the purpose of this document, the terms and definitions given in ISO 9000 apply.

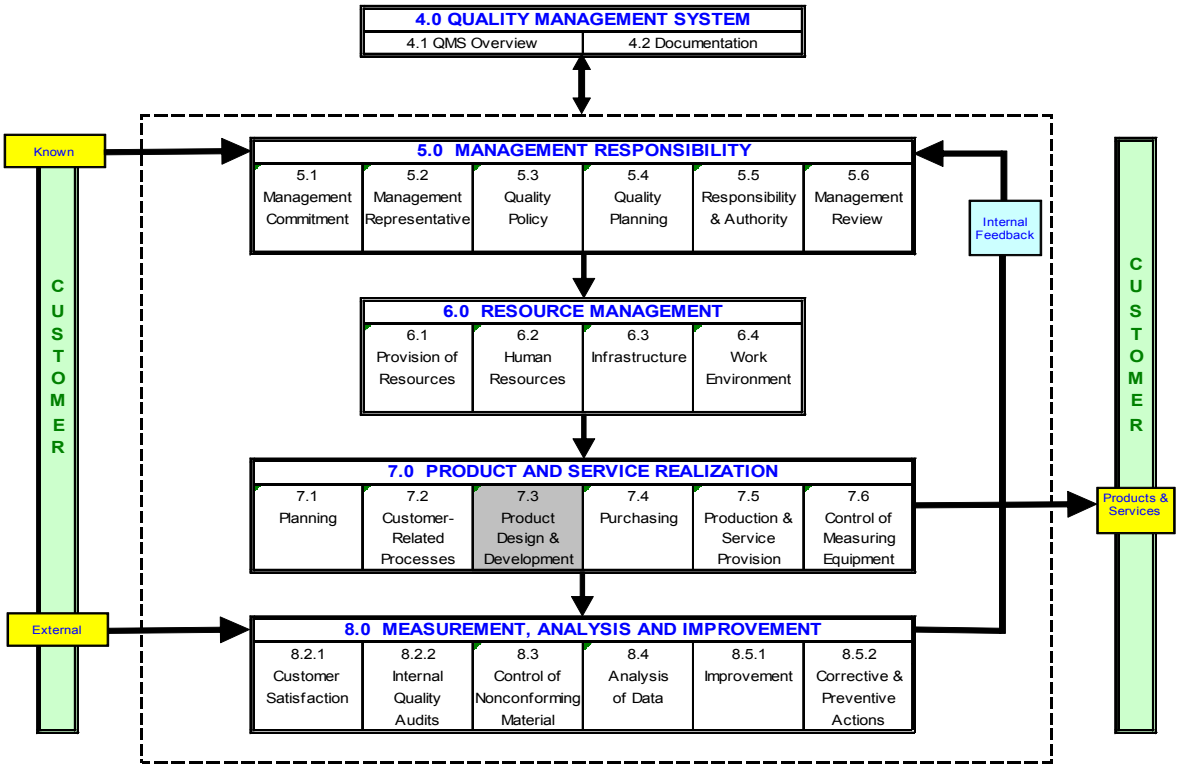
- The following terms, used in ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:
  supplier -> organization -> customer
- **the organization** refers to Cygnus Manufacturing Company LLC (CMC), and
- **supplier** refers to a third party organization that supplies a product or service that affects CMC's quality management system.

4 Quality Management System

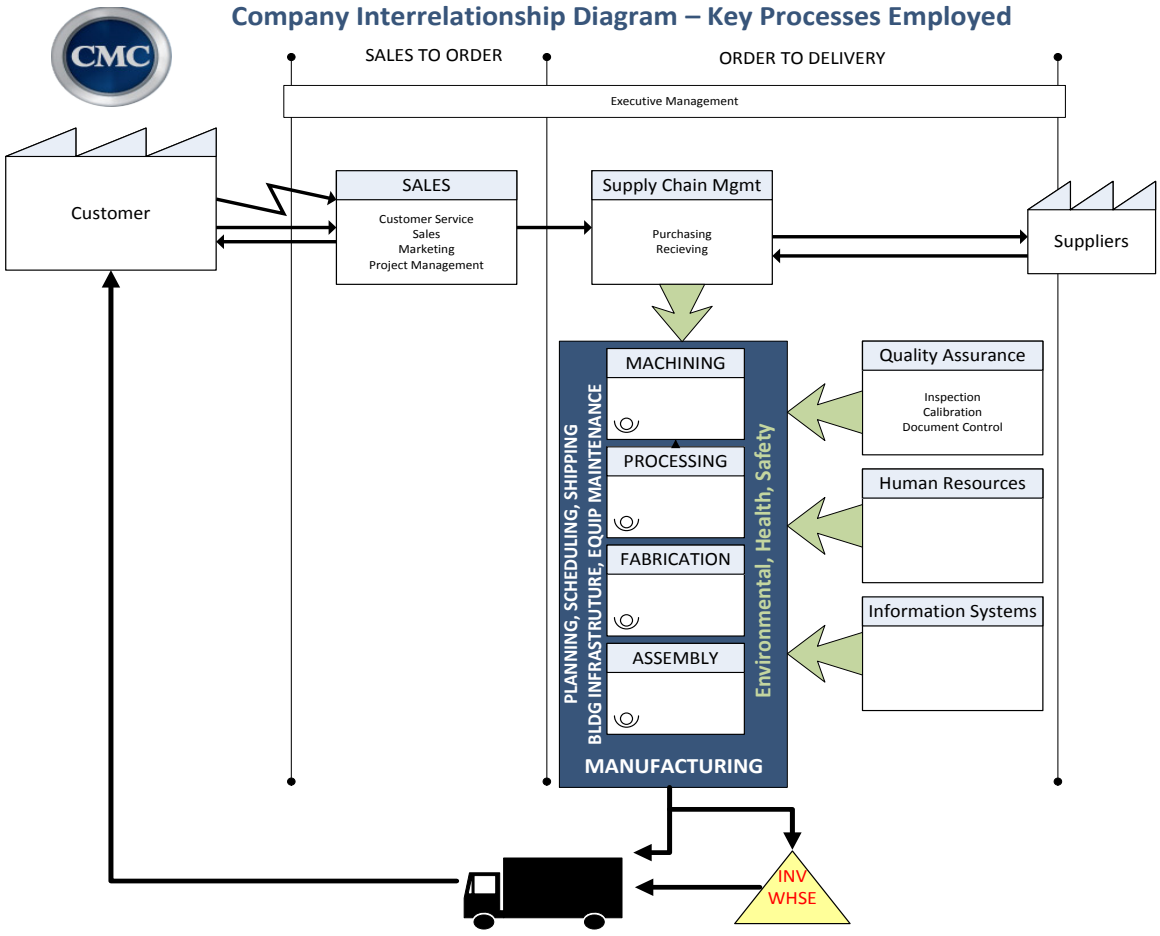
4.1 General

This section describes the quality management system (QMS) in general terms. The requirements of this section establish a basic structure for the QMS in the form of documents and records. Subsequent sections describe the processes of the system and delineate policies to be met by the organization in implementing each process. The CMC quality system shall be appropriate for the specific devices manufactured for our customers as applicable. Note: Processes needed for the quality management system include processes for management activities, provision of resources, product realization, and measurement, analysis and improvement.

The quality management system consists of the quality policy, quality manual, quality objectives, organizational structure, responsibilities, procedures, documents, records, specifications, processes, and resources that work together to identify, determine and meet the requirements of our quality policy, customers and applicable statutory and regulatory requirements. The QMS shall be monitored and analyzed to determine the effectiveness of the processes to ensure attainment of planned results. Where outsourcing of processes that affect product conformity with requirements occurs, CMC has established procedures that ensure control over these processes. The general structure of the quality management system is shown below.



The quality management system involves several key processes at CMC. These are depicted in the diagram below:



4.2 Documentation

NOTE: See CMC QSP-01 Document Control and QSP-02 Quality Records Procedures

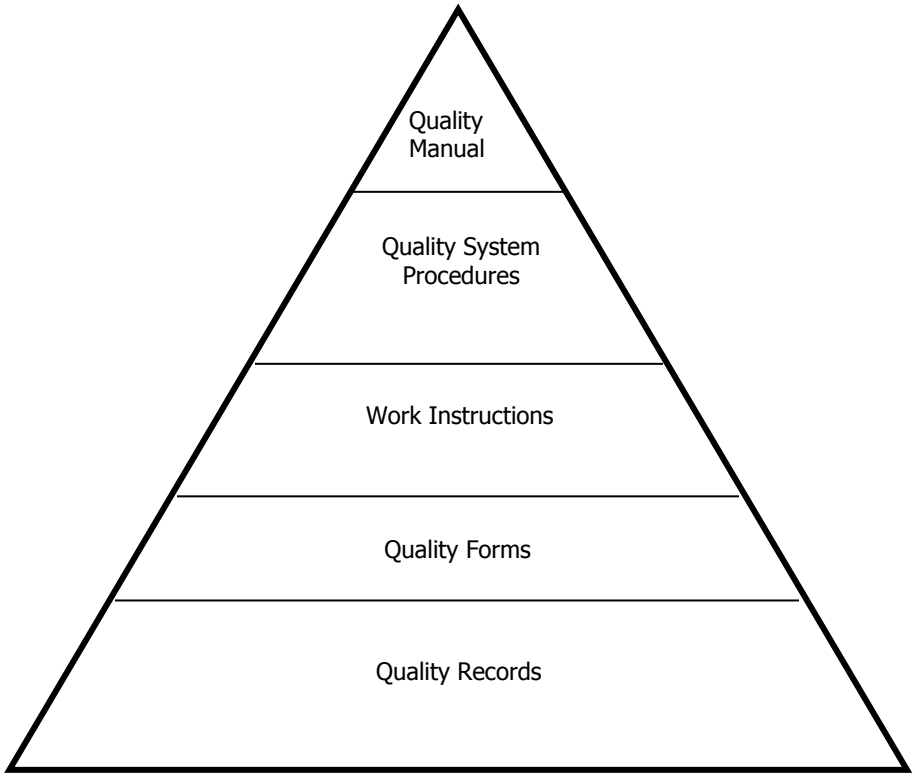
4.2.1 General and 4.2.2 Below

4.2.2 Quality Manual

The quality management system documentation consists of the quality policy and manual, quality objectives, documents and records required by international, national or regional requirements. Documents and data may be in the form of any type of media. Documents shall remain legible and be readily identifiable throughout all change, approval, and distribution processes. Personnel shall have access to QMS documentation and shall be aware of relevant procedures. All documents and data related to the QMS shall be controlled to ensure that the proper revision is provided for use and that changes are made only with the proper authorization prior to use. All documents and data that are part of the quality management system are considered proprietary and access may be restricted to third parties; however, CMC shall recognize the need to provide documentation to regulatory

authorities and customers as required to maintain compliance as well as to support customer requirements relative to maintaining regulatory documentation.

The quality management system is documented by this quality manual, along with quality system procedures, work instructions, forms, and records as structured below.



- This **Quality Manual** describes the quality management system structure and specifies policy to the organization for each process of the system. To facilitate review of the system, an appendix provides traceability from key regulations and standards to sections of the manual.
- **Quality System Procedures** define the processes, assignment of responsibility and authority, establishment of review and approval mechanisms, and maintenance of records for non-product specific requirements of the QMS.
- **Work Instructions** are used where necessary for effective operation of the product specific elements of the QMS. These documents normally apply to the purchase, manufacture, maintenance, or servicing of specific devices, components, or equipment, or the performance of specific activities within a process, including computer operations.
- **Quality Forms** are used to document the accurate and efficient completion of procedural requirements. Any required forms are either made part of the implementing quality system procedure/work instruction or are controlled as separate documents.
- **Quality Records** are documents that furnish objective evidence of activities performed or results achieved. They include forms completed by hand or printed by a computer, as well as electronic records.

4.2.3 Control of Documents

Procedures shall be established and maintained to describe requirements and methods for control of quality management system documents including identification, format, document processing, retrieval, retention, periodic review, data control, distribution, and implementation. Procedures shall also define approval requirements for each type of QMS document including the coordination with customers and/or regulatory agencies according to contract or regulatory requirements. Records of approval shall be maintained. Records containing the current revision level of all quality system documents and data shall be maintained.

Changes to documents or data shall be made with approval by designated individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise. Records of all changes to documents shall be maintained, containing the description of the change, identification of the affected document(s), approval signatures, approval date, and effective date of the change.

Procedures shall provide for the controlled release and distribution of new and revised documents. These procedures shall provide for distribution of current copies and for prevention of the use of outdated procedures or standards. Documents shall be approved prior to being issued. Distribution may be by issue of printed copies or through electronic media. In any case, methods shall be provided for clear distinction between controlled, uncontrolled, superseded and obsolete documents.

Distribution of documents shall be controlled to ensure that the proper versions of all documents are available in a timely manner to those requiring them. Document revision notifications shall be communicated to the appropriate personnel.

Reference copies of documents may be issued to outside parties having a need to review quality management system documentation or for internal training or informational purposes. Reference copies will be updated only by request. All copies of superseded or obsolete documents shall be promptly removed from the point of use or otherwise prevented from unintended use.

Procedures shall be established and maintained to identify, obtain, and maintain current copies of applicable external standards related to the quality management system and to the design and evaluation of devices that are designed and manufactured under the quality management system. External standards shall be clearly identified and distributed through a controlled process to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution is controlled.

4.2.4 Control of Records

A record is a document that furnishes objective evidence of activities performed or results achieved. The scope of records shall include records from regulatory agencies, suppliers, or other external parties where such records are necessary to demonstrate conformance to specific requirements or the effective operation of the quality management system. Quality Records include, but are not limited to:

- management reviews of the quality system;
- quality audits;
- customer contract review;
- design and drawing reviews;
- results of any verification and validation activities;
- calibration results of M&TE;
- in-process and final inspection;
- customer complaints;
- corrective and preventive actions;
- nonconforming material concessions / approvals;
- employee training;

- supplier records; and
- process and equipment qualification results.

Records shall be prepared in a legible format, and appropriately identified.

In addition:
- Records, paper or electronic, shall be identified, collected, indexed, stored, and maintained for easy retrieval. Where applicable, records shall be maintained on approved forms.
- Records may be maintained in electronic form (of any appropriate media).

All quality records shall be maintained at the manufacturing location or be accessible to management and regulatory agencies. Records shall be maintained in an environment that prevents damage, deterioration, and loss. Adequate flood and fire protection shall be provided to ensure that records are always protected. All completed forms and inspection reports are considered quality records and are stored in a secured area to protect customer's proprietary information. Quality records may be made available to customers or regulatory agencies for their inspection, subject to appropriate consideration of confidentiality of the records. Procedures shall define methods for record retention.

5 Management Responsibility

5.1 Management Commitment and 5.2 Below

5.2 Customer Focus

Executive Management shall demonstrate a commitment to the establishment, maintenance, and continuing improvement of the quality management system by:
- Establishing and communicating a quality policy
- Appointing a Management Representative
- Conducting regular Management Reviews
- Communicating the importance of meeting customer, regulatory and statutory requirements applicable to the product, and CMC's organizational requirements
- Maintaining a focus on customers and ensuring that customer requirements are determined and met to increase customer satisfaction through the effective application of the QMS, including processes for continual improvement of the QMS.
- Establishing and evaluating quality objectives
- Conducting quality management system planning
- Ensuring the availability of resources
- Customer requirements are determined and met

5.3 Quality Policy

The CMC Quality Policy:

C omply with mutually agreed upon valid requirements 100% of the time, to Regulatory, the Customer & applicable Quality Standards

M inimize defects through a culture of prevention rather than detection, including the establishment and review of Quality Objectives

C ontinually improve and maintain the quality of our products and services

Executive management regularly reviews the policy for suitability. The policy and its meaning is communicated to all levels of the organization through publication of the quality manual, quality system training, bulletin board postings, display of quality measurements, and periodic review at organization meetings.

5.4 Quality Planning

Management shall plan for any necessary changes to the quality management system to maintain the integrity of the QMS:

- As an integral part of business planning
- When making significant changes in responsibilities
- When significantly modifying facilities or processes
- In response to adverse findings from quality audits by external parties
- For significant changes in regulatory requirements
- To maintain and improve the effectiveness of the quality management system

Where appropriate, this planning shall be documented in the form of a quality plan. The quality plan for the manufacture of products shall specify quality requirements, resources and activities relevant to the devices that are manufactured.

5.5 Responsibility, Authority and Communication

The implementation, maintenance, and improvement of the quality management system are the shared responsibility of all associates throughout the organization.

Process Ownership is defined within each quality system procedure. The Process Owner shall be responsible to:

- Establish and maintain procedures for the process, based on the requirements of the quality manual
- Continually improve the effectiveness of the process

The responsibility, authority, and interrelation of all associates who manage, perform, and verify work that affects quality shall be specified as part of the documented quality management system, including the quality manual, quality system procedures, and, if necessary, other documents. Management shall provide all such associates with appropriate independence and authority to perform these tasks.

When a position described in the quality system is vacant, or the incumbent is absent, any responsibility or authority assigned to that position shall normally be assigned to the next higher level of management.

Any changes of title, position, responsibility, delegation of responsibility, or significant changes in titles shall be communicated by the next level of management to all affected associates and the Management Representative. Any affected quality management system documents shall be revised within a reasonable time.

CMC maintains an Organization Chart to describe the organizational structure of the organization.

The Chief Executive Officer shall appoint the Management Representative. The Management Representative shall have the responsibility and authority to:

- Ensure that a quality management system is established and maintained in accordance with the requirements of this quality manual, applicable regulations and standards, and organization policies
- Regularly assess the quality management system
- Reports regarding the compliance and performance of the quality management system
- Facilitate external agency audits, inspections, and visits relative to the quality management system

- Ensure the promotion of awareness of customer requirements and regulatory requirements throughout the organization

The effectiveness of the Quality Management System will be communicated to executive management during Management Review Meetings. Communication to the organization is achieved verbally and through postings on organization bulletin boards, organization meetings, paycheck attachments, and the organization intranet site.

5.6 Management Review

NOTE: See CMC QSP-18 Quality Management Review Procedure

Executive Management shall formally review and assess the suitability and effectiveness of the quality management system in planned Management Review meetings on a quarterly basis. During Management Review meetings, the management team shall consider opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Management Review inputs shall include the following:
- Status of identified actions from previous Management Review Meetings
- Internal and external quality audits
- Corrective and preventive actions
- Customer feedback
- Performance of processes and associated quality measurements to defined goals and objectives.
- Changes that could affect the QMS
- Improvement opportunities

Management Review output shall include as applicable:
- The effectiveness of the QMS
- Recommendations for improvement

Records of Management Review shall be maintained.

6 Resource Management

6.1 Provision of Resources

Management shall determine the need for and provide adequate human resources and infrastructure to achieve quality requirements including implementation, maintenance, effectiveness and continuous improvement of the quality management system, as well as maintenance of customer satisfaction by ensuring the fulfillment of customer requirements. Resources shall be determined and provided to meet regulatory and customer requirements.

6.2 Human Resources

NOTE: See CMC QSP-03 Competence, Training and Awareness Procedure

For each job function, management shall provide sufficient personnel with appropriate background, education, and experience necessary. Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience. The required competence to carry out those jobs affecting product quality shall be determined, and appropriate training or other action shall be performed to provide or ensure this competence. Each associate shall be provided with the necessary training or other actions to ensure that the assigned tasks are performed in accordance with the quality system and associated policies, procedures, and work instructions. Training shall include instruction on the importance of

the associate's activities and their contribution to the quality objectives. Training records shall be maintained. The effectiveness of training shall be evaluated.

Requirements for hiring or promoting of associates shall include the background and education necessary to learn to perform the assigned tasks.

New associates shall complete an orientation program. Records of all such orientation and training shall be maintained.

Any training mandated by federal, state, or local law shall be provided.

Procedures shall be established and maintained to ensure that each CMC associate and temporary worker receive the training necessary to ensure proper performance in the assigned area(s) of responsibility. Management shall identify the training needs for each job function related to the quality management system and plan the training of associates accordingly. Records of all job-specific training shall be maintained.

6.3 Infrastructure

NOTE: See CMC QSP-19 Machine Maintenance Procedure

CMC shall determine, provide and maintain the infrastructure and supporting services (such as transport, communication, or information systems) required to comply with applicable product and customer requirements. Infrastructure includes, as applicable

- Infrastructure and business environment updates, changes or risks
- Buildings, workspace and associated utilities,
- Process equipment (both hardware and software), and
- Supporting services (such as transport or communication).

All manufacturing and service processes shall be carried out under controlled conditions, including adequate buildings, process equipment, working conditions, and personnel, to ensure that all devices produced and released for distribution meet their intended requirements and are shipped free of contamination by any substances that could reasonably be expected to have an adverse effect on product quality.

Buildings shall contain sufficient space and be adequately arranged to ensure orderly handling of all material and equipment and orderly execution of all processes that affect device quality, in order to enable maintenance and prevent mix-up. Buildings and grounds shall be designed and constructed and the environment of the building suitably controlled to prevent contamination by external environmental sources and pests. A suitable pest control program shall be established.

All process equipment, including hardware and software, shall be selected or designed to meet specified requirements and shall be constructed and installed to facilitate maintenance, adjustment, cleaning, and use.

Process equipment shall be regularly cleaned, maintained, inspected and adjusted as required to maintain product quality. A preventive maintenance schedule shall be established and shall be readily available to the associates who perform the maintenance activities or the associates' supervisor(s). A record of maintenance activities shall be maintained.

Information systems shall be provided as necessary to achieve conformity to product requirements and to support business processes. Information systems and computer-related systems that support the quality management system shall be developed, operated, and maintained under controlled conditions, including adequate equipment, environment, software, operating procedures, and personnel.

All computer-related equipment shall be selected or designed to meet specified requirements.

Computers shall be located in areas that contain sufficient space and environmental controls. Computers should be adequately arranged to assure orderly execution of all processes and to enable maintenance.

CMC shall ensure secure and reliable operation of computer-related systems, encompassing the following:

- Maintenance of the computer system and associated network equipment
- Periodic back up of programs and records

6.4 Work Environment

NOTE: See CMC QSP-22 ESD Procedure

CMC shall determine and maintain the work environment required to meet applicable statutory, regulatory, product and customer requirements. All manufacturing and service processes shall be performed in compliance with applicable Environmental, Health, and Safety (EH&S) regulatory requirements. All employees shall receive appropriate safety training.

Components and devices that have been identified as sensitive to electrostatic discharge (ESD) shall be handled per approved methods.

Smoking shall be prohibited in the building(s). Eating and drinking shall be limited to designated areas to prevent device contamination. Each associate shall be responsible to help maintain a clean and safe work environment.

7 Product Realization

7.1 Planning of Product Realization

NOTE: See CMC QSP-12 Product Realization, QSP-21 Business Continuity, QSP-26 Risk Management and QSP-28 Configuration Management Procedures

Management shall plan, define, implement, and maintain processes and documents to meet customer, regulatory and statutory requirements applicable to the product, and CMC's organizational requirements, with due consideration for quality objectives, compliance with the requirements of the quality management system, and any unique requirements of the products. In the event that a customer contract requires CMC to assist in Risk Management activities, a procedure will be established to support this requirement. Similarly, if contract requires CMC to identify the resources to support operation and maintenance of the product, procedures will be developed to support this requirement.

As appropriate to the product being manufactured for aerospace contracts, CMC management shall plan and manage product realization in a structured and controlled manner to meet all customer requirements at acceptable risk, within resource and schedule constraints. The Product Realization Process (PRP) shall ensure each project plan (product routing/router/traveler) created is documented and tracked to ensure plans are met.

CMC shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements for aerospace products, that includes as appropriate to CMC and the product.

- assignment of responsibilities for risk management,
- definition of risk criteria (e.g., likelihood, consequences, risk acceptance),
- identification, assessment and communication of risks throughout product realization,
- identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and

- acceptance of risks remaining after implementation of mitigating actions

For aerospace products, CMC shall establish, implement and maintain a configuration management process that includes, as appropriate to the product

a) Configuration management planning,
b) Configuration identification,
c) Change control,
d) Configuration status accounting, and
e) Configuration audit.

CMC shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work (e.g., between our work areas, from CMC to a supplier, from one supplier to another supplier, and to verify the conformity of the work to requirements). CMC routings/routers/travelers and inspection processes facilitate planning and control.

NOTE: Requirements related to the product shall include special processing requirements, where applicable.

7.2 Customer-Related Processes

NOTE: See CMC QSP-12 Product Realization, QSP-13 Customer Complaints, QSP-15 Estimating, QSP-23 Customer Returns and QSP-26 Risk Management Procedures

Processes shall be established to ensure effective interfaces with customers, including regulatory and statutory requirements applicable to the product, and CMC's organizational requirements, the receipt and entry of customer orders and capturing the requirements for delivery, quantity, terms and any additional requirements considered necessary by the organization.

Within the policy of this section and supporting procedures, the use of the word "order" shall also mean "contract," such that entry of a customer order constitutes review and acceptance of a contract.

Contracts and orders shall be reviewed prior to acceptance, to ensure that the customer's product requirements are clearly defined and documented, and that the organization is capable of meeting those requirements within a reasonable time. Where appropriate, a formal contract review is held. This review includes a review and communication of any additional regulatory requirements necessary to support the contract, an evaluation of risks, as well as any different or new requirements to existing contracts. Records of contract review shall be maintained.

The order entry and contract review process(es) shall ensure that customer requirements are determined and met with the aim of enhancing customer satisfaction. Any differences between specified customer requirements and the manufacturer's capability to meet the requirements should be resolved prior to acknowledgement of the order.

Management shall establish effective methods for communicating with customers on product information, quotes, pricing, inquiries, contracts, order entry, order status, and any changes affecting the products and services. Processes shall be established for the recording of customer complaints and for the collection of customer feedback. In the event that a customer contract requires CMC to issue advisory notices or adverse event reporting, a procedure will be established to support this requirement.

7.3 Design and Development

CMC offers technical assistance to our customers in the form of manufacturing engineering support for the initial design phase, prototype production, and manufacturing problem resolution. CMC does not have design and development responsibility for any of the products provided to our customers. Verification and validation approval of all designs remain the responsibility of the customer.

7.4 Purchasing

NOTE: See CMC QSP-04 Purchasing Procedure

Processes shall be established and maintained to manage the supply of material and outsourced products and services. Procedures shall provide for the evaluation and control of purchased products, the identification of potential sources for purchased materials, the development of suppliers or partners, and the evaluation and re-evaluation, as necessary, of their ability to supply the required products. These processes shall ensure that all purchased or otherwise received products, components, and services conform to specified requirements.

CMC shall evaluate and select suppliers based on their ability to supply products or services in accordance with the specified requirements. Criteria for selection, evaluation, and re-evaluation shall be established. Records of results of supplier evaluation and any necessary actions rising from the evaluation shall be maintained.

The type and extent of control applied to the supplier and the purchased product or outsourced service shall be defined and shall be dependent upon the effect of the purchased product on subsequent product realization or the final product. Supplier performance shall be reviewed and monitored according to established criteria. Suppliers of goods or services that do not directly affect the quality management system or the quality of CMC-supplied product or services may be deemed acceptable based solely on their ability to meet purchase order requirements. NOTE: An outsourced process is identified as one being needed for the organization's quality management system chosen to be performed by a party external to the organization.

Purchasing information shall clearly describe or refer to the requirements for the product or service to be purchased, including where appropriate requirements placed on the supplier for:

- Requirements for approval of product, or supplier procedures, processes, and equipment
- Qualification of supplier personnel
- Supplier's quality management system
- Traceability requirements as defined by customer contract.

The adequacy of specified purchase requirements shall be reviewed prior to their communication to the supplier.

To satisfy the requirements of a specific aerospace contract, purchasing shall assure that all the AS 9100C Quality requirements applicable to the purchased item are passed on to the supplier.

CMC shall established and implement activities to ensure that purchased or otherwise received material conforms to specified requirements by inspecting, testing, or otherwise verifying the material prior to acceptance. In the event that CMC or a customer intends to perform verification at a supplier's premises, the intended verification arrangements and method of product release shall be stated in purchasing information.
Material shall not normally be made available for manufacturing use until all acceptance procedures have been completed and the authorized personnel have released the material. Procedures may however allow for the release of material for manufacturing use prior to completion of receiving inspection, provided that control is maintained over the unapproved material such that it could be retrieved prior to distribution of the associated finished product.

Where specified in the contract, Cygnus Manufacturing Company's customers (or customers' designee) shall be permitted to verify, at the supplier's premises and/or at CMC, that subcontracted product conforms to specified requirements; however, this inspection does not absolve CMC from providing acceptable product.

The inspection of labeling shall include an examination for accuracy. The record of this review shall be maintained.

Records shall be maintained of the acceptance or rejection of each lot of received components. They shall include, at a minimum:

- Date inspected
- Supplier name
- Signature or electronic record of the associate performing the acceptance

7.5 Production and Service Provision

All manufacturing processes, inspection, and testing shall be performed under controlled conditions in accordance with written instructions or drawings by qualified and trained personnel to assure that the devices conform to the approved original or modified design. These instructions shall include assembly procedures, work instructions, and any necessary controls on the process. Records of these processes shall be maintained.

If servicing or installation is required by contract, CMC shall establish documented procedures, as necessary, for performing servicing activities and verifying that they meet the specific requirements.

7.5.1 Control of Production and Service Provision

NOTE: See CMC QSP-11 Production Control, QSP-12 Product Realization, QSP-16 Process Validation and QSP-27 FOD Procedures

All manufacturing processes shall be performed in accordance with drawings and documented instructions, where applicable, that define and control the process and identify the characteristics of the product. These may include or make reference to criteria for workmanship, which may be expressed in work instructions, documented standards or by means of identified and approved representative samples. These documents may be CMC documents or customer drawings, as applicable.

Process monitoring and measurement systems shall be utilized to evaluate product quality in the manufacturing process. Information derived from these systems shall be available and used to initiate corrective or preventive action as appropriate.

Where deviations from device specifications could occur as a result of the manufacturing process, process control procedures shall be established and maintained to describe any process controls necessary to ensure that the device conforms to specifications.

Each process of applying a label to a medical device or of using packaging that includes medical device labeling shall be controlled to prevent labeling errors and mix-up.

Records shall be maintained to ensure that all manufacturing and inspection operations have been performed as planned. Changes or deviations to any manufacturing process, method, procedure, equipment or tools shall be documented, reviewed and approved and the appropriate associates notified of the change.

Production Process Verification CMC shall use a representative item from the first production run (FAI) of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet customer’s requirements. This process shall be repeated when

changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

Production Planning and Scheduling personnel, in conjunction with the New Product Development Project Manager as applicable, are responsible for the generation of shop travelers/routers and for planning and controlling each manufacturing operation. Manufacturing Engineering and Support personnel (i.e. programmers) are responsible for planning and coordinating all programming activities. Manufacturing and Quality Assurance personnel are responsible for the verification of and compliance with the applicable specifications for all CMC products.

Changes to production processes shall be approved, including customer or regulatory approval where required by contract. These changes shall be reviewed for effectiveness.

A tool crib is maintained in order to control the purchase and use of machining fixtures and tools. Identification methods shall ensure the proper use and replacement of all items.

The tool crib attendant is responsible for controlling production tooling. All operators are responsible for production tooling in their areas. Production equipment, tools and CNC programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.

Storage requirements, including periodic preservation/condition checks, shall be defined for production equipment or tooling in storage. This shall be done during internal audit process.

Control of Production Process Changes

Personnel authorized to approve changes to production processes shall be identified.

CMC shall control and document changes affecting processes, production equipment, tools or software programs.

The results of changes to production processes shall be assessed to confirm that the desired effect has been achieved without adverse effects to product conformity. A new piece is generated and inspected.

Production Validation

A first article verification shall be performed for aerospace products in order to validate the production equipment being used. A First Article Report shall be documented and issued to the customer, where required by contract. A new first article report shall be done for changed products and for when previous inspections have been invalidated. When equipment used for production is transferred from a storage area, an inspection of the equipment shall be performed to ensure its suitability for manufacturing.

Outside Services - SUBCON

When product realization work is transferred outside the facility (SUBCON operation on the routing/router/traveler), an inspection of the product shall be performed as required by customer contract; stated Purchase Order requirements shall be verified by Quality Assurance per the routing/router/traveler prior to

incorporation into CMC products.

Qualified Personnel

There may be some special processes performed during the creation of aerospace products. Special processes are those which are difficult to detect the quality via normal inspection, for example brazing or welding. A special process certification shall be attained for personnel who are performing these functions within CMC. The proper training shall help ensure that all significant operations are done properly, and that defined parameters are adhered to.

A job description shall be created for each employee who performs tasks which impact product quality. Training records shall be in place which provides evidence that each employee is qualified to perform the processes to which they are assigned and are familiar with the relevant procedures.

Internal audits shall be used to ensure the validity of and employee compliance with process instructions. Quality Assurance and customer return data shall be evaluated in order to provide the information needed to take corrective action for product or process deficiencies.

All processes within CMC manufacturing which are considered special processes are performed by qualified personnel or approved subcontractors. Subcontractors who perform special processes shall be verified as having a suitable Quality Assurance System via a subcontractor survey. Certification (i.e. C of C) is required for all products processed by subcontractors. Stated Purchase Order requirements shall be verified by Quality Assurance per the routing/router/traveler prior to incorporation into CMC products.

CMC Foreign Object Detection Program

A program shall be established within CMC to prevent, detect, and remove foreign objects.

Post Delivery Support

Post-delivery support shall provide as applicable for the:

a) collection and analysis of in-service data
b) actions to be taken, including investigation and reporting, when problems are detected after delivery
c) control and updating of technical documentation
d) approval, control and use of repair schemes, and
e) controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).

Note: CMC takes an exclusion to items a,c,d,e

7.5.2 Validation of Processes for Production and Service Provision

NOTE: See CMC QSP-07 Inspection and Acceptance, QSP-12 Product Realization, QSP-16 Process Validation and QSP-24 Software Validation Procedures

Procedure(s) shall be established and maintained for acceptance activities including receiving, in-process, final inspection and final acceptance, implementation of product release, delivery, and post delivery activities.

CMC will support the documented requirements of medical device customers as required by contract.

Procedures shall be established and maintained to provide for the rework as necessary of nonconforming material, including components, subassemblies, and finished devices. All rework shall be performed in accordance with written instructions unless the rework is an obvious repetition or reversal of another documented process. Reworked material shall be identified as nonconforming and shall be segregated from conforming material until disposition, to prevent mix-up. The rework shall be documented on the forms controlling nonconforming material, on the device history record, or on a corrective action document.

Rework instructions shall identify any limitations on the amount or the nature of the rework. Procedures shall include re-testing and re-evaluation of the nonconforming material after rework to ensure that it meets its current approved specification. Rework and re-evaluation activities, including the determination of any adverse events from the rework on the product, shall be documented.

The Medical Device History Record (DHR) is a compilation of records containing the production history of a device or a batch of medical devices. CMC will support the documented requirements of medical device history records as required by contract.

A procedure shall be established and maintained to define the requirements for Process Validation. A special process is one in which the product quality characteristic cannot fully be verified in the finished product by inspection or testing. Any special processes shall be identified and validated.

Where computers or automated data processing systems are used as part of a manufacturing process or for any purpose in the quality management system, computer software shall be validated for its intended use. All software changes shall be validated before approval and use.

If a change is made to a process the process shall be revalidated as appropriate.

The key characteristics of aerospace products, as required shall be identified on drawings, Quality Reports, and work instructions. The methods for monitoring and control of these characteristics shall be defined on CMC's Process Control Plans (PCP).

7.5.3 Identification and Traceability

NOTE: See CMC QSP-12 Product Realization and QSP-23 Customer Returns Procedures

Materials shall be identified by material number and, as necessary, by status with respect to monitoring and measurement requirements, or by other appropriate method throughout all stages of product realization.

Material returned for rework or reprocessing shall be identified to distinguish them from normal production.

Where stipulated by contractual requirements, when traceability is required CMC shall control the unique identification of the product (devices and components) and maintain records. Records shall be maintained to provide traceability of all such items from the supplier, through manufacturing, and to finished goods items in order to facilitate corrective action. The responsibility for component traceability may be assigned to suppliers.

CMC shall ensure we are in compliance the Dodd-Frank Act on conflict materials. When required by the customer a certificate shall be sent to testify that our products do not contain any conflict minerals originating from or regionally near the Democratic Republic of Congo as defined by the Dodd-Frank Act. The Dodd-Frank act identifies Tantalum, Tin, Tungsten or Gold originating or mined from the Democratic Republic of Congo as conflict minerals.

CMC shall ensure we are in compliance with regard to the prevention of distributing counterfeit parts. Our policy is to buy all our products from reputable American manufacturers and distributors. When required by the customer, a certificate shall be sent to testify to the products origin and that our products do not contain any

parts deemed as counterfeit. Where required by an aerospace contract CMC shall be in compliance with AS 6174 for prevention of counterfeit materials.

7.5.4 Customer Property

Customer property shall be identified, verified and protected while it is in CMC's care. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the customer shall be notified and records maintained. Note: Customer property can include intellectual property and personal data.

7.5.5 Preservation of Product

NOTE: See CMC QSP-14 Material Preservation, QSP-22 ESD and QSP-27 FOD Procedures

Procedures and practices shall provide for the identification, handling, storage, cleaning, labeling, packaging, protection of materials and prevention, detection and removal of foreign objects while in the warehouse, production process, distribution, or servicing as applicable. These procedures shall also address shelf-life for products, special handling for any hazardous materials and any necessary special storage guidelines for sensitive product such as electrostatic sensitive components and products labeled as sterile.

The procedures for handling, storage and distribution preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. Any documentation required by the contract shall be attached to the product for delivery and are protected against loss or damage.

Product labels, package labeling, and user instructions shall be treated as components in document control, purchasing, and product validation.

Storage areas for finished devices shall be designed to prevent mix-up, damage, deterioration, or other adverse effects and to facilitate location and withdrawal for shipment. Finished goods shall be identified with a part number, at a minimum, to facilitate storage and withdrawal.

7.6 Control of Measuring Equipment

NOTE: See CMC QSP-06 Control and Calibration of Measurement & Test Equipment Procedure

All measuring equipment used to provide evidence of conformity to determined requirements shall be controlled to ensure that it is suitable for its intended use and to assure confidence in the measurements. These controls shall comprise, as appropriate, selection, qualification, identification, preservation, calibration, and corrective action and shall meet requirements of international standards on quality assurance requirements for measuring equipment. This shall include any such items that are owned by another organization or by a CMC associate. Any custom software shall be verified and the associated measurement system shall be validated.

Measuring equipment shall be qualified to establish that it is suitable for its intended use. When computer software is used to monitor or measure specified requirements, the ability of the computer software to satisfy the intended application shall be confirmed prior to initial use at appropriate stages as necessary to satisfy the intended application. The quality plan for development of a new product or implementation of a new process shall include consideration of measuring equipment selection and qualification. Any custom software shall be verified and the associated measurement system shall be validated.

Measuring equipment shall be handled, transported, stored, and maintained in a manner to preserve its accuracy and fitness for use. When necessary, measuring equipment shall be maintained, calibrated, and used in a controlled environment. Measuring equipment shall be protected from any adjustments, software changes, or tampering that would adversely affect its accuracy or invalidate the measurement results.

Processes shall be established to provide for the inspection, maintenance, adjustment and re-adjustment, as necessary, of measuring equipment at periodic intervals to ensure that it meets the intended accuracy and precision. Equipment calibration status shall be identified.

Calibration standards shall be used for inspection, measuring and test procedures. If national or international standards are not available, CMC shall use an independent reproducible standard. In the event that no applicable standard is available, CMC shall establish and maintain an in-house standard. Calibration procedures ensure that environmental conditions are suitable and specified, if appropriate.
Equipment calibration records shall include: equipment identification, calibration dates, the individual performing each calibration and the next due date. Calibration records shall be displayed on or near each piece of equipment or readily available to the individual using or calibrating the equipment.

8.0 Measurement, Analysis and Improvement

8.1 General

CMC shall utilize measurement, analysis and improvement to demonstrate conformity of product, ensure the conformity, maintain effectiveness and continually improve the Quality Management System.

8.2 Monitoring and Measurement

8.2.1 Feedback

NOTE: See CMC QSP-13 Customer Complaints Procedure

Information relating to customer perception will be routinely gathered during customer visits and customer service calls to determine if CMC is meeting customer requirements. If this information indicates that requirements are not being met, corrective or preventive action will be initiated as necessary.

8.2.2 Internal Audit

NOTE: See CMC QSP-08 Quality Audit Procedure

Internal quality audits shall be conducted at planned intervals to ensure that all aspects of the quality management system are effectively implemented and maintained and to identify areas for improvement. Procedures provide for the performance of audits at planned intervals based on the status and importance of the activity and results of previous audits. Note: When determining suitable methods, CMC considers the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.3 Monitoring and Measurement of Processes

NOTE: See CMC QSP-07 Inspection and Acceptance and QSP-16 Process Validation Procedures

Product inspections are performed at CMC in accordance with 8.2.4 outlined below. Special processes are all performed by CMC and qualified subcontractors. When process nonconformities are found action shall be taken, including the review of any products created using the nonconforming process.

In the event of process nonconformity, CMC shall:

- Take appropriate action to correct the nonconforming process,
- Evaluate whether the process nonconformity has resulted in product nonconformity,

- Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
- Identify and control any nonconforming product (see Section 8.3).

8.2.4 Monitoring and Measurement of Product

NOTE: See CMC QSP-07 Inspection and Acceptance, QSP-10 Non-Conforming Material Handling and QSP-23 Customer Returns Procedure

CMC inspection methods are planned and implemented to ensure that products are manufactured in accordance with all internal and customer requirements. All inspection operations for products are performed by CMC personnel and/or qualified subcontractors.

Quality Procedures and CMC Work Instructions shall be used as guidelines to all inspections performed at CMC. Products are inspected at described intervals to ensure all shipped products meet all customer specifications; inspection requirements are defined on the Shop Traveler.

Procedures shall govern all incoming, in-process, final inspection and returned material evaluation activities. Inspection results are considered Quality Records and shall be maintained per CMC's Quality Record Procedure.

Measurement requirements for product acceptance shall be documented and include:

- Criteria for acceptance and/or rejection
- Where in the sequence measurement and testing operations are to be performed
- Required records of the measurement results (at a minimum, indication of acceptance or rejection) any specific measurement instruments required
- Any specific instructions associated with their use.

When critical items, including key characteristics, have been identified, CMC shall ensure they are controlled and monitored in accordance with the established processes.

When CMC uses sampling inspection as a means of product acceptance, the sampling plan shall be justified on the basis of recognized statistical principles and appropriate for use (i.e. matching the sampling plan to the criticality of the product and to the process capability). A Zero Acceptance Sampling Plan shall be used.

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Where required to demonstrate product qualification, CMC shall ensure that records provide evidence that the product meets the defined requirements.

CMC shall ensure that all documents required to accompany the product per customer contract are present at delivery.

Incoming Inspection

Incoming inspection/review (i.e. Receiving) is performed for all parts and raw materials received which are intended for production use. The items received shall be compared to the Purchase Order. Each lot shall be inspected for damage, correct identification and marking. Supplier counts are accepted. Raw materials are inspected to ensure they are the proper grade and that appropriate material certification(s) is received. Manufacturer labels describing hardware counts are accepted as correct.

Additional quality inspections (i.e. dimensional, documentation, etc.), as required by the Purchase Order, shall be performed as required.

When incoming inspection results in rejected parts or materials a Non-Conforming Material Report (NCMR) will be completed and a copy shall remain with the parts describing the product rejection. The form is also used for documenting the rejection of customer-supplied parts or materials.

Inspection

When required by the Shop Traveler, the first article produced from each machine or assembly operation shall be inspected for all dimensions to ensure the accuracy of the setup. A First Article Report shall be documented and issued to the customer, where required by contract. A new first article report shall be done for changed products and for when previous inspections have been invalidated.

During the manufacturing process, parts shall be checked periodically to ensure all machine settings are correct. The frequency of the inspections shall be determined by the following factors: lot quantity, part complexity, and the run time of each part. If an out of tolerance condition is found during an in-process inspection, the operation shall be temporarily stopped and corrections to the machine or setup initiated immediately. Quality Department personnel shall be contacted to assist, if applicable, with inspecting the parts run up to that point from the time of the last inspection in order to determine how many parts are in error.

When sampling methods are use, they shall preclude the acceptance of known nonconformities. When required by contract, sampling plans shall be submitted to the customer for approval.

Pre and Post sub-vendor process (i.e. plate, coat, etc.) inspections are performed per the Shop Traveler to confirm that the product meets customer specifications and workmanship standards. The correct special process certification is verified as complete.

When final inspections are performed for completed parts prior to shipment to customers, it shall be done as outlined on the Shop Traveler.

When sampling is used, zero rejection is the acceptance number on all samples taken.

All documentation required to be shipped to the customer with the parts shall be verified as ready for shipment. Upon completion of final inspection, the Shop Traveler step shall be annotated as completed.

Defects found shall be identified per documented Non-Conforming Material Report (NCMR) procedure.

Key Characteristics

The key characteristics of aerospace/medical products shall be identified on the drawing and PCP form as required. The methods for monitoring and control of these characteristics shall be defined.

8.3 Control of Nonconforming Product

NOTE: See CMC QSP-10 Non-Conforming Material Handling Procedure

A procedure shall be established and maintained to provide for the identification of nonconforming material and prevent its inadvertent use or delivery, including reviews and controls over products that are not yet distributed and those already distributed. All nonconforming material shall be clearly identified and appropriately segregated from acceptable material. In the event of a process nonconformity, CMC shall determine whether the product was affected and if so, disposition the product per the requirements of this action. Further, action shall be taken to correct the process nonconformity.

For customer designed aerospace products, special dispositions must be done by the customer. All nonconforming aerospace product which cannot be reworked to the drawing shall be submitted to the customer for review, where required by contract.

The CMC documented procedure shall define the responsibility and authority for the review and disposition of nonconforming product, and the process for approving personnel making these decisions.

The CMC nonconforming product control process shall provide for timely review and disposition. CMC Leadership is responsible for taking actions necessary to contain the effect of the nonconformity on other processes or products.

NOTE: Parties requiring notification of nonconforming product can include suppliers, internal organizations, customers, distributors and regulatory authorities.

CMC shall not use dispositions of use-as-is or repair for aerospace projects, unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

Aerospace product disposition for scrap shall be conspicuously and permanently marked, or positively controlled, and physically rendered unusable.

8.4 Analysis of Data

Appropriate data related to customer satisfaction, conformity to product requirements, corrective and preventive action and suppliers shall be collected, maintained and reported for the purposes of management review. (See section 5.6.)

Statistical techniques shall be identified, developed, and used to draw inferences from data when establishing, controlling, and verifying evaluations of product characteristics and manufacturing processes and customer feedback.

When appropriate, procedures shall be established and maintained to identify and provide for appropriate use of statistical techniques in those cases where required for measurement, evaluation, and improvement, and for effective implementation of the quality management system.

8.5 Improvement

NOTE: See CMC QSP-09 Corrective and Preventive Actions Procedure

CMC shall use the evaluations and measurement processes of the QMS to continually improve the effectiveness and adequacy of the system through the use of the quality policy, quality objectives, audit results, analysis of data corrective and preventive actions, customer feedback and management review.

Corrective and preventive action (CAPA) procedures shall be documented and maintained to ensure that the causes or potential causes of nonconforming product, material or processes are identified, evaluated, documented, and corrected, to prevent recurrence of the problem or to prevent the problem from initially occurring. Provisions shall be made for review and control of products that may be nonconforming, including those distributed and those not yet distributed.

The corrective action processes shall provide a systematic, problem-solving approach to continuous quality improvement with the primary objective of determining and eliminating all causes of nonconforming product, material, and processes. The preventive action process shall help prevent the occurrence of nonconforming material, product, and conditions by identifying, analyzing, and eliminating potential quality problems, and analyzing and trending information on quality. Identified quality problems and the status and effectiveness of corrective and preventive actions shall be reported as part of Management Review.

The corrective and preventive action process shall include the analysis and investigation of the causes of nonconforming material, product, and conditions. The process shall also provide for identifying, documenting, evaluating the need for action to prevent recurrence of the issue, determination and implementation of necessary actions and records of the results of the actions taken.

Any containment actions required related to the nonconformance shall be documented. A deadline (CAPA due date) of thirty days shall be used as a guideline to answer (investigate, root cause, action plan) a corrective and preventive action. A guideline of 90 days shall be used to confirm action plans are complete and effectiveness verified (CAPA closed date); no CAPA shall be closed until all actions have been properly achieved. Extensions to these guidelines may be given by the Quality Leadership.

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8	6/10/10	D Kaminski	1110
9	7/6/11	A. Lehto	1598
10	4/12/12	D. Meteny	2264
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