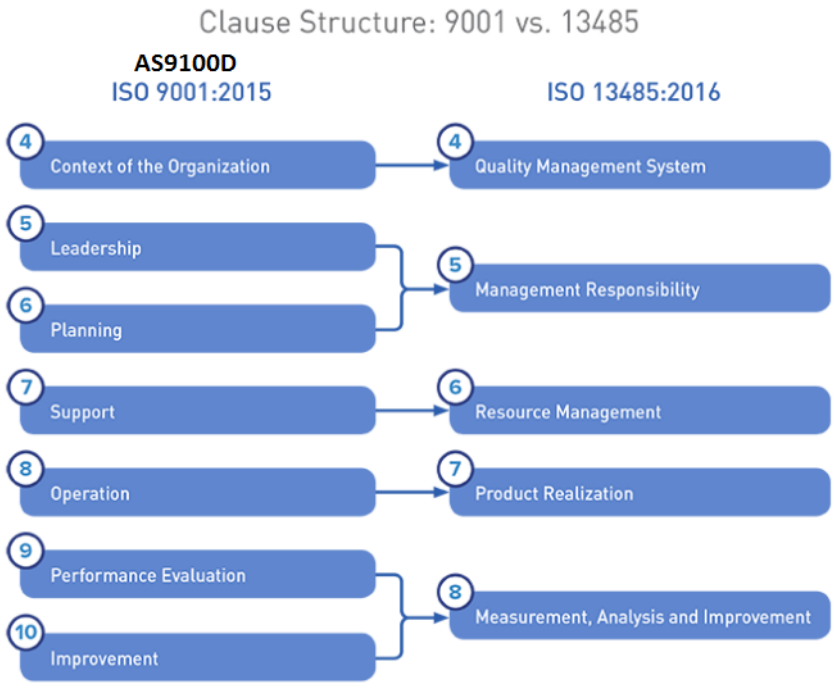
Cygnus Manufacturing Co.
Saxonburg, Pennsylvania
Quality Management System Manual

TABLE OF CONTENTS:

1. Scope

This section is intended to describe the scope of CMC's Quality Management System (QMS). Subsequent sections describe the QMS and the elements of the system and set policies to be met by the organization. This quality management system and this quality manual apply to the operations of Cygnus Manufacturing Company LLC (CMC), 491 Chantler Drive, Victory Road Business Park; Saxonburg, PA.

In that CMC's QMS covers multiple Standards, the visual comparison below illustrates the Table of Contents structure and how CMC's Quality Manual is organized:



Source: Oriel STAT A MATRIX
http://www.orielstat.com/blog/alignment-of-iso-9001-2015-and-iso-13485-2016/

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 9001:2015, Quality management systems – Requirements
- ISO 13485:2016, Medical devices - Quality management systems - Requirements for regulatory purposes
- AS 9100D, Aerospace - Quality management systems - Requirements
- Not Applicable:

4.2.3	(ISO 13485) Medical device file
7.3	(ISO 13485) Design and Development
7.5.3	(ISO 13485) Installation activities
7.5.4	(ISO 13485) Servicing activities
7.5.5	(ISO 13485) Particular requirements for sterile medical devices
7.5.7	(ISO 13485) Particular requirements for validation of processes for sterilization and sterile barrier systems
7.5.9.2	(ISO 13485) Particular requirements for implantable medical devices
8.3	(AS9100) Design and Development of Products and Services

2. Normative References

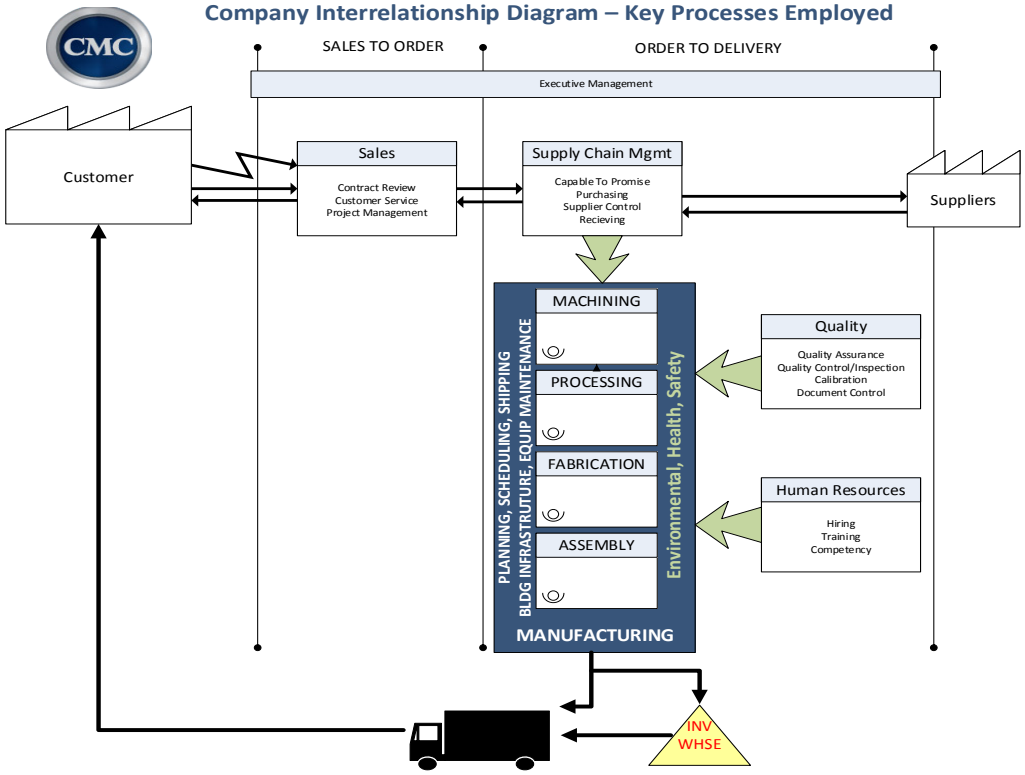
Refer to ISO 9001:2015, AS9100D and ISO 13485:2016 Standards.

3. Terms and Definitions

Refer to ISO 9001:2015, AS9100D and ISO 13485:2016 Standards.

A. Context of the Organization (AS9100D/2016, Section 4) AND Quality Management System (ISO 13485:2016, Section 4)

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



A.1. AS9100D/2016, Section 4.1, Understanding CMC and Its Context

Refer to the following CMC Procedures: QSP-18 Quality Management Review

CMC shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of our quality management system. CMC shall monitor and review information about these external and internal issues. During Management Review process these issues are discussed - Issues can include positive and negative factors or conditions for consideration. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, and economic environments, whether international, national, or local. Understanding the internal considering issues related to values, culture, knowledge, and performance of CMC - this shall be part of our human resources performance appraisal process.

A.2. AS9100D/2016, Section 4.2, Understanding the Needs and Expectations of Interested Parties

Refer to the following CMC Procedures: QSP-18 Quality Management Review

Due to their effect or potential effect on CMC's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, CMC shall determine:

- The interested parties that are relevant to the quality management system;
- The requirements of these interested parties that are relevant to the quality management system.

Interested parties for CMC are maintained in CMC's Quality Management Review procedure. CMC shall monitor and review information about these interested parties and their relevant requirements; this review is conducted during CMC's Quality Management Review.

A.3. AS9100D/2016, Section 4.3, Determining the Scope of the Quality Management System

CMC shall determine the boundaries and applicability of the quality management system

- the external and internal issues referred to in A.1;
- the requirements of relevant interested parties referred to in A.2;
- the products and services of CMC.

This quality manual and the quality management system described within apply. CMC's scope is "Manufacturer of precision machined components, electro-mechanical assemblies and fabrications; and manufacturing technical assistant to customers supplied specifications". Only those requirements of the Standard are applied if they are applicable. Standard Clause 8.3 "Design and Development of Products and Services" are not applicable to CMC, as CMC customers have responsibility to establish, implement and maintain design and development processes.

A.4. AS9100D/2016, Section 4.4, Quality Management System and Its Processes

Refer to the following CMC Procedures: QSP-18 Quality Management Review, QSP-08 Quality Audits

CMC shall establish, implement, maintain, and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of the Standard. CMC's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

CMC shall determine the processes needed for the quality management system and their application throughout CMC, and shall:

- Determine the inputs required and the outputs expected from these processes (Mgmt Review);
- Determine the sequence and interaction of these processes (Interrelationship Diagram/Mgmt Review);
- Determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes (Quality Audit);
- Determine the resources needed for these processes and ensure their availability (Mgmt Reivew);
- Assign the responsibilities and authorities for these processes (CMC ORG Chart);
- Address the risks and opportunities as determined in accordance with the requirements (Mgmt Review).

During Management Review there shall be an overall review of risks and opportunities

- Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; Each process shall be reviewed during the CMC internal quality audit process.
- Improve the processes and the quality management system. Improvements shall be documented and reviewed during Management Review process

To the extent necessary, CMC shall:

- Maintain documented information to support the operation of its processes;
- Retain documented information to have confidence that the processes are being carried out as planned.

CMC shall establish and maintain documented information that includes:

- a general description of relevant interested parties;
- the scope of the quality management system, including boundaries and applicability
- a description of the processes needed for the quality management system and their application throughout CMC; refer to CMC's Company Interrelationship Diagram – Key Processes Employed
- the sequence and interaction of these processes; refer to CMC's Company Interrelationship Diagram – Key Processes Employed
- assignment of the responsibilities and authorities for these processes.

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.

NOTE: The above description of the quality management system has been in our quality manual. References are included in this manual to CMC Quality Procedures that apply to the process.

A.5. ISO 13485:2016, Section 4.1, General Requirements

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-02 Quality Records, QSP-03 Competence, Training and Awareness, QSP-04 Purchasing, QSP-07 Inspection and Acceptance, QSP-08 Quality Audits, QSP-12 Product Realization, QSP-16 Process Validation, QSP-18 Quality Management Review, QSP-24 Software Validation, QSP- 26 Risk Management

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 products 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.

A.6. ISO 13485:2016, Section 4.2, Documentation Requirements

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-02 Quality Records

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.

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 evaluation of products that are customer-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.

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;
- 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.

B. Leadership (AS9100D/2016, Section 5) AND Planning (AS9100D/2016, Section 6) AND Management Responsibility (ISO 13485:2016, Section 5)

B.1. AS9100D/2016, Section 5.1, Leadership and Commitment

Refer to the following CMC Procedures: QSP-08 Quality Audits, QSP-18 Quality Management Review, QSP- 26 Risk Management

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

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

These criteria are verified during CMC Management Review and internal quality audit process.

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- Customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
- the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed.
- the focus on enhancing customer satisfaction is maintained;
- product and service conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

CMC shall provide for the metrics to measure our quality and on time delivery performance. This shall be reviewed during Management Review process.

B.2. AS9100D/2016, Section 5.2, Policy AND ISO 13485:2016, Section 5.3, 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 and postings (hard copy and electronically). It is periodically presented at company-wide/organization meetings.

B.3. AS9100D/2016, Section 5.3, Organizational Roles, Responsibilities and Authorities

Refer to the following CMC Procedures: QSP-03 Competence, Training and Awareness, QSP-18 Quality Management Review, QSP- 26 Risk Management

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within CMC. An approved job description shall be in place for all employees.

Top management shall assign the responsibility and authority for:

- Ensuring that the quality management system conforms to the requirements of the Standard;
- Ensuring that the processes are delivering their intended outputs;
- Reporting on the performance of the quality management system and on opportunities for improvement
- Ensuring the promotion of customer focus throughout CMC;
- Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

Top management shall appoint a specific team member, identified as the management representative, who shall have the responsibility and authority for oversight of the above requirements.

The management representative shall have the freedom and unrestricted access to top management to resolve quality management issues.

B.4. AS9100D/2016, Section 6.1, Actions to Address Risks and Opportunities

Refer to the following CMC Procedures: QSP- 26 Risk Management

When planning for the quality management system, CMC shall consider the issues and requirements to determine the risks and opportunities that need to be addressed to:

- Give assurance that the quality management system can achieve its intended result(s);
- Enhance desirable effects;
- Prevent, or reduce undesired effects;
- Achieve improvement.

CMC shall plan:

- Actions to address these risks and opportunities;
- How to:
    - integrate and implement the actions into its quality management system processes;
    - evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.

B.5. AS9100D/2016, Section 6.2, Quality Objectives and Planning to Achieve Them

Refer to the following CMC Procedures: QSP-18 Quality Management Review

CMC shall establish quality objectives at for each primary process identified in our quality management system.

CMC quality objectives shall:

- be consistent with the quality policy;
- be measurable;
- take into account applicable requirements;
- be relevant to conformity of products and services and to enhancement of customer satisfaction;
- be monitored;
- be communicated;
- be updated, as appropriate.

Quality Objectives are established and monitored during CMC Management Review process.

CMC shall maintain documented information on the quality objectives.

When planning how to achieve its quality objectives, CMC shall determine:

- what will be done;
- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated

B.6. AS9100D/2016, Section 6.3, Planning of Changes

Refer to the following CMC Procedures: QSP-18 Quality Management Review

When CMC determines the need for changes to the quality management system, the changes shall be carried out in a planned manner. CMC shall consider:

- the purpose of the changes and their potential consequences;
- the integrity of the quality management system;
- the availability of resources;
- the allocation or reallocation of responsibilities and authorities.

Changes made to the CMC quality management system shall be reviewed by top management and described in Management Review minutes.

B.7. ISO 13485:2016, Section 5.1, Management Commitment AND Section 5.2, Customer Focus

Refer to the following CMC Procedures: QSP-12 Product Realization, QSP-18 Quality Management Review, QSP-13 Customer Complaints and Customer Feedback

Executive Management shall demonstrate a commitment to the establishment, maintenance, and continuing improvement of the quality management system by:

- Communicating the importance of meeting customer, regulatory and statutory requirements
- Establishing and communicating a quality policy
- Establishing and evaluating quality objectives
- Conducting regular Management Reviews
- Ensuring the availability of resources
- Customer requirements and applicable regulatory requirements are determined and met

B.8. ISO 13485:2016, Section 5.4, Planning

Refer to the following CMC Procedures: QSP-18 Quality Management Review

Measurable quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, shall be established. These objectives shall be consistent with the quality policy.

Management shall ensure the planning of the quality management system (QMS) is carried out to meet requirements, as well as quality objectives, and for any changes to the quality management system to maintain the integrity of the QMS. Where appropriate, this planning shall be documented in the form of a quality plan.

B.9. ISO 13485:2016, Section 5.5, Responsibility, Authority and Communication

Refer to the following CMC Procedures: QSP-03 Competence, Training and Awareness, QSP-07 Inspection and Acceptance

Responsibilities and authorities are defined, documented and communicated via individual job descriptions. CMC maintains an Organization Chart to describe the organizational structure of the organization. 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.

A Management Representative shall be appointed who has 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
- Reports regarding the compliance and performance (including effectiveness and need for improvement) 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

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.

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, organizational/employee meetings, paycheck attachments, and CMC's intranet site.

B.10. ISO 13485:2016, Section 5.6, Management Review

Refer to the following CMC Procedures: QSP-18 Quality Management Review

Executive Management shall formally review and assess the suitability and effectiveness of the quality management system in planned Management Review meetings. During Management Review meetings, the management team shall review inputs and outputs (see below), including review of the quality policy.

Management Review inputs shall include the following as applicable:

- Previous Management Reviews: Status of identified actions/Follow-up actions

- Audits: Internal and external quality audits
- Nonconformites, Corrective Action, and Preventive Action
- Customer satisfaction and Feedback
- Reporting to Regulatory Authorities
- Quality Objectives, including Process performance and Product Conformity
- On-Time Delivery
- External Provider Performance
- Monitory and Measurement Results, of processes and of product
- Changes that could affect the QMS, inclusive of regulatory requirements, external conditions/requirements and/or internal infrastructure
- Improvement: recommendations

Management Review outputs shall include the following as applicable:

- Improvement: Opportunities and recommendations, including product related
- Resource Adequacy & Needs: Equipment and personnel
- Changes: Need for changes to the QMS
- Risk and Opportunities

Records of Management Review shall be maintained.

C. Support (AS9100D/2016, Section 7) AND Resource Management (ISO 13485:2016, Section 6)

C.1. AS9100D/2016, Section 7.1, Resources

Resources-General

Refer to the following CMC Procedures: QSP-18 Quality Management Review

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.

Resources-People

Refer to the following CMC Procedures: QSP-03 Competence, Training and Awareness, QSP-18 Quality Management Review

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.

Resources-Infrastructure & Environment for the Operation of Processes
Refer to the following CMC Procedures: QSP-02 Quality Records, QSP-03 Competence, Training and Awareness, QSP-19 Machine Maintenance, QSP-22 ESD Protection, QSP-24 Software Validation, QSP-27 Foreign Object Detection

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 products 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 product 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

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 assemblies 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 contamination. Each associate shall be responsible to help maintain a clean and safe work environment CMC has established, and will maintain, a work environment and organizational structure that is conducive to achieving the quality objectives and producing products that conform to all customer requirements. This will be done by providing a safe and ergonomic work environment as well as providing any and all training necessary to all levels of employees. CMC management must first approve any non-standard test method(s) requested by the customer. Specific requirement for the work environment for aviation, space and defense products shall be described on the Work Order and shall be adhered to.

CMC works to ensure a suitable environment is in place through a combination of human and physical factors, such as:

- social (e.g., non-discriminatory, calm, non-confrontational);
- psychological (e.g., stress-reducing, burnout prevention, emotionally protective);
- physical (e.g., temperature, heat, humidity, light, airflow, hygiene, noise).

Resources-Monitoring and Measuring

Refer to the following CMC Procedures: QSP-06 Control and Calibration of Measurement & Test Equipment

CMC shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

CMC shall ensure that the resources provided:

- are suitable for the specific type of monitoring and measurement activities being undertaken;
- are maintained to ensure their continuing fitness for their purpose.

CMC shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. All employees have an approved job description and training files to document their competence and where applicable, their measurement abilities.

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.

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 during the instrument calibration process. The quality plan for development of a new product or implementation of a new process shall include consideration of measuring equipment selection and qualification.

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.

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.

Resources-Organizational Knowledge

Refer to the following CMC Procedures: QSP-03 Competence, Training and Awareness

CMC shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge shall be maintained and be made available to the extent necessary.

When addressing changing needs and trends, CMC shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.

NOTE: Organizational knowledge is knowledge specific to CMC; it is generally gained by experience. It is information that is used and shared to achieve CMC's objectives.

NOTE: Organizational knowledge can be based on:

- internal sources (e.g., intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);
- external sources (e.g., standards; academia; conferences; gathering knowledge from customers or external providers)

At CMC, Operational Knowledge is captured in company job descriptions, training sessions, and employee appraisal process.

C.2. AS9100D/2016, Section 7.2, Competence

Refer to the following CMC Procedures: QSP-03 Competence, Training and Awareness

CMC shall:

- determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- ensure that these persons are competent on the basis of appropriate education, training, and/or experience;
- where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- retain appropriate documented information as evidence of competence.

CMC has a documented employee evaluation/appraisal process which includes an evaluation of their effectiveness.

C.3. AS9100D/2016, Section 7.3, Awareness

Refer to the following CMC Procedures: QSP-03 Competence, Training and Awareness

CMC shall ensure that persons doing work under CMC's control are aware of:

- the quality policy;
- relevant quality objectives;
- their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- the implications of not conforming with the quality management system requirements;
- relevant quality management system documented information and changes thereto;
- their contribution to product or service conformity;
- their contribution to product safety;
- the importance of ethical behavior.

These subjects are all covered during CMC's annual Quality Management System training.

Safety aspects are covered via company safety program. Ethical behavior is also stressed during the employee evaluation/appraisal process.

C.4. AS9100D/2016, Section 7.4, Communication

CMC shall determine the internal and external communications relevant to the quality management system. Meetings and emails are the primary communications tools. Technical data communications include communications with our suppliers and customer.

Communication can include specific internal and external feedback via customer surveys and employee appraisal / training related to the program.

C.5. AS9100D/2016, Section 7.5, Documented Information

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-02 Quality Records

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 evaluation of products that are customer-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.

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;
- specification 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. 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.

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.

Documented information of external origin determined by CMC to be necessary for the planning and operation of the quality management system shall be identified, and reviewed each year to ensure correct versions are available.

Documented information retained as evidence of conformity shall be protected from unintended alterations. When documented information is managed electronically, data protection processes shall be defined (e.g., protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

CMC ensures access to view the documented information only. Authority to change the documented information is controlled.

C.6. ISO 13485:2016, Section 6.1, Provision of Resources

Refer to the following CMC Procedures: QSP-03 Competence, QSP-07 Inspection and Acceptance, Training and Awareness, QSP-18 Quality Management Review

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.

C.7. ISO 13485:2016, Section 6.2, Human Resources

Refer to the following CMC Procedures: QSP-03 Competence, Training and Awareness, QSP-07 Inspection and Acceptance

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. 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.

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

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

C.8. ISO 13485:2016, Section 6.3, Infrastructure

Refer to the following CMC Procedures: QSP-02 Quality Records, QSP-12 Product Realization, QSP-19 Machine Maintenance, QSP-22 ESD Protection, QSP-24 Software Validation

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

- Buildings, workspace and associated utilities
- Process equipment (both hardware and software), and
- Supporting services (such as transport or communication).

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.

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. Periodic back-up of programs and records shall ensure secure and reliable operation of computer-related systems.

C.9. ISO 13485:2016, Section 6.4, Work Environment and Contamination Control

Refer to the following CMC Procedures: QSP-22 ESD Protection, QSP-27 Foreign Object Detection

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

All manufacturing processes shall be carried out under controlled conditions, including adequate buildings, process equipment, working conditions, and personnel, to ensure that all products 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.

Components and assemblies 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 contamination. Each associate shall be responsible to help maintain a clean and safe work environment. A suitable pest control program shall be established.

D. Operation (AS9100D/2016, Section 8) AND Product Realization (ISO 13485:2016, Section 7)

D.1. AS9100D/2016, Section 8.1, Operational Planning and Control

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-07 Inspection and Acceptance, QSP-11 Production Control, QSP-12 Product Realization, QSP-14 Material Preservation, QSP-26 Risk Management, QSP-27 Foreign Object Detection

When planning each project CMC shall determine requirements for the products during contract review and job traveler package creation (Quality Planning) which include, where applicable:

- personal and product safety
  * At CMC personal and product safety are addressed - a safety committee is established and customers are alerted as to product safety via shipping documentation
- produce ability and inspect ability;
- reliability, availability, and maintainability;
- suitability of parts and materials used in the product;
- selection and development of embedded software;
- product obsolescence;
- prevention, detection, and removal of foreign objects;
- handling, packaging, and preservation;
- recycling or final disposal of the product at the end of its life.

Test and inspection, and workmanship criteria shall be included in the job traveler package; this provides objective evidence that production processes are controlled and the acceptance criteria for products is followed.

Some process control methods employed at CMC are:

- Product verification (e.g., reliability, maintainability, product safety);
- Production process control; (traveler process)
- Selection and verification of key characteristics; (inspection processes)
- Failure mode, effects, and analysis

Determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services;

Implementing control of the processes in accordance with the criteria;

Determining, maintaining, and retaining documented information to the extent necessary:

- to have confidence that the processes have been carried out as planned;
- to demonstrate the conformity of products and services to their requirements;

Determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified;

Engaging representatives of affected organization functions for operational planning and control;

Determining the process and resources to support the use and maintenance of the products and services;

Determining the products and services to be obtained from external providers;

Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

As appropriate to CMC, customer requirements, and products and services, CMC shall plan and manage product and service provision in a structured and controlled manner including scheduled events performed in a planned sequence to meet requirements at acceptable risk, within resource and schedule constraints.

Contract/Customer Order Planning is done for each new customer purchase order (e.g. Product Realization Process/PRP). The Job Order Packet generated details all job requirements. The output of this planning shall be suitable for CMC's operations.

CMC shall have a Company Interrelationship Diagram – Key Processes Employed and in specific procedures in place to describe the quality management system.

CMC shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. An document control change process is in place to ensure no unintended changes are ever made.

CMC shall ensure that outsourced processes are controlled (see Section D.4 Below).

CMC shall establish, implement, and maintain a process to plan and control the temporary or permanent transfer of work, to ensure the continuing conformity of the work to requirements. The process shall ensure that work transfer impacts and risks are managed. All work transfers are described in the job order Traveler.

Operational Risk Management
Refer to the following CMC Procedures: QSP-26 Risk Management

CMC shall plan, implement, and control a process for managing operational risks to the achievement of applicable requirements, which includes as appropriate to CMC and the products and services:

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

NOTE: Within the aviation, space, and defense industry, risk is generally expressed in terms of the likelihood of occurrence and the severity of the consequences.

Configuration Management
Refer to the following CMC Procedures: QSP-28 Configuration Management

CMC shall plan, implement, and control a process for configuration management as appropriate to CMC and its products and services in order to ensure the identification and control of physical and functional attributes throughout the product life cycle.

This process shall:

- control product identity and traceability to requirements, including the implementation of identified changes;
- ensures that the documented information (e.g., requirements, qualification, and acceptance documentation) is consistent with the actual attributes of the products and services.

Product Safety

CMC shall plan, implement, and control the processes needed to assure product safety during the entire product life cycle, as appropriate to CMC and the product.

- assessment of hazards and management of associated risks;
- management of safety critical items;
- analysis and reporting of occurred events affecting safety; and,
- communication of these events and training of persons.

At CMC personal and product safety are addressed. A safety committee is established and customers are alerted as to product safety via shipping documentation.

Prevention of Counterfeit Parts

Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-07 Inspection and Acceptance, QSP-13 Customer Complaints and Customer Feedback

CMC shall plan, implement, and control processes, appropriate to CMC and the product, for the prevention of counterfeit or suspect counterfeit part use and their inclusion in product(s) delivered to the customer.

NOTE: Counterfeit part prevention processes at CMC shall consider:

- training of appropriate persons in the awareness and prevention of counterfeit parts;
- application of a parts obsolescence monitoring program;
- controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources;
- requirements for assuring traceability of parts and components to their original or authorized manufacturers;
- verification and test methodologies to detect counterfeit parts;
- monitoring of counterfeit parts reporting from external sources;
- quarantine and reporting of suspect or detected counterfeit parts.

D.2. AS9100D/2016, Section 8.2, Requirements for Products and Services

Customer Communication

Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-12 Product Realization, QSP-13 Customer Complaints and Customer Feedback, QSP-23 Customer Returns

Customer Communication Communications with customers shall include:

- providing information relating to products and services;

- handling enquiries, contracts, or orders, including changes;
- obtaining customer feedback relating to products and services, including customer complaints;
- handling or controlling customer property;
- establishing specific requirements for contingency actions, when relevant.

Determining the Requirements for Products and Services

Refer to the following CMC Procedures: QSP-11 Production Control, QSP-12 Product Realization, QSP-26 Risk Management

When determining the requirements for the products and services to be offered to customers, CMC shall ensure that:

- the requirements for the products and services are defined, including:
  - any applicable statutory and regulatory requirements;
  - those considered necessary by CMC;
- CMC can meet the claims for the products and services it offers;
- special requirements of the products and services are determined;
- operational risks (e.g., new technology, ability and capacity to provide short delivery timeframe) have been identified.

Review of the & Changes to Requirements for Products and Services

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-11 Production Control, QSP-12 Product Realization, QSP-16 Process Validation, QSP-26 Risk Management

CMC shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. CMC shall conduct a review before committing to supply products and services to the customer, to include:

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 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.

CMC shall retain documented information, as applicable:
- on the results of the review;
- on any new requirements for the products and services.

CMC shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

D.3. AS9100D/2016, Section 8.3, Design and Development of Products and Services

CMC's scope is "Manufacturer of precision machined components, electro-mechanical assemblies and fabrications; and manufacturing technical assistant to customers supplied specifications". Standard Clause 8.3 "Design and Development of Products and Services" are not applicable to CMC, as CMC customers have responsibility to establish, implement and maintain design and development processes.

D.4. AS9100D/2016, Section 8.4, Control of Externally Provided Processes, Products, and Services

Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-07 Inspection and Acceptance, QSP-10 Non-Conforming Material Handling, QSP-12 Product Realization

CMC shall ensure that externally provided processes, products, and services conform to requirements.

CMC shall be responsible for the conformity of all externally provided processes, products, and services, including from sources defined by the customer.

CMC shall ensure, when required, that customer-designated or approved external providers, including process sources (e.g., special processes), are used.

CMC shall identify and manage the risks associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

CMC shall require that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.
CMC shall determine the controls to be applied to externally provided processes, products, and services when:
- products and services from external providers are intended for incorporation into CMC's own products and services;
- products and services are provided directly to the customer(s) by external providers on behalf of CMC;
- a process, or part of a process, is provided by an external provider as a result of a decision by CMC.

CMC shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. CMC shall retain documented information of these activities and any necessary actions arising from the evaluations.

CMC shall:

- defines the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
- maintain a register of its external providers that includes approval status (e.g., approved, condition, disapproved and the scope of the approval (e.g., product type, process family);
- periodically review external provider performance including process, product and service conformity, and on- time delivery performance;
- define the necessary actions to take when dealing with external providers that do not meet requirements;
- defines the requirements for controlling documented information created by and/or retained by external providers.

CMC shall ensure that externally provided processes, products, and services do not adversely affect CMC's ability to consistently deliver conforming products and services to its customers.

CMC shall:

- Ensure that externally provided processes remain within the control of its quality management system;
- define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- take into consideration:
  - the potential impact of the externally provided processes, products, and services on CMC's ability to consistently meet customer and applicable statutory and regulatory requirements;
  - the effectiveness of the controls applied by the external provider;
  - the results of the periodic review of external provider performance;
- determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

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 contract, purchasing shall assure that all the Quality requirements applicable to the purchased item are passed on to the supplier.

CMC shall establish 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 activity

Verification activities can include:

- review of objective evidence of the conformity of the processes, products, and services from the external provider (e.g., accompanying documentation, certificate of conformity, test documentation, statistical documentation, process control documentation, results of production process verification and assessment of changes to the production process thereafter);
- inspection and audit at the external provider's premises; review of the required documentation;
- review of production part approval process data;
- inspection of products or verification of services upon receipt;
- review of delegation so product verification to the external provider.

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

When CMC delegate's verification activities to the external provider, the scope and requirements for delegation shall be defined and a register of delegations shall be maintained. CMC shall periodically monitor the external provider's delegated verification activities.

When external provider test reports are utilized to verify externally provided products, CMC shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk (e.g., critical items), CMC shall implement a process to validate the accuracy of test reports. One sample is chosen per year for testing evaluation.

When incoming inspection results in rejected parts or materials, a Nonconforming Material Report shall be completed.

Where specified in the contract, CMC personnel, customers, or government representatives shall be afforded the right to verify at the sub-contractor that product conforms to requirements. Verification by the customer does not absolve CMC of the responsibility to provide acceptable product.

Verification activities of externally provided processes, products, and services shall be performed according to the risks identified by CMC. These shall include inspection or periodic testing, as applicable, when there is high risk of nonconformities including counterfeit parts.

NOTE 1: Customer verification activities performed at any level of the supply chain does not absolve CMC of its responsibility to provide acceptable processes, products, and services and to comply with all requirements.

CMC shall communicate to external providers its requirements for:

- Processes, products, and services to be provided including the identification of relevant technical data (e.g., specifications, drawings, process requirements, work instructions);
- The approval of:
    - products and services;
    - methods, processes, and equipment;
    - the release of products and services;
    - competence, including any required qualification of persons;
- The external providers' interactions with CMC;
- Control and monitoring of the external providers' performance to be applied by CMC;
- Verification or validation activities that CMC, or its customer, intends to perform at the external providers' premises;
- Special requirements, critical items, or key characteristics;
- Test, inspection, and verification, including production process verification;
- The use of statistical techniques for product acceptance and related instructions for acceptance by CMC;
- CMC flow down requirements to all external providers.

The following appears on the CMC website - there is a reference to this site on each CMC Purchase Order:

- specific quality system requirements or inspection/testing instruction

- Use customer-designated or approved external providers, including process sources (e.g., special processes);
- Notify CMC of nonconforming processes, products, or services and obtain approval for their disposition;
- Prevent the use of counterfeit parts;
- Notify CMC of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain CMC's approval;
- Flow down to external provider's applicable requirements including customer requirements;
- Provide test specimens for inspection/verification, investigation, or auditing;
- Retain documented information, including retention periods and disposition requirements;
- The right of access by CMC, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;
- Ensuring that supplier ensure their employees are aware of:
    - Their contribution to product or service conformity;
    - Their contribution to product safety;
    - The importance of ethical behavior.

D.5. AS9100D/2016, Section 8.5, Production and Service Provision

Control of Production and Service Provision

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-03 Competence, Training and Awareness, QSP-07 Inspection and Acceptance, QSP-08 Quality Audits, QSP-11 Production Control, QSP-12 Product Realization, QSP-16 Process Validation, QSP-24 Software Validation, QSP-26 Risk Management, QSP-27 Foreign Object Detection

CMC shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

- The availability of documented information that defines:
    - the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
    - the results to be achieved;
- The availability and use of suitable monitoring and measuring resources;
- The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;
    - ensuring that documented information for monitoring and measurement activity for product acceptance includes:
        - criteria for acceptance and rejection;
        - where in the sequence verification operations are to be performed;
        - measurement results to be retained (at a minimum an indication of acceptance or rejection);
        - any specific monitoring and measurement equipment required and instructions associated with their use;
    - ensuring that when sampling issued as a means of product acceptance, the sampling plan is justified on the basis of recognized statistical principles and appropriate for use (i.e., matching the sampling plan the criticality of the product and to the process capability).
- The use of suitable infrastructure and environment for the operation of processes;
- The appointment of competent persons, including any required qualification;

- The validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- The implementation of actions to prevent human error;
- The implementation of release, delivery, and post-delivery activities;
- The establishment of criteria for workmanship (e.g., written standards, representative samples, illustrations);
- The accountability for all products during production (e.g., parts quantities, split orders, nonconforming product);
- The control and monitoring of identified critical items, including key characteristics, in accordance with established processes;
- The determination of methods to measure variable data (e.g., tooling, on-machine probing, inspection equipment);
- The identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
- The availability of evidence that all production and inspection/verification operations have been completed as planned, or as otherwise documented and authorized;
- The provision for the prevention, detection, and removal of foreign objects;
- The control and monitoring of utilities and supplies (e.g., water, compressed air, electricity, chemical products) to the extent they affect conformity to product requirements;
- The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.

Equipment, tools, and software programs used to automate, control, monitor, or measure production processes shall be validated prior to final release for production and shall be maintained.

Storage requirements shall be defined for production equipment or tooling in storage including any necessary periodic preservation or condition checks. An annual review shall be performed during internal quality audit process.

For processes where the resulting output cannot be verified by subsequent monitoring or measurement, CMC shall establish arrangements for these processes including, as applicable:

- Definition of criteria for the review and approval of the processes;
- Determination of conditions to maintain the approval;
- Approval of facilities and equipment;
- Qualification of persons;
- Use of specific methods and procedures for implementation and monitoring the processes;
- Requirements for documented information to be retained.

CMC shall implement production process verification activities to ensure the production process is able to produce products that meet requirements.

CMC shall retain documented information on the results of production process verification.

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 product 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 product conforms to specifications.

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.

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.

A first article verification shall be performed for 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.

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.

There may be some special processes performed during the creation of 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.

Identification and Traceability

Refer to the following CMC Procedures: QSP-11 Production Control, QSP-12 Product Realization, QSP-14 Material Preservation, QSP-23 Customer Returns, QSP-27 Foreign Object Detection

CMC shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

CMC shall maintain the identification of the configuration of the products and services in order to identify any differences between the actual configuration and the required configuration.

CMC shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

When acceptance authority media are used (e.g. incoming quality receiving inspection), the ERP system shall have user accounts established with password protection. CMC does not employ electronic signatures for acceptance authority media.

CMC shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

NOTE: Traceability requirements can include:

- the identification to be maintained throughout the product life;

- the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap);
- for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;
- for a product, a sequential record of its production (manufacture, assembly,
- inspection/verification), to be retrievable.

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 products 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.

Property Belonging to Customers or External Providers

Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-12 Product Realization, QSP-23 Customer Returns

CMC shall exercise care with property belonging to customers or external providers while it is under CMC's control or being used by CMC.

CMC shall identify, verify, protect, and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

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.

Preservation

Refer to the following CMC Procedures: QSP-14 Material Preservation, QSP-22 ESD Protection, QSP-27 Foreign Object Detection

CMC shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

- cleaning;
- prevention, detection, and removal of foreign objects;
- special handling and storage for sensitive products;
- marking and labeling, including safety warnings and cautions;
- shelf life control and stock rotation;
- special handling and storage of hazardous materials.

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 products 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.

Post-Delivery Activities

Refer to the following CMC Procedures: QSP-12 Product Realization, QSP-13 Customer Complaints and Customer Feedback, QSP-23 Customer Returns

CMC shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, CMC shall consider:

- statutory and regulatory requirements;
- the potential undesired consequences associated with its products and services;
- the nature, use, and intended lifetime of its products and services;
- customer requirements;
- customer feedback;
- collection and analysis of in-service data (e.g., performance, reliability, lessons learned);
- control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
- controls required for work undertaken external to CMC (e.g., off-site work);
- product/customer support (e.g., queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

When problems are detected after delivery, CMC shall take appropriate action including investigation and reporting.

NOTE: Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

Control of Changes

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-12 Product Realization, QSP-16 Process Validation

CMC shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes shall be identified.

NOTE: Production or service provision changes can include the changes affecting processes, production equipment, tools, or software programs.

CMC shall retain documented information describing the results of the review of changes, the person(s) authorizing the change, and any necessary actions arising from the review.

D.6. AS9100D/2016, Section 8.6, Release of Products and Services

Refer to the following CMC Procedures: QSP-07 Inspection and Acceptance, QSP-11 Production Control, QSP-12 Product Realization

CMC shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

CMC shall retain documented information on the release of products and services. The documented information shall include:

- Evidence of conformity with the acceptance criteria;
- Traceability to the person(s) authorizing the release.

When required to demonstrate product qualification, CMC shall ensure that retained documented information provides evidence that the products and services meet the defined requirements.

CMC shall ensure that all documented information required to accompany the products and services are present at delivery.

D.7. AS9100D/2016, Section 8.7, Control of Nonconforming Outputs

Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-10 Non-Conforming Material Handling, QSP-13 Customer Complaints and Customer Feedback, QSP-23 Customer Returns

CMC shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

CMC shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

CMC's nonconformity control process shall be maintained as documented information including the provisions for:

- defining the responsibility and authority for the review and disposition of nonconforming outputs and the process for approving persons making these decisions;
- taking actions necessary to contain the effect of the nonconformity on other processes, products, or services;
- timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- defining corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts(see10.2).

NOTE: Interested parties requiring notification of nonconforming products and services can include external providers, internal organizations, customers, distributors, and regulatory authorities.

CMC shall deal with nonconforming outputs in one or more of the following ways:

- correction;
- segregation, containment, return, or suspension of provision of products and services;
- informing the customer;
- obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

Dispositions of use-as-is or repair for the acceptance of nonconforming products shall only be implemented:

- by persons having delegated authority from the design organization;
- after authorization by the customer, if the nonconformity results in a departure from the contract requirements.

Product dispositional for scrap shall be conspicuously and permanently marked, or positively controlled, until physically rendered unusable.

Counterfeit, or suspect counterfeit, parts shall be controlled to prevent reentry into the supply chain.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

CMC shall retain documented information that:

- Describes the nonconformity;
- Describes the actions taken;
- Describes any concessions obtained;
- Identifies the authority deciding the action in respect of the nonconformity.

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 shall be decided upon. Further, action shall be taken to correct the process nonconformity.

For customer designed products, special dispositions must be done by the customer. All nonconforming 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 unless specifically authorized by the customer and if the nonconformity results in a departure from the contract requirements.

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

If nonconforming products are identified after delivery an evaluation shall be conducted to determine if in-house products or similar products delivered to other customers are affected. The customer shall be contacted in the event of an escape that may affect the performance, reliability and safety of the product. The action will be documented on the Nonconforming Material Report, where applicable.

In addition to any contractual or regulatory authority reporting requirements, the CMC Quality System shall provide for reporting to customers of delivered nonconforming product that may affect reliability or safety. The notification shall contain a clear description of the nonconformity, which includes as necessary, parts affected, customer part numbers, quantity, and date(s) delivered.

D.8. ISO 13485:2016, Section 7.1, Planning of Product Realization

Refer to the following CMC Procedures: QSP-02 Quality Records, QSP-12 Product Realization, QSP-16 Process Validation, QSP-21 Business Continuity, QSP-26 Risk Management

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.

As appropriate to the product being manufactured, 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. The PRP process shall:

- Consider product requirements;
- Need to establish processes and documents and provide resources, including infrastructure and work environment;
- Required qualification, monitoring, measurement, inspection and test, handling, storage, traceability specific to the product in concert with the customer's defined criteria for product acceptance.

Records of PRP's shall be maintained.

D.9. ISO 13485:2016, Section 7.2, Customer-Related Processes

Refer to the following CMC Procedures: QSP-12 Product Realization, QSP-13 Customer Complaints and Customer Feedback, QSP-15 Estimating, QSP-23 Customer Returns, QSP-26 Risk Management

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.

D.10. ISO 13485:2016, Section 7.3, Design and Development

CMC offers technical assistance to our customers in the form of manufacturing 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.

D.11. ISO 13485:2016, Section 7.4, Purchasing

Refer to the following CMC Procedures: QSP-04 Purchasing

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.

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 contract, purchasing shall assure that all the Quality

requirements applicable to the purchased item are passed on to the supplier. Relevant purchasing information shall be maintained.

CMC shall establish 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. 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.

D.12. ISO 13485:2016, Section 7.5, Production and Service Provision

Refer to the following CMC Procedures: QSP-01 Document Control, QSP-02 Quality Records, QSP-04 Purchasing, QSP-07 Inspection and Acceptance, QSP-10 Non-Conforming Material Handling, QSP-11 Production Control, QSP-12 Product Realization, QSP-14 Material Preservation, QSP-16 Process Validation, QSP-21 Business Continuity, QSP-22 ESD Protection, QSP-23 Customer Returns, QSP-24 Software Validation, QSP-26 Risk Management, QSP-27 Foreign Object Detection

Control of 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 product conforms 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 activities shall be maintained.
- Each process of applying a label to a medical product or of using packaging that includes medical labeling shall be controlled to prevent labeling errors and mix-up.
- Production Planning and Scheduling personnel, in conjunction with the New Product Development personnel (e.g. Project Manager) as applicable, are responsible for the generation of shop travelers/routers and for planning and controlling each manufacturing operation.
- Manufacturing Technical and Support personnel (e.g. programmers) are responsible for planning and coordinating all programming activities.
- Manufacturing and Quality personnel are responsible for the verification of and compliance with the applicable specifications for all CMC products.
- 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 per the routing/router/traveler prior to incorporation into CMC products.
- The key characteristics 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), also referred to as In-Process Inspection (IPI) forms.

Cleanliness of Product

- Requirements for cleanliness of product or contamination control of product shall be defined on shop travelers/routers per customer contract requirements.

Validation of Processes for Production and Service Provision

- Procedure(s) shall be established and maintained for process validation (e.g. First Article Inspection – FAI/part qualification – PQ and equipment qualification – EQ)

  - Processes shall be validated where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, consequently, deficiencies become apparent only after the product has been delivered or is in use; such processes shall be identified and validated per customer contract requirements.
- Changes to production processes shall be approved, including customer or regulatory approval, where required by contract.
- CMC shall use a representative item from an initial (e.g. depicted by NPD, NS, etc.) production run, First Article Inspection (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. When applicable, this process shall be repeated when changes occur that invalidate the original results (e.g. customer drawing changes, manufacturing process changes).
- Approval to production process changes shall be identified.
- CMC shall control and document changes affecting processes, production equipment, tools or software programs.
- A documented procedure shall provide for software validation. Records of the results and conclusions of software validation, including necessary actions if applicable from that validation, shall be maintained.

Identification

- Procedures shall provide for product identification and assurance that the product is identified throughout product realization.
- Product (components, subassemblies, assemblies) status shall be maintained during production and storage.
- Materials shall be identified by material number (e.g. PN, SKU) and, as necessary, by status with respect to monitoring and measurement requirements, or by other appropriate method throughout all stages of product realization.
- If required by contract driven from customer-specific requirements, including regulatory, unique product identification (e.g. serial numbers, batch number, date code) shall be assigned.
- Material returned for rework or reprocessing shall be identified to distinguish them from normal production.

Traceability

- Where stipulated by contractual requirements, when traceability is required CMC shall control the unique identification of the product (components, subassemblies and/or assemblies) 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 with regard to the prevention of distributing counterfeit parts. 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.

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.

Preservation of Product

- Procedures and practices shall provide for the identification, handling, storage, cleaning, labeling, packaging, protection of materials while in receiving, stores, the production process, finished goods room, and shipping.
- 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.
- Handling, storage and distribution preservation of the product during internal processing and delivery to the intended destination shall be conducted in a manner which maintains conformity to requirements and prevents alteration, contamination or damages.
- Product labels, package labeling, and user instructions shall be treated as components in document control, purchasing, and product validation.
- Storage areas for finished products 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.

D.13. ISO 13485:2016, Section 7.6, Control of Measuring Equipment

Refer to the following CMC Procedures: QSP-06 Control and Calibration of Measurement & Test Equipment, QSP-24 Software Validation

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.

E. Performance Evaluation (AS9100D/2016, Section 9) AND Improvement (AS9100D/2016, Section 10) AND Measurement, Analysis and Improvement (ISO 13485:2016, Section 8)

E.1. AS9100D/2016, Section 9.1, Monitoring, Measurement, Analysis, and Evaluation

CMC shall determine:

- What needs to be monitored and measured;
- The methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results;
- When the monitoring and measuring shall be performed;
- When the results from monitoring and measurement shall be analyzed and evaluated.

General

Refer to the following CMC Procedures: QSP-02 Quality Records, QSP-07 Inspection and Acceptance, QSP-08 Quality Audits, QSP-10 Non-Conforming Material Handling, QSP-12 Product Realization, QSP-23 Customer Returns

The Quality Manual and Quality Procedures shall be used as guidelines to all inspections performed at CMC. All products are inspected at the described intervals to ensure all shipped products meet all customer design specifications. Inspection steps are outlined on the product traveler. Only authorized personnel may perform these functions.

Quality Manual Procedures shall be in place to govern all incoming, in-process, and final inspections. Inspection results are considered Quality Records and shall be maintained per the CMC Quality Manual Procedure on Quality Records.

Incoming inspections shall be performed in accordance with our Quality Procedures. The Purchase Order is reviewed to ensure the correct products were received.

Product shall receive in-process inspection and testing, as required, by travelers/work instructions. Technicians are authorized to perform their own in-process inspections and tests. Travelers shall be used to outline all inspection and testing requirements. Each operation on the traveler shall be initialed and dated upon completion to provide evidence of product realization. When required by contract, sampling plans shall be submitted to the customer for approval.

Product shall not be released for shipment until all required inspection and test activities have been performed. Where customer review is specified within a contract, customer approval shall be incorporated into the travelers/work instructions prior to product release/shipment.

An Inspection Report may be used to document specific measurements made. All documentation required to be shipped to the customer shall be verified as complete. Upon completion of final inspection the traveler shall be annotated as completed.

Records of inspection results shall be maintained on the traveler, and inspection data sheets. Procedures describe methods and forms used. Nonconformities found shall be documented on a Nonconforming Material Report. Where required, other potential rejects shall be gathered for evaluation.

Critical Items, including key characteristics, may be identified. The methods for monitoring and controlling these characteristics shall be defined. Customer drawings and Product Inspection Plans shall be used to determine key characteristics.

All products returned from customers due to workmanship or other problems shall be inspected upon receipt. The problem will be evaluated to determine the need for any corrective/preventive action.

A First Article Report shall be documented and issued to the customer, where required by contract

CMC shall evaluate the performance and the effectiveness of the quality management system during internal quality audits.

CMC shall retain appropriate documented information as evidence of the results.

Customer Satisfaction
Refer to the following CMC Procedures: QSP-13 Customer Complaints and Customer Feedback

CMC shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. CMC shall determine the methods for obtaining, monitoring, and reviewing this information.

NOTE: Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims, and dealer reports.

Information to be monitored and used for the evaluation of customer satisfaction shall include, but is not limited to, product and service conformity, on-time delivery performance, customer complaints, and corrective action requests. CMC shall develop and implement plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results. The Sales Department shall implement a process for customer visits to attain direct feedback from our customers.

Analysis and Evaluation
Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-09 Corrective And Preventive Actions, QSP-18 Quality Management Review

CMC shall analyze and evaluate appropriate data and information arising from monitoring and measurement.

NOTE: Appropriate data can include information on product and service problems reported by external sources (e.g., government/industry alerts, advisories).

The results of analysis shall be used to evaluate:
- Conformity of products and services;
- The degree of customer satisfaction;
- The performance and effectiveness of the quality management system;
- If planning has been implemented effectively;

- The effectiveness of actions taken to address risks and opportunities;
- The performance of external providers;
- The need for improvements to the quality management system.

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.

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.

E.2. AS9100D/2016, Section 9.2, Internal Audit

Refer to the following CMC Procedures: QSP-08 Quality Audits

CMC shall conduct internal audits at planned intervals to provide information on whether the quality management system conforms to:

- CMC's own requirements for its quality management system;

  NOTE: CMCs own requirements should include customer and applicable statutory and regulatory quality management system requirements.

- The requirements of the Standard and that they are effectively implemented and maintained.

  NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.

CMC shall:

- Plan, establish, implement, and maintain an audit program(s) including the frequency, methods, responsibilities, planning requirements, and reporting, which shall take into consideration the importance of the processes concerned, changes affecting CMC, and the results of previous audits;
- Define the audit criteria and scope for each audit;
- Select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- Ensure that the results of the audits are reported to relevant management;
- Take appropriate correction and corrective actions without undue delay;
- Retain documented information as evidence of the implementation of the audit program and the audit results.

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.

E.3. AS9100D/2016, Section 9.3, Management Review

Refer to the following CMC Procedures: QSP-18 Quality Management Review

Refer to Section B.10 Above.

E.4. AS9100D/2016, Section 10.1, General

CMC shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

- Improving products and services to meet requirements as well as to address future needs and expectations;
- correcting, preventing, or reducing undesired effects;
- improving the performance and effectiveness of the quality management system.

E.5. AS9100D/2016, Section 10.2, Nonconformity and Corrective Action

Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-09 Corrective And Preventive Actions, QSP-10 Non-Conforming Material Handling, QSP-13 Customer Complaints and Customer Feedback, QSP-18 Quality Management Review

When a nonconformity occurs, including any arising from complaints, CMC shall:

- React to the nonconformity and, as applicable, take action to control, correct it and deal with the consequences.
- Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
  - reviewing and analyzing the nonconformity;
  - determining the causes of the nonconformity, including, as applicable, those related to human factors;
  - determining if similar nonconformities exist, or could potentially occur;
- Implement any action needed;
- Review the effectiveness of any corrective action taken;
- Update risks and opportunities determined during planning, if necessary;
- Make changes to the quality management system, if necessary;
- Flow down corrective action requirements to an external provider when it is determined that the external provider is responsible for the nonconformity;
- Take specific actions when timely and effective corrective actions are not achieved.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

CMC shall maintain documented information that defines the nonconformity and corrective action management processes.

CMC shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken and the results of any corrective action.

Corrective and preventive action 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. No corrective actions shall be closed until all actions have been properly achieved. A deadline of thirty days shall be used as a guideline for the closure of each corrective action documented; extensions may granted by Quality Leadership.

E.6. AS9100D/2016, Section 10.3, Continual Improvement

Refer to the following CMC Procedures: QSP-08 Quality Audits, QSP-09 Corrective And Preventive Actions, QSP-18 Quality Management Review

CMC shall continually improve the suitability, adequacy, and effectiveness of the quality management system.

CMC shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.

CMC shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

NOTE: Examples of continual improvement opportunities can include lessons learned, problem resolutions, and the benchmarking of best practices.

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.

The CMC Quality Policy contains the company philosophy concerning continuous improvement. The Quality Policy is posted throughout the facility. Management considers continuous improvement of all processes a key element of the company's Quality Management System.

The activities and processes that are considered to be the most important to our customers are those which involve the, manufacture, inspection, and delivery of completed products. Specific action plans are implemented to help the company meet its goal of continuous improvement.

Quality, delivery, and other customer issues identified may be targeted for improvement and monitored on an ongoing basis. The goal is to continuously improve our processes in order to reduce the variation around each target value. Improvement is sought to consistently meet all customer requirements during all assembly and verification processes.

Measures of the progress of continuous improvement efforts shall be maintained. CMC's company goals for the continuous improvement process are conformance to specifications and customer satisfaction. During Management Review, CMC management shall evaluate overall quality results and customer complaints in order to determine the measurable success of the continuous improvement process.

Continuous improvement shall be sought in quality and on-time delivery results. CMC is continually striving to meet all of our customer's needs and expectations. Our results in terms of quality and on time performance are monitored. Communications with the customer and our subcontractors are used to improve our understanding of our capabilities to meet all customer requirements.

E.7. ISO 13485:2016, Section 8.1, General

Refer to the following CMC Procedures: QSP-07 Inspection and Acceptance, QSP-08 Quality Audits, QSP-09 Corrective And Preventive Actions, QSP-18 Quality Management Review, QSP-13 Customer Complaints and Customer Feedback, QSP-23 Customer Returns

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

E.8. ISO 13485:2016, Section 8.2, Monitoring and Measurement

Feedback, Complaint Handling, Reporting to Regulatory Authorities:
Refer to the following CMC Procedures: QSP-12 Product Realization, QSP-13 Customer Complaints and Customer Feedback, QSP-18 Quality Management Review, QSP-26 Risk Management

Information relating to customer perception will be routinely gathered during customer visits and customer service calls to determine if CMC is meeting customer requirements. CMC shall document a customer feedback process. Data collected shall be serve as potential inputs into risk management, product realization and/or improvement (management review) processes. If applicable regulatory requirements require CMC to gain specific experience from post-production activities, the review of this experience shall form part of the feedback process.

CMC shall document procedures for complaint handling (Customer Service Inquiries/CSI); procedural requirements and responsibilities shall be defined. Justification shall be documented if a complaint is not investigated. Actions resulting from the complaint (e.g. correction, corrective, preventive) shall be documented directly within the complaint's case details. If an investigation determines activities outside of CMC contributed to the complaint (e.g. subvendor, etc.), relevant information shall be exchanged between CMC and the party/parties involved. Complaint handling records shall be maintained.

If applicable regulatory requirements require notification of complaints (e.g. adverse events), CMC shall document communications/notification to the appropriate regulatory authorities within the complaint's case details. Records of these regulatory notifications shall be maintained.

Internal Audit:
Refer to the following CMC Procedures: QSP-08 Quality Audits, QSP-09 Corrective And Preventive Actions

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. Audit results and records shall be maintained. Management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay. Follow-up activities (e.g. check of effectiveness) shall include verification of the actions taken and the reporting of verification results.

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.

Monitoring and Measurement of Processes:
Refer to the following CMC Procedures: QSP-09 Corrective And Preventive Actions, QSP-16 Process Validation, QSP-18 Quality Management Review

Processes identified as pertinent to CMC's quality management system are monitored and measured. Processes identified outside of CMC's footprint/expertise/capability are all performed by 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.

Monitoring and Measurement of Product
Refer to the following CMC Procedures: QSP-07 Inspection and Acceptance, QSP-10 Non-Conforming Material Handling, QSP-11 Production Control, QSP-12 Product Realization

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 (e.g. Routings/Router/Shop Traveler) and CMC Work Instructions (e.g. Visual Method Sheets "VMS") shall be used as guidelines to inspections performed. 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.

E.9. ISO 13485:2016, Section 8.3, Control of Nonconforming Product

Refer to the following CMC Procedures: QSP-02 Quality Records, QSP-10 Non-Conforming Material Handling, QSP-13 Customer Complaints and Customer Feedback, QSP-23 Customer Returns

General: 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. 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.

Before Delivery: Special dispositions (e.g. Non-Conforming Material Report/NCMR disposition = use as is, condition does not meet customer specifications) must be done by the customer. All nonconforming product which cannot be reworked to meet the drawing specifications shall be submitted

to the customer for review/approval. Records of customer acceptance (e.g. use as is, repair not to specification, etc.) including the person authorizing the acceptance shall be maintained.

After Delivery: A procedure shall be established to define process when nonconforming product is detected after delivery or use (e.g. Return Material Authorization/RMA). Records of actions taken shall be maintained.

Rework: Rework activities to meet the drawing specifications may be incorporated into job order/Traveler operations if applicable. Following rework activities, product shall be verified to ensure that it meets applicable acceptance criteria and/or regulatory requirements. Records involving rework products shall be maintained (e.g. NCMR, Traveler, electronic "Smart Form" in-process inspections, PCP/IPI, etc.).

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

E.10. ISO 13485:2016, Section 8.4, Analysis of Data

Refer to the following CMC Procedures: QSP-04 Purchasing, QSP-08 Quality Audits, QSP-10 Non-Conforming Material Handling, QSP-13 Customer Complaints and Customer Feedback, QSP-18 Quality Management Review

Appropriate data related to customer feedback, conformity to product requirements, process and product characteristics and trends (including opportunities for improvement), suppliers, audits, and service reports as appropriate shall be collected, maintained and reported for the purposes of management review.

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. If the analysis of data shows that the quality management system is not suitable, adequate or effective, results that serve as an input to improvement. Management review shall document records of the results of analyses.

E.11. ISO 13485:2016, Section 8.5, Improvement

Refer to the following CMC Procedures: QSP-18 Quality Management Review, CMC QSP-09 Corrective and Preventive Actions

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.

Records of the results of any investigation and of action taken shall be maintained.

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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
11	11/30/12	C. Crouse	2450
12	5/13/13	C. Crouse	2678
13	13-Mar-2015	C. Crouse	Powerway
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