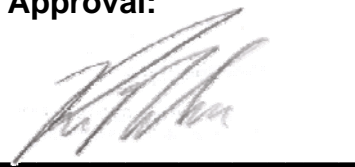


# Quality Management System Manual

ClosedMold  
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Composites  
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**Approval:**



Ron Nelson, President  
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**9/26/05**

Date

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## A. Introduction

ClosedMold Carbon Composites Production LLC. (CMC) developed and implemented a Quality Management System in order to document and continually improve the company's best business practices, better understand and satisfy the requirements and expectations of its customers and improve the overall performance of the company.

CMC's Quality Management System (QMS) complies with the intent of the international standard ISO 9001 (2000) and Aerospace standard AS9100. This system addresses the development, production, and servicing of the company's products.

The manual is divided into eight sections that correlate to the QMS sections of ISO 9001 - 2000. Each section begins with a policy statement expressing CMC's obligation to implement the basic requirements of the referenced QMS section. Each policy statement is followed by specific information pertaining to the procedures that describe the methods used to implement the necessary requirements.

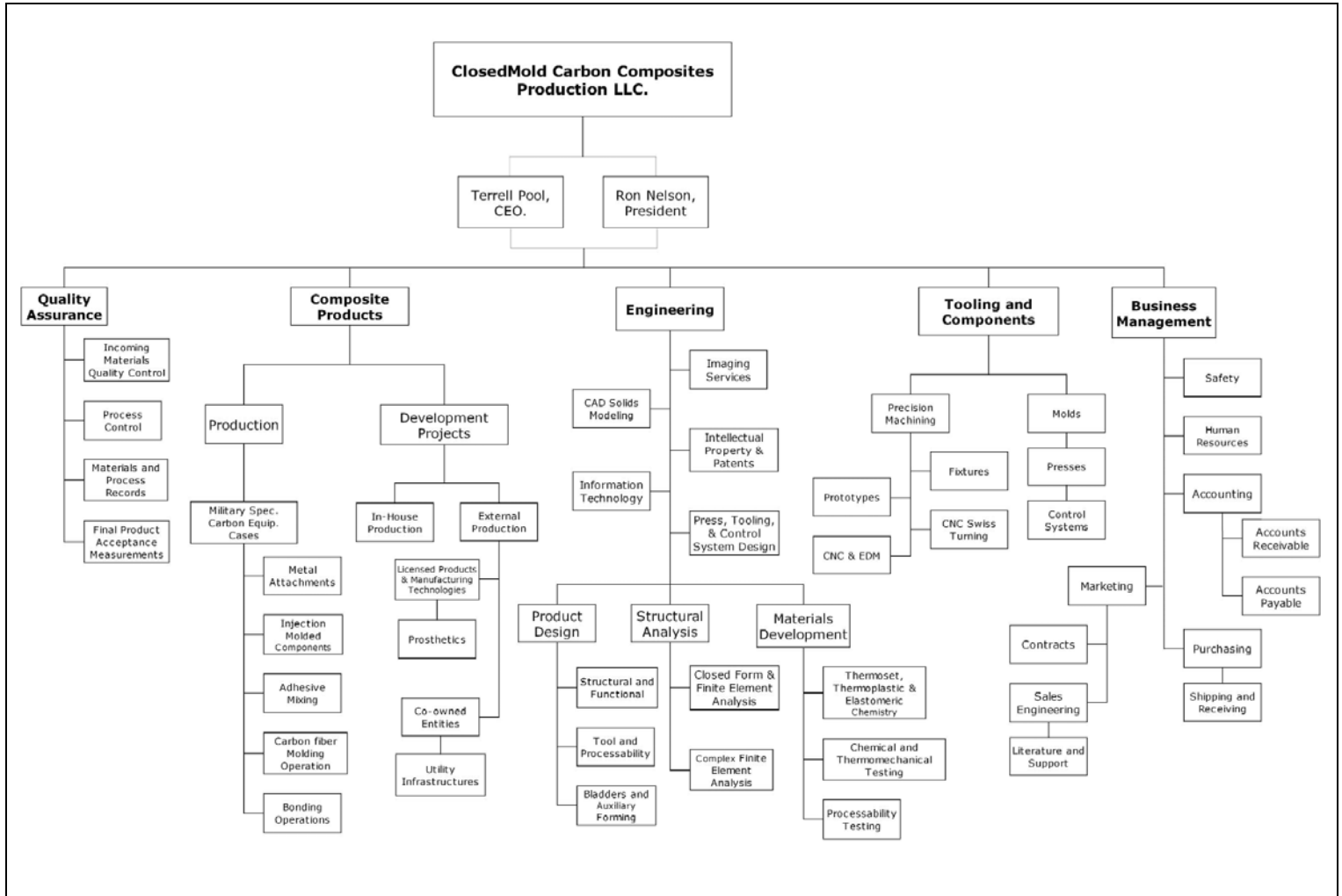
This manual describes the QMS, delineates authorities, inter relationships and responsibilities of the personnel responsible for performing within the system. The manual also provides procedures or references for all activities comprising the QMS to ensure compliance to the necessary requirements of the standard.

This manual is used internally to guide the company's employees through the various requirements of the ISO standard and the company's best business practices. These business practices are dynamic and maintained in order to ensure customer satisfaction and continuous improvement.

This manual is used externally to introduce our QMS to our customers and other external organizations or individuals. The manual is used to familiarize them with the controls that have been implemented and to assure them that the integrity of the QMS is maintained and focused on customer satisfaction and continuous improvement.

## B. Quality Manual Distribution

CMC is a small company with less than 25 employees. The QMS Documentation; Quality Manual, procedures, process flows and many of the forms are on line documents. The most current revision of each document is the on-line version. With the exception of some hard copy forms in use all paper copies of the QMS documents are considered "reference only" and their current revision level verified before use. Training on how to access the QMS documentation will be provided to all employees as part of their new employee orientation.




## 1. Scope

### 1.1 General

The quality manual outlines the policies, procedures and requirements of the QMS. The system is structured to meet the intent of the conditions set forth in the International Standard ISO 9001:2000 and to comply with market specific customer needs.

### 1.2 Application

CMC has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

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Additionally, ClosedMold Composites services a wide range of customers. To assure all customer needs are met, ClosedMold has a robust system for determining customer needs through the contract review activity CMC-102. This wide range of customers often has dramatically different needs from the QMS. In support of these diverse needs, ClosedMold Composites maintains three distinct different levels of performance and documentation within the QMS. These levels are identified during contract review and are communicated to the customer for approval. The three distinct levels are defined in this manual under section 3.0 Definitions.

## 2. Normative Reference

### 2.0 Quality Management System References

The following documents were used as reference during the preparation of the QMS:

#### 2.0.1 Military Specifications

U.S. Department of Defense Specification and standards Mil-Q-9858A

U.S. Department of Defense Specification and standards Mil-45208A

MIL HDBK 17, The Composite Materials Handbook, Guidelines for Characterization of Structural Composite Materials, [www.mil17.org](http://www.mil17.org), maintained by Materials Sciences Corporation, Horsham, PA.

#### 2.0.2 ANSI Specifications

American National Standard ANSI/ISO/ASQ Q9000-2000, Quality Management Systems - Vocabulary.

American National Standard ANSI/ISO/ASQ Q9001-2000, Quality Management Systems ' Requirements

American National Standard ANSI/ISO/ASQ Q9004-2000, Quality Management Systems ' Guidelines for performance Improvements

#### 2.0.3 SAE Standards, AMS-P Polymeric and Composite Materials Committee

AMS3688B, Adhesive, Foaming, Honeycomb Core Splice, Structural, -55 to +82Mdc (-65 to +180Mdf), 5/31/2005

AMS3690B, Adhesive Compound, Epoxy, Room Temperature Curing, 12/1/2000

AMS3692C, Adhesive Compound, Epoxy Resin, High Temperature Application, 5/31/2005

AMS3695, Adhesive Film, Epoxy Base, for High Durability Structural Adhesive Bonding, 2/1/2001

AMS3711E, Core, Honeycomb Fibrous, Aramid Base, Phenolic Coated, 3/1/2001

AMS3713D, Core, Flexible Honeycomb, Polyamide Paper Base, Phenolic Coated, 3/4/2003

AMS3714D, Core, Overexpanded Honeycomb, Polyamide Paper Base, Phenolic Coated, 3/4/2003

AMS3715D, Core, Honeycomb, Glass/Phenolic, 5/3/2004

AMS3751B, Microspheres, Hollow Glass, 3/4/2003

AMS3753A, Microspheres, Carbon, Hollow, 9/1/1998

AMS3832C, Roving, Type "S-2" Glass, Epoxy Resin Impregnated, 5/1/1994

AMS3837D, Cloth, Type "S" Glass, 181 Style Fabric, Finish No. Hts-904, 6/1/1994

AMS3867B, Boron Filament Tape, Epoxy-Resin-Impregnated, 4/1/2001

AMS3892/3B, Tow Or Yarn, Carbon (Graphite) Fibers - for Structural Composites, Gf 400 (2760) Tensile Strength, 40 (275) Tensile Modulus, 5/31/2005

AMS3894/14A, Carbon Fiber Tape and Sheet, Epoxy Resin Impregnated, G 90,000 (621) Tensile, 40,000,000 (276) Modulus, 175 (347), 6/1/2005

AMS3895B, Broadgoods and Tape, Carbon Fiber-Epoxy Resin Impregnated, Multi-Ply, Uniform Fiber, 7/1/1994

AMS3897, Cloth, Carbon Fiber, Resin Impregnated, 6/8/2005

AMS3906/1B, Glass Non-Woven Fiber Tape and Flat Sheet-Epoxy Resin Impregnated, for Hand and Machine Layup GI-I-36-120 (248), 10/1/1997

AMSPRF46194A, Foam, Rigid, Structural, Closed Cell, 2/11/2003

AMSSTD401, Sandwich Constructions and Core Materials; General Test Methods, 6/1/1999

ARP1524A, Surface Preparation and Priming of Aluminum Alloy Parts for High Durability Structural Adhesive Bonding, 5/31/2005

ARP1611A, Quality Inspection Procedure, Composites, Tracer Fluoroscopy and Radiography, 11/1/1995

ARP1674A, Automated Manufacture of Continuous Multi-Ply Graphite Fiber/Epoxy Resin Impregnated Broadgoods, 6/1/2005

ARP1843A, Surface Preparation for Structural Adhesive Bonding, Titanium Alloy Parts, 6/1/2005

## **3. Definitions**

### ***3.0 Quality Management System Definitions***

This section is for definitions unique to CMC.

**Source Inspection-** An agreement made with the customer, government or their designee, to verify conformance of a product at CMC or at CMC supplier's premises.

**Customer owned property** - Any type of instrumentation, accessories, manuals, or shipping containers that belong to a customer.

**Customer supplied product** - Any type of service or material supplied to be utilized in the manufacture, modification or repair of customer-owned property.

**Product** ' The end item result of meeting all contract terms and conditions. (eg: manufactured goods, merchandise, services etc.)

**Work Order-** The documentation that describes the methodology for production and records pertinent data for a given component or assembly. This document may be for individual components, a lot of components or a static document tied to a production line of products.

**Quality Records** ' Documentation of those activities wherein records of said activities must be maintained will be specified in the procedure or work instruction level documents, as applicable

**Quality Level I-** Applies to work that is simple in nature and minimal quality, inspection and documentation is required at the customer's discretion. Approval of quality related activities can be made by the area supervisor.

**Quality Level II-** Applies to work that has some degree of complexity where quality planning is based upon ClosedMold standard practice and internal documentation. Specifications of performance will be determined for each work package and ClosedMold reserves the right to perform Material Review activities on Quality level II projects.

**Quality Level III-** Applies to work where the customer provides all specification, drawings and applicable inspection plans. The customer will be closely involved in all stages of production and shall reserve the right to conduct the material review activity on these programs.

**Key Feature-** Those characteristics of the product that have the greatest impact on the end users fit, form and function of the component.

## **4. General Requirements**

### **4.1 General requirements**

CMC has established, documented and implemented a Quality Management System (QMS) in to meet the intent of the requirements of ISO 9001:2000. The system is maintained and continually improved through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action and management review.

To design and implement the QMS CMC has:

Identified the processes needed for the QMS and their application throughout the organization and documented them on the Macro Business Process Diagram at the end of this section of the Quality Manual

Determined the sequence and interaction of these processes, and illustrated them on the Business Process Diagram

Determined criteria and methods needed to ensure that the operation and control of the processes are effective, and documented them in the component specific Work Order, the floor work instructions and the Performance metrics table.

Ensured the continuing availability of materials personnel and documents necessary to achieve planned results and continual improvement of these processes

Established systems to monitor, measure and analyze these processes, and

Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes

## ***4.2 Documentation Requirements***

### **4.2.1 General**

Figure 1 demonstrates the relationship of the QMS documentation. The QMS documentation includes:

A documented Quality Policy

This Quality Manual

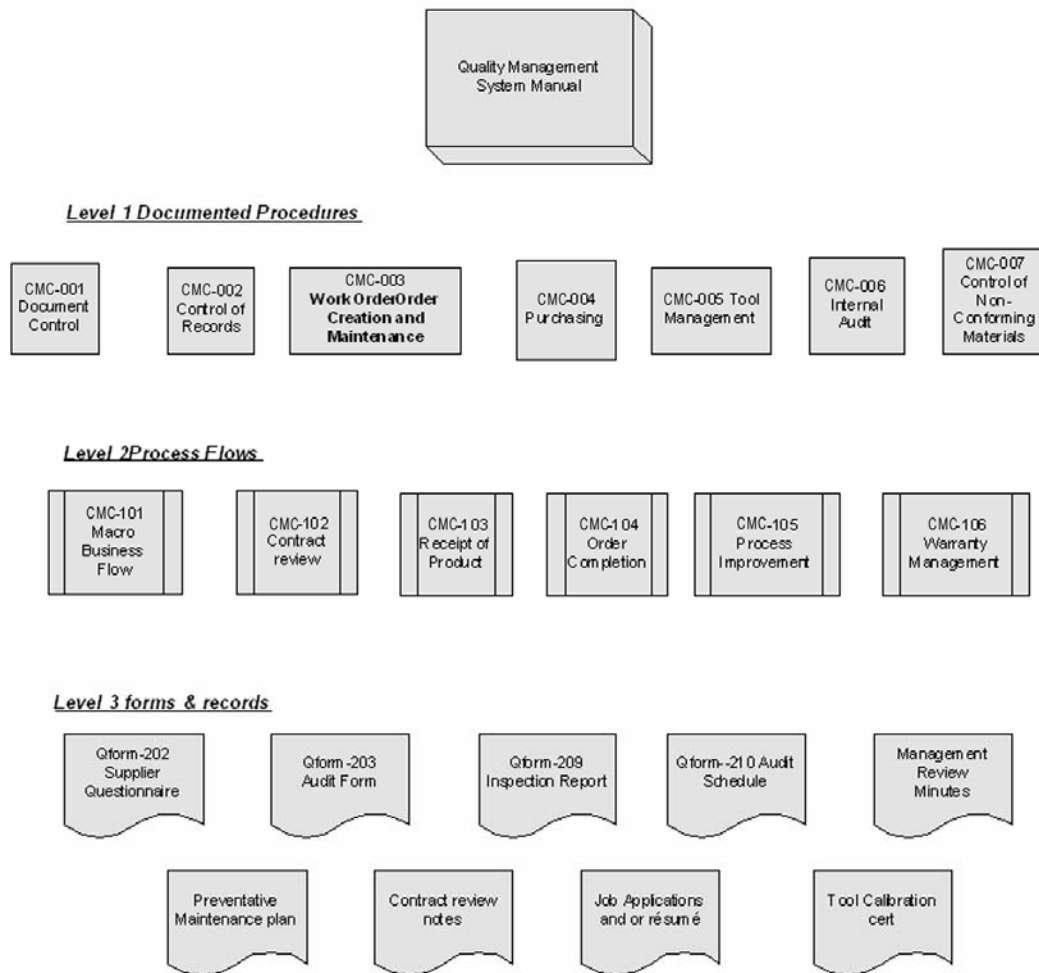
Documented Procedures

Documents identified as needed for the effective planning, operation and control of our processes, and

Quality Records

# ClosedMold Composites

## Document Hierarchy



### 4.2.2 Quality manual

This Quality Manual has been prepared to describe CMC QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The Business Process Diagram at the end of section 4 provides a description of the interaction between the processes of the QMS system.

### **4.2.3 Control of documents**

All of the QMS documents are controlled according to the Document Control Procedure (CMC-001) This procedure defines the process for:

Approving documents for adequacy prior to issue

Reviewing and updating as necessary and re-approving documents

Ensuring that changes and current revision status of documents are identified

Ensuring that relevant versions of applicable documents are available at points of use

Ensuring that documents remain legible and readily identifiable

Ensuring that documents of external origin are identified and their distribution controlled, and

Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose

### **4.2.4 Control of quality records**

Quality records are maintained to provide evidence of conformity to requirements and of the effective operation of the QMS. The records are maintained according to the Control of Quality Records Procedure (CMC-002). This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

### **Related Procedures**

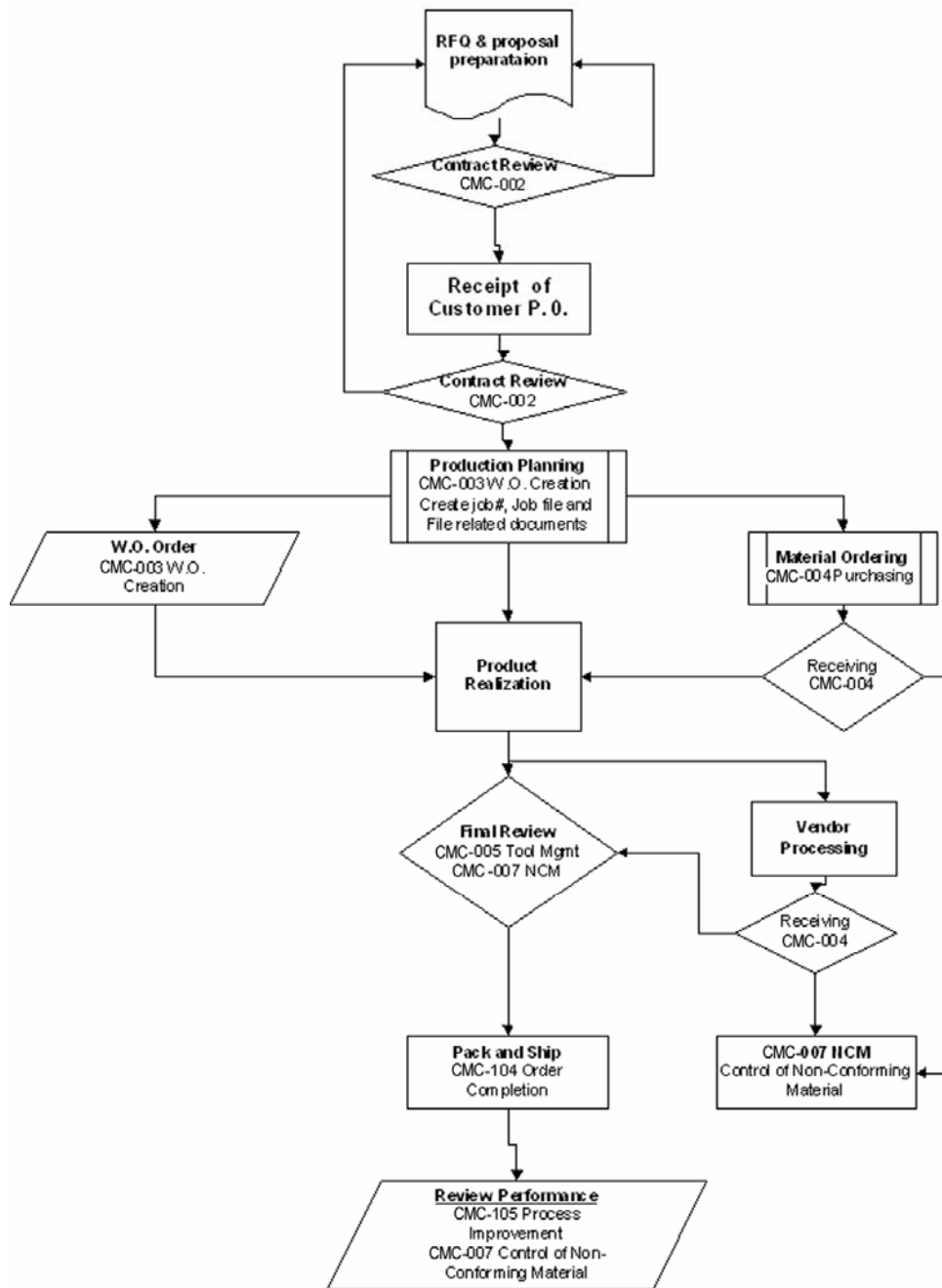
Document Control CMC-001

Control of Quality Records CMC-002

Work Order Creation and Maintenance CMC-003

## CMC Macro Business Process

CMC-101 Rev A



## **5. Management Responsibility**

### **5.1 Management commitment**

CMC is a small entity that is managed with a very hands on approach by the Managing Director of the company. The Director and his management staff have been actively involved in implementing the quality management system (QMS). The Team has provided the vision and strategic direction for the growth of the QMS, and established quality objectives and the quality policy.

To continue to provide leadership and show commitment to the improvement of the QMS, management will do the following.

Communicate the importance of meeting customer, statutory, and regulatory requirements by direct communication with the staff.

Establish quality objectives

Establish the quality policy.

Conduct Annual management reviews.

Ensure the availability of resources.


### **5.2 Customer focus**

CMC strives to identify current and future customer needs, to meet customer requirements and exceed customer expectations. This is accomplished through direct customer interface and discussion of current and future projects

Top management ensures that customer requirements are understood and met, by requiring strong customer interface throughout the proposal and initial contract stage of all projects. Customer requirements are determined and confirmed, converted into internal requirements, and communicated to the appropriate staff in our organization in accordance with CMC-104 Contract Review.

### **5.3 Quality policy**

***Quality Policy: CMC objectives are to provide the customer with quality products and services, provide the best cost solution, meet or exceed all delivery needs and maintain business success.***

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Top management ensures that the quality policy is communicated to all employees. It is included in new employee training and training on the QMS. It is posted in prominent places throughout the facility to maintain high standards within our organization.

Management reviews the quality policy at each management review meeting to determine the policy is continuing suitability for our organization.

## **5.4 Planning**

### **5.4.1 Quality objectives**

Quality objectives are established to support our organization's efforts in achieving our quality policy and reviewed annually for suitability. Objectives have been established for the following:

***Scrap and rework cost to be less than 5% of revenue***

***Warranty returns to be less than 2% of revenue***

***Variance of less than 10% between target hourly earnings(\$/hour) and actual hourly earnings.***

These Quality objectives are measurable, and are reviewed against performance goals at each management review meeting.

### **5.4.2 Quality management system planning**

The quality system has been planned and implemented to meet our quality objectives and the requirements of 4.1 of the ISO 9001 standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

## **5.5 Responsibility, authority and communication**

### **5.5.1 Responsibility and authority**

An organizational chart has been established to show the interrelation of personnel in the organization. As CMC is a small company and individual employees perform many functions; discrete job descriptions do not exist for each employee. The specific tasks assigned to each employee are noted on the organizational chart. Job functions and the organizational chart are reviewed and approved by top management for adequacy. This chart is available throughout the organization to help employees understand responsibilities and authorities. An organizational chart is located on page 6 of this manual.

### **5.5.2 Management representative**

The Quality Assurance manager has been appointed by the Managing Director as the management representative. As management representative, they have the following responsibility and authority:

Ensure that processes needed for the QMS are established and implemented.

Report to top management on the performance of the QMS, and note needed improvements.

Promote awareness of customer requirements throughout the organization.

Act as a liaison with external parties such as customers or auditors on matters relating to the QMS.

Assist with training of new and revisions to existing procedures.

### **5.5.3 Internal communication**

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS are performed and include regular staff meetings and the annual management review. This communication may take the form of review of the quality objectives, results of both internal and customer audits and new business opportunities.

## **5.6 Management review**

### **5.6.1 General**

Top management reviews the QMS annual at management review meetings. This review assesses the continuing QMS suitability, adequacy and effectiveness, identifying opportunities for improvement and needed changes. Records are maintained for each management review meeting.

### **5.6.2 Review input**

Assessment of the QMS is based on a review of information inputs to management review. These inputs include the following:

Results of audits

Customer feedback

Specific job performance variance

Scrap and rework cost

On time delivery

Status of preventive and corrective actions

Follow-up actions from previous management reviews

Planned changes that could affect the QMS

Recommendations for improvement

### **5.6.3 Review output**

During these review meetings, management will identify appropriate actions to be taken regarding the following issues:

Improvement of the effectiveness of the QMS and its processes

Improvement of product related to customer requirements

Resource needs

Responsibilities for required actions are assigned to members of the staff in attendance. Any decisions made during the meeting, assigned actions, and their due dates are recorded in the minutes of management review.

#### **Related Procedures:**

Process Improvement CMC-105

Non-Conforming Material CMC-007

Work Order Creation and Maintenance CMC-003

## **6. Resource Management**

### **6.1 Provision of resources**

CMC has implemented a QMS that complies with the ISO 9000 2000 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system, management determines and provides necessary resources.

### **6.2 Human resources**

#### **6.2.1 General**

To ensure competence of our personnel new employees are hired depending upon their qualifications in the manufacturing industry. New employees are given an orientation by a senior employee who includes a copy of the QMS documentation. A senior employee then provides on the job training to the new employee, evaluating the new employee's performance at each task to determine their competence

#### **6.2.2 Competence, awareness and training**

Qualifications are reviewed upon hire, when an employee changes positions or the requirements for a position change. If any differences between the employee's qualifications and the requirements for the job are found, training or other action is taken to provide the employee with the necessary competence for the job.

All employees are trained on the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

### **6.3 Infrastructure**

To meet quality objectives and product requirements CMC has determined the infrastructure needed. The infrastructure has been provided, and includes buildings, workspace, utilities, process equipment and supporting services. As new infrastructure requirements arise, they will be documented in the management review and or regular staff meetings. Existing infrastructure is maintained as required as noted in the machine maintenance records.

## **6.4 Work Environment**

A work environment suitable for achieving product conformance is maintained. Requirements are determined during the contract review CMC-102 and Work Order creation CMC-003 as required. The work environment is managed for continuing suitability. Data from the quality system is evaluated to determine if the work environment is sufficient for achieving product conformance, or if preventive or corrective action related to the work environment is required.

### **Related Documents**

Contract Review CMC-102

Work Order creation CMC-003

## **7. Product Realization**

### **7.1 Planning of product realization**

Quality planning is required before new products or processes are implemented. The quality planning takes place as the Work Order is created per CMC-003. During this planning, management or assigned personnel identify:

The quality objectives and requirements for the product,

Processes, documentation and resources required

Verification, validation, monitoring, inspection and test requirements, and

Criteria for product acceptance

The output of quality planning is included in the completed Work Order for the specific work to be performed.

### **7.2 Customer-related processes**

#### **7.2.1 Determination of requirements related to the product**

CMC determines customer requirements before acceptance of an order. Customer requirements include those:

Requested by the customer

Customer specifications

Required for delivery and post-delivery activities

Not stated by the customer but necessary for specified use or known and intended use

Statutory and regulatory requirements related to the product

Additional requirements determined by CMC

Customer requirements are determined according to the Contract Review CMC-102.

### **7.2.2 Review of requirements related to the product**

CMC has a process in place for the review of requirements related to the product Contract Review CMC-102.

The review is conducted before the order is accepted. The process ensures that:

Product requirements are defined

Contract or order requirements differing from those previously expressed are resolved

CMC has the ability to meet the defined requirements

Records are maintained showing the results of the review and any actions arising from the review. These records are letters and notes generated in accordance with CMC - 102 contract review

Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance

When product requirements are changed, CMC communicates changes to relevant personnel and amends relevant documents

### **7.2.3 Customer communication**

CMC is always in close contact with their customers. As an order progresses thru the manufacturing cycle the customer is kept up to date on progress and problems. Regular communication with the customer is maintained in the following areas:

Product Information

Enquiries, contracts and order handling, including amendments

Customer Feedback, including customer complaints

## **7.4 Purchasing**

### **7.4.1 Purchasing process**

A documented procedure control of purchasing CMC-004 is followed to ensure that purchased product conforms to the specified purchase requirements. The procedure outlines the extent of control required for suppliers. Suppliers are evaluated and selected based on their ability to supply product in accordance with requirements as outlined in the procedure. Criteria for selection, evaluation and re-evaluation are documented in the procedure. Records of the evaluation and any necessary actions are maintained as quality records.

### **7.4.2 Purchasing information**

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

Requirements for approval of product, processes and equipment

Requirements for qualification of personnel

QMS requirements

The purchasing documents are reviewed to ensure the adequacy of requirements before orders are placed with the supplier.

### **7.4.3 Verification of purchased product**

The Purchasing Procedure CMC-004 describes the process used to verify that purchased product meets specified purchase requirements and process flow CMC'104 Receipt of product defines the actions upon receipt of the product. If CMC or the customer will perform Source Inspection at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

## ***7.5 Production and Service Provision***

### **7.5.1 Control of production and service provision**

CMC plans and carries out production and service provision under controlled conditions according to the developed Work Order per CMC-003. Controlled conditions include, as applicable:

The availability of information that describes the characteristics of the product

The availability of work instructions

The use of suitable equipment

The availability and use of monitoring and measuring devices

The implementation of monitoring and measurement

The implementation of release, delivery and post-delivery activities

### **7.5.2 Validation of processes for production and service provision**

CMC validates any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use. Validation demonstrates the ability of these processes to achieve planned results. These validation requirements will be defined as required in the creation of the Work Order per CMC-003.

Process validation may include the following:

Defined criteria for review and approval of the processes

Destructive test of sample parts

Compliance to qualified customer or other recognized method of manufacture

Approval of equipment and qualification of personnel

Use of specific methods and procedures

Requirements for records

Revalidation

### **7.5.3 Identification and traceability**

CMC identifies the product throughout product realization in accordance with CMC-003 Work Order Creation and Maintenance. The Work Order is the primary document for identifying all identification requirements and capturing all traceability needs. CMC controls and records the unique identification of the product where ever traceability is a contract specified requirement. The specific method of identification will be determined on a case by case basis and will be defined in the Work Order.

### **7.5.4 Customer property**

CMC exercises care with customer property while it is under the organization's control or being used. Control of Customer property is outlined in the following procedures and process flows; CMC-003 M.O. creation CMC -005 Tool Management, CMC-104 Receipt of product and CMC-007 Control of NCM. These processes outline the Identification, verification, protection and safeguarding of customer property provided for use. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

### **7.5.5 Preservation of product**

CMC preserves the conformity of product during internal processing and delivery to the intended destination per process flow CMC-104 actions upon receiving and CMC-107 order completion. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

## **7.6 Control of monitoring and measuring devices**

CMC has determined the monitoring and measurement to be undertaken during the manufacture of each component as specified in the component M.O. (CMC-003). The monitoring and measuring devices needed to provide evidence of product conformity have also been identified and are contained on the calibration tool list. Calibration is performed in accordance with CMC-005 Tool Management.

Where necessary to ensure valid results, measuring equipment is:

Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards

Adjusted or re-adjusted as necessary;

Identified to enable the calibration status to be determined;

Safeguarded from adjustments that would invalidate the measurement result;

Protected from damage and deterioration during handling, maintenance and storage.

In addition, during each calibration interval, if a tool is found to be out of calibration, CMC takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

## Related Documents

M.O Creation and Maintenance CMC-003

Purchasing CMC-004

Control of Measurement and test equipment CMC-005

Receipt of product CMC-103

Order Completion CMC-104

## **8. Measurement, Analysis and Improvement**

### **8.1 General**

CMC has planned and implements the monitoring, measurement, analysis and improvement processes as needed

To demonstrate conformity of the product,

To ensure conformity of the QMS, and

To continually improve the effectiveness of the QMS.

### **8.2 Monitoring and Measurement**

#### **8.2.1 Customer Satisfaction**

As one of the measurements of the performance of the QMS, CMC monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. This is done by continual verbal discussions with the customers concerning past performance and pending orders.

#### **8.2.2 Internal Audit**

CMC conducts internal audits at planned intervals to determine whether the QMS

Conforms to the existing documentation of the QMS requirements established by the organization

Is effectively implemented and maintained.

An audit program has been designed and implemented and identifies an audit schedule based on the importance of the areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities and requirements for planning and conducting audits, and for reporting and maintaining results, are defined and documented in the Internal Audit procedure CMC-006.

### **8.2.3 Monitoring and measurement of processes**

CMC applies suitable methods for monitoring and, where applicable, measurement of the QMS processes. These elements are defined previously in section 5.4 above. When targets are not met, correction and corrective action is taken.

### **8.2.4 Monitoring and measurement of product**

CMC monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the product realization process identified in the component Work Order and as required per CMC'103 receipt of product and CMC '104 order completion.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release does not occur until all the process defined by CMC'104 Order completion has been completed, unless otherwise approved by a management authority, and where applicable by the customer.

## **8.3 Control of Nonconforming Product**

CMC ensures that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product are defined in the Control of Nonconforming Product procedure CMC-107.

## **8.4 Analysis of Data**

CMC determines, collects and analyzes performance data to continually evaluate the QMS to look for improvement opportunities. The data as noted in 5.4 above, is collected and reviewed in accordance with CMC-105 Process Improvements. This data may also include information generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data provides information relating to

Customer satisfaction

Conformance to product requirements

Characteristics and trends of processes and products including opportunities for preventive action

Suppliers

## **8.5 Improvement**

### **8.5.1 Continual improvement**

CMC continually improves the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

### **8.5.2 Corrective action**

CMC takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

Documented procedures CMC-003, CMC-007, CMC-105 define requirements for

Reviewing nonconformities (including customer complaints),

Determining the causes of nonconformities,

Evaluating the need for action to ensure that nonconformities do not recur,

Determining and implementing action needed,

Records of the results of action taken

Reviewing corrective action taken.

### **8.5.3 Preventive action**

CMC determines action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions are appropriate to the effects of the potential problems.

A documented procedures CMC-006 Internal audit, CMC-007 control of NCM, and CMC-105 process improvement define requirements for:

Determining potential nonconformities and their causes

Evaluating the need for action to prevent occurrence of nonconformities

Determining and implementing action needed

Records of results of action taken

Reviewing preventive action taken

Related Documents

Process Improvements CMC-105

Internal Audits CMC-006

Control of Nonconforming Product CMC-007