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# Quality Management Systems Manual

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Carr Manufacturing Company, Inc.



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Revision D

This Quality Manual meets the requirements of  
**ISO 9001:2015**

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# Quality Management Systems Manual

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## Foreword

This Quality Manual has been written to be compliant with all of the requirements of ISO 9001:2015 except for the exclusions noted below in section 4.3. This Quality Manual may be used by internal and external parties, including certification bodies, to assess CMC's ability to meet customer, regulatory and our own requirements. The quality management principles stated in ISO 9001 have been taken into consideration during the development of this Quality Manual.

## 1. Scope

This Quality Manual specifies requirements for a quality management system to:

- a) Demonstrate our ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
- b) Enhance customer satisfaction through the effective application of the system, including processes for improvement and regulatory requirements.

All the requirements of this Quality Manual are intended to be applicable to CMC, regardless of its type or size, or the products and services it provides

## 2. Normative Resources

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

## 3. Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

## 4. Context of the organization

### 4.1. Understanding the organization and its context

CMC determines external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

CMC monitors and reviews information about these external and internal issues.

### 4.2 Understanding the needs and expectations of interested parties

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 determines:

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

CMC monitors and reviews information about these interested parties and their relevant requirements.

### **4.3 Determining the scope of the quality management system**

CMC determines the boundaries and applicability of the quality management system to establish its scope.

When determining this scope, CMC considers:

- a) The external and internal issues referred to in 4.1;
- b) The requirements of relevant interested parties referred to in 4.2
- c) The products and services of CMC.

CMC applies all the requirements of this Quality Manual within the determined scope of its quality management system.

The scope of CMC's quality management system covers all of the sections of ISO 9001 except for the following : section 8.3 Design and development of products and services.

Section 8.3 does not apply to CMC as:

- a) CMC does not plan and control the design and development of product(s)
- b) CMC only supplies product(s) made to the customer's existing design.

### **4.4 Quality management system and its processes**

**4.4.1** CMC establishes, implements, maintains and continually improves a quality management system, including the processes needed and their interactions, in accordance with the requirements of this Quality Manual.

CMC determines the processes needed for the quality management system and their application throughout the organization, and:

- a) Determines the inputs required and the outputs expected from these processes;
- b) Determines the sequence and interaction of these processes;
- c) Determines and applies the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) Determines the resources needed for these processes and ensure their availability;
- e) Assigns the responsibilities and authorities for these processes;
- f) Addresses the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) Evaluates these processes and implements any changes needed to ensure that these processes achieve their intended results;
- h) Improves the processes and the quality management system

**4.4.2** To the extent necessary, CMC:

- a) maintains documented information to support the operation of its processes;
- b) retains documented information to have confidence that the processes are being carried out as planned.

## **5 Leadership**

### **5.1 Leadership and commitment**

#### **5.1.1 General**

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

- a) taking accountability for the effectiveness of the quality management system;
- b) 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;
- c) ensuring the integration of the quality management system requirements into CMC's business processes;
- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

#### **5.1.2 Customer focus**

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

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

## **5.2 Policy**

### **5.2.1 Establishing the quality policy**

Top management establishes, implements and maintains a quality policy that:

- a) is appropriate to the purpose and context of CMC and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

**5.2.2 Communicating the quality policy**

The quality policy is

- a) available and maintained as documented information;
- b) communicated, understood and applied within CMC;
- c) available to relevant interested parties, as appropriate.

**5.3 Organizational roles, responsibilities and authorities**

Top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated and understood within CMC.

Top management assigns the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of this Quality Manual ;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

**6 Planning****6.1 Actions to address risks and opportunities**

**6.1.1** When planning for the quality management system, CMC considers the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

**6.1.2** The organization plans:

- a) actions to address these risks and opportunities;
- b) how to:
  - 1) integrate and implement the actions into its quality management system processes (see 4.4);
  - 2) evaluate the effectiveness of these actions.

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

## **6.2 Quality objectives and planning to achieve them**

**6.2.1** The organization establishes quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives:

- a) are consistent with the quality policy;
- b) are measurable;
- c) take into account applicable requirements;
- d) are relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) are monitored;
- f) are communicated;
- g) are updated as appropriate.

CMC maintains documented information on the quality objectives.

**6.2.2** When planning how to achieve its quality objectives, the organization determines:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

## **6.3 Planning of changes**

When CMC determines the need for changes to the quality management system, the changes will be carried out in a planned manner (see 4.4).

The organization considers:

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

## **7 Support**

### **7.1 Resources**

#### **7.1.1 General**

CMC determines and provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

CMC considers:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

#### **7.1.2 People**

CMC determines and provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

#### **7.1.3 Infrastructure**

CMC determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

#### **7.1.4 Environment for the operation of processes**

CMC determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services.

#### **7.1.5 Monitoring and measuring resources**

##### **7.1.5.1 General**

CMC determines and provides 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 ensures that the resources provided:

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

CMC retains appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

##### **7.1.5.2 Measurement traceability**

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment is:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification is retained as documented information;
- b) identified in order to determine their status;



- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

CMC determines if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

#### **7.1.6 Organizational knowledge**

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

This knowledge is maintained and made available to the extent necessary.

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

### **7.2 Competence**

CMC:

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

### **7.3 Awareness**

CMC ensures that persons doing work under its control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) the implications of not conforming with the quality management system requirements.

### **7.4 Communication**

CMC determines the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate
- d) how to communicate;
- e) who communicates.

## **7.5 Documented information**

### **7.5.1 General**

CMC's quality management system includes:

- a) documented information required by the ISO Standard;
- b) documented information determined by CMC as being necessary for the effectiveness of the quality management system.

### **7.5.2 Creating and updating**

When creating and updating documented information, CMC ensures appropriate:

- a) identification and description (e.g. a title, date, author, or reference number)
- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

### **7.5.3 Control of documented information**

**7.5.3.1** Documented information required by the quality management system and by this Quality Manual is controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

**7.5.3.2** For the control of documented information, CMC addresses the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

Documented information of external origin determined by the CMC to be necessary for the planning and operation of the quality management system is identified as appropriate, and controlled.

Documented information retained as evidence of conformity is protected from unintended alterations.

## **8 Operation**

### **8.1 Operational planning and control**

CMC plans, implements and controls the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

- a) determining the requirements for the products and services;

- b) establishing criteria for:
  - 1) the processes;
  - 2) the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and service requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) determining, maintaining and retaining documented information to the extent necessary:
  - 1) to have confidence that the processes have been carried out as planned;
  - 2) to demonstrate the conformity of products and services to their requirements.

The output of this planning is suitable for CMC's operations

CMC controls planned changes and reviews the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

CMC ensures that outsources processes are controlled (see 8.4).

## **8.2 Requirements for products and services**

### **8.2.1 Customer communication**

Communication with customers includes:

- a) providing information relating to products and services;
- b) handling enquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

### **8.2.2 Determining the requirements for products and services**

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

- a) the requirements for the products and services are defined, including:
  - 1) any applicable statutory and regulatory requirements;
  - 2) those considered necessary by CMC;
- b) CMC can meet the claims for the products and services it offers.

### **8.2.3 Review of the requirements for products and services**

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

- a) Requirements specified by the customer, including the requirements for delivery and post delivery activities;
- b) Requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) Requirements specified by CMC;
- d) Statutory and regulatory requirements applicable to the products and services;
- e) Contract or order requirements differing from those previously expressed.

CMC ensures that contract or order requirements differing from those previously defined are resolved.

The customer's requirements are confirmed by CMC before acceptance, when the customer does not provide a documented statement of their requirements.

#### **8.2.3.2 CMC retains documented information, as applicable:**

- a) On the results of the review;
- b) On any new requirements for the products and services.

#### **8.2.4 Changes to requirements for products and services**

CMC ensures 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.

### **8.3 Design and development of products and services**

#### **This section does not apply to CMC**

CMC does NOT plan and control the design and development of product

CMC is a supplier of products made to the customer's specifications.

### **8.4 Control of externally provided processes, products and services**

#### **8.4.1 General**

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

CMC determines the controls to be applied to externally provided processes, products and services when:

- a) Products and services from external providers are for incorporation into CMC's own products and services;
- b) Products and services are provided directly to the customer(s) by external providers on behalf of CMC;
- c) A process, or part of a process, is provided by an external provider as a result of a decision by CMC.

CMC determines and applies 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 retains documented information of these activities and any necessary actions arising from the evaluations.

**8.4.2 Type and extent of control**

CMC ensures 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:

- a) Ensures that externally provided processes remain within the control of its quality management system;
- b) Defines both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) Takes into consideration:
  - 1) 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;
  - 2) The effectiveness of the controls applied by the external provider;
- d) Determines the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

**8.4.3 Information for external providers**

CMC ensures the adequacy of requirements prior to their communication to the external provider.

CMC communicates to external providers its requirements for:

- a) The processes, products and services to be provided;
- b) The approval of:
  - 1) Products and services;
  - 2) Methods, processes and equipment;
  - 3) The release of products and services;
- c) Competence, including any required qualification of persons;
- d) The external providers' interactions with the organization;
- e) Control and monitoring of the external providers' performance to be applied by the organization
- f) Verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

**8.5 Production and service provision****8.5.1 Control of production and service provision**

CMC implements production and service provision under controlled conditions.

Controlled conditions include, as applicable

- a) The availability of documented information that defines:
  - 1) The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
  - 2) The results to be achieved;
- b) The availability and use of suitable monitoring and measuring resources;
- c) 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;
- d) The use of suitable infrastructure and environment for the operation of processes;
- e) The appointment of competent persons, including any required qualification;
- f) 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;
- g) The implementation of actions to prevent human error;
- h) The implementation of release, delivery and post-delivery activities.

#### **8.5.2 Identification and traceability**

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

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

CMC controls the unique identification of the outputs when traceability is a requirement, and retains the documented information necessary to enable traceability.

#### **8.5.3 Property belonging to customers or external providers**

CMC exercises care with property belonging to customers or external providers while it is under CMC's control or being used by CMC and extends the same level of control as it does with its own property.

When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, CMC will report this to the customer or external provider and retain documented information on what has occurred with the production records.

#### **8.5.4 Preservation**

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

#### **8.5.5 Post-delivery activities**

CMC meets requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, CMC considers:

- a) Statutory and regulatory requirements;
- b) The potential undesired consequences associated with its products and services;
- c) The nature, use and intended lifetime of its products and services;

- d) Customer requirements;
- e) Customer feedback.

#### **8.5.6 Control of changes**

CMC reviews and controls changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

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

### **8.6 Release of products and services**

CMC implements 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 will not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer.

CMC retains documented information on the release of products and services. The documented information includes:

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

### **8.7 Control of nonconforming outputs**

**8.7.1** CMC ensures that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

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

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

- a) Correction;
- b) Segregation, containment, return or suspension of provision of products and services;
- c) Informing the customer;
- d) Obtaining authorization for acceptance under concession.

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

**8.7.2** CMC retains documented information that:

- a) Describes the nonconformity;
- b) Describes the actions taken;
- c) Describes any concessions obtained;
- d) Identifies the authority deciding the action in respect of the nonconformity.

## **9 Performance evaluation**

### **9.1 Monitoring, measurement, analysis and evaluation**

#### **9.1.1 General**

CMC determines:

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

CMC evaluates the performance and the effectiveness of the quality management system.

CMC retains appropriate documented information as evidence of the results.

#### **9.1.2 Customer satisfaction**

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

#### **9.1.3 Analysis and evaluation**

CMC analyses and evaluates appropriate data and information arising from monitoring and measurement.

The result of analysis is used to evaluate:

- a) Conformity of products and services;
- b) The degree of customer satisfaction;
- c) The performance and effectiveness of the quality management system;
- d) If planning has been implemented effectively;
- e) The effectiveness of actions taken to address risks and opportunities;
- f) The performance of external providers;
- g) The need for improvements to the quality management system.

## **9.2 Internal audit**

**9.2.1** CMC conducts internal audits at planned intervals to provide information on whether the quality management system:

- a) Conforms to:
  - 1) CMC's own requirements for its quality management system;



2) The requirements of this Quality Manual;

b) Is effectively implemented and maintained.

#### **9.2.2 CMC:**

- a) Plans, establishes, implements and maintains an audit program(s) including the frequency, methods, responsibilities, planning requirements and reporting, which take into consideration the importance of the process concerned, changes affecting CMC, and the results of previous audits;
- b) Defines the audit criteria and scope for each audit;
- c) Selects auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) Ensures that the results of the audits are reported to relevant management;
- e) Takes appropriate correction and corrective actions without undue delay;
- f) Retains documented information as evidence of the implementation of the audit program and the audit results

### **9.3 Management review**

#### **9.3.1 General**

Top management reviews the organization's quality management system, at planned intervals to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of CMC.

#### **9.3.2 Management review inputs**

The management review is planned and carried out taking into consideration:

- a) The status of actions from previous management reviews;
- b) Changes in external and internal issues that are relevant to the quality management system;
- c) Information on the performance and effectiveness of the quality management system, including trends in:
  - 1) Customer satisfaction and feedback from relevant interested parties;
  - 2) The extent to which quality objectives have been met;
  - 3) Process performance and conformity of products and services;
  - 4) Nonconformities and corrective actions;
  - 5) Monitoring and measurement results;
  - 6) Audit results;
  - 7) The performance of external providers;
- d) The adequacy of resources;
- e) The effectiveness of actions taken to address risks and opportunities (see 6.1)
- f) Opportunities for improvement.

### 9.3.3 Management review outputs

The outputs of the management review include decisions and actions related to:

- a) Opportunities for improvement;
- b) Any need for changes to the quality management system;
- c) Resource needs.

CMC retains documented information as evidence of the results of management reviews.

## 10 Improvement

### 10.1 General

CMC determines and selects opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These include:

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

### 10.2 Nonconformity and corrective action

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

- a) Reacts to the nonconformity and, as applicable:
  - 1) Takes action to control and correct it;
  - 2) Deals with the consequences;
- b) Evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not occur elsewhere, by:
  - 1) Reviewing and analyzing the nonconformity;
  - 2) Determining the causes of the nonconformity;
  - 3) Determining if similar nonconformities exist, or could potentially occur;
- c) Implements any action needed;
- d) Reviews the effectiveness of any corrective action taken;
- e) Updates risks and opportunities determined during planning, if necessary;
- f) Makes changes to the quality management system, if necessary.

Corrective actions are appropriate to the effects of the nonconformities encountered.

**10.2.2** CMC retains documented information as evidence of:

- a) The nature of the nonconformities and any subsequent actions taken;
- b) The results of any corrective actions.

### **10.3 Continual improvement**

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

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

## ANNEX A

### CHANGE HISTORY PAGE

<u>Revision</u>	<u>Change</u>	<u>Date</u>
1 <sup>st</sup> draft	Initial issue to meet the requirements of ISO 9000;2008 Made various edits to made this document fit CMC better	5/27/11
A	This version of the Quality Manual approved and released for use	6/29/11
B	Revised the Quality Policy (para. 5.3) and added Annex C Process Interaction Flow Chart. (ref. para. 4.2.2. c)	9/21/11
C	Revised Annex B	9/22/11
<b>D</b>	Rewrite to meet requirements of ISO 9001:2015	<b>7/10/17</b>

## Annex B Cross Reference between ISO 9001 and level 2 QMS procedures

Section of ISO 9001:2008 standard	QMS Proc #	Procedure Title:
<b>4 Context of the organization</b>		
4.1 Understanding the organization and its context	6	Quality Risk and Opportunities
4.2 Understanding the needs and expectations of interested parties	6	Quality Risk and Opportunities
4.3 Determining the scope of the quality management system	→	<i>(covered by quality manual)</i>
4.4 Quality management system and its processes	→	<i>(covered by quality manual)</i>
<b>5 Leadership</b>		
5.1 Leadership and commitment		
5.1.1 General	→	<i>(covered by quality manual)</i>
5.1.2 Customer focus	→	<i>(covered by quality manual)</i>
5.2 Quality policy		
5.2.1 Developing the quality policy	→	<i>(covered by quality manual)</i>
5.2.2 Communicating the quality policy	→	<i>(covered by quality manual)</i>
5.3 Organizational roles, responsibilities and authorities	1	Organizational Roles, Responsibilities, and Authorities
<b>6 Planning</b>		
6.1 Actions to address risks and opportunities	6	Quality Risk and Opportunities
6.2 Quality objectives and planning to achieve them	→	<i>(covered by quality manual)</i>
6.3 Planning of changes	→	<i>(covered by quality manual)</i>
<b>7 Support</b>		
7.1 Resources		
7.1.1 General		
7.1.2 People	9	Resources, Competence, and Awareness
7.1.3 Infrastructure	8	Calibration of Test and Measuring Equipment
7.1.4 Environment for the operation of processes	→	<i>(covered by quality manual)</i>
7.1.5 Monitoring and measuring resources	8	Calibration of Test and Measuring Equipment
7.1.6 Organizational knowledge	→	<i>(covered by quality manual)</i>
7.2 Competence	9	Resources, Competence, and Awareness
7.3 Awareness	9	Resources, Competence, and Awareness
7.4 Communication	→	<i>(covered by quality manual)</i>
7.5 Documented information		
7.5.1 General	→	<i>(covered by quality manual)</i>
7.5.2 Creating and updating	2	Creating, Updating, and Control of Documented Information
7.5.3 Control of documented information	2	Creating, Updating, and Control of Documented Information
<b>8 Operation</b>		
8.1 Operational planning and control	10	Operation Planning and Control – Products, Production, and Service Provisions
8.2 Requirements for products and services		
8.2.1 Customer communication	10	Operation Planning and Control – Products, Production, and Service Provisions
8.2.2 Determining the requirements related to products and services	10	Operation Planning and Control – Products, Production, and Service Provisions

8.2.3 Review of requirements related to products and services		
8.2.4 Changes to requirements for products and services	10	Operation Planning and Control – Products, Production, and Service Provisions
8.3 Design and development of products and services		<b>NOT APPLICABLE</b>
8.4 Control of externally provided processes, products and services	4	Externally Provided Processes, Products, and Services
8.4.1 General	4	Externally Provided Processes, Products, and Services
8.4.2 Type and extent of control	4	Externally Provided Processes, Products, and Services
8.4.3 Information for external providers	4	Externally Provided Processes, Products, and Services
8.5 Production and service provision		
8.5.1 Control of production and service provision	11	Preventive Maintenance of Production Equipment
8.5.2 Identification and traceability	10	Operation Planning and Control – Products, Production, and Service Provisions
8.5.3 Property belonging to customers or external providers	10	Operation Planning and Control – Products, Production, and Service Provisions
8.5.4 Preservation	10	Operation Planning and Control – Products, Production, and Service Provisions
8.5.5 Post-delivery activities	10	Operation Planning and Control – Products, Production, and Service Provisions
8.5.6 Control of changes	10	Operation Planning and Control – Products, Production, and Service Provisions
8.6 Release of products and services	12	Evaluation and Release of Products
8.7 Control of nonconforming outputs	5	Nonconformity and Corrective Action
<b>9 Performance Evaluation</b>		
9.1 Monitoring, measurement, analysis and evaluation		
9.1.1 General	7	Management Review
9.1.2 Customer satisfaction	13	Management Review
9.1.3 Analysis and evaluation	13	Management Review
9.2 Internal audit	3	Internal Audit
9.3 Management review	13	Management Review
9.3.1 General	13	Management Review
9.3.2 Management review inputs	13	Management Review
9.3.3 Management review outputs	13	Management Review
<b>10 Improvement</b>		
10.1 General	13	Management Review
10.2 Nonconformity and corrective action	5	Nonconformity and Corrective Action
10.3 Continual improvement	5	Nonconformity and Corrective Action

ANNEX C

PROCESS INTERACTION FLOW CHART



