

# Coast Composites, Inc.

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## ISO 9001:2000/AS9100B Quality Systems Manual

1395 S. Lyon Street  
Santa Ana, Ca. 92705

### Approvals

Paul Walsh (President)\_\_\_\_\_ Mark Joanis (Dir. Of Quality)\_\_\_\_\_

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## Scope and Introduction

### 1. Scope

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This standard includes ISO 9001:2000 and AS9100b quality system requirements and specifies additional requirements for the quality system of the aerospace industry.

It is emphasized that the quality system requirements specified in this standard are complementary (not alternative) to contractual and applicable law and regulatory requirements.

#### 1.1 General

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This Quality System Manual describes the organization and policies of the *Coast Composites, Inc.* quality system, and defines the methods and activities that the company uses to accomplish quality objectives, meet customer requirements, and conform to the applicable quality system standards.

The *Coast Composites, Inc.* quality system, as documented in the Quality System Manual and operating procedures, is designed to meet the requirements of its customers and the ISO 9001:2000 / AS9100B standards.

#### 1.2 Application

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*Coast Composites, Inc.* has determined that the following requirements are not applicable to the operations at this site and are documented as exclusions:

- § 7.5.1.5 Service: Coast Composites does not provide service operations on its manufactured tooling systems. Tool servicing would be addressed after delivery through Coast Composites Corrective Action process.

## Normative Reference

### 2.0 Quality Management System References

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The following documents were used as reference during the preparation of the Quality Management System:

- 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
- ISO 10007:1995, Quality management – Guidelines for configuration management
- ISO 10012:2003, Measurement management systems – Requirements for measurement processes and measuring equipment
- ISO 10012-1:1992, Quality assurance requirements for measuring equipment – Part1: Metrological confirmation system for measuring equipment
- ISO 10012-2:1997, Quality assurance for measuring equipment – Part 2: Guidelines for control of measurement processes
- ISO 19011:2002, Guidelines for quality and/or environmental management systems auditing
- AS/EN/SJAC 9102, Aerospace First Article Inspection Requirement

## Definitions

### 3.0 Quality Management System Definitions

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This section is for definitions unique to *Coast Composites, Inc.*

- 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. (e.g.: manufactured goods, merchandise, services etc.)
- 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
- Add, delete and revise definitions as appropriate to your quality system.
- Key Characteristics – The features of a material, process, or part whose variation has a significant influence on product fit, performance, service life, or manufacturability.

## Quality Management System

### 4.1 General requirements

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*Coast Composites, Inc.* has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of ISO 9001:2000 and AS9100b. 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 *Coast Composites, Inc.* has:

- § Identified the processes needed for the QMS and their application throughout the organization and documented them on the Process Flow Diagram at the end of this section of the Quality Manual
- § Determined the sequence and interaction of these processes, and illustrated them on the Process Flow Diagram
- § Determined criteria and methods needed to ensure that the operation and control of the processes are effective. Ref Process Flow Procedure
- § Ensured the continuing availability of resources and information 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

When *Coast Composites, Inc.* chooses to outsource any process that affects product conformity, *Coast Composites, Inc.* ensures control over such processes. Control of such outsourced processes is identified within the quality management system.

### 4.2 Documentation Requirements

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#### 4.2.1 General

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

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- § Quality system requirements imposed by the applicable regulatory authorities.

Coast Composites, Inc. ensures that personnel have access to quality management system documentation and are aware of relevant procedures. Customer and/or regulatory authorities representatives shall have access to quality management system documentation.

#### 4.2.2 Quality manual

This Quality Manual has been prepared to describe *Coast Composites, Inc.* 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. In addition, attachment I AS 9100B Procedure Matrix provides a breakdown of the standard and related Coast Composites, Inc. QMS documents. The Process Flow 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. 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

Coast Composites, Inc. coordinates document changes with customers and/or regulatory authorities in accordance with contract or regulatory requirements.

#### 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. This procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines

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the controls needed for identification, storage, protection, retrieval, retention time and disposition of quality records.

The procedure defines the method for controlling records that are created by and/or retained by suppliers.

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

### 4.3 Configuration Management

Coast Composites, Inc. has established, documented and maintains a configuration management process appropriate to the product.

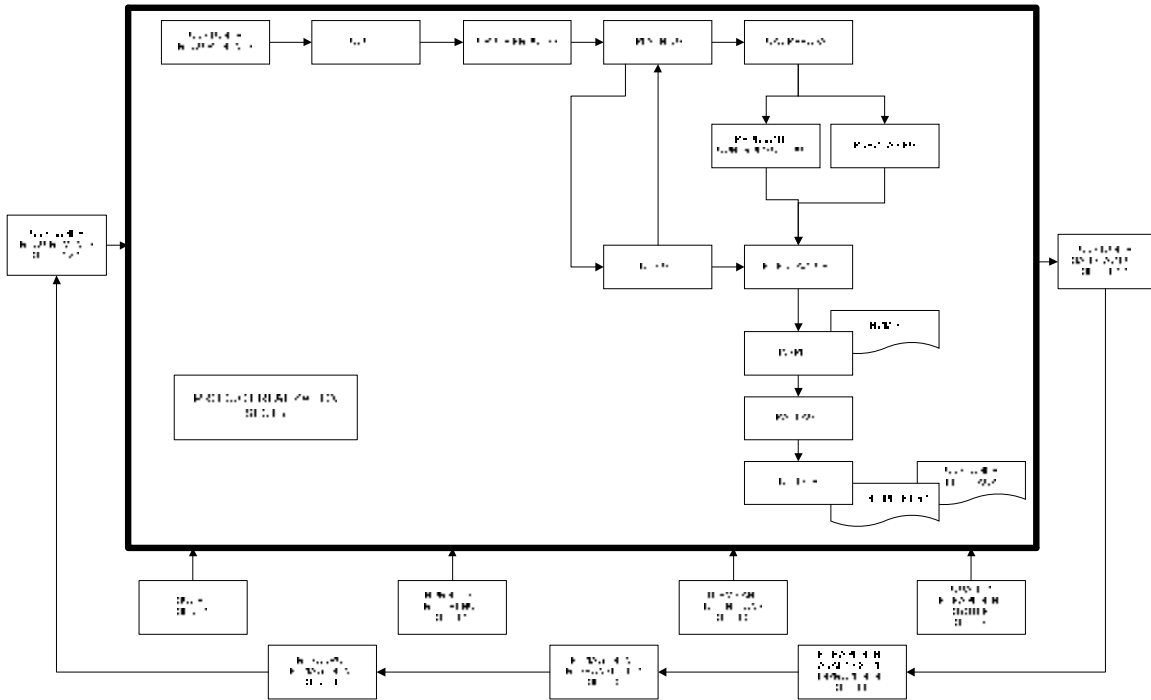
#### Related Procedures

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Document Control	Op-05
Control of Quality Records	Op-16
Purchasing	Op-06a
Procurement of outside processes	WI-06a-001
Document Control	WI-05-001
CAD/CAM/CAI Product Assurance Plan	

4.4 Coast Composites, Inc.

Process Based Quality Management System



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## Management Responsibility

### 5.1 Management commitment

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*Top management* has been actively involved in implementing the quality management system (QMS). It 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.
- § Establish quality objectives *annually* as a minimum.
- § Establish the quality policy.
- § Conduct *annual* management reviews as a minimum.
- § Ensure the availability of resources.

### 5.2 Customer focus

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*Coast Composites, Inc.* strives to identify current and future customer needs to meet customer requirements and exceed customer expectations.

Top management ensures that customer requirements are understood and met, by requiring compliance with documented customer focus procedures. Customer requirements are determined, converted into internal requirements, and communicated to the appropriate people in our organization.

### 5.3 Quality policy

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Top management has established the following quality policy.

“We ship quality products on time to meet customer expectations, and continually strive for continuous improvement and customer satisfaction”

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 and objectives at each management review meeting to determine the policy's continuing suitability for our organization.

## 5.4 Planning

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### 5.4.1 Quality objectives

Quality objectives are established *annually* to support our organization's efforts in achieving our quality policy. Objectives have been established, Quality objectives are measurable, and reviewed against performance goals at each management review meeting.

#### *Quality Objectives*

- *Produce defect-free tools and products.*
- *Consistently meet customer delivery schedules.*
- *Achieve continuous improvement in quality and productivity.*
- *Customer Satisfaction*

Coast Composites, Inc.'s quality goals will be documented in the management review meeting minutes.

### 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 9001:2000/AS9100b standard. Quality planning takes place as changes that affect the quality system are planned and implemented.

## 5.5 Responsibility, authority and communication

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### 5.5.1 Responsibility and authority

An organizational chart has been established to show the interrelation of personnel in the organization. Job skill requirements define the responsibilities and authorities of each of the positions on the organizational chart. Job skill requirements and the organizational chart are reviewed and approved by top management for adequacy. These documents are available throughout the organization to help employees understand responsibilities and authorities. *An organizational chart is located at the end of this section.*

### 5.5.2 Management representative

The Quality Assurance Manager has been appointed by top management as the management representative. As management representative they have the following responsibility and authority:

- § Ensure that processes needed for the quality management system are established and implemented.
- § Report to top management on the performance of the quality management system, 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.
- § The organizational freedom to resolve matter pertaining to quality.

### 5.5.3 Internal communication

Processes are established for communication within the organization. Methods of communicating the effectiveness of the QMS include *department and management meetings, management review, circulation of minutes of management review meetings, Internal Audit Closing meetings, and other routine business communication*. Ref. Communication Procedure.

## 5.6 Management review

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### 5.6.1 General

Top management reviews the QMS *annually* at management review meetings as a minimum. 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
- § Process performance and product conformity
- § Status of preventive and corrective actions
- § Follow-up actions from previous management reviews
- § Planned changes that could affect the quality management system

§ Recommendations for improvement

5.6.3 Review output

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

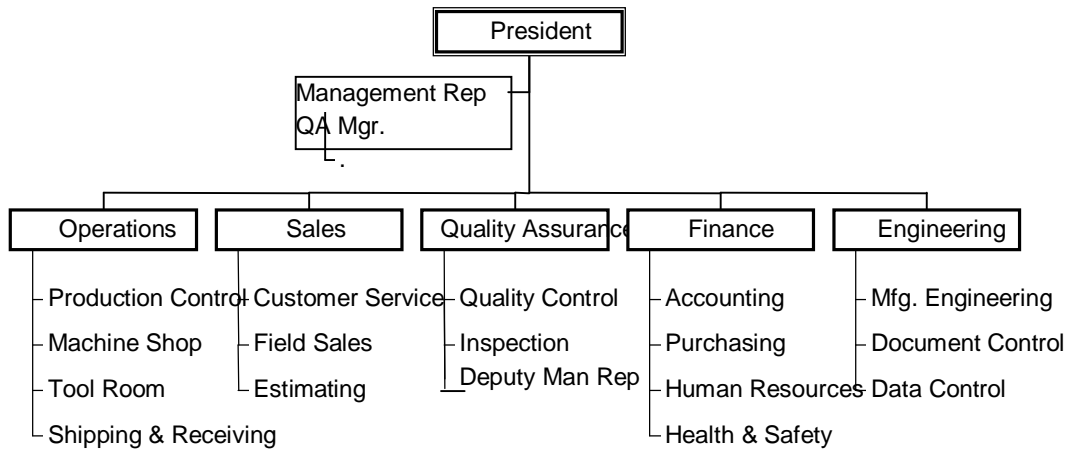
- § Improvement of the effectiveness of the quality management system and its processes
- § Improvement of product related to customer requirements
- § Resource needs

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

Related Procedures:

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Management Responsibility and Review	Op-01
Quality System and Quality Planning	Op-02a
Customer Focus	Op-21
Internal Communication	Op-22
Process Flow	Op-23
Continuous Improvement	Op-19



Names are maintained by Human Resources

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## Resource Management

### 6.1 Provision of resources

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*Coast Composites, Inc.* has implemented a Quality Management System that complies with the ISO 9001:2000 standard. This implementation was achieved with management commitment and with sufficient resources for the implementation. To effectively maintain and continually improve the system to meet customer requirements and maintain customer satisfaction, management determines necessary resources and provides those resources.

### 6.2 Human resources

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#### 6.2.1 General

To ensure competence of our personnel, job skill requirements have been prepared identifying the qualifications required for each position that affects product quality. Qualifications include requirements for education, skills and experience. Appropriate qualifications, along with required training, provide the competence required for each position.

#### 6.2.2 Competence, awareness and training

Qualifications are reviewed upon hire, when an employee changes positions and as the requirements for a position change. *Human resources* maintain records of employee qualifications. 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. The results are then evaluated to determine if they were effective. Training and evaluation are conducted according to the Training procedure.

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

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- § To meet quality objectives and product requirements *Coast Composites, Inc.* has determined the infrastructure needed. The infrastructure has been provided and includes buildings, workspace, utilities, process equipment and supporting services.

### 6.4 Work Environment

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A work environment suitable for achieving product conformance is maintained. Requirements are determined during quality planning and documented in the quality plan. The work environment is managed for continuing suitability. Factors that may affect the conformity of the product include temperature, humidity,

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lighting, cleanliness, protection from electrostatic discharge, etc. 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

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Training Op-18

Process Control Op-09

## Product Realization

### 7.1 Planning of product realization

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Quality planning is required before new products or processes are implemented. The quality planning may take place as a design project, or according to the Process Control procedure. 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 identification of resources to support operation and maintenance of the product.

The output of quality planning includes documented quality plans, processes, procedures and design outputs.

### 7.2 Customer-related processes

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

*Coast Composites, Inc.* determines customer requirements before acceptance of an order. Customer requirements include those:

- § Requested by the customer
- § 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 *Coast Composites, Inc.*

Any additional requirement determined by *Coast Composites, Inc.* will be documented in writing with customer approval and forwarded to document control.

### 7.2.2 Review of requirements related to the product

*Coast Composites, Inc.* has a process in place for the review of requirements related to the product. 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
- § *Coast Composites, Inc.* has the ability to meet the defined requirements
- § Records are maintained showing the results of the review and any actions arising from the review
- § Where a customer does not provide a documented statement of requirement, the customer requirements are confirmed before acceptance
- § When product requirements are changed, *Coast Composites, Inc.* communicates changes to relevant personnel and amends relevant documents
- § Risks (e.g., new technology, short delivery time scale) have been evaluated.

### 7.2.3 Customer communication

*Coast Composites, Inc.* has implemented an effective process for communicating with customers in relation to:

- § Product Information
- § Enquiries, contracts and order handling, including amendments
- § Customer Feedback, including customer complaints

## 7.3 Design and Development

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### 7.3.1 Design and Development Planning:

*Coast Composites, Inc.* plans the design and development of product to customer specifications and requirements. CCI does not possess customer design approval authority. All CCI designs get customer approvals at various stages throughout the design process.

During the design and development planning, *Coast Composites, Inc.* will determine

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- a) the design and development stages,
  - in respect of organization, task sequence, mandatory steps, significant stages and method of configuration control,
- b) the review, verification and validation that are appropriate to each design and development stage, and
- c) the responsibilities and authorities for design and development.

Where appropriate, *Coast Composites, Inc* will give consideration to the following activities:

- structuring the design effort into significant elements;
- for each element, analyzing the tasks and the necessary resources for its design and development. This analysis shall consider an identified responsible person, design content, input data, planning constraints, and performance conditions. The input data specific to each element will be reviewed to ensure consistency with customer requirements.

*Coast Composites, Inc* manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output will be updated, as appropriate, as the design and development progresses.

The different design and development tasks to be carried out will be defined according to specified safety or functional objectives of the product in accordance with customer and/or regulatory authority requirements.

### 7.3.2 Design and Development Inputs:

Inputs relating to product requirements will be determined by *Coast Composites, Inc* customer specifications and records maintained (see 4.2.4).

These inputs may include

- a) functional and performance requirements,
- b) applicable statutory and regulatory requirements,
- c) where applicable, information derived from previous similar designs, and
- d) other requirements essential for design and development.

### 7.3.3 Design and Development Outputs:

The outputs of design and development will be provided to the customer in a format that enables verification against the design and development input and will be approved by the customer prior to release.

Design and development outputs will

- a) meet the customer input requirements for design and development,
- b) provide appropriate information for purchasing and production,
- c) contain or reference customer product acceptance criteria,
- d) specify the characteristics of the product that are essential for its safe and proper use, *and*
- e) identify key characteristics, when applicable, in accordance with customer design or contract requirements.

All pertinent data required to allow the product to be identified, manufactured, inspected, used and maintained will be defined by the customer; for example:

- drawings, part lists, specifications;
- a listing of those drawings, part lists, and specifications necessary to define the configuration and the design features of the product;
- information on material, processes, type of manufacturing and assembly of the product necessary to ensure the conformity of the product.

### 7.3.4 Design and Development Review

At suitable stages, systematic reviews of design and development will be performed by the customer in accordance with planned arrangements (see 7.3.1)

- a) to evaluate the ability of the results of design and development to meet requirements,
- b) to identify any problems and propose necessary actions, *and*
- c) *to authorize progression to the next stage.*

Participants in such reviews will include a representative from *Coast Composites, Inc* design group and the customer. Records of the results of the reviews and any necessary actions will be maintained (see 4.2.4).

#### 7.3.5 Design and Development Verification:

Verification will be performed by the customer in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the customer design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

#### 7.3.6 Design and Development Validation:

Design and development validation is the responsibility of the customer. All *Coast Composites, Inc* design efforts are per customer requirements and specifications.

##### 7.3.6.1 Documentation of Design and/or Development Verification and Validation:

At the completion of design, *Coast Composites, Inc* will send design to the customer for final design verification and if needed, validation.

##### 7.3.6.2 Design and/or Development Verification and Validation Testing:

Design and development verification/validation testing is the responsibility of the customer. All *Coast Composites, Inc* design efforts are per customer requirements and specifications.

#### 7.3.7 Control of Design and Development Changes:

Customer design and development changes are identified and records maintained. The changes will be reviewed by *Coast Composites, Inc* Project Manager and designer as appropriate, and approved before implementation. The review of design changes that effect changes on constituent parts and product is the responsibility of the customer.

*Coast Composites, Inc* change control process will provide for customer and or regulatory authority approval of changes, when required by contract or regulatory requirement.

Records of the customer review and any necessary actions will be maintained (see 4.2.4).

## 7.4 Purchasing

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### 7.4.1 Purchasing process

A documented procedure is followed to ensure that purchased product conforms to the specified purchase requirements.

Coast Composites, Inc. is responsible for the quality of all products purchased from suppliers, including customer-designated sources.

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.

Coast Composites, Inc. will:

- § Maintain a register of approved suppliers that includes the scope of the approval
- § Periodically review supplier performance; records of these reviews shall be used as a basis for establishing the level of controls to be implemented
- § Define the necessary actions to take when dealing with suppliers that do not meet requirements
- § Ensure where required that both the organization and all suppliers use customer-approved special process sources
- § Ensure that the function having responsibility for approving supplier quality systems has the authority to disapprove the use of sources

### 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
- § Quality management system requirements
- § The name or other positive identification, and applicable issues of specifications, drawings, process requirements, inspection instructions and other relevant technical data
- § Requirements for design, test, examination, inspection and related instructions for acceptance by the organization

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- § Requirements for test specimens (e.g., production method, number, storage conditions) for design approval, inspection, investigation or auditing
- § Requirements relative to
  - § supplier notification to organization of nonconforming product and
  - § arrangements for organization approval of supplier nonconforming material
- § requirements for the supplier to notify the organization of changes in product and/or process definition and, where required, obtain organization approval
- § right of access by the organization, their customer, and regulatory authorities to all facilities involved in the order and to all applicable records, and
- § requirements for the supplier to flow down to sub-tier suppliers the applicable requirements in the purchasing documents, including key characteristics where required.

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 describes the process used to verify that purchased product meets specified purchase requirements. If *Coast Composites, Inc.* or the customer will perform verification at the supplier's premises, the verification arrangements and method of product release are documented in the purchasing information.

Verification activities may include:

- § obtaining objective evidence of the quality of the product from suppliers (e.g., accompanying documentation, certificate of conformity, test reports, statistical records, process control)
- § inspection and audit at supplier's premises
- § review of the required documentation
- § inspection of products upon receipt
- § delegation of verification to the supplier, or supplier certification.

Purchased product shall not be used or processed until it has been verified as conforming to specified requirements unless it is released under positive recall procedure.

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Where Coast Composites, Inc. utilizes test reports to verify purchased product, the data in those reports shall be acceptable per applicable specifications. Coast Composites, Inc. will periodically validate test reports for raw material.

Where Coast Composites, Inc. delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations maintained.

Where specified in the contract, the customer or the customer's representative shall be afforded the right to verify at the supplier's premises and the organization's premises that subcontracted product conforms to specified requirements.

Verification by the customer will not be used by Coast Composites, Inc. as evidence of effective control of quality by the supplier and shall not absolve Coast Composites, Inc. of the responsibility to provide acceptable product, nor shall it preclude subsequent rejection by the customer.

## 7.5 Production Provision

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### 7.5.1 Control of production provision

Planning shall consider, as applicable,

- § The establishment of process controls and development of control plans where key characteristics have been identified
- § The identification of in-process verification points when adequate verification of conformance cannot be performed at a later stage of realization.
- § The design, manufacture, and use of tooling so that variable measurements can be taken, particularly for key characteristics, and
- § Special processes.

*Coast Composites, Inc.* plans and carries out production provision under controlled conditions. 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
- § Accountability for all product during manufacture (e.g., parts quantities, split orders, nonconforming product)
- § Evidence that all manufacturing and inspection operations have been completed as planned, or as otherwise documented and authorized,
- § Provision for the prevention, detection, and removal of foreign objects
- § Monitoring and control of utilities and supplies such as water, compressed air, electricity and chemical products to the extent they affect product quality.
- § Criteria for workmanship, which shall be stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations).

#### 7.5.1.1 Production Documentation

Coast Composites, Inc. operations are carried out in accordance with approved data. This data shall contain as necessary.

- § Drawings, parts lists, process flow charts including inspection operations, production documents (e.g., manufacturing plans, traveler, router, work order, process cards); and inspection documents.
- § A list of specific or non-specific tools and numerical control machine programs required and any specific instructions associated with their use.

#### 7.5.1.2 Control of Production Process Changes

Coast Composites, Inc. identifies persons with authority to approve changes to production process.

Coast Composites, Inc. identifies and obtains acceptance of changes that require customer and/or regulatory authority approval in accordance with contract or regulatory requirements.

Changes affecting processes, production equipment, tools and programs will be documented. Procedures are available to control their implementation.

The results of changes to production processes are assessed to confirm that the desired effect has been achieved without adverse effects to product quality.

#### 7.5.1.3 Control of Production Equipment, Tools and Numerical Control Programs

Production equipment, tools and programs are validated prior to use and maintained and inspected periodically according to documented procedures.

Validation prior to production use will include verification of the first article produced to the design data/specification.

Storage requirements, including periodic preservation/condition checks, are established for production equipment or tooling in storage.

#### 7.5.1.4 Control of Work Transferred, Temporary Basis, Outside the Company

When planning to temporarily transfer work to a location outside of the company, a process to control and validate the quality of the work will be defined.

#### 7.5.1.5 Control of Service Operations

Where servicing is a specified requirement, a service operation process will be provided for

- § A method of collecting and analyzing in-service data
- § Actions to be taken where problems are identified after delivery, including investigation, reporting activities, and actions on service information consistent with contractual and/or regulatory requirements.
- § The control and updating of technical documentation
- § The approval, control, and use of repair schemes
- § The controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).

#### 7.5.2 Validation of processes for production provision

*Coast Composites, Inc.* 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 or the service has been delivered. Validation demonstrates the ability of these processes to achieve planned results.

NOTE: These processes are frequently referred to as special processes.

*Coast Composites, Inc.* has documented the process for validation including:

- § Defined criteria for review and approval of the processes
  - qualification and approval of special processes prior to use

- § Approval of equipment and qualification of personnel
- § Use of specific methods and procedures
  - control of the significant operations and parameters of special processes in accordance with documented process specifications and changes thereto
- § Requirements for records
- § Revalidation

### 7.5.3 Identification and traceability

*Coast Composites, Inc.* identifies the product throughout product realization according to the Identification and Traceability procedure. Product is identified with respect to monitoring and measurement requirements.

Coast Composites, Inc maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

When acceptance authority media is used (e.g., stamps, electronic signatures, passwords), Coast Composites, Inc. uses documented controls for the media.

*Coast Composites, Inc.* controls and records the unique identification of the product where ever traceability is a specified requirement

According to the level of traceability required by contract, regulatory, or other established requirement, Coast Composites, Inc. system will provide for:

- § identification to be maintained throughout the product life;
- § all the products manufactured from the same batch of raw material or from the same manufacturing batch to be traced, as well as the destination (delivery, scrap) of all products of the same batch;
- § for an assembly, the identity of its components and those of the next higher assembly to be traced;
- § for a given product, a sequential record of its production (manufacture, assembly, inspection) to be retrieved.

### 7.5.4 Customer property

*Coast Composites, Inc.* exercises care with customer property while it is under the organization's control or being used. A procedure outlines the Identification, verification, protection and safeguarding of customer property provided for use or incorporation into the product. 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

*Coast Composites, Inc.* preserves the conformity of product during internal processing and delivery to the intended destination. This preservation includes identification, handling, packaging, storage and protection. Preservation also applies to the constituent parts of a product.

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

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

Coast Composites, Inc. ensures that documents required by the contract/order to accompany the product are present at delivery and are protected against loss and deterioration.

## 7.6 Control of monitoring and measuring devices

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*Coast Composites, Inc.* has determined the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements. A documented procedure outlines the process used to ensure that monitoring and measurement to be carried out are carried out in a manner that is consistent with the monitoring and measurement requirements.

Coast Composites, Inc. maintains a register of these monitoring and measuring devices, and has defined the process employed for their calibration including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

NOTE: Monitoring and measuring devices include, but are not limited to: test hardware, test software, automated test equipment (ATE) and plotters used to produce inspection data. It also includes personally owned and customer supplied equipment used to provide evidence of product conformity.

Coast Composites, Inc. will ensure that environmental conditions are suitable for the calibrations, inspections, measurements and tests being carried out.

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

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- § 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.
- § Be recalled to a defined method when requiring calibration.

In addition, Quality Control assesses and records the validity of the previous measuring results when the equipment is found not to conform to requirements. *Coast Composites, Inc.* takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

## Related Documents

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Process Control	Op-09
Contract and Sales Order Review	Op-03a
Purchasing	Op-06a, Op-06b
Product Identification and Traceability	Op-08
Handling, Storage, Packaging and Preservation	Op-15
Control of Test and Measuring Equipment	Op-11
Inspection and Testing	Op-10
Inspection and Test Status	Op-12
Customer Supplied Product	Op-07

## 8 Measurement, Analysis and Improvement

### 8.1 General

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*Coast Composites, Inc.* has planned and implemented the monitoring, measurement, analysis and improvement processes needed

- § To demonstrate conformity of the product,
- § To ensure conformity of the quality management system, and
- § To continually improve the effectiveness of the quality management system.

This process is identified in documented procedures and includes determination of applicable methods, including statistical techniques, and the extent of their use.

NOTE: According to the nature of the product and depending on the specified requirements, statistical techniques may be used to support:

- § design verification (e.g., reliability, maintainability, safety)
- § process control
- § selection and inspection of key characteristics
- § process capability measurements
- § statistical process control
- § design of experiment
- § inspection-matching sampling rate to the criticality of the product and to the process capability
- § failure mode and effect analysis

### 8.2 Monitoring and Measurement

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#### 8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management system, *Coast Composites, Inc.* monitors information relating to customer perception as to whether the organization has fulfilled customer requirements. The method for obtaining and using this information is identified in the Customer related processes and the Management Responsibility procedures.

#### 8.2.2 Internal Audit

*Coast Composites, Inc.* conducts internal audits at planned intervals to determine whether the quality management system

§ Conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system 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 processes and 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 results and maintaining are defined and documented in the Internal Audit procedure. Auditors are not allowed to audit their own work.

The management responsible for the area being audited is responsible for ensuring that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the actions taken and the reporting of verification results.

Detailed tools and techniques have been developed such as check sheets, process flowcharts, or any similar method to support audit of the quality management system requirements. The acceptability of the selected tools, are measured against the effectiveness of the internal audit process and overall organization performance.

Coast Composites, Inc. assures all internal audits meet contract and/or regulatory requirements.

### 8.2.3 Monitoring and measurement of processes

*Coast Composites, Inc.* applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate, to ensure conformity of the product. The process for identifying and carrying out the required monitoring and measuring of processes is documented in the Continuous Improvement and Management Responsibility procedures.

In the event of process nonconformity, the organization shall

- § Take appropriate action to correct the nonconforming process
- § Evaluate whether the process nonconformity has resulted in product nonconformity
- § Identify and control the nonconforming product in accordance with clause 8.3

#### 8.2.4 Monitoring and measurement of product

*Coast Composites, Inc.* 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 Continuous Improvement procedure.

When key characteristics have been identified, they will be monitored and controlled.

When Coast Composite, Inc. uses sampling inspection as a means of product acceptance, the plan will be statistically valid and appropriate for use. The plan will preclude the acceptance of lots whose samples have known nonconformities. When required, the plan will be submitted to the customer for approval.

The product will not be used until it has been inspected or otherwise verified as conforming to specified requirements, except when product is released under positive-recall procedures pending completion of all required measurement and monitoring activities.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release and service delivery does not proceed until all the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority, and where applicable by the customer.

##### 8.2.4.1 Inspection Documentation

Measurement requirements for product or service acceptance will be documented. The documentation may be part of the production documentation, but will include:

- § Criteria for acceptance and/or rejection.
- § Where in the sequence measurement and testing operations are performed.
- § A record of the measurement results.
- § Type of measurement instruments required and any specific instructions associated with their use.

Test records will show actual test results data when required by specification or acceptance test plan.

Where required to demonstrate product qualification Coast Composite, Inc. will ensure that records provide evidence that the product meets the defined requirements.

#### 8.2.4.2 First Article Inspection

Coast Composites, Inc. is a tooling manufacturing company that provides one-off or single piece product to our customers. Coast Composites does not deal in multi-piece or production runs of product. All products manufactured at Coast Composites get 100% inspected per contract.

### 8.3 Control of Nonconforming Product

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*Coast Composites, Inc.* 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.

NOTE: The term “nonconforming product” includes nonconforming product returned from a customer.

Coast Composites, Inc. procedure defines the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

*Coast Composites, Inc.* shall deal with nonconforming product by one or more of the following ways:

- § By taking action to eliminate the detected nonconformity
- § By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable by the customer
- § By taking action to preclude its original intended use of application

Coast Composites, Inc. does not use dispositions of use-as-is or repair, unless specifically authorized by the customer, if

- § the product is produced to customer design, or
- § the nonconformity results in a departure from the contract requirements.

Unless otherwise restricted in the contract, Coast Composites, Inc. product which is controlled via a customer specification may be dispositioned by Coast Composites, Inc. as use-as-is or repair, provided the nonconformity does not result in a departure from customer-specified requirements.

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

Records of the nature of nonconformities and by subsequent actions taken, including concessions obtained, shall be maintained.

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

When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects or potential effects of the nonconformity.

In addition to any contract or regulatory authority reporting requirements, Coast Composites, Inc. will provide for timely reporting of delivered nonconforming product that may affect reliability or safety. Notification will include a clear description of the nonconformity, which includes as necessary parts affected, customer and/or Coast Composites, Inc. part numbers, quantity, and date delivered.

## 8.4 Analysis of Data

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*Coast Composites, Inc.* determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. The process for determining, collecting and analyzing this data is defined in the Management Responsibility and Review procedure. Appropriate data includes data 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

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### 8.5.1 Continual improvement

*Coast Composites, Inc.* continually improves the effectiveness of the quality management system 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

*Coast Composites, Inc.* takes action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

A documented procedure defines 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 (see 4.2.4), and
- § Reviewing corrective action taken.
- § Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause.
- § Specific actions where timely and/or effective corrective actions are not achieved.

### 8.5.3 Preventive action

*Coast Composites, Inc.* 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 procedure defines 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

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Management Responsibility and Review	Op-01
Continuous Improvement Process	Op-19
Internal Quality Audits	Op-17

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Control of Nonconforming Product	Op-13
Corrective and Preventive Action	Op-14
Process Flow	Op-23
Inspection and Testing	Op-10
Statistical Techniques	Op-20
Customer Focus	Op-21
Process Control	Op-09

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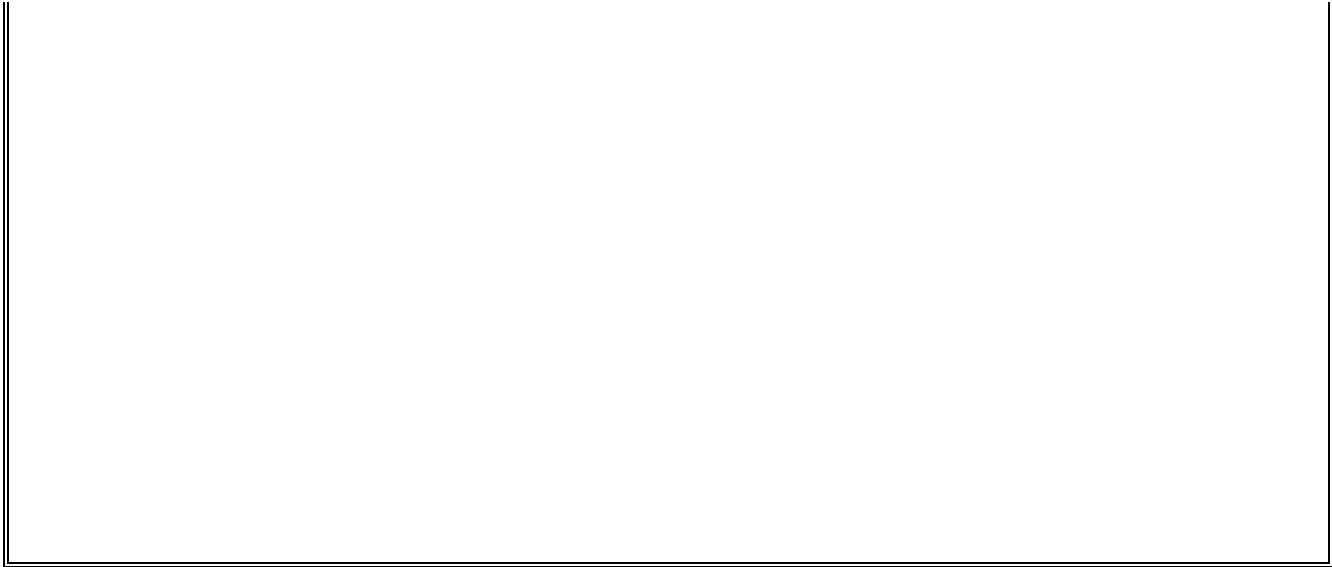
## QUALITY SYSTEM MANUAL REVISIONS

REV.	SECTION	SUB-SEC.	PARA.	CHANGE	DATE	AUTHORIZED BY
7	All	All	All	Re-write to ISO 9000:2000	06/16/03	M. Joanis (Q.A. Manager)
8	All			Name from "UCAR Composites" to "Coast Composites"	07/01/03	M. Joanis (Q.A. Manager)
9	Process Chart			Removed internal audit from chart	08/25/03	M. Joanis (Q.A. Manager)
10	7.5	All		Removed ref to "service" in entire section	09/05/03	M. Joanis (Q.A. Manager)
	4.2	Flow chart		Revised flowchart to reflect management controls	09/05/03	
11				Add AS9100 requirements to entire manual	07/26/07	M. Joanis (Q.A. Manager)
12	7.3	all	all	Added in CCI design process	09/17/09	M. Joanis (Q.A. Manager)
13	7.3	7.3.1		Added:CCI does not possess customer design approval authority. All CCI designs get customer approvals at various stages throughout the design process.	09/22/09	M. Joanis (Q.A. Manager)

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