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	Quality Manual	Revision	: E
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SEEMANN COMPOSITES

Quality Management System (QMS) Manual

In compliance with
AS9100:2016 and ISO 9001:2015


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Approvals

Role	Name	Position
Approved By	Sid Charbonnet	President
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Digital signatures are located in the QMS along with document details (active date, document changes, and previous revisions). For further assistance reference the link below.

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Revision History

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ALL	ALL	A	03/05/2020	Initial Release	TH / 1322
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8.4.3	24	B	11/03/2020	Formatted to align with AS9100 standard	TH / 1322
8.5.1	25	B	11/03/2020	Added control schemes for mills	TH / 1322
5.3.1	14	C	07/08/21	Updated Organization Chart	TH / 1322
6.2.2	15	C	06/29/2021	Removed detailed language of quality objectives from the quality manual.	TH / 1322
6.3.1	14	D	03/28/2022	Added additional references	MC/1433
Table of contents	4	D	03/28/2022	Updated table of content page numbers due to document reformatting	MC/1433
1.0	6	E	01/30/2023	Changed to reference Q-Pulse	TH/1322
4.1.2	9	E	01/30/2023	Added employment market challenges to external issues	TH/1322
5.3	15	E	01/30/2023	Changed titles and updated org chart	TH/1322
6.1.1	16	E	01/30/2023	Deleted reference to SWOT	TH/1322


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Definitions

Quality Assurance Procedure – QAP procedures specify processes that meet the requirements of Seemann Composites Quality Management System in compliance with AS9100 Aerospace Standard. These procedures are approved by Senior Management and are controlled.

Quality Assurance Forms – QAF forms are controlled. They are approved by Quality / affected management to be the latest revision of the form and suitable for use in the quality processes.

Quality Assurance Logs – QAL logs are developed to assure that quality systems are established and meet the requirements of Seemann Composites Quality Management System in compliance with AS9100 Aerospace Standard.


SWOT: Strength Weakness Opportunity Threat Analysis – SWOT analysis is used as a determination of risks to the company.

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SECTION 1: Quality Manual Distribution

1.0 Quality Manual Distribution

This Quality Management System Manual shall be available to all staff employees through electronic format via the Seemann Composites Q-Pulse system. All other copies of the manual issued will be marked uncontrolled.

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SECTION 2: Scope

2.0 Scope


Seemann Composites, LLC (SCI) developed and implemented a quality management system to:

- demonstrate our ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements
- enhance customer satisfaction through the effective application of the system
- ensure continual processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements
- address risks and opportunities.

This system complies with the requirements stated in AS9100D and the international standard ISO 9001:2015. This system applies in varying extent to all of our business activities including the development and production of Seemann Composites' products at: 12481 Glasscock Drive, Gulfport, MS 39503

This manual is divided into ten (10) sections correlating to the section of AS9100D Quality Management Systems – Requirements for Aviation, Space and Defense Organizations. The purpose of this quality management system manual is to delineate authorities, inter relationships and responsibilities of the personnel within the quality management system; and to provide procedures or references for all activities comprising the quality management system to ensure compliance to the necessary requirements of the standard. The range and detail of these procedures are dependent upon the complexity of the work, the methods used, and the skills and training needed by personnel involved in the activity.

This manual is used internally to guide our employees through the various requirements of the AS9100 standard that must be met and maintained in order to ensure customer satisfaction, continuous improvement and provide the necessary instruction that create an empowered work force. This manual is also used externally to introduce our quality management system to our customers and other external organizations and to inform them of what specific controls are implemented at Seemann Composites to assure quality and promote continuous improvement, risk mitigation and customer satisfaction.

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SECTION 3: Quality Policy

Seemann Composites LLC is committed to providing superior products and services, On schedule at a competitive price. We will strive to meet and exceed the product And our customer requirements. Through focused continuous improvement and active employee participation in the quality management system, we are dedicated to exceeding customers' expectations.



Sid Charbonnet, President




Will Seemann, Chief Financial Officer



Randy Bardwell, Chief Operations Officer



Riley Woodham, Chief Technology Officer

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SECTION 4: Context of the Organization

4.1 Context of The Organization


4.1.1 SCI was founded on its research and development innovation with composite fabrication processes and is a recognized leader in large scale resin infusion technology. SCI is committed to providing state of the art composite solutions and technologies for DOD and commercial platforms while maintaining a significant research and development capability to remain on the forefront of composites processing technology. Through pervasive quality and continuous improvement, SCI will strive to maintain our strategic advantage by providing the best value, and quality products to our US military, and major defense and commercial customers while adding value to our owners, employees, and our community.

4.1.2 SCI identifies, monitors, and reviews on an annual or as-needed basis the external and internal issues that affect its ability to achieve the intended results of its quality management system and factors that are relevant to the organization's purpose and strategic direction.

- Internal Issues:
 - ✓ Continual Improvement
 - ✓ Employee Competency
 - ✓ Performance
 - ✓ Capacity and Infrastructure
 - ✓ Resources
- External Issues:
 - ✓ Customer Satisfaction
 - ✓ Supplier Performance
 - ✓ Economic Climate
 - ✓ Markets and Competitors
 - ✓ Regulations
 - ✓ Employment market challenges

4.2 Understanding the needs and expectations of interested parties

4.2.1 Due to their effect or potential effect on SCI's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements SCI identifies and assesses the potential impact of any relevant needs and expectations that may be elicited from our interested parties. This information is reviewed at Management Review Meetings on an annual basis. Such needs and expectations broadly include the following:

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Interested Party	Needs and Expectations
Customers	Quality, Cost-effective, state of the art solutions on schedule
Owners	Profitability and return on investment that reflects its value and subjected
Employees	Job security, financial incentives and rewards, career development & training within a safe, positive work environment
Suppliers	Mutually beneficial working relationship allowing for continued growth
Community	Ethical behavior, environmental protection and compliance with statutory and regulatory requirements
US Warfighter	Innovative and reliable equipment to support a safer work environment


4.3 Determining the scope of the quality management system

4.3.1 Based on the analysis of the issues and requirements identified in Sections 4.1 and 4.2, SCI has established the Scope of our quality management system in order to implement our objectives and our policies that are relevant to our contexts, products, and interested parties. Our business has four (4) key or core processes that include Customer Requirements, Purchasing, Engineering, and Manufacturing.

4.3.2 SCI applies all the requirements of the AS9100 standard within the determined scope of our Quality Management System. SCI uses the manual as an effective communication tool to our employees, customers, and other external organizations and aids in informing them of what specific controls are implemented at SCI to assure quality and promote continuous improvement, risk mitigation, and customer satisfaction.

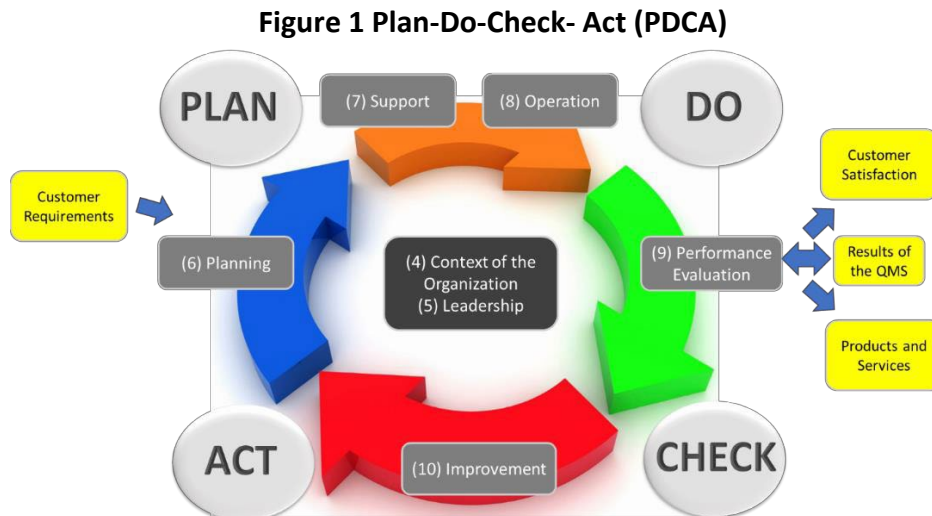
4.3.3 The Quality Management System is structured as below:




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4.4 Quality Management System and its processes

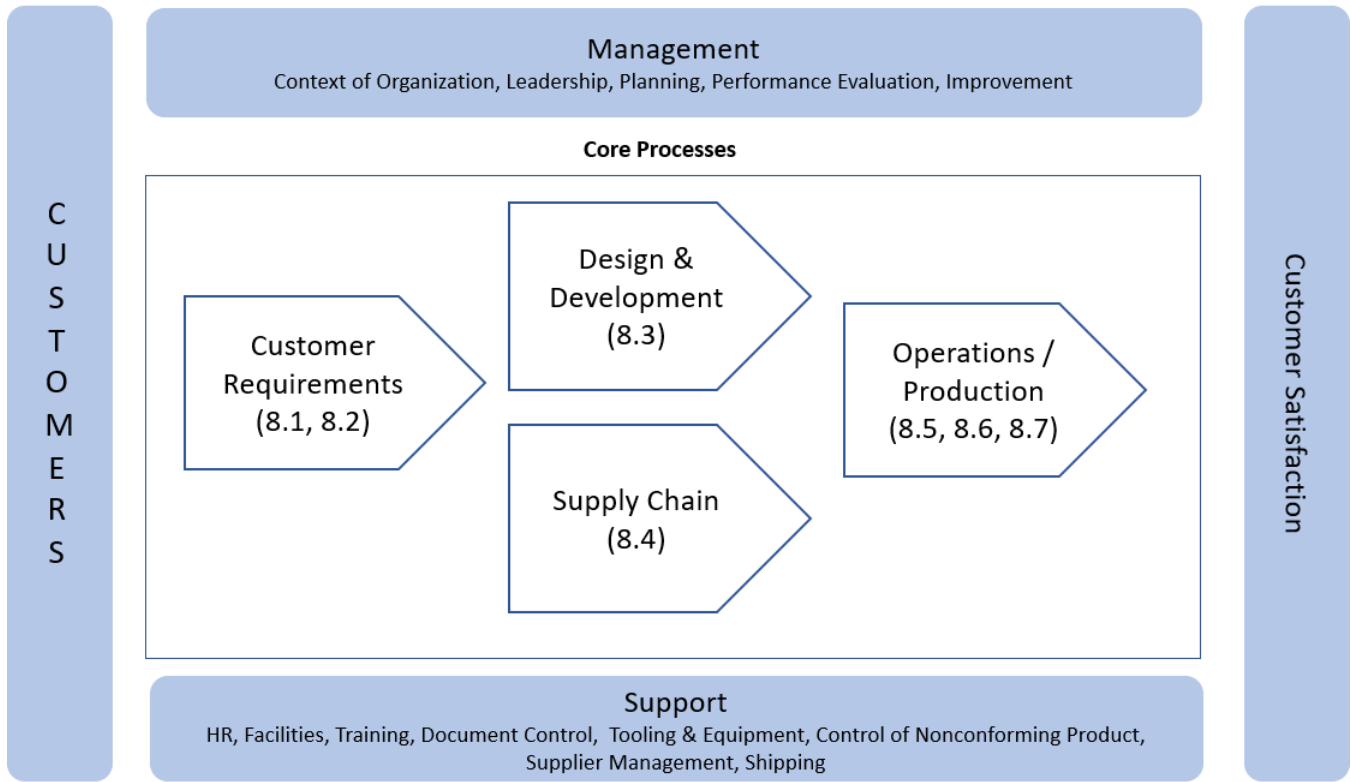
4.4.1 SCI has established, documented and implemented a quality management system that is based on a process approach advocated by AS9100. SCI has determined the processes needed and their application throughout SCI. All of the main activities in the company can be categorized into the Plan-Do-Check-Act cycle and the 10 sections of the AS9100 standard as noted in Figure 1 below.



4.4.2 The sequence and interrelation between the categories and individual processes are illustrated in Figure 2 below. The processes are documented in this quality management system manual and in associated procedures and work instructions. This QMS documentation defines these processes and their sequence and interaction and instructs on how to implement and apply them throughout the organization. The documentation also defines criteria and methods needed to ensure that the operation and control of processes are effective. This includes the assignment of responsibilities and allocation of resources for the process, instructions on how to carry out the process, and the definition of methods for monitoring and measuring the effectiveness of the process.

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Quality Management System Process Interaction



Risk Management is performed in all appropriate areas of the Quality Management System

Figure 2 Quality Management System Process Interaction

- 4.4.3 The quality management 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 reviews.
- 4.4.4 All outsourced processes are clearly defined using purchase orders that have been approved by Quality and by Suppliers who are on the Authorized Supplier List. As part of the approval process Quality ensures the Supplier is capable of providing products and services that meet the requirements of our Customers, this Standard, and all Regulatory requirements.

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SECTION 5: Leadership

5.1 Leadership Commitment

5.1.1 SCI executive management team is actively involved in the implementation of the quality system. The executive management team demonstrates leadership and commitment through providing the vision and strategic direction for the growth of the company and quality system and establishing objectives, initiatives, measurements, and targets. The executive team is responsible for:

- a) 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 SCI;
- c) ensuring the integration of the quality management system requirements into SCI'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 SCI executive management team ensures customer focus is maintained by ensuring that customer, applicable statutory, and regulatory requirements, are determined, understood, and met and that risks and opportunities that can affect conformity of products and services and our ability to enhance customer satisfaction are determined and addressed and that the focus of enhancing customer satisfaction is maintained. For all contracts, the contract review is comprised of verification that the customer's requirements are adequately defined, documented, understood and that SCI has the capacity to meet the contractual requirements, and that these requirements are communicated throughout the organization to the appropriate individuals. Verification that products and services meet customer requirements will occur prior to the product leaving the facility with the End Item Review Form. On-time delivery is monitored and tracked by Program Management for all orders.

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5.2 Quality Policy

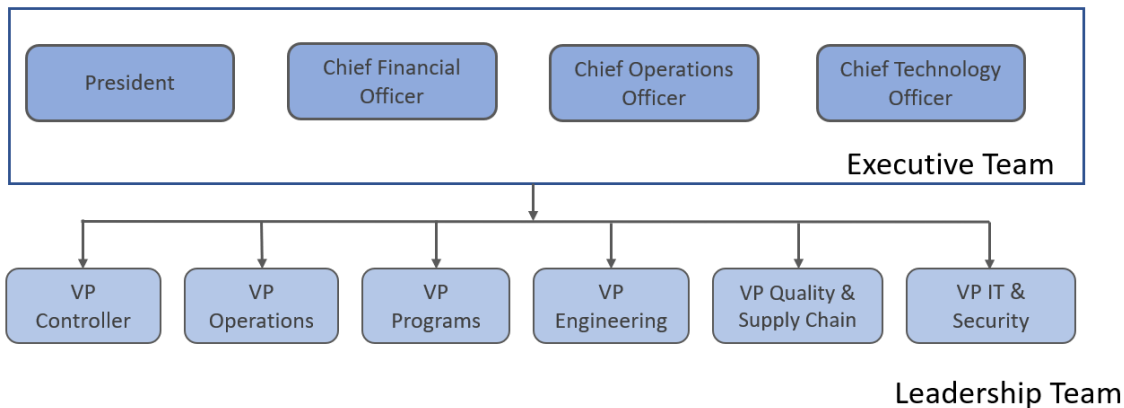
5.2.1 The SCI quality policy defines the company's commitment to quality and continuous improvement. The executive management team reviews the quality policy as part of the management review meetings to determine the policy's continuing suitability for the organization. A copy of the quality policy is contained in Section 3 of this manual along with the executive management signatures.


5.2.2 The policy and quality management system are reviewed as part of the new employee and temporary contract employee orientation training. The quality policy is also communicated through operational and department meetings, management reviews and by signs posted throughout the company.

5.3 Organizational roles, responsibilities, and authorities

5.3.1 The chart below shows the interrelation of personnel who lead, perform and verify work-affecting quality. Position descriptions define the responsibilities and authorities of SCI positions and are reviewed by executive management for adequacy. The VP of Engineering & Quality is the appointed management representative and has the responsibility and authority for oversight of the quality management system and has unrestricted access to the Executive management team. The management representative has the responsibility and authority for:

- Ensuring the QMS conforms to the requirements of AS9100D
- Ensuring the processes are delivering intended outputs
- Reporting on the performance of the QMS and opportunities for improvement
- Ensuring the promotion of customer focus at all levels
- Ensuring the integrity of the QMS is maintained when changes to the QMS are planned and implemented.
- Ensuring that external suppliers meet the requirement of AS9100D.



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SECTION 6: Planning

6.1 Actions to address risks and opportunities

- 6.1.1 By understanding the context of the organization and the needs and expectations of the stakeholders, SCI develops the strategic goals of the company, identifies measurements for objectives, and develops plans to achieve objectives, and defines the direction of the company. High-level identification of risk assessment is documented and reviewed annually. SCI addresses the risks and opportunities by establishing, monitoring, and communicating Quality Objectives identified at relevant functions, levels, and processes throughout the company. The objectives are based on the highest priority risks and opportunities for improvement in the quality management system.
- 6.1.2 Priority is based on the potential impact of the risk or opportunities impact on SCI's ability to give assurance that the quality management system can achieve its intended result(s), enhance desirable effects, prevent or reduce, undesired effects, and achieve improvement.

6.2 Quality objectives and planning to achieve them


- 6.2.1 SCI company and quality objectives are established and communicated to support our organization's efforts in achieving our quality policy as well as to ensure products and services meet the requirements of this standard. Objectives are measurable and reviewed against performance goals at management review meetings.
- 6.2.2 Objective action plans are created in order to document the steps taken to meet the goals of our quality objectives as well as required resources and timeframe. Quality objectives are periodically reviewed and targets are established for suitability by management.

6.3 Planning of changes

- 6.3.1 In the event SCI determines the need for a change to the quality management system, SCI will consider the purpose of the changes, potential consequences, availability of resources, and responsibilities/authorities. The changes will be carried out in the planned manner as described in Section 4.4 of this quality management system manual.

References:


SCI-QP-020 Control of Documents
 SCI-QP-004 Management Review
 SCI-QP-027 Control of Nonconforming Product
 SCI-QP-058 Customer Complaint Process
 SCI-QF-026 Customer Complaint Response Form

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SECTION 7: Support

7.1 Resources

- 7.1.1 Provision of resources is the responsibility of the executive management team who considers the capabilities and constraints on internal resources as well external resource needs when determining the competency, and training requirements necessary for effective implementation and continual improvement of the quality management system. Resource needs are addressed as part of management review meetings and are reviewed as an integral part of the annual budget process.
- 7.1.2 People: SCI determines and provides the personnel necessary for the effective implementation of its quality management system and for the operation and control of its processes.
- 7.1.3 Infrastructure: SCI executive management team has determined the infrastructure needed and maintenance required. The infrastructure has been provided and includes buildings, workspace, utilities, equipment, and supporting services. As new infrastructure needs arise, resources and personnel will be provided to develop and fulfill the needs to assure SCI company, quality objectives, and product requirements continue to be achieved.
- 7.1.4 Environment for the operation of processes: SCI executive management team determines, provides, and manages the environment that is suitable for the operation to achieve quality objectives and conformity to product requirements.
- Employee safety is addressed at an operation level as appropriate with both engineering controls and company-supplied Personal Protective Equipment. All personnel is expected to report work environment changes to management that could result in unsafe conditions or affect our ability to achieve conformity to product requirements. Corrective action shall be taken to restore the work environment back to its intended function.
- 7.1.5 Monitoring and measuring resources: SCI identifies the measurements to be made and the monitoring and measuring equipment and resources required to assure conformity of product or service to specified requirements. SCI procedures and work instructions outline the process to ensure that monitoring and measuring equipment are used and controlled in a manner to ensure measurement capability is consistent with the measurement requirements. Where necessary to ensure valid results, measuring equipment is:

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- Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards
- Adjusted or re-adjusted as necessary
- Identified to enable the calibration status to be determined
- Safeguarded from adjustments that would invalidate the measurement result
- Protected from damage and deterioration during handling, maintenance, and storage

In addition, the validity of the previous measuring results is assessed and recorded when the equipment is found not to conform to requirements. SCI takes appropriate action on the equipment and any product affected. Records of the results of calibration and verification are maintained.

Reference:

SCI-QP-024 Tool Control

SCI-QP-025 Control of Measuring and Monitoring Equipment


7.1.6 Organizational knowledge: SCI recognizes that organizational knowledge is a valuable resource necessary for the operation of its processes and achieving conformity of products and services. SCI determines the knowledge necessary for processes to operate and achieve conformity of products and services. The knowledge required for the business is determined and maintained. It is made available as necessary.

When addressing changing needs and trends, SCI considers its current knowledge and determines how to acquire access of the necessary additional knowledge and any updates needed. Most of the base organizational knowledge is derived from hiring sufficiently trained staff. Typical requirements for performing engineering determinations are integral to coursework from an ABET-accredited engineering institution. Operational knowledge can be archived in Work instructions stored in the QMS for open access to any employee or stored and shared as needed by function leaders for sensitive knowledge.

7.2 Competence

SCI recognizes the importance of hiring qualified employees and successfully training employees and contractors and the direct correlation this has with the performance of the various processes and the quality of the final product. To ensure the competence of our personnel, position descriptions 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. SCI performs periodic reviews of the necessary position competencies.

Qualifications are reviewed upon hire when an employee changes positions or the requirements

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for a position change. Records of employee qualifications are maintained. If any difference

between the employee's qualifications and the requirements for the position 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 in accordance with SCI quality procedures. An employee review process is used to verify the employee competence has been achieved.

Reference:

SCI-QP-005 Competence, Awareness & Training

7.3 Awareness

All employees are trained on the quality policy and quality management system, the relevance and importance of their activities, and how they contribute to the achievement of the quality objectives. Employees are aware of the implications of non-conformances and also of their contribution to product safety and the importance of ethical behavior.

7.4 Communication

Internal communication within SCI regarding the quality management system follows standard processes as defined in this manual, procedures, and work instructions. Methods of communication include department meetings, safety meetings, management reviews, meeting minutes, electronic database notices, emails, and other routine business communications. Internal audits may be used to verify the effectiveness of this communication.


7.5 Documented Information

7.5.1 The documentation of the SCI quality management system is sufficient to ensure the effective and consistent operation control of the system as required by AS9100 Aerospace Quality Management Systems standards. The documentation is structured as displayed in Section 4.3 of this manual. The following is a description of the documentation that defines the SCI quality management system and are referenced throughout this manual:

Quality Policy – A documented description of SCI's overall intentions and direction of the company.

Quality Management System Manual – A description of SCI's method of establishing, implementing, and maintaining a quality management system. It documents SCI's processes and the interaction between these processes.

SCI Quality Procedures – Procedures that describe complete activities corresponding to the processes identified in Table 1 of this manual. These are the policies and processes, which describe the actions and responsibilities of individuals.

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Work Instructions - Instructions or procedures detailing such activities as how to: fabricate, assemble, lay-up, infuse, operate a specific machine, inspect and/or test a product or calibrate a specific instrument or perform a specific process or task.

Quality Records – Document communicating results achieved or providing evidence of activities performed.


- 7.5.2 SCI has established procedures to implement requirements for the establishment, review, approval, issue, distribution and revisions of the quality management system documentation.
- 7.5.3 All of the SCI quality management system documents are controlled in accordance with SCI Quality procedures. These procedures define the processes 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 point of use
 - Ensuring that documents remain legible and readily identifiable
 - Ensuring that documents of external origin are identified, reviewed and their distribution controlled.
 - Preventing the unintended use of obsolete documents and to apply suitable identification to them if they are retained for any purpose.

Quality records are maintained to provide objective quality evidence (OQE) of conformity to requirements and the effective operation of the quality system. The records are identified and maintained in accordance with the SCI Quality Procedures. The procedure requires that quality records remain legible, readily identifiable and retrievable. The procedure defines the controls needed for identification, storage, protection, retrieval, retention, and disposition of quality records.

Reference:

SCI-QP-002 Records Retention Policy

SCI-QP-020 Control of Documents

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SECTION 8: Operation

8.1 Operation planning and control

The requirements for quality will be met by pursuing the guidelines addressed in this quality management system manual and by adhering to the requirements identified in the quality procedures. Additional quality planning is required before new products or processes are implemented. The quality planning will take place as a design/engineering project and the output will be documented as part of each new project deliverable, processes, procedures and design outputs. Note: Formal Quality Plans are only prepared when required by customers or when processes or requirements are significantly different from those documented in the QMS. During the quality planning the following will be determined:

- a) The quality objectives and requirements for the product
- b) Processes, documentation and resources required
- c) Verification, validation, monitoring, inspection and test requirements
- d) Criteria for product and process acceptance


As appropriate to SCI, determination of the above for the products and services will include consideration of:

- Personal and product safety
- Producibility and inspectability
- Reliability, availability and maintainability
- Suitability of product parts and materials
- Product obsolescence
- Prevention, detection and removal of foreign objects
- Handling, packaging and preservation
- Recycling or final disposal of the product at the end of its life
- Components and services to be obtained from vendors.

8.1.1 Operation Risk Management – SCI plans, implements and controls a process for managing operational risks to the achievement of applicable requirements as appropriate to SCI and the products and/or services.

The process includes:


- a) Responsibilities assigned for operational risk management
- b) Risk assessment criteria defined
- c) Identification, assessment, and communication of risks throughout operations
- d) Identification, implementation, and management of actions to mitigate risks that exceed the defined risk acceptance criteria
- e) Identification and management of risks associated with external provision

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of processes, products, and services

f) Acceptance of risks remaining after implementation of mitigating actions

- 8.1.2 Configuration Management - SCI plans, implements, and controls configuration management activities as appropriate to its products and services in order to ensure the identification and control of physical and functional attributes throughout the product lifecycle. The process controls product identity and traceability to requirements including the implementation of identified changes. The process ensures that documented information is consistent with the actual characteristic of products and services.
- 8.1.3 Product Safety – Operational controls shall be implemented to assure product safety during the entire product lifecycle, where this is appropriate relative to SCI’s products and services. These activities may include:
- Assessment of hazards and management of associated risks
 - Management of safety critical items
 - Analysis and reporting of occurred events affecting safety
 - Communication of these events and training of persons
- 8.1.4 Prevention of Counterfeit Parts – Operational controls shall be implemented to assure the prevention of counterfeit or suspect counterfeit part use and their inclusions in product(s) delivered to the customer. These activities are defined per the documented QMS procedures.
- 8.2 **Determination of requirements for products and services**
- 8.2.1 Customer Communication – SCI communicates with customers to determine customer requirements before acceptance of an order. Method for communicating with customers includes:
- Inquiries, RFQs, contracts and order handling, including amendments
 - Customer feedback including customer complaints
 - Product information
 - Handling or controlling customer property
 - Establishing specific requirements for contingency actions, when relevant
- 8.2.2 SCI has established procedures ensuring the requirements for products and services that are offered to our customers are defined including any statutory and or regulatory requirements as well as any requirements considered necessary by SCI. SCI assures that the company has the capabilities to meet product and service claims. Any special requirements of the products and services are determined and operational risks such as

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new technology, ability and capacity to provide, and short delivery time frame are identified.

Reference:

SCI-QP-016 Proposals, Contract Review and Authorizations

SCI-QP-038 Contract Management

8.2.3 Review of requirements related to the product or services is accomplished and documented through the Customer Requirements review process per the quality procedure. The review process coordinated with applicable organizational functions is conducted prior to order acceptance. The review process ensures that:

- Product and service requirements are clearly defined and documented
- Differences between the proposal and final order are resolved prior to contract acceptance
- Any exceptions or amendments to contract specifications are agreed upon in writing with the customer before acceptance or order
- Risks have been identified and considered
- SCI has the ability to meet the specified requirements.


8.2.4 When contract requirements are changed SCI communicates changes to relevant personnel and amends relevant documentation. Records are maintained documenting the results of the review and any actions arising from the review in accordance with the quality procedure.

8.3 Design and development of products and services

8.3.1 SCI has an effective design and development process in accordance with our implemented quality procedures.

8.3.2 SCI maintains quality procedures and work instructions for controlling the design and development process. For every project, engineering is responsible for the planning and updating of the plan as the design and development progress. This plan includes:

- a) Scheduling performance of the required design and development tasks in coordination with Project Management
- b) Determining internal and external resources needed for the design and development process
- c) Assigning responsibility for implementation of the required tasks to qualified personnel equipped with adequate resources
- d) Defining verification and validation methods appropriate to each design and development stage
- e) Defining control of organization and technical interfaces between appropriate departments

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- f) Establishing a design schedule including design review activity and updating as the design progresses.

8.3.3 Engineering identifies, documents, and reviews for adequacy of the design input requirements per quality procedures. Sources of input requirements are:

- Customer specifications, which includes material specifications, functional, performance, and safety requirements, labeling, preservation and packaging
- Applicable statutory codes and regulatory requirements
- Where applicable, information derived from similar designs
- Potential consequences of failure due to the nature of the products and services
- Other applicable documents or requirements essential for design and development
- As applicable, potential consequences of obsolescence for materials, components, and/or equipment.


For incomplete, ambiguous, or conflicting input requirements, engineering resolves the deficiency with those responsible for imposing the requirement.

8.3.4 Design controls are planned, performed, and documented to ensure that:

- Results to be achieved are defined
- Reviews are conducted to evaluate the ability of the results of design and development to adequately meet requirements. This includes any products or processes to be vendor provided.
- Verification activities are conducted to ensure that the design and development outputs meet the input requirements
- Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use
- Any necessary actions are taken on problems determined during the reviews or verification and validation activities
- Documentation of these activities is retained
- Progression to the next stage is authorized

Design controls may include the following:

- Reviewing the design-stage documents before release
- Performing alternate calculations or analysis
- Undertaking tests
- If available, comparing the new design with a similar proven design

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Design verification is performed in accordance with planned arrangements to ensure the design outputs comply with design input requirements.

Design validation is performed and documented to ensure that the product conforms to design outputs. Design validation is normally performed on the final product but may be necessary in earlier process stages prior to product completion. Design validation is performed and activities are recorded in accordance with quality procedures.

When tests are determined to be necessary for verification and validation of product, the test is planned, controlled, reviewed, and documented to ensure test items and criteria being tested are defined. Test plans and procedures are utilized and results are recorded and maintained. Any monitoring and measuring devices used for testing are to be controlled as defined by QMS requirements.

8.3.5 Engineering identifies, documents, reviews for adequacy, and approves the design and development outputs. The design outputs:

- Meet the design input requirements
- Adequately provide specifications through the processes for product
- Where applicable, contains or makes reference to acceptance criteria
- Provides appropriate information for purchasing, production, and for servicing provisions
- Identifies the design characteristics crucial to the safe and proper functioning and installation of the product
- Specify critical items, including key characteristics and specific actions to be taken for the product.

8.3.6 SCI quality procedures define the process for identifying, recording, verifying, validating, and approving design and development changes. If applicable, the review of the design and development changes includes an evaluation of the effect of the changes on constituent parts and the delivered product. Records are maintained to show authorization of the changes, the results of the review, and any necessary actions identified during the review.


Reference:

SCI-QP-006 Design Process and Control

SCI-QP-037 Design Output Control

8.4 Control of externally provided products and services

8.4.1 SCI ensures that vendors' processes, products and services conform to established requirements. When processes are outsourced, SCI ensures control over those processes. When a customer designates or requests their approved vendors, including process sources, SCI ensures they are used as required.

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SCI has documented quality procedures defining how vendors are evaluated and selected during the requisition phase of procuring products and services. External suppliers are monitored and annually reevaluated according to the established quality procedure.

SCI considers the risks associated with processes, products and services that are provided by external suppliers and takes these risks into consideration in the determination of the selection and use of vendors.

Appropriate controls for processes, products, and services are established for direct and sub-tier vendors to ensure that established requirements are met when vendor provided products and services are incorporated into SCI's products or services or when a process or part of a process is provided by a vendor.

SCI has established criteria for the evaluation, selection, monitoring of performance, and reevaluation of vendors, based on their ability to provide processes or products and services in accordance with requirements. This can include certification from an accredited quality management system or process certification bodies if available.

SCI is responsible for verifying that externally provided processes, products, and services meet specified requirements. SCI's quality procedure for the approval of vendors defines:


- the process, responsibilities, and authority for the approval status decision
- changes in the approval status
- conditions for controlled use of vendors depending on their approval status
- SCI maintains an Approved Supplier List of its vendors that includes:
- status reflecting whether the supplier is approved, conditional, or disapproved.
- What type of product or process is the vendor approved to supply

As part of the Management Review meeting, SCI routinely reviews vendor performance including process, product, and service conformity, and on-time delivery performance.

8.4.2 SCI ensures that purchased products do not adversely affect our ability to consistently

deliver conforming products or services to our customers. Purchased products remain within the control of our QMS. Control of the vendors' process and the purchased parts are defined.


Verification of vendor-provided processes, products, and services are performed according to the risks identified by SCI. When determined necessary by the assessment of risks (including counterfeit parts), inspection or testing of products is performed. If purchased parts are released for production use pending completion of required verification activities, identification of the parts is maintained to allow for recall and replacement if subsequently found that the product does not meet requirements.

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When purchased parts are verified by the vendor, the scope and requirements are defined and documented. Vendor verification is monitored periodically. When vendor-provided test reports are used to verify purchased products, SCI evaluates the data to assure the product meets requirements. When raw material is determined to be a significant operational risk, a process is implemented to validate the accuracy of test reports.

8.4.3 Purchasing documents clearly define the product or service to be purchased. They include as appropriate but not limited to the following:

- a. The processes, products, and services provided (this includes specifications, drawings, process requirements, and/or work instructions)
- b. The approval of:
 1. Products and services
 2. Methods, procedures, processes, and equipment
 3. Release of products or services
- c. Competence, including any required qualification of persons
- d. External provider's interactions with the organization
- e. Control and monitoring of 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
- g. Design and development control
- h. Special requirements, critical items, or key characteristics
- i. Test, inspection, and verification (including production process validation)
- j. The use of statistical techniques for product acceptance and related instructions for acceptance by the organization
- k. The need to
 - Implement a quality management system
 - Use customer-designated or approved external providers, including process sources (e.g., special processes)
 - notify the organization of nonconforming processes, products, or services and obtain approval for their disposition
 - prevent the use of counterfeit parts
 - notify the organization of changes to processes, products, or services
 - flow down to external provider's applicable requirements
 - including customer requirements
 - provide test specimens for design approval, inspection/verification, investigation, or auditing
 - retain documented information, including retention periods and disposition requirements
- l. The right of access by the organization, their customer, and regulatory authorities to the applicable areas of facilities and to applicable documented

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information, at any level of the supply chain

m. Ensuring that persons are aware of:

- Their contribution to product or service conformity
- Their contribution to product safety
- The importance of ethical behavior.

Procedures are in place for the review and approval of purchasing documents for adequacy of the specified requirements prior to release to the supplier and/or sub-contractor.

Reference:

SCI-QP-017 Purchasing

SCI-QP-021 Receiving

SCI-QP-023 Material Control

SCI-QP-007 Identification and Traceability

8.5 Production and Service Provision

8.5.1 SCI has procedures that identify production, installation, and servicing processes necessary for the work to be accomplished within a controlled condition. The production and quality plan are specified in a Manufacturing and Inspection Procedure (MIP). The MIP documents the controlled conditions including:


- Lists all production, test, and inspection operations necessary to manufacture and verify products
- References instructions, drawings, worksheets and lay-ups, required equipment, monitoring, and measuring devices, and workmanship criteria.
- Control schemes for mills
- Serves as the means of inspection and test status identification and records of in-process and final inspection.

References:

SCI-QP-006 Design Process and Control

SCI-QP-037 Design Output Control

8.5.2 SCI identifies the product throughout the production process according to SCI quality procedures. Product is identified with respect to monitoring and measurement requirements and status throughout the production and/or service process. SCI maintains the configuration of products and/or services to identify differences between actual and required configuration. SCI records the unique identification of the product and/or material through Manufacturing and Inspection Procedures (MIP) to achieve traceability.

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Traceability requirements include:

- identification of product maintained throughout the product life
- traceability of all products manufactured from the same batch of raw material to the destination
- traceability of assembly to its components and on to the next higher assembly
- retrievable sequential records of product through production including manufacture, assembly, inspection, and verification
- Stamps, electronic signatures, and passwords are controlled.

Reference: SCI-QP-007 Identification and Traceability

- 8.5.3 SCI exercises care with customer property while it is under the organization's control or being used. SCI quality procedures outline the identification, verification, protection, and safeguarding of customer property provided for use. If despite all of our care, any customer property is lost, damaged or otherwise found to be unsuitable for use, this is reported to the customer and records maintained.

Reference:

SCI-QP-022 Property Management System


- 8.5.4 SCI preserves the conformity of products and outputs during internal processing and during storage and delivery to the intended destination per SCI quality procedures. This preservation includes identification, handling, packaging, storage, protection, and transportation. Preservation also applies to the constituent parts of a product.

When signatures are required by contract and will be provided electronically, protection from unauthorized changes of recorded data shall be provided.

- 8.5.5 SCI determines the requirements from post-delivery activities associated with the products and services during the design phase. In determining the extent of post-

delivery activities that are required, SCI considers:

1. Statutory and regulatory requirements
2. The potential undesired consequences associated with its products and services
3. The nature, use and intended lifetime of its products and services
4. Customer requirements
5. Customer feedback
6. Collection and analysis of performance, reliability and lessons learned
7. Control, updating and provision of technical documentation relating to product use, maintenance, repair and overhaul

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8. Controls of any work undertaken outside of SCI
9. Product or customer support to include queries, training, warranties, maintenance, replacement parts, recycling, final disposition or obsolescence

Appropriate action is established and taken including investigation and reporting when problems are detected after delivery.

Reference:

SCI-QP-018 Post-Delivery Activities

- 8.5.6 SCI quality procedures define the process for identifying, recording, verifying, validating and approving design changes. If applicable, the review of the design and development changes includes an evaluation of the effect of the changes on constituent parts and delivered product. Records are maintained to show the results of the review and any necessary actions identified during the review.

8.6 Release of products and services

SCI monitors and measures the characteristics of the product to verify that product requirements are fulfilled. This is carried out at appropriate stages of the entire product life. Evidence of conformity with the acceptance criteria is maintained. Records indicate the person authorizing release of product. Product release 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. SCI's Engineering department has developed instructions for the final verification of finished equipment.

Reference:


SCI-QP-029 Product Acceptance and Release

8.7 Control of nonconforming process outputs, products and services

SCI ensures that product which does not conform to the product requirements is identified and controlled to prevent its unintended use or delivery. Products or services, whether internal, external or identified by the customer, that are not in conformance with requirements are identified and controlled. The controls and related responsibilities and authorities for dealing with nonconforming product are identified in the SCI quality procedures.

Reference:

SCI-QP-027 Control of Nonconforming Product

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SECTION 9: Performance Evaluation

9.1 Monitoring, measurement, analysis, and evaluation

9.1.1 SCI plans and implements the monitoring, measurement, analysis, and evaluation processes needed:

- To demonstrate conformity of the product
- To ensure conformity of the quality system
- To continually improve the effectiveness of the quality system

These processes are identified in quality procedures and include determination of applicable methods and the extent of their use. The results of analysis from improvement activities are a required input to the management review meeting.

9.1.2 SCI monitors and evaluates information relating to customer perception as to whether the organization has fulfilled customers' requirements, met product and service conformity, on-time delivery expectations, and responsiveness to complaints and corrective action requests as applicable. Customer satisfaction is determined through the acquisition of customer and end-user information available in written and/or verbal forms, from internal and external sources. The method for obtaining and using this information is identified in SCI quality procedures. Sources of information on customer satisfaction may include but are not limited to:

- Customer complaints
- Direct communication with customers; meetings and program reviews
- Questionnaires and surveys
- Frequency of repeat customers


Reference:

SCI-QP-018 Post-Delivery Activities

SCI-QP-027 Control of Nonconforming Product

9.1.3 SCI determines, collects, and analyses appropriate data to demonstrate the suitability and effectiveness of the quality system and to evaluate where continual improvement of the quality system can be made. Appropriate data includes data generated as a result of monitoring and measurement and from other internal or external relevant sources. The analysis of data provides information relating to:

- Conformance to product requirements
- Customer satisfaction
- Performance and effectiveness of Quality Management System

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- Characteristics and trends of processes including opportunities for improvement
- Effectiveness of risk mitigation actions
- Supplier performance

Reference:

SCI-QP-004 Management Review

9.2 Internal audit

SCI conducts internal audits at planned intervals to determine whether the quality system:

- Conforms to the planned arrangements, to the requirements of the AS9100 standard and the ISO 9001 standard, and to the quality system requirements established by SCI and its customers including applicable statutory and regulatory requirements
- Is effectively implemented and maintained

An audit program has been designed and implemented and identifies an audit Schedule based on the importance of the areas to be audited, performance indicators, as well as the results of previous audits. The audit criteria, scope, frequency, methods, responsibilities, and requirements for planning and conducting audits and for reporting and maintaining results are defined and documented in SCI quality procedures. The management responsible for the area being audited is responsible for ensuring that corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities include the verification of the corrective actions taken and the reporting of verification results.


Reference:

SCI-QP-031 Internal Audit

9.3 Management Review

Executive management reviews the quality system at least once per calendar year to determine the continued suitability, adequacy, and effectiveness of the quality system. The Vice Presidents review the same information on a more frequent basis, typically quarterly or semi-annually, to monitor processes more closely. This review includes assessing opportunities for improvement and an evaluation of the need for changes to the quality system including the quality policy and quality objectives. Records for each management review are maintained in accordance with the SCI quality procedure.

The management review follows the agenda described in the SCI quality procedure. This review may include, but is not limited to, current performance and improvement opportunities related to the following:

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- Results of audits, internal and external
- Customer Feedback
- Nonconformities and corrective actions
- On-time delivery performance
- Supplier performance
- Follow-up actions of previous management reviews
- Changes that could affect the quality system
- Effectiveness of actions taken to address risks and opportunities
- Recommendations for improvement
- Needs and expectations of interested parties.


As part of the management review meetings, management will identify appropriate actions to be taken regarding the following issues:

- Improvement of the effectiveness of the quality system and its processes
- Improvement of product related to customer requirements
- Resource needs
- Risks identified.

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 the management review.

Reference:

SCI-QP-004 Management Review

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SECTION 10: Improvement

10.1 General

SCI determines and selects opportunities to improve the quality management system in order to enhance customer satisfaction and meet customer requirements. These actions include product and design improvements, implementation of preventative actions, and improving the effectiveness and performance of the quality management system

10.2 Non-conformity and corrective action

SCI 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 SCI quality procedure defines the requirements for:

- Reviewing nonconformities (including customer complaints, and supplier performance)
- Determining the cause of nonconformities, including, as applicable, those related to human factors
- Evaluating the need for action to ensure that nonconformities do not recur
- Determining and implementing action needed
- Records of the results of action taken
- Reviewing corrective action taken and ensuring effectiveness
- Update risks and opportunities determined during planning, if necessary,
- Make changes to the QMS if necessary
- Flow down corrective action requirements to suppliers when it is determined that the supplier is responsible for the nonconformity,
- Take specific actions when timely and effective corrective actions are not achieved.

10.3 Continual Improvement

SCI continually improves the suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, and corrective and preventive actions. SCI considers the results of this analysis and evaluation and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement. Implementation of improvement activities are monitored and effectiveness of the results are evaluated.

Reference:

SCI-QP-027 Control of Nonconforming Product