 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	i of xix	V

QUALITY MANUAL

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 President

UNCONTROLLED COPY

Release Date: January 30th, 2025

This document is current on the FCI Website,
www.fluidcomponents.com and on FCI's ADEPT.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	ii of xix	V


COMMITMENT TO QUALITY

FLUID COMPONENTS INTERNATIONAL LLC will hire experienced personnel, continually train them, and clearly define their responsibilities in order to provide the highest level of quality products and services to the wide variety of markets and industries that we support. All employees will be responsible for quality and are expected to participate in continuous quality improvement functions so that industry standards will be met or exceeded. Employees will also be expected to take initiative for continuously improving processes and their skills. Employees will be provided tools, instructions, and the authority to act in the best interest of the company with regard to the quality of our products and or service. The Quality Assurance and Quality Control organizations will function as a catalyst to establish informational quality needs, compliance standards, improvement targets quality metrics and KPIs, process changes, and an overall quality focus. These quality organizations will demonstrate continuous communications and collaboration with all operational departments.

The Quality Assurance organization is chartered with defining and enforcing the standards that are specific to the various industries that we service. Quality Assurance shall either integrate or isolate those requirements so that we effectively meet these industry specific quality expectations.

The Quality Manual that follows shall be used as an internal baseline for quality processes. The Manual will serve as a standard for which we will compare our performance. The Manual will be a living document and will be regularly updated with improvements and changes that are necessary to meet the evolving business environment. The Manual will additionally reflect our commitment of quality to our customer base and will be readily available for review and recommendations.

The President

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	iii of xix	V

SAFETY

Fluid Components International LLC (FCI) is committed to the safety of FCI's products, customers, employees, public and those listed in the Parties of Interest.

- 1) FCI Products may be designed and qualified to meet one or more safety standards of the applicable end use industry. FM, UL, CSA, IEEE, ATEX, IEC/IECEX, UKEX, UKCA, CPA, EAC/TR CU, NEPSI, SIL, QAL1, CE, CRN, Inmetro, FAA, DOD, NRC, ...and others as required.
- 2) FCI Customers rely on FCI products to operate safely and further to provide process measurement and monitoring to ensure safe facility, process and plant operations.
- 3) FCI Employees are safe due to strict adherence to FCI's Injury and Illness Prevention Program (IIPP) and protocols that are periodically adopted to ensure both safe on premise and remote work conditions.
- 4) FCI addresses safety to the public by instituting controls to protect the environment and ensuring the products delivered meet the standards required by the customer and the environments in which they will be used.
- 5) FCI protocols further inform our team on safety best practices both at work, in the field on FCI's behalf and during non-working hours.


 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION General	PAGE iv of xix	REVISION V

TABLE OF CONTENTS

<i>DESCRIPTION</i>	<i>SECTION</i>	<i>PAGE</i>
Title Page	General	i
Commitment to Quality	General	ii
Safety	General	iii
Table of Contents	General	iv
Revision Page	General	v-vii
Scope of Work	General	viii
Quality Management System	General	viii-ix
Appendix A: Structure, Responsibility and Authority of the QMS.	General	x-xiv
Appendix B: Interrelation of Quality System and ISO 9001/AS9100 and NQA-1	General	xv-xvii
Section One: Commercial Product to ISO9001	1	1 – 19
Section Two: FCI Aerospace to AS9100	2	1 – 29
Section Three: FCI Nuclear to ASME NQA-1	3	1 -- 17

SUBJECT**Quality Manual****CAGE CODE****64818****DATE****1/10/2025****SECTION****General****PAGE****v of xix****REVISION****V****REVISION PAGE**

REVISION	DESCRIPTION	DATE
Previous Revisions	On File	4/8/2016
M	<p>Header Changed "-" to "General"</p> <p>Table of Contents – Updated.</p> <p>Revision Page -Removed content up to L revision referring to Revision L on file.</p> <p>Quality Management System – Removed reference to 14CFR and added paragraph for 07QA070004.</p> <p>Appendix A Revised Organization Chart. (Removed the DMIR due to 07QA070004)</p> <p>Appendix B – Removed references to the FAA clauses (moved to 07QA070004), 04QA704105, 01DM000025 (Governed by 01DM000064), and instructions to the old format QA procedures.</p> <p>Appendix B – Added 04QA704082, 04QA704106, 04QA704104, 04QA704118, 04QA704122, 04QA704117, 09QA11XXXX.</p> <p>Appendix C Revised Interaction diagram and split Industrial from FCI Aerospace.</p> <p>Appendix D Added responsibility for notifying Certified Body/ Test institute for escaped product affecting the public. (QAL-1)</p> <p>Appendix E Added to easily find the Quality Policy</p> <p>Section 1, 1.0 SCOPE added "There are..."</p> <p>Section 1, 5.3 QUALITY POLICY moved Quality Policy to Appendix E.</p> <p>Section 2, Moved FAA Commitments to 07QA070004.</p> <p>Section 2, 1.0 SCOPE Moved FAA comments to 07QA070004</p> <p>Section 2, 3.0 REFERENCES Removed Obsolete specification MIL-I-45208 and FAA -PMA 14CFR21.137.</p> <p>Section 2, 4.2.2 QUALITY MANUAL a) Added (There are...)</p> <p>Section 2, 4.2.3 CONTROL OF DOCUMENTS removed "As a regulatory requirement..."</p> <p>Section 2, 5.3 QUALITY POLICY moved Quality Policy to Appendix E.</p> <p>Section 2, 7.5.1.3 CONTROL... "Added Note: FCI Machine shop..."</p> <p>Section 2, 7.5.3 IDENTIFICATION AND TRACEABILITY Moved FAA-PMA Identification... to 07QA070004.</p> <p>Section 2, 8.3 CONTROL OF NONCONFORMING MATERIAL Moved reference to FAA-PMA and 14CFR21.3 to 07QA070004</p> <p>Section 2, 8.5.2 CORRECTIVE ACTION removed reference to FAA-PMA</p> <p>Section 3, 2.1.1 Engineering Procedures Removed 01DM000025</p> <p>Section 3, 3.5 Design Changes Removed 01DM000025</p> <p>Section 3, 5.1 Corrected Order Verification Packages to Order Acknowledgements.</p> <p>Section 3, 5.1 Corrected reference to procedure 07QA704002 to 04QA704002.</p> <p>Section 3, 5.3 Changed Process Sheets to Manufacturing procedures and removed 01DM000025.</p> <p>Section 3, 5.7, 5.8, 6.2, 6.3.1 Removed 01DM000025</p> <p>Section 3, 6.3.4, 10.4, 11, & 13.3 Changed Order Verification to Order Acknowledgement.</p> <p>Section 3, 7.1.1 Corrected paragraph "All Services..." and "For ISO 17025..."</p>	9/23/2016

SUBJECT**Quality Manual****CAGE CODE****64818****DATE****1/10/2025****SECTION****General****PAGE****vi of xix****REVISION****V**

REVISION	DESCRIPTION	DATE
N	SCOPE OF WORK: changed from "FCI manufactures Flow, Liquid Level, Temperature and Pressure Instrumentation, and Flow Conditioners" QUALITY MANAGEMNT SYSTEM – No Change HIEARCHY OF QUALITY SYSTEM DOCUMENTS – No Change Appendix A Addition of Director of Aerospace Engineering/Manufacturing, Moving of Configuration management Appendix B Complete Revision Appendix C Complete Revision Appendix D Addition of the General Manager of FCI Aerospace Appendix E No Change Appendix F Added Section 1 Complete Revision Section 2 Complete Revision Section 3 No Change	8/26/2017
P	Title page added General Manager Approvals. SCOPE OF WORK: changed from "FCI manufactures Flow, Liquid Level, Temperature and Pressure Instrumentation, and Flow Conditioners" to include "Measurement". Appendix A revised now referring to 05QA000220. Appendix B added 04QA704013, 07CP000015, 04QA704125,04QA704132,01EN804019 Corrected 01DM00064 Appendix D: Moved the Responsibility of the internal audit from the President to the Director of Quality General Manager added FCI Nuclear and complete revision of responsibilities. Director of Administration added Compliance and Legal executive Quality Assurance Manager added the reporting to the General Managers Managers and Supervisors added the initiation of the Control of Nonconformance. Quality Assurance Staff added the specific reviewing and approval of purchase orders and contracts; add the administering of the corrective action system. Contracts Manager specifying "agreed to contracts" and advising and negotiating... Material Control, Production and Test added the requirement of notification to Quality Added Test Engineer\ -Section 1 Commercial Added 1.2 for applicable locations. -Section 2 FCI Aerospace Added 1.2 for applicable locations -Section 3 FCI Nuclear Added FCI Nuclear Logo Added to 1.1 about the locations. Added to 3.1 for Risk Analysis Reword 3.4 from "...if imposed by the customer for all other industries and regions." Added to 5.4, "Under certain contracts..." Added to 5.7, "Drawing submitted under..." Corrected 7.1.1 Paragraph previously stated, Vendors that are certified to ISO 17025 shall be evaluated monthly to assure continued accreditation (04QA704044). The accreditation shall cover the scope of the contracted services." Section 8.1 Replaced Metal Stamping with Tagging. Section 8.2 Corrected terminology from "calibrateable" to "calibrated". Section 10.4 Added statement, "or waived in writing by the customer". Section 15 & 16 Rewritten for the Material Review Report (MRR) replacing the DR. Section 16.1 Replaced "Discrepancy Reports" with MRR. Added "Management Review" Section 16.2 added paragraph, "Any such corrective..." Section 16.3 & 16.4 replaced, "Discrepancy Report" with "MRR".	12/20/2020

SUBJECT**Quality Manual****CAGE CODE****64818****DATE****1/10/2025****SECTION****General****PAGE****vii of xix****REVISION****V**

REVISION	DESCRIPTION	DATE
R	Corrected the Table of Contents. SCOPE OF WORK exception for FCI Aerospace from the same as commercial work but without Conditioners. Removed Appendix A (Form 05QA000220) Removed Appendix C (Form 05QA000162) Appendix D has been moved and renamed as Appendix A. Removed Appendix E (Form 05QA000219) Removed Appendix F (Form 05QA000201) Section 1, 4.2.a) Pol Moved from Appendix F to Form 05QA000201. Section 1, 5.2 Quality Policy Moved from Appendix E to form 05QA000219 Section 2, 4.2.a) Pol Moved from Appendix F to Form 05QA000201. Section 2, 5.2 Quality Policy Moved from Appendix E to form 05QA000219 Section 3, 1.1 "Appendix D to this manual ..." is "Appendix A to this manual..." Section 3, 1.1 "see Appendix A, Company Organization Chart" is "see 05QA0000220, FCI Organization Chart"	10/5/2021
T	Section General, Signature page Director of Administration & Quality, Ron Ogle replaced with Director, Legal & Administration, Melissa Alexander, Added Eric Wible, Director of Industrial Operations. Section General, page iii added for Safety Section General, Appendix A President removed the Directory of Administration & Quality from the implementation of the Quality Management System. Section General, Appendix A General Manager FCI Aerospace and FCI Nuclear corrected Responsible Manager to Accountable Manager. Section General, Appendix A, Added Executive Director, Industrial Operations (From Director of Engineering...) Section General, Appendix A, Director of Administration changed to Director Legal & Administration with responsibilities changed removing Quality and Maintenance. Section General, Appendix A, Quality Manager removed the reporting to the Director of Administration. Section General, Appendix A, Removed the Director of Engineering...to Executive Director... Section General, Appendix A, Removed Director of Manufacturing leaving manufacturing Manager Section General, Appendix A, Added Document Management. Section General, Appendix B, Added Column for ISO9001. Section 1, Para 6.2.1. b) Typo Fixed Section 1, Note: Notification ISO IEC 80079-34 Removed Director of Quality and QA Manager to Quality Assurance Management. And revised retention from "for ten years" to "for a minimum of ten years. See 05QA000182 Quality Record Retention." Section 1, Para 9.2.2. B Fixed Typo Section 2, Para 1.2.2 Added for ASY15A in the Tech Center Section 3, Para 7.1.1 Removed "For ISO 17025 accredited Calibration Service & Testing providers that have a third party accreditation approval from sources recognized by the Nuclear Regulatory Commission, a survey may be waived (04QA704044) Section 3, Para 7.1.1 Added "ILAC Process..." [CPAR 21B015 NIAC 2021-054]	7/22/2022
U	Scope of Work: Added "For FCI Aerospace in the Tech Center the Scope is: The manufacturing of sensors for Aviation, Space & Defense applications."	6/15/2023

SUBJECT**Quality Manual****CAGE CODE****64818****DATE****1/10/2025****SECTION****General****PAGE****viii of xix****REVISION****V**

V

Headers changed from FCI to FCI a PST Brand

General: COMMITMENT TO QUALITY; "...Employees will also be expected to take initiative in continuously improving processes and in their own self-development skills. Employees will be provided the tools, instructions, and authority to act in the best interest of the company with regard to the quality of our products and or service. The Quality Assurance and Quality Control organizations will function as a catalyst to establish informational quality needs, compliance standards, mutual improvement targets, process changes, and overall quality focus. These organizations will demonstrate continuous communications and collaboration with all operational departments..." to "...Employees will be provided tools, instructions, and the authority to act in the best interest of the company with regard to the quality of our products and or service. The Quality Assurance and Quality Control organizations will function as a catalyst to establish informational quality needs, compliance standards, improvement targets quality metrics and KPIs, process changes, and an overall quality focus. These quality organizations will demonstrate continuous communications and collaboration with all operational departments..."

General: COMMITMENT TO QUALITY; Changed from "...Quality Assurance shall either integrate or isolate those requirements so that we efficiently meet all industry specific quality expectations..." to "...Quality Assurance shall either integrate or isolate those requirements so that we effectively meet these industry specific quality expectations..."

General: SAFETY; 1) changed from "FCI Products are designed and qualified to meet the safety standards of the applicable industry" to "FCI Products may be designed and qualified to meet one or more safety standards of the applicable end use industry."

General: SAFETY; 2) Changed "FCI Customers rely on FCI products operating safely and further to provide process monitoring to ensure safe facility and process operations." to "FCI Customers rely on FCI products to operate safely and further to provide process measurement and monitoring to ensure safe facility, process and plant operations"

General: SAFETY; 4) Changed "FCI addresses safety to the public by instituting controls to protect the environment and ensuring the products delivered meet the standards required by the customer and the environments they will be used in." to "FCI addresses safety to the public by instituting controls to protect the environment and ensuring the products delivered meet the standards required by the customer and the environments in which they will be used."

General: Scope of Work for FCI Aerospace – Added "and Flow Conditioners."

General: Scope of Work for FCI Aerospace - Tech Center added "populate Circuit Boards"

General: Quality Management System – Changed (current revision) to (current revision & amendment)

General: Quality Management System – Changed ANSI NQA-1-2000 to ASME NQA-1-2015. {CPAR 24B17 NIAC SCAR 2024-021}

General: Appendix A; Changed "General Manager FCI Aerospace and FCI Nuclear" to "General Manager"

General: Appendix A; General Manager –Changed "General Manager, FCI Aerospace is the primary contact for the FAA as the Accountable Manager." to "General Manager, FCI Aerospace is the FAA Accountable Manager for the PAH."

General: Appendix A; Executive Director... -Changed "Executive Director, Industrial Operations" to "Operational Director"

General: Appendix A; Director, Legal & Administration has been removed.

General: Appendix A; Manager or Supervisor; Changed from "Managers and Supervisors" to "Manager or Supervisor"

General: Appendix A; Employee Removed "s".

Section 1; 4.1 Added, "FCI will also determine whether climate change is a relevant issue. FCI addresses climate change by meeting Federal, State, County and City regulatory requirements." For ISO9001:2015 Amd.1:2024

1/10/2025



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Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115

DOCUMENT NUMBER

07QA070003

SUBJECT

Quality Manual

CAGE CODE

64818

DATE

1/10/2025

SECTION

General

PAGE

ix of xix

REVISION

V

REVISION

DESCRIPTION

DATE


Section 1; 4.2c) Added "Note..." For ISO9001:2015 Amd.1:2024

Section 2; Title Page, Changed FCI Aerospace Logo to FCI Aerospace a PST Brand.

Section 2; 4.1 Added, "FCI will also determine whether climate change is a relevant issue. FCI addresses climate change by meeting Federal, State, County and City regulatory requirements." For ISO9001:2015 Amd.1:2024

Section 2; 4.2c) Added "Note..." For ISO9001:2015 Amd.1:2024

Section 3; Title Page, Changed FCI Nuclear logo to FCI Nuclear a PST Brand.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	x of xix	V

Scope of Work

FCI designs, manufactures and services Flow, Liquid Level, Temperature and Pressure Measurement Instrumentation, and Flow Conditioners.

For FCI Aerospace the Scope of Work is:

FCI Aerospace designs, manufactures and services Flow, Liquid Level, Temperature and Pressure Measurement Instrumentation and Flow Conditioners.

For FCI Aerospace in the Tech Center the Scope is:

Manufacture of sensors and populate Circuit Boards for Aviation, Space & Defense applications.

Quality Management System

This Quality Manual provides an overview of FCI's quality system and identifies the processes used to ensure that our products and servicing (customer and Field Services) meet specified requirements. The processes described in this Manual are aimed at achieving customer satisfaction by preventing nonconformities at all stages of design, product realization, service, and delivery.

The Quality Manual shall be in English and is available in the database system.

FCI developed and implemented a quality management system, based on the ISO 9001 and AS9100 (current revision & amendment), the Quality System Requirements of 10CFR50 Appendix B and the basic Quality System Requirements of ASME NQA-1-2015 to support our quality policy. This Manual defines the quality management system. Procedures and work instructions provide additional detail. Procedures address the "what, when and where" and include responsibilities, objectives, and activities for each applicable function in the company. Those procedures referring to particular revisions of the above standards shall be viewed as complying with the current standards and not limited to the revisions that are referenced. Work instructions provide step-by-step details on performing specific tasks and include criteria for determining compliance.

Customer specific requirements, which are not addressed by the current quality system, are considered on an individual project/contract/order basis and communicated throughout FCI as required.

The Quality Management system at FCI has been developed to accommodate three levels of quality management. The level of quality management to be applied to a specific project/contract/order is set at Contract Review and is suitably identified thereafter. The three levels are defined as follows:

Industrial "Controlled" Projects: These projects include (but are not limited to) Nuclear Safety. These types of projects/contracts/orders adhere to all the requirements of ISO 9001 as defined in Section One of this manual, the Quality System Requirements of 10CFR50 Appendix B, and the basic Quality System Requirements of ANSI NQA-1 as defined in Section Three of this manual. These projects/contracts/orders and all associated data and documentation have the unique identification of "Controlled".

Aerospace Projects: These projects include all Aerospace identified projects. These types of projects/contracts/orders adhere to all the requirements of ISO 9001, and AS9100, as defined in Section Two of this manual. These projects/contracts/orders and all associated data and documentation are also identified as "Controlled". There are no exclusions taken from AS9100.

FCI FLUID COMPONENTS INTERNATIONAL LLC A PST BRAND Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	xi of xix	V

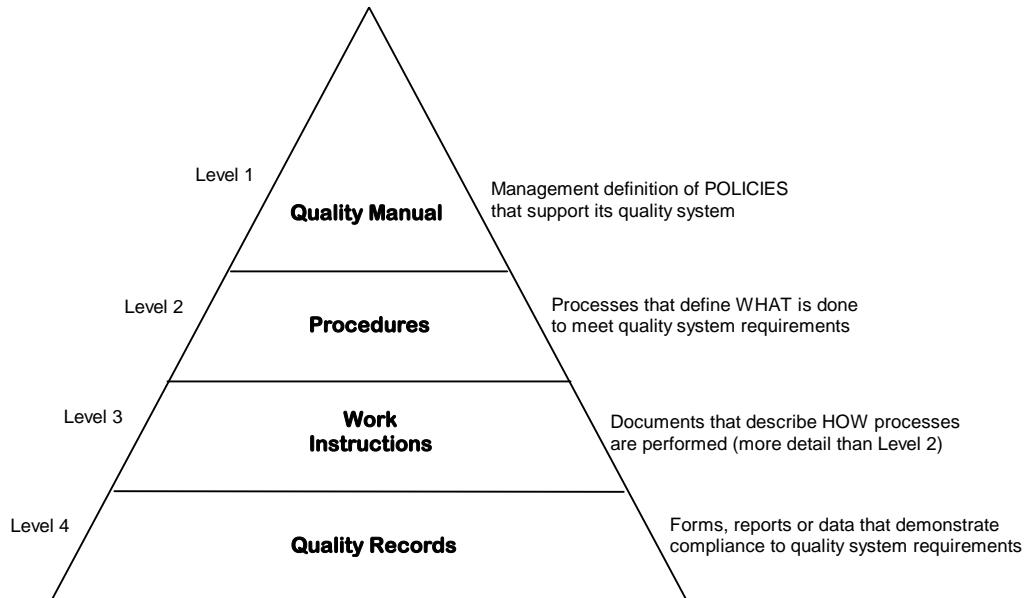
All Other Projects: These projects include (but are not limited to) Commercial projects. These types of projects/contracts/orders adhere to all the requirements of ISO 9001 as defined in Section One of this manual. Any and all projects/contracts/orders, data, and/or documentation **not** identified as "Controlled" is deemed to fall within this level of quality management. There are no exclusions taken from ISO9000.


Aerospace Projects that are considered Parts Manufacture Approved per the FAA are processed to FCI PMA Quality Manual; 07QA070004 that is constructed based on 14CFR Part 21.137 (a)-(n).

Hierarchy of Quality System Documents

- **Quality Manual:** Level 1 document that provides a general overview of the quality system and defines the quality policy.
- **Quality System Procedures:** Level 2 documents that provide more detailed explanation of the quality system elements and describe the structure of the quality system.
- **Work Instructions:** Level 3 documents that provide step-by-step instructions for executing activities.
- **Quality Records:** Level 4 documents or data that contain the data, charts, checklists, or other records which demonstrate conformance to specified requirements and the effective operation of the quality system.

Quality System Documentation Structure



 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	xii of xix	V

Appendix A: ***Structure, Responsibility, and Authority of the Quality Management System***

President

The President is responsible, through the Quality Assurance Manager, for the authorization and implementation of the Quality Management System throughout the company, including:

- The overall responsibility for the definition of, and adherence to, the quality policy.
- Establishing quality goals and monitoring progress to ensure continued suitability and effectiveness of the quality management system.
- Providing the necessary resources to maintain the quality management system.
- Conducting management reviews of the quality management system.

The President shall resolve matters regarding quality that the Quality Assurance Manager determines necessary to bring to the attention of executive management or cannot be resolved to the satisfaction of the Quality Assurance Manager by any other means.

General Manager

In support of the President, and is responsible for:

- Supporting the implementation and improvement of the Quality Management System.
- Overseeing the division, maintaining the following:
 - Adequate personnel and their abilities.
 - Adequate equipment including measurement tools.
 - Adequate environment
 - Adequate methods are used.
 - Adequate safety is ensured for the public and FCI personnel.
- General Manager, FCI Aerospace is the FAA Accountable Manager for the PAH.


Operational Director

- Responsible for incorporating customer specifications, codes, standards, and requirements into all approval and sub-assembly drawings to be used by the Production and Quality Assurance/Control Departments.
- Responsible for the generation of Operations Sheets, Process Sheets, Process Manuals, and other such instructions and procedures required by the Production Department to consistently build quality products.
- Has the authority to participate as a member of the Material Review Board Committee.
- Under the direction of Quality Control Metrology and Engineering, the Engineering Test Group may be responsible for the calibration and maintenance of Flow Stands and Measuring & Test Equipment used to calibrate product.

Quality Assurance Manager

In support of the President, the Quality Assurance Manager is responsible for:

- Administering the Quality Management System and defining, measuring, and maintaining the overall effectiveness and enforcement of the Program.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	xiii of xix	V

- Identifying resources to maintain the quality management system.
- Reporting to the President and General Managers at minimum of a yearly basis as to the effectiveness of the Quality Management System.
- Reviewing organizational requirements and providing recommendations for changes.
- Directing and auditing quality-related activities; reporting to and advising the President and executive staff on quality matters.
- Ensuring the quality management system is maintained through appropriate audits, tests, inspections, and surveys.
- Leading and initiating actions to prevent the occurrence of any nonconformities relating to product, process, and quality management system.
- Reporting quality and nonconformance data and trends.

The Quality Assurance Manager delegates quality responsibilities to persons and organizations within the company. (References to the Quality Assurance Manager throughout this manual and the supplementary Quality Assurance Procedures shall mean the Quality Assurance Manager or the Quality Assurance Manager's Representative.)

1. The QA Manager is to liaise with the notified body responsible for the assessment of the quality system in case of changes to the quality system, together with the EX Representative.
2. The QA Manager is to notify the regulatory body/certified body/test institute of escaped product that may adversely affect the public.

Manager or Supervisor

Actively support those responsible for implementing and improving the quality management system.

Ensure the quality policy is fully supported, understood, implemented, and maintained at appropriate levels of their organizations.

Ensure appropriate supporting procedures are documented and followed throughout their respective departments.

Ensure adequate resources and prioritization; assign trained personnel to perform work and verification activities including internal audits, and work affecting product quality.

When appointing a designee to act on their behalf for the purposes of any element of this quality system, ensure the person appointed is adequately trained and given sufficient organizational freedom and authority to execute the responsibility.

Initiate Control of Nonconformance process.


Initiate "stop shipment" as appropriate to prevent nonconformance, and then,

Initiate a documented corrective action procedure.

Maintain the "stop" until receipt of authorization and associated data and documentation to release the "stop".

Employee

Understand and support the quality policy and the appropriate elements of the quality management

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	xiv of xix	V

system for their areas of work

Dedicate their efforts to the reduction, elimination, and prevention of quality deficiencies

Initiate action to prevent the occurrence of nonconformities related to product, process, and quality system.

Specific Task performed throughout the organization

Quality Assurance Staff (Reports directly to the Quality Assurance Manager) has responsibility for the following:

- Reviewing, approving, and generating instructions, procedures, & forms,
- Reviewing, approving supplier purchase orders and customer contracts,
- Compiling special customer requirements,
- Administering the Discrepancy Report program,
- Administering the corrective action system.
- Auditing, and
- Training and certifying personnel performing activities affecting quality.
- Administering the ESD program.

Metrology Department (Reports to the Quality Assurance Manager)

All in-house calibration of Measuring and Test Equipment shall be performed under the direction of the Metrology Department. The Metrology Department is responsible for all Measuring and Test Equipment and shall assure that the equipment is maintained in accordance with Quality Assurance Procedure 04QA704006, "Calibration program". The Metrology Department is also responsible for generating calibration procedures for Measuring and Test Equipment calibrated in house.

Contract Manager has authority and responsibility for the following:

- Assuring that all agreed to contractual items, terms, and conditions are identified complied with and/or met.
- Participating as a Material Review Board member,
- Acting as a drawing checker, and reviewing and approving Operation Sheets, Test Procedures, and Test Reports for conformance with contractual requirements and FCI practices.
- Act as the primary liaison between the customer and FCI once a contract has been accepted and obtaining customer response on all documents and drawings sent to the customer for approval.
- Advising and negotiating with the customer on scope changes.

Nuclear Qualification Engineering (QE)

- Responsible for maintaining qualification of Safety-Related Class 1E product through the use of Similarity Analyses, Testing, and other appropriate methods.
- Responsible for overseeing qualification test programs.

SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	xv of xix	V

- Participating in drawing reviews and the Material Review Board to address qualification related issues.
- Identifying critical characteristics for Commercial Grade Dedication of Components and services.

Manufacturing Manager

Operations Management is responsible for the activities of the Planning, Purchasing, Material Control, and Production.

Planning

Planners have the responsibility to schedule projects through the factory areas, obtain controlled documents, requisition items, and issue Job Orders needed for each contract.

Purchasing


Purchasing is responsible for purchasing items, services, and equipment in accordance with specific instructions and requirements.

Material Control

Material Control is responsible for all inventories; for providing items as required to fill orders and maintaining lot control of items so identified. Material Control also has the responsibility for receiving parts and outside processed goods as well as all aspects of shipping product. In the event of a nonconformance production is to notify quality for processing the nonconformance

Document Management

Document Management has the responsibility of controlling copies of the above referenced documents and ensuring only current or specified revisions are used during the manufacturing process. Document Management shall also ensure that obsolete or expired documents have been removed from the factory floor.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	xvi of xix	V

Production

The Production groups perform the fabrication and assembly of shippable product in accordance with applicable instructions, procedures, and drawings. Production is also responsible to record the work and processing performed as required by these documents. In the event of a nonconformance production is to notify supervision for processing the nonconformance.

Test

Test shall perform all calibrations of instruments supplied to the customer. All calibrations and tests shall be in accordance with the applicable contract requirements and approved procedures. Test shall also perform such other tests as requested by the Engineering, Production, or Quality Assurance Departments. In the event of a nonconformance production is to notify supervision for processing the nonconformance.


Test Engineering

Test Engineering is responsible for developing calibrations and tests to meet the customer's expectations, regulatory and certifying agency requirements. Test Engineering can perform calibrations and testing. In the event of a nonconformance production is to notify supervision for processing the nonconformance

EX Representative

The EX Representative shall have the following responsibilities and authority:

- Effective monitoring, dissemination, review and implementation of the latest applicable technical knowledge
- Effective coordination of activities with respect to products intended for use in potentially explosive atmospheres
- To liaise with the notified bodies in case of changes to the design in the EC-Type Examination Certificate and the technical documentation
- To liaise with the notified body responsible for the assessment of the quality system in case of changes to the quality system, together with the Quality Assurance representative.
- Authorize the initial approval and changes to related drawings
- Authorize concessions if it does not take the product outside the design as defined in the EC-Type Examination Certificate
- Communicate information to the customer of special conditions or limitations
- Participate in the Management Review Meeting
- Assist in notifying the certified body/test institute of escaped product that may adversely affect the public.

 FLUID COMPONENTS INTERNATIONAL LLC A PST BRAND <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	General	xvii of xix	V

Appendix B: Interrelation of Quality System and ISO 9001/AS9100; and NQA-1.


Interrelation of Quality System and ISO 9001/AS9100 and NQA-1				
Procedure	Subject	ISO9001	AS9100	NQA-1
Quality Manual	General Requirements	4.4	4.4	1.0
04QA704062 Management Review	Leadership	5.1 & 5.1.1	5.1 & 5.1.1	1.1
04QA704062 Management Review	Customer Focus	5.1.2	5.1.2	1.1
04QA704062 Management Review	Quality Policy	5.2, 5.2.1 & 5.2.2	5.2, 5.2.1 & 5.2.2	N/A
04QA704062 Management Review Quality Manual	Organization roles, responsibilities and authorities	5.3	5.3	2.6
04QA704062 Management Review 04QA704105 Risk Management 07CP000015 Risk Mitigation and Management Policy	Actions to address risks and opportunities	6.1	6.1	16.2
04QA704062 Management Review	Quality objectives and planning to achieve them	6.2	6.2	N/A
04QA704062 Management Review	Planning of changes	6.3	6.3	N/A
Quality Manual	Resources	7.1	7.1	
04QA704062 Management Review	General	7.1.1	7.1.1	2.0
04QA704034 Competence, Awareness & Training	People	7.1.2	7.1.2	2.0
04QA704097 Building Preventive Maintenance	Infrastructure	7.1.3	7.1.3	2.2
Quality Manual 04QA704125 Inspection Environment	Environment for the operation	7.1.4	7.1.4	2.2
04QA704006 Calibration Program	Monitor and measuring resources, Measurement Traceability	7.1.5, 7.1.5.1, 7.1.5.2	7.1.5, 7.1.5.1, 7.1.5.2	12, 12.1
Quality Manual	Organizational knowledge	7.1.6	7.1.6	N/A
04QA704034 Competence, Awareness & Training	Competence	7.2	7.2	2.6
04QA704034 Competence, Awareness & Training	Awareness	7.3	7.3	2.5
Quality Manual	Communication	7.4	7.4	2.1
04QA704007 QA Doc & Data Control 04QA704013 Quality Records 01DM000064 Document Management	Documented information Creating and Updating Control of Document Information	7.5, 7.5.1 7.5.2 7.5.3	7.5, 7.5.1 7.5.2 7.5.3	2.1
Quality Manual	Operation	8	8	2.4
04QA704082, Process Control 04QA704132, Quality Plans	Operational planning and control	8.1	8.1	5.0
04QA704103 Risk Management 07CP000015 Risk Mitigation and Management Policy	Operation risk management	N/A	8.1.1	N/A
04QA704082, Process Control	Configuration management	N/A	8.1.2	5.0

Interrelation of Quality System and ISO 9001/AS9100 and NQA-1

Procedure	Subject	ISO9001	AS9100	NQA-1
Quality Manual	Product Safety	N/A	8.1.3	N/A
04QA704104, Counterfeit Protection	Prevention of Counterfeit products	N/A	8.1.4	N/A
Quality Manual	Requirements for Products and Services	8.2	8.2	3.1
04QA704093 Customer Response	Customer Communication	8.2.1	8.2.1	2.4, 3.1
04QA704005, Contract Review	Determining requirements for the products and services.	8.2.2	8.2.2	3.1
04QA704106 Aerospace Contract Review	Review requirements related to products and services	8.2.3	8.2.3	3.5
	Changes to requirements for products and services	8.2.4	8.2.4	
04QA704091 Product Design and Development	Design of development of products and services	8.3,	8.3,	3.0
01DM00064, Document Management	Design and Development planning	8.3.1	8.3.1	3.3
	Design and Development inputs	8.3.2	8.3.2	3.4
	Design and Development Controls	8.3.3	8.3.3	3.4
	Design and Development outputs	8.3.4	8.3.4	3.5
	Design and Development changes	8.3.5	8.3.5	
		8.3.6	8.3.6	
04QA704003 Purchase Order Procedure	Control of Externally provided processes, products and services.	8.4	8.4	4.0, 7.0
04QA704077 Evaluation of Subcontractors		8.4.1	8.4.1	
04QA704044 Vendor Surveys				
04QA704008 Audits				
01EN804019 Electrical Component and Electronic Parts Review and Obsolescence Policy				
04QA704003 Purchase Order Procedure	Type and extent of control	8.4.2	8.4.2	4.0, 7.0
04QA704001, Receiving Inspection	Verification of externally provided products and services	8.4.2	8.4.2	7.1
04QA704003 Purchase Order Procedure	Information for external providers	8.4.3	8.4.3	7.2
Quality Manual	Production and service provision	8.5	8.5	8
04QA704020 Job Orders	Control of Production and service provision	8.5.1	8.5.1	8
04QA704118 Aerospace Controlled production				
04QA704122 Nuclear Product.				
04QA704137 Visual Inspection Manual				
04QA704117 Software Control Procedure	Control of production equipment, tools and software programs	N/A	8.5.1.1	11
04QA704084 Tooling Procedure				13
04QA704006 Calibration Procedure.				12
04QA704121 Welding Manual	Validation and control of special processes	N/A	8.5.1.2	9
04QA704039 Welder Qualification				
04QA704057 Solder Workmanship Manual				
04QA704088 Special processes				
04QA704049 First Article Inspection	Production Process Verification	N/A	8.5.1.3	10
04QA704020	Identification & traceability	8.5.2	8.5.2	8
Job Orders				
04QA704118 Aerospace Controlled Documentation				
04QA704122 Nuclear Product				
04QA704067 Issuing Serial Numbers				
04QA704085 Product ID				

Interrelation of Quality System and ISO 9001/AS9100 and NQA-1

Procedure	Subject	ISO9001	AS9100	NQA-1
04QA704055 Customer Supplied Material 04QA704050 Return of Controlled Items for Repair /Rework 04QA704074 Aerospace Returned Items	Property belonging to customers or external providers	8.5.3	8.5.3	7.6
04QA704018 Standard Handling, Packaging & Shipping 04QA704010 Special Handling , Storage & Shipping 04QA704019 Final Cleaning 04QA704048 FOD Prevention. 04QA704081 Storage Procedure 04QA704053 Date Coded Material	Preservation	8.5.4	8.5.4	13
04QA704092 Return Authorization Report 04QA704063 Inspection History 04QA704111 Validity Check Certified Product	Post-Delivery activities	8.5.5	8.5.5	N/A
01DM000064 Document Management	Control of Changes	8.5.6	8.5.6	6.3
04QA704071 Testing Commercial Grade Items 04QA704073 Process for CRN Jobs 09QA110001 PMI FCI Standard 04QA704026 In-Process Inspection 04QA704038 Final Inspection 04QA704105 Return to Service for PMA	Release of products and services	8.6	8.6	13.3.1.a
04QA704004 Nonconforming Product 04QA704075 Reporting Failures to the FAA. 04QA704011 10CFR21 Reporting Defects NRC	Control of nonconforming outputs	8.7	8.7	15
Quality Manual	Performance evaluation	9	9	N/A
04QA704063 Inspection History 04QA704076 On Time Delivery Report	Monitoring, measurement, analysis and evaluation	9.1 9.1.1	9.1 9.1.1	11
04QA704098 Customer Satisfaction	Customer satisfaction	9.1.2	9.1.2	N/A
04QA704062 Management Review	Analysis and evaluation	9.1.3	9.1.3	N/A
04QA704008 Audits	Internal Audit	9.2	9.2	18
04QA704062 Management Review	Management Review Management Review Input Management Review output	9.3,9.3.1 9.3.2, 9.3.3	9.3,9.3.1 9.3.2, 9.3.3	2.2
Quality Manual	Improvement	10	10	16
04QA704062 Management Review	General	10.1	10.1	16
04QA704083 Corrective & Preventive Action	Nonconformity and corrective action	10.2	10.2	15, 16
04QA704062 Management Review	Continual improvement	10.3	10.3	N/A

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	1 of 20	V

COMMERCIAL SECTION 1

Table of Contents

1.SCOPE

2

2.REFERENCES

2

3.TERMS & DEFINITIONS

2

4.CONTEXT OF THE ORGANIZATION

2

5.LEADERSHIP

3

6.PLANNING

5

7.SUPPORT

6

8.OPERATION.....


10

9.PERFORMANCE EVALUATION.....

17

10.IMPROVEMENT

19

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	2 of 20	V

1. SCOPE

- 1.1. Section 1 of the Quality Manual (QM-1) is for the Quality Management System for FCI commercial products. Section 1 applies to Design, Parts and Services provided by FCI.
- 1.2. Section 1 applies to the following locations and the services it provides:
 - 1.2.1. 1755 La Costa Meadows Drive, San Marcos, California USA 92078
 - 1.2.2. 1645 Rancho Santa Fe Road, Suite 105, San Marcos, California USA 92078
- 1.3. The QM-1 is complementary to the customer and applicable statutory and regulatory requirements.
 - 1.3.1. If there is conflict between the requirements of the manual and other approved requirements, the latter will prevail.
- 1.4. QM-1 is to demonstrate FCI's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

2. REFERENCES

The QM-1 is made in reference to ISO9001.

3. TERMS & DEFINITIONS

- 3.1. Product Safety – The state in which a product is able to perform to its' designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

4. CONTEXT OF THE ORGANIZATION

4.1. Understanding FCI and its context

FCI Management reviews the internal and external issues to determine the strategic direction and that affect its ability to achieve the intended result of the quality management system.


FCI will also determine whether climate change is a relevant issue.

FCI addresses climate change by meeting Federal, State, County and City regulatory requirements.

4.2. Understanding the Needs and Expectations of Interested Parties.

- a) The quality management system is made to recognize the interested parties; See 05QA000201, Parties of Interest.
- b) FCI reviews customer, statutory and regulatory requirements and either has the customer change the requirements to meet quality management system or change the quality management system to meet the needs.
- c) FCI monitors and reviews the requirements of the interested parties.

Note: Relevant interested parties can have requirements related to climate change.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	3 of 20	V

4.3. Determine the Scope of the Quality Management System- FCI determined the boundaries and applicability of the quality management system to establish its scope. Determination of the scope will be based on:

- a) The external and internal issues
- b) The requirements are relevant interested parties.
- c) The products and services of the organization

4.3.1.FCI has determined that all the requirements of ISO9001 are applicable to FCI.

4.3.2.The Scope of FCI's quality management system is published in this Quality Manual.

4.3.3.Conformity to this procedure does not affect FCI's requirements to ensure conformity of its parts or services

4.4. Quality Management System and Its processes

4.4.1.FCI establishes, implements, maintains and continually improves the quality management system, including the process needed and their interactions, in accordance with the requirements of ISO9001.

FCI has determined the process needed for the quality management system and our application throughout the organization and has:

- a) Determined the inputs required and the outputs expected from these processes;
- b) Determined the sequence and interaction of these processes;
- c) Determined and applied the criteria and methods (including monitoring, measurements and related performance indicators)
- d) Determined the resources needed for these processes and ensure their availability;
- e) Assigned the responsibilities and authorities for these processes;
- f) Addressed the risks and opportunities as determined in accordance with the requirements;
- g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.
- h) Improve the processes and the quality management system.


4.4.2.FCI:

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

5. LEADERSHIP

5.1. Leadership Commitment

5.1.1.General- FCI Management demonstrates leadership and commitment with respect to the quality management system by:

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	4 of 20	V

- a) Taking into accountability for the effectiveness of the quality management system;
- b) Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of FCI;
- c) Ensuring the integration of the quality management system requirements into FCI's business process;
- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring the resources needed for the quality management system are available;
- f) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) Ensuring that the quality management system achieves its intended results;
- h) Engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;
- i) Promoting improvement;
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2. Customer Focus – FCI Management demonstrates leadership and commitment with respect to customer focus by ensuring that;

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


5.2. Quality Policy – 05QA000219, Quality Policy

5.2.1. Establishing a Quality Policy – FCI top management demonstrates leadership and commitment and maintain a quality policy that:

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

5.2.2. Communicating the Quality Policy – The Quality Policy is:

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

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 1	PAGE 5 of 20	REVISION V

5.3. Organizational Roles, Responsibilities and Authorities – FCI top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization. FCI has assigned the responsibility and authority for:

- a) Ensuring that the quality management system conforms to the requirements of AS9100;
- b) Ensuring that the processes are delivering their intended outputs;
- c) Reporting on the performance of the quality management system and on opportunities for improvement, in particular top management;
- d) Ensuring the promotion of customer focus throughout the organization;
- e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6. PLANNING

6.1. Actions to Address Risks and Opportunities

6.1.1.FCI will determine the Risks and Opportunities based on the internal and external issues based on the interested parties. FCI shall address the Risks and Opportunities:

- a) Give assurance that the quality management system can achieve its intended results;
- b) Enhance desirable effects;
- c) Prevent or reduce undesirable effects;
- d) Achieve improvement.

6.1.2.FCI plans;


- a) Action to address these risks and opportunities
- b) How to;
 - 1) Integrate and implement the actions into its quality management system processes;
 - 2) Evaluate the effectiveness of these actions.

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

6.2. Quality Objectives and planning to achieve them

6.2.1.FCI establishes quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives are:

- a) Consistent with the Quality Policy
- b) Measurable
- c) Taking account applicable requirements
- d) Relevant to conformity of products and services and to enhance customer satisfaction
- e) Monitored
- f) Communicated

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	6 of 20	V

g) Updated as appropriate

6.2.2. Quality Objectives are to be achieved by planning. The organization shall determine:

- a) What will be done
- b) What resources will be required
- c) Who will be responsible
- d) When it will be completed
- e) How the results will be evaluated

6.3. Planning of Changes

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

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

7. SUPPORT

7.1. Resources

7.1.1. General

FCI determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system. Consideration is made for:

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

7.1.2. People


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

7.1.3. Infrastructure

FCI determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure includes:

- a) Buildings and associated utilities;
- b) Equipment, including hardware and software;
- c) Transportation resources;
- d) Information and communication technology.

7.1.4. Environment for the Operation of Processes

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 1	PAGE 7 of 20	REVISION V

FCI determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. Suitable environment is a combination of human and physical factors like;

- a) Social
- b) Psychological
- c) Physical

7.1.5. Monitoring and Measuring Resources

7.1.5.1. General

FCI has determined and provided the resources needed to ensure valid and reliable results when monitoring or measurement is used to verify the conformity of products and services to requirements. FCI ensures that the resources provided:

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

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

7.1.5.2. Measurement Traceability

FCI considers measurement traceability an essential part of providing confidence in the validity of measurement results, measurement equipment are:

- a. Calibrated or verified, or both at specified intervals, or prior to use, against measurement standards traceable to NIST; when no standards exist, the basis used for calibration or verification shall be retained as documented information.
- b. Identified in order to determine their status;
- c. Safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results

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

7.1.6. Organizational Knowledge


FCI has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and is available to extent necessary.

When addressing changes or trends, FCI considers its current knowledge and determined how to acquire or access any necessary additional knowledge and required updates.

7.2. Competence

FCI:

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	8 of 20	V

- a. determines the necessary competence of personnel doing work under its control that effects the performance and effectiveness of the quality management system;
- b. ensures that the personnel are competent on the basis of appropriate education, training or experience;
- c. where applicable, takes actions to acquire the necessary competence and evaluate the effectiveness of the actions taken;
- d. retains appropriate documented information as evidence of competence.

7.3. Awareness

FCI ensures that persons doing work under FCI's control are aware of:


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

7.4. Communication

FCI has determined the internal and external communications relevant to the quality management system including;

- a. On what it will communicate;
- b. When to communicate
- c. With whom to communicate
- d. How to communicate;
- e. Who communicates.

NOTE for NOTIFIED BODIES ATEX, IECEX, QAL-1, FM, UL: Changes to this manual that substantially affect the Quality System (e.g. Change of Quality Assurance manager or EX Representative ..) shall be submitted to a Notified Body by the appropriate Representative (EX Representative, Director of Quality, Quality Assurance Manager,...)

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	9 of 20	V

NOTE: Notification ISO/IEC80079-34 for Nonconformance

FCI takes appropriate to the degree of risk, where nonconforming product has been supplied to a customer.

FCI's Contract Manager, Quality Assurance Management or designated representative will liaise with the notified body responsible for the EC Type certification.

When nonconforming product is deemed unsafe, FCI will inform, by e-mail, the customer and the notified body responsible for the quality system notification.

FCI maintains records of the notification for a minimum of ten years. See 05QA000182 Quality retention List.

7.5. Documented Information

7.5.1.General

FCI's quality management system includes

- Documented information required by this manual
- Documented information determined by FCI as being necessary for the effectiveness of the quality management system.

7.5.2.Creating and Updating

When creating and updating documented information, FCI shall ensure appropriate:

- Identification and description
- Format
- Review and approval for suitability and adequacy

7.5.3.Control of Documented Information


7.5.3.1. Documented information required by the quality management system and by ISO9001 shall be controlled to ensure:

- It is available and suitable for use, where and when it is needed;
- It is adequately protected

7.5.3.2. For the control of documented information, the organization shall address the following activities, as applicable:

- Distribution, access, retrieval and use;
- Storage and preservation, including preservation of legibility;
- Control of changes
- Retention and disposition;

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

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	10 of 20	V

Documented information retained as evidence of conformity shall be protected from unintended alterations

8. OPERATION

8.1. Operational Planning and Control

FCI shall plan, implement and control the processes need to meet the requirements for the provisions of products and services and to implement the actions determined in Planning by:

- a) Determining the requirements for the products and services;
- b) Establishing criteria for:
 - 1) The processes
 - 2) The acceptance of products and services;
- c) Determining the resources needed to achieve conformity to the product and service requirements;
- d) Implementing control of the processes in accordance with the criteria;
- e) Determining, maintaining, and retaining documented information to the extent necessary;
 - 1) To have confidence that the processes have been carried out as planned;

The output of this planning shall be suitable for the organization's operations.

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

FCI ensures that outsourced processes are controlled.

8.2. Requirements for Products and Services

8.2.1. Customer Communication


Communication with customers includes:

- a) Providing information relating to products and services;
- b) Handling enquires, contracts, or orders, including changes;
- c) Obtaining customer feedback relating to products and services, including customer complaints;
- d) Handling or controlling customer property;
- e) Establishing specific requirements for contingency actions, when relevant.

8.2.2. Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, FCI ensures that;

- i. The requirements for the product and services are defined, including;
 - a. Any applicable statutory and regulatory requirements;
 - b. Those considered necessary by the organization;

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	11 of 20	V

ii. FCI can meet the claims for the products and services FCI offers;

8.2.3. Review of the Requirements for Products and Services

- A. FCI ensures that it has the ability to meet the requirements for products and services to be offered to customers. FCI conducts a review before committing to supply products and services to the customer, to include;
- 1) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
 - 2) Requirements not stated by the customer, but necessary for the specified or intended use, when known;
 - 3) Requirements specified by FCI;
 - 4) Statutory and regulatory requirements differing from those previously expressed.
 - 5) Contract or order requirements differing from those previously expressed.

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

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

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

- B. FCI retains documented information, as applicable:
- 1) On the results of the review
 - 2) On any new requirements for the products and services

8.2.4. Changes to Requirements for Products and Services

FCI ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed

8.3. Design and Development of Products and Services


8.3.1. General

FCI establishes, implements, and maintains a design and development process that is appropriate to ensure the subsequent provision for products and services.

8.3.2. Design and Development Planning

In determining the stages and controls for design and development, FCI shall consider:

- a) The nature, duration, and complexity of the design and development activities;
- b) The required process stages, including applicable design and development reviews;
- c) The required design and development verification and validation activities;
- d) The responsibilities and authorities involved in the design and development process;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 1	PAGE 12 of 20	REVISION V

- e) The internal and external resources needs for the design and development of products and services;
- f) The need to control interfaces between persons involved in the design and development process;
- g) The need for involvement of customers and users in the design and development process;
- h) The requirements for subsequent provision of products and services;
- i) The level of control expected for the design and development process by customers and other relevant interested parties;
- j) The documents information needed to demonstrate that design and development requirements are met.

8.3.3.Design and Development Inputs

FCI determines the requirements essential for the specific types of products and services to be designed and developed. FCI shall consider:

- a) functional performance requirements;
- b) informational derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that FCI has committed to implement;
- e) potential consequences of failure due to the nature of the products and services;

Inputs are adequate for design and development purposes, complete and unambiguous.


Conflict design and development inputs shall be resolved.

FCI retains documented information on design and development inputs.

8.3.4.Design and Development Controls

FCI applies controls to the design and development process to ensure that;

- a) The results to be achieved are defined;
- b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements
- d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use.
- e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) Documented information of these activities is retained;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 1	PAGE 13 of 20	REVISION V

NOTE: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in combination, as is suitable for the products and services of FCI.

8.3.5.Design and Development Outputs

FCI ensures that design and development outputs:

- a) Meet the input requirements;
- b) Are adequate for the subsequent processes for the provision of products and services;
- c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) Specify the characteristics of products and services that are essential for their intended purpose and their safe and proper provision;

FCI retains documented information on design and development outputs.

8.3.6. Design and Development Changes

FCI identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

FCI retains documented information on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

8.4. Control of Externally Provided Processes, Products, and Services


8.4.1.General

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

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

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

FCI determines and applies criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	14 of 20	V

products and services in accordance with requirements. FCI retains documented information of these activities and any necessary actions arising from the evaluations.

8.4.2. Type and Extent of Control

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

FCI shall;

- a) Ensure that externally provided processes remain within the control of its quality system.
- b) Define both the controls that it intends to apply to an external provider and those it tends to apply to the resulting output;
- c) Take into consideration:
 - 1) The potential impact of externally provided processes, products, and services on FCI's ability to consistently meet customers and applicable statutory and regulatory requirements;
 - 2) The effectiveness of the controls applied by the external provider;
- d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

8.4.3. Information for External Providers

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

FCI communicates to external providers its requirements for:


- a. The process, products and services to be provided;
- b. The approval of:
 - i. Products and services;
 - ii. Methods, processes, and equipment;
 - iii. The release of products and services;
- c. Competence, including any required qualification of personnel;
- d. The external providers' interactions with FCI;
- e. Control and monitor of the external providers' performance to be applied by FCI
- f. Verification or validation activities that FCI, or its customer, intends to perform at the external providers' premises;

8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

FCI implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

- a. The availability of documented information that defines:

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	15 of 20	V

- i. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
- ii. The results to be achieved;
- b. The availability and use of suitable monitoring and measuring resources;
- c. The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;
- d. The suitable infrastructure and environment for the operation of processes;
- e. The appointment of competent persons, including any required qualification;
- f. The validation, periodic revalidation, of the ability to achieve planned results of the process for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; (Special Processes)
- g. The implementation of actions to prevent human error;
- h. The implementation of release, delivery and post-delivery activities;

8.5.2. Identification & Traceability

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

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

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

8.5.3. Product belonging to Customers or External Providers

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

FCI identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

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


NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.

8.5.4. Preservation

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

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

8.5.5. Post-Delivery Activities

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	16 of 20	V

FCI meet requirements for post-delivery activities associated with the products and services.

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

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

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

8.5.6. Control of Changes

FCI reviews and controls change for production or service provision to the extent necessary to ensure continuing conformity with requirements.

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

8.6. Release of Products and Services

FCI implements planned arrangements, at appropriate stages, to verify that the product and service requirements are met.

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

FCI retains documented information on the release of products and services. The documented information shall include:

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


8.7. Control of Nonconforming Outputs

8.7.1. FCI ensures that the outputs that do not conform to their requirements are identified and controlled to prevent their unintended use of delivery.

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

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

- a) Correction;
- b) Segregation, containment, return or suspension of provision of products and services;
- c) Informing the customer;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 1	PAGE 17 of 20	REVISION V

- d) Obtaining authorization for acceptance under concession by a relevant authority and, when applicable, by the customer.

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

8.7.2.FCI retains documented information that:

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

9. PERFORMANCE EVALUATION

9.1. Monitoring, measurement, Analysis, and Evaluation

9.1.1.General

FCI determines:

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

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

FCI retains appropriate documented information as evidence of the results.

9.1.2.Customer Satisfaction

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


9.1.3.Analysis and Evaluation

FCI analyze and evaluate appropriate data and information arising from monitoring and measurement.

NOTE: Appropriate data can include information on product and service problems reported by external sources.

The results of analysis shall be used to evaluate:

- a) Conformity of products and services;
- b) The degree of customer satisfaction;
- c) The performance and effectiveness of the quality management system;
- d) If planning has been implemented effectively;

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	18 of 20	V

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

NOTE: methods to analyze data can include statistical techniques.

9.2. Internal Audit

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

- A. Conforms to
 - 1) FCI's own requirements for its quality management system;
 - 2) The requirements of ISO9001;
- B. Is effectively implemented and maintained.

9.2.2.FCI shall

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

9.3. Management Review


9.3.1.General

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

9.3.2.Management Review Inputs

The management review shall be planned and carried out taking into consideration:

- A. The status of the actions from previous management reviews
- B. Changes in external and internal issues that are relevant to the quality management system;
- C. Information on the performance and effectiveness of the quality management system, including trends in:
 - 1) Customer satisfaction and feedback from relevant interested parties;

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	1	19 of 20	V

- 2) The extent to which quality objectives have been met;
- 3) Process performance and conformity of products and services
- 4) Nonconformities and corrective actions;
- 5) Monitoring and measurement results;
- 6) Audit results;
- 7) The performance of external providers;

- D. The adequacy of resources;
- E. The effectiveness of actions taken to address risks and opportunities;
- F. Opportunities for improvement.

9.3.3. Management Review Outputs

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

- A. Opportunities for improvement;
- B. Any need for changes to the quality management system;
- C. Resource needs.

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

10. IMPROVEMENT

10.1. General

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

These include:

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

NOTE: Examples of improvement can include correction , corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2. Nonconformity and Corrective Action

10.2.1. When a nonconformity occurs, including any arising from complaints, FCI shall:

- A. React to the nonconformity and, as applicable:
 - 1) Take action to control and correct it;
 - 2) Deal with the consequences;
- B. Evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) Reviewing and analyzing the nonconformity;

SUBJECT**Quality Manual****CAGE CODE****64818****DATE****1/10/2025****SECTION****1****PAGE****20 of 20****REVISION****V**

- 2) Determining the causes of the nonconformity;
- 3) Determining if similar nonconformities exist, or could potentially occur;
- C. Implement any action needed;
- D. Review the effectiveness of any corrective action taken;
- E. Update risks and opportunities determined during planning, if necessary;
- F. Make changes to the quality management system, if necessary.

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

10.2.2. FCI retains documented information as evidence of:

- A. The nature of the nonconformities and any subsequent actions taken;
- B. The results of any corrective action.

10.3. Continual Improvement

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

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

FCI FLUID COMPONENTS INTERNATIONAL LLC <small>A PST BRAND</small> <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	1 of 29	V



FCI Aerospace Section 2

Contents

1.SCOPE	2
2.REFERENCES	2
3.TERMS & DEFINITIONS	2
4.CONTEXT OF THE ORGANIZATION	2
5.LEADERSHIP	4
6.PLANNING	5
7.SUPPORT	6
8.OPERATION.....	10
9.PERFORMANCE EVALUATION.....	26
10.IMPROVEMENT	28

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	2 of 29	V

1. SCOPE

- 1.1. Section 2 of the Quality Manual (QM-2) is for the Quality Management System for FCI Aerospace. Section 2 applies to Design, Parts and Services provided by FCI Aerospace.
- 1.2. Section 2 applies to the following location in FCI Aerospace area and associated supporting departments within FCI.
 - 1.2.1. 1755 La Costa Meadows Drive, San Marcos, California 92078 USA
 - 1.2.2. Tech Center area ASY15A at 1645 Rancho Santa Fe Road, Suite 105, San Marcos, California USA 92078
- 1.3. The QM-2 is complementary to the customer and applicable statutory and regulatory requirements.
 - 1.3.1. The QM-2 is complementary to 07QA070004, FCI PMA Quality Manual.
 - 1.3.2. If there is conflict between the requirements of the manual and other approved requirements, the latter will prevail.
- 1.4. QM-2 is to demonstrate FCI Aerospace's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements and aims to enhance customer satisfaction through effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

2. REFERENCES

The QM-2 is made in reference to AS9100 and therefore ISO9001.

3. TERMS & DEFINITIONS

- 3.1. Product Safety – The state in which a product is able to perform to its' designed or intended purpose without causing unacceptable risk of harm to persons or damage to property.

4. CONTEXT OF THE ORGANIZATION

4.1. Understanding FCI Aerospace and its context


FCI Management reviews the internal and external issues to determine the strategic direction and that affect its ability to achieve the intended result of the quality management system.

FCI will also determine whether climate change is a relevant issue.

FCI addresses climate change by meeting Federal, State, County and City regulatory requirements.

4.2. Understanding the Needs and Expectations of Interested Parties.

- a) The quality management system is made to recognize the interested parties; See 05QA000201 Parties of Interest

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	3 of 29	V

b) FCI reviews customer, statutory and regulatory requirements and either have the customer change the requirements to meet quality management system or change the quality management system to meet the needs.

c) FCI monitors and reviews the requirements of the interested parties.

Note: Relevant interested parties can have requirements related to climate change.

4.3. Determine the Scope of the Quality Management System- FCI determined the boundaries and applicability of the quality management system to establish its scope. Determination of the scope will be based on:

- a) The external and internal issues
- b) The requirements are relevant interested parties.
- c) The products and services of the organization

4.3.1.FCI has determined that all the requirements of AS9100 are applicable to FCI Aerospace.

4.3.2.The Scope of FCI's quality management system is published in this Quality Manual.

4.3.3.Conformity to this procedure does not affect FCI's requirements to ensure conformity of its parts or services

4.4. Quality Management System and Its processes

4.4.1.FCI establishes, implements, maintains and continually improves the quality management system, including the process needed and their interactions, in accordance with the requirements of AS9100.

4.4.1.1. FCI's Quality Management System also addresses customer and applicable statutory and regulatory quality management system requirements

4.4.1.2. FCI has determined the process needed for the quality management system and our application throughout the organization and has:

- a) Determined the inputs required and the outputs expected from these processes;
- b) Determined the sequence and interaction of these processes;
- c) Determined and applied the criteria and methods (including monitoring, measurements and related performance indicators)
- d) Determined the resources needed for these processes and ensure their availability;
- e) Assigned the responsibilities and authorities for these processes;
- f) Addressed the risks and opportunities as determined in accordance with the requirements;
- g) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.
- h) Improve the processes and the quality management system.

4.4.2.FCI:

- a) maintains documented information to support the operation of its processes.

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	4 of 29	V

- b) retains documented information to have confidence that the processes are being carried out as planned.

Establish and maintain documented information that includes:

- A general description of relevant interested parties;
- The scope of the quality management system, including boundaries and applicability;
- A description of the processes needed for the quality management system and their application throughout the organization;
- The sequence and interaction of these processes;
- Assignment of the responsibilities for these processes.

5. LEADERSHIP


5.1. Leadership Commitment

5.1.1.General- FCI Management demonstrates leadership and commitment with respect to the quality management system by:

- a) Taking into accountability for the effectiveness of the quality management system;
- b) Ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of FCI;
- c) Ensuring the integration of the quality management system requirements into FCI's business process;
- d) Promoting the use of the process approach and risk-based thinking;
- e) Ensuring the resources needed for the quality management system are available;
- f) Communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) Ensuring that the quality management system achieves its intended results;
- h) Engaging, directing, and supporting persons to contribute to the effectiveness of the quality management system;
- i) Promoting improvement;
- j) Supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2.Customer Focus – FCI Management demonstrates leadership and commitment with respect to customer focus by ensuring that;

- a) Customer and applicable statutory and regulatory requirements are determined, understood, and consistently met;
- b) The risk and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	5 of 29	V

- c) The focus on enhancing customer satisfaction is maintained;
- d) Product and services conformity and on-time delivery performance are measured and appropriate action is taken if planned results are not, or will not be, achieved.

5.2. Quality Policy – 05QA000219

5.2.1. Establishing a Quality Policy – FCI top management demonstrates leadership and commitment and maintain a quality policy that:

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

5.2.2. Communicating the Quality Policy – The Quality Policy is:

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

5.3. Organizational Roles, Responsibilities and Authorities – FCI top management ensures that the responsibilities and authorities for relevant roles are assigned, communicated, and understood within the organization. FCI has assigned the responsibility and authority for:

- a) Ensuring that the quality management system conforms to the requirements of AS9100;
- b) Ensuring that the processes are delivering their intended outputs;
- c) Reporting on the performance of the quality management system and on opportunities for improvement, in particular top management;
- d) Ensuring the promotion of customer focus throughout the organization;
- e) Ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6. PLANNING

6.1. Actions to Address Risks and Opportunities

6.1.1. FCI will determine the Risks and Opportunities based on the internal and external issues based on the interested parties. FCI shall address the Risks and Opportunities:

- a) Give assurance that the quality management system can achieve its intended results;
- b) Enhance desirable effects;
- c) Prevent or reduce undesirable effects;
- d) Achieve improvement.

6.1.2. FCI plans;

- a) Action to address these risks and opportunities
- b) How to;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	6 of 29	V

- 1) Integrate and implement the actions into its quality management system processes;
- 2) Evaluate the effectiveness of these actions.

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

6.2. Quality Objectives and planning to achieve them

6.2.1. FCI establishes quality objectives at relevant functions, levels and processes needed for the quality management system. The quality objectives are:

- a) Consistent with the Quality Policy
- b) Measureable
- c) Taking account applicable requirements
- d) Relevant to conformity of products and services and to enhance customer satisfaction
- e) Monitored
- f) Communicated
- g) Updated as appropriate

6.2.2. Quality Objectives are to be achieved by planning. The organization shall determine:

- a) What will be done
- b) What resources will be required
- c) Who will be responsible
- d) When it will be completed
- e) How the results will be evaluated

6.3. Planning of Changes

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

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

7. SUPPORT

7.1. Resources

7.1.1. General

FCI determines and provides the resources needed for the establishment, implementation, maintenance, and continual improvement of the quality management system. Consideration is made for:

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	7 of 29	V

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

7.1.2. People

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

7.1.3. Infrastructure

FCI determines, provides and maintains the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. Infrastructure includes:

- a) Buildings and associated utilities;
- b) Equipment, including hardware and software;
- c) Transportation resources;
- d) Information and communication technology.

7.1.4. Environment for the Operation of Processes

FCI determines, provides and maintains the environment necessary for the operation of its processes and to achieve conformity of products and services. Suitable environment is a combination of human and physical factors like;

- a) Social
- b) Psychological
- c) Physical

7.1.5. Monitoring and Measuring Resources

7.1.5.1. General

FCI has determined and provided the resources needed to ensure valid and reliable results when monitoring or measurement is used to verify the conformity of products and services to requirements. FCI ensures that the resources provided:


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

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

7.1.5.2. Measurement Traceability

FCI considers measurement traceability an essential part of providing confidence in the validity of measurement results, measurement equipment are:

- a. Calibrated or verified, or both at specified intervals, or prior to use, against measurement standards traceable to NIST; when no standards exist, the basis used for calibration or verification shall be retained as documented information.

 FLUID COMPONENTS INTERNATIONAL LLC A PST BRAND <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	8 of 29	V

- b. Identified in order to determine their status;
- c. Safeguarded from adjustments, damage, or deterioration that would invalidate the calibration status and subsequent measurement results

FCI has established, implemented and maintained a process for the recall of monitoring and measuring equipment requiring calibration or verification.

FCI maintains a register of the monitoring and measuring equipment. The register includes the equipment type, unique identification, location, and the calibration or verification method, frequency, and acceptance criteria.

Calibration or verification of monitoring and measuring equipment shall be carried out under suitable environmental conditions.

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

7.1.6.Organizational Knowledge

FCI has determined the knowledge necessary for the operation of its processes and to achieve conformity of products and services.

This knowledge is maintained and is available to extent necessary.

When addressing changes or trends, FCI considers its current knowledge and determined how to acquire or access any necessary additional knowledge and required updates.

7.2. Competence


FCI:

- a. determines the necessary competence of personnel doing work under its control that effects the performance and effectiveness of the quality management system
- b. ensures that the personnel are competent on the basis of appropriate education, training or experience
- c. where applicable, takes actions to acquire the necessary competence and evaluate the effectiveness of the actions taken
- d. retains appropriate documented information as evidence of competence.

7.3. Awareness

FCI ensures that persons doing work under FCI's control are aware of:

- a. the quality policy
- b. relevant quality objectives
- c. their contribution to the effectiveness of the quality management system, including the benefits of improved performance
- d. the implications of not conforming with the quality management system requirements
- e. relevant quality management system documentation information and changes thereto
- f. their contribution to product or service conformity

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	9 of 29	V

- g. their contribution to product safety
- h. the importance to ethical behavior.

7.4. Communication

FCI has determined the internal and external communications relevant to the quality management system including:

- a. On what it will communicate
- b. When to communicate
- c. With whom to communicate
- d. How to communicate
- e. Who communicates.

7.5. Documented Information

7.5.1.General

FCI's quality management system includes

- a. Documented information required by this manual
- b. Documented information determined by FCI as being necessary for the effectiveness of the quality management system.

7.5.2.Creating and Updating

When creating and updating documented information, FCI shall ensure appropriate:

- a. Identification and description
- b. Format
- c. Review and approval for suitability and adequacy


7.5.3.Control of Documented Information

7.5.3.1. Documented information required by the quality management system and by AS9100 shall be controlled to ensure:

- a. It is available and suitable for use, where and when it is needed
- b. It is adequately protected.

7.5.3.2. For the control of documented information, the organization shall address the following activities, as applicable:

- a. Distribution, access, retrieval and use
- b. Storage and preservation, including preservation of legibility
- c. Control of changes
- d. Retention and disposition

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	10 of 29	V

- e. Prevention of the unintended use of obsolete documented information by removal or by application of suitable identification or controls if kept for any purpose.

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

Documented information retained as evidence of conformity shall be protected from unintended alterations

When documented information is managed electronically, data protection process shall be defined (e.g. protection from loss, unauthorized changes, unintended alteration, corruption, physical damage).

8. OPERATION

8.1. Operational Planning and Control

FCI shall plan, implement and control the processes need to meet the requirements for the provisions of products and services and to implement the actions determined in Planning by:

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

Note: Determination of requirements for the products and services should include consideration of:


- Personal and product safety
- Producibility and inspect ability
- Reliability, availability and maintainability
- Suitability of parts and materials used in the product
- Selection and development of embedded software
- Product obsolescence
- Prevention, detection, and removal of foreign objects
- Handling, packaging, and preservation
- Recycling or final disposal of the product at the end of its life.

- b) Establishing criteria for:

- 1) The processes
- 2) The acceptance of products and services:

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

- Design Verification
- Process Control;
- Selection and verification of key characteristics

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	11 of 29	V

- Process capability measurements
- Statistical process control
- Design of experiments.
- Verification
- Failure mode, effects, and criticality analysis.
- c) Determining the resources needed to achieve conformity to the product and service requirements and to meet on-time delivery of products and services
- d) Implementing control of the processes in accordance with the criteria
- e) Determining, maintaining, and retaining documented information to the extent necessary:
 - 1) To have confidence that the processes have been carried out as planned
 - 2) To demonstrate the conformity of products and services to their requirements
- f) Determining the processes and controls needed to manage critical items, including production process controls when key characteristics have been identified.
- g) Engaging representatives of affected organization functions for operational planning and control
- h) Determining the process and resources to support the use and maintenance of the products and services
- i) Determining the products and services to be obtained from external providers
- j) Establishing the controls needed to prevent the delivery of nonconforming products and services to the customer.

NOTE: One method to achieve operational planning and control can be through using integrated phased processes.

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

NOTE: This activity is generally referred to as project planning, project management, or program management.

The output of this planning shall be suitable for the organization's operations.

NOTE: As an output of this planning, documented information specifying the process of the quality management system and the resources to be applied to a specific product, service, project, or contract can be referred to as a quality plan.

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

FCI ensures that outsourced processes are controlled.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	12 of 29	V

FCI establishes, implements, and maintains a process to plan and control the temporary or permanent transfer of work, to ensure the continued conformity of the work requirements. The process shall ensure that work transfer impacts and risks are managed.

NOTE: For the control of work transfer from the organization to an external provider or from an external provider to another external provider See 8.4 For the control of work transfer from one organization facility to another, or from an external provider to FCI, see 8.5.

8.1.1.Operational Risk Management

FCI plans, implements, and controls a process for managing operational risk to the achievement of applicable requirements, which includes as appropriate to FCI and the products and services:

- a) Assignment of responsibilities for operational risk management
- b) Definition of risk assessment criteria
- 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) Acceptance of risks remaining after implementation of mitigating actions.

8.1.2.Configuration Management

FCI plans, implements, and controls a process for configuration management as appropriate to FCI and its products and services to ensure the identification and control of physical and functional attributes throughout the product lifecycle. This process shall:

- a) Control product identity and traceability to the requirements, including the implementation of identified changes
- b) Ensure that the documented information is consistent with the actual attributes of the products and services.

8.1.3.Product Safety

FCI plans, implements and controls the processes needed to assure product safety during the entire product life cycle, as appropriate to FCI and the product.

NOTE: Examples of these processes include:

- a) Assessment of hazards and management of associated risks
- b) Management of safety critical items
- c) Analysis and reporting of occurred events and training of persons.

8.1.4.Prevention of Counterfeit Parts

FCI plans, implements, and controls processes, appropriate to FCI and the product for the prevention of counterfeit or suspect counterfeit part use and their inclusion in products delivered to the customer.

NOTE: Counterfeit part prevention process includes;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	13 of 29	V

- a) Training of appropriate persons in the awareness and prevention of counterfeit parts;
- b) Application of parts obsolescence monitoring program;
- c) Controls for acquiring externally provided product from original or authorized manufacturers, authorized distributors, or other approved sources.
- d) Requirements for assuring traceability of parts and components to their original or authorized manufacturers;
- e) Verification and test methodologies to detect counterfeit parts;
- f) Monitor of counterfeit parts reporting from external sources;
- g) Quarantine and reporting of suspect or detected counterfeit parts

8.2. Requirements for Products and Services

8.2.1. Customer Communication

- A. Communication with customers includes:
 - 1) Providing information relating to products and services;
 - 2) Handling enquires, contracts, or orders, including changes;
 - 3) Obtaining customer feedback relating to products and services, including customer complaints;
 - 4) Handling or controlling customer property;
 - 5) Establishing specific requirements for contingency actions, when relevant.


8.2.2. Determining the Requirements for Products and Services

When determining the requirements for the products and services to be offered to customers, FCI ensures that;

- i. The requirements for the product and services are defined, including;
 - a. Any applicable statutory and regulatory requirements;
 - b. Those considered necessary by the organization;
- ii. FCI can meet the claims for the products and services FCI offers;
- iii. Special requirements of the products and services are determined;
- iv. Operational risks have been identified.

8.2.3. Review of the Requirements for Products and Services

- A. FCI ensures that it has the ability to meet the requirements for products and services to be offered to customers. FCI conducts a review before committing to supply products and services to the customer, to include;
 - 1) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
 - 2) Requirements not stated by the customer, but necessary for the specified or intended use, when known;

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	14 of 29	V

- 3) Requirements specified by FCI;
- 4) Statutory and regulatory requirements differing from those previously expressed;
- 5) Contract or order requirements differing from those previously expressed.

This review is coordinated with applicable functions of FCI.

If upon review FCI determines that some customer requirements cannot be met or can only partially be met, FCI negotiates a mutually acceptable requirement with the customer.

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

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

NOTE: In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.

B. FCI retains documented information, as applicable:

- 1) On the results of the review
- 2) On any new requirements for the products and services

8.2.4. Changes to Requirements for Products and Services

FCI ensures that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed

8.3. Design and Development of Products and Services

8.3.1. General

FCI establishes, implements, and maintains a design and development process that is appropriate to ensure the subsequent provision for products and services.

8.3.2. Design and Development Planning

In determining the stages and controls for design and development, FCI shall consider:

- a) The nature, duration, and complexity of the design and development activities;
- b) The required process stages, including applicable design and development reviews;
- c) The required design and development verification and validation activities;
- d) The responsibilities and authorities involved in the design and development process;
- e) The internal and external resources needs for the design and development of products and services;
- f) The need to control interfaces between persons involved in the design and development process;
- g) The need for involvement of customers and users in the design and development process;
- h) The requirements for subsequent provision of products and services;

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 2	PAGE 15 of 29	REVISION V

- i) The level of control expected for the design and development process by customers and other relevant interested parties;
- j) The documents information needed to demonstrate that design and development requirements are met.

When applicable, FCI shall divide the design and development effort into distinct activities and, for each activity, define the tasks, necessary resources, responsibilities, design content, and inputs and outputs.

Design and Development planning shall consider the ability to provide, verify, test, and maintain products and services.

8.3.3.Design and Development Inputs

FCI determines the requirements essential for the specific types of products and services to be designed and developed. FCI shall consider:

- a) functional performance requirements;
- b) informational derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that FCI has committed to implement;
- e) potential consequences of failure due to the nature of the products and services;
- f) when applicable, the potential consequences of obsolescence.

Inputs are adequate for design and development purposes, complete and unambiguous.

Conflict design and development inputs shall be resolved.

FCI retains documented information on design and development inputs.

8.3.4.Design and Development Controls

FCI applies controls to the design and development process to ensure that;

- a) The results to be achieved are defined;
- b) Reviews are conducted to evaluate the ability of the results of design and development to meet requirements;
- c) Verification activities are conducted to ensure that the design and development outputs meet the input requirements
- d) Validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use.
- e) Any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
- f) Documented information of these activities is retained;
- g) Progression to the next stage is authorized.

Participants in design and development reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed.

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 2	PAGE 16 of 29	REVISION V

NOTE: Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in combination, as is suitable for the products and services of FCI.

- A. When tests are necessary for verification and validation, these tests shall be planned, controlled, reviewed, and documented to ensure and prove the following:
 - a) Test plans or specifications identify the test item being tested and the resources being used, define test objectives, and conditions parameters to be recorded and relevant acceptance criteria;
 - b) Test procedures describe the test methods to be used, how to perform the test, and how to record the results;
 - c) The correct configuration of the test item is submitted for the test;
 - d) The requirements of the test plan and the test procedures are observed;
 - e) The acceptance criteria are met.

Monitoring and measuring devices used for testing are controlled.

At the completion of design and development, FCI ensures that reports, calculations, test results, etc., are able to demonstrate that the design for the product or service meets the specification requirements for all identified operational conditions.

8.3.5.Design and Development Outputs

FCI ensures that design and development outputs:

- a) Meet the input requirements;
- b) Are adequate for the subsequent processes for the provision of products and services;
- c) Include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) Specify the characteristics of products and services that are essential for their intended purpose and their safe and proper provision;
- e) Specify, as applicable, any critical items, including key characteristics, and specific actions to be taken for these items;
- f) are approved by authorized person(s) prior to release.

FCI defines the data required to allow the product to be identified, manufactured, verified, used, and maintained.

NOTE: Data can include:

- a) The drawings, parts lists, and specifications necessary to define the configuration and the design features of the product;
- b) The material, process, manufacturing, assembly, handling, packaging, and preservation data needed to provide and maintain a conforming product or service.
- c) The technical data and repair schemes for operating and maintaining the product.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	17 of 29	V

FCI retains documented information on design and development outputs.

8.3.6. Design and Development Changes

FCI identifies, reviews and controls changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

FCI implements a process with criteria for notifying its customer, prior to implementation, about changes that affect customer requirements.

FCI retains documented information on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

Design and development changes are controlled in accordance with the configuration management process requirements.

8.4. Control of Externally Provided Processes, Products, and Services

8.4.1.General

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

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

FCI ensures, when required, that customer –designated or approved external providers, including process sources are used.


FCI identifies and manages the risk associated with the external provision of processes, products, and services, as well as the selection and use of external providers.

FCI requires that external providers apply appropriate controls to their direct and sub-tier external providers, to ensure that requirements are met.

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

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

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

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	18 of 29	V

NOTE: During external provider evaluation and selection, FCI can use quality data from objective and reliable external sources, as evaluated by FCI. Use of such data would be only one element of FCI's external provider control process and FCI remains responsible for verifying that externally provided processes, products and services meet specified requirements.

FCI:

- a) defines the process, responsibilities, and authority for the approval status decision, changes of the approval status, and conditions for a controlled use of external providers depending on their approval status;
- b) maintains a register of its external provides that includes approval status and the scope of the approval;
- c) periodically reviews external provider performance including process, product and service conformity, and on-time delivery performance;
- d) defines necessary actions to take when dealing with external providers that do not meet requirements;
- e) defines the requirements for controlling documented information created by and/or retained by external providers.

8.4.2. Type and Extent of Control


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

FCI shall;

- a) Ensure that externally provided processes remain within the control of its quality system.
- b) Define both the controls that it intends to apply to an external provider and those it tends to apply to the resulting output;
- c) Take into consideration:
 - 1) The potential impact of externally provided processes, products, and services on FCI's ability to consistently meet customers and applicable statutory and regulatory requirements;
 - 2) The effectiveness of the controls applied by the external provider;
 - 3) The results of the periodic review of external provider performance;
- d) Determine the verification, or other activities, necessary to ensure that the externally provided processes, products, and services meet requirements.

NOTE: Verification activities can include:

- Review of objective evidence of the conformity of the process, product, and services from the external provider;
- Inspection and audit at the external provider's premises;
- Review of the required documentation;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	19 of 29	V

- Review of the production part approval process data;
- Inspection of products or verification of services upon receipt;
- Review of delegations of product verification to external provider.

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

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

When external provider test reports are utilized to verify externally provided products, FCI shall implement a process to evaluate the data in the test reports to confirm that the product meets requirements. When a customer or organization has identified raw material as a significant operational risk, FCI shall implement a process to validate the accuracy of test reports.

8.4.3.Information for External Providers

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

FCI communicates to external providers its requirements for:

- The process, products and services to be provided including the identification of relevant technical data;
- The approval of:
 - Products and services;
 - Methods, processes, and equipment;
 - The release of products and services;
- Competence, including any required qualification of personnel;
- The external providers' interactions with FCI;
- Control and monitor of the external providers' performance to be applied by FCI
- Verification or validation activities that FCI, or its customer, intends to perform at the external providers' premises;
- Design and development control; {Design Authorization is not given to suppliers in exception to Commercial-Off-The-Shelf (COTS) design organizations.}
- Special requirements, critical items, or key characteristics;
- Test, inspection, and verification;
- The use of statistical techniques for product acceptance and related instructions for acceptance by FCI;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	20 of 29	V

k. The need to:

- i. Implement a quality management system;
- ii. Use customer designated or approved external providers, including process sources;
- iii. Notify FCI of nonconforming processes, products, or services and obtain approval for their disposition;
- iv. Prevent the use of counterfeit parts;
- v. Notify FCI of changes to processes, products, or services, including changes of their external providers or location of manufacture, and obtain FCI's approval;
- vi. Flow down to external providers applicable requirements including customer requirements;
- vii. Provide test specimens for design approval, inspection/verification, investigation or auditing;
- viii. Retain documented information, including retention periods and disposition requirements;

l. The right of access by FCI, the customer, and regulatory authorities to the applicable areas of facilities and to applicable documented information, at any level of the supply chain;

m. Ensuring that persons are aware of:

- i. Their contribution to product or service conformity;
- ii. Their contribution to product safety;
- iii. The importance of ethical behavior.

8.5. Production and Service Provision

8.5.1. Control of Production and Service Provision

FCI implements production and service provision under controlled conditions. Controlled conditions include, as applicable:

a. The availability of documented information that defines:

- i. The characteristics of the products to be produced, the services to be provided, or the activities to be performed;
- ii. The results to be achieved;


NOTE: Documented information that defines characteristics of products and services can include digital product definition data, drawings, parts lists, materials, and process specifications.

NOTE: Documented information for activities to be performed and results to be achieved can include process flow charts, control plans, production documents, and verification documents.

b. The availability and use of suitable monitoring and measuring resources;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	21 of 29	V

- c. The implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services have been met;
 - i. Ensuring that documented information for monitoring and measurement activity for product acceptance includes
 - Criteria for acceptance and rejection;
 - Where in the sequence verification operations are to be performed;
 - Measurement results to be retained;
 - Any specific monitoring and measurement equipment required and instructions associated with their use;
 - ii. Ensuring that when sampling is used as a means of product acceptance , the sampling plan is justified on the basis of recognized statistical principles and appropriate for use.
 - d. The suitable infrastructure and environment for the operation of processes;
- NOTE: Suitable infrastructure can include product specific tools and software programs.
- e. The appointment of competent persons, including any required qualification;
 - f. The validation, periodic revalidation, of the ability to achieve planned results of the process for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; (Special Processes)
 - g. The implementation of actions to prevent human error;
 - h. The implementation of release, delivery and post-delivery activities;
 - i. The establishment of criteria for workmanship;
 - j. The accountability for all products during production;
 - k. The control and monitoring of identified critical items, including key characteristics, in accordance with the established processes;
 - l. The determination of methods to measure variable data;
 - m. The identification of in-process inspection/verification points when adequate verification of conformity cannot be performed at later stages;
 - n. The availability of evidence that all production and inspection/verification operations have been completed as planned or as otherwise documented and authorized;
 - o. The provision for the prevention, detection and removal of foreign objects;
 - p. The control and monitoring of utilities and supplies to the extent they affect conformity to product requirements.
 - q. The identification and recording of products released for subsequent production use pending completion of all required measuring and monitoring activities, to allow recall and replacement if it is later found that the product does not meet requirements.
- A. Control of Equipment, Tools, and Software Programs

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	22 of 29	V

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

Storage requirements shall be defined for production equipment or tooling storage including any necessary periodic preservation or condition checks.

FCI Machine Shop software is not controlled. FCI Aerospace does not use the machine shop automation without full verification of characteristics.

B. Validation and Control of Special Processes

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

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

C. Production process Verification

FCI has implemented production process verification activities to ensure the production process is able to produce products that meet requirements.

NOTE: These activities can include risk assessments, capacity studies, capability studies and control plans.

FCI uses a representative item from the first production run of a new part or assembly to verify that the production process, production documentation, and tooling can produce parts and assemblies that meet requirements. This activity shall be repeated when changes occur that invalidate the original results. (FAI)

FCI retains documented information on the results of production process verification.

8.5.2. Identification & Traceability


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

FCI maintains the identification of the products and services to identify any differences between the actual configuration and the required configuration.

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

When acceptance authority media are used, FCI shall establish controls for the media.

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

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	23 of 29	V

NOTE: Traceability requirements include:

- I. the identification to be maintained throughout the product life;
- II. the ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination;
- III. for an assembly, the ability to trace its components to the assembly and then to the next higher assembly;
- IV. for a product, a sequential record of its production to be retrievable.

8.5.3.Product belonging to Customers or External Providers

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

FCI identifies, verifies, protects and safeguards customers' or external providers' property provided for use or incorporation into the products and services.

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

NOTE: A customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property, and personal data.

8.5.4.Preservation

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

NOTE: Preservation can include identification, handling, contamination control, packaging, storage, transmission or transportation, and protection.

Preservation of Outputs include, when applicable in accordance with specifications and applicable statutory and regulatory requirements, provisions for:


- a) Cleaning;
- b) Prevention, detection, and removal of foreign objects;
- c) Special handling and storage for sensitive products;
- d) Marking and labeling, including safety warnings and cautions;
- e) Shelf life control and stock rotation;
- f) Special handling and storage for hazardous materials.

8.5.5.Post-Delivery Activities

FCI meet requirements for post-delivery activities associated with the products and services.

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

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

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	24 of 29	V

- d) Customer requirements;
- e) Customer feedback;
- f) Collection and analysis of in-service data (e.g. performance, reliability, lessons learned);
- g) Control, updating, and provision of technical documentation relating to product use, maintenance, repair, and overhaul;
- h) Controls required for work undertaken external to FCI;
- i) Product/customer support (e.g. queries, training, warranties, maintenance, replacement parts, resources, obsolescence).

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

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

8.5.6.Control of Changes

FCI reviews and controls change for production or service provision to the extent necessary to ensure continuing conformity with requirements.

Persons authorized to approve production or service provision changes are identified.

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

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

8.6. Release of Products and Services

FCI implements planned arrangements, at appropriate stages, to verify that the product and service requirements are met.

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

FCI retains documented information on the release of products and services. The documented information shall include:

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

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

FCI ensures that all documented information required to accompany the products and services are present at delivery.

8.7. Control of Nonconforming Outputs

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	25 of 29	V

8.7.1.FCI ensures that the outputs that do not conform to their requirements are identified and controlled to prevent their unintended use of delivery.

NOTE: The term “nonconforming outputs” includes nonconforming product or service generated internally, received from an external provider, or identified by the customer.

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

FCI’s “nonconformity outputs” controlled process is maintained as documented information including provisions for:

- I. Defining the responsibility and authority for the review and disposition of nonconforming outputs an the process for approving persons making these decisions;
- II. Taking actions necessary to contain the effect of the nonconformity on other processes, products and services;
- III. Timely reporting of nonconformities affecting delivered products and services to the customer and to relevant interested parties;
- IV. Define corrective actions for nonconforming products and services detected after delivery, as appropriate to their impacts.

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

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

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

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


- I. After approval by an authorized representative of FCI responsible for design or by persons having delegated authority from the design organization;
- II. After authorization by the customer, if the nonconformity results in a departure from the contracted requirements.

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

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

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

8.7.2.FCI retains documented information that:

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	26 of 29	V

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

9. PERFORMANCE EVALUATION

9.1. Monitoring, measurement, Analysis, and Evaluation

9.1.1.General

FCI determines:

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

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

FCI retains appropriate documented information as evidence of the results.

9.1.2.Customer Satisfaction

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

Information to be monitored and used for the evaluation of customer satisfaction include, but not limited to, product and service conformity, on-time delivery performance, customer complaints, corrective action requests. FCI develops and implements plans for customer satisfaction improvement that address deficiencies identified by these evaluations, and assess the effectiveness of the results.


9.1.3.Analysis and Evaluation

FCI analyze and evaluate appropriate data and information arising from monitoring and measurement.

NOTE: Appropriate data can include information on product and service problems reported by external sources.

The results of analysis shall be used to evaluate:

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

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	27 of 29	V

- f) The performance of external providers;
- g) The need for improvements to the quality management system.

NOTE: methods to analyze data can include statistical techniques.

9.2. Internal Audit

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

- A. Conforms to
 - 1) FCI's own requirements for its quality management system;
 - 2) The requirements of AS9100;
- B. Is effectively implemented and maintained.
 - 1) NOTE: When conducting internal audits, performance indicators can be evaluated to determine whether the quality management system is effectively implemented and maintained.

9.2.2.FCI shall

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

9.3. Management Review

9.3.1.General

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

9.3.2.Management Review Inputs

The management review shall be planned and carried out taking into consideration:

- A. The status of the actions from previous management reviews
- B. Changes in external and internal issues that are relevant to the quality management system;

 <i>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</i>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	28 of 29	V

C. Information on the performance and effectiveness of the quality management system, including trends in:

- 1) Customer satisfaction and feedback from relevant interested parties;
- 2) The extent to which quality objectives have been met;
- 3) Process performance and conformity of products and services
- 4) Nonconformities and corrective actions;
- 5) Monitoring and measurement results;
- 6) Audit results;
- 7) The performance of external providers;
- 8) On-time delivery performance;

D. The adequacy of resources;

E. The effectiveness of actions taken to address risks and opportunities;

F. Opportunities for improvement.

9.3.3. Management Review Outputs

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

- A. Opportunities for improvement;
- B. Any need for changes to the quality management system;
- C. Resource needs;
- D. Risks identified.

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

10. IMPROVEMENT

10.1. General

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

These include:

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

NOTE: Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2. Nonconformity and Corrective Action

10.2.1. When a nonconformity occurs, including any arising from complaints, FCI shall:

- A. React to the nonconformity and, as applicable:

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, CA 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	2	29 of 29	V

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

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

FCI maintains documented information that defines the nonconformity and corrective action management process.

10.2.2. FCI retains documented information as evidence of:

- A. The nature of the nonconformities and any subsequent actions taken;
- B. The results of any corrective action.

10.3. Continual Improvement

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

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

FCI monitors the implementation of improvement activities and evaluates the effectiveness the effectiveness of the results.

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

FCI FLUID COMPONENTS INTERNATIONAL LLC A PST BRAND <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT Quality Manual	CAGE CODE 64818	DATE 1/10/2025	SECTION 3	PAGE 1 of 17	REVISION V



A PST BRAND

NUCLEAR CONTROLLED - SECTION 3

	DESCRIPTION	PAGE
1	Organization	2
2	Quality Assurance Program	2
3	Design Control	4
4	Procurement Document Control	5
5	Instructions, Procedures, and Drawings	5
6	Document Control	7
7	Control of Purchased Material, Equipment and Services	8
8	Identification and Control of Material, Parts, and Components	11
9	Control of Special Processes	11
10	Inspection	12
11	Test Control	13
12	Control of Measuring and Test Equipment	13
13	Handling, Storage, and Shipping	14
14	Inspection, Test, and Operating Status	14
15	Non-Conforming Materials, Parts, or Components	15
16	Corrective Action	15
17	Quality Assurance Records	16
18	Audits	17

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	2 of 17	V

1 ORGANIZATION

1.1 Scope

This section, Section Three, of the Manual sets forth the Quality Assurance Program and the methods used to achieve implementation and documentation of the "Controlled" program. This program complies with the Requirements of ISO 9001; the Quality System requirements of 10CFR50 Appendix B; and the basic Quality System Requirements of ANSI NQA-1.

This Manual, in its entirety, unless identified otherwise, shall be issued as a controlled document to Fluid Components International LLC's customers having contractual obligation to this section of the manual.

Appendix A to this manual list job descriptions to show the activities that affect quality and how they interface with the Quality Assurance Program. For their relationship to the Organization, see 05QA000220, FCI Organization Chart.

Section 3 is limited to the following location and the services it provides:

1755 La Costa Meadows Drive, San Marcos, California 92078

And 1645 Rancho Santa Fe Road, San Marcos, California 92078 (when using controlled materials)

2 QUALITY ASSURANCE PROGRAM

2.1 Referenced Documents

Fluid Components International LLC's Quality Manual 07QA070003 is supplemented by numerous implementing procedures listed in Appendix B and referenced throughout this section of the Manual. Procedures other than those referenced in this section may also be used to implement the Quality Assurance Program. When determined necessary, any of the procedures listed may be deleted from the program; however, the Quality Assurance Manager shall ensure that if a procedure is deleted the requirements stated in this manual are not compromised.

2.1.1 Engineering Procedures

01DM000064

Engineering Document Management, General Operating Procedure

2.2 Review and Approval by Management

A review of this manual shall be performed every calendar year at the direction of the Quality Assurance Manager. The purpose of this review is to determine the adequacy of the Quality Assurance Program in meeting Quality System Requirements outlined in the "Scope" in this section of this Manual. The review shall also consider other codes or regulations as they apply to Fluid Components International LLC. The Internal Audit Team shall typically accomplish this review during the annual internal audit. Additional reviews may be performed when determined necessary by the Quality Assurance Manager. Reviews of the Quality Manual shall be documented. Changes found during the review that are necessary to improve the clarity or effectiveness of the Quality Assurance Program shall be incorporated.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	3 of 17	V

The President hereinafter shall approve changes or revisions to the manual.

2.3 Quality Assurance Program Implementation

Organizations participating in the Quality Assurance Program shall be reviewed on an annual basis. This review shall substantiate the effectiveness of implementation of the portion of the program for which each organization has responsibility. This review shall be accomplished during the internal audit of the Quality Assurance Program.

2.4 Quality Plans

In some instances there are customers with unique contractual quality requirements that are not specifically addressed in this manual or the supporting Quality Assurance Procedures. Some of these requirements may even come in conflict with stated policies in this Manual. To ensure unique contractual requirements relating to quality are incorporated, Quality Plans may be used to document and accomplish these requirements.

Quality Plans will state when and for whom they are applicable. They will also state that Quality Manual 07QA070003 will be used as a basis for the quality system. All additional or conflicting requirements will be addressed. Quality Plans shall take precedence over the Quality Manual. Quality Plans shall be generated by the Quality Assurance Manager and submitted to the customer for approval prior to implementation as required by contract.

2.5 Indoctrination and Training

To the degree necessary, as determined by the Quality Assurance Manager, personnel performing quality functions and activities affecting quality shall be properly trained and indoctrinated in their respective areas of responsibility. Learning tools, such as on-the-job training, seminars, classes, testing, and the like, shall be used to accomplish these tasks. The documentation of indoctrination and training of Quality personnel and other personnel performing activities affecting quality shall be in accordance with Quality Assurance Procedure 04QA704034.

2.6 Qualification of Personnel Performing Verification and Auditing Activities

Personnel performing verification and auditing activities shall have the experience and training commensurate with the activity being performed. The capabilities of personnel performing these activities shall be determined initially by a review of their education, experience, training, and test results or capability demonstration. Performance shall be re-evaluated periodically to assure continued satisfactory performance. Qualification requirements are more thoroughly described in Quality Assurance Procedure 04QA704034 for verification personnel and 04QA704054 for Auditing personnel.

NOTE: Fluid Components International LLC does not employ Nondestructive Examination personnel; this is considered a "Special Process" and is covered in paragraph 10 of this Manual, Section 3.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	4 of 17	V

3 DESIGN CONTROL

3.1 Contract Review

Upon receipt of all new Customer Contracts, the customer's Purchase Order and accompanying documents (i.e., specifications and drawings) shall be assigned to a Contract Manager. The Contract Manager, Quality Assurance Manager and when necessary an assigned Engineer; shall perform a Contract Review. At the option of the Contract Manager, other personnel from disciplines such as Qualification Engineering, Design Engineering, Production, and Purchasing may participate in this review. This review identifies design, regulatory and specification requirements, suitable materials and processes, and applicable codes and standards that shall be incorporated into drawings, procedures, and instructions. This review will also include a risk assessment and output for the customer outlining potential for delays, test failures and mitigation activities put into the project to prevent or avoid and may include commercial considerations for the customer to consider. Refer to Risk Mitigation and Management policy 07CP000015 or 04QA704103 Risk Management. The review shall also include assignments for contract related design tasks. The review and assignments shall be documented on Contract Review forms described in Quality Assurance Procedure 04QA704005.

3.2 Design Document Review

Documents created to support a customer contract such as Outline Drawings, Acceptance Test Procedures, etc. shall be reviewed by Engineering, and Quality Assurance at a minimum to assure contractual requirements have been incorporated. Additional parties may participate in the review of these documents when specifically requested by the Contract Manager.

3.3 New Designs

New product requiring qualification to specific requirements shall have a Qualification Test Procedure developed to accomplish the testing. When required, this document shall be submitted to the customer for approval.

The results of completed qualification testing shall be documented in the Qualification Test Report.

3.4 Qualification Design Verification

Design applications based on previously qualified designs and requiring traceability to an existing qualification test report shall be reviewed against the original design to ascertain any possible design changes or deviations made necessary by the customer's application and/or qualification envelope. Written documentation of the verification shall be required for all domestic Nuclear customers, and if imposed by contract for international customers alike.

Qualified personnel not responsible for initiating the original design for all nuclear applications shall perform this design verification and analysis.

This verification shall incorporate as appropriate, suitable testing programs, alternate or simplified calculations, design reviews, similarity analysis, or other approved methods. The

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	5 of 17	V

verification shall be documented in accordance with Quality Assurance Procedure 06QA020013, Qualification Verification Analysis”.

3.5 Design Changes

Changes to or deviations from existing engineering design documents (i.e., revisions, temporary “Deviations” and “Use As Is” or “Repair” dispositions of nonconforming items) shall be properly documented and controlled. Design changes or deviations to engineering documents shall be reviewed, approved, and recorded in accordance with Engineering Procedure 01DM000064 and the nonconforming material procedure 04QA704004.

Any of the above-described design changes that affect the customer’s specifications or the Company’s documents approved by the Customer, shall require customer participation in the formal approval cycle. Customer approval shall be documented.

4 PROCUREMENT DOCUMENT CONTROL

4.1 Fluid Components International LLC Purchase Order Review

Quality shall ensure that controlled item Purchase Orders incorporate the applicable quality requirements. When applicable, the Purchase Order shall require vendors to impose the Company’s Customer Quality Assurance and contractual requirements on sub-tiers. The Purchase Orders shall identify and be reviewed for inclusion of applicable information such as Drawings and Drawing Revisions. As appropriate, provisions for compliance to contract and federal regulations shall be included. When appropriate, provisions shall be included for access to the vendor’s plant to perform audits, surveys, or source inspection. After review and approval, an authorized Quality Assurance Representative shall sign each Purchase Order. The signing of the Purchase Order by Quality Assurance acts as the official issuance of the contract.

4.2 Purchase Order Procedure

For detailed instructions on completing, reviewing, correcting, or changing Controlled Purchase Orders and related documents, see Quality Assurance Procedure 04QA704003.

5 INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the circumstances. The documents described in this section of the Manual shall provide the means by which these activities are accomplished. The purpose for these documents is to supply Inspectors, Production and Test personnel, and vendors with adequate information to satisfactorily perform their respective activities and functions affecting quality.

5.1 Customer Orders and Order Acknowledgements

All contracts subject to the requirements of this manual shall be processed in accordance with Quality Assurance Procedure 04QA704002.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	6 of 17	V

For reorders or long term-scheduled purchases, parts may be built for “Stock” and placed in finished goods inventories. Finished goods may be pulled directly from stock and shipped using only the Order Acknowledgements, no cross- referenced Job Orders are required, see Paragraph 5.2 for further details.

5.2 Job Orders

Job Orders subject to the requirements of this Manual shall be described and processed in accordance with Quality Assurance Procedure 04QA704020. In addition to basic information, Job Orders can list Bills of Materials, Special Requirements, and Procedures required for completing the item being built or created. The Job Order may also act as a substitute for the Parts List as part of the Lot Number Data Package when the Engineering Parts List is on the face of the drawing and not a separate page.

5.3 Manufacturing Procedures

Manufacturing Procedures are identified on the Operation Sheet. A Manufacturing Procedure outlines an individual, specific process contained within a workstation and designates specific tools and instructions necessary to accomplish a particular process. Manufacturing procedures are controlled in accordance with Document Management's Procedure 01DM000064.

5.4 Final Acceptance Test Procedures

Final Acceptance Test Procedures (FATP) is typically model specific documents (although a few generic procedures exist). These documents delineate all necessary functional and performance testing instructions, both electrical and mechanical. FATP's also include inspections necessary for final acceptance by the customer, the government, and or the Company. The purpose of these procedures is to assure that each instrument is within the scope of the intended application and FCI established acceptance criteria. To carry out this objective, the procedure contains sequential instructions, acceptance criteria, and requirements for recording the test equipment used and objective evidence of the results of the tests and inspections. Under certain contracts, in the event the customer imposes additional testing beyond FCI's proposed FATP testing, such testing will be identified in a customer's inspection plan and shall be reviewed and agreed to in advance of customer source or site inspections. Should additional testing be requested at the time of the visit, FCI will prepare an additional FATP and reference any additional testing as customer or contract specific and such testing may incur additional commercial review.

5.5 Quality Assurance Procedures

Quality Assurance Procedures outline detailed functions or activities directly related to or affecting quality. This may include, but not be limited to, functions such as Purchasing, Inspections, Calibration of Measuring & Test Equipment, Internal Audits, Discrepancy Reports, and Quality Assurance Contract Review. The Quality Assurance Procedures assure that all applicable criteria, specifications, and requirements are met each time an activity is performed, and assure proper record keeping of the activity or function.

 <small>A PST BRAND</small> <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	7 of 17	V

5.6 Departmental Procedures

Various departments may generate other procedures to provide consistency in tasks performed. These procedures shall be controlled in accordance with Paragraph 6, Document Control, of this section of the manual when they are determined by the Quality Assurance Manager to be related to quality activities.

5.7 Drawings

Drawings shall be created to ensure that parts, equipment, and services are manufactured, assembled, and/or performed identically each time an item is processed. Each drawing shall have an identifying number assigned which shall also be the Part Number for the item depicted. As appropriate, customer requirements, quantitative criteria such as dimensions, tolerances, angles, and surface finishes, fabrication instructions, installation instructions, material requirements, and the like may be delineated in drawings. Drawings are controlled in accordance with Document Management's Procedure 01DM000064. Drawings submitted under contract to the customer for approval shall have formal written indication of approval before proceeding with procurement or manufacturing unless customer has waived such pre-approval and that waiver is documented specifically in writing with risk or reward and responsible party identified.

5.8 Operation Sheets

All assembly drawings shall have an Operation Sheet (Op Sheet) detailing the step-by-step processes used to manufacture, assemble, fabricate, and test the item depicted on the drawing. Op sheets shall carry the same number and revision letter as the drawing for which they are written. Assembly Kits and assemblies fabricated solely by outside vendors do not require an accompanying Op Sheet. Operation Sheets are controlled in accordance with Document Management's Procedure 01DM000064.

6 DOCUMENT CONTROL

6.1 Identification

Documents such as Drawings, Operation Sheets, Quality Assurance Procedures, Forms, Test Procedures, Test Reports, Purchase Orders, and other quality related documents shall be controlled to assure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved by authorized personnel only.

6.2 Methods and Distribution

Documents released for production shall be stamped or marked as controlled copies. Approvals, responsibility, and distributions, and controls shall be in accordance with Quality Assurance Procedure 04QA704007, for Quality Assurance Procedures and Manuals and in accordance with procedure number 01DM000064 for Engineering Documents. These procedures assure that only current revisions are used, unless a specific revision is required, and that obsolete documents are removed from the shop floor.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	8 of 17	V

6.3 Change Control

Changes to documents affecting quality shall be recorded and approved using the following methods to ensure changes have been approved by all applicable organizations.

6.3.1 Engineering Change Notice

Changes to Drawings, Operation Sheets, and Process Sheets, shall be recorded on an Engineering Change Notice (ECN). For more information please refer to Engineering Procedure 01DM000064.

6.3.2 Revision Page

A Revision Page can be used in lieu of an ECN for book type documents such as Qualification Reports, Test Reports or Instruction Manuals. The revision page shall identify the changed pages contain a brief description of the change.

6.3.3 Cover Sheet

Documents such as Departmental Procedures that have a cover page containing new approval signatures at each revision may be revised without use of an ECN or Revision Page. Copies of each preceding revision shall be kept as change history for that document.

6.3.4 Use of Initials

Other controlled documents such as FCI Purchase Orders, Order Acknowledgement documents, and Job Orders shall have changes initialed as approved by those departments or personnel generating and approving the original document.

7 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

7.1 Vendor Control

Quality shall perform Vendor Surveys, Audits and Receiving Inspection activities as appropriate to assure that purchased items and services conform to procurement documents and that the items are of required quality. Additionally, requests for certifications of tests, inspections, or contract compliance may be made.

7.1.1 Quality Approved Vendors (QAV)

Quality Approved Vendors document 08QA080004 shall be maintained as a controlled document for calibration services, test laboratories, special process and 10CFR50 Appendix B items.

All QAV providing nuclear services shall receive an Evaluation of the Critical Safety Characteristics of their service (04QA704044). All QAV providing 10CFR21 part B items shall get an audit (04QA704008).

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	9 of 17	V

All services not verified by FCI shall be procured for nuclear product using vendors that have been dedicated post survey or audit.

(ASME NPT Certificate of Authorization may be accepted in lieu of a vendor survey for Nuclear Grade items for "non-domestic" orders.)

Suppliers of items or services having independent nuclear qualification are not required to be on the QAV when the purchase of these items has been at the direction of the customer for use on the customer's contract.

Vendors that are certified to ISO 17025 are being tracked and reviewed per the QAV listing. Evaluation of the QAV is performed monthly to ensure accreditations are continued. The accreditation shall cover the scope of the contracted services and will be stated in the contract.

For calibration services, the Purchase Order shall require that the supplier provide a report with the as-found data of items found out-of-tolerance; and, referencing the calibration procedure and equipment/standards used. The report shall include the vendor's name, the calibration date, and a statement that the calibration is traceable to NIST. The Purchase Order Number shall appear on the Certificate of Calibration. (From NUPIC audit)

The vendors on QAV 08080004 are reflected on the Approved Vendor List (AVL) 08QA080002, including the vendor's approval status.

ILAC Process NEI 14-05A Revision 1, ML20322A019 (04QA704077)

FCI may be allowed to waive the survey of a Test or Calibration facility. During the periodic update of the QAV a review of the laboratory's accreditation is performed and includes a verification of the following:

- The test or calibration laboratory holds accreditation be an accrediting body recognized by the ILAC MRA per ISO/IEC 17025:2017, "General Requirements for the Competence of Testing and Calibration Laboratories"
- Testing Services – The published scope of accreditation for the test laboratory covers the needed testing services including test methodology and tolerances/uncertainty. (This process is not allowed for Non-Destructive Examination.)
- Calibration Services – The published scope of accreditation for the laboratory covers the needed measurement parameters, ranges and uncertainties.
- The laboratory has achieved accreditation based on an onsite accreditation assessment by the selected accreditation body within the past 48 months. (The laboratory's accreditation cannot be based on two consecutive remote accreditation assessments.)

7.1.2 Vendor Performance Record & Approved Vendor List (AVL)

Vendor performance is evaluated per 04QA704077. A Vendor Performance Record (VPR) shall be maintained. The record shall be used to document the receipts of goods or services of vendors contained on the AVL (08QA080002). A review of these records shall be conducted periodically and a determination made to either keep or delete each vendor from the Approved Vendors List. A review may be conducted on any particular vendor at any time deemed necessary by the Quality Assurance Manager. Reviews shall be conducted in accordance with Quality Assurance Procedure 04QA704044.

 FLUID COMPONENTS INTERNATIONAL LLC <small>A PST BRAND</small> <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	10 of 17	V

7.2 Purchasing Method

Purchased items with special requirements such as Shelf Life, Special Processing, or Material Certifications where traceability to those requirements is essential shall be purchased as "Controlled." See Paragraph 4, "Procurement Document Control", of this section of the manual.

Standard items that can be verified by inspection to engineering documents may be transferred to Controlled items. When those commercially purchased items are to be used for Controlled production they shall be re-evaluated to controlled stock by being submitted to inspection and re-inspected in accordance with Quality Assurance Procedures 04QA704001 or 04QA704026.

Non-Conforming items shall be handled in accordance with paragraph 15, "Non-Conforming Items", of this section of the manual.

7.3 Certificates

A Certified Material Test Report (CMTR) shall accompany parts used for pressure boundary/wetted surfaces or surfaces exposed to the process media. The Receiving Inspection checklist, 05QA000104, shall be used as a guideline to assure that all required information is listed on the CMTR. When material to be used on wetted surfaces, etc. can only be purchased with "typical" test reports or a certificate of conformance, an independent chemical analysis shall be performed to verify compliance to the stated specification. Quality Assurance Procedure 04QA704032 gives more detail on the process used for Testing Wetted Surface/or Pressure Boundary Materials.

When a Purchase Order requests a Certificate of Conformance/Compliance, the certificate shall be reviewed to assure that all information required by the Purchase Order and applicable Engineering Drawing has been met. The Receiving Inspection checklist, 05QA000104, shall be used as a guideline to assure that all required information is listed on the Certificate.

7.4 Age Sensitive Materials

All age sensitive materials are listed in the Quality System Database; Date Coded Material, are required to be purchased with the date of manufacture and/or an expiration date. If codes are used for either date, an interpretation of the code must be provided. Rotation practices, date code extensions, and internal shelf life policies are documented in Quality Assurance Procedure 04QA704053.

7.5 Commercial Grade Item (CGI) Dedication

Special consideration must be addressed for Commercial Grade Items intended for use in Safety-Related, Class 1E product. These include how the product will be used, critical characteristics for the environment and application, and qualification maintenance. These issues are addressed in Quality Assurance Procedure 06QA020014 and supported by numerous documents classified by FCI as "Technical Evaluations".

Testing methods of Commercial Grade Items are defined in Quality Assurance Procedure 04QA704071.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	11 of 17	V

7.6 Government or Purchaser Supplied Items

Government or purchaser supplied items are discussed in Quality Assurance Procedure 04QA704055.

8 IDENTIFICATION AND CONTROL OF ITEMS

8.1 Lot Number Control

Lot Numbers shall be used as traceability and identification methods. These Lot Numbers establish the means whereby the traceability to processes performed, material certifications, and receipt inspection is assured. All "Controlled" items shall be identified by a Lot Number as described in Quality Assurance Procedures 04QA704001, 04QA704026, and 04QA704038 for Receiving, In Process, and Final Inspections. Labels, Tags, and Decals are exempt from this requirement. When items require additional processing, the initial Lot Number(s) for each item will be identified on a Parts List of the item being processed. The Lot Number shall be marked on the item by tagging, , vibro peening, scribing, electro-chem-etching, or by marking with permanent ink. When the marking of each piece is not practical or is impossible, other methods such as bagging and tagging shall be used. Care should be used in choosing a marking method so as not to compromise the integrity of item(s) being marked. All records associated with an inspection shall be identified with the inspection Lot Number.

8.2 Serialization

Items submitted to Final Inspection, including complete instruments and all calibrated subassemblies intended as spare parts shall be identified by a unique Serial Number. This Serial Number provides a link between units in the field and production history documentation at the factory. It also provides a means of identifying specific calibration and Final Acceptance Test records for each unit shipped.

Serial Numbers are issued by the FCI Business System.

9 CONTROL OF SPECIAL PROCESSES

9.1 Types of Processes

Special processes include Welding, Coating, Soldering, Non-Destructive Examination (NDE), Painting, Plating, Passivation, and Brazing. When special processes are brought in-house, a review shall be conducted to determine applicable specification compliance as well as training and certification requirements.

Welding and Soldering are performed in-house. Measuring & Test Equipment used to control or verify quality of special processes shall be in accordance with Paragraph 12, "Control of Measuring & Test Equipment", of this section of the manual.

Weld filler metal used for special processes shall be controlled to assure only accepted and correct items are used, and to assure that the filler metal is kept clean and free of contamination. Incoming Weld Fillers shall be processed through Receiving Inspection in accordance with Quality Assurance Procedure 04QA704021, Weld Filler Metal Control", and

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	12 of 17	V

certified as directed in Paragraph 7, "Control of Purchased Material, Equipment, and Services", of this section of the manual.

Special processes performed by outside vendors (NDE, Painting, Plating, Passivation, and Brazing) are performed in accordance with applicable specifications documented on the Purchase Order or applicable drawings. Special Processes shall be processed on Controlled Purchased Orders in accordance with Quality Assurance Procedure 04QA704003. Items sent out for special processing shall pass through Receiving Inspection where the item and the processing certification shall be reviewed for conformance to the required specifications. The Receiving Inspection Checklist, 05QA000104, shall be used as a guideline to assure that all required information is contained on the Certification.

9.2 Personnel Qualifications

Vendors performing NDE shall have personnel qualified to SNT-TC-1A perform the work.

Welders and Welding Procedures shall be qualified and their records shall be maintained in accordance with Quality Assurance Procedure 04QA704039.

Soldering personnel shall be certified to FCI Workmanship Standards Manual, 04QA704057 or J Standard, as a minimum requirement. Personnel shall be trained and certified to other contractually specified requirements as necessary.

10 INSPECTION

10.1 Areas of Inspection

FCI's inspection activities are divided into three categories: Receiving, In-Process, and Final Inspection. Receiving Inspection shall be performed in accordance with Quality Assurance Procedure 04QA704001, Quality Assurance Procedure 04QA704026 shall be used for In-Process Inspection, and Quality Assurance Procedure 04QA704038 for Final Inspection. These procedures contain inspection methods, and acceptance and rejection criteria necessary to verify and document conformance to Quality, Engineering, and Customer requirements.

10.2 Inspection Plan

Receiving Inspections shall be performed by using sampling plans in accordance with Quality Assurance Procedure 04QA704001. Depending on the complexity of the items being inspected, In-Process Inspections are performed per a sampling plan or performed 100%. Final Inspections shall be performed 100%.

10.3 Inspection Personnel

Properly trained Inspectors shall perform inspections. Training and qualification records for Inspection personnel shall be kept on file per Quality Assurance Procedure 04QA704034.

Personnel other than those who performed the activity being inspected shall perform inspection activities.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	13 of 17	V

10.4 Inspection Hold Points

Mandatory hold or witness points required by the customer shall be listed on the Order Acknowledgement document and Job Order as noted in Paragraph 5 "Instructions, Procedures, and Drawings", of this section of the manual. Work shall not proceed past individual hold points unless authorized and initialed by the assigned Contract Manager or waived in writing by the customer.

11 TEST CONTROL

Tests performed on items during fabrication, final assembly and inspection are controlled through documents such as Operation Sheets, Process Sheets, Test Procedures, and Final Acceptance Test Procedures. These documents describe the test equipment to be used, environmental constraints, and instructions for properly conducting the tests. These documents may also include instructions for documenting test results, and the calibration control numbers of the actual test equipment used to perform the test. They may also include acceptance and or rejection criteria. When acceptance or rejection criteria are not identified specifically in the test document, this information shall be obtained from the Job Order or project Order Acknowledgement package. A more complete description of these documents can be found in Paragraph 5, "Instructions, Procedures and Drawings" of this section of the manual. The above listed documents shall be reviewed and approved by the Quality Assurance Department before implementation, as required by Paragraph 6, "Document Control" of this section of the manual.

12 CONTROL OF MEASURING AND TEST EQUIPMENT

12.1 Calibration Traceability

Measuring and Test Equipment used to determine product acceptance shall be controlled and calibrated in accordance with Quality Assurance Procedure 04QA704006. Calibrations performed in-house or by outside vendors shall be traceable to the National Institute of Standards and Technology (NIST) or other recognized standard. All equipment entered into the calibration program shall be assigned a unique Calibration Control Number (CCN).

12.2 Personnel Qualification

Calibrations of Measuring & Test Equipment shall be performed at the Company by qualified personnel. Records of the qualifications of calibration personnel shall be kept on file by the Quality Assurance Department in accordance with Quality Assurance Procedure 04QA704034.

12.3 Equipment Calibration Status

Measuring & Test Equipment shall have the current calibration status marked on the instrument. Where the marking of the instrument is impractical, a container shall be provided and marked with the instrument's calibration status. Whenever the instrument is not in use, it shall be stored in a marked container.

"Out of Service" and "Out of Calibration" Measuring & Test Equipment shall be so marked or segregated from regularly available equipment. Items found to be past due for calibration or

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	14 of 17	V

damaged during service shall be immediately removed from service, identified as to its condition, and returned to the Metrology Department.

Measuring & Test Equipment used to perform Final Acceptance Tests and Final Inspections found out of tolerance shall cause the test and inspection results to be reevaluated to determine if retest is necessary. If any other Measuring & Test Equipment was calibrated by the out of tolerance Measuring & Test Equipment, it shall also be reevaluated to determine if re-calibration is necessary. For more details, please refer to Quality Assurance Procedure 04QA704029.

13 HANDLING, STORAGE, AND SHIPPING

13.1 In-Process Handling and Storage

Items shall be handled and stored using good commercial practices to protect them from contamination, damage, or loss of identification and traceability.

13.2 Final Cleaning

Unless otherwise specified by contract, items to be supplied to the customer shall be cleaned prior to packaging in accordance with Quality Assurance Procedure 04QA704019.

13.3 Packaging

Unless otherwise specified by contract, Quality Assurance Procedure 04QA704018 shall be used.

Special packaging and shipping requirements or requirements in addition to those listed above shall be identified on the Order Acknowledgement package specific to the contract.

13.3.1 Special Packaging

When ANSI N45.2.2 compliance is required by contract, Quality Assurance Procedure 04QA704010 shall be used as a guideline.

13.3.1.a Inspection

Prior to shipment, Inspection personnel shall review the packaged equipment to assure that all quality and contractual requirements have been met. The Inspector shall stamp the appropriate area on the Inspection Checklist to signify acceptance of the packaging and preparation for shipment.

14 INSPECTION, TEST, AND OPERATING STATUS

14.1 Test Status Identification

Inspection, test, and operating status are identified through the use of stampings and data recorded on Job Orders, Test Reports, Inspection Records, and the like.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	15 of 17	V

14.2 Non-Conforming Items

Non-conforming items are immediately removed from regular production, as described in Paragraph 15, "Non-Conforming Items" of this section of the manual.

14.3 Stamp Control

Weld, Production, Test, and Inspection personnel are provided unique stamps that are used to identify records where they have entered information, test data, inspection data or where they have performed a specific assembly activity. The types of stamps and how they are controlled is explained in Quality Assurance Procedure 04QA704024.

15 NON-CONFORMING ITEMS

Items removed from regular production flow due to a nonconformance or discrepancy shall have the problem recorded on a Material Review Report (MRR) as described below and in Quality Assurance Procedure 04QA704004. Items will be removed, marked and isolated from the manufacturing area until MRB is performed. Items disposition scrap will be properly destroyed to ensure it is not returned to production.

15.1 MRR Review

The initial review of the nonconforming item shall be made by the Material Review Board (MRB) Preliminary to determine what action is to be taken or if further review is necessary. Additional review may be accomplished through submittal of the MRR to the Qualification Engineer.

Discrepant items shall be dispositioned per Quality Assurance Procedure 04QA704004.

Technical justification for the acceptability of items dispositioned "Repair" or "Use As Is" shall be documented.

15.2 Customer Notification

Non-Conformances dispositioned "Repair" or "Use As Is" which result in a deviation from the customer's specification or from customer approved documents shall be submitted by the Contract Manager to the customer for review and approval prior to implementation of the corrective action.

15.3 10 CFR 21 Compliant

When imposed by contract, non-conformances determined to be subject to 10 CFR 21 shall be processed in accordance with Quality Assurance Procedure 04QA704011. A copy of 10CFR21, Section 206 of the Energy Reorganization Act of 1974 and Quality Assurance Procedure 04QA704011 shall be posted in a conspicuous location on the premises.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	16 of 17	V

16 CORRECTIVE ACTION

16.1 Adverse Conditions

When conditions adverse to quality are discovered (i.e., failures, deficiencies, deviations, defective material or equipment), steps shall be taken to correct the condition. Correction may be accomplished through, but is not limited to, MRR (Material Review Board action), Management Reviews, Internal Audit Reports, and the Corrective and Preventive Action procedure.

16.2 Significant Conditions

Significant conditions adverse to quality as determined by the Quality Assurance Manager shall be addressed in a memo to the President, a CPAR per 04QA704083 or if discovered during an internal audit, on an Audit Finding Report, with the following information included:

- A description and/or cause of the condition.
- Recommended corrective action to be taken to eliminate the condition and preclude repetition.
- Proposed follow-up action to verify implementation of the corrective action.
- Any such corrective action will be documented in the company CPAR system including audit findings.

When determined necessary by the Quality Assurance Manager, copies of the memo shall be distributed to management personnel responsible for the area affected.

16.3 Document Non-Conformances

Document Change Requests (DCR's) are used to initiate changes to drawings and other documents found necessary during Production or Inspection activities. They may be used in conjunction with a MRR as a vehicle to notify Engineering that a document change is needed as part of a discrepancy corrective action. DCR's may be generated by anyone discovering a document-related error.

16.4 Product Non-Conformances

Non-conformances related to product are best documented on MRRs as described in Paragraph 15, "Non-Conforming Items", of this section of the Manual. The Corrective Action section is used to initiate actions that will preclude the product nonconformance from recurring.

17 QUALITY ASSURANCE RECORDS

Quality records are maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.

Documented procedures describe the identification, collection, indexing, accessing, filing, storage, maintenance, and disposition of quality records.

 <small>Company Headquarters: 1755 La Costa Meadows Drive, San Marcos, California 92078-5115</small>			DOCUMENT NUMBER 07QA070003		
SUBJECT	CAGE CODE	DATE	SECTION	PAGE	REVISION
Quality Manual	64818	1/10/2025	3	17 of 17	V

Quality records are stored to minimize deterioration and damage and prevent loss; they are legible, identifiable and readily retrievable.

The Quality Assurance Department shall process and maintain Quality records per Quality Assurance Procedures 04QA704007 and the Quality System Database; Quality Records.

18 AUDITS

18.1 Internal Audits

An internal audit of the FCI Quality Assurance Program shall be performed per Quality Assurance Procedure 04QA704008. This audit shall cover all sections of the Quality Manual and applicable addendums. An Audit Plan shall be issued for each Internal Audit. The Audit Plan will describe the audit team, audit timetable, and audit assignments.

A report to Management (including the President) shall be issued at the end of the audit describing the audit results. The report shall include copies of all Audit Findings and discuss the status, adequacy, and effectiveness of the Quality System. See Quality Assurance Procedure 04QA704008 for detailed instructions.

18.2 External Audits

FCI shall perform audits of vendors providing nuclear qualified items. The scope and content of the audit shall be in accordance with Quality Assurance Procedure 04QA704008.

18.3 Vendor Surveys

The Company shall perform surveys of vendors providing calibration services and testing services. Surveys of special process vendors shall be performed when determined necessary by the Quality Assurance Manager. These surveys shall be performed to determine the vendor's capability in complying with FCI contractual requirements or determining continued compliance to contractual requirements. The scope and content of the survey shall be in accordance with Quality Assurance Procedure 04QA704044. Vendors surveyed shall also be evaluated for Critical Safety Characteristics of their service.

18.4 Auditor Qualification

The audit or survey shall be conducted by a qualified Lead Auditor and can be assisted by other qualified Auditors. Auditors shall not have direct responsibility for the activities being audited.

Auditor qualifications shall be documented and shall conform to the requirements of Quality Assurance Procedure 04QA704054.