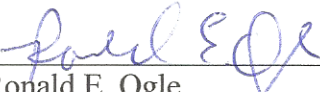


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QUALITY MANUAL

PREPARED BY:



Ronald E. Ogle
Quality Assurance Manager

APPROVED BY:

Signature on File _____
President

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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 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.

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 efficiently meet all 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

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| Table of Contents - - - - - | - | iii |
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REVISION PAGE

| PAGE | REV | DESCRIPTION | APPROVALS | | |
|--|--|---|-----------|-----|------------|
| | | | DATE | QA | CO.MGMT. |
| | H | 8003 | 6-07-84 | SM | MMQ RD |
| | J | 8003 | 5-18-87 | SM | MMQ RD |
| | K | 8003 | 1-10-91 | SM | MMQ RD |
| N/A | A | COMPLETELY REVISED from QA Manual 8003 Rev. K. Changed to new numbering system. Initial release at new number is Rev. A | 7-1-97 | SM | DMQ DMF |
| | B | Revised to incorporate process changes required as a result of installing a new business system | 2-03-98 | SM | DMQ DF |
| | C | Completely revised to incorporate AS9100 and ISO9001 requirements. Made changes to what is now "Section Three", (previous "Control Manual in its entirety). | 8-24-00 | REO | DMQ REO |
| 2 of Section 2 | D | Added the second paragraph in "1.0 Scope" | 10-9-00 | REO | DMQ REO |
| All, (four places) | | Changed "AS9100" to include "AS9000", i.e., "AS9000/AS9100". | | | |
| 28 of Section 2 | | Added "customers and" (regulatory authorities ...) to the last sentence in 4.16. | | | |
| All v | E | Renumbered pages as necessary | 7-31-02 | REO | DMQ REO |
| viii | | Added (customer and Field Services) | | | |
| ix | | Added and corrected "NQA-1" references | | | |
| x | | Updated Org Chart | | | |
| 2 | | Reformatted, deleted 04QA704027, added several procedures. | | | |
| 17 of Section 1 | | Added second paragraph to 1.0 | | | |
| 12 of Section 3 | | Added "Notification" paragraph to 4.14.3 | | | |
| 14 of Section 3 | | Changed the reference from 04QA704027 to 01DM000064 in paragraphs 5.3 & 5.4 | | | |
| 16 of Section 3 | Deleted sentence pertaining to superscript on Op-Sheet and changed reference from 04QA704027 to 01DM000064 in paragraph 5.9. | | | | |
| 17 of Section 3 | Added sentence pertaining to ASME Certificate to paragraph 7.1.1 | | | | |
| | F | Completely revised | 8-19-03 | REO | DMQ REO |
| | G | Completely revised | | | |
| PAGE | REV | DESCRIPTION | APPROVALS | | |
| | | | DATE | QA | CO.MGMT. |
| vi, x, xi, section 2 pages 2, 10, 15, 16, 20, 22, & 23 | G | Made references to 8100.7 in Appendix B and where applicable in Section 2 of the manual per FAA request. | 11-12-03 | REO | DMQ REO |

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| | | | | | |
|-----------------|---|--|----------|-----------|---|
| ii | | Updated company's name | | | |
| vi | | Added " Industrial " to Controlled projects paragraph | | | |
| ix | | Change "ATEX" to "EX" in Appendix A | | | |
| x | | Deleted QAP 04QA704025, procedure was inactivated. Corrected procedure # "07QA04044" to "04QA704044" Corrected procedure # "04QA404062" to "04QA704062" Renumbered index | | | |
| xi | | Corrected manual # "007QA070003" to "07QA070003" Deleted "20" from the 8100.7 reference column for procedure 04QA704091. (No such paragraph exists) Renumbered index Updated company's name | | | |
| xii | | Updated procedure number reference to correlate to renumbering of index on pages xi and xii Added note to explain the number references | | | |
| Sect 1;2 | H | Revised the end of the first paragraph in 1.0 – Scope from " <i>quality system as it relates to all projects not identified as Controlled</i> " to " <i>minimum quality system requirements</i> " | 09/30/05 | REO | DMQ REO |
| Sect 1;2 | | Included reference to "Ex" representative in paragraph 1.0 – Scope | | | |
| Sect 1; 18 & 19 | | Included reference to "Ex" representative and 10 year record retention requirement in 8.3 – Notification | | | |
| Sect 3;2 | | Included the "B" in "Appendix B" in paragraph 1.1 Corrected "Appendix B of the manual" to Appendix D of the manual" in paragraph 1.1 Corrected "Appendix B of the manual" to "Appendix A of the manual" in paragraph 1.1 | | | |
| Sect 3;2 | | Updated company's name in paragraphs 1.1, 2.1 and 2.2 | | | |
| Sect 3;3 | | Updated company's name in paragraph 2.2 | | | |
| Sect 3; 4 | | Updated company's name in paragraphs 2.6 and 3.1 | | | |
| Sect 3;5 | | Updated company's name in paragraph 3.5 | | | |
| Sect 3;6 | | Updated company's name in paragraph 4.1 | | | |
| Sect 3;12 | | Updated company's name in paragraph 5.1 | | | |
| Sect 3;14 | | Updated company's name in paragraph 9.1 | | | |
| Sect 3;21 | | Updated company's name in paragraph 18.3 | | | |
| Sect. 7.1. | J | revised the end of paragraphs "(a)" & (b) to add "Planning" | 9/11/06 | REO | REO |
| APX B | J | Made references in Appendix B and where applicable per UL AS9100/ISO Audit request 2006 | 9/11/06 | REO | REO |
| Sec 3 7.1.1 | J | EDITED 7.1.1 APPROVED VENDORS LIST requirements of ANSI/ISO/ISE 17025 | 9/11/06 | REO | REO |
| APXD | K | updated table of contents, added new revision page, added "EX Representative" to Appendix D, deleted "pr", Sec. 2 8.3 and "DQS100" from 8.3, Changed all ISO9000 references from Rev. A to "current rev." Section 2, 3.0 added "Note" Removed "Conformal Coat" from section 9.1(section 3) as a special process. Removed personnel qualifications for Conformal Coat from section 9.2 Revised Section 1 and 2 to ISO9001 2008 and AS9100C respectively. Added new FAA regulations 21.137, etc. to Section 2. Revised the org chart Appendix A and updated Appendix B. Updated Appendix C. Revised pages vi, vii, xv, and xviii | 11/10/10 | BC REO |  |

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Quality Management System

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

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 has developed and implemented a quality management system, based on the ISO 9001 and AS9100 (current revision), the Quality System Requirements of 10CFR50 Appendix B, ANSI N45.2-1977, MIL-I-45208A, 14CFR Part 21.137 (a)-(n) and the basic Quality System Requirements of ANSI NQA-1-2000 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 9001:2000 as defined in Section One of this manual, the Quality System Requirements of 10CFR50 Appendix B, ANSI N45.2-1977, and the basic Quality System Requirements of ANSI NQA-1-2000 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 9001:2000, AS9100, and the Quality System Requirements of MIL-I-45208A and 14CFR Part 21.137 (a)-(n) as defined in Section Two of this manual. These projects/contracts/orders and all associated data and documentation are also identified as "Controlled".

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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.

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.

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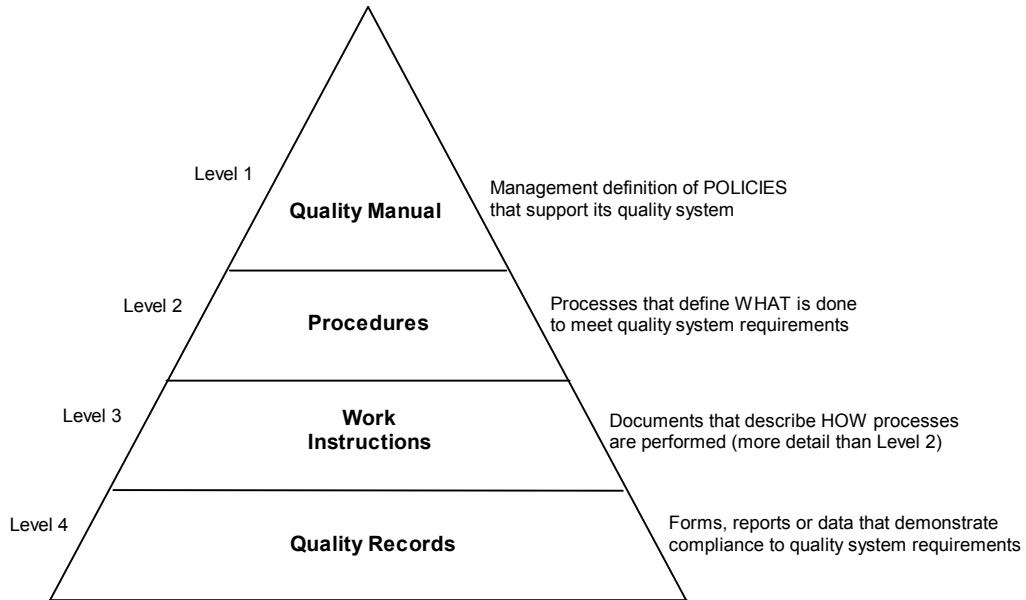
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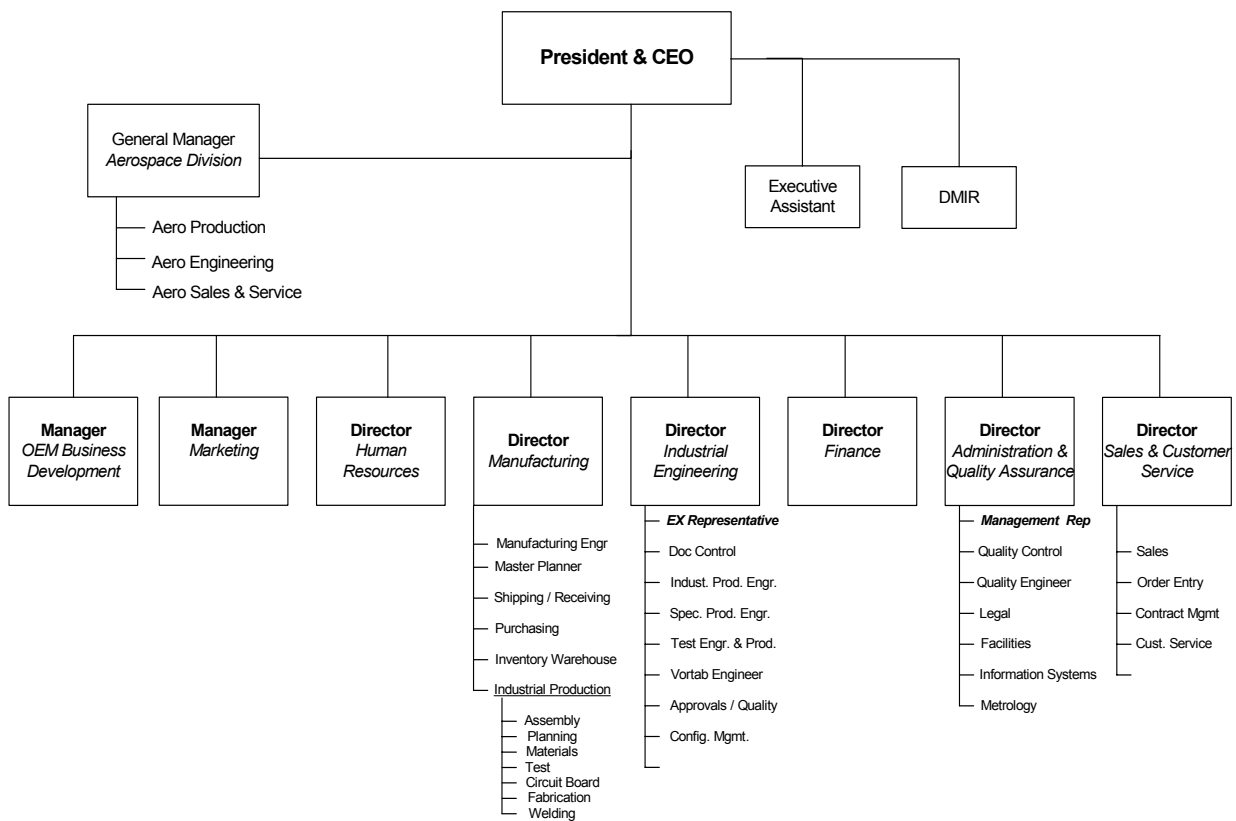
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Quality System Documentation Structure



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Appendix A: Company Organization Chart



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Appendix B: Interrelation of Quality System and ISO 9001/AS9100; 21.137; and NQA-1-2000.

Manual Sections

| Level 1 & 2 Documents | ISO/AS Requirements Sections 1 & 2 | 1 & 2 | 2 | 3 |
|--|---|---------------|----------------------|---------|
| | | AS / ISO | (per 21.137 etc.) | [NQA-1] |
| QA Manual | Quality Management System | 4.1 | | |
| QA Manual | Documentation Requirements | 4.2.1 | | |
| 07QA070003, Quality Manual | Quality Manual | 4.2.2 | | 1 |
| 01DM0000064/01DM000025, Engineering Document Control | Control of Documents | 4.2.3 | 21.137(b) | 6 |
| 04QA704007, 04QA704102, Quality System | Control of Documents | 4.2.3 | | 6.2 |
| 04QA704013, Control of Quality Records | Control of Records | 4.2.4 | 21.137(k) | 17 |
| 04QA704052, Project Notebooks | Control of Records | 4.2.4 | | 17 |
| 04QA704078, Back-Up Procedure | Control of Records | 4.2.4 | | 17 |
| QA Manual | Management Responsibility | 5.1 - 5.5.3 | | |
| 04QA704062, Management Review | Management Review | 5.6.1 - 5.6.3 | | 2.2 |
| QA Manual | Resource Management | 6.1 | | |
| 04QA704034, Competence, Awareness, and Training | Human Resources | 6.2.1- 6.2.2 | | 2.6 |
| 04QA704097, Preventive Maintenance of the Building | Infrastructure | 6.3 | | -- |
| 04QA704086, Preventive Maintenance of Process | Infrastructure | 6.3 | | -- |
| QA Manual | Work Environment | 6.4 | | |
| QA Manual | Planning | 7.1- 7.1.4 | | |
| 04QA704002, Order Entry Procedure | Customer - Related Processes - Identification of Product Related Requirements | 7.2.1 | | 3.1 |
| 04QA704005, Contract Review | Review of Product Requirements | 7.2.2 | | 3.1 |
| QA Manual | Customer Communication | 7.2.3 | | |
| 04QA704091, Design and/Or Development | Design / Development | 7.3.1 - 7.3.6 | | 3 |
| 01DM000010, Design & Development Changes / ECO | Design and Development Changes | 7.3.7 | 21.137(a) | 3.5 |
| 04QA704044, Vendor Surveys | Purchasing Process | 7.4.1 | 21.137(c) | 7.1 |
| 04QA704077, Evaluation of Subcontractors | Purchasing Process | 7.4.1 | | 7.1.2 |
| 04QA704077, 04QA704046, Evaluation of | Purchasing Process | 7.4.1 | | 7.1 |
| 04QA704003, Purchasing Information | Purchasing Information | 7.4.2 | | 4 |
| 04QA704094, Signature Authorization | Purchasing Information | 7.4.2 | | 4 |
| 04QA704058, Plastic Coated Sensor Head Testing | Verification of Purchased Product | 7.4.3 | | |
| 04QA704032, Testing Wetted Surfaces | Verification of Purchased Product | 7.4.3 | | 7.3 |
| 04QA704064, Hardness Testing | Verification of Purchased Product | 7.4.3 | | 7.3 |
| 04QA704001, Receiving Inspection | Verification of Purchased Product | 7.4.3 | | 8.1, 10 |
| 04QA704026, In-Process Inspection | Verification of Purchased Product | 7.4.3 | | 8.1, 10 |
| 04QA704020, Process Control Procedure: Controlled | Production – Control | 7.5.1 | 21.137(d) | 5.2 |

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|---|---|-----------------------------------|--|-------------------|------------------------------|
| 04QA704048, Foreign Object Prevention | Production – Control | 7.5.1 | | -- | |
| 04QA704050, Controlled Repair | Production – Control | 7.5.1 | | | 10 |
| 04QA704074, Aerospace Return Product Procedure | Production – Control | 7.5.1 | | | -- |
| 04QA704079, Field Service/Installation Procedure | Production – Control | 7.5.1 | | | -- |
| 04QA704080, Repair Service Procedure | Production – Control | 7.5.1 | | | -- |
| 04QA704082, Production and Service Provision / Process Control Procedure: Non-Controlled Jobs | Production – Control | 7.5.1 | | | -- |
| 04QA704084, Tooling Procedure | Production – Control | 7.5.1 | | | -- |
| 04QA704039, Welder Qualification | Production - Validation | 7.5.2 | | | 9.2 |
| 04QA704057, Workmanship Standard | Production - Validation | 7.5.2 | | | 9.2 |
| 04QA704088, Validation of Processes For Production and Service Provision / Special Procedure | Production - Validation | 7.5.2 | | | 9.1 |
| 04QA704024, Issuing Stamps | Id & Traceability | 7.5.3 | 45.15 | | 14.3 |
| 04QA704067, Mil/Aero Serial Numbers | Id & Traceability | 7.5.3 | | | -- |
| 04QA704085, Product Id | Id & Traceability | 7.5.3 | | | -- |
| 04QA704055, Customer Property | Customer Property | 7.5.4 | | | 7.6 |
| 04QA704018, Standard Packaging | Product Preservation | 7.5.5 | 21.137(j) | | 13.3 |
| 04QA704019, Final Cleaning | Product Preservation | 7.5.5 | | | 13.2 |
| 04QA704048, Foreign Object Prevention | Product Preservation | 7.5.5 | | | -- |
| 04QA704053, Dated Coded Materials | Product Preservation | 7.5.5 | | | 7.4, 8.1 |
| 04QA704081, Storage | Product Preservation | 7.5.5 | | | 13.1 |
| 04QA704010, Special Packaging | Product Preservation | 7.5.5 | | | 13.3.1 |
| 04QA704006, Calibration Program | Control of Monitoring / Measuring Equipment | 7.6 | | | 12.1 |
| 04QA704029, Evaluation of Measuring & Test | Control of Monitoring / Measuring Equipment | 7.6 | 21.137(f) | | 12.3 |
| 04QA704063, Inspection History | Measurement, Analysis & Improvement | 8.1 | | | -- |
| 04QA704076, On Time Delivery | Measurement, Analysis & Improvement | 8.1 | | | -- |
| 04QA704089, Statistical Techniques | Measurement, Analysis & Improvement | 8.1 | | | -- |
| 04QA704092, Return Authorization | Measurement, Analysis & Improvement | 8.1 | | | -- |
| 04QA704098, Customer Satisfaction | Customer Satisfaction | 8.2.1 | | | -- |
| 04QA704008, Audits | Audits – Internal | 8.2.2 | 21.137(l) | | 18.1, 18.2 |
| 04QA704054, Auditor Qualification | Audits – Internal | 8.2.2 | | | 303 & /2S-3 |
| QA Manual | Monitoring & Measurement Processes | 8.2.3 | | | |
| 04QA704026, In-Process Inspection | Monitoring & Measurement Product | 8.2.4 | 21.137(g) 21.137(n) & 21.137(e) | | 8.1, 10.1 |
| 04QA704038, Final Inspection | Monitoring & Measurement Product | 8.2.4 | | | 8.1, 10.1 |
| 04QA704058, Plastic Coated Sensor Head Testing | Monitoring & Measurement Product | 8.2.4 | | | 8.1, 10.1 |
| 04QA704049, First Article | Monitoring & Measurement Product | 8.2.4 | | | -- |
| 04QA704004, Control of Nonconforming Product | Control of Nonconforming Product | 8.3 | 21.137(h) | | 15 |
| 04QA704011, 10 CFR 21.3 Reporting | Control of Nonconforming Product | 8.3 | | | 15.3 |
| 04QA704075, Reporting to the FAA | Control of Nonconforming Product | 8.3 | 21.137(n) | | -- |
| QA Manual | Analysis of Data | 8.4 & 8.1 | 21.137(n) | | |
| QA Manual | Continual Improvement | 8.5.1 | | | |
| 04QA704070, Vendor Corrective Action | Corrective Action | 8.5.2 | | | 16.1 |

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| 04QA704083, Corrective and Preventive Action | Corrective Action | | 8.5.2 - 8.5.3 | 21.137(i), 21.137(m) and 21.137(n) | 16 |
| 04QA704070, Vendor Corrective Action | Preventive Action | | 8.5.3 | | |
| 04QA704093, Customer Response | Preventive Action | | 8.5.3 | | 16 |
| 04QA704071, Commercial Grade Item Testing | | | -- | | 7.5 |
| 06QA020013, Qualification Verification Analysis | | | -- | | 3.4 |
| 06QA020014, Nuclear Item Dedication Plan | | | -- | | 7.5 |

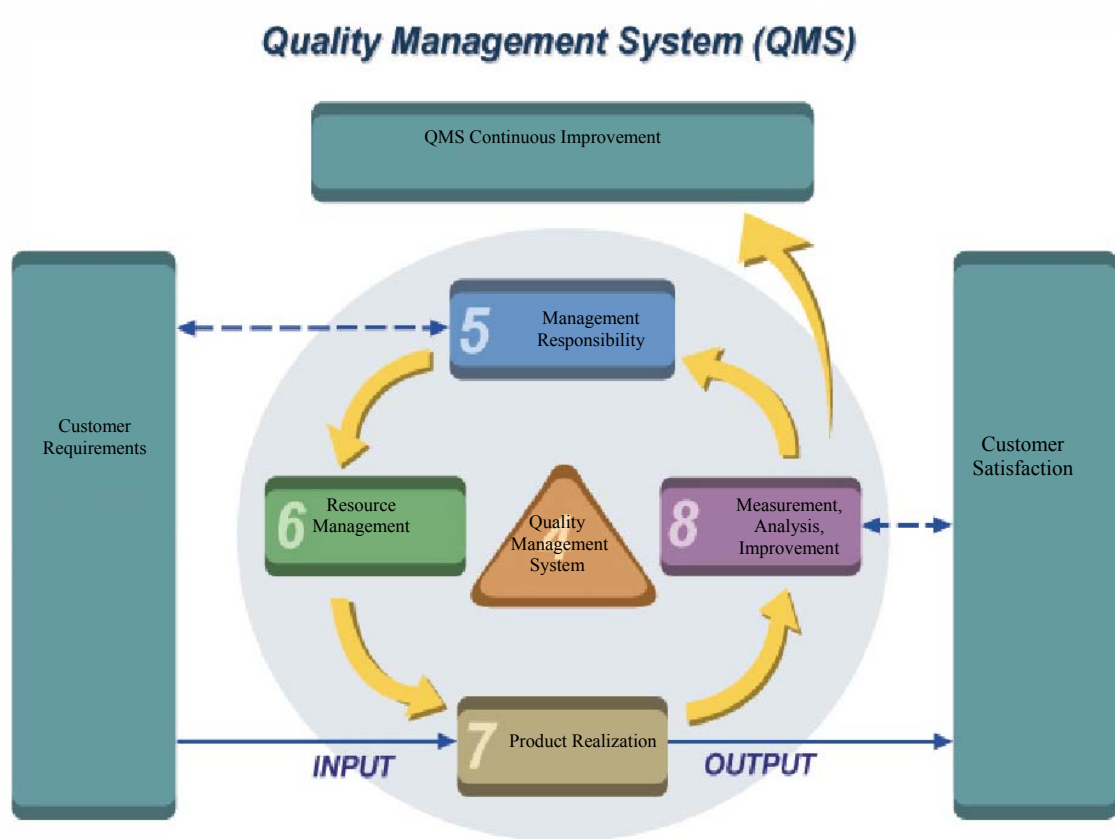
**Paragraphs 425 & 612 are met by the procedures referenced, no cross-reference to the manual paragraphs. Paragraph 612 is also met by manual paragraph 7.4.*

Note: all "04QA" number sequences listed in this manual reflect Fluid Components International LLC's current numbering system. The core number of the document is 704xxx, which remains the same regardless of the prefix added. Some of the quality assurance procedures listed in this manual have not been revised since the implementation of the 04QA system; therefore this note serves as notice that the document with the core number 704xxx, regardless of the prefix represents the same document.

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Appendix C: *Interrelationships Diagram*

A description of the interaction between the processes of the quality management system:



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

President

The President is responsible, through the Management Representative/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.
- Monitor the audit team for timely completion of the annual Internal Quality Assurance Program audit.

The President shall resolve matters regarding quality that the Management Representative/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. The President shall act as the Quality Assurance Manager in the Quality Assurance Manager's absence.

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.
- Identifying resources to maintain the quality management system.
- Reporting to the President on 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; and, 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

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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.)

- 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

Managers and Supervisors

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 “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”.

Employees

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

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- Reviewing, approving internal and customer Purchase Orders,
- Compiling project record notebooks,
- Administering the Discrepancy Report program,
- Auditing, and
- Training and certifying personnel performing activities affecting quality.

Quality Engineer/Inspection Supervisor (Reports directly to the Quality Assurance Manager) has responsibility for the following:

- Directing the activities of all Quality Control Inspection and Metrology personnel (Receiving, In-Process Mechanical, In-Process Electrical, Final, and Metrology)
- Participate in all other Quality activities as delegated by the Quality Assurance Manager.
- Training personnel performing activities affecting quality, and
- The ESD program.

Metrology Department (Reports to the Inspection Supervisor)

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 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.

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- Ultimately responsible for design control.
- 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 responsibility of controlling copies of the above referenced documents and ensuring only current or specified revisions are used during the manufacturing process. Engineering shall also ensure that obsolete or expired documents have been removed from the factory floor.
- 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.

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.
- Participating in drawing reviews and the Material Review Board to address qualification related issues.

Directors Of Manufacturing/Manufacturing Manager

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

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.

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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.

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.

Production Test

Production 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. Production Test shall also perform such other tests as requested by the Engineering, Production, or Quality Assurance Departments.

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

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SECTION ONE

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1.0 SCOPE

The requirements described in this section, Section One, of the Quality Manual provide an overview of FCI's minimum quality system requirements.

Issuance and changes to the manual shall be performed in accordance with "Document and Data Control, paragraph 4.2.3 of this section of the manual. Changes to this Manual that substantially effect the Quality System e.g. Change of Quality Assurance Manger or EX Representative (ATEX, IECEX, etc.), Certifications i.e. ISO, etc., shall be submitted to a Notified Body (ATEX, IECEX, etc.) by the appropriate Representative (EX Representative, Management Representative, Quality Assurance Manager, etc.) if required by the standard.

In addition, FCI shall know and understand the monitoring requirements and applicable performance criteria for AMS and the impact of these requirements on instrument design, manufacturing and certification pursuant to EN15267.

2.0 REFERENCED DOCUMENTS

This manual is supplemented by numerous procedures as identified in Appendix "B" and referenced throughout this manual. Procedures other than those referenced may also be used to implement the Quality Management system.

3.0 REFERENCES

ISO 9001-(current revision), Quality management systems - Requirements

4.0 QUALITY MANAGEMENT SYSTEM

4.1 GENERAL

FCI has established, documented, implemented, and maintains and continually improves a quality management system in accordance with the requirements of ISO 9001.

To implement the quality management system FCI will:

- a) Determine the processes needed for the quality management system and their application throughout the organization,
- b) Determine the sequence and interaction of these processes,
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

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- e) Measure, monitor and analyze these processes, and
- f) Implement action necessary to achieve planned results and continual improvement of these processes.

FCI manages these processes in accordance with the requirements of the ISO 9001 International Standard.

Where FCI chooses to outsource any process that affects product conformity with requirements, the organization ensures control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

Documentation for the quality management system includes:

- a) Documented statements of a quality policy and quality objectives,
- b) A quality manual,
- c) Documented procedures and records required by ISO 9001,
- d) Documents including records determined by FCI to be necessary to ensure the effective planning, operation and control of its processes.

4.2.2 QUALITY MANUAL

A quality manual is established and maintained that includes the following:

- a) The scope of the quality management system, including details of, and justification for, any exclusions,
- b) The documented procedures established for the quality management system, or reference to them (See Appendix B), and
- c) A description of the interaction between the processes of the quality management system (See Appendix C).

4.2.3 CONTROL OF DOCUMENTS

Documents required for the quality management system are controlled.

A documented procedure is established to define the controls needed:

- a) To approve documents for adequacy prior to issue,
- b) To review, update as necessary, and re-approve documents,

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- c) To ensure that changes and the current revision status of documents are identified,
- d) To ensure that relevant versions of applicable documents are available at points of use,
- e) To ensure that documents remain legible and readily identifiable,
- f) To ensure that documents of external origin determined by FCI to be necessary for the planning and operation of the Quality Management System are identified and their distribution controlled,
- g) To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 CONTROL OF QUALITY RECORDS

Records are established to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records will remain legible, readily identifiable, and retrievable. FCI shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time, and disposition of records.

5.0 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

Top management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to the organization via email, presentations, postings, and/or a newsletter the importance of meeting customer as well as statutory, and regulatory requirements,
- b) Establishing the quality policy,
- c) Ensuring that quality objectives are established,
- d) Conducting management reviews, and
- e) Ensuring the availability of resources.

5.2 CUSTOMER FOCUS

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction. (See section 7.2.1, and 8.2.1)

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5.3 QUALITY POLICY

Top management ensures that the quality policy:

- a) Is appropriate to the purpose of the organization,
- b) Includes a commitment to meeting requirements and to continually improve the effectiveness of the quality management system,
- c) Provides a framework for establishing and reviewing quality objectives,
- d) Is communicated and understood within the organization, and
- e) Is reviewed for continuing suitability.

FCI's quality policy is as follows:

“To continually meet and exceed customer expectations and requirements for products and services and to continually improve the effectiveness of the quality management system.”

5.4 PLANNING

5.4.1 QUALITY OBJECTIVES

Top management ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

5.4.2 QUALITY PLANNING

Top management ensures that:

- a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 RESPONSIBILITIES, AUTHORITY, AND COMMUNICATION

5.5.1 RESPONSIBILITY AND AUTHORITY

Top Management ensures that responsibilities and authorities are defined and communicated within the organization through this Quality Manual (also see Appendix A and D) and individual organizational charts at the departmental level.

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5.5.2 MANAGEMENT RESPONSIBILITY

Top Management has appointed (by virtue of this document) the Quality Assurance Manager as the Management Representative. This individual is a member of the management structure of FCI. Irrespective of other responsibilities the Management Representative has the responsibility and authority that includes:

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) Reporting to top management on the performance of the quality management system and any need for improvement, and
- c) Ensuring the promotion of awareness of customer requirements throughout the organization.

5.5.3 INTERNAL COMMUNICATION

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. This includes the posting of Quality Objective data to communicate information to the employee population regarding the effectiveness of the quality management system.

5.6 MANAGEMENT REVIEW

5.6.1 GENERAL

Top management reviews the quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained.

5.6.2 REVIEW INPUT

The input to management review includes information on:

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,

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- e) Follow-up actions from previous management reviews,
- f) Changes that could affect the quality management system, and
- g) Recommendations for improvement.

5.6.3 REVIEW OUTPUT

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

- a) Improvement of the effectiveness of the quality management system and its processes,
- b) Improvement of product related to customer requirements, and
- c) Resource needs.

6.0 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

FCI determines and provides the resources needed;

- a) To implement and maintain the quality management system and continually improve its effectiveness, and
- b) To enhance customer satisfaction by meeting customer requirements.

On an annual basis, the Directors submit all proposed resource needs for the upcoming fiscal year to the Chief Financial Officer (CFO). These proposed resource needs include, the infrastructure and resources needed to:

- a. Achieve conformity to product requirements,
- b. Implement and maintain the quality management system and continually improve its effectiveness, and
- c. Enhance customer satisfaction by meeting customer requirements.

The President, with input from other corporate entities, determines the departmental budgets. The approved departmental budgets document the determination of the infrastructure and resources needed.

The individual Directors then provide the needed resources based on the approved annual departmental budgets.

The CFO maintains the individual departmental budgets on the corporate server by date for a minimum of two years.

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6.2 HUMAN RESOURCES

6.2.1 GENERAL

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience.

6.2.2 COMPETENCY, AWARENESS, AND TRAINING

FCI will:

- a) Determine the necessary competence for personnel performing work affecting conformity to product requirements,
- b) Where applicable, provide training or take other actions to satisfy the necessary competencies,
- c) Evaluate the effectiveness of the actions taken,
- d) Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and
- e) Maintain appropriate records of education, training, skills, and experience.

6.3 INFRASTRUCTURE

FCI determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) Buildings, workspace and associated facilities;
- b) Process equipment (both hardware and software), and
- c) Supporting services (such as transport or communication).

6.4 WORK ENVIRONMENT

It is each departmental manager/supervisor's responsibility to determine and manage the work environment needed to achieve conformity to product requirements.

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REVISION**K****7.0 PRODUCT REALIZATION****7.1 PLANNING OF PRODUCT REALIZATION**

FCI plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system.

The planning of the processes for realization to determine the following occurs as appropriate:

- a) Quality objectives and requirements for the product during the Design and Planning Phase;
- b) The need to establish processes, documents, and provide resources specific to the product during the Design and Planning Phase;
- c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance during the Design and/or Planning Phase;
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements.

Output from this planning is in a form suitable for FCI's method of operations and may be (but is not limited to) the following:

- Quality System Procedures and/or Documentation
- MRP Data
- Delivery Method Information
- Quality Objectives
- Organizational Infrastructure
- Department Specific Documentation
- Product Realization Documentation

7.2 CUSTOMER RELATED PROCESSES**7.2.1 IDENTIFICATION OF PRODUCT RELATED REQUIREMENTS**

FCI determines:

- a) Requirements specified by the customer, including the requirements for delivery and post delivery activities,
- b) Requirements not stated by the customer but necessary for intended or specified use, where known,

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- c) Statutory and regulatory requirements related to the product, and
- d) Any additional requirements determined by the organization.

7.2.2 REVIEW OF PRODUCT REQUIREMENTS

FCI reviews the requirements related to the product. This review is conducted prior to FCI's commitment to supply a product to the customer and ensures that:

- a) Product requirements are defined,
- b) Contract or order requirements differing from those previously expressed are resolved, and
- c) The organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review are maintained.

Where the customer provides no documented statement of requirements, the customer requirements are confirmed by FCI before acceptance.

Where product requirements are changed, FCI ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 CUSTOMER COMMUNICATION

FCI determines and implements effective arrangements for communicating with customers in relation to:

- a) Product information,
- b) Enquiries, contracts or order handling, including amendments, and
- c) Customer feedback, including customer complaints.

Effective arrangements include (but may not be limited to) the following:

- a) Pre-Sales: All customer communication is forwarded to the Sales Department, and
- b) Post-Sales: All customer communication is forwarded to the Customer Service Department.

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FCI plans and controls design and/or development of the product.

Design and/or development planning determines:

- a) Stages of design and/or development,
- b) Review, verification and validation activities appropriate to each design and/or development stage, and
- c) Responsibilities and authorities for design and/or development.

Interfaces between different groups involved in design and/or development are managed to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and/or development progresses.

7.3.2 DESIGN AND/OR DEVELOPMENT INPUTS

Inputs relating to product requirements are determined and records maintained. These include:

- a) Functional and performance requirements,
- b) Applicable regulatory and legal requirements,
- c) Applicable information derived from previous similar designs, and
- d) Any other requirements essential for design and/or development.

These inputs are reviewed for adequacy. Incomplete, ambiguous, or conflicting requirements are resolved.

7.3.3 DESIGN AND/OR DEVELOPMENT OUTPUTS

The outputs of the design and/or development shall be in a form that is suitable for verification against the design and/or development inputs and shall be approved prior to release.

Design and/or development output:

- a) Meets the design and/or development input requirements,
- b) Provides appropriate information for purchasing, production, and service provisions,
- c) Contains or references product acceptance criteria,

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- d) Specifies the characteristics of the product that are essential to its safe and proper use.

7.3.4 DESIGN AND/OR DEVELOPMENT REVIEW

At suitable stages, systematic reviews of design and/or development is performed in accordance with planned arrangements to:

- a) Evaluate the ability of the results of design and development to meet requirements, and
- b) Identify problems and propose necessary actions.

Participants in such reviews include representatives of functions concerned with the design and/or development stage(s) being reviewed. The results of the reviews and any necessary actions are maintained.

7.3.5 DESIGN AND/OR DEVELOPMENT VERIFICATION

Verification is performed in accordance with planned arrangements to ensure the design and development outputs have met the design and/or development input requirements. The results of the verification and any necessary actions are maintained.

7.3.6 DESIGN AND/OR DEVELOPMENT VALIDATION

Design and/or development validation is performed in accordance with planned arrangements to ensure that resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of the validation and any necessary actions are maintained.

7.3.7 CONTROL OF DESIGN AND/OR DEVELOPMENT CHANGES

Design and/or development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered.

Records of the results of the review of changes and any necessary actions are maintained.

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7.4 PURCHASING

7.4.1 PURCHASING PROCESS

FCI ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

FCI evaluates and selects suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

7.4.2 PURCHASING INFORMATION

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

- a) Requirements for approval of product, procedures, processes, and equipment,
- b) Requirements for qualification of personnel, and
- c) Quality management system requirements

FCI ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 VERIFICATION OF PURCHASED PRODUCT

FCI establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where FCI or its customer intends to perform verification at the supplier's premises, the organization will state the intended verification arrangements and method of product release in the purchasing information.

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

FCI plans and carries out production and service provisions under controlled conditions. Controlled conditions include, as applicable:

- a) The availability of information that describes the characteristics of the

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product,

- b) The availability of work instructions, as necessary,
- c) The use of suitable equipment,
- d) The availability and use of measuring and monitoring devices,
- e) The implementation of monitoring and measurement,
- f) The implementation of product release, delivery, and post-delivery activities.

7.5.2 VALIDATION OF PROCESSES

FCI validates any processes for production and service where the resulting output cannot be verified by subsequent measurement or monitoring; and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered (aka Special Processes).

Validation demonstrates the ability of the processes to achieve planned results.

FCI establishes arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes,
- b) Approval of equipment and qualification of personnel,
- c) Use of specific methods and procedures,
- d) Requirements for records, and
- e) Revalidation.

7.5.3 IDENTIFICATION AND TRACEABILITY

Where appropriate, FCI identifies the product by part number throughout product realization.

FCI identifies the status of the product with respect to measurements and monitoring requirements on the associated Operation Sheet or in the Business System.

Where traceability is a requirement, FCI controls and records the unique identification of the product via the Receiving Inspection, In Process Inspection, Job Order, and Final Inspection procedures.

7.5.4 CUSTOMER PROPERTY

FCI exercises care with customer property (including intellectual property and

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personal data) while it is under the organization's control or being used by the organization. FCI identifies, verifies, protects, and safeguards customer property provided for use or incorporation into the product. Occurrence of any customer property that is lost, damaged, or otherwise found to be unsuitable for use is recorded and reported to the customer and records maintained.

7.5.5 PRESERVATION OF PRODUCT

FCI preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, this preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to constituent parts of a product.

7.6 CONTROL OF MEASURING AND MONITORING DEVICES

FCI determines the monitoring and measurements to be undertaken and the measuring and monitoring equipment needed to provide evidence of conformity of product to determined requirements.

FCI establishes processes to ensure the monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment is:

- a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national standards; where no such standards exist, the basis used for calibration or verification is recorded,
- b) Be adjusted or re-adjusted as necessary,
- c) Be identified in order that the calibration status is determined,
- d) Be safeguarded from adjustments that would invalidate the measurement result, and
- e) Be protected from damage and deterioration during handling, maintenance, and storage.

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

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application is confirmed. This

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is undertaken prior to initial use and reconfirmed as necessary.

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

FCI plans and implements the monitoring, measurement, analysis, and improvement processes needed:

- a) To demonstrate conformity to product requirements,
- b) To ensure conformity of the quality management system, and
- c) To continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 MEASUREMENT AND MONITORING

8.2.1 CUSTOMER SATISFACTION

As one of the measurements of the performance of the quality management system, FCI monitors information relating to customer's perception as to whether FCI has met customer requirements. The methods for obtaining and using this information are determined.

8.2.2 INTERNAL AUDIT

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

- a) Conforms to the planned arrangements, to the requirements of the ISO 9001 International Standard, and to the quality management system requirements established by FCI,
- b) Is effectively implemented and maintained.

The audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits will ensure objectivity and impartiality of the audit process. Auditors will not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

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

8.2.3 MEASUREMENT AND MONITORING OF PROCESSES

FCI applies suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate.

8.2.4 MEASUREMENT AND MONITORING OF PRODUCT

FCI measures and monitors the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements.

Evidence of conformity with the acceptance criteria is maintained. Records indicate the person(s) authorizing release of product for delivery to the customer.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 CONTROL OF NONCONFORMING PRODUCT

FCI ensures that product which does not conform to requirements is identified and controlled to prevent unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, FCI deals with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity,
- b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
- c) By taking action to preclude its original intended use or application.
- d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or

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use has started;

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

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

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

NOTIFICATION EN 13980:2002 and IECEx/OD005, Version 2

FCI shall take action appropriate to the degree of risk, where non-conforming product has been supplied to a customer.

- FCI's Contract Manager, Quality Assurance Manager, or designation representative (i.e., EX Representative – "ATEX", "IECEX", etc.) will notify the customer or Notified Body within the time frame required per contract or in a timely manner if no contractual requirements are set forth.
- FCI shall, in writing, inform our customer and/or Notified Body responsible for the quality system notification.

FCI shall maintain records of the above notification for ten years.

8.4 ANALYSIS OF DATA

FCI determines, collects, and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvements of the quality management system can be made. This includes data generated by measuring and monitoring activities and other relevant sources.

FCI analyses this data to provide information on:

- a) Customer satisfaction,
- b) Conformity to product requirements,
- c) Characteristics and trends of processes and product including opportunities for preventive action, and
- d) Suppliers.

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8.5 IMPROVEMENT

8.5.1 CONTINUAL IMPROVEMENT

FCI shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

8.5.2 CORRECTIVE ACTION

FCI takes corrective action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is appropriate to the effects of the nonconformities encountered.

The documented procedure for corrective action is established to define requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes of nonconformity,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing the action needed,
- e) Records of the results of action taken, and
- f) Reviewing the effectiveness of the corrective action taken.

8.5.3 PREVENTIVE ACTION

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

The documented procedure for preventive action defines requirements for:

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,
- c) Determining and implementing action needed,
- d) Recording results of action taken, and
- e) Reviewing preventive action taken.

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SECTION TWO

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FAA COMMITMENTS

FCI shall comply with FAA Part 21 regulations as follows:

Location of or change to manufacturing facilities:

FCI will immediately notify the FAA, in writing, of any change to the manufacturing facilities that may affect the inspection, conformity, or airworthiness of its PMA articles.

Inspections and Tests:

- (a) FCI will allow the FAA to inspect its quality system, facilities, technical data, and any manufactured articles and witness any tests, including any inspections or tests at a supplier facility, necessary to determine compliance with Paragraph 21.310.
- (b) Unless otherwise authorized by the FAA, FCI –
 - (1) May not present any article to the FAA for an inspection or test unless compliance with Chapter 21.303(b)(2) through (4) has been shown for that article; and
 - (2) May not make any change to an article between the time that compliance with Chapter 21.303(b)(2) through (4) is shown for that article and the time that the article is presented to the FAA for the inspection or test.

FCI will also–

- (a) Amend the Manual as required by Chapter 21.305 as necessary to reflect changes in the organization and provide these amendments to the FAA;
- (b) Maintain the quality system in compliance with the data and procedures approved for the PMA;
- (c) Ensure that each PMA article conforms to its approved design and is in a condition for safe operation;
- (d) Mark the PMA article for which an approval has been issued. Marking will be in accordance with part 45 of this chapter, including any critical parts;
- (e) Identify any portion of the PMA article (e.g., sub-assemblies, component parts, or replacement articles) that leave the manufacturer's facility as FAA approved with the manufacturer's part number and name, trademark, symbol, or other FAA approved manufacturer's identification;
- (f) Have access to design data necessary to determine conformity and airworthiness for each

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article produced under the PMA;

- (g) Retain each document granting PMA and make it available to the FAA upon request; and
- (h) Make available to the FAA information regarding all delegation of authority to suppliers.

Design changes initiated by FCI:

(a) Classification of design changes for PMA parts:

- (1) A “minor change” to the design of an article produced under a PMA is one that has no appreciable effect on the approval basis and has no effect on fit, form or function.
- (2) A “major change” to the design of an article produced under a PMA is any change that is not minor.

(b) Approval of design changes:

- (1) Minor changes to the basic design of a PMA may be approved using a method acceptable to the FAA.
- (2) FCI will obtain FAA approval of any major change before including it in the design of an article produced under a PMA.

After the issuance of a PMA –

- (a) Changes to the quality system are subject to review by the FAA; and
- (b) FCI will immediately notify the FAA, in writing, of any change that may affect inspection, conformity, or airworthiness of its article.

FCI, as a holder of a PMA part, will report any failure, malfunction, or defect in any product or article manufactured by it that it determines has resulted in any of the occurrences listed in Paragraph C of Section 21.3. FCI as a holder of a PMA part, will also report any defect in any product or article manufactured by it that has left its quality system and that it determines could result in any of the occurrences listed in Paragraph C of Section 21.3 (see 04QA704075).

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1.0 SCOPE

The requirements described in this section, Section Two, of the Quality Manual provide an overview of FCI's quality system as it relates to all projects identified as "Controlled for Aerospace".

In accordance with the provisions of 14 CFR, Part 21, the Federal Aviation Administration has found that the design data submitted by FCI meets the airworthiness requirements of the Federal Aviation Administration applicable to the product on which the parts are to be installed. Additionally, it has been determined that FCI has established the quality system required by 14CFR Part 21.137 (a) – (n) and is granted Parts Manufacturing Approval for production of the replacement parts or modification parts, as applicable, listed in the Supplements to the Parts Manufacturer Approval Letters in conformity with the Federal Aviation Administration-approved data. The terms and conditions applicable to this approval are documented in the Federal Aviation Administration – Parts Manufacturer Approval Letter.

If the physical location of FCI changes, or if additional locations of FCI are included under this program, the Federal Aviation Administration (FAA) shall be notified immediately in writing of the relocation of any manufacturing facilities or addition in accordance with terms 2 and 7 of the Parts Manufacturing Approval (PMA) Letter.

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

2.0 REFERENCED DOCUMENTS

This manual is supplemented by numerous procedures as identified in Appendix "B" and referenced throughout this manual. Procedures other than those referenced may also be used to implement the quality management system.

3.0 REFERENCES

AS9100 (current revision) Quality Systems – Aerospace- Model for Quality Assurance in Design, Development, Production, Installation, and Servicing

Note: All references to AS9100 in either FCI procedures or this QAM shall be deemed to refer to the latest revision of the standard regardless of the revision stated at the time of conception.

Mil-I-45208A – Military Specification, Inspection System Requirements

14CFR21.137 - Aeronautics and Space, Code of Federal Regulations, Approval of Materials, Parts, Processes, and Appliance - Replacement and Modification Parts

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4.0 QUALITY SYSTEM REQUIREMENTS

4.1 GENERAL

FCI has established, documented, implemented, and maintains, and continually improves a quality management system in accordance with the requirements of AS9100.

The organization's quality management system shall also address customer and applicable statutory and regulatory quality management system requirements.

To implement the quality management system FCI will:

- a) Determine the processes needed for the quality management system and their application throughout the organization,
- b) Determine the sequence and interaction of these processes,
- c) Determine criteria and methods needed to ensure that both the operation and control of these processes are effective,
- d) Ensure the availability of resources and information necessary to support the operation and monitoring of these processes,
- e) Measure, monitor and analyze these processes, and
- f) Implement action necessary to achieve planned results and the continual improvement of these processes.

FCI manages these processes in accordance with the requirements of the AS9100, International Standard.

Where FCI chooses to outsource any process that affects product conformity with requirements, the organization ensures control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the FCI quality management system.

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4.2 DOCUMENTATION REQUIREMENTS

4.2.1 GENERAL

Documentation of the quality management system includes:

- a) Documented statements of a quality policy and quality objectives,
- b) A quality manual,
- c) Documented procedures and records required by AS9100, International Standard,
- d) Documents, including records, determined by FCI to be necessary to ensure the effective planning, operation and control of its processes

FCI:

- Ensures access of documentation of the quality management system to its personnel and customers and/or regulatory authorities representatives, and
- Ensures that personnel are aware of relevant procedures.

4.2.2 QUALITY MANUAL

A quality manual is established and maintained that includes the following:

- a) The scope of the quality management system, including details of, and justification for, any exclusions,
- b) The documented procedures established for the quality management system, or reference to them which is shown in Appendix B, and
- c) A description of the interaction between the processes of the quality management system (See Appendix C).

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4.2.3 CONTROL OF DOCUMENTS

Documents required for the quality management system are controlled.

A documented procedure is established to define the controls needed:

- a) To approve documents for adequacy prior to issue,
- b) To review, update as necessary, and re-approve documents,
- c) To ensure that changes and the current revision status of documents are identified,
- d) To ensure that relevant versions of applicable documents are available at points of use,
- e) To ensure that documents remain legible and readily identifiable,
- f) To ensure that documents of external origin determined by FCI to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
- g) — To prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

As a regulatory requirement, any revision to this section, section two, of the Manual must be submitted to the FAA for approval prior to implementation in accordance with term 13 of the PMA Letter.

4.2.4 CONTROL OF QUALITY RECORDS

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled and retained for at least five (5) years.

FCI shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

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

Records shall remain legible, readily identifiable and retrievable.

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5.0 MANAGEMENT RESPONSIBILITY

5.1 MANAGEMENT COMMITMENT

Top management provides evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by:

- a) Communicating to the organization via email, presentations, postings, and/or a newsletter the importance of meeting customer as well as statutory, and regulatory requirements,
- b) Establishing the quality policy,
- c) Ensuring that quality objectives are established,
- d) Conducting management reviews, and
- e) Ensuring the availability of resources.

5.2 CUSTOMER FOCUS

Top management ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction. (See section 7.2.1, and 8.2.1)

Top management shall ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken if planned results are not, or will not be, achieved.

5.3 QUALITY POLICY

Top management ensures that the quality policy:

- a) Is appropriate to the purpose of the organization,
- b) Includes a commitment to meeting requirements and to continually improve the effectiveness of the quality management system,
- c) Provides a framework for establishing and reviewing quality objectives,
- d) Is communicated and understood within the organization, and
- e) Is reviewed for continuing suitability.

FCI's quality policy is as follows:

“To continually meet and exceed customer expectations and requirements for products and services and to continually improve the effectiveness of the quality management system.”

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5.4 PLANNING

5.4.1 QUALITY OBJECTIVES

Top management ensures that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the organization. The quality objectives are measurable and consistent with the quality policy.

5.4.2 QUALITY PLANNING

Top management ensures that:

- a) The planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and
- b) The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 RESPONSIBILITY, AUTHORITY, AND COMMUNICATION

5.5.1 RESPONSIBILITY AND AUTHORITY

Top Management ensures that responsibilities and authorities are defined and communicated within the organization through this Quality Manual (also see Appendix A & D) and individual organizational charts at the departmental level.

5.5.2 MANAGEMENT REPRESENTATIVE

Top Management has appointed (by virtue of this document) the Quality Assurance Manager as the Management Representative. This individual is a member of the management structure of the organization. Irrespective of other responsibilities the Management Representative has the responsibility and authority that includes:

- a) Ensuring that processes needed for the quality management system are established, implemented and maintained,
- b) Report to top management on the performance of the quality management system and any need for improvement,
- c) Ensure the promotion of awareness of customer requirements throughout the organization, and
- d) The organizational freedom and unrestricted access to top management to resolve quality management issues.

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5.5.3 INTERNAL COMMUNICATION

Top management ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system. This includes the posting of Quality Objective data to communicate information to the employee population regarding the effectiveness of the quality management system.

5.6 MANAGEMENT REVIEW

5.6.1 GENERAL

Top management reviews the quality management system, at planned intervals, to ensure its continuing suitability, adequacy, and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews are maintained.

5.6.2 REVIEW INPUT

The input to management review includes information on:

- a) Results of audits,
- b) Customer feedback,
- c) Process performance and product conformity,
- d) Status of preventive and corrective actions,
- e) Follow-up actions from previous management reviews,
- f) Changes that could affect the quality management system, and
- g) Recommendations for improvement.

5.6.3 REVIEW OUTPUT

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

- a) Improvement of the effectiveness of the quality management system and its processes,
- b) Improvement of product related to customer requirements, and
- c) Resource needs.

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6.0 RESOURCE MANAGEMENT

6.1 PROVISION OF RESOURCES

FCI determines and provides the resources needed;

- a) To implement and maintain the quality management system and continually improve its effectiveness, and
- b) To enhance customer satisfaction by meeting customer requirements.

On an annual basis, the Directors submit all proposed resource needs for the upcoming fiscal year to the Chief Financial Officer (CFO). These proposed resource needs include, the infrastructure and resources needed to:

- a) Achieve conformity to product requirements,
- b) Implement and maintain the quality management system and continually improve its effectiveness, and
- c) Enhance customer satisfaction by meeting customer requirements.

The President, with input from other corporate entities, determines the departmental budgets. The approved departmental budgets document the determination of the infrastructure and resources needed.

The individual Directors then provide the needed resources based on the approved annual departmental budgets.

The CFO maintains the individual departmental budgets on the corporate server by date for a minimum of two years.

6.2 HUMAN RESOURCES

6.2.1 GENERAL

Personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills, and experience.

6.2.2 COMPETENCY AWARENESS AND TRAINING

FCI will:

- a) Determine the necessary competence for personnel performing work affecting, conformity to product requirements.
- b) Where applicable, provide training or take other actions to satisfy the necessary competencies,
- c) Evaluate the effectiveness of the actions taken,
- d) Ensure that personnel are aware of the relevance and importance of their

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activities and how they contribute to the achievement of the quality objectives, and

- e) Maintain appropriate records of education, training, skills and experience.

6.3 INFRASTRUCTURE

FCI determines, provides, and maintains the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:

- a) Buildings, workspace and associated facilities;
- b) Process equipment (both hardware and software), and
- c) Supporting services (such as transport or communication).

6.4 WORK ENVIRONMENT

It is each departmental manager/supervisor's responsibility to determine and manage the work environment needed to achieve conformity to product requirements.

7.0 PRODUCT REALIZATION

7.1 PLANNING OF PRODUCT REALIZATION

FCI plans and develops the processes needed for product realization. Planning of product realization is consistent with the requirements of the other processes of the quality management system.

Upon the identification of the need to make a product available to our customers, the planning of the processes for realization occurs to determine the following as appropriate:

- a) Quality objectives and requirements for the product during the Design and Planning Phase;
- b) The need to establish processes, **documents*, and provide resources specific to the product during the Design and Planning Phase;
- c) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance during the Design and/or Planning Phase;
- d) Records needed to provide evidence that the realization processes and resulting product meet requirements;
- e) Configuration management appropriate to the product; at the design phase

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- e) Resources to support the use and maintenance of the product during the design phase.

Output from this planning is in a form suitable for FCI's method of operations and may be (but is not limited to) the following:

- Quality System Procedures and/or Documentation
- MRP Data
- Delivery Method Information
- Quality Objectives
- Organizational Infrastructure
- Department Specific Documentation
- Product Realization Documentation

7.1.1 PROJECT MANAGEMENT

As appropriate to FCI and the product, FCI shall plan and manage product realization in a structured and controlled manner to meet requirements at acceptable risk, within resource and schedule constraints.

7.1.2 RISK MANAGEMENT

FCI shall establish, implement and maintain a process for managing risk to the achievement of applicable requirements, that includes as appropriate to the organization and the product

- a) Assignment of responsibilities for risk management,
- b) Definition of risk criteria (e.g. , likelihood, consequences, risk acceptance),
- c) Identification, assessment and communication of risks throughout product realization,
- d) Identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria, and
- e) Acceptance of risks remaining after implementation of mitigating actions.

7.1.3 CONFIGURATION MANAGEMENT

The organization shall establish, implement and maintain a configuration management process that includes, as appropriate to the product

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- a) Configuration management planning,
- b) Configuration identification,
- c) Change control,
- d) Configuration status accounting and
- e) Configuration audit

7.1.4 CONTROL OF WORK TRANSFERS

FCI shall establish, implement and maintain a process to plan and control the temporary or permanent transfer of work and to verify the conformity of the work to requirements.

7.2 CUSTOMER RELATED PROCESSES

7.2.1 IDENTIFICATION OF PRODUCT RELATED REQUIREMENTS

FCI determines:

- a) Requirements specified by the customer, including the requirements for delivery and post delivery activities,
- b) Requirements not stated by the customer but necessary for intended or specified use, where known,
- c) Statutory and regulatory requirements related to the product, and
- d) Any additional requirements determined by the organization.

7.2.2 REVIEW OF PRODUCT REQUIREMENTS

FCI reviews the requirements related to the product. This review is conducted prior to the organization's commitment to supply a product to the customer and ensures that:

- a) Product requirements are defined,
- b) Contract or order requirements differing from those previously expressed are resolved,
- c) The organization has the ability to meet the defined requirements,
- d) Special requirements of the product are determined, and
- e) Risks (e.g., new technology, short delivery time scale) have been identified.

The results of the review and actions arising from the review are maintained.

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Where the customer provides no documented statement of requirements, the customer requirements are confirmed by FCI before acceptance.

Where product requirements are changed, the organization ensures that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 CUSTOMER COMMUNICATION

FCI determines and implements effective arrangements for communicating with its customers and sales channels in relation to:

- a) Product information,
- b) Inquiries, contracts or order handling, including amendments, and
- c) Customer feedback, including customer complaints.

Effective arrangements include (but may not be limited to) the following:

- a) Pre-Sales: All customer communication is forwarded to the Sales Department, and
- b) Post-Sales: All customer communication is forwarded to the Customer Service Department.

7.3 DESIGN AND/OR DEVELOPMENT

7.3.1 DESIGN AND/OR DEVELOPMENT PLANNING

FCI plans and controls design and/or development of the product.

Design and/or development planning determines:

- a) Stages of design and/or development,
Review, verification and validation activities appropriate to each design and/or development stage, and
- b) Responsibilities and authorities for design and/or development.

Where appropriate, FCI shall divide the design and development effort into distinct activities and, for each activity, defines the tasks, necessary resources, responsibilities, design content, input and output data and planning constraints.

The different design and development tasks to be carried out shall be based on the safety and functional objectives of the product in accordance with customer, statutory and regulatory requirements.

Design and development planning shall consider the ability to produce, inspect, test and maintain the product.

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Interfaces between different groups involved in design and/or development are managed to ensure effective communication and clear assignment of responsibility.

Planning output is updated, as appropriate, as the design and/or development progresses.

7.3.2 DESIGN AND/OR DEVELOPMENT INPUTS

Inputs relating to product requirements are determined and records maintained.

These include:

- a) Functional and performance requirements,
- b) Applicable regulatory and legal requirements,
- c) Applicable information derived from previous similar designs, and
- d) Any other requirements essential for design and/or development.

These inputs are reviewed for adequacy. Incomplete, ambiguous, or conflicting requirements are resolved.

7.3.3 DESIGN AND/OR DEVELOPMENT OUTPUTS

The outputs of design and/or development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and/or development output:

- a) Meets the design and/or development input requirements,
- b) Provides appropriate information for purchasing, production, and service provisions,
- c) Contains or references product acceptance criteria,
- d) Specifies the characteristics of the product that are essential to its safe and proper use, and
- e) Specify, as applicable, any critical items, including any key characteristics, and specific actions to be taken for these items.

FCI shall define the data required to allow the product to be identified, manufactured, inspected, used and maintained.

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Examples may be:

- Drawings, parts lists and specifications necessary to define the configuration and the design features of the product, and
- Information on the material, process, manufacturing and assembly of the product needed to ensure conformity of the product.

7.3.4 DESIGN AND/OR DEVELOPMENT REVIEW

At suitable stages, systematic reviews of design and/or development is performed in accordance with planned arrangements to:

- a) Evaluate the ability of the results of design and/or development to meet requirements,
- b) Identify problems and propose necessary actions, and
- c) Authorize progression to the next stage.

Participants in such reviews include representatives of functions concerned with the design and/or development stage(s) being reviewed. The results of the reviews and any necessary actions are maintained.

7.3.5 DESIGN AND/OR DEVELOPMENT VERIFICATION

Verification is performed in accordance with planned arrangements to ensure the design and/or development outputs have met the design and/or development input requirements. The results of the verification and any necessary actions are maintained.

7.3.6 DESIGN AND/OR DEVELOPMENT VALIDATION

Design and/or development validation is performed in accordance with planned arrangements to ensure that resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation is completed prior to the delivery or implementation of the product. Records of the results of the validation and any necessary actions are maintained.

7.3.6.1 DESIGN AND/OR DEVELOPMENT VERIFICATION OR VALIDATION TESTING

Where tests are necessary for verification and validation, these tests are planned, controlled, reviewed, and documented to ensure and prove the following:

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- a) Test plans or specification identify the product 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 method of operation, the performance of the test, and the recording of the results;
- c) The correct configuration standard of the product is submitted for the test;
- d) The requirements of the test plan and the test procedures are observed;
- e) The acceptance criteria are met.

7.3.6.2 DOCUMENTATION OF DESIGN AND/OR DEVELOPMENT

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

7.3.7 CONTROL OF DESIGN AND/OR DEVELOPMENT CHANGES

Design and/or development changes are identified and records maintained. The changes are reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes includes evaluation of the effect of the changes on constituent parts and product already delivered.

Objective evidence that design changes necessary to ensure only current, correct and approved changes are used. Records of the results of the review of changes and any necessary actions are maintained.

Design and/or development changes shall be controlled in accordance with the configuration management process (see 7.1.3)

7.4 PURCHASING

7.4.1 PURCHASING PROCESS

FCI ensures that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product is dependent upon the effect of the purchased product on subsequent product realization or the final product.

FCI shall be responsible for the conformity of all products purchased from suppliers, including product from sources defined by the customer.

FCI evaluates and selects suppliers based on their ability to supply product in

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accordance with the organization's requirements. Criteria for selection, evaluation, and re-evaluation are established. Records of the results of evaluations and any necessary actions arising from the evaluation are maintained.

FCI will:

- a) Maintain a register of approved suppliers that includes the status of the approval;
- b) Periodically reviews supplier performance; results of these reviews are used as a basis for establishing the level of controls to be implemented;
- c) Define the necessary actions to take when dealing with suppliers that do not meet requirements;
- d) Ensure where required that both the organization and all suppliers use customer-approved special process sources;
- e) Define the process, responsibilities and authority for the approval status decision, changes of the approval status and conditions for a controlled use of suppliers depending on the supplier's approval status;
- f) Determine and manage the risk when selecting and using suppliers;
- g) Suppliers shall report to FCI if their product has been released from that supplier and subsequently found not to conform to the applicable design data.

7.4.2 PURCHASING INFORMATION

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

- a) Requirements for approval of product, procedures, processes, and equipment,
- b) Requirements for qualification of personnel,
- c) Quality management system requirements,
- d) The identification and revision status of specifications, drawings, process requirements, inspection/verification instructions and other relevant technical data,
- e) Requirements for design, test, inspection, verification (including production process verification), use of statistical techniques for product acceptance, and related instructions for acceptance by the organization, and as applicable critical items including key characteristics,
- f) Requirements for test specimens (e.g. production method, number, storage

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conditions) for design approval, inspection, verification, investigation or auditing,

- g) Requirements regarding the need for the supplier to:
- Notify the organization of nonconforming product,
 - Obtain organization approval for nonconforming product disposition,
 - Notify the organization of changes in product and/or process, changes of suppliers, changes of manufacturing facility location and, where required, obtain organization approval, and
 - Flow down to the supply chain the applicable requirements including customer requirements.
- h) Records retention requirements, and
- i) Right of access by FCI, their customer and regulatory authorities to the applicable areas of all facilities, at any level of the supply chain, involved in the order and to all applicable records.

FCI ensures the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 VERIFICATION OF PURCHASED PRODUCT

FCI establishes and implements the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Verification activities may include:

- a) Obtaining objective evidence of the conformity of the product from suppliers,
- b) Inspection and audit at supplier's premises,
- c) Review of the required documentation,
- d) Inspection of products upon receipt, and
- e) Delegation of verification to the supplier, or supplier certification.

Where purchased 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.

Where the organization delegates verification activities to the supplier, the requirements for delegation shall be defined and a register of delegations

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maintained.

Where FCI or its customer intends to perform verification at the supplier's premises, FCI will state the intended verification arrangements and method of product release in the purchasing information.

7.5 PRODUCTION AND SERVICE PROVISION

7.5.1 CONTROL OF PRODUCTION AND SERVICE PROVISION

FCI plans and carries out production and service provisions under controlled conditions using shop orders. Controlled conditions include, as applicable:

- a) The availability of information that describes the characteristics of the product,
- b) The availability of work instructions and shop orders, as necessary,
- c) The use of suitable equipment,
- d) The availability and use of measuring and monitoring devices,
- e) The implementation of monitoring and measurement,
- f) The implementation of product release, delivery and post-delivery activities,
- g) Accountability for all product during production (e.g.; parts quantities, split orders, nonconforming product),
- h) Evidence that all manufacturing and inspection/verification operations have been completed as planned, or as otherwise documented and authorized using shop orders,
- i) Provision for the prevention, detection, and removal of foreign objects,
- j) Monitoring and control of utilities and suppliers such as water, compressed air, electricity and chemical products to the extent they affect conformity to product requirements, and
- k) Criteria for workmanship, is specified in the clearest practical **way** (e.g.; written standard, representative samples or illustrations).

Planning shall consider, as appropriate

- Establishing, implementing and maintaining appropriate processes to manage critical items, including process controls where key characteristics have been identified,
- designing, manufacturing and using tooling to measure variable data,
- identifying in-process inspection/verification points when adequate verification of conformance cannot be performed at later stages of realization, and

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- special processes (see 7.5.2).

7.5.1.1 PRODUCTION PROCESS VERIFICATION

FCI shall use a representative item from the first production run of a new part or assembly to verify that the production processes, production documentation and tooling are capable of producing parts and assemblies that meet requirements. This process shall be repeated when changes occur that invalidate the original results (e.g., engineering changes, manufacturing process changes, tooling changes).

NOTE: This activity is often referred to as first article inspection.

7.5.1.2 CONTROL OF PRODUCTION PROCESS CHANGES

Personnel authorized to approve changes to production processes shall be identified.

FCI shall control and document changes affecting processes, production equipment, tools or software programs.

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

7.5.1.3 CONTROL OF PRODUCTION EQUIPMENT, TOOLS AND SOFTWARE PROGRAMS

Production equipment, tools and software programs used to automate and control/monitor product realization processes, shall be validated prior to release for production and shall be maintained.

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

7.5.1.4 POST-DELIVERY SUPPORT

Post-delivery support shall provide as applicable for the:

- a) Collection and analysis of in-service data, through use of FAR's (failure analysis reports) and repair tracking programs (not applicable to PMA parts) in the FCI database.
- b) Actions to be taken, including investigation and reporting, when problems are detected after delivery,

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- c) Control and updating of technical documentation,
- d) Approval, control and use of repair schemes (not applicable to PMA parts), and
- e) Controls required for off-site work (e.g., organization's work undertaken at the customer's facilities).

7.5.2 VALIDATION OF PROCESSES, PRODUCTION AND SERVICE PROVISION

FCI validates any processes for production and service where the resulting output cannot be verified by subsequent measurement or monitoring, and as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered (a.k.a.; Special Processes).

Validation demonstrates the ability of the processes to achieve planned results.

FCI establishes arrangements for these processes including, as applicable:

- a) Defined criteria for review and approval of the processes,
- b) Approval of equipment and qualification of personnel,
- c) Use of specific methods and procedures,
- d) Requirements for records, and
- e) Re-validation.

7.5.3 IDENTIFICATION AND TRACEABILITY

Where appropriate, FCI identifies the product by part number throughout product realization.

FCI maintains the identification of the configuration of the product in order to identify any differences between the actual configuration and the agreed configuration.

FCI identifies the status of the product with respect to measurements and monitoring requirements on the associated Operation Sheet or in the Business System.

When acceptance authority media are used (e.g.; stamps, electronic signatures, passwords), FCI establishes and documents controls for the media.

Where traceability is a requirement, FCI controls and records the unique identification of the product via the Receiving Inspection, In Process Inspection, Job Order, and Final Inspection procedures.

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Traceability requirements can include:

- a) Identification throughout the product life;
- b) The ability to trace all products manufactured from the same batch of raw material, or from the same manufacturing batch, to the destination (e.g., delivery, scrap),
- c) For an assembly, the ability to trace its components to the assembly and then to the next higher assembly, and
- d) For a product, a sequential record of its production (manufacture, assembly, inspection/verification) to be retrievable.

FAA-PMA IDENTIFICATION

When the Federal Aviation Administration (FAA) has granted Parts Manufacturing Approval (PMA) for production of modification or replacement parts, the parts shall be marked in accordance with 14CFR45.15 with the following:

- a) "FAA-PMA"
- b) The name, trademark, or symbol of PMA holder
- c) The part number

Note: If the item is too small to record all of the above information, and approval is obtained from the FAA, the information may be placed on a tag attached to the item or attached to the individual container for the item.

7.5.4 CUSTOMER PROPERTY

FCI exercises care with customer property (including intellectual property and personal data while it is under the organization's control or being used by the organization. FCI identifies, verifies, protects, and safeguards customer property provided for use or incorporation into the product. Occurrence of any customer property that is lost, damaged, or otherwise found to be unsuitable for use is recorded and reported to the customer and records maintained.

7.5.5 PRESERVATION OF PRODUCT

FCI preserves the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, this preservation includes identification, handling, packaging, storage, and protection. Preservation also applies to constituent parts of a product.

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

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

7.6 CONTROL OF MEASURING AND MONITORING DEVICES

FCI determines the monitoring and measurements to be undertaken and the measuring and monitoring equipment needed to provide evidence of conformity of product to determined requirements.

FCI maintains a register of these monitoring and measuring equipment, and defines the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria.

The organization establishes processes to ensure the monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

FCI ensures that environmental conditions are suitable for the calibrations, inspections, measurements, and tests being carried out.

Where necessary to ensure valid results, measuring equipment is:

- a) Calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national standards; where no such standards exist, the basis used for calibration or verification is recorded,
- b) Be adjusted or re-adjusted as necessary,
- c) Be identified in order that the calibration status is determined,
- d) Be safeguarded from adjustments that would invalidate the measurement result,
- e) Be protected from damage and deterioration during handling, maintenance and storage,

FCI shall establish, implement and maintain a process for the recall of monitoring and measuring equipment requiring calibration or verification.

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

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

8.0 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

FCI plans and implements the monitoring, measurement, analysis, and improvement processes needed:

- a) To demonstrate conformity to product requirements,
- b) To ensure conformity of the quality management system, and
- c) To continually improve the effectiveness of the quality management system.

This includes determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 MEASUREMENT AND MONITORING

8.2.1 CUSTOMER SATISFACTION

As one of the measurements of the performance of the quality management system, the organization monitors information relating to customer's perception as to whether the organization has met customer requirements. The methods for obtaining and using this information are determined.

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

NOTE: Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and manufacturing representatives and distributor reports.

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8.2.2 INTERNAL AUDIT

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

Is effectively implemented and maintained.

The audit program is planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency, and methods are defined. Selection of auditors and conduct of audits will ensure objectivity and impartiality of the audit process.

Auditors will not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained.

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

The President of FCI shall be notified of the findings and assure that the corrective actions are implemented.

8.2.3 MEASUREMENT AND MONITORING OF PROCESSES

FCI applies suitable methods for monitoring and where applicable, measurement of the quality management system processes. These methods demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action is taken, as appropriate. In the event of process nonconformity, the organization will:

- a) Take appropriate action to correct the nonconforming process,
- b) Evaluate whether the process nonconformity has resulted in product nonconformity, and
- c) Identify and control the nonconforming product
- d) Determine if the process nonconformity is limited to a specific case or whether it could have affected other processes or products, and
- e) Identify and control any nonconforming product (see 8.3).

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8.2.4 MEASUREMENT AND MONITORING OF PRODUCT

FCI measures and monitors the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with planned arrangements. Evidence of conformity with the acceptance criteria shall be maintained, through the use of Lot Packages, Discrepancy Reports, Operation Sheets and Final Acceptance Test Data Sheets.

Measurement requirements for product acceptance shall be documented and shall include:

- a) Criteria for acceptance and/or rejection,
- b) Where in the sequence measurement and testing operations are to be performed,
- c) Required records of the measurement results (at minimum, indication of acceptance or rejection), and
- d) Any specific measurement instrument required and any specific instructions associated with their use.

When critical items, including key characteristics, have been identified the organization shall ensure they are controlled and monitored in accordance with the established processes.

When FCI uses sampling inspection as a means of product acceptance, the plan shall be justified on the basis of reorganized statistical principles and appropriate for use (i.e., matching the sampling plan to the criticality of the product and to the process capability).

Where product is released for production use pending completion of all required measurement and monitoring activities, it shall be identified and recorded to allow recall and replacement if it is subsequently found that the product does not meet requirements.

Records shall indicate the person(s) authorizing release of product for delivery to the customer.

Where required to demonstrate product qualification, the organization shall ensure that records provide evidence that the product meets the defined requirements.

The release of product and delivery of service to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

FCI shall ensure that all documents required to accompany the product are present at delivery.

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8.3 CONTROL OF NONCONFORMING MATERIAL

FCI ensures that product which does not conform to requirements is identified and controlled to prevent unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

FCI's documented procedure defines the responsibility for review and authority for the disposition of nonconforming product and the process for approving personnel making these decisions.

Where applicable, FCI deals with nonconforming product by one or more of the following ways:

- a) By taking action to eliminate the detected nonconformity,
- b) By authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer,
- c) By taking action to preclude its original intended use or application.
- d) By taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started:
 - The organizations nonconforming product control process shall provide for timely reporting of delivered nonconforming product;
- e) By taking actions necessary to contain the effect of the nonconformity on other processes or products.

Disposition of use-as-is or repair (not applicable to PMA parts) shall only be used after approval by an authorized representative of the organization responsible for design.

The organization shall not use dispositions of use-as-is or repair (not applicable to PMA parts), unless specifically authorized by the customer, if the nonconformity results in a departure from the contract requirements.

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

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

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

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14CFR21.3 REPORTING OF FAILURES, MALFUNCTIONS, AND DEFECTS:

Failures, malfunctions, or defects found in any product, part, process, or article manufactured by FCI, including those that have been delivered to customers, that are determined to have resulted in any of the conditions identified in QAP 04QA704075 shall be reported to the Aircraft Certification Office within 24 hours after FCI has determined that the failure, malfunction, or defect has occurred. (Reports due on weekends or holidays shall be delivered the following workday after the weekend or holiday.)

8.4 ANALYSIS OF DATA

FCI determines, collects, and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvements of the quality management system can be made. This includes data generated by measuring and monitoring activities and other relevant sources.

The organization analyses this data to provide information on:

- a) Customer satisfaction,
- b) Conformity to product requirements,
- c) Characteristics and trends of processes and product including opportunities for preventive action, and
- d) Suppliers.

8.5 IMPROVEMENT**8.5.1 CONTINUAL IMPROVEMENT**

FCI shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

The organization shall monitor the implementation of improvement activities and evaluate the effectiveness of the results.

8.5.2 CORRECTIVE ACTION

FCI takes corrective action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective action is appropriate to the effects of the nonconformities encountered.

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The documented procedure for corrective action is established to define requirements for:

- a) Reviewing nonconformities (including customer complaints),
- b) Determining the causes of nonconformity,
- c) Evaluating the need for action to ensure that nonconformities do not recur,
- d) Determining and implementing the action needed,
- e) Records of the results of action taken,
- f) Reviewing the effectiveness of the corrective action taken,
- g) Flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the nonconformity
- h) Specific actions where timely and/or effective corrective actions are not achieved,
- i) Determining if additional nonconforming product exists based on the causes of the nonconformities and taking further action when required,
- j) Addressing any in-service problem involving design changes,
- k) Determining if any changes to the instructions for Continued Airworthiness are necessary, and
- l) Initiating corrective action for products or articles that have been released and do not conform to the applicable design data or quality system requirements.

For FAA-PMA parts FCI utilizes Failure Analysis Reports (FAR's) for each returned part. Completed FAR's are analyzed to determine if there are any trends in part defects, design defects, malfunctions, failures or conformance to requirements. Corrective Action is then initiated using Discrepancy Reports, Corrective and Preventative Action Reports or other tools. As part of the corrective action, Continued Airworthiness is considered.

8.5.3 PREVENTIVE ACTION

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

The documented procedure for preventive action defines requirements for:

- a) Determining potential nonconformities and their causes,
- b) Evaluating the need for action to prevent occurrence of nonconformities,

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- c) Determining and implementing action needed,
- d) Recording results of action taken, and
- e) Reviewing preventive action taken.

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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 9001:2000; the Quality System requirements of 10CFR50 Appendix B; and the basic Quality System Requirements of ANSI NQA-1-2000.

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 D to this manual lists 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 Appendix A, Company Organization Chart.

2 QUALITY ASSURANCE PROGRAM

2.1 Referenced Documents

Fluid Components International LLC's Quality Manual 07QA070003 is supplemented by numerous implementing procedures and are 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

01DM000064/01DM000025 Engineering Document Control

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.

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Changes found during the review that are necessary to improve the clarity or effectiveness of the Quality Assurance Program shall be incorporated.

Both the President and Chief Operations Officer of Fluid Components International LLC approved revisions "A" and "B" of this Quality Manual. Due to changes in the organization, 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 a yearly 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.

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.

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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 either 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.

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 Fluid Components International LLC drawings, procedures, and instructions. 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 Contracts, 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.

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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 the customer, for all other industries and regions.

Qualified personnel not responsible for initiating the original design for all nuclear applications shall perform this design verification and analysis. The same individual for all other industries can perform 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 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 01DM000064/01DM000025 and the nonconforming material procedure 04QA704004.

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

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4 PROCUREMENT DOCUMENT CONTROL

4.1 Fluid Components International LLC Purchase Order Review

Quality Assurance shall review all Purchase Orders containing controlled items for incorporation of all applicable quality requirements and request for certification. When applicable, the Purchase Order shall require vendors to impose the Quality Assurance and contractual requirements of FCI's customers' Purchase Orders on sub-tier suppliers. The Purchase Orders shall identify and be reviewed for inclusion of applicable attachments such as controlled Drawings, and Certified Shippers. 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 describes 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 Verification Packages

All contracts subject to the requirements of this manual shall be processed in accordance with Quality Assurance Procedure 07QA704002.

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 Verification package, no cross-referenced Job Orders are required, see paragraph 5.2 following for further details.

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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 some 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 Process Sheets

A Process Sheet outlines an individual, specific process contained within a workstation's Process Manual and designates specific tools and instructions necessary to accomplish a particular process. Process Sheets are controlled in accordance with Document Management's Procedure 01DM000064/01DM000025.

5.4 Process Manuals

A Process Manual is composed for each production workstation and/or assembly stage (i.e., Spot Weld, Hot Spot, Insulation Resistance, etc.). Depending on the complexity of the workstation and in addition to Process Sheets, a Process Manual may contain a general description of the workstation, equipment used, and qualifications needed to use the equipment and/or carry out the individual processes delineated in the manual. The number of individual process sheets incorporated into a Process Manual shall be contingent upon the complexity and/or variability of the workstation. Process Manuals, are controlled in accordance with Document Management's Procedure 01DM000064/01DM000025.

5.5 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 FCI. 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

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instructions, acceptance criteria, and requirements for recording the test equipment used and objective evidence of the results of the tests and inspections.

5.6 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.

5.7 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.

5.8 Drawings

Drawing 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 01DM000064/01DM000025.

5.9 Operation Sheets

All assembly drawings shall have an Operation Sheet (Op Sheet) written 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 01DM000064/01DM000025.

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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 01DM000064/01DM000025 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.

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 Document Change Notice

Changes to Drawings, Operation Sheets, and Process Sheets, shall be recorded on a Document/Drawing Change Notice (DCN). For more information please refer to Engineering Procedure 01DM000064/01DM000025.

6.3.2 Revision Page

A Revision Page can be used in lieu of a DCN for book type documents such as Qualification 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 a DCN or

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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 Verification 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

The Quality Department shall perform Vendor Surveys 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 Approved Vendors List

An Approved Vendors List (AVL) shall be maintained as a controlled document for calibration services, test laboratories and items or services having independent nuclear qualification. (ASME NPT Certificate of Authorization may be accepted in lieu of a vendor survey for Nuclear Grade items for “non-domestic” orders.) All such items and services shall be procured using vendors contained in the AVL, Quality Assurance Table 08QA080002.

Subject to the customer’s requirements (pursuant to suggestion in the Westinghouse audit), AVL vendors who are not certified to the requirements of ANSI/ISO/ISE 17025 by NAVLAP or A2LA (provided A2LA remains approved by ILAC, International Laboratory Accreditation Cooperation) shall be surveyed or audited.

Those that are certified to 17025 shall be evaluated annually to assure continued accreditation. The accreditation shall cover the scope of the contracted services and at a minimum provide as-found data of items found out-of-tolerance, together with the standards and equipment used for calibration. Suppliers of items or services having independent nuclear qualification are not required to be on the AVL when the purchase of these items has been at the direction of the customer for use on the customer’s contract.

When a supplier is ISO/IEC 17025 certified the Purchase Order shall require that the supplier provide the following information: calibration procedure, equipment/standards used, the vendor’s name, the calibration date, and a statement that the calibration is traceable to NIST.

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The Purchase Order Number shall appear on the Certificate of Calibration. (From NUPIC audit)

7.1.2 Vendor Performance Record

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. 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 04QA704046.

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" items as described in paragraph 4, "Procurement Document Control", of this section of the manual.

Standard items that can be verified by inspection to engineering documents may be purchased on "Commercial" Purchase Orders. When those commercially purchased items are to be used for Controlled production they shall be transferred 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

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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.

A "Certified Shipper" shall accompany parts sent by Fluid Components International LLC to vendors for fabrication or processing. The Certified Shipper contains information important to maintain traceability of the item(s). The vendor's signature is required on the Certified Shipper to certify that they had complied with the Purchase Order and drawing and that the items have been kept segregated without mixing batches of parts. See Quality Assurance Procedure 04QA704003 for directions in completing and processing the Certified Shipper.

7.4 Age Sensitive Materials

All age sensitive materials as defined in Quality Assurance Table 08QA080000, 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.

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,

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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, see Quality Assurance Procedure 04QA704025 for more details on Parts List. The Lot Number shall be marked on the item by metal stamping, 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.

Limited life item (Age Sensitive Material) identification shall be explained in paragraph 7, “Control of Purchased Material, Equipment, and Services”, of this section of the manual.

8.2 Serialization

Items submitted to Final Inspection, including complete instruments and all calibrateable 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 reserved for “Controlled” product are a sequential set of numbers with a “-S” suffix (-1 was used on items prior to 1997). Serialized units are assigned the next available number without regard to model number or part number. (These numbers are typically used on Nuclear Safety-Related units but can include product sold under this Quality Assurance program for other organization such as Nuclear Non-Safety when those customers require more stringent controls be implemented.)

9 CONTROL OF SPECIAL PROCESSES

9.1 Types of Processes

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

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Currently, 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 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

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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.

10.4 Inspection Hold Points

Mandatory hold or witness points required by the customer shall be listed on the Order Verification 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.

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 Verification 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

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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

Personnel qualified to perform the work shall perform calibrations of Measuring & Test Equipment performed in-house. 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 the 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 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.

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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 Verification 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.

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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 outlined on a Discrepancy Report (DR) as described below and in Quality Assurance Procedure 04QA704004.

15.1 Discrepancy Report Review

The initial review of the discrepant item shall be made by the Inspector to determine what corrective action is to be taken or if further review is necessary. Additional review may be accomplished through submittal of the Discrepancy Report to the Inspection Supervisor, Quality Assurance Manager, or to the Material Review Board.

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.

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15.3 10 CFR 21 Compliance

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 conspicuous positions on the premises of FCI.

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, Discrepancy Reports, Material Review Board action, 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, 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.

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 Discrepancy Report 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.

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16.4 Product Non-Conformances

Non-conformances related to product are best documented on Discrepancy Reports as described in paragraph 15, "Non-Conforming Items", of this section of the manual. Discrepancy Reports are mostly concerned with dispositioning the nonconforming product but do include a section that addresses Corrective Action. 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.

Quality records are stored as 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 & 04QA704013.

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.

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18.3 Vendor Surveys

Fluid Components International LLC shall perform surveys of vendors providing calibration services and vendors providing 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.

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.