

QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM A
	REVISION 7	

SUBJECT: QUALITY ASSURANCE MANUAL

This Quality Assurance Manual describes the FXI Quality Management System, which is based on the requirements of ISO 9001:2008, ISO/TS 16949:2009, and ISO 13485:2003

As a world leader in polyurethane foam products, FXI, Inc. is committed to provide materials that conform to the requirements and expectations of our customers.

The management at each manufacturing facility of FXI has ultimate responsibility for the effective operation of the Quality Management System set forth in this manual as it applies to its facility.



John P. Constantino

Director of Quality
Title

April 22, 2014
Date



QUALITY ASSURANCE MANUAL

DATE
22 Apr 2014

SECTION
QAM A

REVISION
7

SUBJECT: QUALITY ASSURANCE MANUAL

TABLE OF CONTENTS

ISO/TS 16949 REFERENCE	SECTION TITLE NUMBER	PAGE NUMBER	EFFECTIVE DATE
---------------------------	-------------------------	----------------	-------------------

ISO 9001:2008 - BASED REQUIREMENTS

	APPROVAL PAGE	1	22 Apr 14
A	TABLE OF CONTENTS	2	22 Apr 14
B	QUALITY POLICY STATEMENT	3	22 Apr 14
C	QUALITY POLICY – LABORATORY	4	22 Apr 14
1.0	QUALITY PROGRAM SCOPE	5	22 Apr 14
2.0	REFERENCES	7	22 Apr 14
3.0	TERMS AND DEFINITIONS	9	22 Apr 14
4.0	QUALITY MANAGEMENT SYSTEM	13	22 Apr 14
5.0	MANAGEMENT RESPONSIBILITY	20	22 Apr 14
6.0	RESOURCE MANAGEMENT	27	22 Apr 14
7.0	PRODUCT REALIZATION	32	22 Apr 14
8.0	MEASUREMENT, ANALYSIS & IMPROVEMENT	59	22 Apr 14
ANNEX A1	PROCESS FLOW DIAGRAMS	74	22 Apr 14

Note:

- The ISO 9001:2008 requirements are in regular Arial type font and size 12.
- *The ISO/TS 16949:2009 requirements are in italics, Arial type font and size 13*
- The ISO 13485:2003 requirements are in Arial type font and size 13.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM B
	REVISION 7	
SUBJECT: QUALITY POLICY STATEMENT		

FXI Quality Policy

*The FXI Team is committed to do our jobs right the first time...every time...in order to obtain the highest level of “customer delight” and **compliance to regulatory requirements.***

We will achieve this by training all our Team Members in the Continuous Improvement Process and adhering to the highest levels of integrity and personal performance in order to satisfy the expectations of all FXI Stakeholders.

Politica de Calidad de FXI

*Los integrantes del equipo FXI, estamos comprometidos a realizar nuestro trabajo bien a la primera vez...siempre... para lograr un “alto nivel de satisfacción del cliente”, y el **cumplimiento de los requisitos reglamentarios.***

Lo anterior lo lograremos capacitando a todo nuestro personal en un proceso de Mejora Continua apegados a altos niveles de integridad y desarrollo personal para satisfacer las expectativas de los inversionistas de FXI.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM C
	REVISION 7	
SUBJECT: QUALITY POLICY - LABORATORY		

The following applies to the test laboratory facilities at FXI that are registered to ISO/IEC 17025.

FXI QUALITY POLICY - LABORATORY

- FXI laboratory management is committed to good professional laboratory practices and procedures, quality laboratory testing, calibration of laboratory equipment, and integrity in reporting data to the laboratory's clients.
- Laboratory personnel shall be familiar with all relevant lab and plant policies and procedures.
- The laboratory shall use technical procedures and test methods acceptable to its clients.
- FXI laboratory management is committed to full compliance to ISO/IEC 17025.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 1.0
	REVISION 7	
SUBJECT: QUALITY PROGRAM SCOPE		

1.0 SCOPE & APPLICATION

FXI, Inc. is a manufacturer of polyurethane foam products. [The Quality Management System developed and implemented by FXI manufacturing facilities complies with ISO 9001, ISO/TS 16949, ISO 13485, and ISO/IEC 17025 as noted below.](#) The Automotive and Healthcare, Industrial, and Electronics divisions are included in the scope of registration.

The scope statement for the ISO 9001:2008 registration is as follows:

- The design and manufacture of foam products (with the exception of carpet cushion, furniture and bedding product applications).

The scope statement for the ISO 13485:2003 registration is as follows:

- The manufacture and distribution of non-powered flotation therapy mattresses; foam overlays, positioners, and protectors; and foam wheelchair cushions

The scope statement for the ISO/TS 16949:2009 registration is as follows:

- The design and manufacture of foam products for the automotive industry.

All ISO/TS 16949 FXI manufacturing facilities are responsible for the requirements for product design and process design within their facilities.

Scope and application is defined by location: (All facilities are ISO/TS 16949:2009, unless noted)

<u>ISO/TS 16949:2009</u>	<u>EFFECTIVE DATE</u>	<u>ISO/TS 16949:2009</u>	<u>EFFECTIVE DATE</u>
INDIANA, USA		FXI de CUAUTITLAN, S.A. de C.V	
Auburn <i>ISO 9001:2008</i>	06/2004	Cuautitlan, Mexico City (automotive only)	06/2004
Ft. Wayne	06/2004	FXI de JUAREZ, S.A. de C.V	
		Juarez	06/2004
NEW MEXICO, USA			
Santa Teresa	06/2004		
NORTH CAROLINA, USA			
Cornelius <i>ISO 9001:2008</i>	12/2003		
PENNSYLVANIA, USA			
Rose Tree (Corporate) (Attached to Fort Wayne)	06/2004	Quality Assurance Manual, Purchasing (Chemicals and EX-Major Raw Materials), Document and Data Control	



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 1.0
	REVISION 7	

SUBJECT: QUALITY PROGRAM SCOPE

MICHIGAN, USA

Novi (Automotive Sales) 06/2004 Automotive Customer-Oriented Processes
(Attached to Fort Wayne)

NEW JERSEY, USA

East Rutherford 07/25/08

MISSISSIPPI, USA

[Baldwyn ISO 13485:2003\(E\)](#) 01/2014

ISO/IEC 17025

INDIANA, USA, Auburn 06/1/2002



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 2.0
	REVISION 7	
SUBJECT: REFERENCES		

2.0 References

1. ISO 9001:2008, *Quality management systems – Fundamentals and vocabulary*
2. ISO 9001:2008, *Quality management systems – Requirements*
3. ISO/TS 16949:2009(E), *Quality Management Systems – Particular requirements for the application of ISO 9001:2008 for automotive production and relevant service part organizations.*
4. ISO/IEC 17025:2005, *General Requirements for the Competence of Testing and Calibration Laboratories, first edition. 2005-09-13.*
5. ISO 13485:2003(E), *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes*
6. [ISO 14971:2007\(E\)](#), *Medical Devices – Application of Risk Management to Medical Devices*
7. 21CFR820, *Title 21 - - Food and Drugs Chapter I - - Food and Drug Administration Department of Health and Human Services Subchapter H - - Medical Devices, Part 820 Quality System Regulation*
8. Quality Assurance Manual – FXI’s tier 1 documentation
9. Quality Control Procedures – FXI’s tier 2 documentation.
10. Standard Operating Procedures, or, Work Instructions – FXI’s tier 3 documentation.
11. Quality Records – FXI’s tier 4 documentation.
12. FXI technical data sheets, sales brochures and advertising materials
13. FXI website, www.FXI.com
14. FXI, *Supplier Quality Manual, Revision 7, 11/11/10.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 2.0
	REVISION 7	

SUBJECT: REFERENCES

15. FXI *Business Plan*
16. FXI *Quality Policies – general and laboratory*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 3.0
	REVISION 7	
SUBJECT: TERMS AND DEFINITIONS		

This section defines terminology used in the Quality Management System documentation.

3.0 Terms and Definitions

1. QAM – Quality Assurance Manual is FXI’s tier 1 documentation. This level defines the Quality Management System according to international standards and the scope of the system.
2. QCP – Quality Control Procedure is FXI’s tier 2 documentation. This level defines who, what, where, why and when procedures are implemented.
3. SOP – Standard Operating Procedure is FXI’s tier 3 documentation. This level defines how a procedure is performed. These documents are called Work Instructions at some facilities.
4. Quality Records – Tier 4 documentation recording specific information that relates to a procedure, work instruction or regulation.
 - a. Quality records are proof that an organization is complying with its procedures and policies. Quality records can include any other documentation specified by national or regional regulations.
5. CSR – Customer Specific Requirements are maintained as a tier 4 documentation record of individual customer requirements.
6. FXI Stakeholder – A person, group, or organization which can affect or be affected by the actions of the business as a whole. Examples of stakeholders are Government, Employees, Customers, Suppliers, Creditors, Community, Trade Unions, Owners, and Investors.
7. Polyurethane foam – compressible, open-celled plastic material made from polymer chemical reactions.
8. APQP – Advanced Product Quality Planning
9. PPAP – Production Part Approval Process
10. FMEA – Failure Mode Effect Analysis
11. MSA – Measurement System Analysis



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 3.0
	REVISION 7	

SUBJECT: TERMS AND DEFINITIONS

12. SPC – Statistical Process Control

13. Advisory Notice – Notice issued by organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in the use of a device, the modification of a medical device, the return of the medical device to the organization that supplied it, or the destruction of a medical device.

14. Adverse Event – Any undesirable experience associated with the use of a medical product in a patient.

15. Complaint – Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device or product after it has been released for distribution.

16. DHF – Design History File – Compilation of records which describes the design history of a finished device or product

17. DHR – Device History Record – Compilation of records containing the production history of a finished device or product

18. DMR – Device Master Record – Compilation of records containing the procedures and specifications for a finished device or product.

19. Active Medical Device – Medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generate by the human body or gravity.

20. Medical Device – Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used , alone or in combination, for human being for one or more of the specific purpose(s) of

- a. Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- c. Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- d. Supporting or sustaining life,
- e. Control of conception,
- f. Disinfection of medical devices,



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 3.0
	REVISION 7	
SUBJECT: TERMS AND DEFINITIONS		

- g. Providing information for medical purposes by means of in vitro examination of specimens derived from the human body

And which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

- 21. Quality Objective – a standard that is set based on previous historical data to improve performance of the quality management system.
- 22. Quality Goal – an “objective” for quality improvement that requires a higher degree of effort and resources to achieve.
- 23. Special characteristics - those features identified by the customer in which excessive variation might affect a product's safety, compliance with government regulations, fit, function, appearance or quality of subsequent manufacturing operations and therefore require extra attention.
- 24. Satisfy (Satisfaction) – Meet, Maintain, or Exceed the expectations or requirements of a stakeholder.
- 25. Operational Excellence - A philosophy of the workplace where problem-solving, teamwork, and leadership results in the ongoing improvement in an organization. The process involves focusing on the customers' needs, keeping the employees positive and empowered, and continually improving the current activities in the workplace.

26. Labeling – Written, printed or graphic matter

- a. Affixed to a medical device or foam product or any of its containers or wrappers, or
- b. Accompanying a medical device or foam product, and
- c. Related to identification, technical description, and/or use of the medical device or foam product, but excluding shipping documents

27. Laboratory Scope – Controlled document containing

- a. Specific tests, evaluations and calibrations that a laboratory is qualified to perform,
- b. A list of the equipment which it uses to perform the above, and
- c. A list of methods and standards to which it performs the above



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 3.0
	REVISION 7	
SUBJECT: TERMS AND DEFINITIONS		

- 28. Premium Freight – Extra costs or charges incurred additional to contracted delivery
- 29. Remote Location – Location that supports sites and at which non-production processes occur.
- 30. Site – Location at which value-added manufacturing processes occur.

Note: This manual is written to include ISO/TS 16949:2009 and ISO 13485:2003. All QCP's and SOP's contain ISO 9001:2008, ISO/TS 16949:2009 and ISO 13485:2003 requirements ("shall statements").



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 4.0
	REVISION 7	

SUBJECT: QUALITY MANAGEMENT SYSTEM

References:

ISO/TS 16949:2009	QCP 2.1, <i>Quality Management System</i>
ISO 9001:2008	QCP 5.1, <i>Document and Data Control</i>
ISO/IEC 17025:2005	QCP 16.1, <i>Control of Quality Records</i>
ISO 13485:2003	QAM Annex A1, <i>Process Flow Diagrams</i>

4.1 General Requirements

- I. FXI has established and maintains a documented Quality System that meets the requirements of ISO 9001:2008, ISO/TS 16949:2009 and ISO 13485:2003 International Standards as well as customer specific requirements.
- II. Requirements apply to all facilities identified in QAM 1.0, *Scope and Application*.
 - I. Requirements for FXI non-manufacturing facilities attached to a manufacturing facility are included with the designated manufacturing facility. Examples of these requirements include:
 - i. Document and Data Control
 - ii. Control of Records (internal and external)
 - iii. Internal Audits
 - iv. Management Review
 - v. Corrective and Preventive Action
 - vi. Continual Improvement
- III. Additional requirements for ISO/TS 16949 facilities are so noted throughout this Quality Manual as **“ISO /TS 16949 Supplemental”**.
- IV. Additional and superseding requirements for ISO 13485 facilities are so noted throughout this Quality Manual as **“ISO 13485 Supplemental.”**
- V. The processes needed for the Quality Management System have been determined and are identified in QAM Annex A1, *Process Flow Diagrams*.
- VI. The FXI Quality Management System is reviewed annually, at a minimum by each FXI manufacturing facility’s top-level management to ensure continuing suitability and effectiveness in satisfying the requirements of the Standard and FXI’s stated quality policy and objectives.
- VII. Adequate resources are provided for management, performance of work, and verification activities including internal quality audits using the process method.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 4.0
	REVISION 7	
SUBJECT: QUALITY MANAGEMENT SYSTEM		

- VIII. Systems are developed to provide for organizational interfaces of all departments to ensure management of appropriate activities during concept development through production.
- IX. A multi-disciplinary approach is used for decision-making.
- X. Where FXI chooses to outsource any process that affects product conformity to requirements, the control over that process is defined within the Quality Management System, QCP 2.1, Quality Management System.

4.1.1 General Requirements – ISO/TS 16949 Supplemental

FXI manufacturing facilities assume responsibility and control of processes outsourced to assure that customer requirements are met. Outsourced processes are defined in QCP 2.1, Quality Management System.

4.2 Documentation Requirements

4.2.1 General Requirements

- I. FXI’s Quality Management System (QMS) has four levels of documentation:
 - Quality Assurance Manual – Tier 1 – defines QMS according to international standards
 - Quality Control Procedures – Tier 2 – define who, what, why, when and where QMS is implemented
 - Standard Operating Procedures – Tier 3 – define how QMS processes function
 - Customer Specific Documents – Tier 4 – record customer requirements
 - Quality Records – Tier 4 – provide evidence of the QMS in practice
- II. The Quality Control Procedures (QCPs), Standard Operating Procedures (SOPs) and Quality Records are developed for each location identified in QAM 1.0. These are maintained by each location to meet the above requirements and those of applicable international standards. The degree of documentation is controlled by location.
- III. **ISO 13485 Supplemental**
 - For each finished medical device or product the manufacturing plant will maintain a Device Master Record containing documents that



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 4.0
	REVISION 7	
SUBJECT: QUALITY MANAGEMENT SYSTEM		

define the product specifications, quality management system requirements, complete manufacturing process, and if applicable, installation and service.

- IV. Activities and processes impacting conformity to product conformance are documented by written procedures (e.g. work instructions). The responsibility, authority, and interrelation of all personnel who manage, perform, and verify work affecting quality is defined, particularly for personnel who need the organizational freedom and authority to:
- A. Initiate action to prevent the occurrence of product, process and quality system nonconformities.
 - B. Identify and record any quality problems relating to product, process and quality system.
 - C. Initiate, recommend, or provide solutions through designated channels.
 - D. Verify the implementation of solutions.
 - E. Control further product distribution until the deficiency or unsatisfactory condition has been corrected.
 - F. *Represent the requirements of the customer in internal processes while addressing ISO/TS 16949 requirements.*

4.2.2 Quality Manual

- I. The Quality Assurance Manual (QAM) is outlined per ISO 9001, ISO/TS 16949, ISO 13485, and includes the scope of the Quality Management System and justification for any exclusions and/or non-application. A description of the interaction between the processes of the QMS is included in the Annex 1 of the QAM.
 - A. The QAM is controlled electronically. It is available and controlled on the FXI intranet site, www.fmx.com.
 - B. Individual facility Quality Control Procedures, Standard Operating Procedures, Quality Records, and Customer Specific Requirements are



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 4.0
	REVISION 7	
SUBJECT: QUALITY MANAGEMENT SYSTEM		

maintained and controlled locally. Company wide procedures are maintained on the FXI intranet site, www.fmxi.com.

- II. QCP's and SOP's are cataloged in a Table of Contents in ISO 9001:2008 element format. Within each procedure may be references to the QAM, QCP's, SOP's, CSR's, and/or International, National, or Regional regulations and standards.

- III. **ISO 13485 Supplemental – Exclusions and Non-Applications per current Quality Management System scope. (QAM 1.0)**

- A. Exclusions – Design Control

- B. Non-Applications – Sterile and Implantable medical devices, and installations and service.

4.2.3 Control of Documents

This section describes the requirements for the control of all documents and data that affect the quality of product including documents of external origin such as standards and customer supplied specifications.

- I. Controlled documents and data and any changes made to the documents or data are reviewed for adequacy and approved prior to issue by designated functions.
- II. A master list (e.g. Table of Contents) or equivalent control method is established to identify the current revision of documents and be readily available to preclude the use of invalid and/or obsolete documents. This includes documents of external origin.
- III. Control of these documents is necessary to insure that:
 - i. Pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed.
 - ii. Examples of appropriate documents include:
 1. Engineering drawings, FXI & customer-owned
 2. Engineering standards, FXI & customer-owned
 3. Math (CAD) data
 4. Inspection instructions
 5. Test procedures



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 4.0
	REVISION 7	
SUBJECT: QUALITY MANAGEMENT SYSTEM		

6. Work instructions
 7. Operation sheets
 8. Quality manual
 9. Operational procedures
 10. Quality assurance procedures
 11. Material specifications
 12. Process Diagrams with inputs and outputs
- IV. Invalid and/or obsolete documents are promptly removed from all points of issue and use.
- V. Obsolete documents retained for legal and/or knowledge preservation purposes are suitably identified.
- **ISO 13485 Supplemental** – Obsolete documents pertaining to manufacture, testing, and distribution of medical devices and products shall be maintained for at least the defined life of the product, i.e. warranty period. This period shall not be less than 2 years from the date of the medical device/product release or as specified by relevant regulatory requirements
- VI. FXI assures the timely review, (e.g. business “days”, not weeks or months) distribution and implementation of all changes to customer engineering standards/specifications in accordance with documented procedures. The implementation date of change in production is recorded and maintained.
- VII. Implementation shall include updates to all appropriate documents.
- NOTE:** A change to customer, internal, or supplier engineering or process standards/specifications requires an update to Change Management (PPAP, DHF, and/or DMR) documents according to the appropriate guidelines and procedures.
- VIII. Changes to documents and data are reviewed and approved by the same function that performed the original review, unless designated otherwise. The designated reviewer must have access to pertinent background information upon which to base their review and approval.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 4.0
	REVISION 7	
SUBJECT: QUALITY MANAGEMENT SYSTEM		

- IX. Where practicable, changes to documents and data are identified within the document or by attachment.

4.2.3.1 Engineering specifications – ISO/TS 16949 Supplemental

- I. FXI will review, distribute and implement new or changes to existing customer engineering standards in a timely manner, not exceeding two weeks, based on customer-required schedule.*
- II. If more time is required, the customer will be notified.*
- III. FXI will maintain records of dates when changes are implemented in production.*
- IV. Implementation will include the updated documents.*

4.2.4 Control of Records

- I. This section describes the requirements for the record retention system to the requirements of this section of the standard.
- II. Documented procedures are established and maintained for identification, collection, indexing, access, filing, storage, maintenance, and disposition / disposal of quality records, including customer-specified records.
- III. Records are maintained to demonstrate conformance to specified requirements and effectiveness of the Quality System.
- IV. Relevant records from suppliers are included in the quality records.
- V. All quality records are legible and are stored and retained so they are readily retrievable.
- VI. The storage facilities have a suitable environment to prevent damage or deterioration and to prevent loss.
- VII. Retention times of all quality records are established and recorded.
- VIII. Record retention for production part approvals, tooling records, purchase orders and amendments are maintained for the length of time that the part*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 4.0
	REVISION 7	
SUBJECT: QUALITY MANAGEMENT SYSTEM		

(or family of parts) remains active plus one (1) calendar year unless otherwise specified by the customer or by a regulatory agency.

NOTE: This requirement does not supersede any governmental requirements.

IX. Quality records are made available for customer review where contractually agreed.

X. **ISO 13485 Supplemental** – Quality records for medical devices/products pertaining to manufacture, testing, and distribution of medical devices and products shall be maintained for at least the defined life of the product, i.e. warranty period. This period shall not be less than 2 years from the date of the medical device/product release or as specified by relevant regulatory requirements

4.2.4.1 Records retention – ISO/TS 16949 Supplemental

The control of records must satisfy all regulatory and customer requirements.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 5.0
	REVISION 7	
SUBJECT: MANAGEMENT RESPONSIBILITY		

References:

- QCP 1.1, *Management Responsibility*
- QCP 2.2, *Quality Planning*
- QCP 3.1, *Contract Review*

5.1 Management Commitment

- I. This section defines the organizational structure, authorities, and responsibilities of personnel at a top management level who manage, perform, and verify work affecting quality at FXI facilities identified in QAM 1.0.
- II. Top management demonstrates commitment to the Quality Management System by establishing a quality policy and quality objectives and ensures the availability of resources to maintain the quality system.
- III. Top management will conduct reviews, at least once every 12 months, of the Quality System for evidence of effectiveness and continuous improvement and to ensure that all of our customer and statutory and regulatory requirements are met.

5.1.1 Process Efficiency – *ISO/TS 16949 Supplemental*

- I. Top management will review the product realization process and supporting processes to assure their effectiveness and efficiency.*
- II. Systems are developed to provide for organizational interfaces of all departments to ensure management of appropriate activities during concept development through production and shipment.*

5.2 Customer Focus

- I. The method/process used to determine current and future customer expectations is called Voice of the Customer. The aim is to meet customer requirements and further enhance customer satisfaction.
- II. A method/process for determining customer satisfaction, perception of FXI meeting their requirements and key indicators of customer satisfaction is developed, implemented and supported by objective information.
- III. The responsibility for management and implementation of this process is at the FXI manufacturing facilities identified in QAM 1.0



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 5.0
	REVISION 7	

SUBJECT: MANAGEMENT RESPONSIBILITY

5.3 Quality Policy

The FXI Team is committed to do our jobs right the first time...every time...in order to obtain the highest level of “customer delight” and compliance to regulatory requirements.

We will achieve this by training all our Team Members in the Continuous Improvement Process and adhering to the highest levels of integrity and personal performance in order to satisfy the expectations of all FXI Stakeholders.

The Quality Policy is communicated, implemented and maintained at all levels of the Organization and is reviewed for continuing suitability, annually. Objectives for quality are defined in the Business Plan at the corporate level and per plant procedures.

5.4 Planning

- I. In FXI facilities, business planning is utilized to develop strategy related to, but not be limited to, market-related issues, cost objectives, design plans, quality policy and objectives, key internal quality and operational performance measurables, health, safety and environmental issues, plant/facilities plans, and human resource development.
- II. The integrity of the quality management system will be maintained when any changes are planned and implemented.
- III. Plans are based on analysis of competitive products and benchmarking, where appropriate.

5.4.1 Quality Objectives

- I. Top management at FXI facilities identified in QAM 1.0 shall ensure that quality objectives, including those needed to meet requirements for product are established at relevant functions and levels within the organization.
- II. The quality objectives must be measureable and consistent with the quality policy.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 5.0
	REVISION 7	
SUBJECT: MANAGEMENT RESPONSIBILITY		

5.4.1.1 Quality Objectives – ISO/TS 16949 Supplemental

- I. *Top management shall define quality objectives and measurements that shall be included in the business plan and used to deploy the quality policy.*
- II. *Quality objectives should address customer expectations and be achievable within a defined time period.*

5.4.2 Quality Management System Planning

- I. Top management at FXI facilities identified in QAM 1.0 shall ensure that:
 - A. The planning of the quality management system is carried out in order to meet the general requirements given in 4.1 as well as the quality objectives.
 - B. The integrity of the quality management system is maintained when changes are planned and implemented.

5.5 Responsibility, Authority and Communication

5.5.1 Responsibility and Authority

- I. The Chief Executive Officer (CEO) is responsible for line functions, including all the business units, product and process design/development, marketing and sales. He/she has ultimate responsibility for ensuring success in meeting FXI's goals and objectives set forth in the Quality Policy.
- II. The Chief Financial Officer is responsible for all administrative and finance functions, including strategy and finance, treasury, accounting, purchasing, distribution and logistics, investor relations and information technology.
- III. The Vice President, Human Resources is responsible for the development and training of all personnel to assure the attainment of all FXI quality-related goals and objectives.
- IV. The Vice President, Manufacturing is responsible for the manufacturing operations, including EHS and quality and the overall effectiveness of the quality system. He/she reports directly to the CEO.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 5.0
	REVISION 7	
SUBJECT: MANAGEMENT RESPONSIBILITY		

- V. The Vice President, Manufacturing has assigned executive and top management responsibility and authority for quality to the plant manager at the FXI facilities outlined in QAM 1.0, *Quality Program Scope*.
- VI. The plant manager and the Director of Quality appoint a site management representative for quality and to act as a customer representative. He/she is responsible for maintaining the facility's quality system.
- VII. Supplementary executive responsibilities are defined in separate quality system procedures.
- VIII **ISO 13485 Supplemental** – Personnel who manage, perform, and verify work affecting quality are granted the independence and authority necessary to perform these tasks by Top Management.

5.5.1.1 Responsibility for Quality – ISO/TS 16949 Supplemental

- I. *Managers with responsibility and authority for corrective action shall be promptly informed of products or processes which do not conform to requirements.*
- II. *Personnel responsible for product quality have the authority to stop production to correct quality problems.*
- III. *Production operations across all shifts are staffed with personnel in charge of, or delegated responsibility for, ensuring product quality.*

5.5.2 Management Representative

- I. The Director of Quality is the appointed overall FXI Management Representative.
 - a. The Quality Assurance Manager in each facility identified in QAM 1.0 will be its designated Management Representative to address all local issues and requirements concerning the Quality System.
- II. Irrespective of other duties, he/she will ensure that a Quality System is established, implemented and maintained at all FXI facilities outlined in



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 5.0
	REVISION 7	
SUBJECT: MANAGEMENT RESPONSIBILITY		

QAM 1.0, *Quality Program Scope* in accordance with ISO 9001:2008 and ISO/TS 16949:2009.

- III. The management representative will report on the performance of the Quality System to executive-level management for review and as a basis for improvement of the Quality System. Performance measurements, objectives, and responsibilities are described in the annual Quality Plan
- IV. He/she may act as liaison with external parties on matters relating to the Quality System.
- V. The management representative ensures the promotion of awareness of regulatory and customer requirements throughout the FXI organization.

5.5.2.1 Customer Representative – ISO/TS 16949 Supplemental

- I. *The Director of Quality is the appointed Corporate Customer Representative.*
 - a. *The Quality Assurance Manager in each facility identified in QAM 1.0 will be its designated Customer Representative to address all local issues and customer requirements concerning the Quality System.*
- II. *He/she will act as liaison with customers on matters relating to the Quality System and meeting their requirements. This includes selection of special characteristics, setting quality objectives and related training, corrective and preventive actions and product design and development.*
- III. *Necessary information and data is communicated in a customer-prescribed format.*
- IV. *The customer representative represents the needs of the customer in internal functions in addressing ISO 9001 and ISO/TS 16949 requirements.*

5.5.3 Internal Communication

Top management will assure that internal communication processes are established for the transfer of information regarding the effectiveness of the quality system.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 5.0
	REVISION 7	
SUBJECT: MANAGEMENT RESPONSIBILITY		

5.6 Management Review

5.6.1 General

- I. The approved FXI Quality Program is reviewed annually, at a minimum, by top management at FXI facilities identified in QAM 1.0 to ensure continuing suitability, adequacy and effectiveness in satisfying the requirements of customers, the Standard and FXI's stated quality policy and objectives.
- II. Opportunities for improvement and reports on the cost of poor quality are included in the management review process.
- III. Records from management reviews are maintained in accordance with QCP 16.1, *Control of Quality Records*.

5.6.1.1 **Quality Management System Performance– ISO/TS 16949 Supplemental**

- I. *Reviews of the QMS must include all requirements of the QMS and its performance trends as an essential part of continuous improvement.*
- II. *As a minimum, the management review must record results of:*
 - A. *monitoring of quality objectives as specified in the business plan,*
 - B. *evaluation of the reports on the cost of poor quality, and*
 - C. *customer satisfaction feedback.*
- III. *ISO/TS 16949 facility management reviews will cover all elements of the entire quality system and will be conducted with a multi-disciplinary approach.*
- IV. *Adequate resources are provided for management, performance of work, and verification activities including internal quality audits.*

QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 5.0
	REVISION 7	
SUBJECT: MANAGEMENT RESPONSIBILITY		

5.6.2 Review Input

- I. Inputs to Management Review shall include information on:
 - A. Internal and external audit results
 - B. Customer feedback
 - C. Process performance
 - D. Product conformity
 - E. Status of preventive and corrective actions
 - F. Follow-up actions from previous management review
 - G. Changes that could affect the Quality Management System
 - H. Recommendations for improvement
 - I. **ISO 13485 Supplemental – New or revised regulatory requirements**

5.6.2.1 Review Input – *ISO/TS 16949 Supplemental*

ISO/TS 16949 facilities must include an analysis of actual and potential field failures and their impact on quality, safety or the environment.

5.6.3 Review Output

- I. Output from the management review must include decisions and actions as follows:
 - A. Improvement needed to maintain and increase of the effectiveness of the QMS and processes.
 - B. Improvement of product related to customer requirements.
 - C. Resource needs.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 6.0
	REVISION 7	

SUBJECT: RESOURCE MANAGEMENT

Reference:

- QCP 2.5, *Facilities and Tooling Management*
- QCP 9.1, *Process Control*
- QCP 16.1, *Control of Quality Records*
- QCP 18.1, *Employee Training*
- APQP - Advanced Product Quality Planning and Control Plan Reference Manual
- PPAP - Production Part Approval Process Manual

6.1 Provision of Resources

- I. FXI management has provided the necessary resources for implementation and maintenance of the Quality Management System and to maintain and continually improve the effectiveness of the system.
- II. Resource requirements are identified in the Business Plan and the appropriate quality procedures.
- III. Resources are provided to enhance customer satisfaction by meeting regulatory and customer requirements.

6.2 Human Resources

6.2.1 General

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

6.2.2 Competence, Awareness and Training

- I. FXI will determine the necessary competence for personnel performing work affecting product quality and provide training, as required to meet needs.
- II. The effectiveness of training is periodically evaluated during personnel reviews where the need for developmental training may be ascertained.
- III. FXI ensures that all personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.
- IV. Training records are maintained in accordance with QCP 16.1, *Control of Quality Records*.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 6.0
	REVISION 7	
SUBJECT: RESOURCE MANAGEMENT		

6.2.2.1 Product Design Skills– ISO/TS 16949 Supplemental

FXI will ensure that personnel with product design responsibility are competent to achieve design requirements and are skilled in applicable tools and techniques.

6.2.2.2 Training – ISO/TS 16949 Supplemental

FXI establishes and maintains documented procedures for identifying training needs and achieving competence of all personnel performing activities that may affect quality. Personnel performing specific assigned tasks will be qualified, as required, with particular attention to the satisfaction of customer requirements.

6.2.2.3 Training on the Job – ISO/TS 16949 Supplemental

Department Managers document training of newly hired promoted or transferred employees as well as contract or agency personnel. Personnel whose work can affect quality are informed about the consequences to the customer of nonconformity to quality requirements.

6.2.2.4 Employee Motivation and Empowerment – ISO/TS 16949 Supplemental

- I. FXI has a process to motivate employees to achieve quality objectives, to make continual improvements and promote quality and technology innovation.*
- II. FXI has a process to measure the extent to which personnel are aware of their relevance and importance in meeting quality objectives and how they contribute to that end.*

6.3 Infrastructure

FXI determines the need, provides and maintains the infrastructure to achieve conformity to product requirements. Infrastructure includes:

- I. buildings, workspace and associated utilities,
- II. process equipment, both hardware and software, and
- III. supporting services, such as transportation and communication.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 6.0
	REVISION 7	
SUBJECT: RESOURCE MANAGEMENT		

IV. **ISO 13485 Supplemental** – Facilities establish documented procedures for maintenance activities, including their frequency, when these activities, or their absence, can have an impact on product quality.

I. Records of these activities are maintained and controlled per QCP 16.1

6.3.1 Plant, Facility and Equipment Planning – ISO/TS 16949 Supplemental

- I. *FXI uses a multi-disciplinary approach to develop plant, facility and equipment plans.*
- II. *Plant layouts are designed, wherever possible, to optimize material travel, handling, and value-added use of floor space to facilitate synchronous material flow.*
- III. *Methods exist to evaluate and monitor the effectiveness of existing operations.*

6.3.2 Contingency Plans– ISO/TS 16949 Supplemental

At ISO/TS 16949 facilities, FXI will prepare contingency plans to reasonably protect our customers' supply of product in the event of emergency, utility interruptions and labor shortages, excluding natural disasters or acts of God.

6.4 Work Environment

Each manufacturing plant of FXI identified in QAM 1.0, *Quality Program Scope* identifies and plans the production processes which directly affect quality and ensures that these processes are carried out under controlled conditions, which include the following:

- I. Documented procedures defining the manner of production where the absence of such procedures could adversely affect quality;
- II. Use of suitable production equipment and a suitable working environment.

QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 6.0
	REVISION 7	
SUBJECT: RESOURCE MANAGEMENT		

ISO 13485 Supplemental

- I. Each FXI facility establishes documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product.
- II. Each FXI facility establishes documented requirements if the work environment conditions can have an adverse effect on product quality. The requirements shall include:
 - a. Requirements for work environment conditions
 - b. Work instructions to monitor and control environmental conditions.
- III. Each FXI facility ensures that all personnel who are required to work temporarily under special environmental conditions with the work environment are appropriately trained or supervised by a trained person.
- IV. Each FXI facility, where appropriate, establishes and documents special arrangements for the control of contaminated or potentially contaminate product in order to prevent contamination of other product, the work environment or personnel.

6.4.1 Personnel Safety to Achieve Product Quality – ISO/TS 16949 Supplemental

- II. *FXI environmental, health and safety concerns are managed by the corporate EHS department.*
- II. *Safety goals are set for each facility and are monitored.*
- III. *FXI top management expects continuous improvement in meeting safety goals.*
- IV. *The facility managers are responsible for implementing and adhering to safety procedures.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 6.0
	REVISION 7	
SUBJECT: RESOURCE MANAGEMENT		

V. Product safety concerns are addressed from the design and development stage continuing through production process activities.

6.4.2 Cleanliness of Premises – *ISO/TS 16949 Supplemental*

Premises are maintained in a state of order, cleanliness and repair appropriate to the product manufactured.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

Reference:

- QCP 2.2, *Quality Planning*
- QCP 2.3, *Product Approval Process*
- QCP 3.1, *Contract Review*
- QCP 4.1, *Design Control*
- QCP 6.1, *Purchasing*
- QCP 7.1, *Control of Customer-Supplied Product*
- QCP 8.1, *Product Identification and Traceability*
- QCP 9.1, *Process Control*
- QCP 10.1, *Inspection and Testing*
- QCP 11.1, *Control of Inspection, test and Measurement Equipment*
- QCP 12.1, *Inspection and Test Status*
- QCP 13.1, *Control of Nonconforming Material*
- QCP 15.1, *Handling, Storage, Packaging, Preservation and Delivery*
- QCP 16.1, *Control of Quality Records*
- QCP 19.1, *Servicing*
- ISO/IEC 17025:1999 (E)
- [ISO 14971:2007\(E\)](#)
- APQP - Advanced Product Quality Planning and Control Plan Reference Manual
- PPAP - Production Part Approval Process Manual

7.1 Planning of Product Realization

- I. FXI has procedures to plan and develop the processes needed for product realization that are consistent with the other processes of the quality management system.
- II. FXI will determine the following, as appropriate:
 - A. Quality objectives and requirements for the product
 - B. The need to establish processes, documents, and provide resources specific to the product
 - C. Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance
 - D. Records needed to provide evidence that the realization processes and resulting product meet requirements.
- III. The output from this planning will be in a form suitable to the FXI method of operations.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

IV. **ISO 13485 Supplemental** – FXI has established documented requirements for Risk Management throughout product realization.

- A. The requirements for Risk Management are contained in Design Control and Quality Plan Procedures.
- B. Records arising from Risk Management shall be maintained according to Design Control and Quality Plan Procedures.

V. A document specifying the processes of the quality management system and the resources to be applied to a specific product, project or contract, can be referred to as a quality plan.

7.1.1 Planning of Product Realization – ISO/TS 16949 Supplemental

Customer requirements and references to their technical specifications are included in the planning of product realization as a component of the FXI Advanced Product Quality Planning procedure.

7.1.2 Acceptance Criteria – ISO/TS 16949 Supplemental

FXI defines acceptance criteria for all products during Advanced Product Quality Planning and, where required, obtains approval from the customer. The acceptance level goal for attribute data sampling is zero defects.

7.1.3 Confidentiality – ISO/TS 16949 Supplemental

FXI will ensure that confidentiality of customer-contracted products and projects under development and related product information.

7.1.4 Change Control – ISO/TS 16949 Supplemental

- I. *FXI has procedures to control and react to changes that impact the product realization process.*
- II. *FXI will evaluate the effects of any change, including supplier changes.*
- III. *Verification and validation procedures will be defined to ensure*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

compliance with customer requirements. Changes will be validated before implementation.

- IV. For proprietary designs, impact on fit, form or function (including performance and durability) is reviewed with the customer so that all effects can be properly evaluated.*
- V. When customers require additional verification / identification of the effect of change, FXI will comply. This may include new product introduction requirements.*
- VI. Any product realization change affecting customer requirements requires notification to, and agreement from, the customer.*
- VII. This applies to both product and manufacturing process changes.*

7.2 Customer-Related Processes

7.2.1 Determination of Requirements Related to the Product

- I. FXI will determine the following:
 - A. Customer requirements, including delivery and post-delivery activities, such as after sales product service per contract or purchase order.
 - B. Requirements not stated by the customer, but necessary for specified or intended use, where known. This includes recycling, environmental impact and characteristics identified as a result of FXI's knowledge of the product and manufacturing processes.
 - C. Statutory and regulatory requirements related to the product including all government, safety and environmental regulations, applied to acquisition, storage, handling, recycling, elimination or disposal of materials.
 - D. Internal FXI additional requirements.

7.2.1.1 Customer-Designated Special Characteristics– ISO/TS 16949 Supplemental

FXI will demonstrate conformity to customer requirements for



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

designation, documentation and control of special characteristics.

7.2.2 Review of Requirements Related to the Product

- I. FXI will review requirements related to the product prior to the commitment to supply a product to the customer.
 - A. **ISO 13485 Supplemental** – Product requirements shall be defined and documented.
- II. Submission of tenders, acceptance of contracts or orders and changes to contracts or orders will ensure that:
 - A. product requirements are defined
 - B. contract / order requirements differing from those previously expressed are resolved.
 - C. FXI has the ability to meet the defined requirements
- III. Records of contract review actions and results will be maintained.
- IV. If a customer does not provide documented requirements, FXI will confirm requirements with the customer before acceptance of the order.
- V. Where product requirements are changed, FXI will ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.2.1 Review of Requirements Related to the Product – ISO/TS 16949 Supplemental

FXI will obtain customer authorization if waiving the formal review of every contract and order.

7.2.2.2 Organization Manufacturing Feasibility – ISO/TS 16949 Supplemental

FXI will perform, document and confirm manufacturing feasibility of the proposed products in the contract review process, including risk analysis.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

7.2.3 Customer Communication

- I. FXI 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
 - D. **ISO 13485 Supplemental – advisory notices**

7.2.3.1 Customer Communication – **ISO/TS 16949 Supplemental**

FXI has the ability, as appropriate, to communicate necessary information, including data, in a customer-specified language and format. This includes computer-aided design data and electronic data exchange.

7.3 Design and Development

FXI uses the procedures for process and product design and development to focus on error prevention rather than detection.

ISO 13485 Supplemental – The procedures used for design and development of medical devices within FXI shall be documented

7.3.1 Design and Development Planning

- I. FXI plans and controls the design and development of a product.
- II. During design and development planning FXI determines:
 - A. the design and development stages
 - B. the review, verification, validation, and design transfer activities that are appropriate for each design and development stage
 1. Design transfer activities ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.
 - C. the responsibilities and authorities for design and development



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- III. FXI manages the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
- IV. Planning output is documented and updated, as appropriate, as the design and development progresses.

7.3.1.1 Multidisciplinary Approach – ISO/TS 16949 Supplemental

- I. *FXI uses a multidisciplinary approach to prepare for product realization, including:*
 - A. *development / finalization and monitoring special characteristics*
 - B. *development and review of FMEA's, including actions to reduce potential risks, and*
 - C. *development and review of control plans.*
- II. *Multidisciplinary approach usually includes design, sales, manufacturing, engineering, quality, production and other appropriate personnel.*

7.3.2 Design and Development Inputs

- I. Inputs relating to product requirements are determined and records maintained.
- II. Inputs include:
 - A. Functional, performance, and safety requirements according to the intended use,
 - B. applicable statutory and regulatory requirements,
 - C. where applicable, information derived from previous similar designs,
 - D. other requirements essential for design and development
 - E. requirements to control special characteristics
 - F. **ISO 13485 Supplemental - output(s) of risk management**
- III. Inputs are reviewed for adequacy and approved.
- IV. Requirements must be complete, unambiguous and not conflicting.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

7.3.2.1 Product Design Input – ISO/TS 16949 Supplemental

- I. *FXI identifies, documents and reviews the product design input requirements, including:*
 - A. *customer requirements (contract review) such as special characteristics identification, traceability and packaging.*
 - B. *use of information from previous design projects, competitor analysis, supplier feedback, internal input, field data, and other relevant sources, for current and future projects of a similar nature.*
 - C. *targets for quality, life, reliability, durability, maintainability, timing and cost.*

7.3.2.2 Manufacturing Process Design Input – ISO/TS 16949 Supplemental

- I. *FXI identifies, documents and reviews the manufacturing process design input requirements, including:*
 - A. *product design output data*
 - B. *targets for productivity, process capability and cost*
 - C. *customers requirements, if any, and*
 - D. *experience for previous developments.*
- II. *The manufacturing process design includes the use of error-proofing methods to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.*

7.3.2.3 Special Characteristics – ISO/TS 16949 Supplemental

- I. *FXI identifies special characteristics and*
 - A. *includes all special characteristics in the control plan,*
 - B. *complies with customer-specified definitions and symbols,*
 - C. *identifies process control documents including:*
 1. *drawings*
 2. *PFMEA's*
 3. *Control plans*

QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

4. *Operator instructions (SOP's) with the customer's special characteristic symbol or FXI's equivalent symbol or notation to include those process steps that affect special characteristics.*

II. *Special characteristics can include product characteristics and process parameters.*

7.3.3 Design and Development Outputs

I. Outputs of design and development will be in a format that can be verified against the design and development inputs and approved prior to release.

II. Outputs of design and development will:

- A. meet the input requirements for design and development,
- B. provide appropriate information for purchasing, production and, if applicable, for service provision,
- C. contain or reference product acceptance criteria, and
- D. specify the characteristics of the product that are essential for its safe and proper use.

III. **ISO 13485 Supplemental** – Records of the design and development output shall be maintained. These records can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.

7.3.3.1 Product Design Outputs – ISO/TS 16949 Supplemental

I. *Product design outputs must be expressed in terms that can be verified and validated against inputs to include:*

- A. *design FMEA, reliability results,*
- B. *product special characteristics and specifications,*
- C. *product error-proofing, as appropriate,*
- D. *product definition including drawings or mathematically based data,*
- E. *product design review results, and*
- F. *diagnostic guidelines where applicable.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

7.3.3.2 Manufacturing Process Design Output – ISO/TS 16949 Supplemental

- I. *Manufacturing process design output must be expressed in terms that can be verified and validated against inputs to include:

 - A. specifications and drawings,
 - B. flow chart / layout for process,
 - C. process FMEA's,
 - D. control plan,
 - E. work instructions,
 - F. process approval acceptance criteria,
 - G. data for quality, reliability, maintainability and measureability,
 - H. results of error-proofing activities, as appropriate, and,
 - I. methods of rapid detection and feedback of product/manufacturing process nonconformities.*

7.3.4 Design and Development Review

- I. FXI will perform systematic reviews of design and development in accordance with planned arrangements to evaluate the ability of the results of design and development to meet requirements and to identify any problems and propose necessary actions.
- II. Participants in such reviews include representatives of functions concerned with the design and development stages being reviewed, as well as other specialist personnel.
- III. Reviews are normally coordinated with the design phases and include manufacturing process design and development.
- IV. Records of the results of the reviews and any necessary actions are maintained per QCP 16.1, *Control of Quality Records*.

7.3.4.1 Monitoring – ISO/TS 16949 Supplemental

- I. *Measurements at specified stages of design and development are defined, analyzed and reported with summary results as an input to management review.*

QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

II. These measurements include quality risks, costs, lead-times, critical paths and others, as appropriate.

7.3.5 Design and Development Verification

Verification is performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of results and actions are maintained.

7.3.6 Design and Development Validation

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

- II. The validation process includes an analysis of field reports for similar products.

- III. Verification and validation activities apply to both product and manufacturing processes.

- IV. ISO 13485 Supplemental
 - a. Validation shall be completed prior to the delivery or implementation of the product.
 - b. As part of validation, FXI shall perform clinical evaluations and/or evaluation of performance of the medical device, as required by national or regional regulations.
 - c. If a device can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been accepted by the customer.
 - d. Providing the device for the purpose of clinical evaluations and/or evaluation of performance is not considered to be delivery



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

7.3.6.1 Design and Development Validation – ISO/TS 16949 Supplemental

Design and development validation is performed in accordance with customer requirements including program timing.

7.3.6.2 Prototype Program – ISO/TS 16949 Supplemental

- I. *When required by the customer, FXI will have a prototype program and control plan.*
- II. *FXI will use, whenever possible, the same suppliers, tooling and manufacturing processes as will be used in production.*
- III. *All performance-testing activities are monitored for timely completion and conformity to requirements.*
- IV. *FXI is responsible for the performance of outsourced Services, including technical leadership.*

7.3.6.3 Product Part Approval Process – ISO/TS 16949 Supplemental

- I. *FXI conforms to a product and manufacturing process approval procedure recognized by the customer.*
- II. *Product approval should be subsequent to the verification of the manufacturing process.*
- III. *This product and manufacturing process approval procedure will also be applied to key suppliers.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	

SUBJECT: PRODUCT REALIZATION

7.3.7 Control of Design and Development Changes

- I. Design and development changes are identified and records maintained for the life of the part or program.
- II. Changes are reviewed, verified, validated, as appropriate, and approved before implementation.
- III. Review of design and development changes include evaluation of the effect of the changes on constituent parts and product already delivered.
- IV. Records of the results of the review of changes and actions taken are maintained.

7.3.8 Design Transfer - ISO 13485 Supplemental

- I. Procedures shall be established and maintained to ensure that the medical device design is correctly translated into production specifications.

7.3.9 Design History File - ISO 13485 Supplemental

- I. A Design History File (DHF) shall be established and maintained for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements for the part.

7.4 Purchasing

7.4.1 Purchasing Process

- I. FXI ensures that purchased product and services conform to specified purchase requirements.
 - a. **ISO 13485 Supplemental** – FXI has documented procedures to ensure that purchased product conforms to specified purchase requirements.
- II. Control of suppliers will be proportional to the effect of the purchased product on the product realization or the final product of FXI.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- III. FXI evaluates and selects suppliers based on their ability to supply products to meet the requirements of FXI.
- IV. Criteria for selection, evaluation and re-evaluation is established and records of the results of evaluation and actions are maintained.
- V. Purchased products include all products and services that affect customer requirements, such as subassembly, sequencing, sorting, rework and calibration services.
- VI. When there are mergers, acquisitions or affiliations associated with suppliers, FXI may verify the continuity of the supplier's quality management system and it's effectiveness.

7.4.1.1 Regulatory Conformity – ISO/TS 16949 Supplemental

All purchased products and materials conform to applicable regulatory requirements.

7.4.1.2 Supplier Quality Management System Development – ISO/TS 16949 Supplemental

- I. FXI performs supplier quality management system development activities with the goal of supplier conformity to ISO 9001:2008 as a first-step, and further goal of conformity to with ISO/TS 16949.*
- II. Supplier's quality performance and the importance of their product to the products manufactured at FXI will determine the priority of development activities.*
- III. Unless otherwise specified by the customer of FXI, suppliers must be third-party registered to ISO 9001:2008 by an accredited third-party certification body.*

7.4.1.3 Customer-Approved Sources – ISO/TS 16949 Supplemental

- I. Where specified by the contract, drawing or specification,*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

FXI will purchase products, materials or services from approved sources.

II. FXI is still responsible for ensuring the quality of product or services that are sourced as specified by the customer.

7.4.2 Purchasing Information

- I. Purchasing information describes the product to be purchased including, where applicable:
 - A. requirements for approval of product, procedures, processes and equipment,
 - B. requirements for qualification of personnel, and
 - C. quality management system requirements.
- II. FXI shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.
- III. **ISO 13485 Supplemental** – To the extent required for traceability, FXI shall maintain relevant purchasing information, i.e. documents and records.

7.4.3 Verification of Purchased Product

- I. FXI ensures purchased materials meet specified requirements.
- II. If FXI, or the customers of FXI intend to perform verification at the supplier's facility, FXI will state the intended verification arrangements and method of product release in the purchasing documentation.
- III. Records of Verification shall be maintained per QCP 16.1, *Control of Quality Records*.

7.4.3.1 Incoming Product Quality – ISO/TS 16949 Supplemental

- I. *FXI assures quality of purchased product using one of the following methods:*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- A. receipt of, and evaluation of, statistical data by supplier;
- B. receiving inspection and/or testing such as sampling based on performance;
- C. second- or third-party assessments or audits of supplier sites, when coupled with records of acceptable delivered product quality;
- D. part evaluation by a designated laboratory;
- E. another method agreed with the customer.

7.4.3.2 Supplier Monitoring – ISO/TS 16949 Supplemental

- I. FXI monitors supplier performance through the following indicators:
 - A. delivered product quality;
 - B. customer disruptions including field returns;
 - C. delivery schedule performance including incidents of premium freight;
 - D. special status customer notifications related to quality or delivery issues.
- II. FXI encourages its suppliers to monitor the performance of their manufacturing processes by reviewing their process data.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

- I. FXI plans and carries out production under controlled conditions that shall include as applicable
 - A. The availability of information that describes product characteristics,
 - B. The availability of work instructions, as necessary
- **ISO 13485 Supplemental** – The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- C. Use of suitable equipment,
- D. The availability and use of monitoring and measurement devices,
- E. The implementation of monitoring and measurement, and
- F. The implementation of release, delivery and post-delivery activities.
- G. **ISO 13485 Supplemental** – The implementation of defined operations for labeling and packaging

II. **ISO 13485 Supplemental** – FXI shall establish and maintain a record for each batch of medical devices that provide traceability to the extent required and identifies the amount manufactured and amount approved for distribution.

- A. The batch record shall be identified and approved, even if the batch is a single device.

7.5.1.1 **Control Plan – ISO/TS 16949 Supplemental**

- I. *FXI develops control plans at the system, subsystem, component and material level for the product supplied, including those for processes producing bulk materials as well as parts.*
- II. *FXI has control plans for pre-launch and production that takes into account the design FMEA and manufacturing process FMEA outputs.*
- III. *The Control plan:*
 - A. *lists the controls used for the manufacturing process control,*
 - B. *includes methods for monitoring of control exercised over special characteristics defined by both the customer and the organization,*
 - C. *includes customer required information, if any, and*
 - D. *initiates the reaction plan when the process becomes unstable or not statistically capable.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- IV. *Control plans are reviewed and updated when changes occur affecting product, manufacturing process, measurement, logistics, supply sources or FMEA.*
- V. *Customer approval will be obtained, if required, after review or update of the control plan.*

7.5.1.2 Work Instructions – ISO/TS 16949 Supplemental

- I. *FXI maintains documented work instructions for the operation of all processes that impact product quality.*
- II. *These are accessible for use at the work station.*
- III. *Work instructions are derived from sources such as the quality plan, control plan and the product realization process.*

7.5.1.3 Verification of Job Set-ups – ISO/TS 16949 Supplemental

- I. *Jobs set-ups are verified whenever performed, such as an initial run of a job, material changeover or job change.*
- II. *Work instructions are available for set-up personnel.*
- III. *If applicable, FXI will use statistical methods of verification.*
- IV. *Last-off part comparisons are recommended.*

7.5.1.4 Preventive and Predictive Maintenance – ISO/TS 16949 Supplemental

- I. *FXI identifies key process equipment and provides resources for machine / equipment maintenance and develops an effective planned total preventive maintenance system. At a minimum, this system includes the following:*
 - A. *planned maintenance activities,*
 - B. *packaging and preservation of equipment, tooling and gauging,*
 - C. *availability of replacement parts for key manufacturing equipment,*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

D. documenting, evaluating and improving maintenance objectives

II. FXI will use predictive maintenance methods to improve the effectiveness and efficiency of production equipment.

7.5.1.5 Management of Production Tooling – ISO/TS 16949 Supplemental

I. FXI provides resources for tool and gauge design, fabrication and verification activities.

II. FXI established and maintains a system for production tooling management including:

- A. maintenance and repair facilities and personnel,*
- B. storage and recovery,*
- C. set-up,*
- D. tool-change programs for perishable tools,*
- E. tool design modification documentation, including engineering change level,*
- F. tool modification and revision to documentation*
- G. tool identification, defining the status, such as production, repair or disposal.*

III. FXI has implemented a system to monitor these activities if any work is outsourced and includes availability of tools for vehicle service parts.

7.5.1.6 Production Scheduling – ISO/TS 16949 Supplemental

FXI schedules production to meet customer requirements, such as just-in-time and is supported by an information system that permits access to production information at key stages of the process and is order driven.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

7.5.1.7 Feedback of Information from Service – ISO/TS 16949 Supplemental

FXI maintains records of service concerns such as nonconforming material found in the field to the manufacturing, engineering and design activities.

7.5.1.8 Service Agreement with Customer – ISO/TS 16949 Supplemental

FXI does not service product post-delivery for non-medical device products.

7.5.1.9 Control of Production and Service Provision – ISO 13485 Supplemental

7.5.1.9.1 Cleanliness of Product and Contamination Control

FXI shall establish documented requirements for cleanliness of product if

- a. The product is cleaned by FXI prior to sterilization and/or its use, or
- b. The product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and/or its use, or
- c. The product is supplied to be used non-sterile and its cleanliness is of significance in use, or
- d. Process agents are to be removed from the product during manufacturing

If the product is cleaned in accordance with “a” or “b” then the requirements of Paragraphs 6.4 I and 6.4 II do not apply prior to the cleaning process.

7.5.1.9.2 Installation Activities



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

FXI, when appropriate, documents the requirements of the acceptance criteria for installing and verifying the installation of its medical device products.

If the agreed to customer requirements allow installation to be performed other than by FXI or its authorized agent, FXI shall provide the documented requirements for installation and verification.

Records of installation and verification performed by FXI or its authorized agent are maintained according to *QCP 16.1, Control of Quality Records*.

7.5.1.9.3 Servicing Activities

When servicing of a medical device product is a specified requirement, FXI shall establish documented procedures, work instructions and reference materials, and reference measurement procedures as necessary for performing servicing activities and verifying that they meet the specified requirements.

Records of servicing activities performed by FXI are maintained according to *QCP 16.1, Control of Quality Records*.

7.5.1.10 Particular Requirements for Sterile Medical Devices – ISO 13485 Supplemental

FXI does not manufacture or distribute sterile medical devices. Therefore this requirement is not applicable. See Paragraph 4.2.2-III-B



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

7.5.2 Validation of Processes for Production and Service Provision

- I. FXI will validate any process for production where the resulting output cannot be verified by subsequent monitoring or measurement.
- II. This includes any processes where deficiencies become apparent only after the product is in use.
- III. Validation demonstrates the ability of these processes to achieve planned results.
- IV. FXI has established the following arrangements for these processes, 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.
- V. **ISO 13485 Supplemental** - Validation shall include documented procedures for the validation of the application of computer software, changes to the software, and/or its application, for production and service provisions
- VI. **ISO 13485 Supplemental** - Validation records shall be maintained according to *QCP 16.1, Control of Quality Records*.

7.5.2.1 Validation of Processes for Production and Service Provision – **ISO/TS 16949 Supplemental**

Requirements of 7.5.2, applies to all processes for production.

7.5.3 Identification and Traceability

- I. FXI will identify the product by suitable means throughout product realization, where appropriate.
- II. FXI identifies the product status with respect to monitoring and measurement requirements.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- III. FXI controls and records the unique identification of the product.
- IV. Inspection and test status is not indicated by the location of the product in the production flow unless inherently obvious, such as material in an automated production transfer process. Alternatives are permitted, if the status is clearly identified, documented and serves the designated purpose.

7.5.3.1 Identification and Traceability – ISO/TS 16949 Supplemental

FXI must always identify product by suitable means in production.

7.5.3.2 Identification – ISO 13485 Supplemental

FXI identifies product by suitable means throughout its processes and has documented the procedures for its identification.

7.5.3.3 Traceability – ISO 13485 Supplemental

7.5.3.3.1 General

FXI has established documented procedures for traceability. These procedures define the extent of product traceability and the records required.

7.5.3.3.2 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices

FXI does not manufacture or distribute active implantable medical devices or implantable medical devices. Therefore this requirement is not applicable. See Paragraph 4.2.2-III-B



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

7.5.3.4 Status Identification – ISO 13485 Supplemental

FXI identifies the product status with respect to monitoring and measuring requirements.

The identification of product status is maintained throughout production, storage, installation, and servicing of the product to insure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used, or installed.

7.5.4 Customer Property

- I. FXI exercises care with customer property and identifies, verifies, protects and safeguards customer property provided for FXI's use.
- II. If any property is lost, damaged or otherwise found to be unsuitable for use, FXI will report this to the customer and records will be maintained.
- III. Customer-owned property can include intellectual property and returnable packaging.
- IV. FXI safeguards supplier-owned property in the same manner.

7.5.4.1 Customer-Owned Production Tooling – ISO/TS 16949 Supplemental

Customer owned tools, manufacturing, test, inspection tooling and equipment is permanently marked so that the ownership of each item is visible and can be determined.

7.5.5 Preservation of Product

- I. FXI will preserve the conformity of product during internal processing and delivery to the intended destination.
- II. This preservation includes identification, handling, packaging, storage and protection.
- III. Preservation also applies to constituent parts of a product.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

IV. **ISO 13485 Supplemental** – FXI documents the procedures and work instructions for preserving the conformity of product during internal processing and delivery to the intended destination.

V. **ISO 13485 Supplemental** – FXI documents the procedures and work instructions for the control of product with limited shelf life or requiring special storage conditions. These conditions are controlled, recorded and maintained according to QCP 16.1, Control of Quality Records.

7.5.5.1 Storage and Inventory – ISO/TS 16949 Supplemental

- I. *The condition of inventory will be assessed at appropriate planned intervals to detect deterioration.*
- II. *FXI has an inventory management system to optimize inventory turns over time and assure stock rotation, such as FIFO (first-in-first-out).*
- III. *Obsolete product is controlled in a similar manner as nonconforming product. (See 8.3)*

7.6 Control of Monitoring and Measuring Devices

- I. FXI determines the monitoring and measurement methods and devices needed to provide evidence of conformity of product to determined requirements.
- II. FXI has established processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measuring requirements.
 - **ISO 13485 Supplemental** – These processes shall be documented.
- III. Where necessary to ensure valid results, measuring equipment is:
 - A. calibrated or verified at specified intervals, or prior to use, against standards traceable to international or national measurement standards;
 - i. where no such standards exist, the basis used for calibration or verification is recorded;
 - B. adjusted or re-adjusted, as necessary;

QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- C. identified to enable the calibration status to be determined;
 - D. safeguarded from adjustments that would invalidate the measurement result;
 - E. protected from damage and deterioration during handling, maintenance and storage.
- IV. A number or other identifier traceable to the device calibration record meets the Intent of requirement C, above.
 - V. FXI shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements.
 - VI. FXI will take appropriate action on the equipment and any product affected.
 - VII. Records of the results of calibration and verification are maintained.
 - VIII. When software is used in the monitoring and measurement of specified requirements, it will be confirmed to satisfy the intended application. This will be undertaken prior to initial use and reconfirmed as necessary.

7.6.1 Measurement System Analysis – ISO/TS 16949 Supplemental

- I. Statistical studies are conducted to analyze the variation present in the results of each type of measuring and test equipment system.*
- II. This requirement shall apply to measurement systems referenced in the control plan.*
- III. The analytical methods and acceptance criteria used conforms to those in customer reference manuals on measurement systems analysis.*
- IV. Other analytical methods and acceptance criteria may be used if approved by the customer.*

7.6.2 Calibration / Verification Records – ISO/TS 16949 Supplemental

- I. Records of calibration / verification activity for all gauges, measuring and test equipment to provide evidence of conformity of product to determined requirements, including employee-owned and customer-owned equipment includes:*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

- A. *equipment identification, including the measurement standard against which the equipment is calibrated.*
- B. *revisions following engineering changes,*
- C. *any out-of-specification readings as received for calibration / verification,*
- D. *an assessment of the impact of out-of-specification condition,*
- E. *statements of conformity to specification after calibration / verification,*
- F. *notification to the customer if suspect product or material has been shipped.*

7.6.3 Laboratory Requirements – ISO/TS 16949 Supplemental

7.6.3.1 Internal Laboratory

- I. *FXI's internal laboratory facilities have defined scopes to include their capability to perform the required inspection, test or calibration services.*
- II. *The laboratory scope is included in the Quality Management System documentation.*
- III. *The laboratory specifies and implements, as a minimum, technical requirements for:*
 - A. *adequacy of the laboratory procedures,*
 - B. *competency of the laboratory personnel,*
 - C. *testing of the product,*
 - D. *capability to perform these services correctly, traceable to the relevant process standard (such as ASTM, EN, etc.), and*
 - E. *review of the related records.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 7.0
	REVISION 7	
SUBJECT: PRODUCT REALIZATION		

IV. Accreditation to ISO/IEC 17025 may be used to demonstrate supplier in-house laboratory conformity to this requirement but is not mandatory.

7.6.3.2 External Laboratory

- I. External / commercial / independent laboratory facilities used for inspection, test or calibration services have a defined laboratory scope that includes the capability to perform the required inspection, test and calibration, and either:

 - A. there is evidence that the external laboratory is acceptable to the customer, or*
 - B. the laboratory is accredited to ISO/IEC 17025, or national equivalent.**
- II. Such evidence may be demonstrated by customer assessment, for example, or by customer-approved second-party assessment that the laboratory meets the intent of the ISO/IEC 17025, or national equivalent.*
- III. When a qualified laboratory is not available for a given piece of equipment, calibration services may be performed by the equipment manufacturer. In such cases, FXI will ensure that the requirements listed in 7.6.3.1 have been met.*

QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

References

- QCP 2.4, *Continuous Improvement*
- QCP 10.1, *Inspection and Testing*
- QCP 13.1, *Control of Nonconforming Product*
- QCP 14.1, *Corrective and Preventive Action*
- QCP 16.1, *Control of Quality Records*
- QCP 17.1, *Internal Quality Audits*
- QCP 20.1, *Statistical Techniques*

8.1 General

- I. FXI plans and implements the monitoring, measurement, analysis and improvement processes needed to:
 - A. Demonstrate conformity of the product to internal and/or customer requirements.
 - B. Ensure conformity of the quality management system
 - C. Maintain and then Continually improve the effectiveness of the quality management system

- II. FXI shall plan and establish applicable methods of measurement and statistical techniques and determine the extent of their use for all quality system processes as well as incoming materials, work-in-process and final product.

- III. **ISO 13485 Supplemental** – National or regional regulations might require documented procedures for implementation and control of the application of statistical techniques.

8.1.1 Identification of Statistical Tools – **ISO/TS 16949 Supplemental**

Appropriate statistical tools for each process are determined during the Advance Product Quality Planning and are included in the Control Plan and/or documented procedures.

8.1.2 Knowledge of Basic Statistical Concepts– **ISO/TS 16949 Supplemental**

Basic statistical concepts, such as variation, control (stability), process capability and over-adjustment must be understood and utilized throughout the organization.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	

SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction / Feedback

- I. The method used to determine current and future customer expectations is called Voice of the Customer.
- II. A process / method for determining customer satisfaction, perception of FXI meeting their requirements and key indicators of customer dissatisfaction is developed, implemented and supported by objective information. Consideration may be given to both internal and external customers.
- III. Monitoring customer perception can include obtaining input from sources such as:
 - a. Customer satisfaction surveys
 - b. Customer data on delivered product quality
 - c. User opinion surveys
 - d. Lost business analysis
 - e. Complements
 - f. Warranty claims
 - g. Dealer reports
- IV. **ISO 13485 Supplemental** – A documented feedback system exists to provide early warning of quality problems and for input into the corrective and preventive action processes.
- V. **ISO 13485 Supplemental** – If national or regional regulations require FXI to gain experience from the post-production phase, the review of the experience shall form part of the feedback system.

8.2.1.1 Customer Satisfaction – ISO/TS 16949 Supplemental

- I. *Customer satisfaction is monitored through continual evaluation of the realization processes. Performance indicators are based on objective data and include, but not be limited to:*
 - A. *Delivered part quality performance*
 - B. *Customer disruptions including field returns*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	

SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT

- C. *Delivery schedule performance including incidents of premium freight*
 - D. *Customer notifications related quality or delivery issues*
- II. *FXI monitors the performance of the manufacturing processes to demonstrate compliance with customer requirements for product quality and efficiency of the process.*

8.2.2 Internal Audit

- I. This section describes the requirements for planning and implementing internal quality audits to determine the effectiveness of the Quality Management System.
- II. Documented procedures are established and maintained for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and determine the effectiveness of the Quality Management System.
- III. A complete Quality Management System audit is performed at least annually.
- IV. Audits are scheduled on the basis of the status and importance of the activity being audited and results of previous audits. Audit criteria, scope, frequency and methods are defined.
- V. Audits are conducted by personnel independent of those having direct responsibility for the activity being audited.
- VI. Results of the audits are recorded and maintained in accordance with QCP 16.1, *Control of Quality Records*, and provided to management personnel responsible for the area audited.
- VII. Management personnel responsible for the area take timely corrective action on the deficiencies found during the audit.
- VIII. Implementation and effectiveness of the corrective action taken is verified and recorded through follow-up audit activities.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

- IX. Results of internal quality audits are an integral part of the input to management review activities in accordance with QAM 5.0, *Management Responsibility*.

8.2.2.1 Quality Management System Audit – ISO/TS 16949 Supplemental

FXI internal auditors audit the quality management system to verify compliance with requirements of ISO/TS 16949:2009, ISO 9001:2008, and/or customer specific quality system requirements.

8.2.2.2 Manufacturing Process Audit – ISO/TS 16949 Supplemental

FXI internal auditors audit each manufacturing process to determine its effectiveness

8.2.2.3 Product Audit – ISO/TS 16949 Supplemental

At defined frequencies, internal auditors audit products at appropriate stages of production and delivery. They verify conformance to all specified requirements, including product dimensions, functionality, packaging and labeling.

An audit of a product family can serve as a product audit.

8.2.2.4 Internal Audit Plans – ISO/TS 16949 Supplemental

- I. *The internal audit schedule is an annual plan that covers all quality management system related processes, activities and shifts.*
- II. *Internal or external nonconformities, or customer complaints will determine the frequency of audits of specific processes.*
- III. *Checklists should be used for each audit.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

8.2.2.5 Internal Auditor Qualification – ISO/TS 16949 Supplemental

FXI internal auditors are trained to ensure qualification to audit to the requirements of ISO/TS 16949.

8.2.3 Monitoring and Measurement of Processes

FXI will monitor and measure all processes affecting quality through the use of quality metrics, goals, objectives, and/or the internal audit process, to determine the ability of the processes to meet customer requirements and achieve planned results.

If a process fails to achieve planned results, corrective action will be initiated to ensure conformity of the product.

8.2.3.1 Monitoring and Measurement of Manufacturing Processes – ISO/TS 16949 Supplemental

A. FXI performs process studies on all new manufacturing processes to verify process capability and to provide additional input for process control.

Process documentation will include:

- i. Specifications, internal or, if applicable, customer*
- ii. Means of production*
- iii. Measurement and test criteria*
- iv. Maintenance instructions, repair and preventive*
- v. Objectives for manufacturing process capability per customer PPAP, if required*
- vi. Reliability*
- vii. Availability*
- viii. Maintainability*
- ix. Acceptance criteria*

B. FXI maintains manufacturing process capability and performance as



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	

SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT

specified by the customer PPAP requirements. Control plans and process flow diagrams are implemented, including adherence to the specified:

- A. Measurement techniques*
 - B. Sampling plans*
 - C. Acceptance criteria*
 - D. Reactions plans when acceptance criteria are not met*
- C. Effective dates of significant process events and changes, such as tool change or machine repairs will be recorded.*
- D. FXI will initiate a reaction plan from the control plan for characteristics that are either not statistically capable or are unstable.*
- A. Reaction plans include product containment activities and 100% inspection as appropriate with a corrective action plan completed to document activities (timing and assigned responsibilities) to assure that the process develops into a stable and capable process.*
 - B. FXI will keep customers informed of these activities for review and approval when so required.*

8.2.4 Monitoring and Measurement of Product

- I. Each manufacturing facility of FXI identified in QAM 1.0, *Quality Program Scope* establishes and maintains documented procedures for inspection and testing activities at appropriate steps of product realization in order to verify that the specified requirements are met according to planned arrangements and documented procedures.
- II. Required inspection and testing and the records to be established are detailed in the Control Plan or documented procedures.
- III. Evidence of conformity to the acceptance criteria is maintained and records indicate the person(s) authorizing release of product.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

- IV. Product is not released until all planned arrangements are completed satisfactorily unless approved by a relevant authority and where applicable by the customer.
- E. When selecting product parameters to monitor compliance to specified internal and external requirements, FXI determines the types of product characteristics, leading to the types of measurement, method of measurement and capability and skills required.

8.2.4.1 Layout Inspection and Functional Testing – ISO/TS 16949 Supplemental

Layout inspection and functional verification to customer engineering and performance standards by ISO/TS 16949 facilities are performed for all products as specified in the control plans at a frequency established by the customer in writing or in the purchase order confirmation.

8.2.4.2 Appearance Items – ISO/TS 16949 Supplemental

- I. Acceptance criteria for attribute data (appearance items) and sampling plans are determined according to customer requirements or internal standards. Appropriate acceptance criteria for all situations (e.g. visual standards) is documented and approved by the customer.*
- II. FXI will provide resources to include lighting and masters for visual inspections.*
 - a. Masters for color, grain, gloss, metallic brilliance, texture, distinctness of image (DOI), as appropriate.*
- III. FXI will ensure the maintenance and control of visual inspection masters and evaluation equipment.*
- IV. FXI will train personnel making appearance evaluations to verify that they are competent and qualified.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

8.2.4.3 Particular Requirements for Active Implantable Medical Devices and Implantable Medical Devices – ISO 13485 Supplemental

FXI does not manufacture or distribute active implantable medical devices or implantable medical devices. Therefore this requirement is not applicable. See Paragraph 4.2.2-III-B

8.3 Control of Nonconforming Product

- I. FXI ensures that product which does not conform to product requirements is identified and controlled to prevent its intended use or delivery.
- II. Documented procedures exist to ensure that nonconforming product is prevented from unintended use or shipment.
- III. The procedures identify the controls, responsibility and authorities for dealing with nonconforming product.
- IV. When nonconforming product is identified, a material review is conducted and disposition authorized, as follows:
 - A. Rework and reverified to meet specified requirements
 - a. **ISO 13485 Supplemental** – FXI uses a documented procedure for rework that has been controlled according to standard plant review, approval, and distribution procedures for the original product work instructions. The impact of any adverse effect of the rework upon the product has been made and documented prior to authorization and approval of the procedure.
 - B. Accept with/without repair by concession
 - C. Regrade for alternate applications
 - D. Reject or scrap
- V. The proposed use or repair of nonconforming product is reported for concession to the customer, or representative, as required by contract.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

A. **ISO 13485 Supplemental** – The proposed use of nonconforming product is accepted for concession only if regulatory requirements are met. Records of the identity of the person(s) authorizing the concession shall be maintained and included in the nonconforming material records kept in accordance with QCP 16.1, Control of Quality Records.

- VI. Nonconforming product is analyzed and quantified in order to establish a prioritized reduction / elimination plan. The progress towards the plan is recorded by the plants on an individual basis.
- VII. Material shipped on an authorization is to be properly identified.
- VIII. Records of nonconforming material will be kept in accordance with QCP 16.1, *Control of Quality Records*.
- IX. If nonconformity is discovered after delivery or use has started, FXI will take action appropriate to the effects, or potential effects, of the nonconformity.

8.3.1 Control of Nonconforming Product – ISO/TS 16949 Supplemental

Procedures are applicable to suspect as well as nonconforming product.

8.3.2 Control of Reworked or Regraded Product – ISO/TS 16949 Supplemental

Instructions for reinspection requirements and reworked or regraded product are accessible to and utilized by the appropriate personnel.

8.3.3 Customer Information – ISO/TS 16949 Supplemental

Customers will be informed promptly if nonconforming material has been shipped.

8.3.4 Customer Waiver – ISO/TS 16949 Supplemental

- I. *FXI will obtain a customer concession or deviation permit prior to further processing whenever the product or manufacturing process is different from that which is currently approved.*
- II. *FXI will maintain a record of the expiration date or quantity authorized.*



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	

SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT

- III. FXI will also ensure compliance with the original or superseding specifications and requirements when the authorization expires.*
- IV. Material shipped on an authorization will be properly identified on each shipping container.*
- V. This policy applies equally to purchased product. FXI will agree with requests from suppliers before submission to the customer.*

8.4 Analysis of Data

- I. FXI determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system.

ISO 13485 Supplemental – The above actions are taken according to documented procedures.

- II. Evaluations are made to determine where continual improvement of the effectiveness of the quality management system can be made. This includes data generated as a result of monitoring and measurement and from other relevant sources.
- III. The analysis of data provides information relating to:
 - A. Customer satisfaction / Feedback
 - B. Conformity to product requirements
 - C. Characteristics and trends of processes and products including opportunities for preventive action
 - D. Supplier management

NOTE: The AIAG Statistical Process Control reference manual is used as a guide for performing statistical techniques.

ISO 13485 Supplemental – Records of the results of the analysis of data shall be maintained according to QCP 16.1, Control of Quality Records.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	

SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT

8.4.1 Analysis and Use of Data – ISO/TS 16949 Supplemental

- I. *Trends in quality and operational performance must be compared with progress toward objectives and lead to action to support the following:*
 - A. *Development of priorities for prompt solutions to customer-related problems.*
 - B. *Determination of key customer-related trends and correlation for status review, decision-making and longer term planning.*
 - C. *An information system for the timely reporting of product information arising from usage.*
- II. *Data may be compared with those of competitors and / or appropriate benchmarks.*

8.5 Improvement

8.5.1 Continual Improvement

- I. FXI shall identify and implement changes necessary to ensure, maintain, and also continually improve the suitability and effectiveness of the quality management system through the use of:
 - A. Quality policy
 - B. Quality objectives
 - C. Internal, customer and registration audits
 - D. Analysis of data
 - E. Corrective and preventive actions
 - F. Management review
- II. The continuous improvement philosophy of Operational Excellence is fully deployed throughout FXI as is evident in FXI's quality policy.

8.5.1.1 Continual Improvement of the Organization – ISO/TS 16949 Supplemental

FXI has defined a process through Operational Excellence for continual improvement of the organization using both breakthrough projects (revision of existing or implementing new processes) and small-step ongoing process improvements.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

8.5.1.2 Manufacturing Process Improvement – ISO/TS 16949 Supplemental

- I. *Manufacturing process improvement focuses on control and reduction in variation in product characteristics and process parameters.*
- II. *Controlled characteristics are documented in the control plan for ISO/TS 16949 facilities.*
- III. *Continual improvements are implemented once manufacturing processes are capable and stable, or product characteristics are predictable and meet customer requirements.*

8.5.1A Medical Specific General – ISO 13485 Supplemental

- I. FXI uses a documented procedure for the issuance of advisory notices or Recalls which can be implemented at any time.
 - A. The issuance of an advisory notice will be done according to applicable national or regional regulations.
- II. Records of all customer complaint investigations are maintained according to QCP 16.1, Control of Quality Records whether or not corrective and/or preventive actions are taken.
 - A. When a complaint investigation determines that activities outside of FXI contributed to the complaint, relevant information will be exchanged between FXI and the outside organization responsible for these activities.
- III. Customer complaints that are not followed by corrective and/or preventive action will be documented with the reason(s) for no action(s) being taken, and the approval/authorization for not taking action.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

- IV. In the occurrence of an adverse event that meets specified national or regional reporting criteria, FXI will follow all notification procedures required by national or regional regulations. These notification procedures to regulatory authorities will be documented.

8.5.2 Corrective Action

- I. FXI has established and maintains documented procedures for implementing corrective actions for nonconforming processes and products to prevent recurrence.
- II. Any action taken to eliminate the causes of actual or potential nonconformities will be appropriate relative to the magnitude of problems and to the risks encountered.
- III. Documented procedures, forms, and quality records (e.g. process flow diagrams, FMEA's, control plans, complaint records, training records, etc.) are updated to reflect any changes resulting from corrective action.
- IV. FXI responds to external nonconformance's in a manner prescribed by the customer and/or national or regional regulatory agency. If such a process does not exist, FXI will respond using its internal procedures and documentation.
- V. Procedures for corrective action include:
 - A. Effective handling of customer complaints and reports of product nonconformities
 - B. Investigation and determination of the cause of nonconformities relating to product, process, and quality system, and recording the results.
 - C. Determine the corrective action needed to eliminate the cause of nonconformities and to ensure they do not recur.
 - D. Application of controls to ensure that corrective action is taken and that it is effective
 - E. Record the results of the investigation and any corrective actions taken per QCP 16.1, *Control of Quality Records*.
 - F. Review corrective actions in management review sessions.

8.5.2.1 Problem Solving – ISO/TS 16949 Supplemental



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	
SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT		

Disciplined problem solving methods are used to determine and eliminate root causes of internal or external nonconformance to specifications. Customer-prescribed problem solving formats will be used, if required.

8.5.2.2 Error-proofing – ISO/TS 16949 Supplemental

Mistake proofing methodology is used in the corrective and preventive action process to a degree appropriate to the magnitude of the problems and commensurate with the risks encountered.

8.5.2.3 Corrective Action Impact – ISO/TS 16949 Supplemental

Corrective action results and controls implemented to eliminate the cause of a nonconformity will be applied to similar processes and products.

8.5.2.4 Rejected Product Test/Analysis – ISO/TS 16949 Supplemental

I. Timely analysis of returned parts from customer's manufacturing plants is performed and records are kept and made available upon request. FXI will minimize cycle time of the evaluation process.

II. Effective analysis is performed and corrective action and process changes initiated to prevent recurrence.

8.5.3 Preventive Action

- I. FXI has established and maintains documented procedures for determining and implementing preventive actions for potential nonconforming processes and products to prevent their occurrence.

Preventive actions include the use of appropriate sources of information (such as processes which affect product quality, concessions, audit results, quality records, service reports, customer complaints) to detect, analyze, and eliminate potential causes of nonconformities.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM 8.0
	REVISION 7	

SUBJECT: MEASUREMENT, ANALYSIS & IMPROVEMENT

Preventive actions taken will be appropriate to the effects of the potential problems.

II. Procedures for preventive action include

- A. Determine the steps needed to deal potential nonconformities and their causes.
- B. Evaluating the need for action to prevent the occurrence of nonconformities.
- C. Determining and implementing actions needed and if appropriate, updating documentation.
- D. Record of results of any investigation and preventive actions taken per QCP 16.1, *Control of Quality Records*.
- E. Review preventive actions in management review sessions.



QUALITY ASSURANCE MANUAL	DATE 22 Apr 2014	SECTION QAM A1
	REVISION 7	

SUBJECT: PROCESS FLOW DIAGRAM

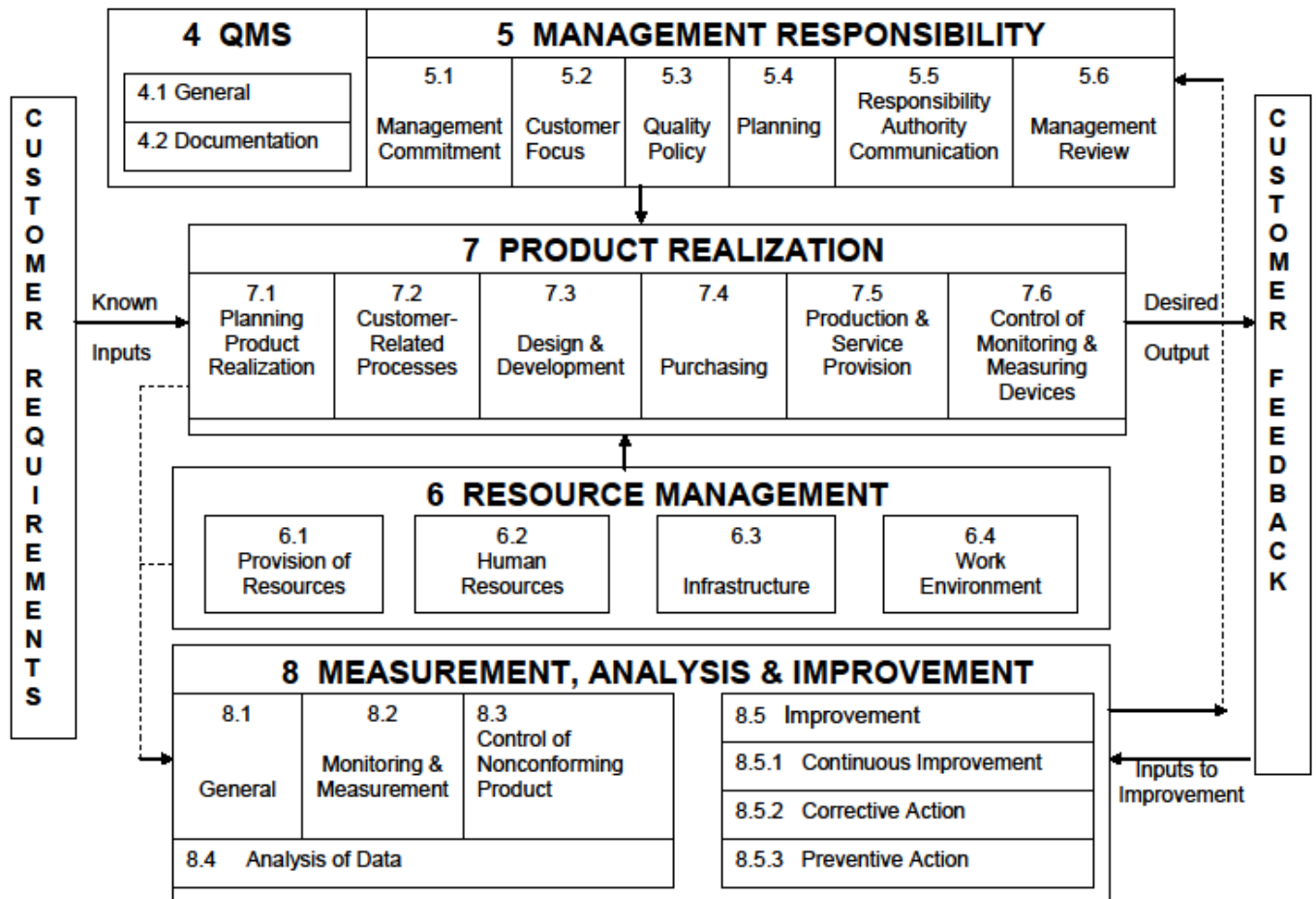
FXI Quality Management System

FXI Quality Management System Process Flow Diagram *ISO TS 16949:2009*



Identification of Remote Supporting Functions and Outsourced Processes:

- Corporate Location – Quality Assurance Manual, Quality Policy, Strategic Quality Planning, Purchasing (Chemicals)
- Automotive Business Group Location – Customer Related Processes, Customer Communication
- Automotive Testing Lab Location – Production Part Approval Processes, External Laboratory Testing (ISO/IEC 17025)



QUALITY ASSURANCE MANUAL

DATE
22 Apr 2014

SECTION
QAM A1

REVISION
7

SUBJECT: PROCESS FLOW DIAGRAM

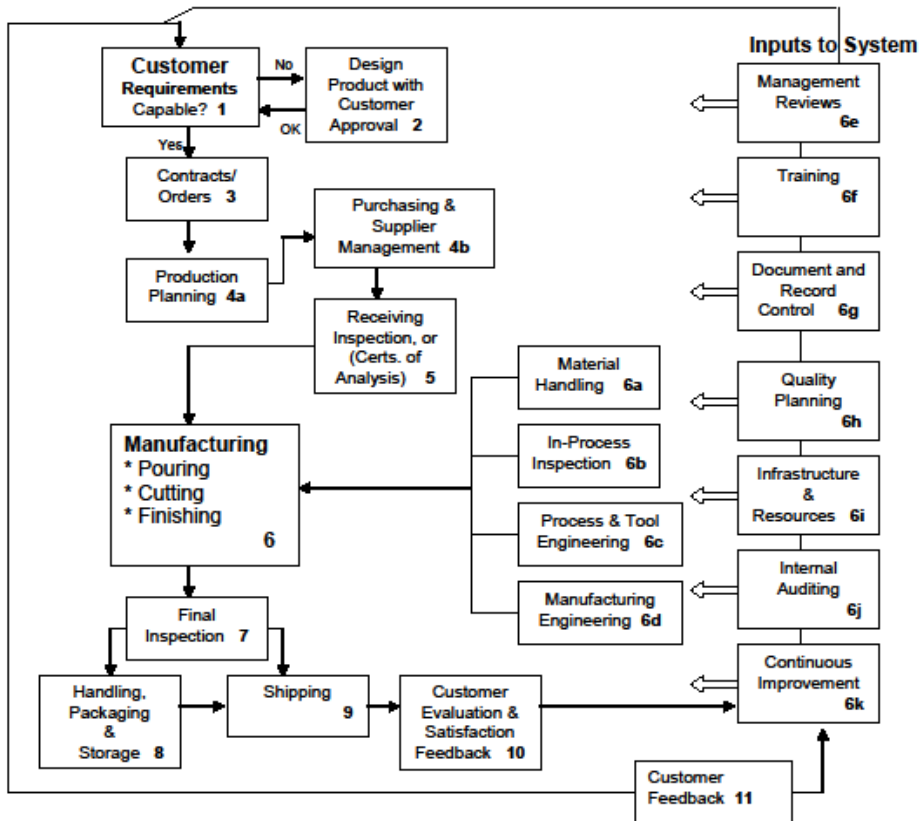
FXI Interaction of Processes Diagram



Interaction of FXI Processes

The sequence and interaction of FXI's processes in relation to the requirements of the ISO 9001 & ISO / TS 16949.

- Identification of Remote Supporting Functions and Outsourced Processes:
 - Corporate Location – Quality Assurance Manual, Quality Policy, Strategic Quality Planning, Purchasing (Chemicals)
 - Automotive Business Group Location – Customer Related Processes, Customer Communication
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April 16, 2014

Process Flow Diagram – Interaction of Processes



QUALITY ASSURANCE MANUAL

DATE
22 Apr 2014

SECTION
QAM A1

REVISION
7

SUBJECT: PROCESS FLOW DIAGRAM

