
	Document Number: QSP-100	Rev. 28
	Title: Quality Manual	

# Quality Manual

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Fluke Biomedical is a brand name under Fluke Electronics.

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**Site Roles: Calibration, Distribution, Service, and Repair of electronic test and measuring equipment, software, radiation detection instruments, their accessories and procurement of Clear PB.**

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Solon, Ohio 44139

**Site Roles: Hardware and Software Design, manufacturing and distribution of Nuclear Radiation Instrumentation. Inside Sales and Service order processing.**


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**Site Roles: Hardware and Software Design, manufacturing and distribution of Biomedical test equipment Hardware and Software Design, manufacturing and distribution of Biomedical test equipment**

[www.flukebiomedical.com](http://www.flukebiomedical.com)


ISO 9001: 20XX  
FDA 21 CFR Part 820  
Energy 10 CFR Part 50 Appendix B  
Energy 10 CFR Part 21  
ASME NQA-1-2015  
ISO 13485:20XX  
ISO 17025 (parts)  
ISO 14971 20XX (parts)  
CMDR: XXXX

The Management Team's signed approval sheet is kept in Intalex

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## ***Section 1***

# ***Quality Policy Statement***

## **1.1 Company Mission Statement**

### **Company Mission Statement**

To continue as the market leader in providing equipment to clinical engineers, radiation physicists, and oncologists, while expanding our range of solutions to a broader range of health and safety professionals.

### **Quality Policy Statement**

The personnel of Fluke Biomedical are committed to achieving quality through the following objectives:


- Focusing on the customer by applying innovation and flexibility to meet their needs
- Fostering a controlled atmosphere for continuous improvement and problem prevention
- Identifying the need for, and providing appropriate training to ensure the development and qualification of our personnel
- Communicating the mission and objectives to our personnel and customers
- Developing relationships with our customers that emphasize continuous improvement in product quality, service and support
- Promoting a supportive work environment that facilitates the delivery of a quality product on a consistent basis
- Working in a manner consistent with our documented quality-management system to ensure our products and services are safe and effective for their intended use

## **1.2 Company Background**

Fluke Biomedical is located at 2 Science Rd., Glenwood, IL 60425, 28775 Aurora Road Cleveland, Ohio 44139-3313 and 6920 Seaway Blvd, Everett, WA 98203.

Fluke Biomedical is brand name of the Fluke Electronics.

Fluke Biomedical designs, manufactures, tests, calibrates, and repairs test and measurement equipment used in the biomedical and radiation-detection community. These test tools are used by medical device manufactures and hospital maintenance personnel to install, service, and maintain various types of medical devices and laboratory equipment. These tools are also used by customers in the medical diagnostic x-ray industry, the radiation therapy industry, nuclear medicine, health physics and the nuclear energy industries for calibration and maintenance of x-ray generators, radiation treatment devices such as linear accelerators, and for radiation detection and measurement in health physics applications, nuclear medicine and nuclear energy systems. Fluke Biomedical through its Global Calibration Laboratory (GCL) and service department also provides calibration and repair services to radiation detection and measurement instruments. **It must be noted that Fluke's manufactured product will not come in contact with any patient. Thus, no confidential information regarding the patients is communicated to Fluke Biomedical at any time.**

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## ***Section 2***

### ***Amendment Record***

#### **2.1 Amendment Record**

The Amendment Record will be maintained in Intelex in the Notes Section.

#### **2.2 Controlled Circulation List –Maintained in Intelex**

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## Section 3 Glossary

**PO** – Purchase Order

**MR** – Management Representative

**Standards/Requirements** – ISO 9001: 20XX, FDA Quality System Regulations for Medical Devices 21 CFR part 820, Energy Regulations 10 CFR part 50 Appendix B and 10 CFR part 21, Reporting of defects and noncompliance, ASME NQA-1 2015, ANSI ANS 15.8 1995 (R2018), ISO 13485: 20XX; ISO 14971 20XX, and **ISO 17025**: 19XX.

**QM** – Quality Manual

**R&A** – Responsibility and Authority

**Medical Device (ISO 13485)**- Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease
- diagnosis, monitoring, treatment alleviation of, or compensation for, an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception, and which does not achieve its principal 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.


**Medical Device (FDA 21CFR)**- An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related articles, including any component, part or accessory, which is:

- Recognized by the National Formulary, or the United States Pharmacopoeia, or any supplement to them.
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its principal intended uses.

**Medical Device (CMDR)** – A device within the meaning of the Act (Food and Drugs Act, Canadian Medical Device Regulation), but does not include any device that is intended for use in relation to animals. (Currently Fluke Biomedical does not market any medical devices in Canada. The CMDR and MDSAP will be addressed if the company decides to sell medical devices in Canada)

**Conditions Adverse to Quality** - An all-inclusive term used in reference to any of the following: Malfunctions, deficiencies, defective items, and nonconformances. (ASME NQA-1-2016)

**Design History File (DHF)** – Means a compilation of records which describes the design history of a finished device.

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**Design input** – Means the physical and performance requirements of a device that are used as a basis for device design

**Design output** – Means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record

**Design review** – Means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems

**Device History Record (DHR)** – Means a compilation of records containing the production history of a finish device

**Device Master Record (DMR)** – Means a compilation of records containing the procedures and specifications for a finished device

**Establish** – Means define, document (in writing or electronically), and implement

**Finished device** – Means any device or accessory to any device that is suitable for use or capable of functioning, whether it is packaged, labeled, or sterilized

**Harm** – Physical injury or damage to the health of people, or damage to property or the environment

**Hazard** – Potential source of harm

**Hazardous situation** – Circumstance in which people, property, or the environment are exposed to one or more hazard(s)

**Intended use – Intended** purpose use for which a product, process or service is intended according to the specifications, instructions, and information provided by the manufacturer

**Labelling** – Written, printed or graphic matter

- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device,


related to identification, technical description, and use of the medical device, but excluding shipping documents

NOTE Some regional and national regulations refer to “labelling” as “information supplied by the manufacturer.”

**Life-cycle** – All phases in the life of a medical device, from the initial conception to final decommissioning and disposal

**Lot or batch** – Means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits

**Management with executive responsibility** – Means those senior employees of a manufacturer who have the authority to establish or make change to the manufacturer’s quality policy and quality system.

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**Manufacturer** – Natural or legal person with responsibility for the design, manufacture, packaging, or labeling of a medical device, assembling a system, or adapting a medical device before it is placed on the market or put into service, regardless of whether these operations are carried out by that person or on that person's behalf by a third party

NOTE 1 Attention is drawn to the fact that the provisions of national or regional regulations can apply to the definition of manufacturer.

**Nonconformity** – Means the non-fulfillment of a *specified requirement*

**Object evidence** – Data supporting the existence or verity of something

Note Objective evidence can be obtained through observation, measurement, testing or other means.

**Post-production** – Part of the life-cycle of the product after the design has been completed and the medical device has been manufactured

EXAMPLES: transportation, storage, installation, product use, maintenance, repair, product changes, decommissioning, and disposal.

**Procedure** – Specified way to carry out an activity or a process

**Process** – Set of interrelated or interacting activities which transforms inputs into outputs

**Product** – Means components, manufacturing materials, in-process device, finished devices, and returned devices

**Quality** – Means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for –use, including safety and performance.

**Quality audit** – Means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures are suitable to achieve quality system objectives.

**Quality policy** – Means the overall intentions and direction of an organization with respect to quality, as established by management with executive responsibility

**Quality system** – Means the organizational structure, responsibilities, processes, and resources for implementing quality management.

**Record** – Document stating results achieved or providing evidence of activities performed

**Residual risk** – Risk remaining after risk control measures have been taken


NOTE 1 Adapted from ISO/IEC Guide 51:1999, definition 3.9.

NOTE 2 ISO/IEC Guide 51:1999, definition 3.9 uses the term "protective measures" rather than "risk control measures." However, in the context of this International Standard, "protective measures" are only one option for controlling risk as described in 6.2.

**Rework** – Means action taken on nonconforming product so that it will fulfill the specified DMR requirements before it is released for distribution

**Risk** – Combination of the probability of occurrence of harm and the severity of that harm



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**Risk analysis** – Systematic use of available information to identify hazards and to estimate the risk

NOTE Risk analysis includes examination of different sequences of events that can produce hazardous situations and harm.

**Risk assessment** – Overall process comprising a risk analysis and a risk evaluation

**Risk control** – Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels

**Risk estimation** – Process used to assign values to the probability of occurrence of harm and the severity of that harm

**Risk evaluation** – Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk

**Risk management** – Systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risk

**Risk management file** – Set of records and other documents that are produced by risk management

**Safety** – Freedom from unacceptable risk

**Severity** – Measure of the possible consequences of a hazard

**Significant Conditions Adverse to Quality** – Is one that, if uncorrected, could have a serious effect on safety or operability. (ASME NQA-1-2015). The identification, cause, and corrective action of any instance of significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

**Top management** – Person or group of people who direct(s) and control(s) a manufacturer at the highest level

**Use error** – Act or omission of an act that results in a different medical device response than intended by the manufacturer or expected by the user

NOTE 1 Use error includes slips, lapses, and mistakes.

NOTE 3 An unexpected physiological response of the patient is not by itself considered use error.

**Validation** – Means confirmation by examination and provision of object evidence that the particular requirement for a specific intended use can be consistently fulfilled


**Process Validation** – Means confirmation by examination and provision of object evidence that a process consistently produces a result or a product meeting its predetermined specifications.

**Design Validation** – Means confirmation by examination and provision of object evidence that device specification conforms to user need and intended use(s)

**Verification** – Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

NOTE 1 The term “verified” is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

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- performing alternative calculations;
- comparing a new design specification with a similar proven design specification;
- undertaking tests and demonstrations;


**Note 3** When :20XX is referenced within the procedures, it means the current revision year to the standard referenced.

**Note 4:** The following procedures in QSP format were revised to meet 10 CFR 50 Appendix B, ASME NQA-1-2015 and ANSI ANS 15.8 Quality Assurance program. They will be recognized by the *NUP*-designation and are located under the NUPOW Procedures-Process document folder.

#### NuPow procedural changes from QSP - NUP

QAM Section	QSP-	New Procedure Title	QAM Section	QSP-	New Procedure Title
4.1	100	QSP-100			
			4.15	215	NUP-215
4.3	203	QSP-203			
	CSOP-03-03	CSOP-03-03	4.17	217 217-1	NUP-217 NUP-217-1
				217-1-F1	NUP-217-1-F1
4.6	206	NUP-206		217-1-F2	NUP-217-1-F2
				17-25	NUP-17-25
				17-30	NUP-17-30
				17-31	NUP-17-31
4.10	210	NUP-210			
	10-09	NUP-10-9	4.18	18-01 18-02 n/a	QSP-18-01 QSP-18-02 QSP-18-03
			4.20	220	NUP-220
4.11	211	QSP-211		20-01	NUP-20-01
	11-03	NUP-11-03			
		NUP-11-04	5.0	n/a	NUP-221
4.14	214	QSP-214			
	14-02	NUP-14-02			
	14-04-F4	NUP-14-04-F4			

## **Section 4**

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## ***Management Responsibility***

### **4.1 Management Responsibility**

#### **4.1.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part I, 10 CFR 50 App. B, ASME NQA-1 2015 requirement 1, ANSI ANS 15.8 1995 (R2018) section 2.1, ISO 13485:20XX, ISO 17025, and CMDR.

#### **4.1.2 Responsibility and Authority (R&A)**

The President, Vice Presidents, Directors, and Managers have the responsibility and authority for the overall administration and management of the quality system activities at Fluke Biomedical. The company's personnel have the responsibility and have been given the authority and freedom to carry out activities relating to its quality policy, quality system documentation and customer requirements. Director of regulatory and quality is the management representative at Fluke Biomedical and has the responsibility to ensure requirements of quality management systems are established and executed.

#### **4.1.3 Quality System Requirements**

Internal Communication- Fluke Biomedical has established as a means of internal communication, regarding the effectiveness of the Quality Management System the following processes: QDIP, Policy Deployment, Key Process Indicators, Management Review meetings and others as deemed appropriate by management.


Quality Policy –Fluke Biomedical has established a quality policy that identifies quality system goals and objectives. This policy is relevant to the company's goal and the expectations and needs of its customers. This policy has been communicated to the employees and is maintained as the highest priority within the company; each associate understands their role.

Responsibility and Authority - The quality system documentation, responsibility matrix, and job descriptions define the R&A and necessary interrelations for all activities.

Resources - The resources required to complete quality system activities are defined in both the quality system documentation and job descriptions. Fluke Biomedical has identified and provides for the resources needed to meet the ISO, QMS, QSR, CMDR and 10 CFR 50 Appendix B criteria including the assignment of trained personnel for management, performance of work and verification activities including internal quality audits.

Management Representative (MR) - The President or General Manager of Fluke Biomedical has appointed a MR for the establishment, implementation, maintenance and reporting of quality assurance system activities. The MR is the Director of Regulatory Affairs/Quality Assurance. The deputy MR is the Quality Manager or the highest-ranking RA/QA personnel at the site designated by RA/QA Director.

Management Review - The MR carries out scheduled Management Review meetings with the management team at defined intervals. These reviews determine the effectiveness, adequacy and suitability of the implemented quality system requirements. Minutes of these review meetings are maintained. The reviews include information on audit results, customer feedback, process performance and product conformity, status of corrective and preventive actions, follow-up actions from previous management reviews, changes that could affect the quality management system, promoting regulatory awareness, new or revised regulatory requirements, decision to report an adverse event to regulatory authorities and/or customers, and recommendations for improvement. Outputs from the reviews include

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any decision and actions related to improvement of the effectiveness of the system and its processes, product improvements related to customer requirements, and resource needs.

#### 4.1.4 Related and Support Documentation

QSP- NN Quality system procedures

QSP-102 Responsibility and Authority Matrix

QSP-201 Management Review Meeting Procedure

Appendix A Organization Structure

Job Descriptions

## 4.2 Quality Management System

### 4.2.1 Scope and Purpose

The quality system described in this section of the QM complies with the requirements of the standard(s) and: ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part II, ASME NQA-1 2015 requirement 2, ANSI ANS 15.8 1995 (R2018) section 2.2, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

### 4.2.2 Responsibility and Authority (R&A)

The Director of RA/QA is responsible for execution of all activities pertaining to this QM. Directors and Managers have the responsibility and authority for carrying out quality system activities in their respective functions. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements. Verification of these activities are carried out by RA/QA Department via matrix reviews.

Exclusions/Not Applicable: Fluke Biomedical does not perform the following activities and claims exclusion to these requirements: The Installation, Sterilization and Implant of medical devices.

**NOTE: Fluke Biomedical products does not come in contact with patients. Thus, there are no confidential information relating to patients.**


### 4.2.3 Organizational Process Requirements

Fluke Biomedical has identified the processes needed for the quality management system and their application throughout the organization. The sequence and interaction of these processes, and the criteria and methods for their operation and control have been addressed. Resources and information for the support and monitoring of these processes is available. Analysis of these processes is done, and actions to achieve planned results and continual improvement are implemented as needed.

Outsourced processes are monitored and controlled to ensure that product conformity with requirements is not adversely affected.

### 4.2.4 Quality System Requirements

A Quality Assurance Manual and Procedures have been created to address all requirements of the ISO 9001, 13485, and 14971 standards, the Quality System Regulations of the FDA, 10 CFR 50 Appendix B criteria, ISO 17025, and CMDR standards as a means of ensuring that product/service conforms to specified requirements. The Quality Manual includes or makes reference to the quality system procedures and outlines the structure of the documentation used in Fluke Biomedical's quality system. The specified requirements, including regulatory requirements, for products, components and accessories that are medical devices are established and documented. The interactions of the various processes for the quality management system are described.

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The Quality System Procedures are consistent with the requirements of the sited ISO and EN standards, the QSR Regulation, 10 CFR 50 Appendix B criteria and the company's Quality Policy. The range and detail of these procedures is dependent on the complexity of the work, the methods used, and the skills and training needed by the associates involved. The procedures may make reference to other device master records/work instructions that define how an activity is performed.

Quality Planning activities are carried out to ensure that processes are established and continually improved to enhance customer satisfaction and to meet the objectives of the Fluke Biomedical quality management system. The integrity of the system is maintained when changes are planned and implemented. Quality planning is also done to plan and develop the processes needed for product realization including the definition and documentation of how specified requirements have been or will be addressed and met. Quality System Documentation controls the processes and methods used to meet these requirements. Quality planning methods and practices identify and control the following:

- Acquisition of equipment, fixtures, resources and skills needed
- Ensuring design, process, installation, servicing and inspection compatibility with the applicable documentation
- Risk management throughout realization through documented procedures
- Quality objectives and requirements for the products
- Updating of QC inspection and testing techniques
- Identification of measurement requirements
- Identification of suitable verification activities
- Standards of acceptability
- Identification and preparation of quality records

For each type/model of medical device, a file is established and maintained that contains or references the location of a document that defines the product specifications and quality system requirements for processing and quality assurance of the device. This technical file, or device master record, includes specifications for the complete manufacturing of each product and its installation and servicing, if appropriate.

#### **4.2.5 Related and Support Documentation**

QSP-NN Quality System Procedures

QSP-202 Procedure for Quality Planning

Structure of Documentation- Appendix B


### **4.3 Contract Review / Customer-Related Processes**

#### **4.3.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:2008, 21 CFR 820.20, 10 CFR 50 App. B part IV, ASME NQA-1 2015 requirement 3, ANSI ANS 15.8 1995 (R2018) section 2.3, ISO 13485:2003, ISO 14971 2012, and ISO 17025, CMDR.

#### **4.3.2 Responsibility and Authority (R&A)**

Depending on the nature of contract, Director of Regulatory and Quality shall review the quality agreement part of the contract., Director of the Global Calibration Laboratory, the Systems Manager, the

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Customer Services Manager and Representatives have the responsibility and authority for carrying out contract review activities so that customer requirements are determined and met. The Director of Engineering or Engineering Manager is responsible for reviewing contract requirements when the contract requires design activities related to nonstandard specifications. The President or Designee reserves the right to review contracts which involve a significant or unusual amount of revenue or resources. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements of QSR, QMS, CMDR and 17025

### **4.3.3 Contract Review Requirements**

Contract Review - Procedures exist to control the methods and practices used to complete customer contract reviews and contract amendments. Contracts (verbal and written) are reviewed to ensure that they adequately define the specified requirements; that differences between the contract and tender are resolved; and that the company is capable of meeting the contract or order requirements in order to enhance customer satisfaction.

Amendments – The amendments to contracts are defined, documented and communicated to affected functional groups.

Records of contract reviews and amendments are maintained. Channels for communication and interfaces with the customer's organization in these contract matters are established.

### **4.3.4 Related and Support Documentation**

QSP-203 Procedure for Contract Review

## **4.4 Design and Development Control**

### **4.4.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part III, ASME NQA-1 2015 requirement 3, ANSI ANS 15.8 1995 (R2018) section 2.3, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.


### **4.4.2 Responsibility and Authority (R&A)**

The Director of R&D, Engineering Manager and the V.P of Marketing have the responsibility and authority for carrying out design control/product development activities. The Director of Operations, the Director of the Global Calibration Laboratory, and the Manager of Regulatory/Quality or Designee and Systems Manager provide a supportive function for this requirement. The company associates have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

### **4.4.3 Design Control**

Documented procedures exist to control all of the following quality system activities and requirements:

Design and Development Planning - Plans outlining design activities and their associated schedules are developed for each design project; these plans define various R&A and are used to ensure that personnel, with appropriate skills, and adequate resources, are assigned to each design project. Plans are formally documented and are modified as the design activities are evolving. Throughout the design process, the need for risk analysis is evaluated and if performed, records of the analyses are maintained.

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Organizational and Technical Interfaces – The company’s various functional groups are involved in reviewing and evaluating the aspects of the design through its stages; the assigned project group has the R&A for defining these interfaces, documenting and transmitting their input and seeing that the information received is regularly reviewed.

Design Input - the project group interfaces with the sales/marketing and regulatory functions in order to ensure a complete understanding of the customer(s) and other requirements (industry and governmental). The input takes into consideration the results of contract review activities. For medical devices, requirements that are related to the safety of the device are identified and included as design inputs and the outputs of risk management.

The design inputs are then documented and reviewed for adequacy. Incomplete, ambiguous or conflicting requirements are resolved with those responsible for imposing these requirements.

Design Output – The output of the design process is documented in various forms. The design output must be expressed in terms that can be verified and, where necessary, validated against the design inputs using suitable methods. The design output must meet the specified design input requirements, and contain or make reference to the appropriate acceptance criteria. In addition, those characteristics that are crucial to the safe and proper functioning of the product such as operation, storage, handling etc. must be identified. Prior to release, the results of design output activities are reviewed by objective design review committee personnel.

Design Review - At appropriate stages of the design, formal, structured and documented design reviews activities are held; these reviews are carried out to determine if all specified requirements for the phase being reviewed have been addressed. Representatives from the functional groups concerned with the design phase being reviewed, as well as other specialist personnel are asked to participate. Records of these reviews are maintained with the design history file for the project.


Design Verification –At appropriate stages of design, design verification is performed to ensure that the design stage output meets the design stage input requirements. The design verification measures are recorded and maintained with the design history file. Design verification may include tests to compare new designs to proven designs. Alternate experiments, tests and demonstrations and a review of design documents before their release are also conducted. For items subject to the requirements of 10CFR 50 Appendix B, where a test program is used to verify the adequacy of a specific design feature in place of other verifying or checking processes, it must include suitable qualification testing of the prototype unit under the most adverse conditions. Independent design verification, performed by someone independent of the design or activity being verified, is to be performed when needed to meet regulatory or customer requirements. All design verification activities for medical devices are documented and maintained, including those where clinical investigation was involved.

Design Validation- Design validation is performed to ensure that the product conforms to defined user needs and/ or requirements. This quality system activity is performed when appropriate and follows successful design verification. When conducted, it follows defined operating conditions, and normally is performed using product made in manufacturing which represents the proposed final product. Multiple validations may be performed if there are different intended uses. Medical devices may require clinical evaluation as part of the design validation. When performed, records of the evaluation are maintained. The clinical evaluation may include a compilation of scientific literature and historical evidence that similar designs and/or materials are clinically safe, or a clinical investigation or trial, to ensure that the device performs as intended.

Design Transfer- Procedures are in use to ensure that the device design is correctly translated into production specifications.

Design Changes - Design modifications are identified, documented, reviewed and approved by the various functional organizations affected by the associated changes. These activities are carried out prior to design change implementation. These controls apply to design changes regardless of the origin or



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ownership of the design. Changes to established products must be handled according to the regular change/engineering control procedures (see sections 4.5 and 4.14)

Design History/Technical File- A design history file (DHF) is maintained for each type of device. This file contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of the standards.

Software Development – As appropriate, the design procedures and requirements for software development are the same as for other designs.

Documents and records relating to product development/design control requirements are kept in the design history file.

#### **4.4.4 Related and Support Documentation**

QSP-204 Product Development / Design Control Procedure

### **4.5 Document and Data Control**

#### **4.5.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part IV, VI, ASME NQA-1 2015 requirement 6, ANSI ANS 15.8 1995 (R2018) section 2.4, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### **4.5.2 Responsibility and Authority (R&A)**

The Manager of Regulatory/Quality or Designee and the Director of Operations have the responsibility and authority for carrying out document and data control activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### **4.5.3 Document and Data Control**


Fluke Biomedical adheres to documented procedures controlling aspects of the creation, review, approval, modification, issue, release, and other activities associated with document and data control. These controls apply to documents regardless of their origin, and whether they are hard copies or electronic records. Device master records and labeling masters are covered by these procedures.

Documents and data are reviewed and approved for adequacy by authorized personnel prior to issue. A listing of quality-related documentation is maintained. This listing includes current revision-level information and is available to associates that need this information to carry out their activities, to preclude the use of invalid or obsolete documents.

Current revision levels of procedural and policy documents are maintained in the areas where the work described in the documents is being carried out. Manufacturing, testing and labeling, forms, and labeling materials are issued as needed from the appropriate Document Control person or Materials Management person in order to maintain control.

Down-level (previous version) and obsolete documents are removed from points of issue and use in manufacturing to ensure that they are not used to make decisions that may affect quality. These documents are segregated and archived. Historical data is maintained for reference purposes. Obsolete documents may be needed in order to conduct repairs and may be used for that purpose. Retention periods for the various types of documents and records are documented. For medical devices, the retention period ensures that specifications to which the products have been manufactured are available for at least two years past the expected lifetime of the medical device, as defined by the company.



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Documents that are to be retained for legal and/or knowledge preservation purposes indefinitely are identified.

Changes to documents and data are reviewed and approved by the same functions/organizations that performed the original review and approval, unless specifically designated otherwise. Pertinent information or background is provided upon which to base their review and approval. Where practicable, the nature of the change is identified in the change request documents or attachments.

#### **4.5.4 Related and Support Documentation**

QSP-205 Document and Data Control Procedure

QSP-103 Document/Quality Record Matrix

QSP-05-28 Procedure Index

### **4.6 Purchasing**

#### **4.6.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part IV, VII, ASME NQA-1 2015 requirement 4, 7, ANSI ANS 15.8 1995 (R2018) section 2.4, 2.7, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### **4.6.2 Responsibility and Authority (R&A)**

The Materials/Purchasing Manager and designated purchasing personnel have the responsibility and authority for carrying out purchasing activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### **4.6.3 Purchasing**


Documented procedures are in use to ensure that purchased product and services conform to specified requirements. The type and extent of control applied to the supplier and the purchased product or service is dependent on the effect of the product or service on subsequent product realization activities and the final product.

Vendors, contractors and consultants are evaluated on the basis of their ability to meet the requirements of the quality system and any specific quality assurance requirements. Records of acceptable vendors, contractors and consultants are maintained.

The procedures also define the type and extent of control to be exercised over the vendors, contractors and consultants dependent upon the type of product or service supplied, its impact on the quality of the final products, and where applicable, the audit reports or performance record of the vendor.

Purchase order (PO) information contains adequate detail to ensure that all specified requirements have been adequately described. Reviews and approvals of all PO and related information are carried out by purchasing personnel in advance of the PO being placed with the vendor, to ensure adequacy of the specified requirements. When appropriate, the purchasing information includes requirements for approval of the product, procedures, processes and equipment, requirements for qualification of personnel, and quality management system requirements. Copies of relevant purchasing documents are retained as needed to the extent required by the particular requirements for traceability discussed in section 6.8 of this manual.

Activities are conducted to ensure that the purchased product or service meets specified purchase requirements. When purchased product is to be verified at the vendor's premises, the verification

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arrangements and the method of product release are in the purchasing documents.

When it is a condition of the contract, the customer has the right to verify that the product conforms to specified requirements on our premises or that of our vendor. Such verification is not used as evidence of effective control of the subcontractor's quality system. The verification by the customer does not absolve Fluke Biomedical of the responsibility to provide acceptable product, nor does it preclude subsequent rejection by the customer.

#### **4.6.4 Related and Support Documentation**

QSP-206 Purchasing Procedure

NUP-206 Nuclear Purchasing Procedure

### **4.7 Control of Customer-Supplied Product**

#### **4.7.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, and ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### **4.7.2 Responsibility and Authority (R&A)**

Management of recipient of customer supplied products have the responsibility and authority for carrying out control of customer-supplied product activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### **4.7.3 Control of Customer-Supplied Product**

Procedures for identification, verification, protection, storage, and maintenance of customer-supplied product are in use. These products may be for incorporation into the final product or for related activities or services.

Any such product that is lost, damaged or is otherwise unsuitable for use is recorded and reported to the customer.

Verification by Fluke Biomedical does not absolve the customer of the responsibility to provide acceptable product.

#### **4.7.4 Related and Support Documentation**

QSP-207 Customer Supplied Product Procedure


### **4.8 Product Identification and Traceability**

#### **4.8.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part VIII, ASME NQA-1 2015 requirement 8, ANSI ANS 15.8 1995 (R2018) section 2.8, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### **4.8.2 Responsibility and Authority (R&A)**

Area managers and their designee have the responsibility and authority for carrying out product identification and traceability activities. The business partners have the responsibility and have been

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given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

### 4.8.3 Product Identification and Traceability

Documented procedures exist for identifying product from receipt and during stages of production, delivery and installation. These procedures ensure that medical devices received for refurbishing or reprocessing to specified requirements are identified and distinguished at all times from normal production.

There are also documented procedures for the unique identification of individual products or batches where traceability is a requirement, as for medical devices. The identification is recorded on the applicable documents and may enable traceability to certain components used in the product. Traceability is maintained for the distribution of the devices and ensures that the record of the original consignee for the device is maintained to facilitate corrective or preventive action if needed.

### 4.8.4 Related and Support Documentation

QSP-208 Product Identification and Traceability Procedure

## 4.9 Process Control

### 4.9.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part V, IX, and X, ASME NQA-1 2015 requirement 9, ANSI ANS 15.8 1995 (R2018) section 2.5, 2.9, 2.10, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.


### 4.9.2 Responsibility and Authority (R&A)

All area managers engaged in any activities that effect quality of products or services have the responsibility and authority for carrying out process control activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

### 4.9.3 Process Control

Documented controls, plans and procedures exist to govern the methods and practices used to complete and monitor manufacturing, installation and servicing processes. These controlled conditions include the following:

- Provision and maintenance of the appropriate infrastructure including buildings, workspace and utilities
- Documented procedures defining the manner of these activities, when they affect quality
- Use of suitable process equipment, both hardware and software,
- Use of a suitable working environment if the environmental conditions are of significance in the manufacture of the products. Under such conditions, the requirements are established and documented, and if appropriate controlled and monitored.
- Personnel requirements for health, cleanliness and clothing if contact between such personnel and the product or environment could adversely affect the quality of the product. Personnel who are required to work under special environmental conditions are appropriately trained or supervised by a trained person.

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- Compliance with reference standards/codes, quality plans and/ or documented procedures
- Requirements for the cleanliness of the product if process agents are to be removed from product during manufacture.
- Monitoring and control of suitable materials, process parameters and product characteristics
- Approval and change control of processes and equipment, as appropriate
- Criteria for workmanship, clearly defined
- Suitable maintenance, monitoring and measurement on equipment with established requirements when such activities may affect quality. Records of such maintenance are kept.
- Appropriate procedures for installation when performed, and documentation of such activities.
- Use of documented procedures for the validation of the application of computer software used for process control. The results of the validation are recorded.
- Implementation of release, delivery and post-delivery activities
- Supporting services such as transportation and communication

Where the results of processes cannot be fully verified by subsequent monitoring, inspection, measuring or testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, process validation is performed. Validation is performed to demonstrate the ability of these processes to achieve planned results. The documented validation program includes, where appropriate, installation qualification, operation qualification, performance qualification and process validation, software validation, continuous monitoring of processes, and qualification of operators. The use of specific methods and procedures is defined as applicable. Revalidation is done when needed due to a design change, new product, and new application for the process or as indicated by process monitoring or feedback from customers.

The quality records of such validated special processes identify the work instruction or procedure used the date the special process was performed and the identity of the operator of the special process.

The requirements for any qualification of process operations, including associated equipment and personnel are specified.

Records are maintained of the process control and validation activities, and for qualified processes, equipment and personnel.

#### 4.9.4 Related and Support Documentation

QSP-209 Process Control Procedure


## 4.10 Inspection and Testing / Analysis and Improvement

### 4.10.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part XII, X, XI, ASME NQA-1 2015 requirement 10, 11, ANSI ANS 15.8 1995 (R2018) section 2.10, 2.11, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

### 4.10.2 Responsibility and Authority (R&A)

The Manager of Regulatory/Quality or Designee, Director of Operations and the Director of the Global Calibration Laboratory, the Managers of Calibration Service and Systems, and the Business Unit Directors have the responsibility and authority for carrying out inspection, testing and measuring activities.

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The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### **4.10.3 Inspection and Testing (I &T)**

Documented procedures for inspection and testing activities exist in order to verify that the specified requirements for the products are met. The required inspection and testing activities are detailed in documented procedures or in quality plans.

Incoming product is not used or processed (except for products where pilot testing is specified prior to acceptance) until it has been inspected or otherwise verified as conforming to specified requirements according to documented procedures. The amount and nature of the incoming inspection is based on the nature of the material and its importance in the final product, but also on the amount of control exercised at the vendor's premises and the recorded evidence of conformance available.

Where incoming material is released for urgent production purposes prior to verification, it is positively identified and recorded in order to permit immediate recall and replacement in the event it is found to be nonconforming to specified requirements.

In-process materials and products are inspected and tested as required by documented procedures. Product is held until the required inspection and/or test has been completed or necessary reports and records have been received and verified, except when product is released to the next production stage under positive-recall procedures as described above. Such a conditional release does not preclude the performance of the in-process inspection and test activities.

Final inspection and testing are carried out in accordance with documented procedures to complete the evidence of conformance to the specified requirements. The procedures for the final inspection and testing require that all previously required inspections and tests have been performed and that the results meet specified requirements. No products are released for distribution until the activities specified in the documented procedures have been satisfactorily completed and the associated data and documentation have been approved and accounted for.

Records to demonstrate that the product has been inspected and/or tested are maintained. These records clearly show whether the product has passed or failed according to defined acceptance criteria. Where the product fails to pass any inspection and/or test, the procedures for control of nonconforming product are followed.

The inspection authority responsible for the release of product is identified on the records. Inspection and test activities are performed by individuals other than those who performed the activity being checked.

#### **4.10.4 Measurement, Analysis and Improvement**


Fluke Biomedical has implemented monitoring, measurement, analysis and improvement processes not only to demonstrate conformity of the product, but also to ensure conformity of the quality management system and to continually improve the effectiveness of the quality management system. Information relating to customer perception and satisfaction is monitored by customer service, sales, quality and marketing, and shared at the Management Review meetings. Internal audits are conducted according to part 6.17 of this manual. Processes are monitored and measured to demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, corrective actions are taken, as appropriate, to ensure conformity of the product.

#### **4.10.5 Related and Support Documentation**

QSP-210 Inspection and Test Procedure

NUP-210 Inspection and Test Procedure

Metrics from Management Review Meetings

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## 4.11 Control of Monitoring, Inspection, Measuring and Test Equipment

### 4.11.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part XII, ASME NQA-1 2015 requirement 12, ANSI ANS 15.8 1995 (R2018) section 2.12, , ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

### 4.11.2 Responsibility and Authority (R&A)

The Director of the Global Calibration Laboratory, the Calibration Service Manager, the Director of RA/QA or Designee have the responsibility and authority for carrying out control of monitoring, inspection, measuring and test equipment activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.


### 4.11.3 Inspection, Measuring and Test Equipment (I, M, & TE)

Documented procedures to control, maintain, and calibrate monitoring, inspection, measuring and test equipment (including test software) are in use to demonstrate the conformance of product to the specified requirements. Such equipment is used in a manner, which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Where test software or comparative references are used as suitable forms of inspection, they are checked to prove that they are capable of verifying the acceptability of product, prior to release for use during production, installation or servicing. Periodic rechecks are done according to a procedure and records of such checks are maintained. Technical data, pertaining to the inspection, measuring or test equipment, is made available to a customer when required by their contract or to verify the equipment is functionally adequate.

In order to ensure the control of the equipment, Fluke Biomedical does the following:

- Selection of I, M & TE is based on analysis and determination of the precision required;
- Equipment affecting quality is identified and handled according to the appropriate procedures
- Procedures are established according to equipment type, frequency of use, and nature of use, and include acceptance criteria and reference to actions for nonconforming equipment.
- I, M & TE is identified by either a controlled equipment label, calibration sticker or inscribed identifier number. The calibration status of each piece of equipment is determined by either a calibration sticker or record of calibration status, based on the equipment identification number;
- Calibration status of equipment is determined by equipment vendor documentation, actual calibration of equipment by plant maintenance personnel, calibration personnel or QC/QA personnel, or by the equipment operator when done as part of the work instructions.
- Calibration status for all I, M & TE is traceable to industry, national or international equipment standards, whenever possible;
- Methods and practices of calibration are documented, and these documents are adhered to in carrying out calibration activities;

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- Documented procedures detail methods and practices to be used for assessing I, M & TE found to be out of calibration and the actions related to product(s) that were inspected or tested using this equipment;
- Suitable environmental conditions are maintained to ensure the accurate operation of I, M & TE and for product that will be inspected in these environmental conditions;
- Methods of handling, preservation and storage exist to ensure that I, M & TE are used in a manner that will ensure measurement accuracy and fitness for use; and
- Measures have been taken to protect I, M & TE, including software and hardware, from unauthorized adjustment that may affect the accuracy of the equipment.

#### **4.11.6 Related and Support Documentation**

QSP-211 Control of Inspection, Measuring and Test Equipment Procedure

### **4.12 Inspection, Test and Operating Status**

#### **4.12.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part XIV, ASME NQA-1 2014 requirement 14, ANSI ANS 15.8 1995 (R2018) section 2.14, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### **4.12.2 Responsibility and Authority (R&A)**

The Manager of Regulatory/Quality or Designee, Systems Manager, Calibration Service Manager, Material Logistics Supervisor, and the Directors of Operations and the Global Calibration Laboratory, have the responsibility and authority for carrying out inspection and test status activities. The Quality Engineers and the Facilities Engineer have a supportive role for this function. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### **4.12.3 Inspection and Test Status**

Documented procedures are in use to control the methods for identifying accepted or released (conforming) product and product on hold (which may be nonconforming product) based on their inspection and test results.

The identification of inspection and test status is maintained, as defined in the documented procedures, throughout the production, packaging, labeling, installation and servicing of the product. Only product that has passed the required inspections and tests and is released, is distributed, used or installed.

To meet safety or other requirements, measures are taken for indicating the operating status of equipment, such as by tagging valves and switches, to prevent inadvertent operation.


#### **4.12.4 Related and Support Documentation**

QSP-212 Inspection and Test Status Procedure

### **4.13 Control of Nonconforming Product**

#### **4.13.1 Scope and Purpose**



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The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part XV, ASME NQA-1 2015 requirement 15, ANSI ANS 15.8 1995 (R2018) section 2.15, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### 4.13.2 Responsibility and Authority (R&A)

The Directors of the Global Calibration Laboratory and Operations, the Material Logistics Supervisor, and Purchasing Manager, Manufacturing Engineering, Systems Manager, Service/Repairs Manager, and the Director of RA/QA or Designee have the responsibility and authority for carrying out control of nonconforming product activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### 4.13.3 Control of Nonconforming Product

Documented procedures are in use to ensure that materials, parts, components or finished product that does not conform to specified requirements is prevented from unintended use or installation. These procedures specify the methods for the identification, documentation, evaluation, segregation (when practical), and disposition of such nonconforming product, and the notification to the functions or departments concerned.

Responsibility for review and the authority for the disposition are defined. Nonconforming product is reviewed in accordance with documented procedures to determine the appropriate action to take, which may include:

- rework or repair to specifications
- re-inspection or retest if there is reason to believe the initial results may be due to operator or equipment error
- scrapping or recycling,
- acceptance through customer concession (not an option for FDA-regulated product)
- rejection/return to vendor

Rework and repair are carried out in accordance with documented instructions and product is retested according to the documented procedures. Rework for medical devices is documented in a work instruction that has undergone the same authorization and approval procedure as the original work instruction.

For product not regulated by the FDA and where contractually required, Fluke Biomedical reports the proposed use of nonconforming product to the customer for concession. Descriptions of the accepted nonconformity are recorded to denote the actual condition. Nonconforming product is accepted for concession only if regulatory requirements are met. The identity of the person authorizing concession is recorded.


#### 4.13.4 Related and Support Documentation

QSP-213 Control of Nonconforming Product Procedure

### 4.14 Corrective and Preventive Action

#### 4.14.1 Scope and Purpose



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The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part XVI, ASME NQA-1 2015 requirement 16, ANSI ANS 15.8 1995 (R2018) section 2.16, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### **4.14.2 Responsibility and Authority (R&A)**

The Director of Regulatory and Quality or designee is responsible to ensure an effective CAPA system and mechanism is in place to address nonconformities. All area Directors and Managers and their respective teams are responsible to process CAPAs assigned to them in a timely and effective manner.. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified regulatory requirements.

#### **4.14.3 Corrective and Preventive Action**

A documented feedback system is established to provide early warning of quality problems and for input into the corrective and/ or preventive action system. Experience gained from post-production, or post-marketing surveillance, is reviewed as part of this feedback system when required.

Documented procedures for implementing corrective and preventive action are in use. The determination of action to be taken to eliminate the causes of actual or potential nonconformities is appropriate to the magnitude of the problem and the risks. Changes made to the device master records as a result of corrective and preventive action are handled through established change control procedures for review, implementation and recording.


The procedures for corrective action include methods for documenting and handling customer complaints, returned product, deviations in production, and reports of product nonconformities. An investigation of the cause and the associated risk of the nonconformities, relating to the product, process or quality system is done and the results recorded. The feedback information is investigated, interpreted, collated, and communicated in accordance with defined procedures by designated personnel.

A record is kept of all customer complaint investigations. When the investigation determines that the activities at remote premises contributed to the customer complaint, a copy of the report is sent from Fluke Biomedical to the remote premises. The corrective action needed is then determined and followed up to ensure the action is implemented and effective. If any customer complaint is not followed by corrective and/or preventive action, the reason is recorded.

The procedures for preventive action include the use of information from various sources including internal operation reports, audit results, quality records, service reports and customer complaints to detect, analyze and eliminate potential causes of nonconformities. These procedures include steps to deal with problems requiring preventive action, the initiation of such actions and instructions for follow-up to ensure implementation and effectiveness. Again, such proposed actions are handled according to the established change control procedures, which include management review.

If a customer alleges that one of our medical device products has caused or contributed to a serious injury or death, or that it has malfunctioned, and if that malfunction were to recur it could cause or contribute to a serious injury or death, the Medical Device Reporting regulations are followed as described in 21CFR 803, the Canadian Medical Device Regulations are followed as described in Sections 59-65 Mandatory Problem Reporting, and the requirements of Regulatory Authorities in other countries as applicable. Procedures for the notification of such regulatory authorities are established to meet the reporting criteria.

If a correction or removal of distributed medical devices is needed, then the requirements of the FDA's 21CFR 806, and those of applicable foreign Regulatory Authorities are followed. Procedures are established for the issue of such advisory notices or recalls, which can be implemented at any time.

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For items subject to regulation by the Nuclear Regulatory Commission or the Atomic Energy Act of 1954, a defect or nonconformance is deemed to exist if anyone obtains information reasonably indicating that a basic component, licensed activity or a portion of the facility has a defect or failure that could be associated with a substantial safety hazard. A notification of failure to comply or existence of a defect must be made according to 10 CFR part 21.21.

**NOTE 1:** Risk Management is conducted from Product Development to the Post Market Surveillance. This may include any Risks or opportunities associated with Non-Conformances, Complaints, and CAPA's that may affect product integrity, safety and or any other regulatory requirements.

**NOTE 2:** The corrective and preventive actions shall be examined to ensure product safety and effectiveness has not been affected. The need for decision to inform regulatory authorities or customers are evaluated.

4.14.3.1 "Continual Improvement" in the concept of ISO-9001 (part 10.3). Where possible and applicable, opportunity for continuous improvement shall be evaluated and implemented. During the improvement process, it must be established that the safety and efficacy of the product(s) and intended use will not be affected.

#### 4.14.4 Related and Support Documentation

QSP-214 Corrective and Preventive Action Procedure

EOP-04-12 Risk Management

QSP-14-02 Medical Device Reporting Procedure

NUP-14-02 Nuclear Reporting Procedure

QSP-14-01 Complaint Handling Procedure

## 4.15 Handling, Storage, Labeling, Packaging, Preservation and Delivery

### 4.15.1 Scope and Purpose


The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.120-820.160, 10 CFR 50 App. B part XIII, ASME NQA-1 2015 requirement 13, ANSI ANS 15.8 1995 (R2018) section 2.13, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR..

### 4.15.2 Responsibility and Authority (R&A)

The Materials Logistic Supervisor, Director of Operations, and the Radiation Safety Officer have the responsibility and authority for carrying out handling, storage, labeling, packaging, preservation and delivery activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

### 4.15.3 Handling, Storage, Labeling, Packaging, Preservation and Delivery

Documented procedures are in use for the handling, storage, packaging, preservation and delivery of product, as well as for returned product. These procedures control the following activities:

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Handling - Handling methods and practices are intended to prevent damage and deterioration of material and products throughout the receiving, manufacturing, packaging, preservation and shipping, and return process.

Storage - Receiving, in-process and pre-shipment areas have been identified and are used; these areas have the intended purpose of preventing damage and deterioration to product(s) and or material(s) and for segregating materials released from those that are to be held. Clearly defined methods and practices are in use for the receipt and dispatching of items from these areas. The condition of product in stock is assessed at appropriate intervals.

Packaging and Labeling- Methods of packing, packaging, labeling and marking of packaging materials are controlled to ensure that all specified requirements have been met.

Preservation - Measures are taken to preserve materials and products to prevent damage and deterioration, and to segregate materials released for distribution from those to be held.

Delivery - Practices and procedures are in use that provide for the protection of products after final inspection and testing; as required, this protection applies to the delivery of the product to the customer.

Procedures are established and maintained for the control of product with a limited shelf- life or requiring special storage conditions. Such special storage conditions for medical devices are controlled and recorded as applicable.

If appropriate, special arrangements are established and maintained for the handling and control of used product in order to prevent the contamination of other product, the manufacturing environment or personnel.

#### **4.15.4 Related and Support Documentation**

QSP-215 Handling, Storage, Packaging, Preservation and Delivery Procedure

NUP-215 Handling, Storage, Packaging, Preservation and Delivery Procedure

## **4.16 Control of Quality Records**

### **4.16.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part XVII, 10 CFR 50 App. B part XVIII, ASME NQA-1 2015 requirement 17, ANSI ANS 15.8 1995 (R2018) section 2.17, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.


### **4.16.2 Responsibility and Authority (R&A)**

The Directors, Managers, Supervisors and the Manager of Regulatory/Quality or Designee have the responsibility and authority for carrying out control of quality record activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

### **4.16.3 Control of Quality Records**

Procedures for identification, collection, indexing, access, filing, storage, maintenance, and disposition of maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Applicable records from vendors are also considered and handled as quality records.

The quality records are legible and maintained in a retrievable manner. The records are kept in a storage environment that prevents damage, deterioration and loss. Electronic records are backed-up, via electronic means, and stored to prevent loss or damage. Record retention periods are specified and conform to regulatory and contract requirements. For medical devices, the quality records are retained for

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a period of time at least equivalent to the lifetime of the device as defined by the supplier; but not less than 2 years from the date of dispatch.

A record for each batch, unit or run of medical devices is maintained that provides traceability to the extent required by section 4.8 and identifies the quantity manufactured and the quantity released for distribution. The record is verified and authorized.

Records are available for review by regulatory authorities, quality system auditors, company personnel, and by a customer when specified as part of their contract. Management review and internal or external audit records are not to be provided to FDA inspectors for review.

#### **4.16.4 Related and Support Documentation**

QSP-216 Control of Quality Records Procedure

QSP-103 Document/Quality Record Matrix

### **4.17 Quality Audits**

#### **4.17.1 Scope and Purpose**

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part XVIII, ASME NQA-1 2015 requirement 18, ANSI ANS 15.8 1995 (R2018) section 2.18, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### **4.17.2 Responsibility and Authority (R&A)**

The Regulatory/QA Manager or Designee have the responsibility and authority for carrying out quality audit activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### **4.17.3 Quality Audits**

Documented procedures for planning and implementing internal and external quality audits are in use. Quality audits are carried out to verify that planned and documented procedures, quality and control plans, and other quality system documentation are in conformance, and to assess their effectiveness. The internal audits are scheduled based on the departments or regulatory element's impact on quality and quality performance and are carried out against the requirements of the standard(s) that apply to the operation being audited. External audits are done at intervals consistent with the importance, complexity, performance history and quantity of the product or services obtained from the vendor. Trained and qualified personnel who understand the standard(s), auditing requirements, and basic communication skills, and who are independent of the functional area being assessed, conduct the audits.

The results are documented and are communicated to the personnel having responsibility for the area audited. The management of the audited area must determine and implement timely corrective action. Follow-up activities are carried out to verify the implementation and effectiveness of corrective action. Records of quality audits are maintained.


#### **4.17.4 Related and Support Documentation**

QSP-217 Internal Audit Process Procedure

NUP-217 Internal Nuclear Audit Process Procedure

NUP-217-1 External Nuclear Audit Process

### **4.18 Training**

	Document Number: QSP-100	Rev. 28
	Title: Quality Manual	

#### 4.18.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, 10 CFR 50 App. B part II, ASME NQA-1 2015 requirement 2, ANSI ANS 15.8 1995 (R2018) section 2.2, ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### 4.18.2 Responsibility and Authority (R&A)

All area Directors and Managers have the responsibility and authority for carrying out training activities and to ensure all personnel in their respective areas are trained properly. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### 4.18.3 Training

The necessary competence for personnel performing work affecting product quality has been determined through the job descriptions. Documented procedures for identifying training needs are in use. Training, including Quality System requirements, is provided for personnel performing activities affecting quality. Personnel who perform specific assigned tasks are qualified on the basis of appropriate education, training and/or experience, as required. Records of training and qualifications are maintained.

Personnel are made aware of the relevance and importance of their activities and how they contribute to the achievement of the Fluke Biomedical quality objectives.

Personnel who are required to work under special environmental conditions or who perform special processes or functions are appropriately trained or supervised by a trained person.

#### 4.18.4 Related and Support Documentation

QSP-218 Training Procedure

### 4.19 Servicing

#### 4.19.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, and ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

#### 4.19.2 Responsibility and Authority (R&A)


The Director of the Global Calibration Laboratory, the Calibration Service Manager and the Customer Service/Repair Manager, have the responsibility and authority for carrying out servicing activities. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

#### 4.19.3 Servicing

Where servicing is a specified requirement, documented procedures for scheduling, performing, verifying and reporting the servicing are in use. These procedures ensure that the servicing activities are done under controlled conditions, meet the specified requirements for the product and that the servicing activities are documented. Servicing, like production, is done using correct information for the product, work instructions (as necessary), suitable equipment, monitoring and measuring devices, measuring and monitoring of the service itself, and proper release, delivery and post-delivery activities.

#### 4.19.4 Related and Support Documentation

QSP-219 Service Procedure

	Document Number: QSP-100	Rev. 28
	Title: Quality Manual	

QSP-101 Quality Manual for Calibration Services (Glenwood)-ISO/IEC 17025 Quality Manual Supplement

## 4.20 Statistical Techniques

### 4.20.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): ISO 9001:20XX, 21 CFR 820.20, and ISO 13485:20XX, ISO 14971 20XX, and ISO 17025, CMDR.

### 4.20.2 Responsibility and Authority (R&A)

The Directors and Managers have the responsibility and authority for carrying out statistical technique activities where applicable. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

### 4.20.3 Statistical Techniques

Fluke Biomedical has implemented monitoring, measurement, analysis, and improvement processes needed to demonstrate conformity of the product, and the quality management system, and to continually improve the effectiveness of the quality management system.

Where appropriate, procedures are in use to identify the need for valid statistical techniques required for establishing, controlling and verifying process capability, product characteristics and the ability of the processes to achieve planned results. Where such needs have been identified, procedures or practices are in use to control the application of the statistical techniques and to define the appropriate sampling methods and plans. The sampling methods chosen are adequate for their intended use and are reviewed when there are changes in a product or process. Sampling methods are reviewed in light of the occurrence of nonconforming product, quality audit reports, feedback information and other appropriate considerations. Activities related to these requirements for statistical techniques are documented.

Data analysis provides information relating to customer satisfaction, conformity to product requirements, characteristics and trends of processes and products, and suppliers. This data is typically reviewed as part of the Management Review meetings.

### 4.20.4 Related and Support Documentation

QSP-220 Statistical Techniques Procedure


NUP-220 Statistical Techniques Procedure

QSP-201 Management Review

## 5.0 Commercial Grade Dedication

### 5.0.1 Scope and Purpose

The quality system described in this section of the QAM complies with the requirements of the standard(s): 10 CFR 21, 10 CFR 50 App. B, NQA-1 2015 requirements 3, 7, 10 and 11; Revision 1 to EPRI NP-5652 and TR-102260 **3002002982** Final Report, September 2014

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## 5.0.2 Responsibility and Authority (R&A)


The Directors and Managers have the responsibility and authority for carrying out Commercial Grade Dedication activities where applicable. The business partners have the responsibility and have been given the authority and freedom to carry out activities in accordance with the quality policy, quality system documentation and specified requirements.

## 5.0.3 Commercial Grade Dedication Program

Fluke Biomedical maintains control for its designs and manufacture of Basic Components under a 10 CFR 50 Appendix B QA Program. Additionally, Fluke Biomedical performs Commercial Grade Dedication on items that are not manufactured under a 10 CFR 50 Appendix B QA Program such as procured assemblies, components, or spare parts. In these instances, the Commercial Grade Dedication program is implemented.

## 5.0.4 Related and Support Documentation

NUP-221 Commercial Grade Dedication Program


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## Appendix A

### ***QSP-100***

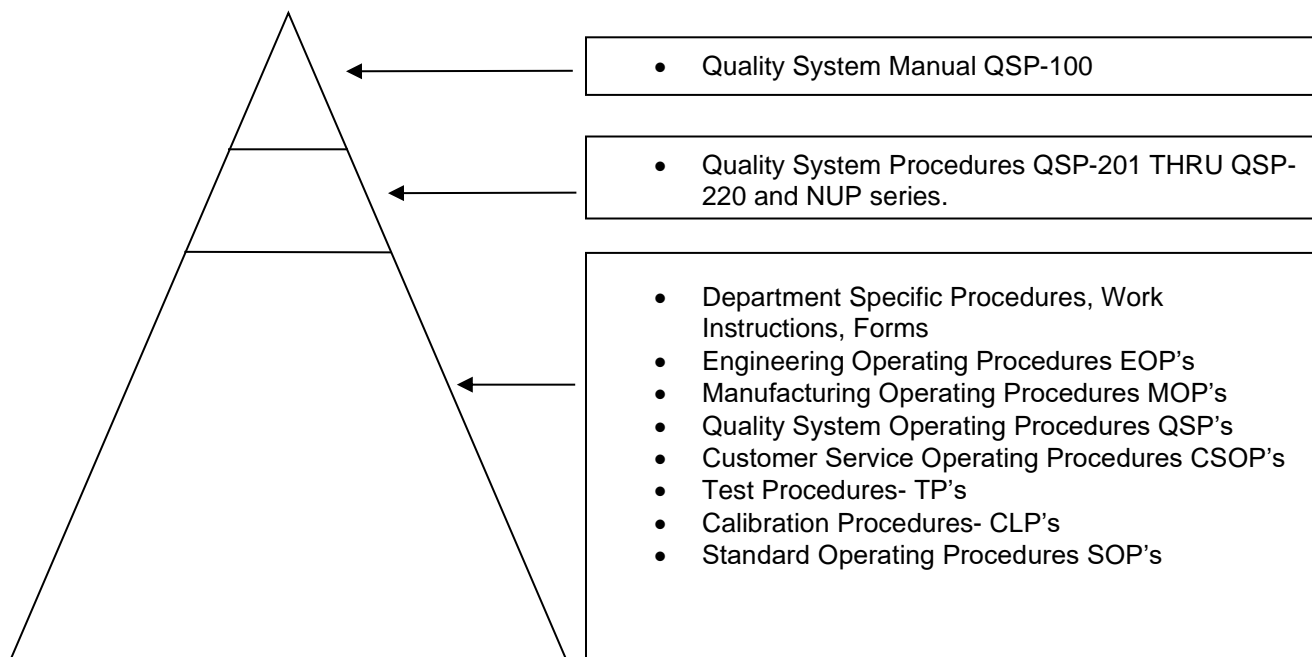
See QSP-105, Organizational Structure, for Organization Chart.




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## Appendix B QSP-100

### FLUKE Biomedical, Documentation Structure



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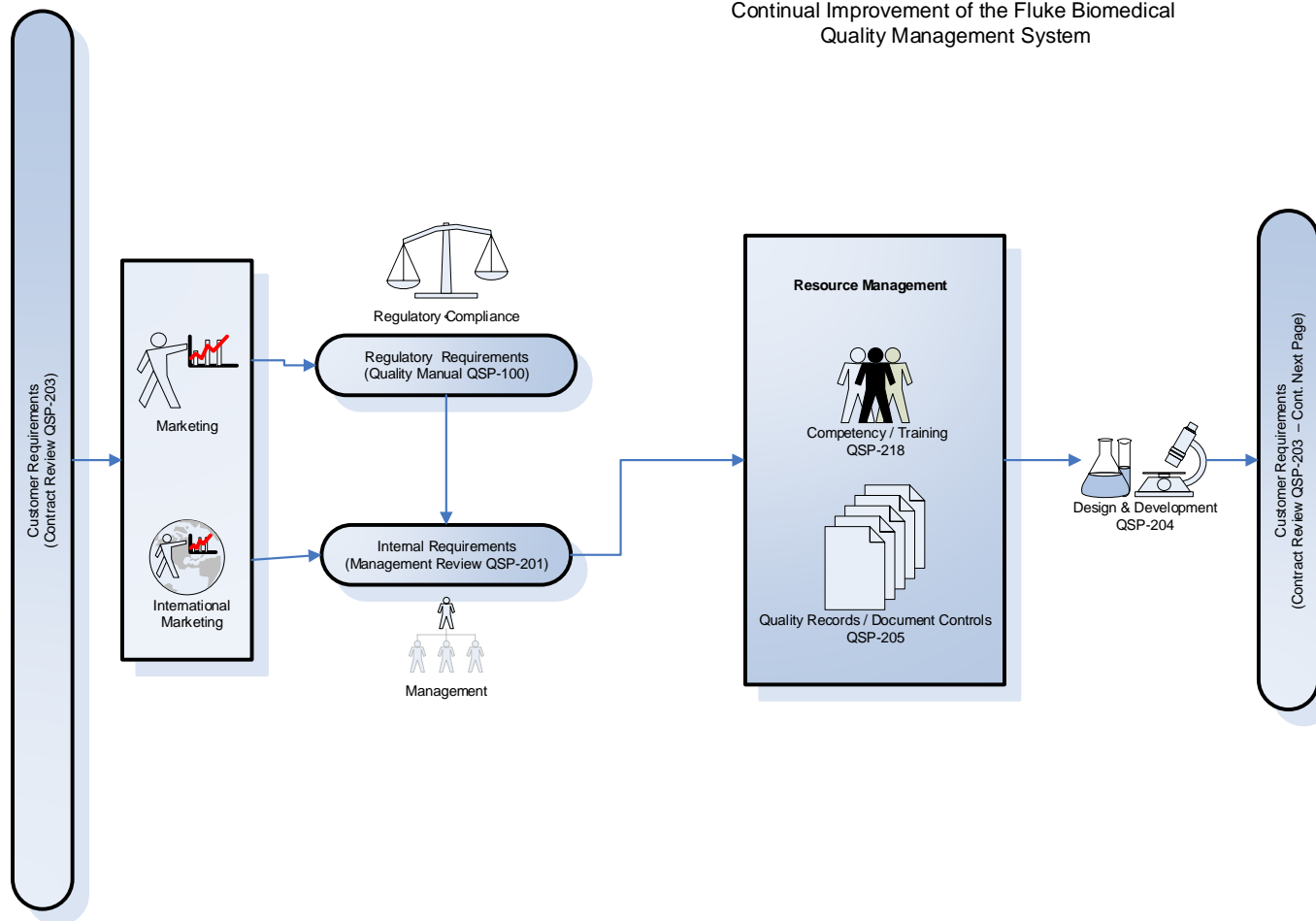
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## Appendix C

### High Level Quality Management System Flow Chart

Continual Improvement of the Fluke Biomedical  
Quality Management System



Continual Improvement of the Fluke Biomedical  
Quality Management System

