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1. GENERAL

1.1 ∆Introduction

This manual provides an overview of the Quality Management System (QMS) at Waters Corporation, Milford, Massachusetts, USA. It includes information related to the design of instrument products, development of applications software, instrument manufacturing, and service support.

The Milford, Massachusetts plant is the world headquarters for Waters Corporation.

Waters Milford is certified to ISO 13485:2003 and ISO 9001:2008 and is registered with the FDA. Waters' Quality Management System follows applicable regulatory requirements and standards as indicated in 730001877, External Standards and Regulations Log.

This manual includes policies, practices, objectives and reference procedures for a quality system that are necessary to consistently design, produce and deliver quality products and services.

It is the responsibility of the Senior Quality Assurance Manager as the site Quality Management Representative to assure this manual is maintained as a current reflection of our Quality System. As such, this manual will be reviewed once every two years at a minimum for changes to the QMS.

Appendix II lists the top level Quality Management System procedures structured according to the appropriate section and sub-sections of ISO 9001:2008 / ISO 13485:2003 which further explain the topics addressed. This appendix also references the appropriate section in Food Drug Administration (FDA) Quality System Regulation: (21 CFR Part 820) and Canadian Medical Regulations SOR/98-282.

1.2 ∆Reference Documents

Document Number	Document Title
730002900	Global Document Management Policy
730000295MP	Quality System Document Control
730001103	Global Policy Template
WAT000050MP	Waters Record Retention Corporate Policy

1.3 Process Approach

Waters uses a process-based QMS approach. Figure 1 illustrates the model used and shows that customers are the focus and an integral part of our process.

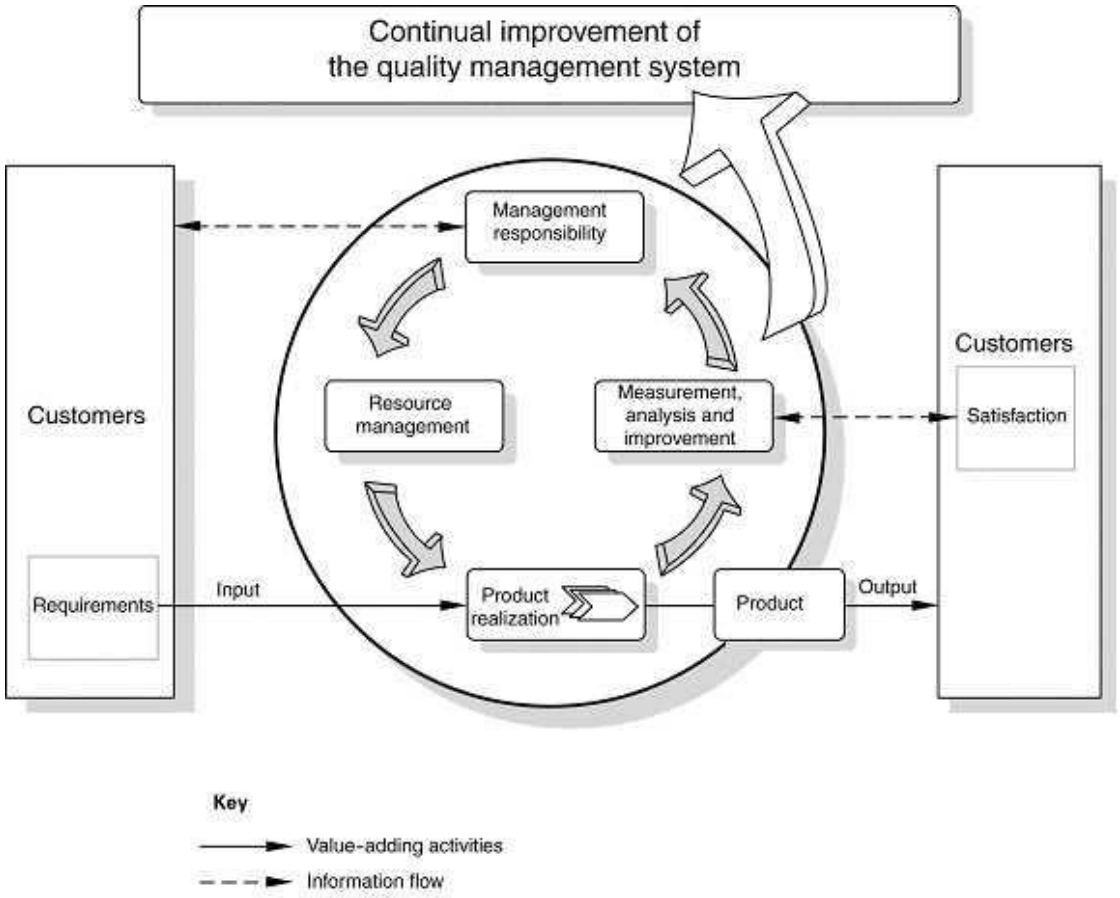

Figure 1. Model of a Process-Based Quality Management System
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Waters monitors customer expectations and satisfaction and evaluates information related to customer perceptions as to whether Waters has met customer requirements. In addition, a **Plan – Do – Check – Act** (**PDCA**) Methodology is used. **PDCA** can be described as follows:

PLAN: Objectives and processes necessary to deliver results in accordance with customer requirements and organization policies are established.

DO: The processes are implemented.

CHECK: The processes and products are monitored and measured against the policy, objectives and requirements and the results are reported.

ACT: Action is taken to continually improve the process.

2. PERMISSIBLE EXCLUSIONS AND ITEMS NOT APPLICABLE

Waters Milford, MA Quality Management System follows the applicable standards and regulations listed in Section 1.2. For exclusions and items not applicable to ISO 13485:2003, please see below.

7.5.1.2.1 Cleanliness of product and contamination control

The portions of section 7.5.1.2.1 addressing sterile medical devices do not apply, as Waters does not sell or distribute sterile medical devices. Sections c & d of Section 7.5.1.2.1 are applicable.

7.5.1.3 Particular requirements for sterile medical devices

The requirements for sterile medical devices are not applicable as Waters does not sterilize its medical devices or distribute sterile medical devices.

7.5.2.2 Particular Requirements for Sterile Medical Devices

The requirements for sterile medical devices are not applicable as Waters does not sterilize its medical devices or distribute sterile medical devices.

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

The requirements for implantable and active implantable medical devices does not apply as Waters does not manufacture, design, or distribute implantable or active implantable medical devices.

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

The requirements for implantable and active implantable medical devices does not apply as Waters does not manufacture, design, or distribute implantable or active implantable medical devices.

2.1 SCOPE

The scope of the Milford Quality Management System is the design, development, manufacture, installation, servicing, sales, technical support, and distribution of high/ultra performance liquid chromatography (HPLC/UPLC) instruments and supplies , mass spectrometry (MS) instruments and supplies, and applications software.

3. COMPANY BACKGROUND

Waters Corporation, headquartered in Milford, Massachusetts, develops, manufactures, and markets instruments, software, accessories and supplies for analytical and preparative Ultra Performance Liquid Chromatography (UPLC), High Performance Liquid Chromatography (HPLC) and Mass Spectrometry (MS) Systems. Waters' market includes In-Vitro Diagnostic medical device and non-medical device industries. In addition, Waters Corporation has maintained a commitment to leading edge programs in the area of service, support, customer education and compliance.

3.1 Customers

Pharmaceutical, biotechnology, semiconductor, chemical, environmental testing, and food and beverage companies; university laboratories, government and private analytical and research laboratories; defense and regulatory agencies; clinical laboratories, hospitals, dialysis centers, medical schools, and medical research institutes. Our customers work from the early stages of discovery and development through final quality control and assurance.

3.2 Sales Offices

Waters sells its products in the United States directly through its own Sales and Service organization. Sales in most European markets, Japan, China, Asia and Canada are made through subsidiaries, which specialize in Sales, Service and Support.

3.3 Research and Development

Waters' Milford Massachusetts, USA, product development includes the design of new Ultra Performance Liquid Chromatography (UPLC), High Performance Liquid Chromatography (HPLC) instruments, Single Quadrupole Mass Spectrometers, software for instrument control, applications and accessories. Design of Waters tandem (triple quadrupole) and other high value mass spectrometry (MS) instruments is performed in Wilmslow UK, under a separate ISO certification and not covered in this manual. Since UPLC, HPLC, MS, and LC/MS instruments are characterized by a rapid rate of technological change, Waters makes significant investments in research, development and product improvements to meet and exceed customers' needs and expectations.

Research of Waters In-Vitro Diagnostic and Research Use Only Reagent Kits is outsourced to Health Sciences, Wilmslow.

Design of Waters In-Vitro Diagnostic and Research Use Only Reagent Kits is outsourced to Consumables Product Development, Wexford.

3.4 ∆Manufacturing

Waters' manufacturing activities are conducted at the facilities in Milford, Massachusetts as well as Wexford, Ireland and Wilmslow, UK. For some products, Waters uses contract manufacturer organizations (CMO) and original equipment manufacturers (OEM). Manufacturing activities include the production of parts and assemblies used in its products. Some of the parts are built by outside qualified suppliers. Products incorporate mechanical, electronic, chemical, and optical components. Prior to shipment to the customer, completed instruments and component products are extensively tested and evaluated to meet specified requirements.

Manufacture of Waters In-Vitro Diagnostic and Research Use Only Reagent Kits is outsourced to Consumables Product Development, Wexford, who may subcontract some of this activity.

3.5 Waters and the Business of Separation Technology

Waters is a publicly held corporation engaged in the business of developing, manufacturing and marketing products incorporating separation and detection technology. Individually, or in combination, these techniques can be used to isolate, purify, select, compare and/or quantitate chemicals in solutions. They can also be used to separate and/or remove microscopic and chemical contaminants from liquids and/or to identify individual chemical components in solutions.

3.6 Consumables Product Development

The Consumables Product Development business works with various groups within Waters and other subcontractors for the design, development, manufacture, installation and servicing of products classified as In-Vitro Diagnostics. The table below displays the responsibilities for products currently marketed as IVD products. Details of responsibilities are documented in Quality Agreements.

Product Family	Design & Develop-ment	Manufacturing	Subcontractor (Manufacturing)	Installation & Servicing	Complaint Handling & Reporting	Authorized Representative (EU)

Product Family	Design & Develop-ment	Manufacturing	Subcontractor (Manufacturing)	Installation & Servicing	Complaint Handling & Reporting	Authorized Representative (EU)
Reagent Kits	Wexford	Wexford	ChromSystems GmbH Recipe GmbH Waters Wexford Fujirebio Diagnostics, Inc.	N/A	Milford	Waters Wilmslow
Chemistry Consumables	Milford	Wexford	Spark Holland	N/A	Milford	Waters Wilmslow
Mass Spectrometers	Wilmslow	Wexford	N/A	Milford	Milford	Waters Wilmslow
Liquid Chromatography	Milford	Milford	ΔFlextronics, Venture, CEI	Milford	Milford	Waters Wilmslow
Software	Milford Wilmslow	Milford Wexford	N/A	Milford	Milford	Waters Wilmslow

4. QUALITY MANAGEMENT SYSTEM

4.1 Δ General Requirements

Waters has established, documented, implemented, and maintains a quality management system in accordance with the requirements of applicable regulatory standards and requirements (as outlined in 730001877, External Standards and Regulations Log). The Waters Quality Management System (QMS) includes the Quality Manual, policies, procedures, organizational structure, requirements and responsibilities for achieving our quality policy and objectives. The foundation for our QMS is found in Waters' Quality Policy. They help to ensure the following objectives:

a. Focus on our Customers

b. Participation of our People

c. Continual Improvements

This Quality Manual and its associated policies and procedures establish and document the means by which we implement, maintain and continually improve our QMS.

Waters ensures that resources and information necessary to support the operation and monitoring of the required processes are adequate. Resource needs are evaluated during product planning and during management reviews.

Processes are monitored, measured, and analyzed to ensure they are effective and to allow for continual improvement.

Waters implements actions necessary to maintain the suitability and effectiveness of the processes. These actions are recorded as part of the Corrective and Preventive Action process.

Waters controls and monitors outsourced processes. The type and extent of control and monitoring shall be commensurate with the risk involved with the process. Control of outsourced processes may include written

agreements, continuous monitoring, on-site auditing, quality surveys, ISO certification, and performance or workmanship evaluation. Specifications and/or requirements are sent to suppliers of outsourced services as appropriate. National or international standards are utilized where applicable.

Outsourced processes and services may include the following:

- Finished Device Manufacturing, Labeling, and Packaging
- Regulatory or Quality Consulting

The controls and requirements of outsourced processes are outlined in document 730001504 - Outsourced Process List. Outsourced suppliers are identified in the Outsourced Process List. Supplier history information is maintained and monitored. Records regarding the control of outsourced processes shall be maintained in the applicable supplier files. Waters Corporation works closely and has regular communication with the suppliers of these outsourced services.
Waters sister sites, supporting the Milford Quality Management System, have oversight and control covered by the central control management approach which utilizes the Management Review process of Waters' Milford site.

4.2 Documentation Requirements

4.2.1 General

QMS documentation includes this Quality Manual, Policies, Procedures, Design Standards (DS's), work instructions, reports, records, forms and other documents. Documents and data are in the form of hard copy and/or electronic media and/or other type of media. Some of the procedures are referenced in various sections of this manual and in Appendix I.

QMS documentation was developed based on the size, type of the related organization, the interaction of the processes, the complexity of the work, the methods used, and the skills and training needed from competent employees involved in carrying out the activities.

These documents reflect activities, materials, equipment, quality standards, and records that ensure our products / services conform to specified requirements. For additional information, see section 4.2.2 titled Quality Manual.

Control of QMS documents is covered in section 4.2.3 of this manual, Control of Documents.

4.2.2 ΔQuality Manual

This Quality Manual is based on the QMS of the applicable standards referenced in 730001877, External Standards and Regulations Log..

A cross-reference index to support the Quality documentation is listed in Appendix II. .

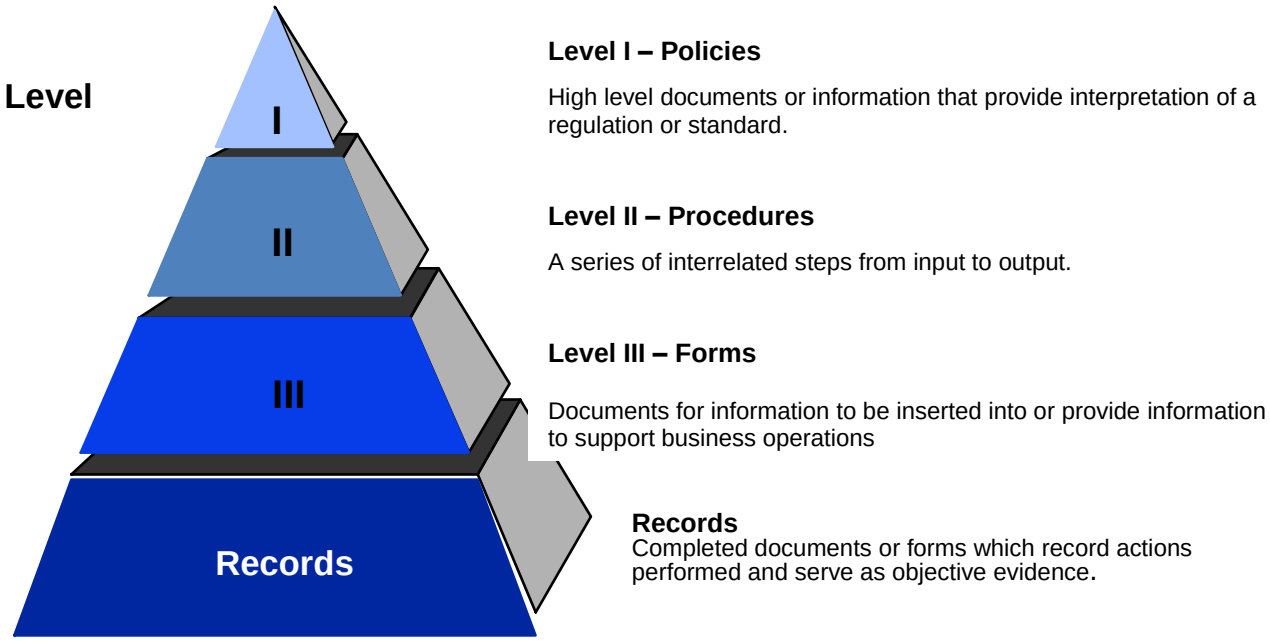


Figure 2. Waters QMS Documentation Structure

Waters integrated the Document Management Viewer, an electronic interactive tool providing easy access to selected documents housed within SAP. This Quality Manual describes processes identified in the ISO 9001:2008 and ISO 13485:2003 standards as applicable to Waters and those which are part of the Waters' QMS.

QMS documents are controlled as described in Section 4.2.3 of this manual, Control of Documents.

4.2.3 ΔControl of Documents

QMS documents and data are maintained in accordance with document control policies and procedures.

Quality Management System Documents are reviewed periodically for accuracy and revised as required to reflect latest practices. Each document control area is responsible for revision control coordination, processing, and distribution of the applicable procedures.

Engineering Services maintains the master list for External Documents, such as, National and International standards / regulations. Control of external documents is decentralized by the appropriate department holder. Impact on the product / process or QMS is assessed by the appropriate department holder when a document is revised.

QMS documents, including those identified as quality records, are controlled by the Global Document Control Policy 730002900.

The following are the requirements for document and data review, approval and issue:

a. Approve documents for adequacy prior to issue
b. Review, update as necessary and re-approve documents
c. Identify the current revision status of documents

d. Ensure that relevant revisions of applicable documents are available at points of use

e. Ensure that documents remain legible, readily identifiable and retrievable

f. Ensure that documents of external origin are identified and their distribution controlled

g. Prevent the unintended use of obsolete documents, and apply suitable controls and identification measures if they are retained for any purpose

Documents will be retained according to Water's Record Retention Corporate Policy, WAT000050MP.

4.2.4 ΔControl of Quality Records

The following are examples of quality records that are maintained to demonstrate conformance to specified requirements and the effective operation of the quality system. Records are identified, collected, indexed, filed, stored and maintained in a manner that provides assurance that they are retrievable when required.

Quality records may consist of:

a. Results of processes performed

b. Product/process evaluation for meeting acceptance criteria.

c. Procedures, drawings or instructions used to perform an activity, including revision and/or date of document.

d. Identification of material, parts, or equipment used in the making of the product.

e. Personnel qualification and training

f. Material or equipment qualifications

g. Calibration information

Quality Records are retained according to Water's Record Retention Corporate Policy, WAT000050MP.

5. MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Senior Management shows evidence of its commitment to the development and improvement of our quality management system. Refer to our Quality Policy (Section 5.3). The Quality Policy documents and communicates the importance of meeting or exceeding customers' expectations, by continually improving our processes, products, and services. We ensure that our Quality Policy is understood, implemented, and maintained at all levels of the organization through documented training, regular communication, and verbal reinforcement.

Senior leadership also demonstrates its commitment to the development and improvement of our QMS by regularly establishing quality objectives (see 5.4.1 Quality Objectives), conducting management reviews (see 5.6 Management Review), and ensuring the availability of necessary resources (see section 6.1 Provision of Resources).

5.2 Δ Customer Focus

Our Quality Policy articulates our commitment to our customers: "Waters strives to provide innovative technological solutions, products, and services to our customers by attaining a keen understanding of their needs and requirements". Customer expectations are determined, understood, converted into requirements, and have processes designed to exceed them in order to fulfill this Quality Policy on a daily basis.

We work hard to be an active partner with our customers, understanding their world and identifying solutions tailored to their needs and applications. Staying close to our customers is our primary method of determining and understanding their requirements and expectations. We accomplish this objective through a multitude of channels. These include Technology Seminars, user meetings, regular customer visits by our sales managers and representatives, trade shows, special customer visits by the leadership of our corporation, phone contact with multiple levels of our customers' organization, and customer audits of our facilities. These communications and interactions ultimately yield clear, explicit customer requirements and expectations in the form of a contractual agreement and/or customer specification. The QMS ensures that these requirements are fulfilled with the aim of meeting and/or exceeding our customers' expectations.
Waters Quality Policy expresses the purpose of our organization. The Quality Policy statement symbolizes the purpose of our organization, and also guides the way we accomplish that purpose.

We ensure that our Quality Policy is communicated and understood at all levels of the organization through documented training, regular communication, and verbal reinforcement.

Our Quality Policy is controlled by itsinclusion in this Quality Manual, and by being reviewed annually at the Executive Management Review meeting for continuing suitability and effectiveness.

5.3 ∆Waters Quality Policy

Quality Policy

We provide innovative technological solutions that enable customer success, by consistently delivering safe, effective, and reliable products and services.

We maintain the effectiveness of our quality management system and foster an environment of continual improvement while meeting statutory and regulatory requirements.

We are dedicated to customer experience excellence through our core values, the engagement of our people, and our strategic vision.

5.4 ∆Planning

5.4.1 Quality Objectives

At the executive management system level, our quality objectives are to achieve our Quality Policy, and to maintain the integrity of and continually improve our QMS that satisfies international regulatory requirements. At the operational level, product, project, and contract objectives are developed, as appropriate, to meet or exceed our customers' expectations.

5.4.2 Quality Management System Planning

Our Quality Management System, as described in this Quality Manual and its associated procedures, is that part of the overall management system which implements our Quality Policy, establishes procedures by which we meet or exceed customer expectations, and satisfies applicable international regulatory requirements. As such, it also constitutes the overall Waters quality plan.

This manual identifies the following documents / processes supporting new products quality planning:

a. Waters Business Operations Quality Manual
b. Marketing Requirements Document
c. Instrument Development Plan
d. New Product Introduction
e. Sustaining Engineering Development
f. Validation and verification

g. Change control
h. Product reviews
i. Test Engineering Plan
j. Reliability Plan
k. Service Plan
l. Manufacturing Plan
m. Production Planning

Quality plans for products in production are contained in documented instructions in the form of routings, process flow charts, standard operating procedures, inspection procedures and test specifications and procedures. Where required, these documents specify and identify suitable resources, controls, and process equipment, test equipment, environmental needs, verification, visual or physical criteria and/or applicable workmanship standards and records.

Executive Management will ensure the integrity of the quality management system is maintained when changes are planned and implemented.

5.5 Responsibility, Authority and Communication

Organizational charts represent management functions within the scope of our Quality System requirements.

5.5.1 Responsibility and Authority

Executive Management sets direction and ensures the success of Waters Corporation.

Responsibilities and authorities are defined in organizational charts, policies and procedures, as well as in job descriptions.

Other senior Managers, while under the direction of the Executive Staff, have primary responsibility for all operations under their control, including the Quality Management System described herein. The following have the key responsibilities and authority for maintaining the integrity of our Quality Management System:

Executive Managers – The Executive Staff is ultimately responsible for the quality of products and services provided by Waters since it controls the systems in which work is accomplished. The Executive Staff is responsible for company-wide Strategic Planning and Quality Improvement Process Planning, the development of our Quality Policy, and provision of the necessary resources for accomplishing our group-level goals and objectives. Additionally, Executive Management is responsible for conducting quality system reviews on a semi-annual basis (refer to section 5.6).

Management - Execution of the Strategic Plan, budgeting, and implementation of the quality management system and policies are the responsibility of Managers throughout the organization with the objective of adhering to specified requirements.

Employee Responsibility - All employees are responsible for the quality of their work and for their part in the overall processes used to provide products, information and services to our customers. Employees identify and record any problems related to the product, process, and quality system. Employees are also the key participants in process improvements and the identification of measures needed to ensure the success of our continual improvement processes.

Responsibility and authority of functions affecting quality are in procedures / job descriptions available from Individual departments / the Human Resources Department.

5.5.2 ∆Management Representative

Senior Manager Quality Assurance is appointed as the Quality Management System Representative. Responsibilities of this position are to ensure that a quality system is established, implemented, and maintained in accordance with standards and regulations (730001877, External Standards and

Regulations Log). In addition, the Quality Management System Representative is responsible for reporting to Executive Management Team on the performance of the QMS, ensuring the promotion of awareness of regulatory and customer requirements throughout the organization, and ensuring that the performance of the system is reviewed as a basis for continual improvement.

The Chief Executive Officer (CEO) of Waters and the Executive Management Team are responsible for ensuring that these standards and guidelines are implemented.

The Management team of Waters has defined authority and responsibility for ensuring that the Quality Management System is implemented effectively.

5.5.3 Internal Communication

We ensure communication regarding QMS processes and their effectiveness among all levels of our organization through documented training, the internal audit program, the corrective and preventive action programs and regular formal and informal communications. Formal communication is facilitated through regular company-wide presentations by the Chief Executive Officer, Organization-wide meetings held by the vice presidents, and department staff meetings.

5.6 ∆Management Review

5.6.1 General

There are two Management Reviews held in Milford. Milford Management Review includes site Vice Presidents and Directors and report on the QMS per 730001930. The Executive Management Review includes the executive staff made up of the CEO, the Senior Vice Presidents, and the Quality Assurance Senior Director or Manager, as a minimum and report on the QMS per WAT0000103MP.

The Executive Management of Waters meets minimally biannually to review and ensure the continuing suitability, adequacy, and effectiveness of the QMS. At this meeting, a number of Quality Management System components are reviewed to ensure that they remain current and applicable with business trends, market shifts and customer needs. These include the Quality Policy, quality objectives, and the need for changes to the QMS.

5.6.2 Review Input

The management review meetings include:

a. Results of audits,
b. Customer feedback (including complaints),
c. Monitoring and measuring of processes
d. Monitoring and measuring product,
e. Regulatory requirements and compliance,
f. Reporting to regulatory authorities
g. Status of preventive and corrective actions,
h. Follow-up actions from previous management reviews,
i. Changes that could affect the QMS, and,
j. Opportunities and recommendations for improvement.

5.6.3 Review Output

Outputs from the management reviews include any decisions and actions related to:

a. Improvement of the QMS and its processes,

b. Improvement of product related to customer

c. Changes needed to respond to applicable new or revised regulatory requirements, and,

d. Resource needs.

6. RESOURCE MANAGEMENT

6.1 Provision of Resources

Appropriate resources, including trained employees, are identified and provided throughout the documented Quality Management System. These include the resources needed to ensure implementation and improvement of the QMS, conduct audits, comply with regulatory requirements, and address customer satisfaction.

We believe that our employees are our most valuable assets. We do our best to help them achieve their full potential through continuous education and training. Employees have assigned responsibilities defined in the QMS and are competent based on education, training, skills, and experience.

Individuals with the necessary education, experience and training carry out quality related activities by following defined procedures. These activities conform to specified requirements to include but not limited to instrument design, applications software design and development, product verification and validation, assembly, inspection, test, monitoring of the production processes, complaint evaluation and audits of the product and of the QMS.

Resource needs are evaluated as part of the management review meetings, as well as part of the regular operations of individual departments. The results are process monitoring and measurement which are evaluated to determine if additional resources are needed to comply with requirements and maintain product quality.

6.2 Human Resources

6.2.1 General

Every advertised position includes details of what the requirements for the position are and what the education, skills or experience of the applicants should be. Based on this process, competency is not compromised and the employees become the most valuable resource for Waters.

6.2.2 ΔCompetence, Awareness and Training

a. Training Needs Determination

Waters hires and trains qualified and competent people. New employees are trained on processes unique to Waters.

Each department determines employee training, awareness, and competency needs through a variety of methods. Position descriptions are maintained for each position. Identified in these descriptions are activities / skills that affect the quality of products and services.

b. Provision

Waters develops and provides training that balances organizational needs with the development and career needs of our employees. Training may be executed by an expert in the subject matter. The subject matter expert is obtained by: 1) hiring an external consultant; 2) an internal employee who comes with the background in education and experience applicable to the subject matter; or 3) an internal employee only after completing an external course in the subject matter.

Quality System training covering applicable regulatory requirements is provided to employees. When a procedure is created / updated and implemented, those employees responsible for that specific process are trained. Individual Personal Development Plans are generated with each employee on an annual basis. Personal Development Plans are used to determine both inside and outside training needs for the fiscal year. Training / Certification records for various training sessions / courses are maintained.

c. Effectiveness

Waters evaluates the effectiveness of the training through immediate feedback and longer-term evaluation through the performance review process. Ultimately, comprehensive measures such as productivity, on-time delivery, and customer satisfaction are the most critical measures of training effectiveness. Effective training will lead to the required competency level of employees.

d. Employee Contributions

Waters ensures that our employees are aware of the relevance and importance of their activities and how they contribute to the achievement of our quality objectives. This is accomplished through QMS training.

6.3 Infrastructure

Waters provides and maintains suitable production, installation and servicing facilities needed to achieve product and service conformance. This includes physical resources (i.e. buildings), specialized equipment, workspace, associated utilities, hardware and software, and supporting services (transport and communications).

Waters ensures equipment used for production and other activities that may affect product quality are maintained in accordance to written schedules. Maintenance records are kept as objective evidence.

6.4 Work Environment

Waters identifies and manages the human and work environment factors needed to achieve product conformance and meet and/or exceed customer expectations. Our people are the key to our success, and the human and physical factors under which they work are of paramount importance. A suitable working environment is maintained.

Regarding physical factors, we employ a wide range of activities to monitor and improve workplace safety, health, and ergonomics. These include adherence to good manufacturing practices, safety team meetings, and training.

One of our objectives is to be an “employer of choice”. In addition to providing generous benefits, we accomplish this by providing flexibility, interesting work, a balance between work and family life and involvement of our employees in an empowered environment of continual improvements. We engender total participation by structuring a team environment, utilizing participative leadership styles, and involving employees in continual improvement teams.

Waters ensures environmental conditions and other factors that may negatively impact product quality are controlled and where appropriate monitored and measured. This may include basic housekeeping and ESD (Electro Static Discharge) controls.

7. PRODUCT REALIZATION

7.1 Planning of Product Realization

Our QMS plans identify and document our realization processes, and thereby ensures consistency with other requirements of the QMS. The QMS development, planning and implementation process includes the following:

a. the identification of product, process and quality objectives,

b. the need to establish processes and documentation and to provide resources and facilities specific to the product and the process,

c. verification and validation activities and the criteria for acceptability, and,

d. records necessary to provide confidence of conformity of processes and product.

These elements are addressed in this manual and its associated procedures.

Whenever our standard established process cannot and does not fit customer’s specified requirements QMS develops a specific quality plan for that process or product.

Our approach to process management involves determining what the customer's requirements are, developing a process capable of meeting these requirements, ensuring that the inputs to the process are appropriate, measuring process performance, and evaluating and improving the process to ensure it continues to perform as designed. The following sections describe our methods for achieving these objectives.

Waters maintains written procedures for risk management throughout product realization. Part of the planning process is the evaluation, analysis, and control of risk. Records of risk management are maintained. The ISO 14971:2012 Standard is used as guidance for the risk management activities at Waters.

7.2 Customer-Related Processes

Waters' primary focus is to be an active partner with our customers, understanding their environment and identifying solutions suitable to their needs and applications, which will both meet and exceed their expectations.

We accomplish this objective through a multitude of channels, which include, but are not limited to, Technology Seminars, user meetings, routine customer visits by our sales team, trade shows, special customer visits by the Waters' leadership team, direct phone contact with key personnel of our customers' organizations, and customer audits of our facilities. These communications and interactions enable Waters to understand our customers' environment, and enables Waters to identify solutions and design applications to meet, or exceed, our customers' expectations. This process is one way that Waters continually strives to be a leader in the analytical scientific industry. The QMS ensures that these requirements are fulfilled with the aim of exceeding our customers' expectations.

7.2.1 Determination of Requirements Related to the Product

a) We determine product requirements through market research, customer forums, individual customer inputs and Waters research groups. Customer input is the core of the process. Customer orders for standard forecasted catalog items are reviewed by Sales Support Staff and accepted based on published specifications, quotes and delivery times. All delivery and post-delivery activities relative to the product are addressed at the time of order placement by the customer. Any differences are resolved prior to accepting the order. Changes to orders after they have been accepted are communicated internally and confirmed to the customer prior to shipment. Waters instruments are manufactured and sent to distribution as standard catalog items.

b) In addition to individual customer requirements, additional requirements may be added, including those that satisfy statutory and regulatory requirements, define delivery and post delivery activities and those that are necessary to specify intended use. Ultimately, product requirements are represented by specifications for each standard part number. These specifications are documented in the Market Requirements Document. The products are manufactured based on a build schedule that is delivered to Production Planning in the form of a forecast received from Global Manufacturing Planning for standard catalog items. The forecast is reviewed and either accepted or revised. Changes are communicated to Global Manufacturing Planning (Master Planning).

c) Waters' products are manufactured in accordance with state and federal statutory and regulatory requirements, which include the FDA.

d) When required, Waters products are installed by Waters-trained service personnel, by setting up / qualifying the system and by training users in the basic operation of the equipment. When necessary, additional training can be provided by the local field support organization and/or Waters Educational Services instructors to satisfy customer expectations.

7.2.2 Review of Requirements Related to the Product

Upon receipt of an order for product and/or service, the appropriate internal support group reviews the order against the customer's quote and any contractual agreements (i.e. Strategic Alliance Agreement), ensuring consistency between the order and established requirements. Contract and order reviews are

performed in accordance with documented procedures to determine whether order criteria can be met prior to accepting and making a delivery commitment.

a. Type of Review–Product Requirements:

(i) Customer orders for standard forecasted catalog items are reviewed prior to acceptance by Sales Administration based on whether Waters can meet specific customer requirements, such as delivery schedule.

(ii) Customer orders for non-forecasted, refurbished catalog items are reviewed by the Global Manufacturing Planning and the Manufacturing Repair Department prior to their acceptance. Orders are accepted based on availability of the returned product.

(iii) Customer orders for service are reviewed against any existing contractual agreements by the Service Plan Support team and a determination is made as to whether Waters can meet the specific customer requirements.

b. In all instances, differences are resolved prior to accepting the order. Changes to orders after they have been accepted are communicated internally and confirmed to the customer prior to shipment.

c. Acceptance of the order ensures that Waters has the ability to meet the defined requirements.

d. Record of Review: The results of the review process and follow-up action are ultimately recorded in Waters' SAP System. Entry of the order into SAP constitutes evidence of contract review.

e. Changes to Product Requirements: Should Waters determine that a change to product requirements is necessary, the change is communicated to the customer by Sales Administration personnel in accordance with documented procedures. An update to the product file is made on SAP.

7.2.3 Customer Communication

Both domestically and internationally, communication with our customers is primarily achieved through our local Waters sales, service and support teams, as well as the Contract Administration department and Strategic Alliance Group. Communications may address information related to product, inquiries, contracts, contract amendments, order handling, complaints, and advisory notices / recalls. We pay particular attention to customer feedback in the form of customer satisfaction surveys and customer complaints.

7.3 Design and Development

7.3.1 Design and Development Planning

Overall Design Control is outlined by interconnected processes owned by various functions; Instrument Development, Evaluation, Core Product Engineering and Data Product Group (DPG) Software Development organizations. Other functions such as Reliability and Engineering Data Services support the efforts, as applicable. The related procedures control and verify that specified requirements are met (refer to section 7.3 of Appendix I for the appropriate support procedures).

A Development Plan is created for each development project or program and outlines the following:

a. Milestones
b. Development phases
c. Design and code reviews
d. Qualified personnel, responsibilities and authorities
e. Review, verification and validation
f. Assigned equipment
g. Sub-projects & sub-project managers
h. External dependencies
i. Project schedule
j. Exit criteria for development phases

A Test Plan is created for each development project.

Plans are reviewed and updated, when necessary, as the design evolves.

The Manufacturing Plan considers the requirements needed for the transfer to manufacturing. As part of the New Product Introduction (NPI), the design transfer ensures that design specifications are correctly translated into manufacturing procedures.

Design records generated during the design process are referenced or included in a Design History File (DHF) as required by Regulatory Agencies and / or QMS requirements.

7.3.2 Design and Development Inputs

The required input includes functional and performance specifications, safety requirements, outputs of risk management activities from previous designed products, applicable regulatory requirements and international compliance, information derived from previous design and other features and requirements essential for design and development. Market Requirements Documents and development plans and processes may include additional information to complement this list of documents.

Design inputs are reviewed for adequacy and approved.

7.3.3 Design and Development Outputs

The required verification procedures for Instrument Products are carried out at each phase of the development plan. The minimum set of document deliverables is outlined in the Waters instrument development process procedures referenced in Appendix I.

The required verification procedures for Application Software development carried out at each phase and a minimum set of document deliverables are outlined in the Waters DPG software development process documents, DPG Quality Plan and the Procedure for Technical Reviews. Sign off of Task Completion Forms (electronic or paper) by the project manager and author signifies acceptance of software module(s) for submission to evaluation.

Records of design outputs are approved and maintained.

7.3.4 Design and Development Review

Suitable and systematic reviews of the design are conducted in accordance with the appropriate development procedures. Reviews are performed to evaluate the ability of the results of design and development to meet requirements. Records of reviews are archived before or at Approved for Shipment Review meeting.

Design control, input, implementation and reviews for Applications Software Products are outlined in the Waters various software development process documents and the Instrument Development Plan. Records of reviews are archived before or at a time software is released to manufacturing.

Design reviews must include participants concerned with the design stage being reviewed as well as other specialists deemed necessary. Each design review includes an individual(s) independent of the design stage being reviewed.

7.3.5 Design and Development Verification

Verification is performed based on the design, development and test plans.

Verification confirms that design outputs meet the design input requirements.

Verification of instrument design occurs as the design matures progressively. Verification of the Applications Software occurs at major milestones as defined in the DPG software development process and Development Plan. A final verification of functionality occurs during the final evaluation phase. The product is validated and verified against the Marketing Requirements Document and Functional

Specification under conditions similar to those existing during customer application. Final design verification is completed at the release meeting.

Records of the results of the verification and any necessary actions are maintained.

7.3.6 Design and Development Validation

Design and development validation is performed based on the design, development and test plans to ensure that resulting product is capable of meeting the requirements for the specified application or intended use.

Test results confirm that required elements of the Marketing Requirements Document for Instrument or Applications Software products are satisfied, and any other elements of the Functional Specification have been implemented. The plan assigns responsibilities for creating, reviewing and executing the test cases and scripts. Results from evaluation are collected at the instrument or application software release meeting and archived. Problems discovered by evaluation at any phase are recorded and tracked according to the Product Change System. Final design validation is done during the Final Evaluation Phase and at the Release Meeting.

Design validation establishes objective evidence that device specifications conform to user needs and intended use. Design validation during Instrument, Chemistry, and Software development life cycles includes testing under actual or simulated use conditions to assess product / device performance. Design validation includes clinical evaluation of the product / device only during the Clinical Chemistry Development lifecycle. Any clinical evaluation of a design is performed in accordance with applicable national or regional regulations.

7.3.7 Control of Design and Development Changes

Changes to the design and development are identified, controlled and recorded.

Changes are reviewed, verified and validated, as approved and appropriate before implementation. Review includes the effect of the changes on products and parts already delivered to customers. Changes are reviewed for regulatory impact on Canadian Licenses, FDA 510(k)'s, and European Technical Files.

Revision Control and Product Structure policies and practices are defined in the Instrument Development Process, Waters Instrument Design Change Control Policy, and Waters Product Structure Development Process.

Configuration management for software items and developer hardware and software is defined in the DPG Configuration Management Plan for Software. Configuration management of specifications and deliverables created by the DPG is defined in the procedures and archival policy used by DPG. Configuration management of test cases and hardware is defined in the Test Plan with any needed addenda and Test Summary Results. Configuration of Automated Test items, including automated test hardware and software, are defined in the DPG Configuration Management Plan for Software.

7.4 Purchasing

7.4.1 Purchasing Process

Waters ensures that purchased products and services that impact the final quality of our products, conform to our requirements. We accomplish this objective by clearly identifying our requirements, working in partnership with our suppliers, and utilizing appropriate verification activities. These efforts are described below.

It is the responsibility of the Purchasing Department to purchase product and services that conform to specified requirements from approved suppliers as defined in documented purchasing procedures.

Purchased material is submitted to the Incoming Material Audit Department to assure initial and continued conformance of material to stated requirements.

Specific requirements of each purchase are defined in purchase orders, which include the purchase specification, item revision, and other data, as required.

During design & development, material might not be submitted to Incoming Material Audit. The Design Material Control Procedure outlines the development / New Product engineer's responsibility to make sure the material is in conformance with the requirements, controlled and identified as Research Only or Quarantined.

This manual, and associated procedures, establish the methods by which we control our purchasing process to ensure product conforms to requirements. The type and extent of control is dependent upon the effect on subsequent realization processes and their output, as well as consideration of other characteristics including: the type of product; the potential impact of the product on our processes, products, or services; the results of supplier evaluations and past performance; Government regulations and industry requirements.

We have defined and documented the supplier approval process, including criteria for selection, the extent of control to be exercised, and periodic evaluation. Suppliers are evaluated and selected based on their ability to supply product in accordance with our requirements. The results of evaluations and follow-up actions are recorded.

Additionally, we maintain a record of approved suppliers. A Qualified Supplier List is maintained based on a supplier's ability to meet Waters quality requirements and design specifications. A supplier's inability to meet Waters quality and/or design requirements is reviewed and the appropriate action is initiated. A review of supplier's performance against the Waters Supplier Rating System takes place on a periodic basis by Supplier Quality Engineers and Purchasing Managers.

When required, one or more of the following activities will take place:

a. Corrective action letter to supplier.

b. Supplier site evaluation.

c. Review Waters' design and/or Quality System.

d. Recommendation for disapproval submitted to the Supplier Quality Manager and the Materials Manager.

7.4.2 Purchasing Information

Purchasing documents contain the appropriate data to clearly and fully describe materials, which are being purchased. When appropriate, this includes requirements for approval or qualification of product, procedures, processes, equipment, personnel, and Waters' QMS requirements.

We conduct review to ensure the adequacy of specified requirements contained in the purchasing documents prior to the placement of an order.

Design engineers are generating most of the orders, during the design phase of product development.

Following product release, orders are computer generated by the Materials Requirement Planning (MRP) System. These orders are then forwarded to Product and Engineering Data Services where the appropriate purchase specification/design drawings are added prior to delivery to Purchasing. This information is communicated to the supplier by referencing the Purchase Specification/Drawing number and revision on Purchase Orders. When Purchase Specifications/Drawings are revised, this updated information is communicated to the supplier. Any specific requirements to a Purchase Order, such as certificates, are addressed on the Purchase Specification. Purchase Orders are checked and verified and signed by the Purchasing Agent prior to issue.

7.4.3 Verification of Purchased Product

Waters has established and implemented inspection and other processes to ensure that purchased product meets specified purchase requirements.

Material used in processing or as part of the product or packaging is released for use after samples have been successfully inspected in accordance with the Incoming Material Audit Policy. The nature and degree of inspection is dependent upon the criticality of the part and the inspection history.

Release of material, prior to required verification, is neither allowed nor practiced. No material is released prior to being verified per requirements and specifications.

At this time, there is no formal customer source verification of product at the sub-contractor's facility. Should this become a requirement, the Milford plant will comply with and assist in any such verifications. This process shall be initiated by the Quality Department. Such verification shall not supersede Waters Quality System requirements.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

7.5.1.1 General Requirements

Waters plans and carries out production and service activities under controlled conditions. Controlled conditions includes availability of information related to the specifications of the product, qualified and competent personnel, documented instructions, suitable equipment, monitoring and measuring devices and the implementation of monitoring, measurement, release, delivery and post-delivery activities.

a. Information: Information inputs to the process include both product characteristics and appropriate work instructions. In addition to final product specifications, raw material characteristics and the required product parameters at critical process steps are available to process operators, as applicable.

b. Work Instructions: Documented instructions in the form of process flow charts, operating procedures, process and routing instructions and assembly and test procedures are used. Where required, these documents reference the necessary equipment, environmental needs, visual or physical criteria and/or applicable workmanship standards, suitable maintenance of equipment, environmental needs, visual, physical or Electrostatic Discharge.

The knowledge, skills, and abilities of our employees and the complexity of the work process determine the generation of and detail level of local work instructions. All production-related processes are performed by trained, qualified / certified operators.

Employees are equipped to perform their process properly through appropriate education / training. Work instructions and other important data are maintained current and accurate. Material must meet specified requirements and is identified, stored, and issued. Adequate equipment and facilities are available for the necessary processes. The appropriateness of these fundamental processes is measured, controlled and evaluated for continual improvement. (Refer to Section 6.2 that minimizes the requirements for detailed work instructions). However, critical production steps are identified and provided in Work Instructions or Process Notes.

c. Equipment: All equipment used for production and service operations is suitable, and is maintained in accordance with documented procedures.

d. Measuring and monitoring devices: Waters has identified and ensures the availability of measuring and monitoring devices capable of meeting our measurement requirements. For additional information refer to Section 7.6, Control of monitoring and measuring devices.

e. Monitoring activities: Waters has identified and implemented the appropriate measurement and monitoring activities necessary to ensure process control.

These are discussed more fully in Section 8.2.3, Monitoring and Measurement of Processes, and 8.2.4, Monitoring and Measurement of Product.

f. Release, delivery, and post-delivery processes: Release of product is dependent on its compliance with all technical specifications and its ability to meet additional customer requirements including packaging, shipping, and delivery, as identified in the contract or order. Records of product approval are maintained and clearly indicate the authorizing employee.

Manufacturing departments manufacture products according to quality plans specified by the documented procedures and other related documents. Manufacturing departments record required data, and make adjustments to the process within acceptable limits to achieve consistent quality. Manufacturing departments build to factory orders that are generated from the Master Build schedule. Factory orders are delivered to a dedicated process/assembly line for each product stream

Service activities are provided by the Marketing and Service Support groups, which are comprised of cross-organizational teams of trained specialists who focus on defined needs of our customers and the field organization. Procedures, work instructions and records of performance exist for each work area. This established process ensures that servicing function meets specified requirements. Under the direction of the respective Vice Presidents, the management team establishes appropriate quality standards for maintaining and improving their services and/or products and for recording and evaluating their performance.

g. Packaging and Labeling Operations

Packaging and labeling operations are conducted in accordance with written procedures and/or work instructions.

A record is maintained for each product by serial number. A serial number relates to one device / instrument. These records consist of manufacturing and inspection records, and are maintained in compliance with Regulatory Agencies and / or QMS requirements.

7.5.1.2 Control of Production and Service Provision – Specific Requirements

7.5.1.2.2 Installation

Waters installs devices in accordance with written installation instructions to ensure they are installed correctly. The devices are inspected and/or tested to ensure they are installed properly. Records of installation are maintained.

7.5.1.2.3 Servicing

Waters provides technical support services for customers that experience difficulties with their devices. Waters also provides field service engineers to perform preventive maintenance on the devices, as well as perform repair and servicing activities as needed. Servicing is conducted in accordance with the applicable Service Manual for the device in question. Records of servicing and repair are maintained.

7.5.2 ΔValidation of Processes

Waters validates manufacturing processes where the Critical to Quality (CTQ) attributes are not fully verified under 730000837, Waters Global Validation Policy. Process Validation establishes by objective evidence that a manufacturing process consistently produces a result or product meeting its predetermined acceptance criteria.

Waters ensures that software tools used for production or as part of the Quality Management System is validated for intended use under 730000617, CSV: Global Software Tool Validation Policy. Test

equipment software is verified under 730000837, Waters Global Validation Policy. Product software is validated as part of design validation.

7.5.3 Identification and Traceability

Waters identifies and records the unique identification of the product throughout product realization by suitable means to ensure effective status and traceability. We identify a unique lot or batch number when product is made in lots or batches.

Identification of inspection and test status of the product is maintained, as necessary, throughout production, as defined by the manufacturing and test procedures.

During the design phase of new product development, product identification, traceability and test status are under the control of the development project manager according to the appropriate Development procedures.

Waters identifies measurement and monitoring status using both a manual paper system and our SAP System. Additionally, physical location is an indicator of product status. All incoming, in-process, and final product is suitably identified and the current status is appropriately tracked and displayed.

Waters product is identified during production through an MRP/BOM (Bill of Material) process, based upon unique part numbers. Sub-assembly and/or assembly part numbers identify stages of certain manufactured parts. Material is identified at various stages of the production process in the following ways: appropriate paperwork (i.e. factory order), part number identification and labeling. Standard part numbers and/or serial numbers are assigned, when required, to identify finished product. Finished products are serial numbered according to a standardized system. This serial number is used as a means of tracing product to customer.

Identification and traceability information is maintained in SAP, our information management system.

Traceability for instruments is maintained through the Serial Number, Device History Record (DHR), Factory Order (FO), BOM, and Genealogy Record. Refer to the traceability work instruction (730003005) which defines the extent of traceability for Milford manufactured instruments.
Traceability for Software is maintained through the Serial Number DHR, FO, and BOM. Refer to the traceability work instruction (WAT000020MP) which defines the extent of traceability for software products.

Traceability for Reagent Kits is maintained through the PO (Purchase Order), Part & Lot Number, FO, BOM, DHR and COA (Certificate of Analysis). The DMR (Device Master Record)/DMP (Device Master Plan) specifies which records are filed in the DHR. Traceability also extends to the reagent kit component supplier and is maintained through the PO, Part & Lot Number, DHR and COA. Traceability for the reagent kits is contained in the product DMP.

Returned products are stored in a designated area segregated from other products and are properly identified to prevent mix-ups with other products.

7.5.4 Customer Property

Waters exercises care with any customer property while it is under our control. We identify, protect and maintain customer equipment provided for repair, applying the same process controls as we do to other material inputs to the process. Currently the only customer-supplied product is Warranty Repair of Customer-Owned Catalog Items.

Waters maintains procedures for identifying, verifying repair requirements and repairing customer-supplied product.

Waters may integrate customer-supplied product into the software products or hardware products. On rare occasions, Waters exchanges confidential information with customers and development collaborators. In these cases, Waters develops appropriate non-disclosure agreements and mechanisms that identify, protect and safeguard customer intellectual property, as applicable.

Waters does include other third party software with the applications software, including, operating systems (e.g., Windows NT) and databases (e.g., Oracle). Validation of this third party software is included in the verification and validation phases of evaluation whereas licensing issues are managed by Purchasing and Marketing.

7.5.5 Preservation of Product

Waters preserves the conformity of the product during the internal processing and delivery to the customer. Our system is designed to address the identification, handling, packaging, storage, preservation and delivery requirements of our in-process and final product.

a. Handling: All products are handled in a manner that prevents damage, contamination, misuse or deterioration at all stages of production. Software is replicated according to Standard Operating Procedures that stipulate types of media, packaging, documentation, copyright, licensing and custody of masters and backups.

b. Packaging: Products approved for delivery are packaged in a manner to protect them during storage and delivery. Appropriate packing materials are used, including pallets, banding, and shrink-wrap. Finished Product is packaged and labeled as specified by the Manufacturing Assembly Procedures, Process Flow Charts, Drawings and/or Standard Operating Procedures.

c. Storage: Products are stored in a Waters owned stockroom and warehouse. Defined storage areas are designated for products to prevent damage or deterioration of the product, pending its use or delivery. Procedures for receipt and dispatch of material are defined and documented. Products that have a shelf life are inspected at specified time intervals to assess their condition. Raw materials are stored in their shipping containers in the stockroom until issued to the factory order to be kitted for use.

d. Preservation: Material is handled in a manner, which prevents damage and/or contamination. It is identified by a unique part number and stored in a designated stock location under appropriate environmental conditions.

e. Delivery: Waters employees or a sub-contracted transportation firm transport finished goods to Waters' Distribution locations. The transportation firm complies with requirements defined by Waters Global Distribution Center.

Product is delivered to our customer in a manner that prevents damage and conforms to legal and customer requirements.

Distribution records are maintained in SAP identifying the consignee name and address, date shipped, product, quantity, and control numbers (serial number or lot number) in order to facilitate corrective action.

Handling, Storage, Packaging, Preservation, and Delivery procedure, combined with the procedures for determining product status and identifying non-conforming product, provide adequate assurance that the condition of the product when our customers receive it is such that it meets their requirements.

7.6 Control of Monitoring and Measuring Devices

Waters has a defined process for the control of measuring and monitoring devices needed to provide evidence of conformity of the product to specified requirements. This includes details of equipment type, unique identification, location, and frequency of checks, check method, acceptance criteria and the action to be taken when results are unsatisfactory.

Waters determines the measurements to be made and the accuracy required to assure conformity of our product to specified requirements. Equipment is selected that is capable of functioning with the required accuracy and precision.

Measuring and monitoring devices are used in a manner that ensures that measurement capability is consistent with the measurement requirements. This includes ensuring that the environmental conditions

are suitable for the calibration, inspections, measurements and tests being carried out. We control all measuring and monitoring devices that can have an effect on product quality.

Waters maintains the following types of tools and equipment. The system for controlling, calibrating and maintaining each type is defined in the appropriate procedures:

a. Equipment and Software developed and manufactured by Waters Test Engineering

b. Commercially manufactured electronic measurement and test equipment

c. Commercially obtained software

d. RD&E Evaluation engineered software

e. Mechanical tools and equipment either purchased or built in-house

Software used for measuring and monitoring of specified requirements shall be checked periodically and validated prior to use.

a. Periodic Calibration: Waters has identified the measuring and monitoring devices that can affect product quality and calibrate and adjust them at prescribed intervals. Calibration is performed against certified standard. Where no such standards exist, the basis used for calibration is documented.

b. Safeguard from Adjustment: We ensure that measuring and monitoring devices are safeguarded from adjustments that would invalidate the calibration.

c. Protection from Damage: Waters ensures that handling, maintenance and storage of measuring and monitoring devices is such that accuracy and fitness for use are maintained.

d. Calibration Records: Waters maintains appropriate calibration records for measuring and monitoring devices. We identify measuring and monitoring devices with unique identification numbers. Calibration status of measuring and monitoring devices is shown on the calibration sticker on the equipment and / or by the information contained in the calibration database.

e. Validity Re-assessment: Should the calibration of an instrument result in an Out of Calibration finding, an Out of Calibration Notice is issued to determine if the Out of Calibration condition would have passed a non-conforming product. In this case, Waters takes an appropriate action including a Field Action or remedial action, if necessary, to address the situation.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

Waters has defined, planned, and implemented the monitoring, measurement, analysis and improvement processes needed to assure product and QMS conformity and achieve continual quality management system improvement.

These activities include assessment of customer satisfaction, QMS performance audits, process control, including statistical techniques, where appropriate, assessment of product characteristics, control of nonconforming material and product, analysis of data in various areas, corrective actions and management reviews.

Waters' operations including software and instrument development activities are periodically reviewed to determine the need for the application of statistical techniques for establishing, controlling, and verifying process capability and product characteristics.

Where applicable, instructions for implementing and controlling the application of statistical techniques are documented in standard operating procedures and work instructions.

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction

Waters is a customer focus organization. It drives our quality policy "to provide innovative technological solutions, products, and services to our customers". We collect, monitor, and evaluate information on customer satisfaction and dissatisfaction in order to determine how well we are performing against this critical objective. There are a number of ways we accomplish this:

a. Waters developed in conjunction with a marketing survey company a customer satisfaction survey which is used to contact customers worldwide (in their local language) and ask a series of questions. The answers are collated, analyzed and a ranking is performed for each question.

b. Regular meetings of a Customer Complaint Committee review customer complaint reports. The committee assigns resources to resolve the issues and follow up at subsequent meetings to ensure the customer's needs have been satisfied and / or to reach a working solution.

c. Waters holds user group meetings and exhibits at trade shows where we speak one-on–one with our customer to understand their satisfaction level with the products, Waters and the employees.

d. Through other market research to understand specific customer expectation and satisfaction in specific products in various market areas.

Our objective is to be particularly responsive to feedback from the field to include customer dissatisfaction or complaints while building on our customer satisfaction level. We have documented and implemented our procedure for obtaining, evaluating, and acting on customer feedback. Customer Feedback provides an early warning of quality problems, which will be entered into the Corrective and Preventive Action system.

8.2.2 ∆Internal Audit

At Waters, internal audits are conducted at planned intervals to determine conformance to applicable regulatory requirements (730001877, External Standards and Regulations Log) and Waters' established Quality Management System. In addition, internal audits are conducted to ascertain whether the QMS is effectively implemented and maintained and to identify opportunities for continual improvements.

Internal Quality audits are performed in accordance with documented procedures. These audits are designed to identify deficiencies / non-compliances, as well as opportunities for continual improvement related to Waters Quality System. In addition, Waters internal audits are also designed to document conformance to processes and procedures. Areas to be audited are based on risk and importance. Results of Internal Audits are evaluated and reviewed to verify effectiveness and are used as inputs to the Management Review process to ensure continued suitability of the Quality System.

8.2.3 ∆Monitoring and Measurement of Processes

Waters applies suitable methods for measurement and monitoring of those processes necessary to meet our customers' requirements. The primary focus of this approach is to be able to control, measure, and monitor processes to assess whether they continue to satisfy their intended purpose and to identify opportunities for continual improvement.

Measures are organized into categories, and include yields, process accuracy, on time delivery, productivity, and improvements as evidenced by cost reduction and meeting project scheduled completion dates.

8.2.4 Monitoring and Measurement of Product

Waters monitors and measures the characteristics of our products throughout all phases of the realization process. This activity serves to guide the production process as well as to verify that all product requirements are met.

In-process testing is conducted throughout the process. All finished product is tested to ensure it conforms to specifications.

a. Receiving Inspection and Testing:

Material used in processing or as part of the product or packaging is released for use after samples have been successfully inspected. The nature and degree of inspection is dependent upon the criticality of the part and the inspection history. Release of material prior to verification is neither allowed nor practiced. No material is released prior to being verified per requirements and specifications.

b. In-Process Inspection and Testing:

In-process inspection and testing for manufactured products are in accordance with the prescribed Standard Operating Procedures, Flow Charts and Manufacturing Assembly work instructions, as required. These procedures specify the acceptance criteria, and action to be taken if non-conformity occurs. Where subjective criteria are referenced, the final decision is made in the Quality Group. For products in development, the Instrument Development Process or Software Development Process and referenced procedures define requirements for verification and validation during development. Task completion reviews and RD&E Evaluation tests results document these activities.

c. Final Inspection and Testing:

Prior to the product release, final evaluation testing is performed on the complete product and/or configuration(s) to simulate customer conditions and environment. Release Meeting(s) are held before the design is released to manufacturing and a new product is first shipped to customers to ensure that records and procedures as outlined in the Instrument Development Process or Software Development process, Development Plan and Test Plan have been completed.
In manufacturing, final inspection and testing are in accordance with Test Specifications, Procedures, Process Flow Charts and Manufacturing Assembly Procedures, as required. These procedures specify the acceptance criteria, and action to be taken if the product fails. Where subjective criteria are referenced, the final decision is made in the Quality Group.

d. Inspection & Test Records:

Records of Design Verification, Validation and product release are maintained in the RDE Project Archives or electronically, according to defined procedures. In manufacturing, records that demonstrate inspection and test results are maintained in accordance with the appropriate procedures. Test results of final product are recorded, reviewed and filed in the instrument test history files by serial number. Records are maintained as evidence of conformity. The records include the person(s) authorizing the release of the product. Products are not released until all requirements have been met.

e. Evidence of conformity:

Test / inspection records are maintained and include final inspection sign off. They identify and confirm that all critical parameters are in accordance with final test requirements.

f. Product release and delivery:

Product is not normally released from the production area until all the required inspection and tests have verified that it meets specification and the appropriate records have been generated. If a product is released without being inspected/tested for any reason, it is done so under conditions of positive recall. Non-conforming product is held until an authorized employee obtains necessary approval (refer to Section 8.3, Control of Nonconforming Product). Inspection and test data is collected, analyzed and used as input for continual improvement.

8.3 ∆Control of Nonconforming Product

Waters ensures that product which does not conform to specifications and requirements is identified and controlled to prevent its unintended use or delivery.

There are procedures for identifying, segregating, notifying, documenting, reviewing, and approving the evaluation and disposition of non-conforming material. Nonconforming material is labeled or tagged to identify that it is not acceptable and segregated by being held in a designated area awaiting further evaluation of disposition.

In Manufacturing:

Nonconforming material is reviewed and the disposition is recorded in the database. The database is used for all nonconforming raw material, assembly, sub-assembly, and finished product.

Products that do not fully conform to all formal specifications but may be used in certain applications must be reviewed by a Material Review Board (MRB).

Procedures have been established which address the following steps involved in the control of nonconforming product:

Identification. Nonconforming product that originates from inspection, internal testing, machine shop, manufacturing, or customer complaints is identified and tagged.

Documentation. Authorized employees will document nonconforming product in the database, including description of nonconformance, and location of material.

Evaluation. Authorized employees will evaluate incoming, in process, and final product in accordance with approved test and inspection procedures.

Segregation. Nonconforming product is segregated pending final disposition.

Disposition. Authorized employees evaluate nonconforming product in accordance with approved procedures and take one or more of the following actions:

a. Rework the raw material or finished product to meet specified requirements
b. Issue a waiver for use “Use as Is”
c. Return to vendor
d. Accept with Correction (documentation)
e. Dispose / Scrap

Products requiring rework must be done in accordance with rework procedures or instructions. A determination of any adverse effect of the rework upon the product shall be made and documented. Once the rework of a product is complete, it must be inspected and/or tested and records are maintained.

8.3.1 Correction and Re-verification:

Nonconforming product is corrected and re-verified / re-inspected to original requirements after correction, to demonstrate conformity. Raw materials identified, as not meeting specifications must be segregated for the Material Review Board decision and dispositioned by designated personnel. Finished product not meeting specifications will be dispositioned.

8.3.2 Product Recall:

In the event of nonconforming finished product leaving our facility we review the nature and impact of the non-conformance and take appropriate action up-to and including recall of the product.

8.3.3 Nonconformance Reporting:

The MRB performs tracking, trending and reporting of nonconforming product. Reports are used as inputs to Management Reviews and used to improve the process.

Nonconformances discovered by a customer during use are documented through the field service representative, customer phone support, Technical Service and Technical Support or the Global Service Support organization.

8.4 Analysis of Data

Data is collected and analyzed to determine the suitability and effectiveness of our QMS and to identify opportunities for continual improvement. This includes data generated by measuring and monitoring activities, customer feedback, our supplier quality process, the Corrective Action System, and our audit process.

We analyze the data to provide information on customer satisfaction including conformance to customer requirements, process and product characteristics and trends, and supplier performance. This data is included as part of the management review process.

8.5 Improvement

8.5.1 Continual Improvement

Waters plans and manages the processes necessary for the continual improvement of the QMS. These include the use of our quality policy, strategic and operational objectives, audit results, analysis of performance data, corrective and preventive actions and management reviews.

Customer Complaints

Waters handles customer complaints in accordance with internal procedures. Customer complaint records include the date the complaint was received, the name of the individual and organization complaining, the product involved, serial numbers and a description of the complaint.

When processing a customer complaint in a clinical application, the complaint records must either include an investigation of the complaint or a justification of why an investigation is not required.

The complaint records must either include a rationale why corrective action is not required or an outline of the root cause, corrective actions, and verification to resolve the problem.

Repetitive complaints or trends may result in the initiation of a Corrective Action.

Adverse Event Reporting

Complaints for clinical applications are evaluated to determine if an adverse event (i.e. death, serious injury, or malfunction that is likely to result in a death or serious injury if it were to recur) has occurred.

The appropriate regulatory authorities (i.e. FDA, European Competent Authorities, Health Canada) must be notified of an adverse event using the required forms submitted within the required timeframes. These requirements are outlined in the procedures for handling adverse event reporting.

Recalls and Advisory Notices

If Waters becomes aware of a situation that warrants a recall or issuance of an advisory notice, it will be done so in accordance with the Recall Procedure. The appropriate regulatory authorities (i.e. FDA, European Competent Authorities, Health Canada) will be notified as required. The procedure can be utilized for advisory notices and recalls (removals and corrections).

8.5.2 Corrective Action

Action is taken to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions are appropriate to the effects of the nonconformities encountered.

Waters has a documented, comprehensive corrective action program, which includes the investigation of cause and correction of product and process complaints to ensure that they do not reoccur. Examples of inputs to the system include Internal Audits, customer complaints and field service reports, nonconforming product, supplier corrective action, and Quality System non-conformances. Product or process failure is an indication that the process or system was not followed, or is inadequate.

Corrective Action data base includes: information related to the problem, containment actions, the root cause, correction to the problem, and follow-up action to ensure effectiveness.

As part of our QMS and continual improvement process, we investigate and document nonconformities to determine the corrective action needed to preclude their recurrence. Based on the results of this investigation, we implement corrective action to eliminate the root cause of the nonconformities in order to prevent their recurrence. We apply controls and follow-up to ensure that corrective action is taken and is effective.

Corrective Action procedures define and document requirements for identifying nonconformities (including customer complaints), determining the causes of nonconformity, evaluating the need for actions to ensure that non-conformities do not reoccur, determining and implementing the corrective action needed, recording results of action taken, and reviewing of corrective action taken. Results of the Corrective Action program are summarized and trended to identify opportunities for improvement. This information is reviewed during management review meetings.

8.5.3 Preventive Action

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

Preventive Action is used to identify continual improvement opportunities and includes the following:

a. Determination of potential nonconformities and their causes,
b. Evaluation of the need for action to prevent occurrence of nonconformities,
c. Determination and implementation of action needed,
d. Records of results of actions taken, and,
e. The review of preventive action taken.

The results of preventive actions are reviewed for effectiveness and relevant information is presented at the management review meetings.

DOCUMENT HISTORY

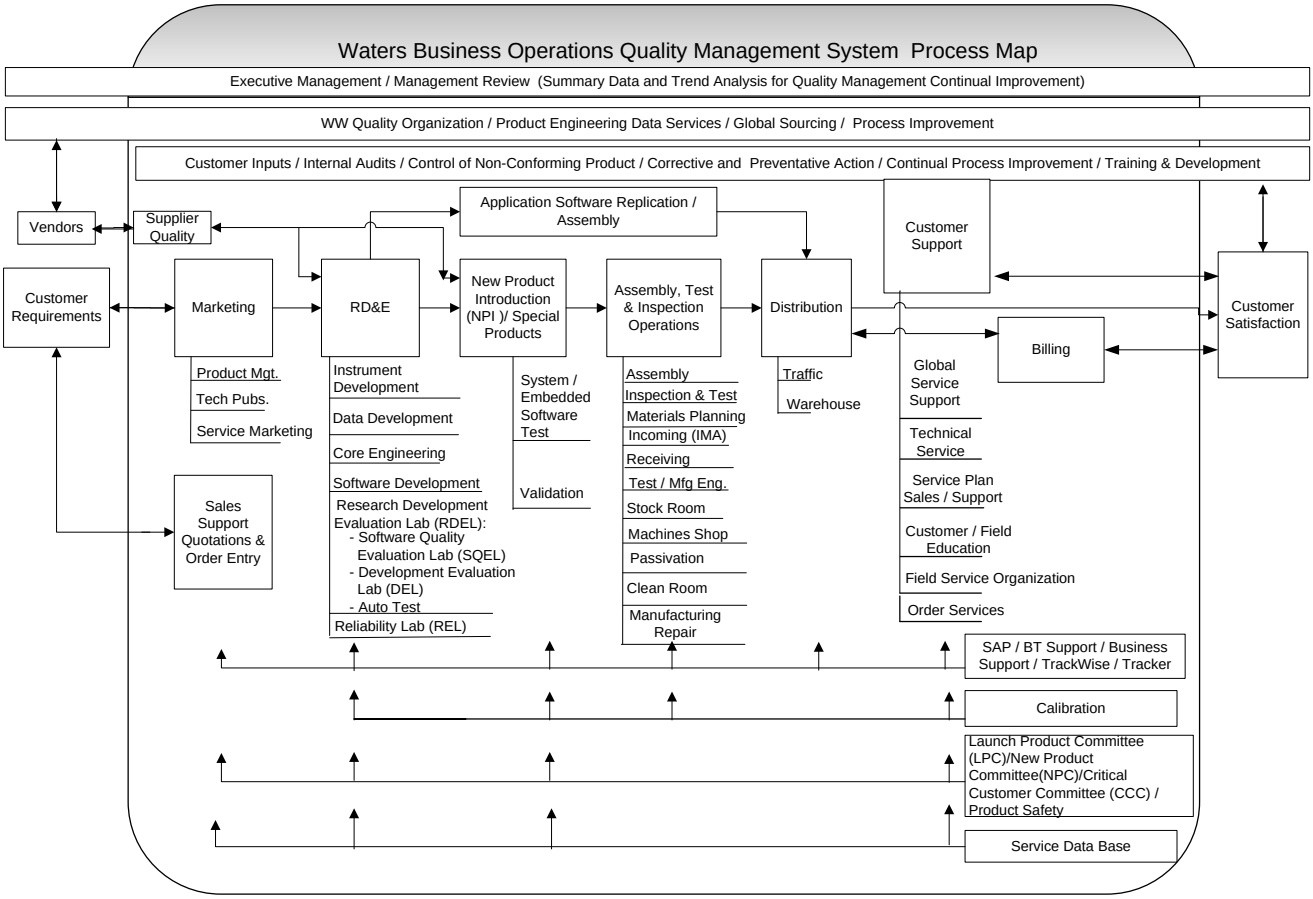
VERSION:	29	**ORIGINATOR:**	Holly Wietgrefe	**Change ID:**	N/A

SUMMARY OF CHANGE: Updated for new Quality Policy. Updates in response to CAPA for clarification of regulatory standards, and correction of errors. Removed Mission statement and references to Mission.

DETAILS:
SECTION 1.1: UPDATED FOR REFERENCE TO REGULATORY STANDARDS AS 730001877, EXTERNAL STANDARDS AND REGULATIONS LOG. ADDED REQUIREMENT FOR QUALITY MANUAL REVIEW. REMOVED REFERENCES TO STANDARDS THROUGHOUT, REFERRING TO 730001877 (SECTIONS 4.1, 4.2.2, 5.4, 5.5.2, 6.2.2, 8.2.2)
SECTION 1.2: REMOVED REGULATORY STANDARDS AND ADDED SOFTWARE STANDARD.
SECTION 3: ADDED SENTENCE
SECTION 4.2:3: ADDED GLOBAL DOCUMENT POLICY REFERENCE AND REMOVED UNNECESSARY DETAIL (ALSO 4.2.4).
SECTION 5.3: REMOVED MISSION STATEMENT AND REFERENCES TO MISSION STATEMENT THROUGHOUT (ALSO 5.2); ADDED NEW QUALITY POLICY
SECTION 5.6, 7.5.2, 8.2.2, 8.2.3: UPDATED FOR CURRENT PRACTICES AND REMOVED UNNECESSARY DETAIL
SECTION 8.3: CORRECTED FOR CURRENT PRACTICES.
SECTION: 8.5.2 CORRECTED TO REMOVE PRODUCT CHANGE SYSTEM (PCS).
APPENDIX II: UPDATED TABLE BY REMOVING DOCUMENTS THAT HAVE BEEN OBSOLETED OR ARE IRRELEVANT AND ADDED NEWLY CREATED AND RELEVANT DOCUMENTS, AS APPLICABLE.

CHANGES TO SECTIONS DENOTED BY Δ.

APPENDIX I: WATERS BUSINESS OPERATIONS PROCESS MAP



∆APPENDIX II: QUALITY DOCUMENTATION SYSTEM CROSS REFERENCE

ISO 9001:2008 / ISO 13485:2003	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Document #	Description
4 Quality Management 4.1 General Requirements	21CFR820.5	Sections 2, 3, 5, 6, 7; 28 – 31; 32 – 34; 43	WAT000001QM 730001504	Waters Business Operations Quality Manual Outsourced Process List
4.2 Documentation Requirements 4.2.1 General 4.2.3 Control of Documents	21CFR820.20e, 40	Sections 10-20, 32 No specific requirement	∆730002900 730000295MP WAT000006MP WAT000010MP ∆730001877	Global Document Management Policy Quality System Document Control Engineering Print Room Policy Production Engineering Practices and Policies External Standards and Regulations Log
4.2.2 Quality Manual	None	Section 32	WAT000001QM	Waters Business Operations Quality Manual
4.2.4 Control of Records	21CFR820.180, 181, 184, 186 21 CFR Part 11	Sections 55, 56	WAT000050MP WAT000130MP WAT089545MP 730000326MP	Waters Record Retention Corporate Policy DPG Records Procedure Waters P/N Policy & Practices Corporate Electronic Records & Electronic Signature Policy – 21 CFR Part 11
5 Management Responsibility 5.1 Management Commitment	21CFR820.20a	No specific requirement	WAT000001QM	Waters Business Operations Quality Manual
5.2 Customer Focus	None	No specific requirement	WAT000103MP 730001930	Executive Management Review Procedure Milford Management Review and CAPA Review Board Procedure
5.3 Quality Policy 5.4 Planning 5.4.1 Quality Objectives	21CFR820.20a	No specific requirement	730000639	Waters Quality Policy

ISO 9001:2008 / ISO 13485:2003	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Document #	Description
5.4.2 Quality Management System Planning	21CFR820.20d	No specific requirement	WAT000004MP WAT000110MP 730000454MP WAT000235MP ∆730001296	Production Planning Procedure for Market Requirements Corporate Instrument Development Process Reliability Engineering Management Procedure Quality Planning
5.5 Responsibility, Authority and Communication	21CFR820.20b1, b3	No specific requirement	WAT000001QM	Waters Business Operations Quality Manual
5.6 Management Review	21CFR820.20c	No specific requirement	WAT000103MP 730001930	Executive Management Review Procedure Milford Management Review and CAPA Review Board Procedure
6 Resource Management 6.1 Provision of Resources 6.2 Human Resources 6.2.1 General	21CFR820.25, 70	No specific requirement	WAT000001QM WAT000055MP	Waters Business Operations Quality Manual Job Description / Evaluation Process
6.2.2 Competence, Awareness and Training	21CFR820.25, 70	No specific requirement	730000945 730000190SO WAT000341MP	Corporate Training Policy Americas Prof Services Trainer Certification Service Training Process
6.3 Infrastructure 6.4 Work Environment	21CFR820.70a,c-h, 21CFR820.75, 21CFR820.170	Section 14 No specific requirement	730000169MP WAT000022MP	Corporate IT Disaster Recovery Process ESD (Electrostatic Discharge)
7 Product Realization 7.1 Planning of Product Realization	21CFR820.20d, 21CFR820.30h, 21CFR820.80a 21CFR820.20d, 21CFR820.30h	Sections 9, 10, 32	730000370MP 730000362MP	Global Policy – Product Risk Management RM: Risk Management Process

ISO 9001:2008 / ISO 13485:2003	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Document #	Description
7.2 Customer Related Processes 7.2.3 Customer Communication	21CFR820.30c	Sections 2 – 5; 6, 7, 8, 9; 10 – 20; 21 – 23; 28 – 31; 32, 34, 43; 52 – 56; 57, 58; 59 – 62; 63, 64; Schedule 1 No specific requirement	730000103MP WAT000107MP WAT000110MP 730000301SO WAT077834SO WAT000335MP	Processing Campaigns Tool Kit Contracting Procedure Procedure for Market Requirements Document Service Plan Support SS-Instrument Sales Support, Americas Technical Service Call Management Process Map
7.3 Design and Development 7.3.1 Design and Development Planning	21CFR820.30a-j	No specific requirement	730001833 WAT000104MP WAT000210MP WAT000230MP WAT000235MP WAT000265MP 730000355MP 730001095 730000985 730000454MP 730001029 730000339MP	Test Engineering Management Policy DPG Software Development Process Design Process Procedure New Product Introduction Process - Milford Operations Reliability Engineering Management Procedure Product Structure Policy SDMS Software Development Life Cycle (SDLC) Global Design Control Policy Waters Product Development Process Corporate Instrument Development Process Services Product Development Procedure Worldwide Software Development Procedure
7.3.2 Design and Development Inputs	21CFR820.30c,h 21CFR820.30c	Sections 10, 11, 13; 14 – 16; 18, 19, 32	ΔWAT000110MP 730000294MP	Procedure for Market Requirements Embedded Code/Logic

ISO 9001:2008 / ISO 13485:2003	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Document #	Description
7.3.3 Design and Development Output	21CFR820.30d	No specific requirement	WAT000104MP WAT000134MP WAT000140MP 730000339MP	DPG Software Development Process DPG Procedure for Request for Test Procedure to Create a Test Summary Worldwide Software Development Procedure
7.3.4 Design and Development Review	21CFR820.30e	No specific requirement	730000238MP WAT000104MP WAT000126MP WAT000156MP WAT000147MP 730001029 WAT000298MP WAT078038MP 730000356MP 730000524	Launched Product Committee DPG Software Development Process Software Release Procedure Procedure to Create Software Master Media Creating Product Documentation Services Product Development Procedure Initial Shipment Process Limited Release Product Shipments SDMS Software Release Procedure Worldwide SDLC Release Procedure
7.3.5 Design and Development Verification	21CFR820.30f,g,j	No specific requirement	WAT000140MP WAT000215MP WAT000216MP	Procedure to Create a Test Summary Validation & Verification Policy Design Verification Process
7.3.6 Design and Development Validation	21CFR20.30g 21 CFR820.70i	Sections 12, 20, 32	WAT000215MP WAT000217MP	Validation & Verification Policy Design Validation Process
7.3.7 Control of Design and Development Changes	21CFR820.30i 21CFR820.70b	Section 1: MDR definition of a "significant change"; Sections 34, 43	WAT000123MP WAT000220MP WAT000260MP	System Change Request Control Process for RDE Group Product Change Control Policy Revision Control Policy
7.4 Purchasing 7.4.1 Purchasing Process	21CFR820.50a	No specific requirement	WAT000016MP 730000464SO	Global Supply Chain Management Contract Manufacturers for Instruments
7.4.2 Purchasing Information 7.4.3 Verification of Purchased product	21CFR820.50b	No specific requirement	WAT000004MP WAT078433SO WAT000270MP	Production Planning Receiving Incoming Material Development Material Control Procedure

ISO 9001:2008 / ISO 13485:2003	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Document #	Description
7.5 Product and Service Provision 7.5.1 Control of Production and Service Provision	21CFR820.70a,c-h, 21CFR820.75, 21CFR820.170, 21CFR820.200	No specific requirement	730000167MP 730000251MP 730000386MP WAT000018MP WAT000022MP WAT000036MP WAT000072MP WAT000245MP WAT000326MP WAT000327MP WAT000332 WAT000335MP WAT000340MP WAT000342MP	Model Shop Management Procedure Service Document Management Process Clinical Technical Service Call Returned Goods Process Electrostatic Discharge (ESD) Procedure Machining Inspection Special Products Assembly Operations Customer Documentation Management Process Waters Educational Services Course Development Process - Std Courses Waters Educational Services Training Process Customer Repair Center Technical Service Call Management Process Map Service Support Process Service Support Activities for New or Revised Products
7.5.2 Validation of Processes		Section 17	730000617 730000837 730000838	CSV: Global Software Tool Val Policy Process V: Process Validation Policy Process V: Process Validation Procedure
7.5.3 Identification and Traceability	21CFR820.60, 21CFR820.65 21CFR820.80e	Sections 21, 52 – 56	730003005 730000208 WAT000020MP WAT079006MP WAT089545MP 730000504	WI for Instrument Traceability ID Number Procedure for Software Plans Data Products Serial Number Procedure Instrument Serial Number Procedure Waters P/N Policy & Practices Finished Product Labeling Requirements
7.5.4 Customer Property	None	No specific requirement	WAT000018MP	Returned Goods Process
7.5.5 Preservation of Product	21CFR820.120 21CFR820.130, 21CFR820.140, 21CFR820.150, 21CFR820.160	Section 14	WAT000046MP	Stockroom Material Handling & Storage Practices

ISO 9001:2008 / ISO 13485:2003	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Document #	Description
7.6 Control of Monitoring and Measuring Devices	21CFR820.72	No specific requirement	730001799	Operating Procedure, Calibration and Preventive Maintenance
8 Measurement, Analysis and Improvement 8.1 General	21CFR820.250	No specific requirement	730000859 730000861 WAT000068MP	Statistical Methods and Techniques Analysis of Data Procedure Use of Statistical Techniques - Management Procedure
8.2 Monitoring and Measurement 8.2.1 Customer Satisfaction (ISO 9001 only) 8.2.1 Feedback (ISO 13485 only)	21CFR820.198	Section 57	730001385 WAT000103MP WAT033347SO 730000384MP 730000394MP WAT000504SO WAT000506SO 730000502	Global Escalation Procedure Executive Management Review Procedure Critical Customer Complaint (CCC) Procedure Feedback Process Corporate Procedure – Complaint Handling Corporate Procedure – Identifying and Processing Medical Device Reportable Events and Incidences Corporate Procedure – Product Recall Corporate Procedure – Health Hazard Assessment for Field Action Determination
8.2.2 Internal Audit	21CFR820.22	No specific requirement	WAT000052MP Δ730000472SO	Quality System Internal Audit Program Quality System Internal Audit Procedure
8.2.3 Monitoring and Measurement of Processes	21CFR820.22, 21CFR820.250	No specific requirement	730000859 730000861 WAT000052MP WAT000068MP	Statistical Methods and Techniques Analysis of Data Procedure Quality System Internal Audit Program Use of Statistical Techniques - Management Procedure
8.2.4 Monitoring and Measurement of Product	21CFR820.80b-e, 21CFR820.250 21CFR820.86	No specific requirement	730001833 WAT078433SO WAT000036MP WAT000235MP	Test Engineering Management Policy Receiving Incoming Material Machining Inspection Reliability Engineering
8.3 Control of Nonconforming Product	21CFR820.90a,b	No specific requirement	Δ730000970 Δ730001028 WAT000074MP	Global Nonconformance Policy Nonconforming Product Process - Milford Stop Ship Procedure

ISO 9001:2008 / ISO 13485:2003	Quality System Regulation - 21CFR Part 820	Canadian Medical Device Regulations (MDR)	Document #	Description
8.4 Analysis of Data	21 CFR 820.250	No specific requirement	730000861	Analysis of Data Procedure
8.5 Improvement 8.5.1 Continual Improvement (ISO 9001 only) 8.5.1 General (ISO 13485 only)	21CFR820.20c	Sections 57, 58, 59 – 62; 64, 65	730001930 WAT000103MP	Milford Management Review and CAPA Review Board Procedure Executive Management Review Procedure
8.5 Improvement 8.5.1 Continual Improvement	None	No specific requirement	WAT000159MP 730000394MP	Worldwide Policy: Customer Audits of Waters Business Units Corporate Procedure - Complaint Handling
8.5.2 Corrective Action	21CFR820.100, 21CFR820.198	Section 58	730000548 ∆730000622	Policy: Global Corrective Action & Preventive Action (CAPA) System Overview Corrective Action and Preventive Action (CAPA) and Process NC Procedure
8.5.3 Preventive Action	21CFR820.100	No specific requirement	730000548 ∆730000622	Policy: Global Corrective Action & Preventive Action (CAPA) System Overview Corrective Action and Preventive Action (CAPA) and Process NC Procedure