

WATERS CORPORATION
QUALITY SYSTEM OVERVIEW

January 2009



January 30, 2009

Dear Current or Prospective Waters Corporation Customer:

Thank you for your interest in Waters Corporation's products and services. Waters is committed to delivering products, information and services, which fully meet or exceed customer expectations. The information provided has been compiled to address questions regarding Waters' Quality Management System. It provides an overview of the business as well as the quality system. Topics covered include product quality, support services, electro-technical certifications, application software development and more. If you have any further questions, please contact me.

Sincerely,

Chris Lewis
Director Quality Management Systems



Chris Lewis
Director Quality Management Systems

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Waters Quality System Overview

Frequently Asked Questions (FAQs)

General Business Questions

- 1. How long has Waters Corporation been in business? How long has Waters Corporation been a supplier of analytical instrumentation and support services?**

Waters Corporation has offered analytical instrumentation and services since 1958 when it was founded by James L. Waters. Waters manufactured its first LC in 1967. It is the leading supplier of High Performance Liquid Chromatography (HPLC) instruments and consumables, as well as Thermal Analysis and Mass Spectrometry (MS) products. The company's largest single market is the pharmaceutical industry.

- 2. What are the annual gross sales of Waters Corporation?**

Waters Corporation annual report is available on Waters' web site at: <http://www.waters.com>. Use the following path *Investors* → *Annual Reports*. This will provide the most recent financial information.

- 3. How many people are currently employed by Waters Corporation?**

Waters and its subsidiaries employ close to 5000 people worldwide.

- 4. Does Waters have an Environmental Health and Safety Policy?**

Yes. Waters Environmental Health and Safety policy is posted on Waters' web site at <http://www.waters.com>. Select *About Waters Corporation* → *Environmental Health & Safety* to view this information.

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Quality System Questions

1. Is Waters ISO certified?

The following Waters Business Units hold ISO certifications:

Business Unit	Location	Certification
Corporate Headquarters Instrument (Hardware & Software) Operations	USA Milford, Massachusetts	ISO 9001:2000 with TickIT; ISO 13485:2003
Instrument (Hardware & Software) Operations	UK Manchester	ISO 9001:2000 with TickIT; ISO 13485:2003
Instrument (Hardware & Software) and Chemical Products	Ireland Wexford	ISO 9001:2000; ISO 13485:2003
Chemical Products	USA Taunton, Massachusetts	ISO 9001:2000; ISO 13485:2003
European Distribution Center (EDC)	The Netherlands Etten-leur	ISO 9001:2000
Nihon Waters K.K.	Japan Tokyo	ISO 9001:2000
Waters GmbH Laboratory Informatics Products	Germany , Frechen Romania , Brasov	ISO 9001:2000
Education & Training (Hardware & Software)	Australia Rydalmere NSW Mount Waverly Vic Woolloongaba Qld	ISO 9001:2000

Refer to Section B for copies of ISO Certificates.

2. Is Waters regulated by the FDA?

Yes. The United States Food and Drug Administration (FDA) has classified HPLC and MS instruments as Class I medical devices, when used for clinical applications. Therefore, these products are designed and manufactured in compliance with the Medical Device Quality System (QS) Regulation (21 CFR 820).

The following facilities are registered with the FDA:

<u>Establishment</u>	<u>Registration Number</u>
Milford, Massachusetts, USA	1218959
Manchester, United Kingdom	3000221947 & 3001145279 & 3006789383
Taunton, Massachusetts, USA	1220107
Wexford, Ireland	9616673

(Note: Registration of a Waters establishment or assignment of a registration number does not in any way denote approval of the establishment or its products by the USFDA, and should not be construed as such.)

3. Does Waters have a stated Corporate Quality Policy?

Yes. Refer to Section A for a copy of the policy.

4. Does Waters have an independent Quality Organization?

Yes. The Quality Organization has, as its critical roles, the following:

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- Ensuring that our products and services meet or exceed customer expectations
- Auditing our quality system to ensure compliance among all organizations
- Analyzing and reporting on quality trends
- Managing corrective actions to ensure appropriate closure
- Providing reliability engineering services, including investigation, failure analysis and testing when necessary

5. Does Waters use a formal change control procedure to change existing procedures and functionalities?

Yes. A documented change control process exists as part of Waters' Quality Management System. Refer to Section D for a copy of the Quality Manual.

6. Does Waters have a formal complaint handling system?

Yes. A documented complaint handling system exists as part of Waters' Quality Management System.

7. Does Waters have a Quality Audit Program?

Yes. Waters Audit Program consists of multi-tier approach to system compliance, including self-assessments, internal audits performed by trained auditors, and audits performed by an independent third party Registrar.

8. What training does staff undergo when joining the company? Are written records of training maintained?

All employees attend New Hire Training. As appropriate, topics include Environmental, Health and Safety, Quality System and Quality System Regulation (QSR). Written records are maintained.

9. Does Waters provide validated products?

Yes. All Waters Application Software and instruments are developed by means of a formal development process. Waters follows established procedures (reference Section D). The resulting project documents, listed below, are maintained in accordance with Waters Record Retention Schedule.

- a. Market Requirements Document
- b. Functional Specification or Design
- c. Test Plan
- d. Test Summary Reports
- e. Defect Status Reports
- f. Source Code Documentation (as applicable)
- g. Hardware Testing Configurations (as applicable)
- h. Revision Status

Certificates of Structural Integrity (reference Section C for example) certify that the products were developed, tested and validated in accordance with Waters' Quality System process. To support this certificate for user cGMPs, GLP, GALP, ISO 9000, ISO 13485 etc. compliance programs, project documents are available for review at Waters Corporation in the context of an audit following the signing of a standard Non-Disclosure Agreement.

10. Has Waters undergone previous pharmaceutical industry audits? If so, please provide details such as: who, when, outcome, references.

Yes. Since 1992, Waters has hosted over 200 on-site audits, with an average of 20 audits yearly. The majority are by domestic and international pharmaceutical firms. The dates, organizations, personnel, and outcomes of audits are company-confidential.

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Application Software Questions

1. How long has Waters Laboratory Informatics Software been available? What are the number of releases per year?

- Empower™ 2 Software was released in 2005. Empower™ Software has been available since 2002 and Millennium Software has been available since 1992.
- Waters NuGenesis Scientific Data Management System (SDMS) V7.1 was released in 2007. SDMS V7.0 was released in 2005. Up until SDMS 6.0x (released 2003), the SDMS offering included 2 products: NuGenesis ARCHIVE and NuGenesis UNIFY/VISION. These products were first available in 1998/99.
- MassLynx Software has been available since 1992.

On average one software release is provided every other year.

2. Is Waters involved with Lab Informatics?

Yes. Waters is a leading provider of laboratory informatics solutions. These software applications encompass the collection, analysis and management of scientific data which can be shared throughout the global workplace.

For more information about Waters Informatics Solutions, please visit Waters web site <http://www.waters.com>. Go to Waters Division Website and select: *Products* → *Informatics & Software*.

3. What is the current version of Waters Laboratory Informatics Software? Are previous versions of the software, source code, and associated documentation readily available?

- Empower™ 2 Software (build 2154) was released in 2005. There is no version number; the product name with build number is a unique identifier. Empower build 1154 is still available and supported. The current version of Millennium³² is version 4.0 and has been discontinued. Version 3.2 is no longer available.
- Waters NuGenesis SDMS V7.1, including SDMS Vision Publisher, is the current released version. Waters NuGenesis SDMS V7.0 is still available and supported. As of December 31, 2008 only telephone support of Waters NuGenesis SDMS V6.0.x will be available. Earlier versions of these products are no longer supported.
- The current version of MassLynx is version 4.1.

Waters' general policy is to support the current and one previous release of software. Source code and associated documentation is available for review by the signing of a Non-Disclosure Agreement, but only in the context of an audit. Review of Empower or Millennium and SDMS documentation is available at our Milford, Massachusetts, USA facility. Review of MassLynx documentation is available at our Manchester, UK facility.

4. What is the Operating System (OS) of Empower™ 2 Software?

Empower™ 2 Software can use Microsoft Windows XP or Windows Vista.

The Empower 2 Enterprise database server can use the following:

- Microsoft Windows 2000 Server
- Microsoft Windows 2000 Advanced Server
- Microsoft Windows 2003 Server
- Sun Solaris 10

5. What is the Operating System (OS) of MassLynx Software?

MassLynx Version 4.1 can use Microsoft Windows 2000 or Microsoft Windows XP Platform.

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6. What is the Operating System (OS) of SDMS Software?

SDMS 7.1 software can be used on multiple Windows and UNIX operating systems, including Windows 2003 Server for the server components and Windows XP for the client components. For more detailed information, please refer to the Release Notes provided in the SDMS 7.1 Documentation Library Media and in the SDMS 7.1 Service Releases.

7. Does Waters Laboratory Informatics Software have network capability? If so, what operating systems and network protocols are supported?

- The Empower™ Enterprise system is a corporate-wide networked version of the Empower™ Personal workstation which operates on a Windows XP or Windows Vista platform. Supported server operating systems include:
 - Intel/Microsoft Windows 2000 Server
 - Intel/Microsoft Windows 2000 Advanced Server
 - Intel/Microsoft Windows 2003 Server
 - Sun Solaris 10Empower™ 2 uses networking protocols of TCP/IP to communicate.
- For SDMS software, please refer to the information provided in item 6.
- The MassLynx™ 4.1 system is a workstation acquisition and processing system which operates on a Windows 2000 or a Windows XP platform. The following server operating systems are supported for installation of the remote logging element and for storage of remote data projects:
 - Intel/Microsoft Windows NT Server
 - Intel/Microsoft Windows 2000 Advanced ServerMassLynx™ 4.1 uses networking protocols of DCOM under TCP/IP to communicate.

8. Is Waters Laboratory Informatics Software compliant ready with the FDA 21 CFR Part 11 (Electronic Records and Electronic Signatures Rule)?

Yes. Empower™ 2, SDMS and MassLynx 4.1 software allow the user to comply with both the Electronic Records and the Electronic Signature requirements of this rule. For additional details, please refer to Waters web site:

<http://www.waters.com>. Go to Waters Division Website and select: *Products* → *Informatics & Software*.

In our continued efforts to help meet our customers' internal compliance and validation needs, Waters offers Empower and MassLynx Software Compliance Packages to assist you in your validation efforts. The documentation set is customized based on the customer validation needs. As an example, the Empower Software Compliance Package is available for Empower 2 (Build 2154) and Empower (Build 1154). In general it contains a Functional Specification Document, from the user's perspective, Test Strategy and Test Case listings, Release Notes and 21 CFR Part 11 White Paper.

A copy of the Software Compliance Package is available upon request.

9. Does Waters use a formal design process or Software Development Life Cycle (SDLC) methodology?

Yes. Refer to Section F for a listing of project documents, phases and milestones.

10. How does Waters handle issuance of software revisions?

Waters classifies Service Packs for Empower, Service Releases for SDMS or Software Change Notes (SCN) for MassLynx. Service Packs / Service Releases / SCNs are developed and released based on issues discovered by our customers or internal people. The same Software Development Life Cycle methodology is followed for Service Packs / Service Releases / SCNs. Once a Service Pack / SCN is formally released, it is placed on Waters web site and can be

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accessed using the Connections® Elite Support Center. Once a Service Release is formally released the SDMS customer base is informed via e mail and appropriate media is sent to them.

11. Does Waters have written standards for software development such as: programming & coding standards, configuration management, programmer qualifications, software version control, maintenance, appropriate formal testing of software/hardware with recorded results, and incident reporting and tracking?

Yes, these processes are addressed in a number of documented procedures that detail the overall process and its requirements. Waters Laboratory Informatics Software has been designed using accepted standards for Windows programming.

12. How does Waters assure that the software programmers and evaluators are qualified?

Waters employs qualified personnel. Resumes and training records are kept for each programmer and evaluator. Internal as well as external training is provided as required.

13. Is the development process such that custom modifications to the software can be completed in a timely fashion? How are custom changes integrated into the development process?

Waters does not do custom modifications to applications software. Empower 2 and SDMS Software's Toolkit option allows the user to integrate other software packages. MassLynx Application Programmers Interface (API) allows the user to integrate other software packages.

14. Is system documentation (e.g. source code, tests, validation) available for review by customers or third party auditors, for use in their own cGMPs, GLP, GALP, ISO 9000, ISO 13485, etc. compliance programs?

Yes. System documentation is available for review at Waters Corporation in the context of an audit, following the signing of a standard Non-Disclosure Agreement. Review of Empower or Millennium and SDMS documentation is available at our Milford, Massachusetts, USA facility. Review of MassLynx documentation is available at our Manchester, UK facility.

These procedures and records are confidential and proprietary business information, and may be reviewed but not copied.

15. Are Escrow Accounts available?

Yes. A software escrow program is available to provide participants access to the source code on deposit in the unlikely event of Waters "failure to continue to do business in the ordinary course". Joining the Escrow Program is a two-step process: 1) for Empower, order part number WAT005417; for SDMS and MassLynx, notify the Software Quality Manager with complete details of your request and 2) after reviewing the documents, fill out the one-page "Preferred Beneficiary Acceptance Form" and return it to the Escrow Agent. The Escrow Agent will return signed copies of all documentation and an accounting of the deposit materials. After the first year, continued participation in the Escrow program requires an annual fee paid to the Escrow Agent.

Waters Escrow Agent is:

Iron Mountain Intellectual Property Management, Inc.
2100 Norcross Parkway, Suite 150
Norcross, GA 30071
Telephone: (770) 239-9200
Facsimile: (770) 239-9201
<http://www.ironmountain-ipm.com/>

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Instruments Quality, Safety, & Electro-Technical Certification Questions

1. How large is Waters Instrument Operations?

Waters Instrument Operations in Milford, Massachusetts, USA comprises over 500 employees, with an average tenure of 12 years. Waters Instrument Operations occupies 195,000 square feet within the Milford facility, with over 170 employees involved in the assembly of 20,000 individual products each year in a 52,000 square foot area assembly floor.

Waters Instrument Operations in Europe comprises over 170 employees, with an average tenure of 6+ years. Waters Instrument Operations occupies over 100,000 square feet between Manchester England and Wexford Ireland, manufacturing over 10 core products types, culminating in over 1200 individual products.

2. Does Waters manufacture its own parts?

A significant percentage of parts in Waters instruments (over 10 million components) are fabricated by Waters Machining Operations. CAD/CAM systems and statistical process control are routinely employed. Typical operations include CNC machining, EDM, surface & centerless grinding, passivation, electro-polishing, and rapid prototyping.

3. Does Waters manufacture its own electronic circuit boards? Are these under some sort of engineering change process? How is the latest product identified?

Waters designs, but does not manufacture electronic circuit boards. A part number and a revision number are visible on each board, and all changes are controlled through our Engineering Change Order Process.

4. Does Waters test components, sub-systems and the complete system?

All products are 100% tested before they are packaged and shipped to our customers. Testing requirements are documented as part of our Quality Management System. The results of the tests are recorded and appropriately stored.

5. Does Waters perform reliability testing?

A dedicated team of engineers is responsible for ensuring robustness of our products in typical customer applications, both for new and enhanced products. Significant investments in test equipment include a walk-in environmental chamber, pseudo-random tri-axis vibration unit, thermographic infrared scanning camera, and AC power generator.

6. How is instrument calibration performed/demonstrated? Are traceable standards included?

There are documented instrument calibration procedures. The results of the calibration is recorded and filed. All calibration equipment is fully traceable to the National Institute of Standards and Technology (NIST).

7. To what standards do Waters instruments comply?

For United States and Canada product safety approvals, testing is conducted by a Nationally Recognized Testing Laboratory (NRTL) recognized by the United States Occupational Safety & Health Administration (OSHA). For other domestic and international approval requirements, 3rd party accredited labs by NIST and/or A2LA are used for final testing. Test results are available for review under a Non-Disclosure Agreement. Waters products carry the following conformance marks, CE for Europe, ETL for Canada and the US, and the C-tick for Australia. Instruments may also carry an IVD symbol if it is intended for in vitro diagnostic use. Waters is a participant in the IECCE CB scheme which is an international program for the exchange and acceptance of product safety test results among participating laboratories and certification organizations around the world.

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Waters manufactures instrumentation that complies with the following standards as applicable:

United States

UL 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use: Part 1: General Requirements

FCC EMC –Federal Code of Regulation (CFR), Title 47, Federal Communications Commission (FCC) Part 15; Per Section 15.103

Canada

CAN/CSA-C22.2 No.61010-1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use: Part 1: General Requirements

ICES-003 EMC-Spectrum Management –Interference Causing Equipment Standard

Australia

CISPR 11 Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement or EN/IEC 61326-1 Electrical equipment for measurement, control and laboratory use – EMC (emission) requirements

Europe

Directive 2006/95/EC Low Voltage Directive

Harmonized Standard: EN 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use: Part 1: General Requirements

Directive 2004/108/EC Electromagnetic Compatibility

Harmonized Standard: EN 61326-1 Electrical Equipment for measurement, control and laboratory use - EMC Requirements

Directive 98/79/EC In Vitro Diagnostic Directive – Medical Devices

Harmonized Standard: EN 61010-2-101 Particular requirements for in vitro diagnostic (IVD) medical equipment

Harmonized Standard: EN 61326-2-6 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

Directive 2002/96/EC Waste Electrical and Electronic Equipment

International

Product Safety: IEC 61010-1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use: Part 1: General Requirements

EMC: IEC 61326-1 Electrical Equipment for measurement, control and laboratory use - EMC Requirements

IVD: IEC 61010-2-101 Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 61326-2-6 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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Waters Instrument Calibration & Qualification Services

1. How are Waters Calibration & Qualification Services defined?

Waters Calibration & Qualification Services are defined as documented evidence that a module or system performs as intended by Waters Corporation.

2. Are calibrations and/or qualifications performed by trained personnel?

Yes. Waters employs trained and qualified personnel. Internal training is provided. Every Waters Field Service Engineer must complete a technical training program and obtain certification on Waters' products prior to delivering services to Waters' customers. The successful completion of an exam determines competency of the field service engineer. Competency is specific to the certification. In the case of Qualification Services, an experienced engineer is required to take a course which focuses on the services and the controlled ways in which these are to be delivered. The specifics on delivery are contained within product-focused training. An engineer cannot deliver this service until they have completed a two part training program. The first part focuses on compliance and Validation fundamentals, while the second part is specific training on Waters Advanced Qualification Technology (AQT), Waters SystemsQT (SQT), and Waters Qualification Workbooks. The certification is valid for two (2) years. Testing is done to renew an engineer's certification. Periodic training is done to update an engineer's certification.

3. Are training records maintained and available for review?

Yes. Training records are maintained for each Field Service Engineer. Requests for training records can be made directly through the Field Service Engineer.

4. Are the procedures used for qualification under revision control?

Yes, the procedures used for qualification purposes follow a formal development and approval process and are under revision control. They contain an organized set of instrument and/or system qualification procedures and forms. Waters AQT (Advanced Qualification Technology) and Waters SystemsQT (Systems Qualification Tool) test instruments as a complete system in the manner in which they are to be used. In addition, these tools add the highest degree of security to the qualification process by removing operator influence for most tests by means of designed in automatic pass/fail functionality as well as by taking full advantage of the Empower Chromatography Data System security features.

5. Are calibration and/or qualification certificates or data reports provided to the customer for instrument calibrations and/or qualifications?

Yes, the results of the calibration and/or qualification performed are documented along with the identification of the instrument, i.e. serial number, the calibration standards used and the calibration date. The calibration due date may be determined by the customer's standard operating procedure and may be documented upon customer request.

6. Are the tools used by Waters Field Service Engineers, during calibration and/or qualification, calibrated?

Yes. Tools used by Waters for calibration and qualification are calibrated and fully traceable to the National Institute of Standards and Technology (NIST) or other appropriate standards agency.

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Waters Information Technology (IT) Services

1. Has Waters established corporate IT policies?

Yes. IT has instituted a number of corporate policies which are maintained and communicated periodically to employees.

2. How does Waters ensure security from natural disasters and malfunctions?

Waters IT Department has a Business Continuity Plan to ensure data can be restored in the event of a natural disaster and malfunctions. Testing of the Business Continuity Plan is performed periodically.

3. What is the frequency of backups of the business production servers?

Backups are performed daily, weekly, monthly, quarterly and yearly. The content and scope of backup coverage is recorded in a job log.

4. Is backup media stored offsite and does it include software and associated documentation?

Yes. Backup tapes are stored offsite with an external company and associated documentation is maintained by the Computer Operations department.

5. Does Waters have an on-site Data Center?

Yes. The Data Center is an enclosed facility, which is staffed 24 hours / day, 365 days / year. Access is restricted through the use of employee badge scanners and keys that have been handed out to a limited number of IT operations staff members. Access to the Data Center is governed by the Waters Corporate High Risk Area Policy.

6. Who is responsible for administering and implementing security functions for the organization?

The IT security manager/analyst has this responsibility from Waters Corporation perspective while the Research, Development & Evaluation (RD&E) System Administrator is responsible from the Engineering server perspective.

7. Are training records maintained and available for review?

Training records are maintained for IT employees and available for review in the context of an audit.

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End User Support Questions

- 1. Are there peer-reviewed publications by non-vendor affiliated groups demonstrating successful application of the systems?**

Waters has an extensive library of applications information on Waters' web site at <http://www.waters.com>. Go to Waters Division Website and select *Resource Library*. Additional information can be obtained by contacting our Pharmaceutical Marketing or Industrial Marketing groups at 1-800-252-4752.

- 2. Is formal user training available?**

Yes. Waters' Connections® University has a wide variety of educational programs. You may register online at <http://www.waters.com> by going to Waters Division Website, select *Training* under the *Services & Support* menu, or by calling 1-800-252-4752.

- 3. Is the cost for training included in purchase price?**

Inclusion of formal user training with the purchase price varies depending upon product and area of the world. Please contact your local Waters office.

- 4. Is there a help-line/e-mail (Internet) address to assist in the timely resolution of problems?**

Telephone help lines are available in most countries. The Connections® Elite Support Center on the Waters website provides Web-based support for customers who maintain their software plan coverage. Assistance by e-mail is not presently available.

- 5. Are there complete manuals available? Please identify key user manuals. If possible, provide an example.**

A "Getting Started" Guide, Operators Manual, and Service Manual are available for all instruments. As an example, Millennium³² / Empower software includes a "Getting Started" Guide. The remaining documentation is available on-line as part of the software.

- 6. Are there systems available for in-house (2-3 week) evaluation?**

Yes, in most cases. Please contact your local sales representatives.

- 7. What is the approximate turnaround time for repairs, availability of spare parts? Are service contracts available, does the equipment have to be returned to the manufacturer?**

Waters references Service Contracts as Total Assurance Plans. Customers under a Total Assurance Plan will receive priority service response (typically within 24 hours of their phone call) to schedule a service visit, if required. Customers not under a Total Assurance Plan may experience slightly longer response times. Emergency service, if required, is available at a surcharge to non-plan customers. Parts ordered directly by customers are generally shipped the same day or next day for delivery the following day. (Parts ordered before 3:00 pm by U.S. customers are shipped Federal Express to arrive the next morning.)

- 8. If an instrument is under warranty or a Total Assurance Plan, will Waters pay for the service engineer's travel costs? Will Waters pay the cost of shipping if it must be returned?**

If an instrument is under warranty or a Total Assurance Plan, Waters will pay travel or shipping costs.

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9. Is qualification support for customers available? Is there an additional cost for these items?

Waters Software Applications are supplied with a Verify Files utility used to verify files in the Program Group, and a recommended procedure for Installation Qualification is included with each base software kit. In addition, Compliance Services are available for most Waters instrument and software products. These services include:

- Instrument Qualification and Calibration Services
- Software Qualification Services
- Advanced Qualification Technology
- Computer Hardware Qualification Services
- Self-Directed Qualification Tools and Accessories
- Customer Education Services

Validation materials are available for Waters NuGenesis SDMS at an additional cost and include:

- Installation and Operational Qualification
- Customized Performance Qualification
- Validation Consulting Services