Waters Qualification Overview

715511111/Revision C
January 2018

Owner's ID: _____

Company: _____

Qualification Start Date: _____

Waters

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1 Qualification overview

This overview describes the Waters® qualification process.

1.1 Purpose of the qualification process

Waters developed its qualification tests to meet the requirements set forth in the United States Code of Federal Regulations. Known as 21 CFR Chapter 1, 211.68 and 211.160, those requirements address the calibration of automatic, mechanical, or electronic equipment.

Qualification ensures that an instrument, device, or system performs as its manufacturer intends regarding accuracy, linearity, and precision, where practical. For the purposes of this overview, the term “module” refers to a device, instrument, or software node, such as a server, client, LAC/E™32, Laboratory Network Device (LND), or personal workstation.

Qualification does not constitute complete testing of all specifications. Rather, it is a test of basic functionality. Unlike system suitability tests, which are associated with specific assays, qualification tests do not ensure a system's suitability for any specific analysis.

Use the qualification process to ensure traceability and accountability in a GxP environment or an ISO 9000-series registered facility. Qualification procedures serve as guides to properly install Waters software products, instruments, the component parts of instruments, and systems. They also verify the proper operation of equipment following maintenance.

The retained records of qualifications provide evidence to industry regulators that the modules of a system individually and collectively perform as intended. They also provide evidence that the system software is properly installed and that the data a system produces meets specified performance criteria.

2 Qualification phases

A vendor-performed qualification provides evidence that a system or module performs as expected by the manufacturer. It is the customer's responsibility to qualify, operate, and maintain their laboratory modules and systems in accordance with their organization's quality system.

To this end, the customer should begin the qualification process by creating a validation master plan that describes their organization's overall approach to qualification. The validation master plan defines intended usage, system requirements, and the criteria for

evaluating products against those system requirements. It also describes the customer's requirements and process for the initial and ongoing installation, operational, and performance qualifications of the modules and systems in their laboratories.

The qualification process comprises four phases: design qualification (DQ), installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) (see Table 2-1).

Table 2-1 Qualification phases:

Phase	Description
DQ	Ensures that the manufacturer's product meets the customer's requirements.
IQ	Verifies that the software, modules, and systems are properly installed.
OQ	Verifies and documents the operational qualification of the configured software, modules, and systems.
PQ	Confirms the system's suitability for its intended application.

This document assumes that the customer procured the Waters system in accordance with their design qualification requirements, and that a Waters representative installed the system. After the installation qualification and operational qualification are complete, the customer must perform performance qualification testing in accordance with their standard operating procedures.

This document describes the typical process for a pre-use qualification, which applies to modules or systems that have not previously been qualified. After the initial pre-use qualification, you must requalify systems periodically, as well as after certain types of maintenance and repair activities. For details about requalification, see the appropriate post-use qualification documentation.

2.1 Design qualification (DQ)

During the design qualification phase, the customer uses information provided by the vendor or manufacturer to determine whether the product suits the customer's requirements. The customer may also evaluate the manufacturer's design, manufacturing, and support processes to ensure that they meet the requirements.

The customer is responsible for defining the requirements and for evaluating the manufacturer's product against those requirements. Customers should complete these activities before acquiring the system.

Waters provides the documentation listed in Table 2-2 to assist customers in determining whether their system components suit their intended use.

Table 2-2 Design documentation available from Waters:

Document	Description
System specifications	Lists the specifications of a system's software and hardware modules. Customers can use these specifications to evaluate whether the system meets their requirements.
Certificate of structural integrity	Certifies that the product undergoing qualification was developed, verified, and validated in accordance with the steps specified for it in the Waters "development life cycle" and that testing at the time of shipping established that the product met all performance specifications, marketing requirements, and functional requirements. The system owner can download the certificate from the Waters Web site and log it with the qualification documentation. **Note:** The certificate of structural integrity is available only for select products.
Product performance certificate	Certifies the satisfactory result of Waters' final product testing.

When a regulatory agency requests documents and source codes to fulfill the requirements of an audit or inspection, Waters provides such information in accordance with the terms of its nondisclosure agreement.

2.2 Installation qualification (IQ)

The installation qualification identifies a system's components and verifies that they are properly installed.

2.2.1 Software IQ

For a Waters software module, such as a server, LAC/E[32], LND, client, or workstation, the IQ confirms the following conditions:

- The software is properly installed.
- The files installed on the module are identical to the files received from Waters and are not corrupted.
- The software options (if any) are properly installed.
- The name of the operating system and its version are correct.
- The software updates (if any) are properly installed and verified.

2.2.2 Hardware IQ

For hardware components, the IQ identifies the modules in the system and confirms the following conditions:

- The installation site is suitable and is prepared in accordance with the instructions in the site preparation guide.
- The performer has gathered and verified the installation materials.
- Electrical and plumbing connections are completed in accordance with the installation instructions.

2.3 Operational qualification (OQ)

Operational qualification verifies and documents that a system performs in accordance with the manufacturer's qualification specifications.

For hardware modules and software, the OQ tests can be a combination of manual and automated tests, and in some cases the entire system OQ can be performed manually.

2.3.1 Software OQ

Depending on which chromatographic data system (CDS) is involved, the software OQ can be manual or automated. The OQ verifies and documents the software's ability to do the following:

- Process standards
- Process unknowns
- Perform peak integration
- Perform quantitation
- Perform calibration
- Generate a report

2.3.2 Hardware OQ

2.3.2.1 Manual OQ

Some operational qualification tests cannot be automated because they require manual interaction with the module or data collection by a measurement device such as a thermometer or stopwatch. On the basis of set and observed parameter values, the results are calculated to determine whether the module passes or fails.

2.3.2.2 Automated OQ

Automated operational qualification uses a system-specific qualification method to verify and document the satisfactory operation of the configured modules.

For hardware modules, the automated OQ tests verify the accuracy, linearity, precision, and other attributes—as appropriate or practical—of all of the components in a system. The specific tests that are used vary depending on the type of module and the system configuration.

2.4 Performance qualification (PQ)

Whereas the OQ tests ensure that a system and its software perform in accordance with the manufacturer's design, the PQ uses of analysis-specific tests to verify that the system meets the customer's application-specific performance requirements.

Because the PQ testing is application-specific Waters does not include such testing in its routine qualifications.

2.5 Maintenance

Although it is not a phase of qualification, all required maintenance must be documented. It is performed on a regular basis after installation depending on the use of the system. All maintenance, repair, and qualification activities are recorded in the appropriate log.

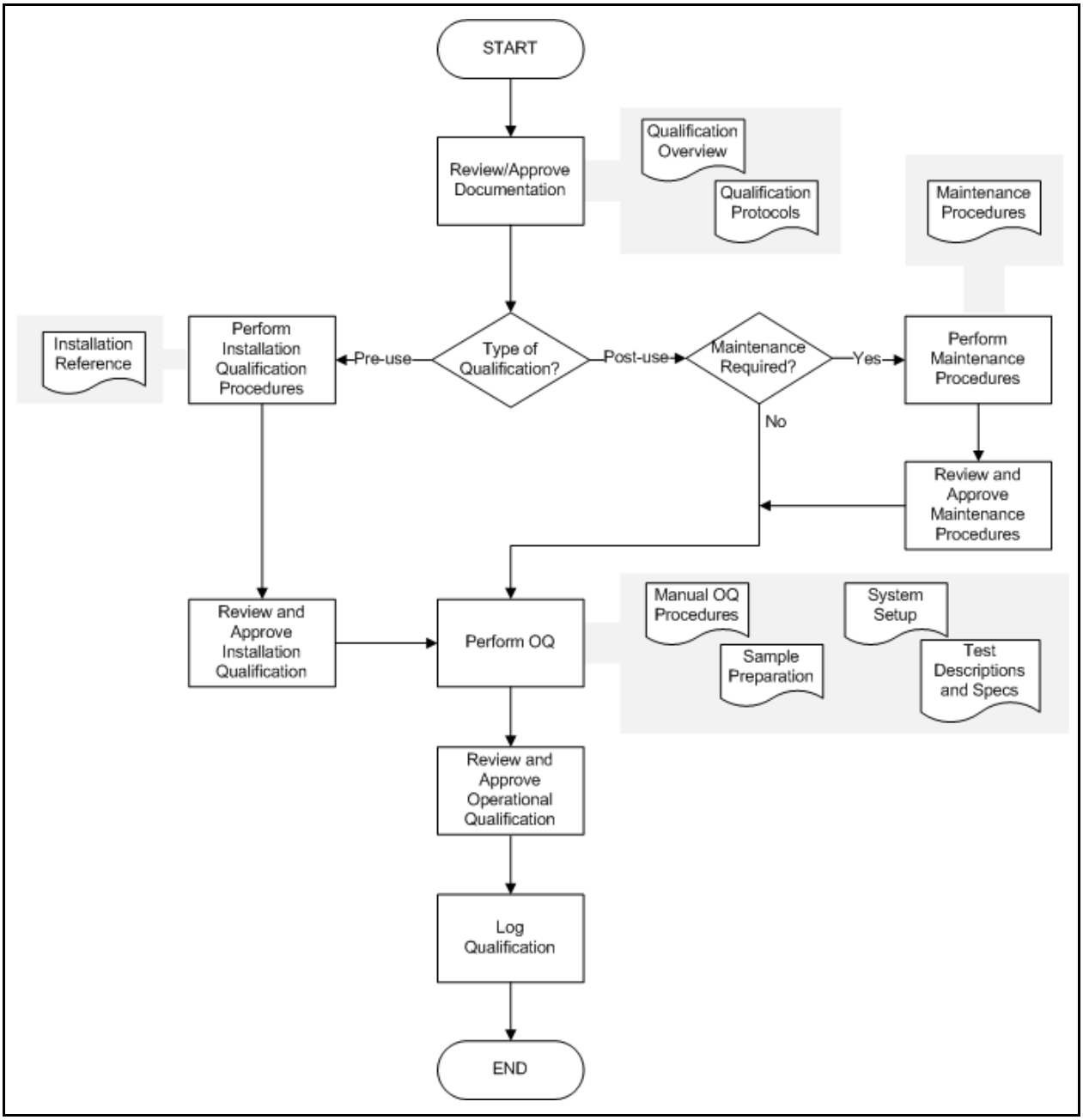
3 The qualification process

Qualification is performed when either of the following conditions apply:

- Pre-use qualification - at the time of hardware and/or software installation
- Post-use qualification - after maintenance of a module and at regular intervals

The qualification process used depends on whether it is a pre-use or post-use qualification (see Figure 3-1).

Figure 3-1 Qualification process:



3.1 Post-use qualification guidelines

Waters offers the following guidelines to help you determine when to perform a post-use qualification:

- Perform a post-use qualification on a system at regular intervals. This qualification should take place after performing routine maintenance.

  Note: The frequency of requalification may vary based on system usage.

- Perform a post-qualification after an extensive repair. Some repairs or routine maintenance may not need requalification, but instead need only verification that the repair or maintenance was successful.

  Note: Contact your Waters representative for requalification guidelines.

3.2 Test failures

When a test fails, it is important to determine whether the module is actually malfunctioning or whether the failure is due to operator error or incorrect test preparation. When you determine the cause of a failure, type an explanation of the cause (such as “inadequate priming”) in the Comments section. When you correct the problem, rerun the test.

If you cannot determine the cause of a test failure, repeat the test twice consecutively. If the rerun test does not indicate passing results both times, contact your local Waters representative.

3.3 Qualification protocol approval

To approve all of the protocols used to qualify the installation, operation, and maintenance of a module or system, the owner's management must do the following:

1. Review all relevant qualification and system documentation.
2. Complete Form 3-1.

Owner's ID: _____

Form 3-1 Qualification approval form

The undersigned owner's management approves the use of the qualification tools and associated procedures to qualify module, system, or software operation.

Comments _____

_____

_____

Manager _____ _____

Name (print) *Signature*

Title _____ **Date** _____

Owner-designated responsible person

Manager _____ _____

Name (print) *Signature*

Title _____ **Date** _____

Owner-designated responsible person

Manager _____ _____

Name (print) *Signature*

Title _____ **Date** _____

Owner-designated responsible person

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3.4 Identifying the performer and the reviewer

To identify the qualified performer of the accompanying procedures, and to identify the reviewer qualified to acknowledge the successful completion of the performer's tasks, complete Form 3-2.

Form 3-2 Identification of the performer and the reviewer

The undersigned performer attests that they are trained and qualified to perform the accompanying procedures.

Performer _____ _____
Name (print) *(Signature)*

Title _____ **Date** _____
(Trained and qualified to perform qualification procedures)

The undersigned reviewer accepts that the performer, above, is trained and qualified to perform the accompanying procedures.

Reviewer _____ _____
Name (print) *(Signature)*

Title _____ **Date** _____
(Owner-designated responsible person)

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4 Revision history

The following tables list the revisions made to this Overview document (715511111).

Table 4-1 Overview document changes from revision B to revision C:

Page	Description
All	The format of the Overview is revised to the latest Waters format. Copyright dates are revised throughout the Overview. The Owner's ID is required at the top of each page that includes a form. (When you fill out the Overview electronically, the Owner's ID that you specify on page 1 automatically repeats at the top of all succeeding pages that include a form.)
Cover	The Overview revision is updated to revision C. The Owner's ID, Company, and Qualification Start Date are required on the cover. (When you fill out the Overview electronically, the Company that you specify on page 1 automatically repeats at the top of all succeeding pages, and the Owner's ID that you specify on page 1 automatically repeats at the top of all succeeding pages that include a form.)
5	Section 1.1 “Purpose of the qualification process” is revised. The former section “Purpose of the Qualification Documentation” is deleted.
5 - 9	Section 2 “Qualification phases” and its subsections are added.
9 - 11	Section 3 “The qualification process” and its subsections are revised. The former Figure 1-1 “Pre-Use Qualification Process” and the former Figure 1-2 “Post-Use Qualification Process” are deleted. The former Table 1-1 “Recommeded Qualification Procedures Following Repair” is deleted. (A separate document, “Recommended Qualification Procedures Following Repair”, [715005511] is available in Service Notes.) Figure 3-1 “Qualification process” is added. The former section 1.2 “The Waters Qualification Documentation Binder” and section 1.3 “Verification Forms” are deleted.
13	Form 3-2 “Identification of the performer and the reviewer” is revised to provide space for one performer and one reviewer.

Table 4-1 Overview document changes from revision B to revision C: (continued)

Page	Description
14 - 15	Section 4 “Revision history” is added.

Table 4-2 Overview document changes from revision A to revision B:

Page	Description
Cover	The part number revision is updated to revision B.
12	A sentence is added before Table 1-1 regarding qualifying non-Waters instruments.

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