

1 PURPOSE

The purpose of this procedure is to describe how Waters personnel manage customer owned qualification protocols and creation of custom documentation.

2 SCOPE

The scope of this procedure applies to all Waters groups involved with requests outside the extent of Waters commercialized instrument test protocols.

3 DEFINITIONS AND ABBREVIATIONS

Term / Abbreviation	Definition
Contract	Document that describes the work to be performed by Waters personnel, and assigns responsibility.
Service Business System	A business system for documenting and monitoring customer interactions from order placement through service delivery
Subject Matter Expert (SME)	An individual exhibiting a high level of expertise by education and /or training/experience in a functional area or specific task. This person can answer questions from internal or external resources and understands the steps required to achieve acceptable and consistent results in a given area or specific task

4 ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Compliance Services	Reviews documentation to ensure equipment is capable to meet customer requirements Involves Subject Matter Experts (SME) as needed Manages requests and escalates as needed
Field Service Resource	A Waters employee or contractor trained and certified to service Waters' products and/or deliver Waters' services
Service Manager / Service Supervisor (SM/SS)	Person responsible for the service process and business
Service Sales Group	Forwards any qualification requests from a customer that is outside of the standard work flow to Compliance Services
Waters Implementation Project Manager (IPM)	Coordinates the installation of instruments Manages requests and escalates as needed

5 REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
WAT000050MP	Waters Record Retention Corporate Policy

6 FORMS

Doc No:	Document Title
Not applicable	Not applicable

6.1 Records

Ref No:	Description of Record
N/A	Completed contracts with customers

Records will comply with Waters Record Retention Corporate Policy (WAT000050MP).

7 HEALTH & SAFETY

Use appropriate health and safety equipment as need for work performed. Examples: safety glasses, laboratory coat, protective gloves and or safety shoes as needed.

Should anyone following this instruction identify a health and safety hazard which has not been highlighted in this section and/or within the body of the text, they should notify their Manager / Supervisor immediately.

7.1 Equipment/Materials of Use Required

Not Applicable

8 PROCEDURE

Roles	Tasks/Instructions
Field Service Resource	8.1 Asks the customer if the testing / documentation recommended with their system is adequate. If so then follows Waters normal qualification process. 8.2 If there is a need to follow a customer's process or custom documentation, the following steps must be followed:
Field Service Resource / Service Manager / Customer	8.2.1 Work performed with customer processes may be at an additional cost to the customer. This should be communicated with the customer.
Field Service Resource / Service Sales / Customer	8.2.2 Customer makes determination of what protocol is to be followed. Customer's requirements may involve previous versions of protocols for qualification purposes. The protocol followed will be documented via customer's signature approval.
Field Service Resource / Compliance Services	8.2.3 If a customer owned protocol is to be used, the Field Service Resource must submit this qualification process to Waters Compliance Services for review and approval before proceeding. Requests are recorded in the Service Business System.
Field Service Resource	8.2.4 Non Waters qualification documentation will not be completed or signed without approval in the Service Business System. If unsure, send to Waters Compliance Services for review.
Field Service Resource / Compliance Services	8.2.5 Any additional information needed to provide the service will be attached to the Service Business System.
Field Service Resource	8.2.6 Waters Field Service Resource must review the protocol and any customer procedures as needed before execution (I.E. Good Documentation Practices, or health and safety). 8.2.7 Complete Service Business System record to close the service event.

9 APPENDICES / ATTACHMENTS

Not Applicable

DOCUMENT HISTORY*(Note: Complete Document History may be obtained via the Document Management System.)*

VERSION:	00	ORIGINATOR:	Ginny Halfpenny	Change ID:	N/A
DESCRIPTION OF CHANGE: SUMMARY OF CHANGE: NEW DOCUMENT CREATED					
VERSION:	01	ORIGINATOR:	Ginny Halfpenny	Change ID:	N/A
DESCRIPTION OF CHANGE: SUMMARY OF CHANGE: SECTION 8.3 UPDATED AND INTEGRATED INTO SECTION 8.1, STEP 8.1.1.2.					
VERSION:	02	ORIGINATOR:	Nick Grow	Change ID:	N/A
DESCRIPTION OF CHANGE: COMPLETE RE-WRITE TO MEET QUALITY SYSTEM AND SERVICE NEEDS.					