

Title: Test Engineering Management Policy

Document No: 730001833

Version No: 03

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1. PURPOSE

This management policy summarizes the activities and deliverables used in the development and support of Waters Corporation product test solutions.

2. SCOPE

The scope of this policy applies to production test equipment purchased, designed and/or constructed by the Waters' Test Engineering Department in Milford MA.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
TE	Test Equipment or Test Engineering
Test Equipment	Equipment, that is typically comprised of hardware and software, and is required to perform a non-destructive test that demonstrates the product meets applicable specifications.
Customer	Within the context of this document, 'customer', applies to the requester and/or end user of the test solution developed by Test Engineering. This may include, but is not limited to: • Research Development and Engineering (RDE) • Continuing Engineering or Sustaining Engineering • Global Operations • Water's Suppliers • Field Service • Repair Operations • Quality
Calibration	A process to ensure that equipment is capable of producing accurate results. This includes verifying measurements and/or making adjustment(s) to ensure measurement accuracy.
PM	Preventive Maintenance: The servicing, for the purpose of maintaining equipment in satisfactory working order, by performing systematic inspection, detection, and correction of potential failures. PM activities may include tests, measurements and parts replacement.
New Product	A new, instrument or sub assembly designed or purchased by a Waters' organization.
Qualification	Δ A series of inspections and tests to ensure that critical requirements necessary for product quality are satisfied, and that documents and procedures necessary to properly operate and maintain the system are in place.
Δ Validation	Δ Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.
Δ Verification	Δ Confirmation by examination and provision of objective evidence that the specified requirements have been fulfilled.
UUT	Unit Under Test
N/A	Not Applicable
SAP	Systeme, Anwendungen und Produkte (Systems, Applications and Products), German Enterprise Resource Planning (ERP) software

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4. ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Test Engineering Manager	- It is the responsibility of Management to ensure implementation of this policy and affiliated Standard Operation Procedures (SOP). - Assign Test Engineering staff to approved development projects. - Approve scope of Test Engineering activities. - Review and/or approve all necessary documentation deliverables.
Test Engineering	- Review new or revised product designs for testability. - Develop Product Test Solutions. - Develop and qualify test equipment required to implement production testing at Water's or its suppliers. - Write review and/or approve all necessary documentation deliverables. - Support, service and maintain test equipment. - Initial test equipment training. - Work with various engineering functions towards problem resolution.
Test Engineering Technician	- Support test equipment development. - Write and/or review all necessary documentation deliverables. - Support, service and maintain test equipment. - Work with various engineering functions towards problem resolution.
Customer	- Request for new test equipment designs. - Request duplication, repair and/or enhancement of released test equipment designs to add functionality or increase production capacity. - Review and/or approve all necessary documentation deliverables.

5. POLICY

5.1. The test engineering group develops test solutions for global operations to ensure Waters' product specifications and customer expectations are met or exceeded. This includes but is not limited to the following:

- Developing, servicing and maintaining test equipment and procedures.
- Supplying information to enable, drive and track improvements.
- Support product compliance through test equipment qualification.

5.2. The Test Engineering process is captured into (4) SOP documents, which are as follows:

730001834 (New Test Equipment Development Procedure)	
Description	*Deliverables
This procedure defines the inputs and deliverables required to design, document and release equipment produced by Test engineering. This procedure applies to test equipment for instruments, sub-assemblies/spares and Printed Circuit Boards (PCB). Also, it defines information/documentation control for design record(s) and software.	➤ Test Equipment Plan • Initial Traceability Matrix ➤ Design Review Checklist ➤ Test Equipment Design Documentation (TEDD) ➤ Test Specification and Procedure (TSP) • Traceability Matrix ➤ Calibration / Preventative Maintenance Procedure ➤ Test Equipment Release Form

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730001835 *Δ (Process Validation Procedure for Milford Site)*

Description	*Deliverables
Δ The purpose of this procedure is to define the validation process and deliverables for all Milford site manufacturing processes, test methods, and equipment.	➤ Δ Submission Form ➤ Δ Validation Assessment Form (VAF) ➤ Δ Equipment Design Verification (EDV) ➤ Δ Test Method Validation (TMV) ➤ Δ Installation Qualification (IQ) ➤ Δ Operational Qualification (OQ) ➤ Δ Performance Qualification (PQ) ➤ Δ Validation Report (VR)

730001836 *(Sustaining Test Equipment Procedure)*

Description	*Deliverables
The purpose of this procedure is to define the process used to maintain, upgrade and track test equipment after it has been released for production usage. This includes the process for repairs, upgrades and duplication of production test equipment, as well as the management of test equipment assets, including obsolescence.	➤ Operations Engineering Service Request (OESR)

730001799 *(Operating Procedure, Calibration and Preventive Maintenance)*

Description	*Deliverables
The purpose of this procedure is to outline the calibration and preventive maintenance (PM) program for assembly, measurement and test equipment.	➤ Calibration/Repair/Maintenance Record ➤ Calibration/Maintenance Slip ➤ Out of Calibration

*Note: All listed deliverables may not be required. Please refer to the appropriate procedure to clarify the deliverables required.

6. REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
730001834	New Test Equipment Development Procedure
730001835	Δ Process Validation Procedure for Milford Site
730001836	Sustaining Test Equipment Procedure
730001799	Calibration and Maintenance of Assembly, Measurement and Test Equipment
730002223	Work Instruction, TE Internal Lab Audit
730001103	Global Policy Template
730000295MP	Quality System Document Control
WAT000050MP	Waters Record Retention Corporate Policy

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DOCUMENT HISTORY

VERSION:	03	ORIGINATOR:	Jaaffar Ismail	Change ID:	N/A
SUMMARY OF CHANGE: All changes have been mark with the change (delta) symbol. This policy was revised to reflect the changes made to procedure 730001835. These changes impact definitions and deliverables.					