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1 PURPOSE

The purpose of this procedure is to define the procedure for the control, calibration and maintenance of measurement and test equipment that require calibration at the WPPL, Contract Manufacturer, and Distribution Centers.

This covers equipment used in verifying conformance of Waters' products to the established quality assembly, inspection and test requirements and specifications.

2 SCOPE

The scope of this procedure applies IMTE control by Waters Pacific Pte Ltd (WPPL) at WPPL, contract manufacturers' sites, and Distribution Centers (DC). This will include:

- Inspection, Measurement, Testing Equipment, Tools, Fixtures and software owned by WPPL
- Inspection Measurement, Testing Equipment, Tools, Fixtures and software issued to CM / DC by Waters.

3 DEFINITIONS AND ABBREVIATIONS

Term / Abbreviation	Definition
IMTE	Inspection Measurement, Testing Equipment Tools
CM	Contract Manufacturers
DC	Distribution Centre manage by Third Party Logistics (3PL)
WPPL	Waters Pacific Private Limited

4 ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Designated WPPL Staff	Assigned by WPPL Manager and is responsible for verifying of calibration summary log/report submitted by the CM / DC.
WPPL Supplier Auditor	Responsible for reviewing and approving CM's QMS procedure for control of IMTE during Supplier Audit.
Equipment user	Equipment user using equipment shall verify that it has been calibrated or maintained. Otherwise; stop using the equipment and notify management/supervisor. Complete the Calibration/PM Change Request (WPPL-FM-87) and provide it to the Calibration Coordinator. The form is only applicable for equipment used by WPPL personnel. Execute Calibration or PM per individual equipment procedure. Ensure that documentation is properly completed; provide documentation to Calibration Coordinator. Calibration or PM activities may be performed by Calibration Coordinators, technicians, engineers or ISO/IEC 17025 accredited vendors or Original Equipment Manufacturer. Trained Equipment users refer to anyone who is trained to operate the equipment.

5 REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
N/A	ISO 13485 (Medical Devices – Quality Management Systems)
N/A	ISO 9001 (Quality Management System Standard)
WPPL-SP-02	Control of Documented Information
WPPL-WI-05	Calibration Work Instruction

6 FORMS

Doc No:	Document Title
N/A	Forms/ Logs and template for this process will be based on CM/ DC QMS
WPPL-FM-87	Calibration/PM Change Request

6.1 Records

Records described below shall be retained in accordance with WPPL-SP-02, Control of Documented Information Procedure.

Ref No:	Records Description
N/A	Calibration Reports

7 HEALTH & SAFETY

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

8.1 General IMTE Requirements for CM / DC

8.1.1. WPPL shall ensure that all IMTE, tool and software used by contract manufacturers, distribution centres for manufacturing, storage and distribution Waters products is suitable for its intended purposes and is capable of producing valid results. This could be verified during annual supplier audit.

8.1.2. The respective CM / DCs shall ensure that a procedure is in place as per their QMS

In general all IMTE;

- Shall be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards that is of higher accuracy and is traceable to international or national measurement standards.
- Should there be no standard exists, the basis used for calibration or verification shall be retained as documented information and approved by WPPL.
- Should be adjusted or re-adjusted as necessary.

- d. Identified and enable calibration status to be determined, e.g. Calibrated, Calibration not required.
- e. Safeguard for adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.
- f. Shall be protected during handling, maintenance, storage or operation.

8.1.3. It is a prerequisite for a calibration laboratory/company to be accredited to ISO/IEC 17025 in order to conduct calibration of the equipment. The calibration laboratory/company must provide evidence of attaining ISO/IEC 17025 certification by Accreditation body in their calibration certificate of the equipment. Exception to this ISO/IEC 17025 requirement is if it is performed by the Original Equipment Manufacturer (OEM).

8.2 Control of Waters transferred IMTE

- 8.2.1. CM/DC to compile a list of Waters transferred IMTE which includes IMTE that are used in the manufacture of Waters products.
- 8.2.2. The CM/DC shall include all Waters transferred IMTE into their QMS calibration control list and manage as per their QMS procedure, taking into account of Waters recommended check interval.
- 8.2.3. A Monthly Calibration Summary Log / Report shall be compiled by respective CM/DC only if there is any calibration performed during particular month.
- 8.2.4. WPPL designated Staff shall verify CM/DC equipment owner has approved the Calibration Report and based on that to verify the CM/DC Calibration Summary Log / Report.
- 8.2.5. The approval party should feedback to the CM if there is any issue and "Calibration Summary Log / Report" shall be updated for changes when necessary.
- 8.2.6. CM/DC shall submit the following on a Monthly to WPPL for payment purposes:
 - Records of payment of services rendered from the process (e.g. Invoices or Quotation plus *Scanned* copy of Calibration Certificates).
 - Monthly "Calibration Summary Log/ Report" as per 8.2.3. above.

8.3 Control of Waters transferred IMTE (Software)

- 8.3.1. Any software that facilitate any IMTE application being transferred to CM during Product Transfer shall be validated/ verified prior for use in production as per DTS requirements by Waters Corporation.
- 8.3.2. Where applicable, Waters shall approve all validation/ verification/ re-validation results conducted by the CM in accordance to Waters approved Protocol/ Verification Testing Instructions/ Specification for recommendation or periodic validation as required.

8.4 Non-conforming IMTE/Software

- 8.4.1. Deviation from Specification/ Procedure
- 8.4.2 Any deviation deriving from Waters approved Protocol/ Verification Testing Instructions/ Specification/ agreed calibration procedure shall be reported clearly on test report/ records. All deviations reported shall be approved by WPPL before use of equipment and software.
- 8.4.3. The CM / DC shall assess and record the validity of the previous measuring results completed in production when any IMTE is found not to conform to requirements. Appropriate action on the IMTE and any affected Waters product shall be recorded and reported to Waters.

8.5 General IMTE Requirements for WPPL

- 8.5.1. Equipment will be assessed and evaluated to determine whether calibration is required.
- 8.5.2. If calibration required, the assessment will also determine the frequency. Reference to **WPPL-WI-05, Calibration Work Instruction**.
- 8.5.3. Calibration of equipment will be performed by companies whose measurement standards are traceable to International/National measurement standards.
- 8.5.4. Internal calibration will be performed by internal trained Equipment users.
- 8.5.5. In the event of equipment not meeting calibration requirements, it will be evaluated as to whether there is any adverse effect to end performance of product. Reference to **WPPL-WI-05, Calibration Work Instruction**.
- 8.5.6. Records of equipment assessment and calibration results shall be maintained in accordance to **WPPL-SP-02, Control of Documented Information**.

9 APPENDICES / ATTACHMENTS

Not Applicable

DOCUMENT HISTORY

VERSION:	05	ORIGINATOR:	Desmond Ann	Change ID:	D17033
DESCRIPTION OF CHANGE: DELETED SECTION 9.2.6 RE-SEQUENCE 9.2.3 to 9.2.7 SECTION 9.3.2 CHANGE TO "Where applicable, Waters shall approve all validation/ verification/ re-validation results conducted by the CM in accordance to Waters approved Protocol/ Verification Testing Instructions/ Specification for recommendation or periodic validation as required."					
VERSION:	06	ORIGINATOR:	Desmond Ann	Change ID:	D17040
DESCRIPTION OF CHANGE: Section 1: Change to " The purpose of this procedure is to define the procedure for the control, calibration and maintenance of measurement and test equipment that require calibration at the WPPL, Contract Manufacturer and Distribution Centers." Section 4: Add Roles and Responsibility for operators. Section 5: Add WPPL-SP-02 and WPPL-WI-05 to the reference. Section 7: Update the records. Add new section 9.5 Section 9.2.1 Clarify CM's responsibility.					
VERSION:	07	ORIGINATOR:	Ng Jie Hui	Change ID:	N/A
DESCRIPTION OF CHANGE: Use updated template. Section 5 Changed procedure name for WPPI-SP-02, WPPL-SP-04 and WPPL-SP-08 to current name. Add new section 8.1.3 added the requirement "It is a prerequisite for a calibration laboratory/company to be accredited to ISO/IEC 17025 in order to conduct calibration of the equipment. The calibration laboratory/company must provide evidence of attaining ISO/IEC 17025 certification by Accreditation body in their calibration certificate of the equipment. Exception to this ISO/IEC 17025 requirement is if it is performed by the Original Equipment Manufacturer (OEM)." Section 8.2.5 revised from "Quarterly" to "Monthly" Section 8.2.7 revised from "Quarterly" to "Monthly" Section 8.5.5. Revised from "WPPL-SP-04, Control of Nonconforming Outputs" to "WPPL-SP-04, Control of Nonconforming Product". Section 8.5.6. Revised from " WPPL-SP-02 Control of Documented Information Procedure " to " WPPL-SP-02 Control of Documented information ".					
VERSION:	08	ORIGINATOR:	Ng Jie Hui	Change ID:	N/A

DESCRIPTION OF CHANGE: Section 4: Responsibility of Designated WPPL Staff change to “Assigned by WPPL Manager and is responsible for verifying of calibration summary log/ report submitted by the CM/ DC”. Delete Section 8.2.4 Section 8.2.5. Re-sequence to Section 8.2.3. Section 8.2.3. Re-sequence to Section 8.2.4. Section 8.2.6. Re-sequence to Section 8.2.5. Section 8.2.7. Re-sequence to Section 8.2.6. Section 8.2.3. Change to “A Monthly Calibration Summary Log / Report shall be compiled by respective CM only if there is any calibration performed during particular month”. Section 8.2.4. Change to “WPPL designated Staff shall verify CM equipment owner has approved the Calibration Report and based on that to verify the CM/DC Calibration Summary Log / Report”. Section 8.2.6. Change to Monthly “Calibration Summary Log/ Report” as per 8.2.3. above”.					
VERSION:	09	ORIGINATOR:	Luo HuaZhen	Change ID:	N/A
DESCRIPTION OF CHANGE: Section 1 Add ‘Field Service’ Section 2 Add ‘Field Service’ and ‘FSO’ Section 3 Add ‘Field Service’ and ‘FSO’ Section 4 Add ‘Field Service’, Replaced ‘Operators’ with ‘Equipment user’, Add ‘The form is only applicable for equipment used at Singapore Operations Lab.’ Section 8.1 Add ‘FSO’ Section 8.1.1 Add ‘field service’, ‘installation, servicing, storage and distribution’ Section 8.1.2 Add ‘FSO’ Section 8.4.3 Add ‘FSO’, Replaced ‘access’ with ‘assess’ Section 8.5.4 Replaced ‘operator’ with ‘Equipment user’					
VERSION:	10	ORIGINATOR:	Chan Yee Hwa	Change ID:	N/A

DESCRIPTION OF CHANGE:

Section 1 Remove 'Field Service'

Section 2 Remove 'Field Service' and 'FSO' & "Inspection Measurement, Testing Equipment, Tools, Fixtures and software owned by CM / DC."

Section 3 Remove 'Field Service' and 'FSO'

Section 4 Remove 'Field Service', Change 'The form is only applicable for equipment by WPPL'

Section 8.1 Remove 'FSO'

Section 8.1.1 Remove 'field service', 'installation, servicing, storage and distribution'

Section 8.1.2 Remove 'FSO'

Section 8.2.1 Remove "application software and attributes tools" and list of classification.

Section 8.4.3 Remove 'FSO',

Section 8.5.5 Remove "via *WPPL-SP-04, Control of Nonconforming Product* and remedial action taken as required.