

Title: Installation Qualification Procedure

Document No: 730004135

Version No: 00

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1. PURPOSE

The purpose of this Installation Qualification (IQ) protocol is to provide a series of Test Scripts to be used to qualify the installation of any Milford site process equipment and ancillary system to ensure compliance to manufacturer's guidelines and/or Waters requirements.

Once completed, the applicable executed Installation Qualification (IQ) protocol test script data sheets will be included within an Installation Qualification Report (IQR), which will serve as objective evidence that all key aspects of the equipment and ancillary system are installed correctly.

2. SCOPE

This Installation Qualification (IQ) protocol shall be used for all equipment within a method or process that makes a decision which can affect product, or that the improper installation and/or configuration would impact the assessment or production of product, as defined in 730001835, Process Validation Procedure for Milford Site.

3. DEFINITIONS AND ABBREVIATIONS

Term	Definition / Abbreviation
IQ	Installation Qualification
IQR	Installation Qualification Report
UUT	Unit Under Test
BOM	Bill of Materials
TSP	Test and Specification Procedure
SAP	Enterprise Resource Planning (ERP) software
N/A	Not applicable
VAC	Voltage Alternating Current
Hz	Hertz

4. ROLES AND RESPONSIBILITIES

Roles	Responsibilities
Engineering Managers	- Ensure implementation of this procedure and affiliated Standard Operation Procedures (SOP). - Review and/or approve all necessary documentation deliverables. - Assign resources as required to support validation activities.
Originator	- Coordinate and assist in the execution of the applicable IQ activities. - Author IQ Report summarizing results upon completion of IQ activities.
Performer	- Execute applicable IQ activities per instructions from Originator and using data collection sheets outlined in the applicable Test Scripts. - Responsible for providing the Originator with all objective evidence and/or data. - Follow all GDP requirements per Waters' Good Documentation Procedure 730000523.
Reviewer	Review and/or approve the finalized IQ Report (IQR).
Approver (Site Quality or Delegate)	

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5. REFERENCES / RELATED DOCUMENTS

Doc No:	Document Title
730000837	Waters Global Validation Policy
730001833	Test Engineering Management Policy
730001835	Process Validation Procedure for Milford Site
730001799	Calibration and Maintenance of Assembly, Measurement and Test Equipment
730000295MP	Quality System Document Control
WAT000050MP	Waters Record Retention Corporate Policy
730000523	Waters' Good Documentation Procedure
730000483	Global WI/Operating Procedure Template
730002232	Process Validation Master Plan
WAT000022MP	ESD (Electrostatic Discharge) Procedure

6. FORMS

Doc No:	Document Title
730002845	Validation Report Template

7. RECORDS

The IQ Report shall be stored in SAP. The IQ Report shall be associated with the appropriate equipment number or nomenclature in SAP, as defined in the Process Validation Procedure for Milford Site (730001835).

8. PROCEDURE

8.1. General Overview

Perform the Test Scripts provided in Section 9, as applicable. The Originator and/or Performer shall write in any specification that is not defined, as explained in the Test Execution for each applicable Test Script.

- 8.1.1. All personnel performing any part of this IQ shall be trained to this protocol, and/or the operating procedures when applicable, prior to the start of any testing. A Training Record shall be filled out and attached to the associated IQR, when applicable. A blank Training Record is provided as part of this instruction.

8.2. Acceptance Criteria

The IQ will be considered successful when all appropriate sections have been completed and an IQR has been written (in accordance with 730002845, Report Template), and has been approved. Only the Test Scripts that apply to the Equipment being qualified shall be performed.

Objective evidence will be included within, or attached to, the associated IQR and referenced to the script and step numbers. Examples of objective evidence include, but are not limited to: all completed protocol test script data sheets, screenshots, calibration certificates, photos, test reports, etc. Do not leave any fields blank. If not applicable fill in N/A.

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8.2.1. Failure to Meet Acceptance Criteria

The pass/fail decision is based on the number and severity of discrepancies found during the Installation Qualification. During the execution of the IQ Protocol, if a discrepancy is found which can be resolved, make the change and then continue with the execution. In the event that a discrepancy is not able to be resolved the Originator must decide to:

Submit the IQR to the defined signatories with a recommendation to accept (with justification) or reject the qualification. The IQR requires all test results, deviations and conclusions to be summarized in the appropriate sections. In the case of a rejected qualification, the appropriate engineering personnel will assess the issue and determine if the necessary changes can be made in order to move forward with the Installation Qualification.

8.3. Installation Qualification Report (IQR)

8.3.1. An Installation Qualification Report shall be written upon completion of all applicable IQ Test Script requirements. The IQR shall summarize the results of the testing performed and any deviations that occurred.

8.3.2. The completed data sheets in Section 9 and Appendix A that are applicable shall be attached to the report as objective evidence.

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IQ Test name: Associated Documentation Verification		Test Script No.: IQ-01	
Equipment No./ID:		Equipment Name:	
Installation Site:			
Purpose: To verify that supporting documentation is available prior to the completion of qualification. Test execution: List all applicable documents (Preventive Maintenance, Calibration, Operating Procedures, Test Specification Procedures, Manufacturing Procedures, etc.) under the Document type header and then complete the table below. If applicable documents are unavailable state why in the comments section. All applicable documents must be in either Ready, Pre-Rel-Prod, or Release General state in SAP. Enter N/A for any parameter or cell that is not used or not applicable. Objective evidence: Completed Test Script Data Sheet SAP Screen shot of below available document(s)			
Document Type	Title; Doc. No.; Revision/Version No.	Status in SAP	Initial & Date
Comments:			
Overall Test Conclusion: ☐ Pass ☐ Fail			

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IQ Test name: Site Verification			Test Script No.: IQ-02	
Equipment No./ID:		Equipment Name:		
Installation Site:				
Purpose: To verify the location in which the test equipment is to be installed is suitable for use. Test execution: List any additional applicable environmental parameters in the Parameters column. Using the applicable equipment documentation, define the specifications in the Acceptance Criteria column, as appropriate. Verify and/or measure the applicable parameters and complete the table below. Do not delete any of the listed defined parameters. Enter N/A for any parameter or cell that is not used or applicable. Objective evidence: Completed Test Script Data Sheet. Photo(s) of the work area, if applicable. Copies of calibration certificates for gauges or meters used for measurement, if applicable.				
Parameters	Acceptance criteria	As found	Pass/Fail	Initial & Date
Ambient Temperature				
Relative Humidity				
Workspace				
Test Station Bench				
Electrical Supply				
Electrical Outlets				
Network Available				
Comments:				
Overall Test Conclusion: ☐ Pass ☐ Fail				

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IOQ Test name: Instrumentation Calibration Verification				Test Script No.: IQ-03	
Equipment No./ID:			Equipment Name:		
Installation Site:					
Purpose: To verify that all critical instruments are in the calibration system and calibrated or a preventive maintenance has been performed, as appropriate. Test execution: List all critical instruments/components and/or sub-systems (System, TUV, Sample Manager, BSM, Column Manager, Test Solutions, Meters, Gauges, Scales, etc.) in the Description column and complete the table below. Verify that all critical instruments have had a preventive maintenance and/or calibration performed, in accordance with the PM and/or Calibration procedures, and have been included in the preventive maintenance/calibration schedule. For test solutions note the expiration date. Enter N/A for any parameter or cell that is not used or applicable. Objective evidence: Completed Test Script Data Sheet Copies of calibration and/or maintenance certificates.					
Description	Waters P/N and Asset No.	Serial Number	Last Cal/PM Performed Date	PM Cal/Due / Expiration Date	Initial & Date
Comments:					
Overall Test Conclusion: ☐ Pass ☐ Fail					

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IOQ Test name: Test Software and Instrument Firmware Version			Test Script No.: IQ-04	
Equipment No./ID:		Equipment Name:		
Installation Site:				
Purpose: To verify that the installed firmware/software is correct per the applicable design/operational documents (TSP, ASP, MPR, BOM, and/or other Design documents). Test execution: List all critical instruments/components and/or sub-systems that require software and/or firmware in the Description column. List the associated required software/firmware version, as defined in the applicable design/operational documents, in the Acceptance criteria column. Verify that the software/firmware version on the Test Equipment match the acceptance criteria and are identical. Enter N/A for any parameter or cell that is not used or applicable. Objective evidence: Completed Test Script Data Sheet Identify the applicable design/operational document that defined the required software/firmware version(s) in the associated Installation Qualification Report.				
Description	Acceptance criteria	As found	Pass/Fail	Initial & Date
Test Equipment Software	Version:	Version:		
	Version:	Version:		
	Version:	Version:		
	Version:	Version:		
	Version:	Version:		
	Version:	Version:		
	Version:	Version:		
Comments:				
Overall Test Conclusion: ☐ Pass ☐ Fail				

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IQ Test name: General Safety and Alarms		Test Script No.: IQ-05	
Equipment No./ID:		Equipment Name:	
Installation Site:			
Purpose: To verify that the test equipment can operate in a safe manner, within its designated location. Test List any additional safety related conditions or alarms in the Safety Inspection column. List the associated safety requirement/specification in the Acceptance Criteria column. Perform an inspection/test of the equipment to assess its safety related conditions. Enter N/A for any parameter or cell that is not used or applicable. Objective evidence: Completed Test Script Data Sheet Photo of the secured glass bottles and/or tanks, if applicable			
Safety Inspection	Acceptance criteria	Pass/Fail	Initial & Date
Mechanical Safety/ Pinch Points/Sharp Edges	None Found		
Electrical Safety Hi Pot/Ground Continuity	Passed per test specification WAT046538		
Glass Bottles are secure	Secure		
Tanks are secure	Secure		
Comments:			
Overall Test Conclusion: ☐ Pass ☐ Fail			

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IOQ Test name: Functional Verification		Test Script No.: IQ-06	
Equipment No./ID:		Equipment Name:	
Installation Site:			
Purpose: To verify that system transfer and/or qualification activities have not adversely affected system functionality.			
Test execution: One UUT shall be tested to verify that the test equipment functions as expected. If the system creates and/or tests more than one part number, the UUT to be tested per this Script should be a “worst case” product, and defined within the associated Installation Qualification Report. Enter N/A for any parameter or cell that is not used or applicable.			
Objective evidence: Completed Test Script Data Sheet Copy of the system Test Record for the UUT, if applicable.			
UUT Part Number/Serial Number	Acceptance criteria	Pass/Fail	Initial & Date
UUT Part Number: UUT Serial Number:	All required CTQ Specification measurements result in a Pass.		
Comments: 			
Overall Test Conclusion: ☐ Pass ☒ Fail			

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Appendix A: TRAINING RECORD

Document No. _____ **Procedure Title** _____ **Version** _____

Training by: _____

Printed name	Signature	Date
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By signing you acknowledge that you have reviewed, understand, and agree to comply with the policies and practices of the procedure defined above.

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DOCUMENT HISTORY

VERSION:	00	ORIGINATOR:	James Stors	Change ID:	N/A
SUMMARY OF CHANGE: INITIAL RELEASE OF THE INSTALLATION QUALIFICATION PROTOCOL.					