

**Installation Qualification & Operational Qualification of Agilent Laboratory Software** 

## **REVIEW DOCUMENT NAME:**

 $Agilent\_Recommended\_EQP\_SW$ 









### **How to Use This Document**

This document provides a full list of the tests and checks performed as part of Agilent's standard IQ and OQ for software products in scope of Enterprise Edition Compliance Services.

The software IQ and OQ procedures listed in this document are a set of tests and checks at Agilent recommended criteria and limits. The automated delivery tool sets-up the right type and number of tests for the installed computer system configuration.

All tests in this document exist in all Agilent delivery tools.

By agreeing to the terms and conditions of the Compliance Services Exhibit (22V) you are also agreeing to the scope and coverage of the Agilent Recommended EQP for the specific qualification service. Changes to the Agilent Recommended plan (EQP) requires prior contractual agreement between customer and Agilent and will be subject to additional charges.

#### Note:

This document provides an IQ and OQ protocol to verify software installation and proper function and record software & hardware configuration. The IQ and OQ reports resulting from execution of the protocol will provide an important component of a complete computer system validation compliance package. A full Computer System Validation package may involve many procedures and use of this protocol alone does not assure compliance. Agilent Technologies makes no promises or representations as to its sufficiency for any specific regulatory program or specific company procedure.

### Approval of EQP

Signature provided for customer internal purposes only. Refer to the attached Test Matrix document for details on applicable OQ tests for all Software platforms and configuration.

Name and Role	Signature and Date

[You cannot save form entries with Adobe Reader. Typed entries and menu selections are printed on your official paper copy when you print.]

DO NOT SEND AGILENT A COPY OF YOUR APPROVED EQP. THIS DOCUMENT IS YOUR OWN RECORD OF APPROVAL.

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# PDF file attachments to this electronic EQP (open the attachments folder for this document in Adobe):







Part 11 Checklist (ACE)

**Test Configuration Tables** 

EE 1.76 Comparison

# **Design Qualification (DQ)**

Design Qualification (DQ) for commercial lab instruments is recommended by some, but not all, guidances and procedures. Defintions of DQ found in guidances and firm-specific validation procedures vary widely around the world. Some firms require nothing more than a record (such as certificate) from the instrument manufacturer demonstrating that the lab system has been designed for purpose and manufactured to a quality standard. Others treat DQ as the development of a user requirement specification document (URS) which can be matched to the IQ and OQ specifications for a manufacturer. Other firms consider DQ as including the vendor selection activities.

For your reference, Agilent provides the following statements for DQ purposes:

- All Agilent LC, LCMS, GC, GCMS, UV-Vis and Dissolution hardware and software laboratory products including the ACE software used to deliver qualification services, are designed, manufactured, and tested according to Agilent internal Quality Life-Cycle Development Procedures.
- 2. Certificates of Agilent testing, validation, and conformance to standards are provided with new Agilent instruments and software. Similar certification is provided for ACE software. These certification documents are checked and recorded in Enterprise Edition Compliance Services IO.
- 3. Agilent maintains information describing how products are manufactured and maintains a problem and bug reporting program as required by international software quality guidelines.
- 4. Agilent Technologies is capable of installation, support, preventive maintenance, on-going qualification and re-qualification after repair and user training worldwide.

# **Installation Qualification (IQ) Software**

Software IQ checks and tests each client and server as appropriate to the installed configuration. A detailed configuration record is made and reported in the final IQ report. The configuration (type of software, number of clients etc.) determines the type and number of subsequent OQ tests.

IQ for Agilent software products includes the following:

- 1. Purchase Order Documents:
  - Allows the customer to verify that the instrument being qualified matches their design requirements (if available) and purchase order. ACCEPTANCE CRITERIA: NONE. JUST A DOCUMENTATION RECORD.
- 2. Preparation and Installation Documents:
  - Gathers and records information about preparation and installation documents. ACCEPTANCE CRITERIA: NONE. JUST A DOCUMENTATION RECORD.
- 3. System and Installation Documentation:
  - Gathers and records information about reference amd user manuals for initial installations. ACCEPTANCE CRITERIA: NONE. JUST A DOCUMENTATION RECORD.
- 4. Product Quality Assurance Documents:
  - Collects and records certificates and other forms that verify that the vendor has developed and built the product according to internal standards. ACCEPTANCE CRITERIA: NONE. JUST A DOCUMENTATION RECORD.
- 5. Start Up Test:
  - Verifies that all modules start up properly. ACCEPTANCE CRITERIA: NO ERRORS IN START-UP.
- 6. Software Installation Qualification:

Verifies the correctness of all files associated with the software product at installation by running the internal software verification batch file or the proprietary automated Installation Qualification Tool (IQT). All key components of the software are scanned and checked for correctness against a known look-up list of components for the validated and released software product.

#### **ACCEPTANCE CRITERIA:**

File Report Summary

- · No missing files or invalid files found
- · No system file differences found

**Registry Report Summary** 

· No invalid registry entries found

Files Registration Report Summary

· Not registered files: NONE

# **Operational Qualification (00) Software**

The full list of Software 00 checks and tests for Agilent software products is shown below. The type and scale of the software installation determines which exact tests are run in a specific software 00.

ACCEPTANCE CRITERIA FOR ALL TESTS: ACTUAL OUTPUT / RESULT matches EXPECTED OUTPUT / RESULT.

#### **General Software Tests**

#### **Security Tests: Basic Access**

This test verifies that administration utilities and the software can only be accessed by valid user/password combinations.

#### Security Tests: Advanced Access

This test verifies that the password policy capabilities function properly.

#### Security Tests: User Interface Locking

This test uses interactive and/or time-based lockout of the application or session to verify that the software can prevent unauthorized access/impersonation by another user.

#### Reporting and Calculation Tests: Self Test

This automated test verifies the calculations of the software.

#### Reporting and Calculation Tests: Reports

This manual test verifies that the software can reproduce report sna dresults according to a predefined template.

### Traceability Tests: User Management Audit Trail

This test verifies that the software records the proper log information (electronic signature, dates and time stamp, and account information).

### Traceability Tests: Data Audit Trail

This test checks that changes to the methods associated with data are properly maintained.

#### **Integrity Tests: Data**

This test verifies data integrity as files are stored, retrieved, and transferred. It also verifies that data can only be altered by authorized users.

#### **Communication Tests**

This test verifies that the software can communicate with instrument modules.

#### Workflow Test

This test verifies the general workflow of the software overall operation, which may include Security, Algorithm test, and additional functionality only available in the specific software.

# **Operational Qualification (0Q) Software (continued)**

### **Mass Spectrometry Software Tests**

#### Spectral Library/Evaluation Test

This test verifies that you can create a library, add a compound to it, and then identify the compound and verify the identification.

#### **Client/Server Software Tests**

#### **Client Test: Server Operation**

This test verifies the connection between the client and server using a workflow operation test.

#### Server Tests: Client Operation

This test verifies that the client used for the server qualification passed the Installation Qualification successfully and can connect to the server.

#### Server Tests: Archive and Restore

This test verifies the server archive and restore capabilities.

#### Server Tests: Load Test

This test stresses the client/server system with a predefined load of simultaneous data transfers from multiple clients.

### Content Management System (CMS) Software (OpenLAB, ECM) Tests

### **CMS File Operations Test**

This test verifies that an authorized user can log on, create a folder structure, and send, delete, and move files to and from the content management repository. The audit trail is used to verify performed steps.

#### CMS check-in Check-out Test

This test verifies that an authorized user can check out a file and that the software forbids another user to check in the file when it is already checked out.

#### **CMS E-Mail Notification Test**

This test verifies that a notification e-mail is sent after deleting a file.

#### **CMS Print Services Tests: Generic Printer**

This test verifies that the print services send data to the content management repository.

### CMS Print Services Tests: Abobe Distiller Printer

This test verifies that the print services send data to the content management repository.

# **Operational Qualification (OQ) Software (continued)**

### Content Management Software (OpenLAB, ECM) Tests (continued)

CMS Adobe Acrobat Tests: E-Signature

This test verifies that you can sign a document.

CMS Adobe Acrobat Tests: Template

This test verifies that the system can extract information from Adobe documents to create keys in database.

**CMS Associate Files Tests** 

This test verifies that files can be associated and associations can be broken.

CMS Content Structure Management Tests: Basic Functions

This test verifies that an authorized user can create, manipulate, and delete a content management structure.

CMS Content Structure Management Tests: Filter Function

This test verifies the system filter capabilities by running an automated test.

**CMS Archive Test** 

This test verifies if the system is able to archive data from the repository.

**CMS Query Test** 

This test verifies that queries can find files and user-defined keys.

CMS Scheduled Services and Viewer Test

This test verifies that data is uploaded to the repository as scheduled, and that the uploaded and original data match.

**ECM Desktop Integration Test** 

This test verifies the Integration functionality with Microsoft Office products.

**ECM Business Process Manager Test** 

These tests verify the general performance, e-mail notification and Adobe forms functionality of the BPM module.

### **Legal and Endorsement**

Enterprise Edition and its primary components (ACE software tool, procedures, test design, metrology tools, chemical reference standards, operator training materials) has been designed, developed, tested, validated, and released for commercial use following Agilent's Life-Cycle Development Quality Assurance methodology.

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A.01.85 April 2014

Added support for (1) OpenLAB CDS A.02.01; OpenLAB DataStore A.02.01; ICP-MS MassHunter

# Standard\_EQP Revision History

### **Revision History of Enterprise Edition Software Protocols**

A.U1.85 April 2014	C.01.01.
	Increased scope for Waters Empower2 FR1-5 and Empower3, adding acquisition data buffering,
	traceability and security tests.
A.01.84 September 2013	Added support for: (1) Cary WinUV Pharma 3.1 to 5.0; (2) Advanced File Security for OpenLAB CDS
	EZChrom Edition; (3) SpectrAA Software 5.2; (4) MassHunter Workstion for ICP-MS B.01.03 with
	Data Store.
A.01.83 April 2013	Added support for (1) OpenLAB CDS A.01.05, (2) OpenLAB DataStore A.01.02; (3) MassHunter for
	ICP-MS B01.01., B01.02., (4) MassHunter QUANT B.06.00, ACQ GM/MS B.07.00; (5) LC Dissolution
	A.01.02; (6) SpectrAA 5.2 Software; (7) Waters Empower 2 RF5 and 3; (8) Digital Converters 35900E and SS420X. No regulatory impact for previously approved EQP's.
A.01.82 December 2012	Added support for: (1) 280 and 400 Dissolution Workstations; (2) LC Dissolution A.01.01; (3)
7.101.02 2000111201 2012	MassHunter ACQ QQQ B.06.00; (4) MassHunter ACQ TOF/Q-TOF B.05.01; (5) MassHunter QUAL
	B.06.00; (7) MassHunter QUANT B.05.02. No regulatory impact for previously approved EQPs.
A.01.81 August 2012	Added support for: (1) MassHunter QUANT B.05.01 & ECM archival; (2) MassHunter ACQ-QQQ B.05.00;
	(3) MassHunter QUAL B.05.00_SP1; (4)OpenLAB CDS A.01.04; (5) OpenLAB DataStore A.01.01; (6) UV-
	Visible ChemStation B.04.02; (7) MSD ChemStation E.02.02_SP1.
A.01.80 July 2012	Added support for (1) Cary WinUv 4.x and 5.0; (2) Dissolution WorkStation 1.3. No regulatory impact to
A.01.79 April 2012	previously approved EQP's.  Added support for: (1) MassHunter ACQ Q-TOF B.05.00; (2) ChemStation B.04.03-SP1; (3) OLIR A.02.03.
A.01.79 April 2012	No regulatory impact for previously approved EQP's.
A.01.78, January 2012	Added support for (1) OpenLAB CDS A.01.03 (ChemStation and EZChrom Editions). Added tests for
,	OpenLab ECM BPM and Desktop Integration. No regulatory impact to previously-approved EQP's.
A.01.77, November 2011	Added support for (1) MassHunter ACQ B.04.01 SP1/2; (2) MassHunter QUAL and QUANT B.05.00 No
	regulatory impact to previously-approved EQP's.
A.01.76, August 2011	Added support for (1) OpenLAB CDS A.01.02 (ChemStation and EZChrom Editions); (2) GCMS
	Productivity ChemStation E.02.02. Protocol revision made independent from ACE revisions. No regulatory impact to previously-approved EQP's.
A 01 7F Manak 2011	
A.01.75, March 2011	Added support for (1) OpenLAB CDS A.01.01 (ChemStation and EZChrom Editions); (2) MassHunter Acquisition QQQ B.04.01; (4) MSD Productivity ChemStation ECM Connectivity No regulatory impact
	for previously approved EQP's.
A.01.74, September 2010	Added support for (1) OpenLAB ECM Enterprise, (2) MassHunter QQQ B.03.01 SP2, (3) MassHunter
	Acquisition Q/TOF B.02.01 SP3, (4) EZChrom Workstation 3.3.2 SP2 No regulatory impact for
	previously approved EQP's.
A.01.73, July 2010	Added support for (1) ChemStation B.04.02 SP1, (2) MassHunter B.03.01, (3) Qualitative B.03.01 SP3,
A.01.72, January 2010	(4) Quantification B.04.01, (5) CTC Addon A.01.06 No regulatory impact.  Added Agilent EZChrom support. No regulatory impact.
A.01.71, October 2009	(1) Added E-signature fields (NO REGULATORY IMPACT); (2) added support for (a) MassHunter ACQ
A.01.71, October 2003	GC-QQQ B.04.01, MassHunter QUAL B.03.01, and MassHunter QUANT B.03.02; (b) MassHunter ACQ
	QQQ/QTOF/TOF B.02.01 SP1; (c) MassHunter GCMS Supplemental; (d) Headspace CTC A.01.05; (e)
	ChemStation LTM A.01.01; (f) ChemStation OpenLab Intelligence Reporter A.02.01.
A.01.70, April 2009	Added support for (1) ChemStation B.04.01 SP1; (2) MassHunter ACQ GC-QQQ B.04.00, MassHunter
	QUAL B.03.00, MassHunter QUANT B.03.01; (3) MassHunter ACQ QTOF/TOF B.02.01.
	Added support for (1) ChemStation B.04.02 SP1, (2) MassHunter B.03.01, (3) Qualitative B.03.01
A.01.60 SR3, February 2009	Added support for (1) ChemStore B.04.02 Client/Server; (2) ChemStore B.04.02 Standalone; (3) Healex ChemLaunch C.01.06 for ChemStore Client/Server.
A.01.60 SR2, November 2008	Added support for (1) ChemStation B.04.01 standalone; (2) ChemStation OpenLab integration (21 CFR
A.UT.UU SIIZ, NUVEIIDEI ZUUO	P11); (3) Ion Trap 6.2; (4) MassHunter Acquisition-QQQ B.02.00 and Qualitative B.02.00; (5) Healex
	ChemLaunch C.01.06 for ChemStation; (6) OpenLab Intelligence Reporter.
A.01.60 SR1, July 2008	Added support for MSD ChemStation B.02.00.

## **Standard EQP Revision History**

### **Revision History of Enterprise Edition Software Protocols**

A.01.60, April 2008 Added support for (1) multi-instrument ChemStation products; (2) client/server for ChemStation Plus

products; (3) GCMS ChemStation E.02.00; (4) MassHunter for QQQ ACQ B.01.04; (5) ChemStation

B.03.01 SR1.1, ChemStation B.03.02, and ChemStore B.04.01.

A.01.54, January 2008 Added support for MassHunter TOF B.01.03 ACQ, QUAL B.01.03 and QUANT B.01.04.

A.01.53, August 2007 Added support for (1) Agilent MassHunter B.01.02 for Q-TOF; (2) Agilent MassHunter B.01.03 for QQQ;

(3) Agilent QQQ Security Pack Module.

A.01.50, March 2007 (1) Added support for MSD Productivity ChemStation, MSD Security ChemStation, and Content

Management System (A.01.40 supported LC/MSD Trap Software, ChemStation, and MassHunter);

(2) added Spectral Library/Evaluation Test.

A.01.40, December 2006 Initial Software - Operational Qualification.

End of EQP Review Document

# www.agilent.com/chem/enterprise

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