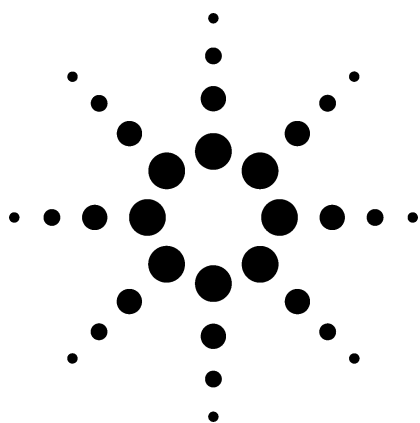




Agilent ChemStation and ChemStation Plus Qualification Services Version B.01.00 (Compliance Wizard) Revision History Changes Service Overview

Introduction

The Agilent Installation Qualification (IQ) and Operational Qualification/Performance Verification (OQ/PV) Compliance Services for the ChemStation and ChemStation Plus Networked Data Systems verify the proper installation and the main three areas of the software functionality: Access Control Security, Chromatographic Evaluation, and Instrument Communication and Control.

The new revision B.01.00 uses a wizard-based approach for reduced system downtime and increased accuracy. This tool was developed and tested according to the Agilent Technologies Life Sciences and Chemical Analysis (LSCA) Lifecycle. No changes have been made in the scope of the qualification services, but

there have been changes made to the form and processes used during the delivery. This new approach increases the quality of the delivery while providing more consistency and flexibility.

Test Execution

The automated protocol is delivered on site by a trained Agilent CE with the Compliance Wizard CD-ROM. The CD-ROM used for test execution is copy-protected, has the version number printed on it and contains the information to run the tests and print the report. No additional software is installed on the computer being qualified. The fulfillment of the protocol is performed during the execution of the compliance wizard-led instructions, by running directly from the Compliance CD-ROM.



Automated Detection and Data Sources

The tests in the Compliance Wizard protocol are done based on a combination of manual and automated entries that are made with the use of the user interface. The automated detection is primarily used to gather system configuration information in a more efficient way by making use of the standard MS Windows® environment variables and resources.

The following table lists the detection type for the different parameters used during the fulfillment of the protocol.

Parameter	Detection type	Data source
WorkStation type (Client/Server, Standalone)	Manual	n/a
Initial or re-occurring tests	Manual	n/a
Sign off per test	Manual	n/a
Sign off per page/data entry	Manual	n/a
Protocol approval basis	Manual	n/a
ChemStation revision	Automated	win.ini
Number of instrument sessions	Automated	win.ini
Online instrument or data analysis	Automated	win.ini
Instrument type (GC, LC A/D, etc.)	Automated	win.ini
ChemStore revision	Automated	registry
Security Pack revision	Automated	registry
Service releases	Automated	registry
ChemAccess revision	Automated	registry and win.ini
MVP software revision	Automated	registry and win.ini
Purify software revision	Automated	registry and win.ini

General Changes

In general, the tests performed are the same ones as in the previous protocol. However, the mechanism and the format of the delivery have changed from a more manual manner to the more efficient wizard-driven execution type. The redundancy of both the security and the access control test has been removed, and ChemStation macros are now employed for a more automated execution of the instrument control and chromatographic evaluation tests.

The following points summarize the main characteristics of the wizard-driven execution:

- Pass/Fail determination based on the given manual inputs is compared with the expected results stored in the Compliance Wizard.
- Expected results are not given beforehand, as in the previous protocol.
- Test confirmation is requested in three different ways: multiple-choice, yes/no, and free entry. Matching between given answers in free-entry mode and expected answers is performed manually.

- A failed test can be rerun several times or skipped. Any test can be rerun after the protocol is complete by manually following the instructions contained in the completed protocol. A deviation is required.
- The number of trials needed for a passing result is reported in the protocol.
- The last entered answer is always displayed in the Compliance Wizard and will be reflected in the protocol. If this is a failed result, it will be listed as such.
- Upon a failed test, the operator can add a comment, which is added to the appendix section of the protocol.
- Server tests can be executed from any client and can be swapped from one client to the other between test sets (this is optional, not mandatory).
- Protocol execution can be stopped and resumed, but it is not possible to alter any of the earlier collected data because they are encrypted and checksum protected.

Protocol Pre-approval and OQ/PV Test Structure

The pre-approval of the implementation of Version B.01.00 qualifications is done with example protocols. Multiple deliveries of the same revision of the protocol can be approved based on the same master example, eliminating the necessity to review and approve individual ChemStation qualification documents. The location of the pre-approved master example is referenced to by each individual protocol. Protocol changes are subject to strict revision control and are properly documented.

The previous revision of the protocol (paper-based, revision A.07.20) had the server tests included within the first and last client section of its protocol. The protocols are now split up to one protocol per workstation, so there is a separate protocol for the server and for each client or standalone workstation. Although the protocols are separate documents, an OQ/PV for the server is still executed from any client in the system.

The following table summarizes the tests executed during the delivery of the OQ/PV for each version of the protocol.

Software	Test	Standalone	Client/Server	Standalone	Client/Server
		A.07.20		B.01.00	
ChemStation	User Access Roles and Security (*)	✓	✓	✓	✓
ChemStation	Instrument communication test	✓	✓	✓	✓
ChemStation	Integration and quantification tests	✓	✓	✓	✓
ChemStation	Report printing test	✓	✓	✓	✓
ChemStore	Database logon	✓		✓	
ChemStore	Audit trail/2nd Pass approval	✓	C1	✓	S
ChemStore	Custom report	✓	✓	✓	✓
ChemStore	Archive/Restore		C1		S
ChemStore	Client transfer	✓	✓	✓	✓
ChemStore	Password administration	v	✓	✓	✓
ChemStore	Lock test (*)	✓	✓	✓	S
ChemStore	Load test		LC		S
ChemStore	Study access	✓	C1		S
ChemStore	ChemStore security (*)	✓	✓	✓	✓
Security Pack	Logon (*)	✓	✓	✓	✓
Security Pack	Sequence/Logbook control (*)	✓	✓	✓	✓
Security Pack	Recalibration control (*)	✓	✓	✓	✓
Security Pack	Batch/Manual Integration and Data Transfer	✓	✓	✓	✓
MVP	Logon	✓	✓	✓	✓
MVP	Database functions	✓	C1	✓	S
MVP	Overall report	✓	✓	✓	✓

(*) Once per instrument session in A.07.20; Once per workstation in B.01.00

(S) On the Server only

(C1) On the first client only

(LC) On the last client only

Revision History Changes

The following table describes the changes in the specific individual tests, from the previous revisions (A.08.10 for the IQ, and A.07.20 for the OQ/PV) to the Compliance Wizard Revision B.01.00.

CONDITION	Standalone	Server	Client	Comments
ChemStore B.02.02 and up		Study access		Removed from standalone ChemStore, only for server protocol, no change in test content.
Security Pack	Security pack logon test		Security pack logon test	No change in test content, security pack tests are executed once per workstation (with instrument session of choice) instead of per instrument session.
Security Pack and ChemStore B.01.03 without spooler patch	Sequence/Sequence logbook control test 1		Sequence/Sequence logbook control test 1	Sequence/Sequence logbook control test has different overall result with or without ChemStore B.01.03 spooler patch installed.
ChemStore B.01.03 without Security Pack and without spooler patch	Sequence/Sequence logbook control test 1		Sequence/Sequence logbook control test 1	Sequence/Sequence logbook control test has different overall result with or without ChemStore B.01.03 spooler patch installed.
Security Pack	Sequence/Sequence logbook control test 2 and 3		Sequence/Sequence logbook control test 2 and 3	No changes
Security Pack and ChemStore B.01.03 or B.02.02	Recalibration control test 1		Recalibration control test 1	No changes
Security Pack and ChemStore B.02.01 SR3	Recalibration control test 1		Recalibration control test 1	This test includes some additional testing as added for B.02.01 SR3. This additional testing was not part of B.01.03 and removed for B.02.02.
Security Pack and ChemStore B.02.01 SR3	Recalibration control test 4 Batch/Manual Integration Control and Data Transfer Spooler Administration Tests 1–4		Recalibration control test 4 Batch/Manual Integration Control and Data Transfer Spooler Administration Tests 1–4	This test includes some additional testing as added for B.02.01 SR3. This additional testing was not part of B.01.03 and removed for B.02.02.
Security Pack	Recalibration control test 2 Batch/Manual Integration Control and Data Transfer Spooler Administration Tests 1–4 and 1–5		Recalibration control test 2 Batch/Manual Integration Control and Data Transfer Spooler Administration Tests 1–4	No changes

Continued

CONDITION	Standalone	Server	Client	Comments
No Security Pack	ChemStation Security		ChemStation Security	Tests are executed once per workstation (with instrument session of choice), instead of per instrument session. Not every combination of manager/operator is tested anymore.
Security Pack and ChemStore B.02.01 SR03	Batch/Manual Integration Control and Data Transfer Spooler Administration Tests 4b		Batch/Manual Integration Control and Data Transfer Spooler Administration Tests 4b	This test includes some additional testing as added for B.02.01 SR3. This additional testing was not part of B.01.03 and has been removed for B.02.02.
Online	Communication test		Communication test	Instead of manually accessing modules, a macro retrieves the state of the instrument. Pass/Fail decision is still made by the operator.
Any instrument (configured)	Internal verification files		Internal verification files	The report is automatically added to the appendix section of the protocol.
				No changes, tests are executed semi-automated via a ChemStation macro instead of manual execution.
				All executed tests are listed in the protocol with their status.
ChemStore without Security Pack	ChemStore Security		ChemStore Security	The summary report is automatically added to the appendix section of the protocol.
				No changes
				No changes
ChemStore	Database logon			No changes
ChemStore	Audit trail/2nd Pass approval (all tests)	Audit trail/2nd Pass approval (all tests)		No changes
ChemStore	Custom report		Custom report	No changes
ChemStore		Archive and restore (all tests)		No changes
ChemStore	Client transfer (all tests)		Client transfer (all tests)	No changes
ChemStore	Password administration	Password administration		No changes

Continued

CONDITION	Standalone	Server	Client	Comments
ChemStore	Lock tests	Lock tests		Lock tests are only executed for the server protocol instead of for each client. Not every combination of private/non-private and direct/time based is verified. The result for the ChemStation lock is different for security pack, installed or not. An additional test is added to verify lock settings on other client (database wide setting).
MVP	MVP logon tests and internal OQ/PV report		MVP logon tests and internal OQ/PV report	No changes
MVP	MVP database functions	MVP database functions		No changes
MVP	MVP overall report		MVP overall report	No changes
ChemAccess		Password administration tests 1–9	Password administration tests 1–9	No changes
ChemAccess		Password administration tests 10–11		No changes
ChemAccess		Access rights	Access rights	Tests split up for positive and negative control; not every possible combination tested
ChemAccess		Status control		No changes
ChemAccess and file storage A.01.03		File storage tests		No changes, tests split up per CA revision.
ChemAccess and file storage A.02.01		File storage tests		No changes, tests split up per CA revision.
ChemStore		Loadtest		No change
Purify and calculation for MS add-on SW	Purify peak purity calculation			No change

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