EQUIPMENT QUALIFICATION PLAN

Agilent CrossLab Compliance Services

Agilent CrossLab
From Insight to Outcome

EQP Name: AgilentRecommended

Service Type: OQ

Company Name: _____

Customer Name/Title: _____

EQP Filename: LC.02.63.eqp

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Scope and Purpose

Overview

An Equipment Qualification Plan (EQP) documents the work performed during qualification services provided using the Agilent Automated Compliance Engine (ACE) software. The EQP must be approved before the work is performed (see customer responsibilities) and the results are reported in an Equipment Qualification Report (EQR), which documents the following.

-Tests performed during the qualification work
-Setpoints used (for example, wavelength, temperature, and flow settings, as applicable)
-Limits (acceptance criteria) applied to tests and setpoints
-Test descriptions and rationales for tests performed (these and test parameters are also reported EQR)
-Traceability of the Agilent qualification protocol

EQP PDF review documents support customer review and approval and are digitally produced directly from the electronic EQP contained within ACE. Two different EQP approval formats can be created.

-Concise: standard format, typically used for Agilent-recommended EQPs
-Tabular: expanded format, typically used for configured EQPs

Many customers approve the Agilent-recommended EQP in the concise format. The tests, setpoints, and limits applied are typically organized in a concise table format (see information below and the Operational Qualification (OQ) test suite). The table can also display which qualification tests can be configured, which Agilent designates as variance (see Glossary).

In a concise EQP approval document used for Agilent-recommended EQPs, the test, setpoints and parameters, and limits (as applicable) are displayed in a concise abbreviated format as shown below.

Key:	Fixed HPLC setpoints/limits	UHPLC setpoints	Variance allowed

Test	Setpoints and Parameters	Limits
CDS Logon Verification	N/A	Evidence of logon used to collect qualification data
Pump Flow Accuracy and Precision (> 400 bar)	Flow Rate 1: 0.500 ml/minute Flow Rate 2: 5.000 ml/minute Flow Rate 2: 2.000 ml/minute (G4220B) Flow Rate 2: 1.500 ml/minute (with ULD kit)	Accuracy Ò3.00% Precision RSD Ò0.50%

By design, ACE EQPs can be configured to align the qualification work to laboratory use of the system and / or satisfy user requirements such as range of use for parameter settings (for example, HPLC flow). This requires close collaboration with Agilent to align the configured EQP with laboratory requirements and may include additional optional tests and/or changes to test setpoints and limits. With configured EQPs, an expanded tabular test format is used. Changes from the Agilent-recommended EQP are displayed at the individual test level (so the test section of a tabular EQP document is longer). The electronic EQP file used to create the customer configured EQP is displayed on front page of the EQP. When the qualification work is complete, the results will be reported in the Equipment Qualification Report (EQR) for review and approval.

Understanding the Test Specification Section in Tabular Review Documents

Tabular formatted EQP PDF review documents are typically used for configured EQPs (or if this format is requested by customers). When this EQP approval format is used, which applies to hardware qualifications only, tests are displayed in an expanded tabular arrangement, where the setpoints and limits are explicitly displayed for each test. Agilent-recommended setpoints and limits and the range of allowable values are designated as L (for low) and H (for high). Changes are noted relative to these limits é W (changes within the Agilent range) and O (changes outside the Agilent range). Where dual reporting limits are enables, these are designated as DW (within the Agilent limits) and DO (outside the Agilent limits). Optional tests that are enabled are included and marked as such. Additionally, any required tests that are disabled at customer request are included and marked as such. The EQP documents changes that are within the Agilent variance range as well as any out of variance range tests (see Glossary).

Note: (1) Agilent is NOT responsible for test failures for O (out of range) setpoints and limits. (2) Limit ranges must be more tightly managed than setpoint ranges because they often reflect physical measurement limits and are directly linked to the testing method. Therefore *within range* user limits are subject to best effort repairs if they cannot be met. In particular, Agilent is not be responsible for test failures for limits tighter (more demanding or challenging) than the recommended values. (3) Changes from the Agilent-recommended EQP are also displayed in the Test Summary section of the EQR. (4) For hyphenated systems (for example, LC-LCMS), an EQP for each system needs to be approved.

In a tabular EQP approval document, the test, setpoints and parameters, and limits are typically displayed in the following representative format.

Pump Flow Accuracy

Flow 1

	Analytical Agilent and non-Agilent pump							
	Setpoint:	0.500	mL/min		L:	0.100	H:	5.000
W	Setpoint:	0.200	mL/min					
	Limit:	<=	5.00	%	L:	5.00	H:	10.00

Injection Precision Additional FLD

This optional test is enabled for this EQP.

Agilent or non-Agilent injector with FLD detector							
Vial verification performed?	No						
Injection Volume on Column:	5	uL		L:	1	H:	5
Area RSD Limit:	<=	1.00	%	L:	1.00	H:	5.00
Height RSD Limit:	<=	1.00	%	L:	1.00	H:	5.00

Column Temperature Accuracy

This standard default test is disabled for this EQP.

Customer Responsibilities

To perform ACE instrument qualification services, requirements associated with instrument control and use of ACE software on site need to be understood and satisfied.

- Instrument control to perform the qualification tests.
- ACE software access by the field service engineer (FSE) to load the electronic EQP, run the qualification workflow, and publish the EQR.

ACE is designed to satisfy ALCOA+ data integrity requirements and provide qualification tests that are independent of the instrument control software. This Agilent qualification design philosophy facilitates a harmonized approach to analytical instrument qualification and ensures consistent application of validated algorithms (such as those used to perform gradient pump HPLC testing), independent of instrument and software manufacturer. Additional documentation is available to provide further information on these subjects.

Agilent recommends that the software routinely used in the lab to control the instrument is used by the FSE to perform qualification tests. Therefore, appropriate access to the instrument control software, such as the customer data system (CDS), needs to be set up for the Agilent representative before they arrive on site. For ACE software access on site, Agilent recommends installation of Network ACE to load the electronic EQP, run the qualification workflow, and publish the EQR.

Customers need to address the following responsibilities.

- EQP review
  - Review the EQP supplied (standard or configured).
  - Request changes to the EQP if required (to meet user requirements such as testing range of use) or approve the supplied EQP (that satisfies user requirements).
  - Return an electronic copy of the EQP to Agilent prior to qualification delivery.

- Agree and set up instrument control access to perform the work (provide a CDS logon for the FSE).
- Agree and approve ACE usage on site (Network ACE).
- For configured EQPs, maintain change control and revision history of the specific approved EQP.
- Safely store and archive an approved copy of this EQP.
- Review and sign the EQR when the qualification work is complete and reported.

NOTE: If Agilent representatives use customer software such as a CDS account to acquire test data during the qualification, they log off from the CDS account at the end of test acquisition. Account credentials created for FSE CDS access are a customer responsibility (that is, some labs disable the account when the work is complete).

Agilent Responsibilities

Agilent representatives follow an approved structured training process, which is represented by the training certificates included in the EQR. Additionally, any customer-specific training that is required to perform the work should be specified and complete before the work is scheduled and can be optionally added as a PDF attachment to an EQR, if required. Agilent representatives do the following.

- Deliver the approved services following the test programs described in the approved EQP;
- Provide a locked and e-signed EQR upon completion of the service;
- If requested, provide an optional ink-signed EQR CD to the customer.

Statement of Intent

The qualification is delivered according to the approved EQP. The standard EQP is followed unless a configured EQP has been requested and approved. If a configured EQP has been created and approved, Agilent defines variances as changes to the default recommended values (stated in the standard EQP) that fall within a well-defined range. These changes are considered to be within the intended use range of the system under test.

Customizations are (a) values that subject the system to limits that exceed the typical operational range or (b) additional tests that are not considered part of the core program required for completion of the selected service. Because user-defined setpoints and limits may exceed the operational envelope of the equipment, Agilent reserves the right to warrant conformance only to the closest variance value. The user is notified of this stipulation at EQP setup time and the qualification report (EQR) reflects this situation.

The service is delivered according to the terms and conditions stated in the corresponding service exhibit. After approval, it is recommended that this EQP be archived with the electronic EQP file.

General Statements on the Testing Program

The hardware OQ tests described within this EQP are designed to satisfy analytical instrument qualification (AIQ) requirements for regulated laboratories. The laboratory is responsible for documenting that analytical instruments are suitable for the analytical procedures they use and the decisions they make on the reportable values / quality attributes being measured. Diligent application of an instrument life cycle framework such as USP <1058> help define and satisfy this requirement.

Agilent-recommended EQPs are derived from Agilent's interpretation of the analytical instrument life-cycle framework defined in USP <1058> and authoritative literature requirements from sources such as ISO9001, FDA, GAMPÉ, PIC/S, ASTM 2500, and others. User requirements and intended use can vary from laboratory to laboratory. Therefore, it is recommended that prior to EQP approval, laboratories determine if additional set points and/or optional additional tests are required to test their user requirements. Additional charges may apply to any changes. This can be accommodated in a configured or customized EQP. In line with the USP <1058> requirements, Agilent qualification services include Installation Qualification (IQ) and Operational Qualification (OQ). Typically, the range of instrument use should be tested in the OQ. Laboratories are responsible for addressing PQ requirements of the USP <1058> life cycle.

Agilent CrossLab Compliance uses a balanced selection of direct metrology and chemical-based tests to directly determine the performance of the systems without unnecessary reliance on graphical extrapolation, interpolation, inferred or derived results. For example, for HPLC qualification, direct metrology measurements are used to test pump flow rate accuracy and precision, and thermal-controlled column compartment and autosampler modules. Holistic chemical testing is used for the evaluation of the following critical instrument characteristics: linearity, precision, signal to noise, and carry over.

EQP Revision History

ACE qualification protocols follow a standardized software development life cycle within Agilent. The electronic EQP files used by ACE are managed under change control within this life cycle. Changes to the core electronic EQP are recorded in the Agilent EQP Revision History and are available on request. Change control processes vary between organizations; therefore, although Agilent maintains a revision history for electronic EQPs contained within ACE, it is recommended that, for configured EQPs, laboratories maintain EQP-independent revision history information appropriate to their own policies and procedural requirements.

CDS Software Pre-requisites for Hardware Qualifications

The software used to control instruments during hardware qualification needs to be suitable. Agilent recommends that software used during the qualification has been qualified within the qualification period specified by the customer s software qualification SOP.

Glossary

Agilent EQP
ACE:
Agilent Automated Compliance Engine or Agilent software used to provide qualification services

EQP:

Equipment Qualification Plan that documents qualification work to be performed

EQR:

Equipment Qualification Report that documents qualification results

CDS:

Customer data system

Network ACE:

ACE is installed on a network node within the laboratory LAN infrastructure

Local ACE:

ACE resides on an independent external drive connected to the LAN infrastructure

Alternative Method:

ACE is installed and run from a PC not connected to the laboratory network

Standard EQP:

EQP pre-defined by Agilent that includes default tests, setpoints, and limits

Configured EQP:

EQP that has been changed based on user requirements

Variance, Range:

The range of operating values for a test parameter within ACE (flow, temperature, and so on) that were defined and tested when the test was first developed and set up

Variance, W:

Change to a test parameter that is within the Agilent variance range

Variance, O:

Change to a test parameter that is outside the Agilent variance range

Variance, DW:

Dual reporting limits within the Agilent supported range

Variance, DO:

Dual reporting limits outside the Agilent supported range

Optional Test:

An optional additional test that is not included in the standard EQP

Additional Setpoint:

Additional measurement value for a test parameter (flow, temperature, and so on)

Qualification Life Cycle Stages

URS:

User Requirement Specification that documents intended instrument use

DQ:

Design Qualification that documents suitability of instrument for intended use

IQ:

Installation Qualification that documents the installation of the instrument

OQ:

Operational Qualification that tests the range of use

PQ:

Performance Qualification that tests the system under conditions of use

RQ:

Repair Qualification that tests the instrument after an instrument repair

PM:

Planned Maintenance for scheduled preventive maintenance

Reference Sources

ASTM:

American Society for Testing and Materials

FDA:

United States Food and Drug Administration

GAMPÉ:

Good Automated Manufacturing Practice

ISO:

International Organization for Standardization

ISO9001:

ISO Standard for Quality Management Systems

PIC/S:

Pharmaceutical Inspection Cooperation Scheme

USP:

United States Pharmacopeia

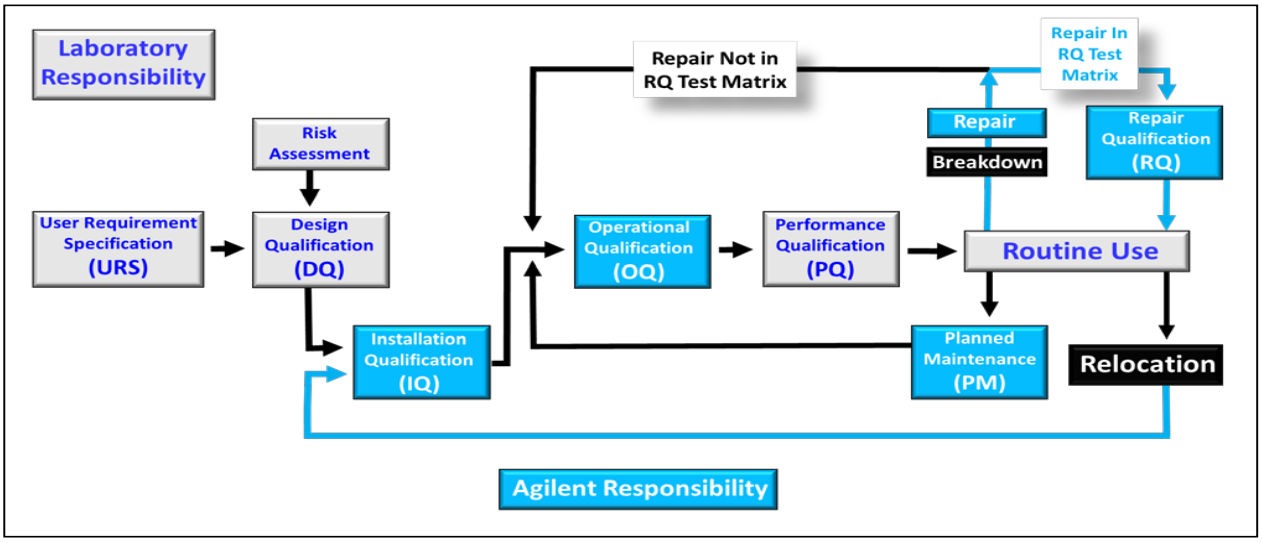
HOW AGILENT CROSSLAB COMPLIANCE SERVICES INTEGRATE WITH QUALITY SYSTEMS AND REGULATIONS

Agilent CrossLab Compliance Services

Agilent CrossLab Compliance Services

Agilent CrossLab Compliance Services are designed to seamlessly integrate with traditional quality systems used by firms and recognized by regulatory agencies worldwide. Analytical instruments must be suitable for their intended use. This requirement is good science in all laboratories and a regulatory requirement in pharma and biopharma laboratories. A life-cycle process for documenting and testing the suitability of laboratory instruments should be followed and Agilent recommends the life cycle framework defined in USP General Chapter <1058> on Analytical Instrument Qualification (AIQ). USP <1058> defines the governing framework and requirements that need to be satisfied, but the laboratory is responsible for how they satisfy these requirements.

- The United States Pharmacopoeia (USP) is the only major pharmacopeia with a general chapter dedicated to analytical instrument qualification, making <1058> an important global regulatory reference. The information is provided in a scientific, risk-based approach to analytical instrument qualification (AIQ). However, the life-cycle framework contained within USP <1058> is not prescriptive in its implementation, making the embedded scientific and risk-based principles flexible and universally applicable.
- The scientific process followed by CrossLab uses the Agilent's Automated Compliance Engine (ACE) to deliver paperless electronic qualification. The life-cycle stages Agilent perform are highlighted in the life-cycle diagram below. As part of this life-cycle, Agilent can configure the qualification tests performed to align with user requirements.



USP <1058> AIQ Framework

***NOTE**: RQ services, described later in this document, can be added to standard qualification services.*

ACE Workflow and Equipment Qualification Plans (EQPs)

Overview

Within the ACE workflow, the qualification tests, setpoints, and limits are defined in an EQP that can be configured to ensure that testing satisfies user requirements. When the qualification work is complete, an Equipment Qualification Report (EQR) is issued. The electronic workflow used within ACE has significant data integrity advantages over traditional paper or Excel-based qualification protocols, as validated calculations can be performed directly using electronic data such as chromatograms and metrology test values. Several of the instrument life-cycle stages are the responsibility of the laboratory, Agilent can provide compliance consultancy services and documentation which can help customers satisfy these requirements. These additional services are not included in our typical qualification offering.

High-level ACE Qualification Workflow

Standard and User-defined Limits

(Hardware qualifications only)

EQPs are available for download and approval as standard documents with Agilent recommended tests, setpoints, and limits, or they can be electronically configured by approved personnel to align with user requirements and intended range of use requirements. The degree of configuration depends on the analytical technology, but most EQPs can be configured to some degree, and one feature that can typically be changed is test limits.

EQPs are designed to be configurable (dependent on the analytical technology and standard requirements), but including additional tests or setpoints can impact the qualification time and associated cost. If a test limit is changed, ACE includes the capability to report results against the Agilent approved limit and any customer required limits (that is, both can be reported simultaneously).

If a user-defined test limit is more stringent than an Agilent recommended limit, Agilent makes no guarantee or obligation regarding the instrument passing the tighter test specification requirements. It is important to appreciate that tests performed under conditions of use (that is, to satisfy pharmaceutical monograph and application requirements) can have different limits than those defined in the OQ. It is the continuum of the combined OQ, PQ, and any point of use testing performed each time the instrument is used that together satisfy regulatory requirements.

User Requirements Specification (URS)

The purpose of user requirements is to document the intended use of the instrument within the life-cycle process and quality management system (QMS) being followed. Therefore, the URS is a customer / laboratory responsibility. Defining user requirements is often used to guide the customer in instrument selection and is stated as the first activity that should be followed in <1058>. The URS is important for two main reasons.

- It is a regulatory requirement for FDA and EU GMP that the intended use of the instrument and any software must be specified.
- Investment protection perspective means getting the right instrument for the right job.

Qualification protocols should test the instrument against any limits or specifications listed in the URS, which should document the intended range of use. Depending on the instrument complexity and how it is classified, a separate URS document may not be needed, but the URS requirements of the <1058> framework must be satisfied. A separate URS is almost always recommended for computerized systems.

An instrument performance specification is a product of the instrument development process by the supplier. It typically documents the performance the instrument can achieve. The URS should be based on intended use of the instrument and not the instrument specification. Additionally, if the intended use of a system changes, this may trigger a need to review the URS and associated qualification testing (for example, to ensure range of use is tested if used with a new analytical procedure).

Agilent offers compliance consultation services and documentation that can help customers address URS requirements.

Design Qualification (DQ)

The main function of the DQ stage of the laboratory instrument life-cycle process is to document why the selected instrument is suitable. Typically, this includes consideration of the instrument specification, how the instrument will be qualified, and the QMS followed by the instrument manufacturer. All together, these confirm that instrument performance is capable of satisfying user requirements. Depending on laboratory instrument life-cycle policy or SOPs being followed, instrument requirements and the relationship between the URS and DQ stages may vary – but as long as the <1058> framework principles are satisfied, this is not a problem, as it is left to each laboratory to justify and document its specific approaches.

The responsibility for satisfying DQ requirements primarily lies with the laboratory, with support from the supplier.

Agilent's approach to satisfying DQ requirements of USP <1058> includes the following.

- All Agilent 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.
- Certificates of Agilent testing, validation, and conformance to standards are provided with new Agilent instruments and similar certification can be provided for ACE software.
- Agilent is capable of installation, support, preventive maintenance, on-going qualification, and re-qualification after repair and user training worldwide.

Agilent offers a compliance consultation service that can help customers with DQ documentation.

Installation Qualification (IQ)

The main functions of the IQ stage are to document that laboratory is suitable (for example, critical systems typically include a site inspection / checklist), that the instrument is installed correctly in the environment, and IQ checks such as module start up are completed. IQ is provided and automated by ACE, which collects, checks, and tests Agilent hardware and software products for the following.

1. Purchase Order Details: Allows the customer to verify that the instrument being qualified matches their design requirements (if available) and purchase order.
2. Preparation and Installation Details: Gathers and records information about preparation and installation documents.
3. Documentation: Gathers and records information about reference and user manuals for initial installations.
4. Product Quality Assurance Details: Collects and records certificates and other forms that verify that the vendor has developed and built the product according to internal standards.
5. Startup: Verifies that all modules/components start up properly.
6. Installation Verification (software only): Verifies the correctness of all installation-related files.

Operational Qualification (OQ)

The main function of the OQ stage is to evaluate and document instrument performance at the intended operational range of use. OQ protocols should include a mix of metrology, functional, and operational tests. ACE qualification protocols include information about the test description and rational, setpoints, and the limits (acceptance criteria) for each technique, category, and instrument configuration.

OQ is provided and automated by ACE. ACE checks and tests for Agilent hardware and software products include the following.

- Metrological tests such as flow, temperature, pressure, and so on that ensure that the system is performing within Agilent (or user) specifications.
- Qualification results are reported in the EQR, which can include details of all test certificates, standards, and training information for the engineer performing the work. (Note that the EQR can be configured to customer requirements.)
- System or "holistic" tests verify the combined functions of the various system components
- The qualification testing can be configured to ensure URS requirements, such as range of use are tested.

For software qualification, the OQ consists of automated diagnostics regression testing and verification of the software installation. This supports continued use of the software in regulated environments (at install and as part of supporting periodic review).

In line with regulatory requirements, the EQPs should be approved before work is performed and the EQR should be reviewed and approved when the work is complete (as illustrated in Figure 2). The EQR contains all the raw data, results, and relevant information and attachments for complete compliance and traceability.

Mechanical Qualification (MQ)

(Dissolution systems only)

The main function of the MQ stage is to document that the mechanical performance of the instrument meets specifications and is functioning properly.

Performance Qualification (PQ)

The main function of the PQ stage is to document that the instrument is fit for purpose under conditions of intended use and to create an approved framework that ensures the instrument continues to perform as required. Because instrument range of use is tested within the OQ stage, it is usually not necessary to test this during PQ. It should be noted that requirements for instrument maintenance and repair fall within the PQ life cycle stage within the USP <1058> framework, as they are components of ensuring the continued performance of the instrument.

The customer is responsible for satisfying PQ requirements. (NOTE: Agilent can provide a PQ for Dissolution systems only.)

It is important to note that PQ is a lifecycle activity and not a one-time event. PQ tests may include activities such as method validation or system suitability tests (SST), but in Agilent's opinion, SSTs contribute towards ensuring continued performance of the instrument (that is, PQ testing), but do may not fully satisfy <1058> PQ requirements.

Repair Qualification (RQ)

After an instrument is repaired, tests should be performed to evaluate the effectiveness of the repair and document that repaired instrument satisfies performance requirements. Agilent offers a service called Repair Qualification (RQ), which refers to the requalification of laboratory instrument hardware after a repair. For some laboratory systems, to document the performance after repair may require a full OQ. However, for some modular or component-based systems, such as HPLC and GC for example, partial qualification testing can be justified. This is accomplished by performing the qualification tests that are applicable to only the module or system component related to the repair, reducing the time the instrument is out of service. Re-qualifying the instrument after repair is a regulatory requirement defined in USP <1058>.

Because of the modular/component-based dependency of RQ service, it is only available for the following instrument platforms: GC, GC/MS, LC, LC/MS, GPC, and SFC.

Agilent offers service contracts to repair and requalify an instrument during the period between scheduled annual OQs.

The level of retesting is prescribed in the RQ section of ACE: a form is displayed for the operator showing all types of repairs possible and the retesting required. Part of an example form for an LC system is shown below.

Re-Qualification After Repair		
Pump Strategies		
Repair/Replace Strategy	Modules	OQ Testing
Internal pump head parts, active inlet valve (or AIV cartridge), (parts of) check valves, reference valves, inlet manifold or pump drive, or taking pump head apart to clean (versus repair)	Any pump	Flow Accuracy & Precision
Pulse damper, pressure transducer	Any pump	Flow Accuracy & Precision
Multi-channel gradient valve	Quaternary	Flow Accuracy & Precision Gradient Composition

The full list of RQ repair and retest guidance is available for customer review.

www.agilent.com/chem/qualification

SERVICE DELIVERY METHODS

CUSTOMER APPROVAL OF ALTERNATIVE METHOD AND EQR STORAGE

Agilent CrossLab Compliance Services

Overview

Agilent recommends use of **Network ACE** for CrossLab qualification services that are enabled using the Agilent Automated Compliance Engine (ACE) software. Network ACE and Local ACE both access data directly (default methods) and are considered equivalent from a data integrity and data traceability perspective (see below). To provide additional flexibility in qualification service delivery, an alternative method is also available that accesses data indirectly. Use of the alternative method requires customer pre-approval using this form.

Available Methods

Method	Definition
Network ACE (Agilent recommended)	ACE software is installed on a network node within the laboratory LAN infrastructure. Raw data locations are always captured in the equipment qualification report (EQR), which provides end to end traceability and a fully characterized data workflow in the delivery. This method requires collaboration with the customer to load ACE behind the customer firewall.
Local ACE	ACE software resides on an independent external drive that can be driven from the system controller, where the customer data system (CDS) resides. Because the external drive is connected to the CDS, the data integrity of this method is equivalent to that of the Network ACE delivery method. Raw data is imported directly into ACE by the Data Manager tool, with the data paths always captured in the report, which provides data traceability assurance.
Alternative (Requires pre-approval)	Pre-approval for this method is required to remove later questions on data integrity. ACE software is installed and run from a PC not directly connected to the CDS, such as the FSE laptop. System data files are transferred indirectly from the CDS to the laptop instead of directly like Network and Local ACE methods. **NOTE**: Software used in this method is qualified for data collection purposes; this method is not an option for software qualification.

EQR Storage

Select the checkbox below to authorize Agilent to store a copies of the EQRs generated by ACE for Agilent internal assessments. The intention of the assessment is to evaluate the delivery of the qualification service, with a focus to improve delivery and assess the appropriateness of data integrity measures. The storage is exclusively for the internal assessment by Agilent and is not shared with other organizations. It is not to be considered a backup for the EQR provided at qualification delivery.

Customer Approval of Alternative Method and EQR Storage

Authorize Agilent to use the alternative method (check for approval):	☐
Authorize Agilent to store EQRs for their internal assessment (check for approval):	☐

Approved By/Title:	
Date Approved:	
Comments:	

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AGILENT CROSSLAB QUALIFICATION SERVICES

USE CASES FOR SERVICE DELIVERY

Agilent CrossLab Compliance Services

Introduction

With heightened scrutiny of data integrity, the Agilent Automated Compliance Engine (ACE) software must be able to access instrument-generated raw data files one of two ways: directly, using the connection between network nodes or with the server; and indirectly, through storage in a secure transfer location. (In this document, data integrity refers to the who, what, and where of data used in generating an ACE equipment qualification report, or EQR.)

ACE includes three main service delivery methods that address data integrity requirements; the rest of this document provides details to determine which one best fits a customer's needs.

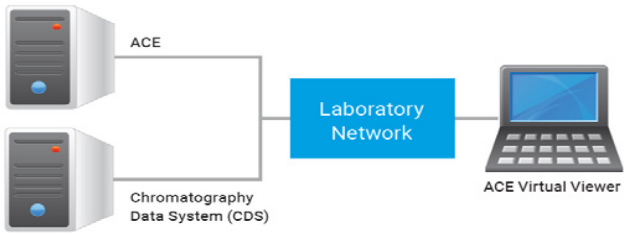
Regardless of the delivery method, ACE features and delivery procedures are compatible.

Network ACE (Agilent Recommended)

Overview

ACE software is installed on a network node within the laboratory LAN infrastructure, which requires collaboration with the customer to load ACE behind their firewall. Raw data locations are always captured in the EQR, which provides end-to-end traceability and a fully characterized data workflow in the delivery.

Details



Typical Network ACE installation diagram

Installing ACE in a separate node (a.k.a. the host PC) on the same network as the system controller offers data traceability that is equivalent to an installation on the system controller itself. The system controller (where the CDS resides) and the ACE host PC are identified and seen by the server and subject to the customer's data access controls and general IT policies. The CDS's audit trail records data movements between nodes or between the client and server, and ACE's data traceability features identify the original data directory and therefore ensures end-to-end data traceability

The ACE host PC has a separate/partitioned drive for ACE software. During ACE's installation, two services are setup on the operating system (OS): one for security and the other as a watchdog. Because the ACE host PC sits on the network as a shared drive, engineers access ACE through the networked drive: ACE is not installed on ACE Virtual Viewer PCs.

Requirements

Installation

- Install on a host PC with a separate drive (different from that of the OS)
- Attach to a network that clients can access
- 500 GB
- NTFS format
- User has local administration rights
- Customer installation instruction document is available

Operational

- User has an ACE node logon with a minimum of power user rights permissions; user also has a personal ACE account and password added through the ACE licensing tool
- Up to 5 users with 3 open sessions each can access the NDA simultaneously
- Exception to ports 11121-11141 on ACE node, clients, and switch's/Smart Hubs to be open on the network

Local ACE

Overview

ACE software resides on an independent drive that can be driven from the system controller, where the CDS resides. Because the drive is connected to the CDS, this method's data integrity is equivalent to preferred 1 method's. Raw data is imported directly into ACE by ACE's Data Manager tool, and data paths are captured in reports to provide data traceability.

ACE software resides on an independent drive that can be driven from the system controller, where the CDS resides. Because the drive is connected to the CDS, this method's data integrity is equivalent to the Network ACE method. Raw data is imported directly into ACE by ACE's Data Manager tool, and data paths are captured in reports to provide data traceability.

Details

ACE is designed to run from a dedicated drive, without leaving a footprint on the host PC. Therefore, it can be connected directly to the system controller (where the CDS resides) without altering the system's qualification status. For additional protection, the drive can be driven by another host PC on the same network; also, the drive can remain on site with the customer for use by the Agilent Field Service Engineer (FSE) during service deliveries only.

Alternative Method

The ACE software is installed on and run from a PC not directly connected to the CDS, such as the FSE's laptop. System data files are transferred indirectly from the CDS to the laptop instead of directly like Network and Local ACE methods.

This method requires customer pre-approval to remove later questions on data integrity.

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ANALYTICAL SCALE HPLC AGILENT SYSTEMS

OPERATIONAL QUALIFICATION

Agilent CrossLab Compliance Services

Standard OQ Test Suite

This document describes the test program for qualifying LC analytical-scale Agilent systems; the following tables lists all OQ tests organized by general tests that apply to all configurations and other tests that are specific to a detector type or whose setpoints and/or limits vary by detector type.

Note: Some test conditions differ depending on the intended operating pressure range; UHPLC test names are orange. And for multiple-detector systems, the Injection Precision and Carry Over tests are performed for one detector in the standard test program and can be run for additional detectors as optional tests for a nominal fee. The only exception is Injection Precision for an additional ELSD, which is a standard (versus optional) test.

Also, UHPLC limits and setpoints are applied to all applicable tests for all Agilent 1220, 1260, and 1290 modules.

See corresponding attachments for test definitions for non-Agilent, capillary scale, and preparative scale systems,

Key: Fixed HPLC setpoints/limits | UHPLC setpoints | Variance allowed

General Tests

Test	Setpoints and Parameters	Limits
CDS Logon Verification	N/A	Evidence of logon used to collect qualification data
Pump Flow Accuracy and Precision (≤ 400 bar)	Flow Rate 1: 0.500 mL/minute Flow Rate 2: 5.000 mL/minute Flow Rate 2: 2.000 mL/minute (G4220B)	Accuracy ≤ 5.00% Precision RSD ≤ 0.50%
Pump Flow Accuracy and Precision (> 400 bar)	Flow Rate 1: 0.500 mL/minute Flow Rate 2: 5.000 mL/minute Flow Rate 2: 2.000 mL/minute (G4220B) Flow Rate 2: 1.500 mL/minute (with ULD kit)	Accuracy ≤ 3.00% Precision RSD ≤ 0.50%
Column Temperature Accuracy and Stability	Temperature 1 (T1): 80.0°C Temperature 2 (T2): 40.0°C Stability measured at T2	Diff. from setpoint ≤ 3.0°C (T1, ≥ 50.0°C) Diff. from setpoint ≤ 2.0°C (T2, < 50.0°C) Stability ≤ 1.0°C
Column Temperature Accuracy and Stability (G7116A, G7130A)	Temperature 1 (T1): 60.0°C Temperature 2 (T2): 40.0°C Stability measured at T2	Diff. from setpoint ≤ 3.0°C (T1, ≥ 50.0°C) Diff. from setpoint ≤ 2.0°C (T2, < 50.0°C) Stability ≤ 1.0°C
Column Temperature Accuracy and Stability (1120/1220 systems)	Temperature 1 (T1): 60.0°C Temperature 2 (T2): 40.0°C Stability measured at T2	Diff. from setpoint ≤ 3.0°C (T1, ≥ 50.0°C) Diff. from setpoint ≤ 3.0°C (T2, < 50.0°C) Stability ≤ 1.0°C
Sample Temperature Accuracy	Temperature: 4.0°C Temperature: 5.0°C (1220 thermostats) Samples four vials of water in different tray positions	Diff. from setpoint ≥ -2.0°C and ≤ 5.0°C
Scouting Run	Injection volume on column: varies by configuration	N/A
Fraction Collection (only if installed)	Select fraction collector 1, 2, or 3; select peak- or time-based collection mode	Peak presence (qualitative)
Solvent Selection Valve (UV/UV-Vis; only if an external valve is installed)	Select port positions 1, 2, and 3 (PH is peak height)	Pos. 1 PH < Pos. 2 PH < Pos. 3 PH Pos. 2 PH ≥ 1.2 x Pos. 1 PH Pos. 3 PH ≥ 1.2 x Pos. 2 PH
Column Selection Valve (only if installed)	Select column numbers 1, 2, and 3 (3 is N/A for 2-column position valves) (Pr is pressure)	Pos. 1 Pr < Pos. 2 Pr < Pos. 3 Pr Pos. 2 Pr ≥ 1.2 x Pos. 1 Pr Pos. 3 Pr ≥ 1.2 x Pos. 2 Pr

Test	Setpoints and Parameters	Limits
Verification 2D-LC (2D-LC systems only)	Time-based collection mode	Peak presence in both dimensions (qualitative)

UV-Vis Tests

Test	Setpoints and Parameters	Limits
Wavelength Accuracy (UV/UV-Vis)	Wavelength 1: 205 nm (max) Wavelength 2: 245 nm (min) Wavelength 3: 273 nm (max)	Accuracy ≤ 2 nm
Noise and Drift (VWD)	ASTM baseline noise Slope of regression fit for drift	Noise ≤ 0.040 mAU Drift ≤ 0.500 mAU/hr
Noise and Drift (MWD)		Noise ≤ 0.050 mAU Drift ≤ 5.000 mAU/hr
Noise and Drift (DAD ≤ 400 bar)		Noise ≤ 0.050 mAU Drift ≤ 5.000 mAU/hr
Noise and Drift (DAD > 400 bar)		Noise ≤ 0.050 mAU Drift ≤ 5.000 mAU/hr
Noise and Drift (DAD > 400 bar) (G4212A/B, G7117A/B/C)		Noise ≤ 0.030 mAU Drift ≤ 3.000 mAU/hr
Signal to Noise (UV/UV-Vis ≤ 400 bar)	Signal height is divided by ASTM baseline noise for known concentration and known conditions.	Signal to noise ≥ 3,000
Signal to Noise (UV/UV-Vis > 400 bar)		Signal to noise ≥ 3,000 Signal to noise ≥ 10,000 (G4212A/B, G7117A/B/C)
Injection Precision Injection Precision Online Valve (only if sampler with online valve installed) (UV/UV-Vis ≤ 400 bar)	Injection volume on column: 20 µL Injection volume on column: 2 µL (G4277A, G4278A samplers)	Height RSD ≤ 2.00% Area RSD ≤ 1.00%
Injection Precision Injection Precision Online Valve (only if sampler with online valve installed) (UV/UV-Vis > 400 bar)	Injection volume on column: 10 µL	Height RSD ≤ 2.00% Area RSD ≤ 1.00%
Injection Carry Over Injection Carry Over Online Valve (only if sampler with online valve installed) (UV/UV-Vis ≤ 400 bar)	Injection volume on column: 20 µL Injection volume on column: 2 µL (G4277A, G4278A samplers)	Height carry over ≤ 0.40% Area carry over ≤ 0.20%
Injection Carry Over Injection Carry Over Online Valve (only if sampler with online valve installed) (UV/UV-Vis > 400 bar)	Injection volume on column: 10 µL Injection volume on column: 2 µL (G4277A, G4278A samplers)	Height carry over ≤ 0.20% Area carry over ≤ 0.10%
Response Linearity* (UV/UV-Vis)	Five concentrations of certified reference standard	Coefficient of determination (r2) ≥ 0.99900 R/F precision RSD ≤ 5.00%
Gradient Composition** (UV/UV-Vis)	20.00, 40.00, 60.00, and 80.00% steps Linear gradient from 100% to 0%; at start, 50:50 zone, end	Accuracy ≤ 2.00% Composition noise ≤ 2.00% Composition drift ≤ 2.00% Coeff. of det. (r2) ≥ 0.99900

* *For Response Linearity, the actual injected volumes can vary depending on the configured system's response as determined by the scouting run.*

***G1311B/C, G7111A/B, G5611A, and G5654A with AIV only run dual gradient.*

FLD Tests

Test	Setpoints and Parameters	Limits
Wavelength Accuracy	Wavelength 1: 350 nm (max) Wavelength 2: 397 nm (max)	Accuracy ≤ 3 nm
Signal to Noise	Signal height is divided by noise at 397 nm in the flat region of emission spectrum.	Signal to noise ≥ 400
Injection Precision Injection Precision Online Valve (only if sampler with online valve installed)	Injection volume on column: 5 µL	Height RSD, Area RSD ≤ 1.00%

Test	Setpoints and Parameters	Limits
Injection Carry Over Injection Carry Over Online Valve (only if sampler with online valve installed)	Injection volume on column: 5 µL	Height carry over ≤ 0.40% Area carry over ≤ 0.20%

RID Tests

Test	Setpoints and Parameters	Limits
Noise and Drift	ASTM baseline noise Slope of regression fit for drift	Noise ≤ 10.000 nRIU Drift ≤ 400.000 nRIU/hr
Signal to Noise	Signal height is divided by ASTM baseline noise for known concentration and known conditions.	Signal to noise ≥ 2,000
Injection Precision Injection Precision Online Valve (only if sampler with online valve installed)	Injection volume on column: 20 µL Injection volume on column: 2 µL (G4277A, G4278A samplers)	Height RSD ≤ 2.00% Area RSD ≤ 1.00%
Injection Carry Over Injection Carry Over Online Valve (only if sampler with online valve installed)	Injection volume on column: 20 µL Injection volume on column: 2 µL (G4277A, G4278A samplers)	Height carry over ≤ 0.40% Area carry over ≤ 0.20%
Response Linearity*	Five concentrations of certified reference standard	Coefficient of determination (r2) ≥ 0.99500 R/F precision RSD ≤ 10.00%

* *For Response Linearity, the actual injected volumes can vary depending on the configured system's response as determined by the scouting run.*

ELSD Tests

Test	Setpoints and Parameters	Limits
Noise and Drift	ASTM baseline noise Slope of regression fit for drift	Noise ≤ 2.000 mV Drift ≤ 5.000 mV/hr
Injection Precision	Injection volume on column: 20 µL	Height RSD, area RSD ≤ 5.00% Height RSD, area RSD ≤ 3.00% (G4218A)

Test Design and Rationale

Overview

Many GMP/GLP enforcement agency inspectors now ask firms to provide a risk assessment of their equipment and computer systems plus a science-based rationale for subsequent validation and qualification testing.

GENERAL RISK STATEMENT: Any laboratory chemical system used for raw material testing or final drug product / medical device testing in GMP or used in formal GLP studies will likely fall into a HIGH RISK category. This risk assessment will imply the need for IQ & OQ & on-going qualification. ANY USER SPECIFIC RISK ANALYSIS SUPERCEDES THIS GENERAL RISK STATEMENT.

The rest of this section outlines the science-based rationale for each test in the Agilent hardware OQ plus a brief test design and procedure description.

The recommended set of hardware OQ tests described in this EQP derives from Agilent's interpretation of FDA, USP, and GAMP guidelines and other authoritative expert literature.

OQ test design incorporates both modular and holistic testing, which is a proven and regulatory acceptable approach. When applicable, direct metrology is used to test pump flow rates and thermal-controlled column compartments, for example. Holistic chemical testing is used to evaluate critical instrument characteristics. When applicable, certified reference standards and calibrated equipment are used.

Considering the number of setpoints, parameters, and conditions of each recommended OQ test, the proven concepts of worst case, range, and representative have been applied. If a property or characteristic is known to have its worst performance at one end of a range of use, this is the setpoint that should be tested and other setpoints are not required. If a property or characteristic has no known worst case, testing at the high and low points of the range of use is required. If there are too many possible use cases and conditions to realistically test (and none is a worst case), a representative sample for test is the best approach.

CDS Logon Verification

Description: To satisfy the attributable requirement of ALCOA+, evidence of the logon used to collect data must be provided.

Procedure: The test uses a screen capture to document who is logged on to the software that controls the instrument being qualified. The capture is automatically included with this test in the EQR.

Pump Flow Accuracy and Precision

Description: Accuracy of flow is important for comparability between systems and transferring methods. Flow precision is critical for repeatability of peak height and area.

Procedure: A calibrated digital flow meter is attached to the waste line of the system flowing pure water at representative back pressure provided by a small guard column. Six readings are taken at each setpoint to determine the flow accuracy and precision. Flow accuracy is calculated as the absolute % difference of the mean of the six flow readings against the setpoint. The precision is calculated as the % RSD of the six flow readings. The two default setpoints (0.5 and 5.0 mL/minute) are evaluated in the core test. Extra setpoints and flexible test range are only available in customer-configured EQPs for flow, temperature, and some other tests. The repeat measurements of flow in the flow precision test eliminate the need for measurement of retention time precision (which is an indirect approach to determining flow precision).

Column Temperature Accuracy and Stability

Description: The thermostat accuracy is important for comparability between systems and transferring methods. Column temperature stability is critical for repeatability of peak height and area.

Procedure: A calibrated digital temperature meter and a proprietary probe are used to measure the temperature of the flowing eluent. With the use of a T-piece, the temperature probe is positioned to be in contact with the heated eluent. A typical column compartment temperature range of use is tested. At the high end of the range, after stabilization, the temperature accuracy is calculated as the absolute difference between what was measured and the setpoint. After completing this measurement at the low end of the range, six readings are taken every four minutes and temperature stability is expressed as the delta between the highest and lowest measured temperatures. All readings are reported in Celsius. If the column compartment has two sides, both are tested at the same time. (For Waters ACQUITY models: A calibrated digital temperature meter and a proprietary probe are used to measure the temperature of the column compartment heat exchanger. A typical column compartment temperature range of use is tested. After stabilization, the temperature accuracy is calculated as the absolute difference between what was measured and the setpoint. After accuracy readings are completed at the low end of the range, six readings are taken every minute and temperature stability is expressed as the delta between the highest and lowest measured temperatures. All readings are reported in Celsius.)

Wavelength Accuracy

Description: Wavelength accuracy is critical for accuracy of quantitative and qualitative analysis. Wavelength accuracy is also important for comparability between systems and transferring methods.

Procedure for UV absorbance detector (UV/UV-Vis, PDA, etc.): A traceable caffeine standard is used to determine the wavelength accuracy. In one procedure, for certain models, the caffeine is trapped in the flow cell and a programmable timetable is used to determine the wavelength maxima (205 and 273 nm) and minimum (245 nm). For other models (for example, DAD and PDA), a caffeine injection is made and a spectrum is acquired. The spectral maxima and minimum are determined directly from the scan or the table of scan results. The wavelength accuracy is determined as the absolute difference between the measured and certified wavelength values.

Procedure for FLD: The detector cell is filled with pure water. Using a programmable timetable, the excitation (350 nm) and Raman band emission (397 nm) wavelengths are determined. The wavelength accuracy is determined as the absolute difference between the measured and theoretical peaks of Raman scattering (in nm).

Noise and Drift

Description: This test gives an indication of detector sensitivity and stability.

Procedure for UV/UV-Vis absorbance detectors: Pumping water at 1 mL/min, the signal is monitored at a specified wavelength over a twenty-minute period. The signal noise is calculated based on ASTM E685-93 as the average peak-to-peak noise in a number of signal segments. The drift is calculated as the slope of the linear regression for the signal.

Procedure for ELSDs and RIDs: Pumping water at 1 mL/minute (or, for some ELSDs, with no flow and the inlet to the detector capped), the signal is monitored over a twenty-minute period. The signal noise is calculated as the average peak-to-peak noise in a number of signal segments. The drift is calculated as the slope of the linear regression for the signal.

Scouting Run

Description: This test is used to determine the chromatogram for presence of expected peaks, sufficient run time, and proper integration events prior to the start of the actual qualification runs. (For MS detectors, this test is used to optimize detector method parameters for sufficient signal intensity prior to the start of the actual qualification runs.)

Signal to Noise

Description: Sensitivity is a critical performance feature in quantitative and qualitative analysis. A signal-to-noise value of a representative compound at known concentration provides sensitivity statistics. This measurement is especially critical to establish level of detection.

Procedure for UV/UV-Vis, RID: An evaluation standard is injected and the calculated height, divided by the ASTM noise monitored over a specified range, provides the signal-to- noise result.

Procedure for FLD: Using pure water in the flow cell, the signal is monitored at the emission maximum wavelength of the Raman band of water and then, using a timetable, switched to a no emission wavelength where the noise is monitored. Signal to noise is calculated as the height of the Raman band peak divided by the monitored noise in a spectral region where no scattering is expected.

Injection Precision

Description: System precision is critical for accuracy of quantitation. Autosampler performance contributes to system precision.

Procedure: A short column is used to separate the evaluation standard from the void volume. Using a traceable standard, six injections from the same standard are made and the height, area, average height, average area, % RSD of height and % RSD of area are determined and calculated.

Injection Precision Online Valve

Only if a sampler with an online valve is installed

Description: System precision is critical for accuracy of quantitation. Valve performance contributes to system precision.

Procedure: A short column is used to separate the evaluation standard from the void volume. Using a traceable standard, six injections from the same standard are made and the height, area, average height, average area, % RSD of height and % RSD of area are determined and calculated.

Injection Carry Over

Description: Low carry over from a previous injection is critical for accuracy of quantitative and reliability of qualitative analysis. This test challenges the injector system in the HPLC system.

Procedure: Following the six-injection precision test, a blank injection is made. The carry over result is calculated as a ratio of the area and height of any residual peak found in the blank injection to the area and height of the previous injection (expressed as a percentage).

Injection Carry Over Online Valve

Only if a sampler with an online valve is installed

Description: Low carry over from a previous injection is critical for accuracy of quantitative and reliability of qualitative analysis. This test challenges the valve in the HPLC system.

Procedure: Following the six-injection precision test, a blank injection is made. The carry over result is calculated as a ratio of the area and height of any residual peak found in the blank injection to the area and height of the previous injection (expressed as a percentage).

Response Linearity

Description: The linearity of a detector is a critical parameter to establish for reliable and accurate quantitative results and is important for comparability between systems and transferring methods.

Procedure: A series of five traceable standards which represent typical concentrations range are injected and evaluated. The response linearity is calculated by determining the coefficient of determination (r2) of the peak areas versus concentration. It is now recognized that regression statistics alone are insufficient and non-sensitive indicators of linearity. Therefore, the % RSD of the response factors for all five peaks is also calculated. In addition, as an optional extra linearity statistic, ratios of peak areas in the set of five injections can be reported. For example, up to two ratios such as Peak 2 to Peak 1 and Peak 5 to Peak 2 can be selected in the EQP Record of Variances section.

Gradient Composition

Description: Accuracy and stability of solvent mixing online is critical for consistent and accurate quantitative analysis. Gradient composition is also important for comparability between systems and transferring methods.

Procedure: [Pre-requisite: UV/UV-Vis is installed.] An acetone tracer is used to determine the solvent gradient composition accuracy, stability, and linearity. The test challenges the system by making compositional changes from 0% to 100% in 20% increments. In addition, a linear ramp down from 100% to 0% is performed where the composition linearity is determined between ranges 95, 75, and 25%. All composition accuracies (or composition errors) are calculated as the absolute difference between the mean composition at each setpoint and the theoretical composition. Stability is determined by the noise and drift at each composition step. Linearity is calculated from 95% to 5% in the linear portion of the gradient.

Sample Temperature Accuracy

Description: The thermostat accuracy is important for comparing systems and transfer methods.

Procedure: Four vials are filled with water and allowed to equilibrate to the temperature setpoint. Similar to the column compartment, the temperature of the water is measured using a traceable digital temperature meter and proprietary probe. Accuracy is determined as the difference between the measured temperature and the setpoint.

Fraction Collection

Only if installed

Description: It is important to demonstrate that a fraction collector can collect fractions based on peak detection or time.

Procedure: A single injection of a traceable standard is made and fractions are collected in peak-based or time-based mode. This is a qualitative test in which collected fractions are re-injected to prove that they are fractions of the traceable standard.

Verification 2D-LC

Only for 2D-LC systems

Description: The 2D-LC valve must demonstrate that it can transfer peaks from the first dimension to the second dimension.

Procedure: A single injection of a traceable caffeine sample is made into the 2D-LC system and a peak is detected in the first dimension. That peak is collected in the valve's capillary (or capillaries), released to the second dimension, and detected there.

Solvent Selection Valve

Only if installed

Description: This test demonstrates that the valve is working correctly when a specific valve position is chosen.

Procedure (requires a UV/UV-Vis): Increasing acetone tracer solutions are introduced at three different valve positions. Their responses are monitored and their peak heights are recorded. There must be at least a 20% peak height differential between each peak for the test to pass.

Column Selection Valve

Only if installed

Description: This test demonstrates that the valve is working correctly when a specific valve position is chosen.

Procedure (does NOT require a UV/UV-Vis): Restriction capillaries are installed in the port and the system backpressure is monitored. There must be at least a 20% pressure differential between each position for the test to pass.

www.agilent.com/chem/qualification

Report and Delivery Options

This list below includes options selected for inclusion in the EQR. By default, repeated run logs and transaction logs are always included; all other options can be included or excluded.

(For hyphenated system types only) If different options are chosen for the primary and supported system types, the primary system options are used for both techniques.

- Show chromatograms
- Show header and footer on cover
- Include repeated run logs
- Include Transaction logs

Selected Signature Options

Status: EQP is not locked

- Reporting variance is allowed in this EQP

Customer Approval

Name:	
Title:	
Date:	
Signature:	

Name:	
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-Product Description / Specification
-Life Cycle Phases / Transition Approval
-Quality Assurance / Testing
-Documentation and Change Management
-Source Code

Validation certificates for the ACE software and associated protocols are generated automatically as part of the life cycle process, prior to software release, and are available on request. The certificate includes a declaration of intent statement and is representative of the life cycle process followed.

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