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Service Type: OQ

Company Name: _____

Customer Name/Title: _____

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Scope and Purpose

Overview

The Equipment Qualification Plan (EQP) documents the activity program that is performed during the qualification services for the applicable systems. A complete description of the test specifications is provided for the supported services, including setpoints and acceptance criteria (or limits) for each test. The test specification section of this document is created directly from the EQP file name listed on the cover. This document is an abstraction of the EQP file used to perform the service and is generated directly from the electronic Agilent Equipment Qualification Plan (eEQP) Editor. The purpose of this document is to allow the user to review and record approval of the EQP that guides the delivery of compliance services provided by the Agilent Automated Compliance Engine.

CDS Software Pre-requisite for Hardware Qualifications

(Applies to hardware qualifications only) Agilent recommends that the customer data system (CDS) software used during the qualification has been qualified within the qualification period specified by the customer's software qualification SOP.

Statement of Intent

Unless otherwise requested, the qualification is delivered according to the standard test program described in the Agilent_Recommended EQP. Agilent defines variances as changes to the default recommended values (as stated in the Agilent Recommended 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 values that (a) 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 custom 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) will reflect this situation.

A set of ink signature fields, as determined by the creator of this document, can be included at the end of this document. All fields should be completed or a single set of fields, initialed by an appropriate approver, run through any signature fields that are not to be used. This is an optional process that allows a paper record of signoff by the appropriate reviewers where a hybrid (electronic/ink) signature SOP is followed. If this document will be saved electronically and digitally signed in a document management system, it should be generated without ink signature fields. The customer must sign the EQP review documents and return an electronic copy to Agilent prior to qualification delivery. The delivery of the services is done according to the terms and conditions stated in the corresponding service exhibit. It is recommended that after approval, this EQP be archived with the electronic EQP file.

Understanding the Test Specification Section in Tabular Review Documents

(Applies to hardware qualifications only) For Agilent-recommended setpoints and limits, the range of allowable values (L for low, H for high) is included. As applicable, variances, customizations, and additional setpoints are listed beneath the Agilent recommended values and marked W (within range) or O (outside of range) in the left margin; values for added setpoints are also marked W or O and displayed after all configurations values. Dual limits are marked DW or DO. Agilent is NOT responsible for test failures for out of range setpoints and limits. Optional tests that are enabled are included and marked as such; required tests that are disabled by the customer are included and marked as such.

NOTE: 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 will not be responsible for test failures for limits tighter (more demanding or challenging) than the recommended values.

Customer Responsibilities

If Agilent representatives use a customer CDS account to acquire test data, they log off from the CDS account at the end of test acquisition. Agilent Technologies has no responsibility for those account credentials. It is up to the customer to protect the CDS from misuse.

- o (As applicable) Disable the account used by the Agilent representative to acquire CDS data.
- o Safely store and archive this EQP
- o Maintain change control and revision history
- o Review and optionally sign the EQP, making sure the service delivery is what was approved
- o Review and approve any of the following variances from the Agilent recommended:
 - Within Variance Range: changes to the Agilent recommended that are identified by Agilent as within the operation ranges determined in our test development
 - Outside of Variance Range: changes to the Agilent recommended that Agilent identifies as outside of the operational ranges determined in our test development. Agilent is not under any obligation to make the instrument pass the more stringent limits that fall in this range and this detail is called out in the EQP Test Specification
 - Optional Tests: additional tests that are available but not part of the core testing suite and cost extra
 - Disabled Tests: test for which all possible configurations have been disabled (tests are flagged in the test specification)

Agilent Responsibilities

- o Deliver the services following the test programs described in the customer EQP
- o Provide a locked and e-signed Qualification Report (EQR) upon completion of the service
- o If requested, provide an optional ink-signed EQR CD to the customer

General Statements on the Testing Program

The recommended set of hardware OQ tests described in this EQP derives from Agilent's interpretation of authoritative expert literature issued by the FDA, USP, GAMP, ASTM 2500, and others. The OQ test design incorporates both modular and holistic testing, which is a proven approach, acceptable to regulators. As prescribed by the 4Q qualification methodology for Analytical Instrumentation Qualification (AIQ), the OQ step is separated from the PQ as recommended by the regulatory guidelines.

Agilent CrossLab Compliance uses a balanced selection of metrology and chemical tests to directly determine the performance of the systems without unnecessary reliance on inferred or derived results. For example, direct metrology is used to test pump flow rates 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.



Agilent CrossLab Compliance Services

Agilent CrossLab is designed to fit traditional quality systems used by firms and recognized by regulatory agencies worldwide.

Note: Enterprise Edition has been renamed Agilent CrossLab Compliance; all functionality remains the same.

How Agilent CrossLab aligns with a traditional, paper-based methodology:

- Policy documents dictate the need for validation and qualification of GMP/GLP systems and usually mention the DQ/IQ/OQ/PQ model. The precise procedures for IQ and OQ for each type of equipment are prescribed in an approved SOP, perhaps called SOP #123: Qualification of HPLC Systems. In Agilent CrossLab, the equipment qualification plan (EQP) has the same role as the traditional qualification SOP.
- The traditional SOP provides lists of tests and limits for the range of system configurations found in the laboratory. The EQP follows this concept. The inventory of systems covered by an SOP or EQP changes over time, so this is kept as a separate record.
- The traditional qualification SOP typically has blank results forms as attachments to be photocopied for each IQ or OQ event—the results recorded in ink with manual calculations. In Agilent CrossLab, this execution process is streamlined and automated by use of Adobe forms and the Agilent Compliance Engine (ACE) delivery tool. It provides reports with no handwriting errors; validated calculations; automated pass/fail report; traceability to raw data and the number of times a test was run. This automation provides efficiency and enforces compliance to procedure.
- The traditional qualification SOP is approved and released only once—replacing the need to author individual protocols for each chromatography system. This is the same concept for the EQP. The appropriate tests for each individual configuration are automatically selected by ACE from the list in the approved EQP—at time of delivery. The final reports are unique for each system and each qualification event—but the single approved EQP can cover a lab, department, or as wide a scope as desired.
- In the traditional qualification methodology, there is no convenient provision to record the actual workflow of the tests execution and results. In the event that a test is repeated during the Agilent CrossLab delivery, ACE maintains a counter per test which is automatically incremented for GxP compliant work, and the engineer generates a deviation note within the ACE report.



Design Qualification (DQ)

DQ for commercial lab instruments is recommended by some, but not all, guidances and procedures. Definitions 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.

USP Chapters literature definition of DQ:

Design qualification (DQ) is the documented collection of activities that define the functional and operational specifications of the instrument and criteria for selection of the vendor, based on the intended purpose of the instrument. Design qualification (DQ) may be performed not only by the instrument developer or manufacturer but also may be performed by the user. The manufacturer is generally responsible for robust design and maintaining information describing how the analytical instrument is manufactured (design specifications, functional requirements, etc.) and tested before shipment to users. Nonetheless, the user should ensure that commercial off-the-shelf (COTS) instruments are suitable for their intended application and that the manufacturer has adopted a quality system that provides for reliable equipment. Users should also determine capability of the manufacturer for support installation, services, and training.

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

1. 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.
2. Certificates of Agilent testing, validation, and conformance to standards are provided with new Agilent instruments and similar certification is provided for ACE software. These documents are checked and recorded in Agilent CrossLab Compliance Services IQ.
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. The OQ specifications in this EQP can be used, as appropriate, by the user to prepare URS. The OQ specifications in this EQP represent the levels of performance acceptable to regulatory agencies for the technique; conform to typical specifications found in validation literature; are equally suitable for OQ at installation and on-going OQ throughout operational lifetime; are equivalent to the OQ specifications published in the legacy Agilent Classic OQPV protocols; and are suitable for most user requirements.
5. Agilent Technologies is capable of installation, support, preventive maintenance, on-going qualification, and re-qualification after repair and user training worldwide.

Installation Qualification (IQ)

IQ checks and tests for Agilent hardware and software products include 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 start up properly.
6. Instrument Check (hardware only): Demonstrates that all modules of the instrument are correctly installed and connected. It does not test instrument performance as fully as OQ. This test is not necessary and therefore skipped if an OQ is to be performed by Agilent operator at installation after IQ.
7. Installation Verification (software only): Verifies the correctness of all installation-related files.

Operational Qualification (OQ)

Refer to the appropriate Test Definitions document for a detailed description of the testing program, setpoints, and acceptance limits for each system technique, category, and instrument configuration.

Dual-Acceptance Limits

(Applies to hardware qualifications only)

Within the EQP of Agilent CrossLab, each of the tests final result can be compared against two different limits if required. This allows customer-configured OQ to report against a User Limit (Limit1) and the Agilent Recommended Limit (Limit2) simultaneously.

In the standard EQP documents, Limit 1 and 2 values are the same – effectively de-activating this feature. Custom EQPs can also be prepared on request, making effective use of the two-limit feature of the Agilent Compliance Engine (ACE). In those cases, Limit 2 will always be the Agilent Recommended limit, and Limit 1 will be the limit requested by the user.

Agilent will not be under any obligation regarding the OQ testing results against user-requested limits that are more stringent than the Agilent Recommended ones.

Re-Qualification after Repair (RQ) Hardware

(Applies to hardware qualifications only)

In the event of a hardware breakdown followed by an engineering repair of a qualified instrument, it is necessary to re-qualify the system to an appropriate level before release back into operational use.

For some of the instrument techniques, Agilent offers a service contract to repair and re-qualify an instrument during the period between scheduled annual OQs.

The level of re-testing is prescribed in the RQ section of ACE: a form is displayed for the operator showing all types of repair possible and the re-testing required. Part of an example form is shown below.

Re-Qualification After Repair		
Pump Strategies		
Repair/Replace Strategy	Modules	OQ/PV 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 repair and re-test guidance is available for review by customers of the RQ service.

The RQ form in ACE prescribes which tests the operator must perform for each repair circumstance. The test procedure, setpoints, and limits will be an exact repeat of the previous OQ test (a regression-testing strategy).

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Overview

Agilent CrossLab qualification services offer flexible choices for the delivery method as described below. The desired service delivery method is chosen according to the laboratory data integrity and general procedural requirements. To ensure complete data traceability, Agilent has devised two delivery methods that access data directly (default methods). An alternative method is also available that accesses data indirectly through a transfer location. If neither of the default methods is chosen, this document captures customer approval of the alternative delivery method.

Available Methods

Method	Definition
Preferred 1	Network-distributed ACE (NDA), where the ACE software is installed on a network node within the laboratory LAN infrastructure. Requires collaboration with the customer to load ACE behind the customer firewall. 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.
Preferred 2	Dedicated spinning USB drive, where the ACE software resides on an independent drive that can be driven from the system controller, where the CDS resides. Because the USB spinning drive is connected to the CDS, the validity of this method is equivalent to the preferred 1 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. This is the most commonly used method.
Alternative	The ACE software is installed on and run from a PC not directly connected to the customer data system (CDS), such as the FSE's laptop. System data files are transferred indirectly from the CDS to the laptop instead of directly like preferred 1 and 2 methods. Requires customer pre-approval to remove later questions on data integrity.

EQR Storage

Select the checkbox below to authorize Agilent to store a copy of the Equipment Qualification Reports (EQRs) generated by Agilent Compliance Engine for internal audits. The intention of the audit 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 audit by Agilent and will not be shared with other organizations. It is not to be considered a backup for the EQR provided at qualification delivery.

Customer Approval of EQR Storage and Alternative Method

Authorize Agilent to store EQRs for their internal audit program (check for approval):

Approved by/ title:

Comments:

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Introduction

With heightened scrutiny of data integrity, Agilent’s ACE (Automated Compliance Engine) software must be able to access instrument-generated raw data files one of two ways: (1) directly, using the connection between network nodes or with the server; (2) indirectly, through temporary storage in a 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 use cases 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.

Preferred Method 1:	Network-distributed ACE (NDA)
Preferred Method 2:	Dedicated spinning USB drive (most commonly used method)
Alternative:	Service portable laptop or other PC not directly connected to customer data system (CDS)

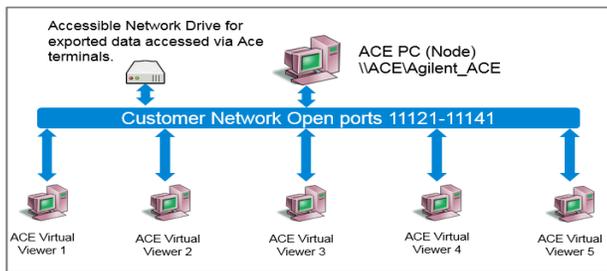
Preferred Method 1: Network-Distributed ACE (NDA)

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



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

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

Preferred Method 2: Dedicated Spinning USB Drive

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.

Details

A dedicated spinning USB drive can run ACE software 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 USB drive can remain on site with the customer for use by the Agilent FSE during service deliveries only.

Alternative Method

The ACE software is installed on and run from a PC not directly connected to the customer data system (CDS), such as the FSE's laptop. System data files are transferred indirectly from the CDS to the laptop instead of directly like preferred 1 and 2 methods.

Requires customer pre-approval to remove later questions on data integrity.

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Standard OQ Test Suite

This document describes the test program for qualifying GC systems, and the following table lists all OQ tests.

Note: Headspace tests apply only if a headspace sampler is an integral part of the system; Injection Carry Over is included in the standard OQ for GCs with headspace configurations but not for liquid sampler configurations (it can be ordered as EXTRA COST TEST). Inlet Pressure Decay is not included for GCs configured with mass spectrometer detectors.

Key: Fixed setpoints/limits Variances allowed

Test	Setpoints and Parameters	Limits
System Inspection and Basic Safety and Operation	N/A	Gases, chassis electric grounding, interlocks, hydrogen shutdown, and so on all correct
GC Oven Temperature Accuracy and Stability (Agilent Intuvo 9000)	Column connector = 230.0°C Oven 1 = 230.0°C Oven 2 = 100.0°C Stability measured at oven 2	Accuracy ≥ -5.0% and ≤ 5.0% of setpoint in K (oven) Accuracy ≥ -1.0% and ≤ 2.0% of setpoint in K (column connector) Stability ≤ 0.5°C
GC Oven Temperature Accuracy and Stability	Temperature 1 = 230.0°C Temperature 2 = 100.0°C Stability measured at temperature 2	Accuracy ≥ -1.0% and ≤ 1.0% of setpoint in K Stability ≤ 0.5°C (Agilent) Stability ≤ 1.0°C (Others)
Headspace Leak (7697A only)	N/A	Valve functions properly and HSS is leak tight
Headspace Vent and Pressurization Valve Integrity (G1888A and older)	N/A	Valve functions properly
Headspace Heated Zones Temperature Accuracy	Tline: 115.0°C Sample Loop: 110.0°C Syringe Heater: 110.0°C Oven: 100.0°C Agitator: 100.0°C (Applicable zones vary by model; * TurboMatrix 40, TurboMatrix 16, TurboMatrix 110, HS40XL, HS110, HS110XL models only) Tline is transferline.	Tline accuracy ≥ -1.8 and ≤ 5.2% of setpoint (7697A, 7697A w/tray) Tline accuracy ≥ -4.3 and ≤ 4.3 % of setpoint (Others) Sample loop accuracy ≥ -4.0°C and ≤ 4.0°C (G1883, G1888A, 7697A, 7697A w/tray) Sample loop accuracy ≥ -5.0°C and ≤ 5.0°C (Others) Syringe heater accuracy ≥ -2.0°C and ≤ 2.0°C (CTC) Syringe heater accuracy ≥ -5.0°C and ≤ 5.0°C (Others) Oven accuracy ≥ -6.0°C and ≤ 6.0°C (7694, G1289B, G1290B) Oven accuracy ≥ -4.0°C and ≤ 4.0°C (G1883, G1888A) Oven accuracy ≥ -5.0°C and ≤ 5.0°C (PerkinElmer*) Oven accuracy ≥ -4.0°C and ≤ 4.0°C (PerkinElmer other models) Oven accuracy ≥ -4.0°C and ≤ 4.0°C (7697A, 7697A w/tray) Oven accuracy ≥ -5.0°C and ≤ 5.0°C (Others) Agitator accuracy ≥ -2.0°C and ≤ 2.0°C (CTC)
Vial Heater Temperature Accuracy	Temperature: 60.0°C	Diff. from setpoint ≥ -2.0°C, ≤ 2.0°C
Inlet Pressure Decay (non-MS) (EPC or manual control only)	Inlet gas flow control	Pressure change / 5 minutes ≥ -2.0 psi and ≤ 0.5 psi
Inlet Pressure Accuracy (EPC or manual control only)	Inlet pressure: 25.0 psi	Accuracy ≤ 1.2 psi
Inlet Flow Stability (EFC control only)	Inlet flow: 4.0 ml/minute	Accuracy ≤ 10.0% Precision ≤ 5.0%

Test	Setpoints and Parameters	Limits
Detector Flow Accuracy	Flow rate varies by detector type (N/A for NPD)	Accuracy ≤ 10.0% of setpoint (or 0.5 ml/minute, whichever is larger)
Noise and Drift (FID)	Detector signal	Noise ≤ 0.10 pA Drift ≤ 2.50 pA/hour
Noise and Drift (TCD)	Detector signal	Noise ≤ 0.15 DU (He or H ₂ carrier and makeup [or no makeup]) Noise ≤ 0.25 DU (N ₂ carrier and makeup [or no makeup]) Drift ≤ 2.20 DU/hour
Noise and Drift (NPD)	Detector signal (N/A for 5890)	Noise ≤ 0.15 pA Drift ≤ 3.50 pA/hour
Noise and Drift (ECD)	Detector signal (N/A for 5890)	Noise ≤ 0.15 DU Drift ≤ 1.00 DU/hour
Noise and Drift (uECD)		Noise ≤ 3.00 DU Drift ≤ 15.00 DU/hour
Noise and Drift (FPD new style)	Detector signal, sulfur (N/A for 5890)	Noise ≤ 5.00 DU Drift ≤ 5.00 DU/hour
Noise and Drift (FPD+)		Noise ≤ 4.00 DU Drift ≤ 3.00 DU/hour
Noise and Drift (FPD new style)	Detector signal, phosphorous (N/A for 5890)	Noise ≤ 5.00 DU Drift ≤ 5.00 DU/hour
Noise and Drift (FPD+)		Noise ≤ 2.00 DU Drift ≤ 1.50 DU/hour
Noise and Drift (NCD, SCD)	Detector signal	Noise ≤ 5.00 pA Drift ≤ 50.00 pA/hour
Scouting Run	Injection volume on column: varies by configuration	N/A
Signal to Noise (FID/SS/MMI/ALS)	Signal height divided by ASTM baseline noise for known concentration and conditions.	S/N ≥ 300,000 (N ₂ makeup gas) S/N ≥ 240,000 (He makeup gas)
Signal to Noise (FID/SS/MMI/HSS)		S/N ≥ 5,000 (N ₂ makeup gas) S/N ≥ 4,000 (He makeup gas)
Signal to Noise (FID/VI/HSS)		S/N ≥ 4,000 (N ₂ makeup gas) S/N ≥ 3,200 (He makeup gas)
Signal to Noise (FID/non-SS/using 18710-60170)		S/N ≥ 800 (N ₂ makeup gas) S/N ≥ 600 (He makeup gas)
Signal to Noise (FID/non-SS/using 5188-5372)		S/N ≥ 200 (N ₂ makeup gas) S/N ≥ 160 (He makeup gas)
Signal to Noise (NPD)		S/N ≥ 300
Signal to Noise (TCD/SS/MMI)		S/N ≥ 750 (N ₂ makeup gas) S/N ≥ 5,000 (He or H ₂ makeup gas)
Signal to Noise (TCD/non-SS/MMI)		S/N ≥ 4 (N ₂ makeup gas) S/N ≥ 100 (He or H ₂ makeup gas)
Signal to Noise (uECD)		S/N ≥ 1,500
Signal to Noise (FPD new style)		S/N ≥ 700 (sulfur) S/N ≥ 1,000 (phosphorous)
Signal to Noise (FPD+)		S/N ≥ 1,400 (sulfur) S/N ≥ 2,400 (phosphorous)
Signal to Noise (NCD)		S/N ≥ 600 (NCD)
Signal to Noise (SCD)		S/N ≥ 550 (SCD) S/N ≥ 55 (SCD on FID base)
Injection Precision (Split/Splitless)	Injection volume on column: 1.0/1000/250 ul (ALS/Agilent HSS/CTC HSS with split/splitless FID) Injection time: 0.2 minutes (pressure-balanced HSS only)	Retention time RSD ≤ 1.00% Area RSD ≤ 3.00% (ALS, Agilent HSS) Area RSD ≤ 4.00% (CTC HSS) Area RSD ≤ 8.00% (NCD, SCD; ALS only)

Test	Setpoints and Parameters	Limits
Injection Precision (Purged/Packed)	ALS with purged/packed injection port; without HSS	Retention time RSD \leq 1.00% Area RSD \leq 3.00% (FID, TCD) Area RSD \leq 5.00% (other detectors)
Injection Carry Over (HSS only)	Same as Injection Precision	Area carry over \leq 1.00%

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.

System Inspection and Basic Safety and Operation

Description: System must be in safe and operational condition before starting the OQ tests.

Procedure: The instrument is given a general inspection and its basic safety features are challenged to ensure proper operation.

GC Oven Temperature Accuracy and Stability

Description: Oven temperature accuracy is important for comparability between systems and transferring methods. Oven temperature stability is critical for qualitative and quantitative analysis.

Procedure: At two different temperatures, accuracy is measured using an external calibrated thermometer and expressed as the difference between found and setpoint values. At one of these, a statistically significant number of additional readings are taken during the total duration of the test and stability is expressed as the delta between the highest and lowest temperatures.

Headspace Leak

Description: Proper operation of the valves is critical for repeatable peak areas and carry over.

Procedure: This test verifies that the valves operate properly with no excessive leaks or restricted internal flow paths.

Headspace Vent and Pressurization Valve Integrity

Description: Proper operation of the valves is critical for repeatable peak areas and carry over.

Procedure: This test verifies that the valves operate properly: with no excessive leaks or restricted internal flow paths.

Headspace Heated Zones Temperature Accuracy

Description: Temperature accuracy of the heated zones is important for comparing systems and transferring methods. Oven accuracy is critical to quantitative headspace methods.

Procedure: The temperature is measured using an external calibrated thermometer with appropriate probe design. Accuracy is determined as the difference between found and setpoint values.

Vial Heater Temperature Accuracy

Description: The 7693A vial heater option can be used during sample preparation. This test verifies that it heats accurately.

Procedure: The heater temperature is measured with an external thermometer and accuracy is calculated as the difference between the measured value and setpoint.

Inlet Pressure Decay

Description: Inlet pressure integrity is critical for repeatable injection and retention times. The pressure decay and pressure accuracy tests combine to demonstrate pressure integrity. **NOTE:** If there is too much air in the system, the MS system's Tune test indicates a leaking detector, so pressure decay is not necessary for MS-only systems.

Procedure: Inlet is capped, a pressure applied, and inlet flow turned off. The pressure decay is recorded over a specified time range.

Inlet Pressure Accuracy

Description: Inlet pressure integrity is critical for repeatable injection and retention times. The pressure decay and pressure accuracy tests combine to demonstrate pressure integrity. This test checks for accurate pressure to the head of the column. Column flow is achieved by maintaining a constant pressure against a known restriction. Because the restriction is a function of the column geometry, measuring pressure in the inlet is the most accurate way to determine flow.

Procedure: The inlet is capped, a pressure is applied, and the inlet pressure is recorded using an external calibrated manometer connected to the inlet.

Inlet Flow Stability

Description: Inlet flow stability is critical for repeatable injection and retention times. Inlet flow accuracy and precision tests combine to demonstrate inlet flow stability.

Procedure: Column flow setpoint is achieved, all detector flows are turned off, and calculations are made: flow accuracy as the absolute % difference of the mean of the ten flow readings and the setpoint; flow precision as the % RSD of ten flow readings.

Detector Flow Accuracy

Description: Detector flow accuracy is critical for a stable detector signal. Incorrect flows may have an impact on detector performance.

Procedure: Flow accuracy is determined by measuring the flows with a calibrated mass flowmeter and then comparing the results to the test setpoints and the values displayed by the GC.

Noise and Drift

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

Procedure: The signal is monitored at specified conditions appropriate to the type of detector over a twenty-minute period. The signal noise is calculated based on ASTM E594-96 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. Detector type and the gases used all contribute to different performance and therefore different limits for each configuration.

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.

Signal to Noise

Description: Sensitivity of GC detection 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.

Procedure: A traceable standard is injected and signal to noise is calculated.

Injection Precision

Description: System precision is critical for quantitative analysis.

Procedure: An initial stabilizing injection is made, followed by six repeat injections of a traceable standard followed by a final blank injection. The % RSD of the six injections is calculated to provide precision statistics. There are separate dedicated instrument parameters and reference standards applicable to each inlet/detector combination. This test is performed with liquid and headspace sampler configurations.

Injection Carry Over

Description: Low carry over from a previous injection is critical for accuracy of quantitative and reliability of qualitative analysis. For headspace samplers, the engineering condition contributes to carry over performance, so this is a core OQ test for these samplers.

For liquid samplers, carry over performance is contingent on many variable factors independent of the engineering condition of the GC system. Many different syringe wash programs are available that can eliminate carry over. These are user selectable and may be application specific. The condition of the injection syringe is the only controllable engineering factor. The injection syringe is typically replaced for new during PM before OQ. Therefore, the carry over test for liquid samplers is offered only as an optional extra fee test in a customer-configured EQP.

Procedure: The blank injection after the six repeat injections of the precision test is evaluated for carry over, and the result is expressed as a percentage.

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Report and Delivery Options

(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 in the EQR.

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

Selected Signature Options

Status: EQP is not signed

- Setpoint/Limit variance is allowed in this EQP
- Reporting variance is allowed in this EQP

Customer Approval

Name:

Title:

Date:

Signature:

Name:

Title:

Date:

Signature:

Name:

Title:

Date:

Signature:

Name:

Title:

Date:

Signature:

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Protocol Details

Protocol Revision Used for this Document

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GC.02.50

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NOTE: The Revision History - EQP Editor document includes details for above and other available revisions.