EQP Name: AgilentRecommended

Service Type: OQ

Company Name: _____

Customer Name/Title: _____

EQP Filename: Es.02.50.eqp

EQP Release Date: March 2020

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Table of Contents

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 hand-writing 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 (Limit 1) and the Agilent Recommended Limit (Limit 2) 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 descried 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:

Updated: November 2019 **www.agilent.com/chem/qualification**

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.

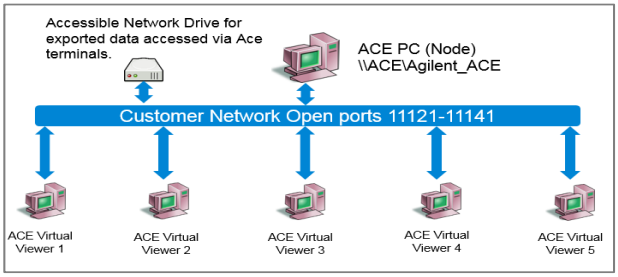
Preferred Method 1:	Network-distributed ACE (NDA)
Preferred Method 2:	Dedicated spinning USB drive (most commonly used method)
Alternative:	Service portable laptop or other PC not directly connected to customer data system (CDS)

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 ICP-OES instruments and their autosamplers. The ICP-OES tables list all tests run from software that controls the instrument; setpoints and limits cannot be changed and, for Agilent instruments, are internal to the controlling software.

ICP-OES: Agilent 5100, 5800, and 5900 Series

Note: Tests and test components are configuration specific as noted.

RV:	Radial Dual View
SVDV:	Synchronous Vertical Dual View
VDV:	Vertical Dual View

Test		Setpoint	Limits
Preparation			
Plasma ignition		N/A	Within three attempts
Detector calibration		N/A	Completes successfully
Wavelength calibration		N/A	Completes successfully
Instrument Test			
Resolution		N (174.213 nm)	≤ 9.4
		As (188.980 nm)	≤ 8.2
		C (193.027 nm)	≤ 11.5
		Mo (202.032 nm)	≤ 8.2
		Cr (206.158 nm)	≤ 13.4
		Zn (213.857 nm)	≤ 8.7
		Pb (220.353 nm)	≤ 9.5
		Co (228.615 nm)	≤ 17.2
		Ba (230.424 nm)	≤ 9.4
		Mn (257.610 nm)	≤ 13.3
		Mn (260.568 nm)	≤ 20.3
		Cr (267.716 nm)	≤ 11.0
		Cu (324.754 nm)	≤ 25.0
		Cu (327.395 nm)	≤ 14.2
		Sr (338.071 nm)	≤ 33.5
		Ba (455.403 nm)	≤ 44.0
		Sr (460.733 nm)	≤ 36.0
		Ba (493.408 nm)	≤ 36.0
		Ba (614.171 nm)	≤ 42.0
		Ar (675.283 nm)	≤ 74.0
		K (766.491 nm)	≤ 80.0
Sensitivity, Axial	(VDV, SVDV)	As (188.980 nm)	≥ 208.0
		Se (196.026 nm)	≥ 159.0

Test	Setpoint	Limits
	Zn (206.200 nm)	≥ 234.0
	Zn (213.857 nm)	≥ 1743.0
	Cd (214.439 nm)	≥ 4227.0
	Pb (220.353 nm)	≥ 320.0
	Mn (257.610 nm)	≥ 10625.0
	Cr (267.716 nm)	≥ 1048.0
	Cu (324.754 nm)	≥ 19.0
	Al (396.152 nm)	≥ 6.0
	Ba (493.408 nm)	≥ 60.0
	K (766.491 nm)	≥ 24.0
Sensitivity, Radial	As (188.980 nm)	≥ 46.0
	Se (196.026 nm)	≥ 41.0
	Zn (206.200 nm) (RV)	≥ 70.0
	Zn (213.857 nm)	≥ 1421.0
	Cd (214.439 nm) (RV)	≥ 522.0
	Pb (220.353 nm)	≥ 46.0
	Mn (257.610 nm)	≥ 3518.0
	Cr (267.716 nm) (RV)	≥ 379.0
	Cu (324.754 nm) (RV)	≥ 15.0
	Al (396.152 nm)	≥ 3.4 (VDV, SVDV)
		≥ 4.6 (RV)
	Ba (493.408 nm)	≥ 34.0 (VDV, SVDV)
		≥ 55.0 (RV)
	K (766.491 nm)	≥ 1.8 (VDV, SVDV)
		≥ 3.0 (RV)
Precision (RSD), Axial (VDV, SVDV)	As (188.980 nm)	≤ 1.5%
	Se (196.026 nm)	
	Zn (206.200 nm)	
	Zn (213.857 nm)	
	Cd (214.439 nm)	
	Pb (220.353 nm)	
	Mn (257.610 nm)	
	Cr (267.716 nm)	
	Cu (324.754 nm)	
	Al (396.152 nm)	
	Ba (493.408 nm)	
	K (766.491 nm)	
Precision (RSD), Radial	As (188.980 nm)	≤ 2.6%
	Se (196.026 nm)	
	Zn (206.200 nm) (RV)	≤ 1.5%
	Zn (213.857 nm)	
	Cd (214.439 nm) (RV)	
	Pb (220.353 nm)	≤ 2.6%
	Mn (257.610 nm)	≤ 1.5%
	Cr (267.716 nm) (RV)	
	Cu (324.754 nm) (RV)	
	Al (396.152 nm)	
	Ba (493.408 nm)	
	K (766.491 nm)	

ICP-OES: Agilent 700 Series

Note: Tests and test components are configuration specific as noted.

ACK:	Axial Cyclonic Spraychamber, K-style Nebulizer
ACO:	Axial Cyclonic Spraychamber, OneNeb Nebulizer
ACS:	Axial Cyclonic Spraychamber, Seaspray Nebulizer
ATO:	Axial Twister Spraychamber, OneNeb Nebulizer
ATS:	Axial Twister Spraychamber, Seaspray Nebulizer
RSMO:	Radial Sturman Masters Spraychamber, OneNeb Nebulizer
RSMV:	Radial Sturman Masters Spraychamber, V-groove Nebulizer
RTO:	Radial Twister Spraychamber, OneNeb Nebulizer
RTS:	Radial Twister Spraychamber, Seaspray Nebulizer

Test	Setpoint	Limits	
Preparation			
Plasma ignition	N/A	Within three attempts	
Detector calibration (71x-ES)	N/A	Completes successfully	
RF power check	N/A	Completes successfully	
Argon ratio check (72x-ES and 73x-ES)	N/A	Completes successfully	
Zinc wavelength position check	N/A	Completes successfully	
Dark current scan (72x-ES and 73x-ES)	N/A	Completes successfully	
Wavelength calibration	N/A	Completes successfully	
Hardware calibration (71x-ES)	N/A	Completes successfully	
Torch alignment	N/A	Completes successfully	
Instrument Test		Models	
		71x-ES	72x-ES
Resolution (72x-ES and 73x-ES)	Al (167.019 nm)	N/A	≤ 9.7
	N (174.213 nm)		≤ 9.4
	As (188.980 nm)	≤ 10.5	≤ 8.2
	C (193.027 nm)	N/A	≤ 11.5
	Mo (202.032 nm)		≤ 8.2
	Cr (206.158 nm)		≤ 13.4
	Zn (213.857 nm)	≤ 11.5	≤ 8.7
	Pb (220.353 nm)	N/A	≤ 9.5
	Co (228.615 nm)		≤ 17.2
	Ba (230.424 nm)		≤ 9.4
	Mn (257.610 nm)		≤ 13.3
	Mn (260.568 nm)		≤ 20.3
	Cr (267.716 nm)		≤ 11.0
	Cu (324.754 nm)		≤ 25.0
	Cu (327.395 nm)		≤ 14.2
	Sr (338.071 nm)	≤ 42.0	≤ 33.5
	Ba (455.403 nm)	≤ 55.0	≤ 44.0
	Sr (460.733 nm)	N/A	≤ 36.0
	Ba (493.408 nm)		≤ 36.0
	Ba (614.171 nm)		≤ 42.0
	Ar (675.283 nm)	≤ 88.0	≤ 74.0
	K (766.491 nm)	≤ 101.0	≤ 80.0
		Models	
		710-ES	715-ES
Signal Background Ratio	Pb (182.143 nm)	≥ 7.2	≥ 2.7

Test	Setpoint	Limits			
	As (188.980 nm)	≥ 13.0		≥ 6.0	
	Se (196.026 nm)	≥ 7.5		≥ 3.8	
	Zn (206.200 nm)	≥ 60.0		≥ 11.0	
	Pb (220.353 nm)	≥ 12.0		≥ 3.4	
	Co (228.615 nm)	≥ 49.0		≥ 15.0	
	Ni (231.604 nm)	≥ 34.0		≥ 11.0	
	Cu (327.395 nm)	≥ 15.0		≥ 9.0	
	K (766.491 nm)	≥ 37.5		≥ 2.3	
		Models			
		720-ES 730-ES ACK ACS ACO	720-ES 730-ES ATO ATS	725-ES 735-ES RSMO RSMV	725-ES 735-ES RTO RTS
Signal Background Ratio	Al (167.019 nm)	≥ 300	≥ 265	≥ 75.0	≥ 112.0
	Pb (182.143 nm)	≥ 11	≥ 9	≥ 6	≥ 8
	As (188.980 nm)	≥ 15.0	≥ 12.0	≥ 7.5	≥ 11.0
	As (193.696 nm)	≥ 7.5	≥ 6.0	≥ 6.0	≥ 9.0
	Se (196.026 nm)	≥ 9.0	≥ 7.0	≥ 4.5	≥ 6.5
	Zn (206.200 nm)	≥ 105	≥ 84	≥ 15	≥ 22
	Zn (213.857 nm)	≥ 190	≥ 150	≥ 110	≥ 150
	Cd (214.439 nm)	≥ 260	≥ 210	≥ 56.5	≥ 85.0
	Pb (220.353 nm)	≥ 15.0	≥ 12.0	≥ 3.8	≥ 6.0
	Mn (257.610 nm)	≥ 375	≥ 300	≥ 150	≥ 225
	Cr (267.716 nm)	≥ 52.5	≥ 45.0	≥ 22.5	≥ 34.0
	Cu (324.754 nm)	≥ 22.5	≥ 19.0	≥ 19.0	≥ 26.0
	Al (396.152 nm)	≥ 7.5	≥ 6.0	≥ 3.8	≥ 6.0
	Ba (493.408 nm)	≥ 75.0	≥ 60.0	≥ 75.0	≥ 112.0
	K (766.491 nm)	≥ 30.0	≥ 24.0	≥ 2.0	≥ 4.0
		All models			
QC Test - Accuracy	Same as precision setpoints	± 3.0%			
		Models			
		710-ES	715-ES	720-ES 730-ES	725-ES 735-ES
QC Test - Precision	Al (167.019 nm)	N/A	N/A	≤ 1.50%	≤ 2.60%
	Pb (182.143 nm)	≤ 1.60%	≤ 1.50%		
	As (188.980 nm)	≤ 1.00%	≤ 2.60%		
	As (193.696 nm)	N/A	N/A		
	Se (196.026 nm)	≤ 1.00%	≤ 2.60%		
	Zn (206.200 nm)	≤ 1.60%	≤ 1.50%		≤ 1.50%
	Zn (213.857 nm)	N/A	N/A		
	Cd (214.439 nm)				
	Pb (220.353 nm)	≤ 1.60%	≤ 1.50%		≤ 2.60%
	Co (228.615 nm)			N/A	N/A
	Ni (231.604 nm)				
	Mn (257.610 nm)	N/A	N/A	≤ 1.50%	≤ 1.50%
	Cr (267.716 nm)				
	Cu (324.754 nm)				
	Cu (327.395 nm)	≤ 2.00%	≤ 1.50%	N/A	N/A
	Al (396.152 nm)	N/A	N/A	≤ 1.50%	≤ 1.50%

Test	Setpoint	Limits			
	Ba (493.408 nm)				
	K (766.491 nm)	≤ 1.00%	≤ 2.60%		
		Models			
		710-ES	715-ES	720-ES 730-ES	725-ES 735-ES RSMO RMSV	725-ES 735-ES RTO RTS
Detection Limits	Al (167.019 nm)	N/A	N/A	≤ 2.00	≤ 13.0	≤ 9.0
	As (188.980 nm)	≤ 10.0	≤ 65.0	≤ 10.0	≤ 65.0	≤ 45.0
	Se (196.026 nm)	N/A	N/A	≤ 13.0	≤ 80.0	≤ 50.0
	Mo (202.032 nm)			≤ 2.00	≤ 11.0	≤ 8.0
	Cd (214.439 nm)			≤ 0.50	≤ 5.50	≤ 4.0
	Pb (220.353 nm)	≤ 6.50	≤ 65.0	≤ 6.50	≤ 65.0	≤ 45.0
	Mn (257.610 nm)	≤ 0.20	≤ 0.90	≤ 0.20	≤ 0.90	≤ 0.60
	Cr (267.716 nm)	N/A	N/A	≤ 2.00	≤ 5.50	≤ 5.50
	Cu (324.754 nm)			≤ 2.00	≤ 5.50	≤ 5.50
	Al (396.152 nm)			≤ 6.50	≤ 13.0	≤ 13.0
	Ba (493.408 nm)			≤ 0.70	≤ 0.90	≤ 0.90
	K (766.491 nm)			≤ 20.0	≤ 265	≤ 265

ICP-OES: PerkinElmer 4300DV, 5300DV, 7300DV, and 8000DV

Note: Test components are model specific as noted; **Scott** refers to an instrument with a Scott spray chamber and Gem tip crossflow nebulizer, as opposed to an instrument with a glass cyclonic spray chamber and concentric nebulizer.

Test	Setpoint	Limits
Preparation		
OQ user creation	N/A	Completed
Software user paths defined	N/A	Completed
OQ support files loaded	N/A	Completed
Results data set and log files setup	N/A	Completed
Plasma ignition	N/A	Within three attempts
Detector calibration	N/A	Completes successfully
Optics initialization (8000 DV only)	N/A	Completes successfully
Radial and axial torch alignment	N/A	Completes successfully
UV wavelength calibration (4300DV, 5300DV, 7300DV only)	N/A	Completes successfully
VIS wavelength calibration (4300DV, 5300DV, 7300DV only)	N/A	Completes successfully
Spectral Resolution		
8000DV	As (193.696 nm)	≤ 0.009
	Ni (231.604 nm)	≤ 0.011
	Ni (341.476 nm)	≤ 0.015
	Ba (455.403 nm)	≤ 0.020
4300DV, 5300DV, 7300DV DV	As (193.696 nm)	≤ 0.007
	Ni (231.604 nm)	≤ 0.008
	Ni (341.476 nm)	≤ 0.012
	La (408.672 nm)	≤ 0.020
	Ba (455.403 nm)	≤ 0.025
Precision (RSD)		
8000DV	Zn (206.200 nm)	≤ 1.0%
	Mg (280.271 nm)	
	Mg (285.213 nm)	

Test	Setpoint	Limits
	Ba (455.403 nm)	
4300DV, 5300DV, 7300DV	As (193.696 nm)	≤ 1.0%
	Zn (213.856 nm)	
	Mn (257.610 nm)	
	La (379.478 nm)	
	Ba (455.403 nm)	
	Ba (493.408 nm)	
Axial Detection Limits		
8000DV	Tl (190.801 nm)	≤ 10 µg/L
	As (193.696 nm)	≤ 10 µg/L
	Se (196.026 nm)	≤ 5 µg/L
	Pb (220.353 nm)	≤ 3 µg/L
4300DV, 5300DV, 7300DV *(*N/A for Scott)*	Tl (190.800 nm)	≤ 10 µg/L
	As (193.696 nm)	≤ 10 µg/L
	Se (196.026 nm)*	≤ 5 µg/L
	Pb (220.353 nm)	≤ 3 µg/L
Radial Detection Limits		
8000DV	As (193.696 nm)	≤ 60 µg/L
	Zn (213.857 nm)	≤ 2 µg/L
	Mn (257.610 nm)	≤ 1 µg/L
	La (379.478 nm)	≤ 3 µg/L
	Ba (455.403 nm)	≤ 0.3 µg/L
	Ba (493.408 nm)	≤ 0.6 µg/L
4300DV, 5300DV, 7300DV	As (193.696 nm)	≤ 60 µg/L
	Zn (213.856 nm)	≤ 2 µg/L
	Mn (257.610 nm)	≤ 0.75 µg/L
	La (379.478 nm)	≤ 3 µg/L
	Ba (455.403 nm)	≤ 0.3 µg/L
	Ba (493.408 nm)	≤ 0.6 µg/L

Autosamplers and Switching Valve Accessories

This tests are qualitative; no setpoints or limits apply.

Test	Setpoint	Limits
Autosampler Operation		
Autosampler successfully moves to location(s) specified in software	N/A	Completed
Switching Valve Operation		
Automated test results are within acceptance criteria	N/A	Completed

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.

Agilent 5100 Series

Preparation

Description: This preliminary test must be completed before the actual OQ tests. It verifies that:

- plasma ignited;
- detector was calibrated;
- instrument wavelength scale was calibrated.

Procedure: From the Agilent ICP Expert software (1) plasma is ignited and then extinguished; (2) while the plasma is off, the native software is used to calibrate the detector; (3) the instrument wavelength scale is calibrated.

Instrument Tests

Description: This test includes three automated instrument performance tests:

- Resolution
- Sensitivity
- Precision

Procedure: From the Agilent ICP Expert software, execute the Instrument Tests. The software prompts the user to aspirate the blank or standard solution as required. When the tests are completed, the software generates a report with the results.

Agilent 700 Series

Preparation

Description: This preliminary test must be completed before the actual OQ tests. It verifies that:

- plasma ignited;
- (71x-ES only) detector was calibrated;
- RF power was checked;
- (72x-ES and 73x-ES only) argon ratio was checked;
- zinc wavelength position was checked;
- (72x-ES and 73x-ES) dark current was scanned;
- wavelength scale was calibrated;
- (71x-ES) hardware was calibrated;
- torch was aligned.

Procedure: From the Agilent ICP Expert II software (1) plasma is ignited; (2) all applicable functions are completed.

Instrument Tests

Description: This test includes three automated instrument performance tests:

- Resolution
- Signal Background Ratio
- QC Accuracy
- QC Precision
- Detection Limits

Procedure: From the Agilent ICP Expert II software, execute the Instrument Tests. The software prompts the user to aspirate the blank or standard solution as required. When the tests are completed, the software generates a report with the results.

PerkinElmer Optima 4300DV, 5300DV, 7300DV, and 8000DV

Preparation

Description: This preliminary test must be completed before the actual OQ tests. It verifies that:

- prerequisites were completed (software's OQ user, user file paths, and OQ files have been installed; instrument and software log files are set up);
- plasma ignited;
- detector was calibrated;
- (8000DV only) optics initialization was completed;
- axial and radial torch views were aligned;
- (4300DV, 5300DV and 7300DV only) instrument UV wavelength scale was calibrated;
- (4300DV, 5300DV and 7300DV only) instrument VIS wavelength scale was calibrated.

Procedure: From the instrument's software (1) prerequisites are completed; (2) plasma is ignited; (3) detector is calibrated; (3) 8000DV instrument's optics are initialized; (4) instrument's axial and radial torch views are aligned; (5) 4300DV, 5300DV, and 7300DV instrument's UV and VIS wavelength scales are calibrated.

Spectral Resolution

Description: This test measures the resolution, or full width at half height (FWHH), of the relevant element's spectral peak.

Procedure: A standard solution containing the relevant elements is aspirated using a dedicated method. The software is set up to log the three replicate resolution measurements for each element. The highest resolution measurement is recorded in ACE as the result.

Precision

Description: This test determines the precision (% RSD) of the relevant element's emission signal.

Procedure: A standard solution containing relevant elements is aspirated using a dedicated method. The method measures a number of replicates and calculates the % RSD for each element. The calculated result is then recorded in ACE.

Axial Detection Limits

Description: This test determines the minimum concentration at which the relevant element can be detected in the axial viewing mode.

Procedure: A dedicated method is used to aspirate a 2% nitric acid blank and then a multi-element calibration standard solution to formulate a calibration curve. The sample introduction system is then flushed with a 10% nitric acid wash solution. The 2% nitric acid blank solution is aspirated again and the replicate measurements are interpolated from the calibration curve. Statistical calculations are then applied to the interpolated results and the calculated results are recorded in ACE.

Radial Detection Limits

Description: This test determines the minimum concentration at which the relevant element can be detected in the radial viewing mode.

Procedure: A dedicated method is used to aspirate a 2% nitric acid blank and then a multi-element calibration standard solution to formulate a calibration curve. The sample introduction system is then flushed with a 10% nitric acid wash solution. The 2% nitric acid blank solution is aspirated again and the replicate measurements are interpolated from the calibration curve. Statistical calculations are then applied to the interpolated results and the calculated results are recorded in ACE.

Autosamplers and Switching Valve Accessories

Autosampler Operation

Description: This test verifies the functional operation of the installed autosampler.

Procedure: From the instrument software, the autosampler probe is directed to several sample locations and a pass or fail is recorded in ACE.

Switching Valve Operation

Description: This test verifies the functional operation of the installed switching valve.

Procedure: From the instrument software, run the automated switching valve test and follow the prompts. When the tests are completed, the software generates a report with the results and a pass or fail is recorded in ACE.

Updated: November 2019 **www.agilent.com/chem/qualification**

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

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ES.02.50	March 2020

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