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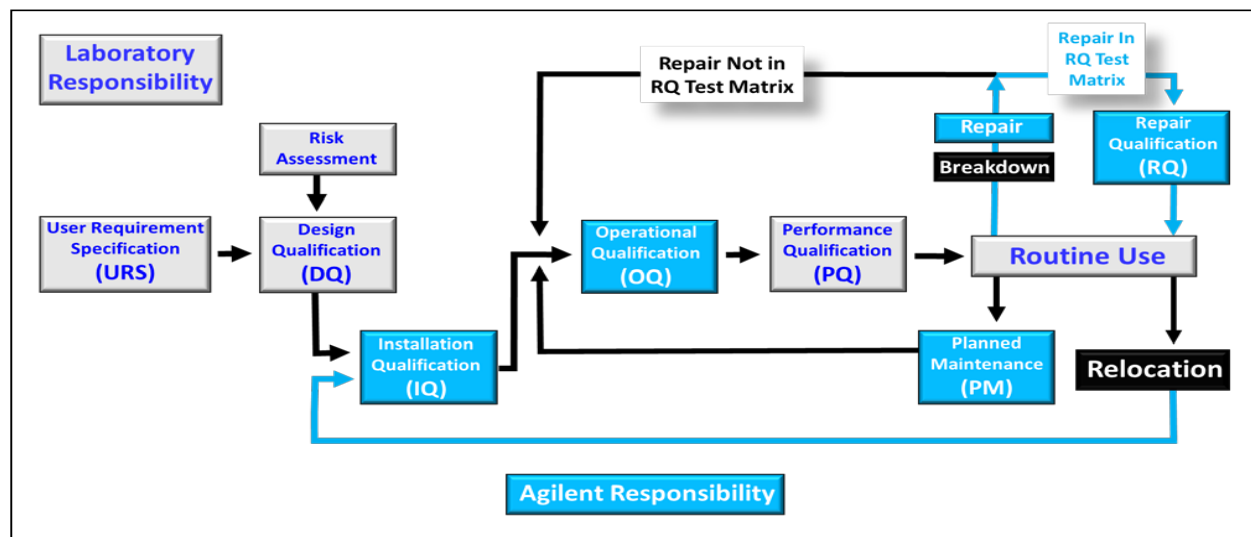
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Agilent CrossLab Compliance Services

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 Pharmacopeia (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 QQ. It is the continuum of the combined QQ, 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>.

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.

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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)	<p>This method requires customer pre-approval due to data integrity implications. <u>Only choose this option in scenarios like the following:</u></p> <ul style="list-style-type: none"> ACE software is not run from a PC directly connected to the customer CDS, such as the FSE's laptop. System data files are transferred indirectly from the CDS to the FSE laptop instead of directly as done with Network and Local ACE methods. Data is acquired using a CDS on the FSE's laptop and transferred directly to ACE. The CDS used in this method is qualified for data collection purposes.

EQR Storage

Select the checkbox below to authorize Agilent to store 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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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.

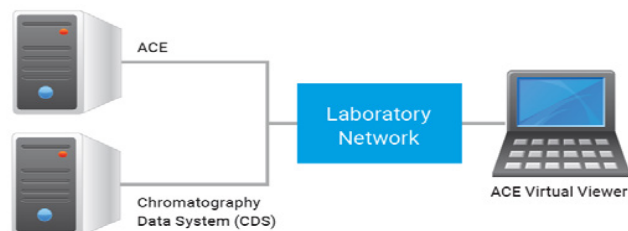
Network ACE (Agilent Recommended)

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

This method requires customer pre-approval due to data integrity implications and only applies in scenarios like the following:

- ACE software is not run from a PC directly connected to the customer CDS, such as the FSE's laptop. System data files are transferred indirectly from the CDS to the FSE laptop instead of directly as done with Network and Local ACE methods.
- Data is acquired using a CDS on the FSE's laptop and transferred directly to ACE. The CDS used in this method is qualified for data collection purposes.

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Standard MQ Test Suite

This document describes the test program for qualifying Dissolution systems with apparatus 1 or 2; the following table lists all MQ tests.

Test	Setpoints and Parameters	Limits
Component Verification	NA	NA
Basket/Paddle Height	Depth (Height): 25 mm	Accuracy $\leq 8\%$ of setpoint (≤ 2 mm)
Wobble	App 1 measured at basket rim; app 2 at paddle shaft; rotation speed of 50 RPM for all measurements	Measurements are ≤ 1.0 mm from the axis
Shaft Verticality	Measurement 1: point on vertical axis Measurement 2: 90° from measurement 1	Measurements are $\leq 0.5^\circ$ from vertical*
Vessel Verticality	Measurement 1: Midway point on cylindrical part of vessel Measurement 2: 90° from measurement 1	Measurements are $\leq 0.5^\circ$ from vertical*
Vessel Centering	Center position set; upper and lower points are measured	Measurements are ≤ 1.0 mm from centerline
Rotational Speed (RPM)	Speed 1: 50 RPM Speed 2: 100 RPM	Speeds are ≤ 1.0 RPM from setpoint
Vessel Temperature Accuracy	Temperature: 37°C	Accuracy $\leq 0.5^\circ\text{C}$
Vessel Temperature Stability	Temperature: 37°C	Stability $\leq 0.5^\circ\text{C}$
Vessel Temperature Variance	NA	Variance $\leq 0.4^\circ\text{C}$

* Or within bubble if a mechanical (vs. digital) gauge is used

Test Design and Rationale

Component Verification

Description: This test captures the status of the verification certificates for components (vessels, shafts, baskets, and paddles, as applicable). Components should comply with the specifications listed in the USP General Chapter <711> Dissolution.

Basket/Paddle Height

Description: This test verifies that the apparatus is set to the desired height (distance from basket/paddle to vessel bottom).

Procedure: The actual distance between the bottom of the vessel and bottom of the basket or paddle is determined. If the depth of the basket/paddle is adjustable, first a depth gauge is used to set the distance between the bottom of the paddle blade or basket and the bottom of the vessel. The depth gauge is set at 25 mm and placed on the bottom of the vessel. Each shaft is raised into the apparatus drive module. The drive unit is then lowered to its operating position. The paddle or basket is then lowered into the vessel until it touches the top of the depth gauge. The shafts are locked into this height. This is repeated for each shaft.

Wobble

Description: This test evaluates wobble, calculated as the absolute value of the difference between maximum and minimum readings.

Procedure (Shaft for App1/2): A runout gauge is placed on top of the vessel plate, and the drive module is positioned so that the gauge probe touches the shaft about 2 cm above the top of the paddle blade or basket. The gauge is placed so that the probe slightly presses in on the turning shaft. If a mechanical gauge is used, the gauge's pointer should read slightly more than zero. The pointer will vary from a minimum to a maximum reading, and the difference is called the wobble.

Procedure (Basket for App 1): A runout gauge is placed on top of the vessel plate and the drive unit is positioned so that the gauge probe touches the bottom rim of the basket. The gauge is placed so that the probe slightly presses in on the turning shaft. If a mechanical gauge is used, the gauge's pointer should read slightly more than zero. The pointer will vary from a minimum to a maximum reading and the difference is called the wobble.

Shaft Verticality

Description: This test verifies shaft verticality in two directions, 90° apart on the vertical axis.

Procedure: Lower the drive unit to where it would be during an actual dissolution test. If necessary, the shaft verticality may be checked with the shafts raised above the drive unit. Place an accurate bubble level on the front edge of each of the shafts. The bubble should be within the lines of the level. Rotate the level 90° so it is on the side of the shaft. The bubble should again be within the lines of the level for each shaft. If the shafts are not vertical adjust the feet of the apparatus until they are vertical. A digital leveling device may also be used to determine the shaft verticality. The shaft must be within the specified limit from vertical.

Vessel Verticality

Description: This test verifies vessel verticality with two measurements 90° apart at a midpoint on the cylindrical portion of the inside vessel wall.

Procedure: The vessel verticality can be calculated using the centering measurements and the difference in height between the two measurements or it can be determined using a digital leveling device placed on the inside wall of the vessel.

The verticality should be determined at two positions 90° apart. After each vessel has been centered and made vertical, each vessel and vessel plate opening must be numbered and a mark must be placed on the lip of each vessel and on the vessel plate directly next to the mark on the vessel lip. Each vessel must be returned to the same vessel plate opening and positioned in the exact same position inside the vessel plate opening for all future dissolution tests.

Vessel Centering

Description: This test verifies vessel centering.

Procedure: A mechanical or digital centering device that centers the inside of the vessel around the shaft or a surrogate shaft can be used. The centering is measured at two positions inside the vessel in the cylindrical portion, one near the top but below the rim and one just above the bottom portion of the vessel. The shaft or surrogate shaft must be centered within the specified limit from the center line.

Rotational Speed (RPM)

Description: This test verifies rotational speed of the shafts.

Procedure: A tachometer is used to measure the rotational speed of the paddle or basket. The shafts should be rotating smoothly within the specified limit of the target value.

Vessel Temperature Accuracy

Description and Procedure: This test uses a calibrated thermometer to verify that the media temperature reaches the system setpoint.

Vessel Temperature Stability

Description: This test uses a calibrated thermometer to determine the stability of the vessel temperature.

Procedure: Stability is calculated as the delta between the highest and lowest measured temperatures.

Vessel Temperature Variance

Description: This test uses the Vessel Temperature Accuracy's high and low temperatures (across all vessels) to determine the vessel variance.

Procedure: Variance is calculated as the delta between the highest and lowest measured temperatures for all vessels.

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