Agilent CrossLab
From Insight to Outcome

# Advantages and Management of Agilent Digital Qualification Templates

- Equipment Qualification Plan (EQP)
- Equipment Qualification Report (EQR)


Agilent

# Components of Agilent Digital Qualification

**Equipment Qualification Plan (EQP)** and **Equipment Qualification Report (EQR)** are digital templates used within Agilent's Automated Compliance Engine (ACE) software. These ensure digital qualification workflow is compliant with regulatory and Data Integrity requirements. The EQP contains details of the qualification tests, set points and limits, while the EQR contains the digital qualification results and meta data. Both are designed to be configurable[1] and require customer approval:


## Features of Agilent EQP

- Compliant
- Configurable
- Digital (see EQP Manager)[2]
- Harmonized
- Secure Data Logging (Metrology Test Data)[4]*
- Test Description Included

* For Chromatography systems (when available in your region)

## Features of Agilent EQR

- Audit Ready / Complete Record
- Configurable
- Digital (see EQR Manager)[3]
- Electronic Deviation
- Failed Test Reporting
- Session Log / Test Counter

## Equipment Qualification Plan (EQP)

EQPs must be reviewed and approved **before** the qualification work is performed. They are digital templates within ACE, which can be reviewed, configured and approved digitally by all customers using Agilent EQP Manager[2]. This removes the need to print and use ink approval, saving costs and data integrity risks.

Many customers approve the **Agilent Recommended** EQP.

However, EQPs are designed to be configured[1], so that the Operational Qualification (OQ) can test the instrument range of use, in line with USP <1058> requiremens[5]. EQP manager facilitates digital management of the configuration.

For chromatography systems, Agilent believe the best way to measure instrument flow, pressure (GC only) and temperature performance is by direct metrology data measurement using ISO17025 calibrated tools and Agilent secure data logging technology[4]. This further enhances Data Integrity of the qualification tests.

## Equipment Qualification Report (EQR)

An EQR is provided to the customer for review and approval **after** the qualification work is complete. EQRs contain overall pass/fail results, granular details of the time stamped qualification work, raw data used in the test calculations, meta data, certified standards, calibrated tools used in the work and training certificates. The EQR is a complete, secure digital record of the work performed. Agilent EQR Manager[3] (for Network ACE customers) enables electronic review and approval of the qualification report (EQR), removing the costs, environmental impact and risks associated with ink approval and management of printed documents.

Agilent EQRs are a complete audit ready digital record of the qualification work, including results for failed tests (if applicable) and digital deviation report management. EQRs can configured to match customer reporting requirements.

# Key Benefits of an Agilent Digital EQP and EQR

Agilent implemented digital qualification plans (EQPs) and qualification reports (EQRs) in 2007, with the Agilent Automated Compliance Engine (ACE). This was years before the regulatory focus on Data Integrity. The Agilent approach of using EQPs and EQRs through the ACE software has a number of significant advantages over other options:

## Audit Ready Reports (EQRs)

EQRs are audit ready because they are a complete digital record of the work performed, including electronic data, meta data, training records, certificates for reference materials and the calibrated tools used. Copies of relevant SOPs can be added to EQRs by customers using EQR Manager[3].

## Configurable Digital Protocols

EQPs are designed to be configurable[1] and are independent of the ACE software platform. The controlled flexibility provided by this ensures the qualification matches user requirements[6] and range of use, in line with USP <1058> requirements (e.g. EQPs can be aligned to your lab, site or global compliance requirements, to drive harmonization).

## Data Integrity Compliant

The validated workflows used within ACE ensure the approved EQP is followed by the engineer. With end-to-end digital traceability, ACE is designed to be compliant with Data Integrity requirements such as ALCOA+[7].

## Digital Deviation Management

Electronic deviation reports are standard within ACE (therefore, no need to try and "interpret" / read handwritten comments). To comply with “Complete Data”, failed qualification test results are automatically reported in the EQR (where applicable). The engineer must investigate the cause and generate an electronic deviation report for electronic review in the EQR.

## Digital Review

EQPs and EQRs are digital templates, consistent across all ACE platforms. Use of EQP Manager and EQR Manager speeds up workflow, review, and approval (Digital Review).

## Harmonized ACE Qualification – Across Your Lab

The regulatory data integrity focus is driving a need for a consistent and harmonized qualification that satisfies data integrity requirements. ACE is designed to be independent of the instrument manufacturer and supports harmonized qualification, valid across multiple platforms with a harmonized structure, layout and workflow.

## Independent Instrument Testing

The validated test calculations and algorithms ACE use provide independent assurance of instrument performance. For example, HPLC pump gradient testing within ACE gives unmatched accuracy and consistency (by using derivatives of detector response). This leverages the independence of ACE from the Chromatography Data System (CDS).

## Validated Software and Digital Templates

Use of validated software removes the need to transcription check the data or check test results calculations (for qualification). This removes the risks associated with paper, Excel or PDF-based qualification[8].


## Customer Responsibilities, Workflow and EQP/EQR Review

Customer responsibilities are defined within each EQP, but specifically, the customer is responsible for review and approval of the EQP **before** the work is performed and timely review and approval of the EQR **when the work is complete**. Additionally, IT responsibilities for Network ACE implementation are clarified elsewhere[9].

**Agilent Recommended** EQPs are available on-line or can be supplied. Review this against your instrument range of use and qualification requirements. This can be done digitally using Agilent EQP Manager, to ensure your regulatory requirements are satisfied. The EQR Manager can be used to electronically review and approve the EQR[3].

# Frequently Asked Questions (FAQ)

### What is an Agilent EQP?
Equipment Qualification Plan (EQP) is a digital template that lists the tests, setpoints, and limits that will be used during the instrument qualification. It can be reviewed and approved digitally using EQP Manager[2].

### What is an Agilent EQR?
Equipment Qualification Report (EQR) is a digital report provided when the qualification work is complete. It can be reviewed and approved digitally using EQR Manager.

### Can an Agilent EQP be configured/customized?
Yes, the Agilent Recommended EQP can be configured to include set points and optional additional tests – to align the EQP with a range of use and user requirements. For example, for HPLC, the EQP should cover the flow, injection volume, temperatures, gradient conditions and wavelength* range the instrument is used with.

### Why are there no instructions in an Agilent EQP?
ACE and the secure EQP files it uses are designed to support digital (paperless) workflow. Protocol instructions are built into ACE, so they are not replicated in the EQP template.

### How does an Agilent EQP comply with USP <1058>[1]?
The ability to configure EQPs to match user requirements is required by USP <1058>[5]. Creating a User Requirement Specification (URS) is fundamental to <1058> compliance[6].

### What is Network ACE?
Copy of ACE designed for customer network installation, to enable data acquisition, transfer, processing, and reporting within security of the customer network[10].

### Should I qualify at the instrument specification?
No, instrument specifications document the capability of new instruments under ideal conditions, which will be different to your laboratory. They should not be used for user requirements[6]. For example, detector noise and drift limits are temperature sensitive. The Operational Qualification (OQ) should satisfy regulatory requirements and test user requirements / range of use.

### Is ACE validated?
Yes, the Agilent ACE software and associated templates are managed under change control and follow an approved validation life cycle within Agilent's global ISO accredited QMS.

### Is ACE compliant with Annex 11 / 21CFR Part 11?
Yes, details are available on request.

### Why are OQ calculations performed in ACE?
The validated test calculations and algorithms used by ACE ensure harmonized qualification, which is independent of the instrument manufacturer, providing independent testing of the instrument performance. The dedicated test algorithms used ensure compliant, consistent and harmonized qualification.

* Where reference materials are available

## References


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2. Digital Equipment Qualification Plan (EQP) Management, **5994-7111EN**
3. Digital Qualification Data and Report Management, **5994-7110EN**
4. Secure Data Logging Technology, **5994-4579EN**
5. **USP General Chapter <1058> Analytical Instrument Qualification**
6. USP General Chapter <1058> Compendium of Agilent White Papers, **5994-1134EN**
7. Agilent Network ACE - How it satisfies ALCOA + data integrity requirements, **5994-1660EN**
8. Technical Overview, Analytical Instrument Qualification, **5994-0506EN**
9. Customer IT Responsibilities, Agilent Network ACE, **5994-5116EN**
10. **Agilent Network ACE**


To find out more about Agilent's analytical instrument qualification services, contact your local Agilent representative.
**www.agilent.com/chem/qualification**


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