

## Agilent CrossLab Compliance

Enhancements provided by the ACE 3 Platform featured in revision A.02.50 of the Equipment Qualification Reports (EQR).

### Equipment Qualification Plan (EQP)



- Validated calculations
- Electronic data traceability
- Complete qualification record
- Automated pass/fail decisions
- Electronic deviation reports
- Audit ready format



Network Distributed ACE:  
*Secure end-to-end qualification workflow*

### Equipment Qualification Report (EQR)



This document describes the improvements provided by the ACE 3 Platform featured in revision A.02.50 of Agilent CrossLab Compliance qualification protocols.

## Introduction

The CrossLab qualification protocols are a result of over 12 years of evolution of a flexible service delivery system based on the Agilent Automated Compliance Engine (ACE). During that period, both the technique protocols and the ACE platform they are based on have undergone sustained development resulting in the highly successful protocol set for the different analytical techniques.

Protocols Revision A.02.50 is the result of the migration of the protocols to the enhanced ACE 3 delivery platform. In that process the thoroughly recognized suite of tests was ported intact. This means that moving to A.02.50 from the previous revision will result in the same approved test coverage as well as set-points and limits.

ACE 3 is fundamentally a technology refresh of the ACE software platform, with the same accuracy and reliability offered previously, but on more modern, modular, and flexible architecture. The new platform maintains the same established user interface all certified users are already familiar with, so transitioning to it is smooth as the additional training requirements are low. Agilent took advantage of this opportunity to strengthen the built-in traceability technical controls and to reinforce the areas in the software that provide improvements in the structure and clarity of the Qualification Reports. The effect is a substantial net gain improvement in overall quality and effectiveness.

### The following section summarizes the main attributes of the CrossLab program:

- The actual electronic version of the Equipment Qualification Plan (EQP) approved for use by the customer is directly used to establish set point and limit conditions. The generated report will give the name and signature information attributed to the Equipment Qualification Report (EQR).
- Complex system configurations support allows a single comprehensive configuration description without the need for attachments or appendix support.
- Chromatographic plots can be displayed along with meta-data within each test.
- Where appropriate, meta-data is also displayed in graphical form.
- All set points for a given test are contained within the test, resulting in an easier-to-review result where a single final Pass/Fail assessment can be made for all set points within a test.
- The individual report sections can now be ordered and configured to specific needs.
- The summary "Certificate of System Qualification" can be issued as a stand-alone document.
- Independent data analysis removes the potential for the impression of self-justifying acceptance and eliminates reliance on other product validations.
- Attachment handling has been enhanced to manage all supporting documentation despite disparate sources and document types. Equipment calibration records, personnel qualification records, certificates of analysis for the samples used as well as time-stamped comments and deviation records are managed in separate sections of the Attachment appendix.
- Validation of the presence of expected attachments prompts the user to assure consistency of final report content.
- The EQR and the supporting information have been optimized for electronic review and storage. Sections required to accept printed versions are added to the document only where printing is the expected model used.

### The following statements can be used to describe the impact analysis of the differences between EQR revisions:

#### 1. No changes to the test definitions or testing methodology have been made

Agilent CrossLab Compliance methodology and approach continue to be based on a balanced combination of metrology and chromatography data, not based on indirect measurement or inference, and without second-level data - to yield a risk-free interpretation of the system characterization. No changes to the calculation algorithms and math engine have been made.

## 2. Choice of Delivery Methods and approval

Approval of the ACE delivery method is documented in the EQP. Agilent CrossLab qualification services offer flexible choices for the delivery method. 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: (a) Network Distributed ACE and (b) Dedicated Workstation. In both cases, the equipment is controlled by the native data system at all times, and original raw data is used for chromatographic tests.

## 3. Strongly enhanced Transaction Log for improved Data Integrity

The benefits of a multi-vendor, multi-technique program capable of qualifying systems driven by different data systems are thoroughly sustained by the data integrity controls implemented in the product. In particular, the Transaction Logs have been enhanced to capture more relevant information pertaining to the qualification work-flow process. The Transaction Log documents in a chronological order all actions performed by the operator during the delivery, capturing those session steps with an impact to ALCOA categories, such as:

- User credentials, Host Name, Date and Time Stamps for each entry
- Session creation, configuration, and termination
- License entitlement
- EQP Used for test program definition
- Test execution with run count details
- Test Unlock for Deviation purposes
- Data management full details
- Reporting and completion of service.

## 4. Enforced electronic controls for end-to-end traceability

Adherence to the approved procedures is ensured by the automation and controls implemented in the delivery tools. Some of the most remarkable are:

- Mandatory electronic deviation reports are enforced if any test fails.
- Test processing and data integration counters are included in every test and cannot be disabled by the operator.
- Deleted sessions are archived with a comment from the FSE captured in the session log. A log viewer is now part of the software to view any completed or aborted session logs.

## 5. More configuration options to choose the content and form of the final EQR

You can continue with the same report layout and contents as before, but more configurable options are available to provide additional details and tailored report formats. For example, adding a Repeated Test Log with the results of failed tests can be specified in your approved EQP for automated inclusion in every EQR. You also have the option to include the full Transaction Log into the EQR.

In general, the EQR consists of the following sections:

- Front Cover w/ system and service id#
- **Enhanced** - Table of Contents
- Test Summary
- Service Details
- Instrument Details
- Calculation Formulas - optionally included
- Protocol Details
- Tests list - as specified in EQP
- **New** - Repeated Test Log - included by default
- Declaration of Change Control
- **Enhanced** - Attachments - as many as defined on Template
- Electronic Signature
- Certificate of System Qualification - optionally included, stand-alone if required
- **New** - Transaction Logs - optionally included

The snapshot below shows the options in the EQP that will determine the EQR contents:

Report and Delivery Options:	
Show chromatograms	<input checked="" type="checkbox"/>
Use full page for chromatograms	<input type="checkbox"/>
Show header and footer on cover	<input checked="" type="checkbox"/>
Include repeated run logs	<input checked="" type="checkbox"/>
Show variance information	<input type="checkbox"/>
Use Alternative Method of Delivery To ensure complete data traceability, Agilent recommends delivering the qualification service by means of a ID-controlled spinning USB drive connected to your systems, or by directly installing ACE within your network. This will be the standard method followed by the Agilent Support Representative unless the alternative delivery method option is selected. This choice will be reflected in the Equipment Qualification Report.	<input type="checkbox"/>
Include Transaction logs	<input checked="" type="checkbox"/>
Include User Log	<input type="checkbox"/>

## 6. Redesigned attachment facility

Your EQR is an audit-ready, self-contained package with all the supporting evidence used for the assessment of the tests. In addition to the Certificates of Analysis and operator training and equipment calibration records this facility can also include custom documents relevant to your lab as specified by your SOPs, embedded as attachments. Thanks to the improved attachment management and EQR integration, your auxiliary documents are an integral part of the qualification reports, properly referenced in the Attachments Table of Contents. You can even define your own templates to ensure consistent application across all your equipment qualification in your lab.

Some typical examples of attachments include, but are not limited to:

- Sample Certificates of Analysis (CofA)
- Operator Certification Records
- Equipment Calibration Records
- Software Certificate of Validation and Revision History
- Equipment Qualification Plan
- Other supportive documents, such as SOPs, etc.

## 7. Overall improvements in page management and charting representation

Better structured and presented information result in additional clarity and legibility of the A.02.50.EQR that further facilitates review and approval of the document. Typically, every test documents the following elements in the report:

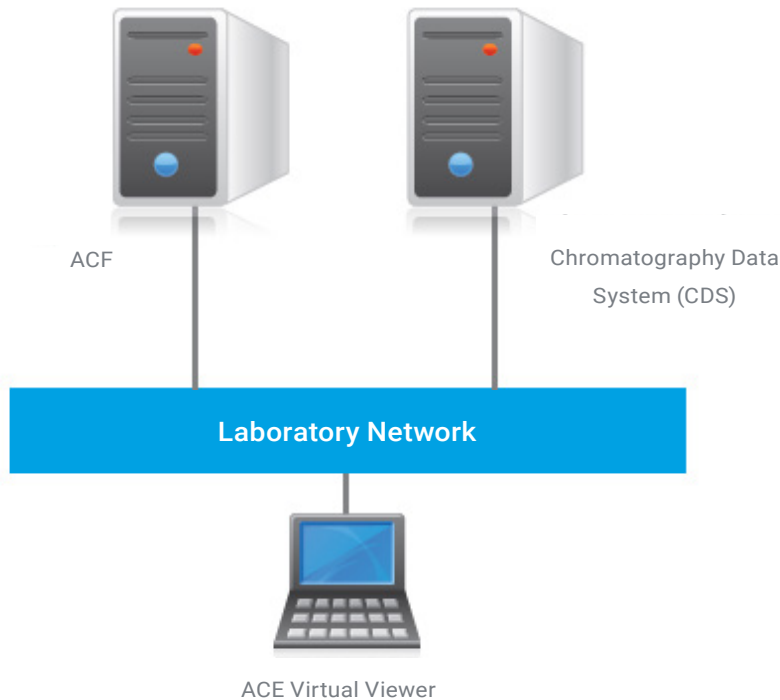
- Test Purpose
- Configuration Details
- Actual measured values for metrology data
- Results and setpoint status
- Automates Pass/Fail decisions without human intervention
- Charts showing reproducibility and concentrations of multiple-point results
- Chromatograms and metadata for chemistry data
- Integration Parameters used by the built-in engine
- Data Audit Log for all data files used in the assessment of the test

Other specialized tests graphics, such as the representation in the Gradient Composition test of the first and second derivatives of the tracer data, for enhanced event-detection reliability in identification and reporting.

Finally, the session vital constants are documented in the front cover and in footer on each page of the report, including system ID and service and creation date/time stamps.

## 8. Greater flexibility for self-maintainers and Agilent Partners

A new ACE License Scheme makes it easier to manage than ever before. A single service credits account can be used for any combination of qualification type and instrument technique. You can download available credits directly to your ACE session from a cloud-based implementation available 24/7 for your convenience. Service credit accounts can be personalized or common to a workgroup, the complete laboratory or even a firm. A simplified, yet more powerful model that adds the flexibility you need for the self-managed qualifications.

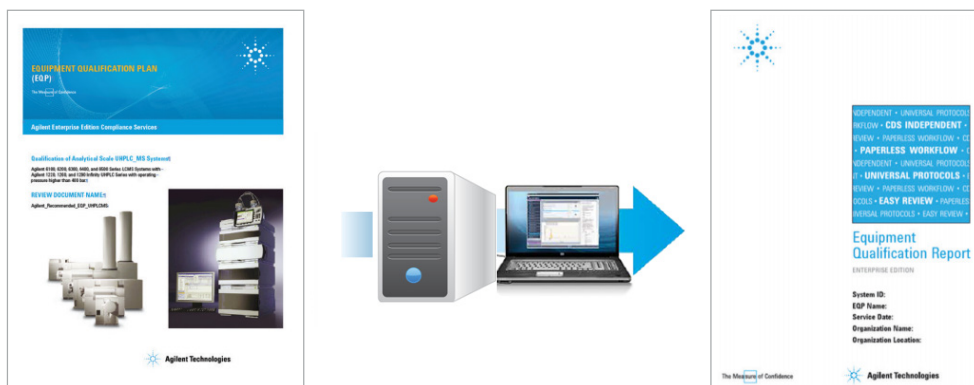


## Call to action

To realize the benefits provided by the new ACE 3 platform the new technique protocols must be used. A migration of the existing EQPs with the same test programs as approved can be as simple as approving the new revision number for Standard EQP.

If you're using Custom EQPs with additional tests or custom-configured testing schedule (e.g.. additional or alternative test set points such as flow or temperature), the migration is also conveniently done using the EQP Editor to re-print your custom EQP with the same contents.

The Standard EQPs based on the current ACE 2.x platform will continue to be supported only for one year after ACE 3 introduction. Custom EQPs should also be converted to the new platform during the year and a half after ACE 3 introduction.



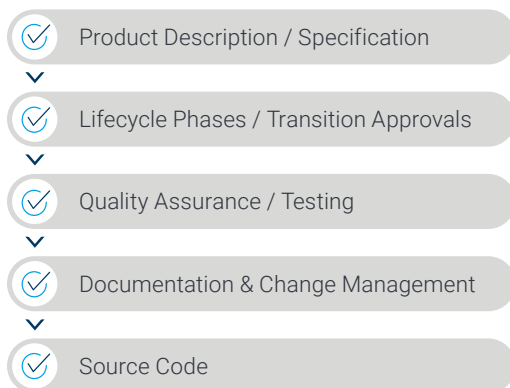
## Summary

Update to the ACE software platform described in this document results in the ACE software designation changing to ACE 3. The ACE software platform and the associated Equipment Qualification Plans (EQPs) and Equipment Qualification Reports (EQRs) are managed under change control and follow approved validation life cycle processes within the Agilent ISO Accredited Quality Management System#.

The changes described in this document include information about some of the enhancements and new features of the Agilent ACE platform. These changes have no regulatory impact on qualification work because:

- **No Changes** – have been made to the qualification test definitions / testing methodology
- **ACE Platform Numbering** – is unchanged and is incremental, from 3 with this release
- **ACE Change Control** – the ACE software, EQPs and EQRs are managed under change control
- **EQP Numbering** – continues to be incremental, with designation A.2.50 from ACE 3
- **EQR Numbering** – continues to be incremental, with designation A.2.50 from ACE 3

#Validation certificates for the ACE software are generated automatically as part of the life cycle process, prior to software release, and are available on request. The certificate includes a declaration of intent statement and is a representation of the life cycle process followed, with high-level details of the key stages listed below:



[www.agilent.com/chem/qualification](http://www.agilent.com/chem/qualification)

This information is subject to change without notice.