Data Integrity for Analytical Instrument Qualification

Agilent CrossLab Network Distributed ACE (NDA)

Technical Overview

Introduction

Agilent CrossLab Compliance provides a fully harmonized qualification approach, delivered by specially trained Agilent service agents, and is robust enough to work across your entire enterprise. It is a single comprehensive qualification protocol built on a fully automated software program – the U.S.-patented Agilent Automated Compliance Engine (ACE) – that provides consistently configured electronic reports, records, and signatures to help speed compliance reviews and virtually eliminate your regulatory risk.

CrossLab Compliance enables you to reduce regulatory risk with:

- Harmonization across instruments and all major chromatography data systems

- The flexibility to configure testing to your standard operating procedures

- Full automation to ensure adherence to protocol

- Electronic reports and signatures

ACE software is designed to fulfill the data integrity and traceability requirements specified by USP<1058>, GMP Annex 15, and the FDA. Agilent authorized service agents use ACE to configure the test schedule for a system in accordance with your approved Equipment Qualification Plan (EQP). Your native control and acquisition software (a chromatography data system, for example) executes the tests. Test results are then consolidated in the Equipment Qualification Report (EQR), which provides a pass/fail assessment based on the acceptance criteria included in the EQP.

ACE can be deployed in multiple configurations depending on your laboratory environment and requirements. The simplest approach is using a spinning USB drive from which the software application runs, driven by a host computer. The USB drive provides a portable, self-contained environment without any impact to the host computer file footprint or other settings This configuration provides a portable environment with the electronic and procedural controls, and the end-to-end traceability that you need to fully comply with Part 11.

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A more controlled approach is to have Agilent install the ACE software directly on a computer (either PC or server) within your network. This approach has the benefit of tighter integration with the data sources, and simpler workflow documentation. It can also be subject to your existing network controls.

Deploying ACE on a network is referred to as Network Distributed ACE (NDA), and is the focus of this Technical Overview. Once deployed, the ACE software is used by the Agilent service representative to perform qualification services, and provides appropriate technical controls for adherence to data integrity best practices.

Main Benefits of Network Distributed ACE Deployment

The conceptual diagram in Figure 1 shows the main steps and network resources involved in the operation and data transfer process. The clear advantage of NDA deployment is that all components involved in the qualification process are located within the same network environment, and can be subject to common data-access and control procedures.

The data transfer process is under your control throughout the qualification service. Agilent Service agents will set up data storage locations and access controls within your laboratory network in accordance with your IT domain policies and access control procedures. Data backup procedures can be scheduled following the same lab guidelines in existence.

EQPs and EQRs can be stored centrally for a permanent record, and circulated for different approvals. EQPs can be electronically signed by authorized personnel per your QA directives.

Table 1 provides a quick comparison of the main attributes of USB-based deployment and NDA configurations.
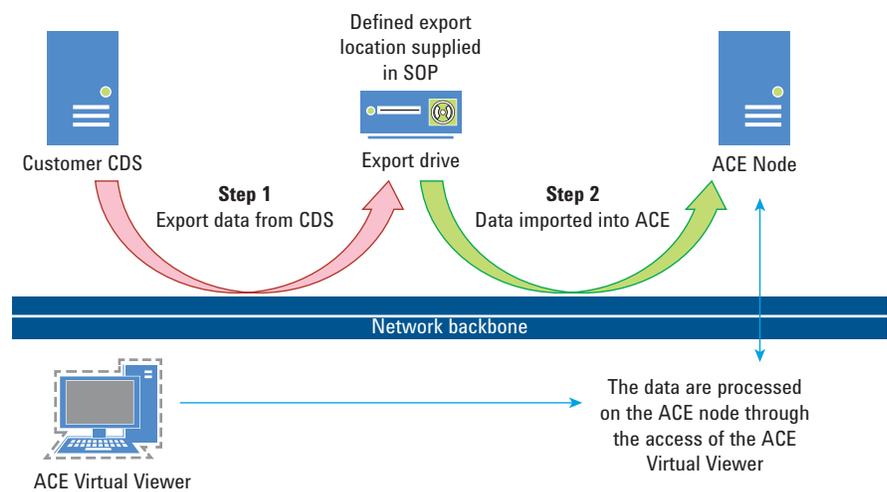

Figure 1. Network-distributed Agilent Automated Compliance Engine deployment.

Table 1. USB-based deployment and NDA configurations.

Attribute	USB-based	NDA–Direct (P2P)	NDA–RDS/Citrix
Part 11 compliant software	✓	✓	✓
Traceable instrument data	✓	✓ Configurable within network	✓ Configurable within network
Raw data records	✓ On DVD	✓ Configurable within network	✓ Configurable within network
EQP/EQR storage location	✓ On DVD	✓ Configurable within network	✓ Configurable within network
EQP signature	✓ External	✓ Available through EQP editor	✓ Available through EQP editor
Session logs review (audit trail)	✓ Static report	✓ Available through Log Viewer	✓ Available through Log Viewer
Backup procedures	N/A	✓ Part of IT policies/procedures	✓ Part of IT policies/procedures
Access security	N/A	✓ Basic permissions	✓ Extended permissions
Thin client	N/A	N/A	

ACE Configuration Considerations

To support the diverse range of qualification needs in laboratories such as yours, NDA can be installed in different ways that add flexibility and additional convenience to the services performed by Agilent. There are three NDA configurations.

- **Direct, peer-to-peer configuration:** The ACE software is installed on a PC node that is part of your network. No additional accounts or technical controls are used; thus, the operation is controlled by the network setup of the host PC. Some manual settings are required to ensure that ports have communication and data access from the chromatography data systems controlling the equipment, (Refer to the NDA Site Preparation Checklist for details.)

- **Microsoft Remote Desktop Services (RDS) configuration:** This facilitates the network privileges and data traffic. This mode makes it easier to operate ACE from the host computer, while maintaining a convenient control of access and privileges common to other applications in your network.

- **Fully integrated, in a thin-client environment (for example Citrix):** This allows advanced and more capable network applications management. This allows a more flexible operation as defined by the Citrix setup and configuration within your laboratory network.

For the Agilent service agent to use the application in all of these configurations, the NDA implementation requires account setup. This includes access to the data files created by the qualified equipment, and privileges to read and write configuration and results files in the ACE working directories. The location and permissions of those directories can be managed manually (direct NDA) or more globally using RDS and Citrix environments.

Once created in accordance with your IT domain policies, these accounts must be maintained on that domain to ensure a sustained ability to perform equipment qualification services.

An NDA installation does not require any additional network functionality over that already required for the normal operation of a distributed chromatography data system. As a result, there are no additional qualification requirements derived from the NDA installation on an already qualified network, which should include data traffic and suitability for intended use.

Supported revisions

Table 2 shows the revision requirements for the three types of Network Distributed ACE supported:

ACE Application Installation and Operational Self-Qualification

ACE is a commercial off-the-shelf (COTS) application developed under the Agilent life-cycle quality program. Every ACE revision is validated, and a certificate of validation is provided to document that status.

All ACE installations – regardless of the media (USB drive, network node) or the server configuration (Direct NDA, RDS/Citrix) – are qualified to confirm their appropriateness for the intended use. This qualification is automatically performed at the end of the software installation by the self-OQ facility in the software, and is documented in the installation verification report.

Table 2. Revision requirements for the three network types supported by NDA.

	NDA (P2P)	RDS	Citrix
ACE Revision	A.02.80.02 SR1 and Higher	A.02.80.02 SR1 and Higher	A.02.80.02 SR1 and Higher
ACE Node O.S (US English)	Windows 7/8/10 (32/64 Bit) Microsoft Server 2008R2/2012R2/2016	Microsoft Server 2008R2/2012R2/2016	Microsoft Server 2008R2/2012R2/2016
ACE Virtual Viewer	Windows 7/8/10 (32/64 Bit) Microsoft Server 2008R2/2012R2/2016 (English/Japanese/Chinese)	Windows 7/8/10 (32/64 Bit) Microsoft Server 2008R2/2012R2/2016	Windows 7/8/10 (32/64 Bit) Microsoft Server 2008R2/2012R2/2016
Citrix revision	N/A	N/A	XA65 – Windows Server 2008 R2 XA76+ – Windows Server 2012 R2

We perform the ACE application qualification, and provide you with a report. The ACE qualification process includes the following components:

- CrossLab software verification tests (SVT) assess the correct installation of file footprint and configuration settings used.

- A concise self-qualification report is always provided with a summary report. An extended self-qualification report is also available by request, detailing the individual test-units that comprise the calculation engine.

- An installation verification report for NDA implementations includes an installation checklist and security test that challenges the authorization rights to access the application.

ACE Software Updates, Revisions, and Maintenance

ACE is used by the Agilent support agent to perform Analytical Instrument Qualification (AIQ) services. No regular updates are needed for the routine operation of the software. When a new release is necessary (for example, new instrument qualifications added or quality enhancements addressing bug fixes), we will provide Change Control documentation for your approval, and procedures will be followed according to standard Change Control procedures, similar to other networked laboratory software policies. ACE updates or upgrades will always be qualified by the Agilent support agent using the built-in self-qualification described earlier.

Data Retention and Backup

An NDA installation provides a centralized way to store and manage qualification documentation — from the qualification plans to the qualification reports. Location, permissions, and retention of the data produced by ACE is to be governed by the criteria you establish for data-access and retention.

Agilent can also deploy Agilent OpenLAB Enterprise Content Manager (ECM) to enable automated report storage with a server-based audit trail and versioning capabilities.

You will define and manage the frequency and other specifics of the data backup process.

Frequently Asked Questions

Would the installation of ACE require network requalification?

No. ACE is a contained application that has no additional impact on the network, or on other applications installed in other client or network nodes. For the direct (peer-to-peer) NDA variant, some ports must remain open during the operation of the ACE software. This may require additional qualification as per your IT Change Control policies. This is not required in the RDS and Citrix versions of an NDA deployment.

Once ACE is installed who is responsible for the management/administration?

ACE is used by the Agilent support agent for AIQ services. Installation in RDS/Citrix environments has some requirements for accounts, access rights, and deployment of the application, which need to be set up and maintained in accordance with your IT domain policies. Once the software is installed, you are responsible for maintaining the accounts on the domain available for the use of your Agilent representative.

Who is responsible for the qualification of ACE (protocols, reports, and so on)?

ACE is a COTS application that has been develop under the Agilent life-cycle quality process. The installation of ACE is always qualified regardless of where it is installed. ACE is qualified using the built-in self-qualification, which includes the IQT report. The documents provided in the self-qualification are:

- SVT report, assessing the file footprint and correctness of settings used

- Concise self-qualification assessment

- Extended self-qualification report (by request only)

- For NDA implementations, an installation checklist is always followed, including a basic security test that challenges the authorization rights on the NDA

How often are software updates required? How are software updates managed?

ACE is used by the Agilent representative to perform AIQ services. No regular updates are needed for the routine operation of the software. There is no need to install new protocol versions unless the equipment to qualify changes (new modules, and so on) covered by the new releases. The ACE platform only requires updates due to quality enhancements addressing bug fixes. You decide if and when to have newly available ACE releases installed, depending on the qualification needs for the equipment in your lab.

Does ACE need to be requalified after a software update?

Yes. Regardless of where it is installed, ACE is always qualified using the built-in self-qualification feature and the IQT. For NDA implementations, there is an installation checklist that covers the NDA specifics.

Can ACE be used with a non-Agilent chromatography data system?

Yes. ACE is compatible with all major chromatography data systems, and the qualification of the analytical equipment is always performed with the native CDS controlling the equipment — exactly as the systems are used in routine operation.

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