Agilent CrossLab
Instrument Qualification Delivery

Flexible service delivery options for instrument qualification services

Agilent

Introduction

With a regulatory focus on data integrity, Agilent continues to develop its qualification services[1] to support this focus, while satisfying different customer requirements; in particular, continued customer support for different service delivery options when using the Agilent Automated Compliance Engine (ACE) software. Data integrity in this context refers to the who, what and where of data that was used in generating an Equipment Qualification Report (EQR). Changes to USP general chapter <1058> on Analytical Instrument Qualification (AIQ), have raised the profile of AIQ[2]. This document reviews the possible ways Agilent uses to install ACE when delivering compliance services.

Option 1, the Agilent primary preferred option is to use Network Distributed ACE, where ACE is installed in a network node within the laboratory LAN infrastructure. The risks of cybersecurity mean that many laboratories are removing USB access to computer ports, making ACE Option 1 the primary option.

Option 2, the Agilent secondary preferred option is to use ACE installed on a dedicated spinning hard disk, where ACE is accessed, but not installed, from another computer with electronic data access.

The alternative option is to use ACE from an engineer's laptop. These three options are represented below and are discussed in detail later in this document.
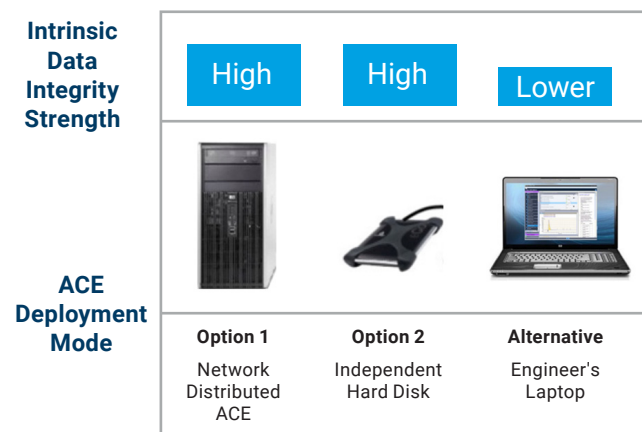
Intrinsic Data Integrity Strength	High	High	Lower
ACE Deployment Mode	Option 1 Network Distributed ACE	Option 2 Independent Hard Disk	Alternative Engineer's Laptop

Figure 1. ACE Options

How does Network Distributed ACE work?

Network Distributed ACE is installed onto a Host PC with a separate/partitioned drive. During the installation process, two services are setup on the O/S, one for security and the second as a watchdog. The ACE PC sits on the network as a shared drive. The engineers access ACE through the networked drive which needn't be installed on to the ACE Virtual Viewer PCs. This is represented in Figure 2 below.
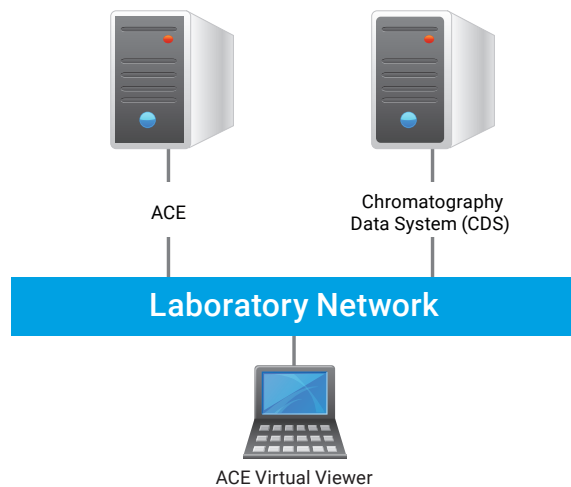
Figure 2. Network Distributed ACE

For the engineers to access the ACE software they need the drive login (Windows NT password, with minimum power user rights) and a personal ACE account which is added through the license tool within ACE with their own unique password.

The data needs to be exported from the Chromatography Data System (CDS), and a shared drive needs to be configured to allow access to the data to be processed by the ACE software.

At any given time the ACE application can handle up to five ACE Virtual Viewers, running three qualification sessions each.

All other features and procedures are the same as ACE installed on a USB drive, Option 2, no other additional training is required.

Definition of ACE qualification use

Depending on the software deployment and installation options, there are three main ways in which the Agilent Automated Compliance Engine (ACE) can be used.

Options 1 and 2 are the strongest data integrity models and are the preferred methods for ACE qualification delivery, and must be used whenever the delivery situation allows. However, the impact of cybersecurity means that many laboratories are moving towards Network Distributed ACE. The remaining options are only to be employed where the first two cannot be satisfied. The customer would still be best served by availing themselves of the protection that ACE provides because of the risks and challenges associated with paper and Excel based qualification protocols[3].

These options are as follows:

– Network Distributed ACE (Option 1), where ACE is installed in a network node within the laboratory LAN infrastructure. This model requires collaboration with the customer to load ACE behind the customer firewall. The data locations are captured in the EQR thus removing concerns regarding the data workflow in the delivery.

– Dedicated spinning USB drive (Option 2), where ACE resides in an independent drive that can be driven from other PCs, such as the Field Service Engineers (FSE) laptop or the system controller (where the CDS resides). Because the USB spinning drive is connected to the CDS, this alternative to Option 1 is an equally valid approach. This has been the most prevalent delivery method for most situations. Data is imported directly into the data manager tool in ACE thus capturing the actual data path in the report, which removes data traceability concerns.

– Service Portable Laptop (Alternative, Option 3), whereby the ACE software is installed on the FSE's portable computer. Installation on service engineer's laptop is typically done for those customers that do not allow access to the CDS, USB port or want ACE installed on the customer network (Options 1 and 2 above) – it is not preferred by Agilent due to the data integrity aspects but may be the only option available. This option requires customer pre-approval to remove later questions on data integrity.

Automated vs. Manual data entry

In all instrument qualification, it must be possible to access the raw data files generated by the instrument during the testing process – be that directly using the connection between network nodes (or with the server); or indirectly through approved transfer location. The raw data files are subsequently used by ACE to produce the compliance data included in the EQR. In that regard, a variation to the schema is also possible whereby the compliance data is generated by the CDS instead of ACE, and then manually transcribed into ACE for the EQR preparation. This option – referred to as **Manual Data Entry** – is also not preferred like Option 3. This option (manual data entry) is a generic compliance delivery possibility that is only used for corner case situations, where no other compliance solution exists (such as customer-requested special hardware or software being used to collect the compliance data). Like above, it requires customer pre-approval to remove later questions about data integrity.

The recommended ACE usage in detail

The choice of which option to use for qualification delivery should be made in accordance with the laboratory data integrity and general procedural requirements.

The following statements summarize the most important aspects of the preferred options listed above:

– Installing ACE in a separate node (a.k.a. the Host PC) on the same network as the system controller, offers an equivalent level of data traceability as if the installation was physically done in the system controller itself. With this arrangement both the System Controller (where the CDS resides) and the ACE Host PC are identified and seen by the server, subject to the same firm's data access controls and general IT policies. The Audit trail within the CDS will record the data movements between nodes or client/ server when done, and the Data traceability features within ACE will identify the processing directory also within the same cluster and therefore ensuring the end-to-end data traceability.

– A spinning USB drive is capable of running the ACE software entirely off the spinning drive, not leaving any footprint on the host computer. Therefore, it can be connected directly to the system controller (where the CDS resides) without any alteration of the qualification status of the system. Alternatively, the spinning drive can be driven by another host PC within the same network for an additional level of topological protection. For additional assurance the USB drive unit can reside permanently on the firm premises, being utilized by the Agilent FSE at the time of the service delivery.

Network Distributed ACE requirements

ACE must be installed in a Host PC with a separate drive, different from that of the Operating System (OS).
The installation requirements are:

- 500 GB in size
- NTFS Format
- Attached to a network which must be accessible by the clients
- The User must have local administration rights for installation

Operational rights to run the ACE software:

- ACE Node PC (where ACE is installed) requires user with permissions with a minimum of power user rights assigned to the shared drive
- A maximum of 5 users can access Network Distributed ACE at any given time, with up to 3 sessions open per user

Firewall requirement: Requires an exception to ports 11121-11141, on ACE node, Clients and on switches/ Smart Hubs to be open on the network.

Further technical details about Network Distributed ACE requirements can be found in References 4 and 5.

References

1. Move Your Analytical Instrument Qualification to Agilent ACE, 5991-9350EN

2. Impact of USP <1058>, Technical Overview, 5991-8463EN

3. Analytical Instrument Qualification, comparison of qualification approaches across electronic, excel, or paper-based protocols for HPLC, 5994-0506EN

4. Assured Data Integrity of Analytical Instrument Qualification, 5991-8563EN

5. Data Integrity for Analytical Instrument Qualification, 5991-8462EN

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