

# AGILENT CROSSLAB QUALIFICATION SERVICES



## Flexible Use Cases for Instrument Qualification Services

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### Introduction

With heightened scrutiny with respect to data integrity, a review of the most important Use cases of the Agilent Automated Compliance Engine (ACE) is presented below. Data integrity in this context refers to the who, what and where of data that was used in generating an Equipment Qualification Report (EQR). This paper reviews the possible ways to install ACE when delivering compliance services. The options are listed with the strongest data integrity models first. The first two are the preferred methods and must be used whenever the delivery situation allows. The remaining options are only to be employed where the first two cannot be satisfied and the customer would still be best served by availing themselves of the protection that ACE provides rather than resorting to paper or other manual options.

### Definition of the Use Cases

Depending on the software deployment and installation options, there are three main utilization cases of the Agilent Automated Compliance Engine (ACE), as follows:

1. Network-Distributed ACE (NDA), 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.
2. Dedicated spinning USB drive, where ACE resides in an independent drive that can be driven from other PCs, such as the 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.
3. Service Portable Laptop, whereby the ACE software is installed on the FSE's portable computer. Installation on service engineer's laptop typically is 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. Requires customer pre-approval to remove later questions on data integrity.



## Automated vs. Manual Data Entry.

In all use cases there 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 the temporary storage in a 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 is referred to as Manual Data Entry, also not preferred as in number 3, but a generic compliance delivery option 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 Use Cases in Detail.

The choice of Use Case for the service 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:

- 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.

### ACE Loaded on a spinning USB drive



- 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.



## How does the Network Distributed ACE work?

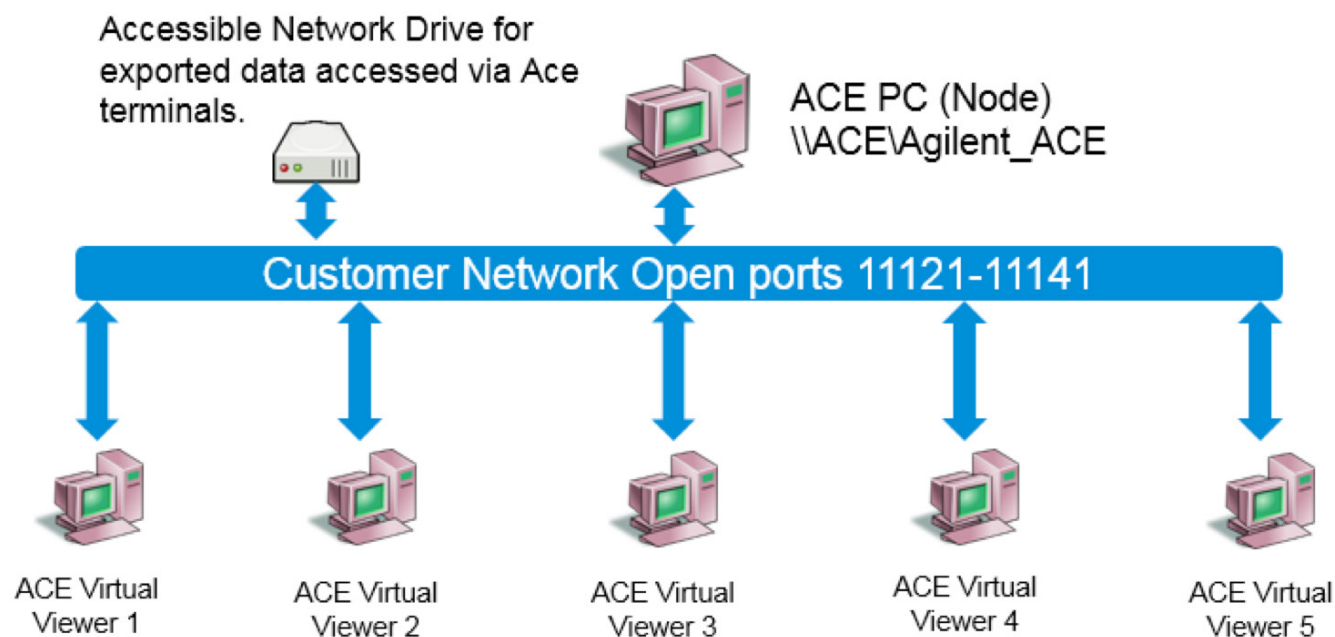
The Network Distributed ACE is installed onto a Host PC with a separate/partitioned drive. During the installation process two services are setup on the O/S, one for security and the second as a watchdog. The ACE PC sits on the network as a shared drive. The engineers access ACE through the networked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

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

If the data needs to be exported from the Chromatography Data System (CDS) then a shared drive should also be available to store and 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, no other additional training is required.



**Figure 1.** Conceptual diagram of Network-Distributed ACE showing the ACE PC Node with multiple Virtual Viewers

## Network Distributed ACE Requirements.

ACE must be installed in a Host PC with a separate drive, different from that of the Operating System (O.S). 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 the NDA 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 switch's/Smart Hubs to be open on the network.

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