Assured data integrity for analytical instrument qualification

Agilent CrossLab Network Distributed ACE (NDA)



Regulatory audit data integrity focus

Data Integrity is driving compliance change, as organizations standardize on fewer, more secure ways of doing things. To successfully defend results, you must be prepared to prove that your data have not been compromised.

In response to the continued regulatory focus on data integrity, Agilent has upgraded our Automated Compliance Engine (ACE), which is an audit-ready, paperless qualification software for instrument qualification and reporting.

Specifically, we've enabled the installation of Network Distributed ACE (NDA) within laboratory networks to simplify deployment and data integrity alignment. Like ACE, NDA is independent of software, such as the Chromatography Data System (CDS). It is also data integrity aligned, and provides qualification across a wider range of analytical technologies than CDS-based solutions

The Agilent CrossLab team can take the stress out of meeting compliance requirements

NDA supports

- · Electronic data transfer
- Automated traceability
- · Consistent IT control
- Electronic approval
- Simplified protocol management
- Data integrity alignment
- ▲ All within your IT domain ▲

NDA documentation

- Site requirements
- Installation checklists
- · Part 11 compliance
- ACE qualification
- Validation certificates





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Imagine how productive you would be if you could access a global team of experts who strive to deliver insight every time they interact with your lab. That's just what you get with Agilent CrossLab—the world leader in innovative laboratory services, software, and consumables.



Practical advantages of Network Distributed ACE

NDA ensures secure, end-to-end traceability in qualification work by enabling direct electronic data transfer from the Chromatography Data System (CDS) into NDA. Qualification data are integrated into qualification reports—automatically retaining traceability between the systems and associated metadata.

What's more, software and data access are protected by the same IT policies, controls, security, back up, and archiving that apply to other systems within your validated IT environment. That means qualification plans and reports are retained within your IT domain, ensuring data integrity and consistency. Implementing NDA also facilitates harmonized qualification within your lab and across your organization, supported by dedicated Agilent compliance specialists.

In addition, NDA is independent of your Chromatography Data Systems (CDS), so you can harmonize Analytical Instrument Qualification (AIQ) practices and simplify audit preparation.

Controlled flexibility

Your lab's compliance priorities are unique. That is why ACE offers three compliance delivery options (use cases): Engineer's laptop, USB hard disk, and Network Distributed ACE.

In all cases, the tests, setpoints, and limits are defined through Equipment Qualification Plans (EQPs), which are the configurable electronic protocols used by ACE. EQPs ensure that the testing performed during Operational Qualification (OQ) includes range of use—a fundamental requirement of USP <1058> and GMP Annex 15.

NDA also allows your laboratory to safely and seamlessly move from Excel- or paper-based protocols, toward harmonized AIQ processes for chromatography, spectroscopy, and other instrument technologies.

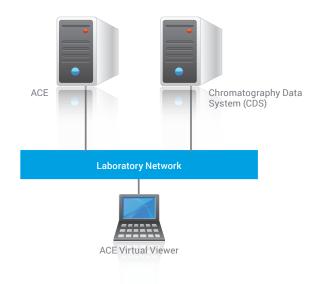
Easy deployment

To facilitate implementation, NDA supports common industry software deployment models—including "thin client" systems, such as Windows remote desktop services (RDS) and Citrix® applications. NDA also runs in several Microsoft Windows operating environments, including Windows Server 2008, 2012, and 2016.

Network Distributed ACE deployment configurations:

- Terminal Services (TS)
- Remote Desktop Services (RDS)
- Citrix (XenApp 6 and 7)
- Windows 7, 8, and 10
- Windows server 2008, 2012, and 2016

Network Distributed ACE



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