



Agilent Network ACE

How it satisfies ALCOA + data integrity requirements

Adapt to evolving data integrity audits

With increasing experience in preparing for data integrity audits, many laboratories have begun to ask the following question:

Is this qualification compliant with ALCOA + requirements?

Many companies and data integrity guidance documents, such as the World Health Organization (WHO) guidance,¹ have largely focused on the foundation of core ALCOA principles, for data integrity requirements. However, laboratories must ensure that qualification satisfies additional requirements associated with ALCOA + and not just core ALCOA*.

Evolve purposefully with best practices

Controlled and secure data export from a Chromatography Data System (CDS) into a LIMS, lab management, Network ACE ([explanation video](#)) or other validated data processing software is quite common. Therefore, making impulse-based software changes, such as locking out analysts from all chromatographic integration, or inhibiting import/export of data from validated systems are not recommended. This is because underlying needs are not addressed, and data integrity best practice requires controlled and planned change.² Data integrity best practice requires gap analysis, risk assessment, and prioritization based on understanding of workflow, access privileges, and regulatory requirements. This drives sustainable change with minimal impact.

Implement Network ACE and avoid IT bottlenecks

IT support is essential for successful Automated Compliance Engine (ACE) implementation. To help facilitate this, Agilent have produced a document that clarifies IT requirements and responsibilities⁴. This can be used as a reference to facilitate a short Agilent meeting with key stakeholders (e.g., Lab Manager, Quality person and an IT representative). This meeting will be used to clarify IT resource requirements to accelerate implementation. This is a data integrity initiative, to enhance ALCOA + compliance, that helps ensure instruments are qualified "as used".



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Again Per independent surveys

* Many data integrity guidance documents are now available, but WHO document 9961 is recognized as providing the most pragmatic guidance on implementing ALCOA, because 41% of the document (Appendix 1) is dedicated to it.³



Network ACE – how it satisfies ALCOA +

Agilent implemented Network ACE to meet evolving data integrity requirements, such as ALCOA +:

ALCOA +	Qualification Requirement	Network ACE Evidence
A Attributable	Qualification work must be attributable to the engineer performing the work.	Unique user log in and audit trail in electronic systems used by the engineer.
L Legible	Engineers qualification work, records and deviations must be legible (readable).	Electronic protocols and reports with clear pass/fail results and test rationale.
C Contemporaneous	Evidence of qualification actions recorded as they are performed (real time).	Information recorded as electronic protocols are completed (networked time stamps).
O Original	Original data or certified true copy.	Imported data is encrypted, checksummed with metadata and end to end traceability. ⁵
A Accurate	Errors, corrections, deviations, amendments, and repeat qualification tests must be recorded.	Validated calculations within workflow driven electronic protocols. Secure, audit trailed reports.
+ Complete	All qualification tests and data, including repeat tests, recorded and available for review.	Complete record of audit trailed work. Secure qualification test counter and all certificates.
Consistent	Consistent qualification work and application of date/time stamps, protocol completion.	Harmonized electronic protocols, workflows, and deviation reports (network time stamps).
Enduring	Qualification protocols and reports recorded in a secure, controlled, and enduring manner.	Electronic protocols and reports are stored (and backed up) on the customer network.
Available	Qualification records must be available throughout the required retention time.	All ACE data and electronic information is stored and backed up on the customer network.

Validated software platform

The Agilent ACE software is developed and validated through standard Agilent processes within our accredited quality management system. Network ACE is the network version of ACE, the software platform used by Agilent to deliver our #1 ranked qualification services.⁶

ACE is classed as GAMP category 3 software⁷ (Commercial of-the-Shelf or "COTS"). During installation, an automated ACE IQ/OQ document is created for the software implementation, which confirms successful completion of installation and functionality tests. Together with the validation certificate, site requirements documents, and ACE 21 CFR Part 11 Compliance certificate, the IQ/OQ satisfies change requirement needs of regulated laboratories.

Contact Agilent

Contact your local Agilent representative to find out more about Network ACE and Agilent [qualification services](#)

www.agilent.com/chem/assured-data-integrity

DE.5302893518

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Published in the USA, July 31, 2022
5994-1660EN

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