



Agilent CrossLab Network Distributed 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

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 Distributed ACE and avoid IT bottlenecks

IT support is essential for successful Automated Compliance Engine (ACE) implementation, but the workload is small. Because Agilent understands IT requirements for Network Distributed ACE, a short meeting with the Lab. Manager, a Quality person, and IT, simplify and accelerate implementation. Without this key meeting, overestimation of IT needs can delay the project, as it competes with other IT projects. This is a data integrity initiative, which ensures ALCOA + compliance, and that ensures instruments are qualified "as used" and simplifies workflow.

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From Insight to Outcome



* 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

For more information, visit:

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

Network Distributed ACE – how it satisfies ALCOA +

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

ALCOA +	Qualification Requirement	Network Distributed 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	Secure electronic data includes metadata and automated end to end data traceability
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 Distributed ACE is the network version of ACE, the software platform used by Agilent to deliver our #1 ranked compliance services.⁴

ACE is classed as GAMP category 3 software⁵ (Commercial off The Shelf). 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.

References

1. Annex 5, Guidance on Good Data and Record Management Practices, World Health Organization (WHO), *WHO Technical Report Series No. 996*, May **2016**.
2. Smith, P. Data Integrity in the Analytical Laboratory, *Volume 38, Issue 5*, May **2014**.
3. Smith, P. Confused by Data Integrity Guidance, *GAMP UK*, Community of Practice ISPE Meeting, May **2019**.
4. Insights From Global Compliance Services Survey, *Agilent Technologies*, publication number 5994-1752EN, February **2020**.
5. GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, February **2008**.

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