Reliable Context

RELIABLE CONTEXT / RESEARCH & PRACTICAL GUIDANCE

ALCOA and ALCOA+ Explained: Data Integrity Attributes

> Reliable Context is a kernel of truth: a system of record for organizations that fuse private and public information and must defend every value they act on. One canonical record per real thing, a cited source and an observation date behind every value, unknowns declared rather than left blank, and any past state of the record reproducible.

Published by Reliable Context · 2026-10-29 · alcoa · alcoa plus · alcoa+ data integrity · alcoa principles · alcoa data integrity examples

Original article: https://reliablecontext.com/articles/alcoa-plus-explained-data-integrity-principles



In this article

1. The short answer
2. Where ALCOA sits in the guidance
3. The original five
4. The additions in ALCOA+
5. Summary table
6. Paper, electronic and hybrid records
7. A worked example: one assay result
8. From principle to system property
9. Self-inspection checklist
10. Sources

The short answer

ALCOA is an acronym for five attributes that regulated records should have: **Attributable, Legible, Contemporaneous, Original and Accurate**. ALCOA+ adds four: **Complete, Consistent, Enduring and Available**. The European Medicines Agency's clinical-trials guideline goes one step further with ALCOA++, adding **Traceable**. The acronyms come from good documentation practice in pharmaceutical and other GxP (good practice) regulated work, and they now appear in the data integrity guidance of the US Food and Drug Administration (FDA), the UK Medicines and Healthcare products Regulatory Agency (MHRA), the World Health Organization (WHO), the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the EMA.

The acronym is not a regulation. In the United States, the binding requirements are in the current good manufacturing practice (CGMP) regulations, and FDA's guidance maps each ALCOA attribute to sections of 21 CFR parts 211 and 212 (FDA, Data Integrity and Compliance With Drug CGMP, Q&A, December 2018, Q1(a) and footnote 5). What the acronym gives quality and data teams is a shared checklist: for any record, can you show who made it, when, what it originally said, and that nothing has been lost or quietly changed since?

This article defines each attribute using the regulators' own wording, shows the failure that typically breaks it, and turns it into a property a record system must be able to demonstrate. It is educational, not regulatory or legal advice.

Where ALCOA sits in the guidance

Each regulator uses the acronym slightly differently.

Source	Jurisdiction / scope	Acronym used	How it is framed
FDA Q&A guidance, Dec 2018	US, drug CGMP	ALCOA	"Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate (ALCOA)"

Source	Jurisdiction / scope	Acronym used	How it is framed
MHRA GXP Data Integrity Guidance and Definitions, Rev. 1, March 2018	UK, all GxP	ALCOA, with ALCOA+ explained	"There is no difference in expectations regardless of which acronym is used" (§3.10)
WHO TRS 1033, Annex 4, 2021	WHO guidance, GxP	ALCOA+	Data governance "should ensure the application of ALCOA+ principles" (§4.4)
PIC/S PI 041-1, 1 July 2021	Participating inspectorates, GMP/GDP	ALCOA and ALCOA+	Table of the nine attributes with a requirement for each (§7.5)
EMA guideline EMA/INS/GCP/112288/2023	EU, clinical trials	ALCOA++	Ten attributes "considered of universal importance to data" (§4.5)

MHRA's note on history is useful: "ALCOA was historically regarded as defining the attributes of data quality that are suitable for regulatory purposes. The '+' has been subsequently added to emphasise the requirements" (MHRA, §3.10). In other words, the four additions make explicit what inspectors already expected.

Two definitions frame everything else. FDA defines data integrity, for the purposes of its guidance, as "the completeness, consistency, and accuracy of data". MHRA defines it as "the degree to which data are complete, consistent, accurate, trustworthy, reliable and that these characteristics of the data are maintained throughout the data life cycle" (MHRA, §6.4). The phrase that matters is "throughout the data life cycle": integrity is not checked once at entry; it must hold until the record is destroyed at the end of its retention period.

The original five

Attributable

PIC/S: "It should be possible to identify the individual or computerised system that performed a recorded task and when the task was performed. This also applies to any changes made to records, such as corrections, deletions, and changes where it is important to know who made a change, when, and why" (PIC/S PI 041-1, §7.5).

Typical failure: shared logins. FDA answers the question directly: "When login credentials are shared, a unique individual cannot be identified through the login and the system would not conform to the CGMP requirements in parts 211 and 212." Shared read-only accounts are acceptable for viewing data, but not for actions such as second-person review (FDA Q&A, Q5). MHRA is equally direct: "shared logins or generic user access should not be used", and where a system supports individual access, "this function must be used. This may require the purchase of additional licences" (MHRA, §6.16).

Checkable property: every create, change and delete event names one individual or one identified system, with a timestamp.

Legible

PIC/S: records should be "readable and unambiguous in order for it to be understandable and of use". EMA adds a requirement that matters for data pipelines: "changes to data, such as compression, encryption and coding should be completely reversible" (EMA guideline, §4.5).

Typical failure: a correction that overwrites the original entry, or a proprietary file format that can no longer be opened.

Checkable property: the original and every corrected value can be displayed in human-readable form for the full retention period.

Contemporaneous

PIC/S: "The evidence of actions, events or decisions should be recorded as they take place." EMA specifies that "the time point of the observation and the time point of the storage should be kept as part of the metadata", and that date and time should be captured automatically and "set by an external standard" (EMA guideline, §4.5). FDA ties the attribute to §§ 211.100(b) and 211.160(a) and states: "You must document, or save, the data at the time of performance to create a record in compliance with CGMP requirements" (FDA Q&A, Q12).

Typical failure: results written on scrap paper and transcribed at the end of the shift; a backdated entry; a workstation clock that users can change.

Checkable property: each value carries two system-generated times, when it was observed and when it was recorded, from a controlled clock.

Original

PIC/S: "the first-capture of information, whether recorded on paper (static) or electronically (usually dynamic...). Information that is originally captured in a dynamic state should remain available in that state." A verified "true copy" can stand in for the original (PIC/S PI 041-1, §7.5 and §7.7).

Typical failure: printing dynamic data. FDA explains that a paper printout may be the original record for a pH meter or balance, but electronic records from instruments such as FT-IR are dynamic and "a printout or a static record does not preserve the dynamic record format that is part of the complete original record" (FDA Q&A, Q10).

Checkable property: the first-captured file or entry is retained in its native form, and any copy is linked to it with a verification of sameness.

Accurate

PIC/S: "Records need to be a truthful representation of facts to be accurate", supported by qualification and calibration, procedures, deviation management and trained staff. EMA adds that "the process of data transfer between systems should be validated to ensure the data remain accurate" (EMA guideline, §4.5).

Typical failure: a validated instrument feeding an unvalidated spreadsheet whose formula silently rounds; a manual transcription with no second check.

Checkable property: every transformation between capture and report is validated or independently verified, and the chain can be shown.

The additions in ALCOA+

Complete

PIC/S: "All information that would be critical to recreating an event is important when trying to understand the event. It is important that information is not lost or deleted." For electronic data, completeness "includes relevant metadata" (PIC/S PI 041-1, §7.5). The US regulation is explicit for laboratories: records "shall include complete data derived from all tests necessary to assure compliance with established specifications and standards" (21 CFR 211.194(a)).

Typical failure: keeping only the final result. FDA's answer to whether a laboratory may save only the final results of reprocessed chromatography is "No": "each result" must be "retained for review" (FDA Q&A, Q14). Trial injections, aborted runs and deleted files are the classic inspection findings.

Checkable property: the system can list every attempt, including failed and superseded ones, and no record can be deleted without leaving a trace.

Consistent

PIC/S: information should be "created, processed, and stored in a logical manner that has a defined consistency", including standard approaches to "chronological sequencing, date formats, units of measurement, approaches to rounding, significant digits". EMA asks for processes "to detect and/or avoid contradictions" (EMA guideline, §4.5).

Typical failure: a timestamp sequence where a review precedes the result it reviews; two sites recording the same unit differently.

Checkable property: event sequences are monotonic and units, formats and rounding rules are defined and enforced.

Enduring

PIC/S: records should "remain intact and accessible as an indelible/durable record throughout the record retention period" (PIC/S PI 041-1, §7.5).

Typical failure: data on an instrument's local drive with no backup; a vendor system decommissioned without migrating its audit trail.

Checkable property: backups and archives are tested by restoration, and system retirement includes migration of records and their metadata.

Available

PIC/S: records "should be available for review at any time during the required retention period, accessible in a readable format to all applicable personnel who are responsible for their review" (PIC/S PI 041-1, §7.5). EMA phrases it as "available when needed".

Typical failure: an archive that can be restored only by a vendor, in weeks, while an inspector is on site.

Checkable property: a defined record can be retrieved, with its metadata, within a stated time.

Traceable (EMA's ALCOA++)

EMA: "Any changes to the data, to the context/metadata should be traceable, should not obscure the original information and should be explained, if necessary. Changes should be documented as part of the metadata (e.g. audit trail)" (EMA guideline, §4.5).

Summary table

Attribute	Short definition	Common failure	Property to demonstrate
Attributable	Who did it, and when	Shared or generic logins	Every event names one person or system
Legible	Readable, unambiguous, reversible	Overwritten corrections	Original and corrected values both visible
Contemporaneous	Recorded when it happened	Transcription later; backdating	Observation and record times, controlled clock
Original	First capture, or verified true copy	Printing dynamic data	Native first capture retained
Accurate	Truthful representation of fact	Unvalidated transfer or formula	Validated transformations end to end
Complete	Nothing critical lost or deleted	Only final results kept	Every attempt listed, deletions traced
Consistent	Defined, logical, contradiction-free	Out-of-order timestamps	Monotonic sequences, enforced formats
Enduring	Intact for the retention period	No tested backup	Restorable archives with metadata
Available	Retrievable for review when needed	Vendor-only restore	Retrieval within a stated time
Traceable (ALCOA++)	Changes explained, original not obscured	Silent edits	Audit trail with who, what, when, why

Paper, electronic and hybrid records

The attributes apply to every medium. WHO calls for regular review of data for consistency with ALCOA+ principles that "includes paper records and electronic records" (§4.11), and where a system "cannot support ALCOA+ principles by design (e.g. legacy systems with no audit trail), mitigation measures should be taken for

defined temporary periods", such as add-on software or paper-based controls (WHO TRS 1033 Annex 4, §11.12). MHRA requires that for hybrid systems, where paper and electronic records coexist, "it should be clearly documented what constitutes the whole data set" (MHRA, §4.3).

The audit trail is the mechanism that makes most attributes demonstrable for electronic records. FDA defines it as "a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record", with an HPLC example that includes user name, date and time, integration parameters and reprocessing details (FDA Q&A, Q1(c)). WHO describes it as capturing "the 'who, what, when and why' of the action" (WHO TRS 1033 Annex 4, Glossary). The site's audit trail glossary entry gives a shorter definition.

A worked example: one assay result

The example is fictional. **Halden Therapeutics AG is a fictional company**; the analyst, instrument and numbers are invented.

An analyst at Halden's Basel laboratory runs an assay on batch HT-2026-0412. The first injection gives 97.1% of label claim; the analyst reprocesses with a different integration and gets 99.4%. The audit trail should allow an inspector to reconstruct the following:

Time (UTC)	User	Action	Value	Reason	Attributes evidenced
2026-04-14 09:12:03	a.keller	Injection 1 acquired (raw file `inj1.raw`)	—	—	Attributable, Contemporaneous, Original
09:14:40	a.keller	Integration v1, result	97.1%	—	Accurate, Complete
09:31:12	a.keller	Reprocessing, integration v2	99.4%	"Baseline drawn through impurity peak; SOP-LAB-022 §5.3"	Traceable, Legible (v1 still visible)
10:05:55	m.roth	Second-person review	both results viewed	"Reprocessing justified"	Attributable (reviewer), Complete

The failure version of the same morning has the same final number and no first row, no second row and no reason. That is exactly what FDA's Q14 and PIC/S's "Complete" requirement prohibit: the 97.1% result is part of the record whether or not it was reported.

From principle to system property

Inspectors test ALCOA+ by asking for evidence. A practical way to prepare is to translate each attribute into a query the system must be able to answer without manual reconstruction:

1. For record X, who created it and who changed it, with times? (Attributable)
2. Show the value as first captured and every later value. (Original, Legible, Traceable)
3. What was the gap between observation time and record time? (Contemporaneous)
4. List every run, including failed and reprocessed ones, for batch Y. (Complete)

5. Are any event sequences out of order? (Consistent)
6. Restore this record from archive, with metadata, now. (Enduring, Available)
7. Which transformations sit between the instrument and the certificate of analysis, and how was each validated? (Accurate)

The same questions apply outside the laboratory, to any fact a regulated organization relies on: a supplier's registered address, a product's approval status, a clinical trial's phase. Each value should be attributable to a source and a person, recorded when read, retained in its original form, and changeable only with a trace. The site's method note on retaining source copies and its pharma sector page apply that reasoning to external facts.

Self-inspection checklist

- Individual user accounts are enforced for every system that creates or changes GxP data; shared accounts are view-only.
- System clocks are synchronized to an external standard and cannot be changed by users.
- Audit trails are on, cannot be disabled by users, and record who, what, when and why.
- Dynamic electronic records are retained in native form; printouts are not treated as originals.
- Every test attempt, including aborted and reprocessed runs, is retained and reviewable.
- Corrections never obscure the original entry.
- Formats, units and rounding are defined in procedures and enforced in systems.
- Backups and archives are restored on a schedule, including metadata.
- Retrieval time for an archived record is known and acceptable for an inspection.
- Hybrid systems have a documented definition of the complete data set.

Reliable Context publishes a related guarantee for organizational facts: a cited, verbatim, dated source behind every value, with any past state reproducible.

Sources

1. FDA, Data Integrity and Compliance With Drug CGMP: Questions and Answers, Guidance for Industry, December 2018 - ALCOA definition and CFR mapping (Q1, fn 5); audit trail; shared logins (Q5); static vs dynamic (Q10); time of performance (Q12); reprocessing (Q14).
2. MHRA, GXP Data Integrity Guidance and Definitions, Revision 1, March 2018 (PDF) - ALCOA vs ALCOA+ (§3.10); data integrity definition (§6.4); shared logins (§6.16); hybrid systems.
3. WHO, Guideline on data integrity, TRS 1033 Annex 4, 2021 (PDF) - ALCOA+ glossary definition; data governance; audit trail definition.
4. PIC/S, PI 041-1, Good Practices for Data Management and Integrity in Regulated GMP/GDP Environments, 1 July 2021 - attribute-by-attribute requirements (§7.4-7.5); true copies (§7.7).
5. EMA, Guideline on computerised systems and electronic data in clinical trials, EMA/INS/GCP/112288/2023 (PDF) - ALCOA++ including Traceable (§4.5).
6. 21 CFR 211.194, Laboratory records (eCFR) - "complete data derived from all tests".

Source links

Links cited in this article, in order of first appearance. Full addresses are provided for readers using extracted text.

1. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-integrity-and-compliance-drug-cgmp-questions-and-answers
2. https://www.gov.uk/government/publications/guidance-on-gxp-data-integrity
3. https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/inspections/trs1033-annex4-guideline-on-data-integrity.pdf
4. https://picscheme.org/docview/4234
5. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-and-electronic-data-clinical-trials_en.pdf
6. https://assets.publishing.service.gov.uk/media/5aa2b9ede5274a3e391e37f3/MHRA_GxP_data_integrity_guide_March_edited_Final.pdf
7. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-211/subpart-J/section-211.194

THE PUBLISHER

About Reliable Context

Reliable Context is a system of record for organizations that fuse private and public information and must defend every value they act on.

The guarantees

One canonical record per real thing: duplicates resolve by rule, ambiguity is shown rather than hidden, and related organizations relate without ever being merged. A verbatim, cited source and an observation date sit behind every value. Unknowns are declared as not found, blocked or not applicable with a reason, never left as an empty cell. Any past state of the record is reproducible, together with what changed since.

Where it runs

It runs inside the customer's perimeter, one database per organization. Permitted sources, model routing, reader clearance and retention are set as the customer's own policies, and every value is exportable with its chain of custody for an auditor or regulator.

What it is not

It is not a vector database or a RAG framework, not a data catalog, MDM or data-quality suite, not a CRM or data-enrichment vendor, and not a chatbot or AI assistant. Where a reader needs one of those, the honest answer is to say so and point them there.

Visit

See Reliable Context.

Reliable Context is in production use in two sectors; more than six thousand of its identity decisions were made by rule and none has been reversed. Articles published here explain general practice, cite their primary and academic sources, and name the jurisdiction of any regulatory rule they describe. They are not legal, regulatory or compliance advice for a specific organization, and requirements change.

Website: https://reliablecontext.com

This article is educational. Verify consequential medical, legal, financial, regulatory and technical decisions with appropriate professionals and the cited primary sources. Company services are described separately from the article's research findings.