

LOGFILE Feature 47/2021

Original Data and True Copies

Excerpt from the [GMP Compliance Adviser, Chapter 15.B.4.4](#)

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For almost all purposes in the GMP sector, it is mandatory to use original data and documents or only true copies thereof. This requirement also forms part of the ALCOA principle. Since it is only possible in a few cases in operational practice to work with the sole original document, the question arises as to what requirements are to be placed on the requisite true copies. Figure 15.B-7 compares different types of copies with the concept of original data.

Definition of a true copy according to WHO
A true copy is a copy of an original recording of data that has been verified and certified to confirm it is an exact and complete copy that preserves the entire content and meaning of the original record, including, in the case of electronic data, all essential metadata and the original record format as appropriate.

Figure 15.B-6 Definition of true copy excerpted from the glossary of the WHO Guidance on good data and record management practices (TRS No. 996, Annex 5, 2016)

Data type	Paper data	Electronic data types
Original data	Initial capture of a document, data entry, or first printout. Primary data or original data is the first or originally captured data or information and any data subsequently required to fully reconstruct the performance of the GxP activity.	Initial e-file
Copy	Collective term for duplicates, transferred data or multiple printouts. "Unchecked" copies, i.e. copies that have not been checked, are only permitted in the GxP sector for information purposes, but not as a basis for	Data transfers or multiple storage of the same record. Digitized paper documents are also often referred to as "electronic copies". Uncontrolled and non-validated electronic copies are not permitted, as there

	evaluations or as work instructions.	is a risk of data loss, e.g. through accidental or intentional overwriting of existing data records
True copy	Also: exact copy, certified copy, one-to-one copy Exact verified copy of a primary recording (certified copy); a true copy must always be labelled as such.	Copy created using a validated process that captures not only the pure numerical values but also the metadata, such as date/time stamps. The exact, verified copy of the original record can be static (e.g., as a PDF file) or dynamic (such as in an electronic record that the user can interact with).
Verified copy	Paper document that is checked and issued to defined recipients according to the distribution list. A verified copy must always be identified as such (e.g. stamp, watermark, colored paper).	Not defined. Access to electronic documents must be regulated via access authorisations. (In companies that have established electronic signatures, control or marking of copies by means of electronic signatures must be ensured).

Figure 15.B-7 Comparison of terms used for copies and original data

To avoid mistaking them for the original documents, copies must be marked (authorised copy, verified copy) and signed and dated by the originator. In the past, companies were often required to use only blue pens for signatures or entries in order to be able to distinguish originals from copies. In the age of modern color copiers, this requirement has become obsolete and has no legal basis.

If copies consist of several pages, it is advisable to either permanently bind them together, e.g. with a rivet, and mark only the first page, or to label each page accordingly (page ... of ...).

Thermal paper is used less and less often and is unsuitable for storage because it is not document-proof. This must be taken into account if, for example, chart recorder printouts are produced on this type of paper. In this case, it is recommended to make a copy on normal paper. The copy and the original with the initials or signature must be attached to the documentation.

Small-format attachments (e.g., labels, weighing records) must be pasted and dated and signed off "over the edge" to protect them from loss, i.e., half of the writing on the pasted slip, the other half on the backing sheet.

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