

<b>ALCOA Standard</b>	<b>Paper Records</b>	<b>Electronic Records</b>
A = Attributable	Data and supporting source can be linked to a unique subject and to the author; i.e. can readily determine who wrote the information and to which subject it pertains.	Same as paper. Electronic signatures must be verifiable and there must be an audit trail.
L = Legible	The handwriting can be read to determine what is written.	If electronic information is encrypted, it should be readable on the screen and/or in print-outs.
C = Contemporaneous	Data is recorded/written at the time that it occurs.	System should time/date stamp electronic entries and have an audit trail to verify timing.
O = Original	Where the pertinent information is documented first. If information is copied from the original and supplied as source documentation, there must be a certification process confirming that it is an exact copy with all the same attributes as the original. Note that “shadow files” typically do not have this certification process and cannot be considered original or source documentation.	Pertinent information may be documented first in an electronic medical record or electronic study system. If printouts are kept as the originals, they must be certified to be an exact copy with all the same attributes as the original.
A = Accurate	Data recorded in the Case Report Forms and other research records must be supported by source documentation.	Same. Note that some electronic medical records systems pre-populate with prior information and demographics about the subject. Care must be taken to ensure that all information recorded is contemporaneous.