Industry Coalition on 21 CFR Part 11
Key Points on Audit Trail Requirements of the Regulation
Version 1.0

The following points with respect to the 21 CFR Part 11 Audit Trail requirements have been agreed by the Industry Coalition as their understanding of the rule and for discussion with FDA at the scheduled for May 30, 2001.

Key Points on Audit Trails Requirements of the Regulation, reference § 11.10 (e):

1) **Records:**
The term "electronic record" is very broad and may be interpreted very differently depending on its context. For clarity in the discussion we suggest electronic records be split into two types: data records and documents.

a) Data Records:
Within these are two types dependent upon the method of creation as follows:

- Those recorded directly to electronic storage by a person.
  Audit trails for these records begin when the record is stored to a durable medium.

- Those recorded by a person from either paper or a non-permanent electronic record.
  These are verified, for example by a dual key entry or similar process. Interim changes to the electronic record, until accepted as a genuine copy of the source (i.e., verified), are not audited. Auditing begins when the electronic record is saved to durable media once verified. Corrections to the source data are recorded on the source document (required by SOP) and would have an audit trail.

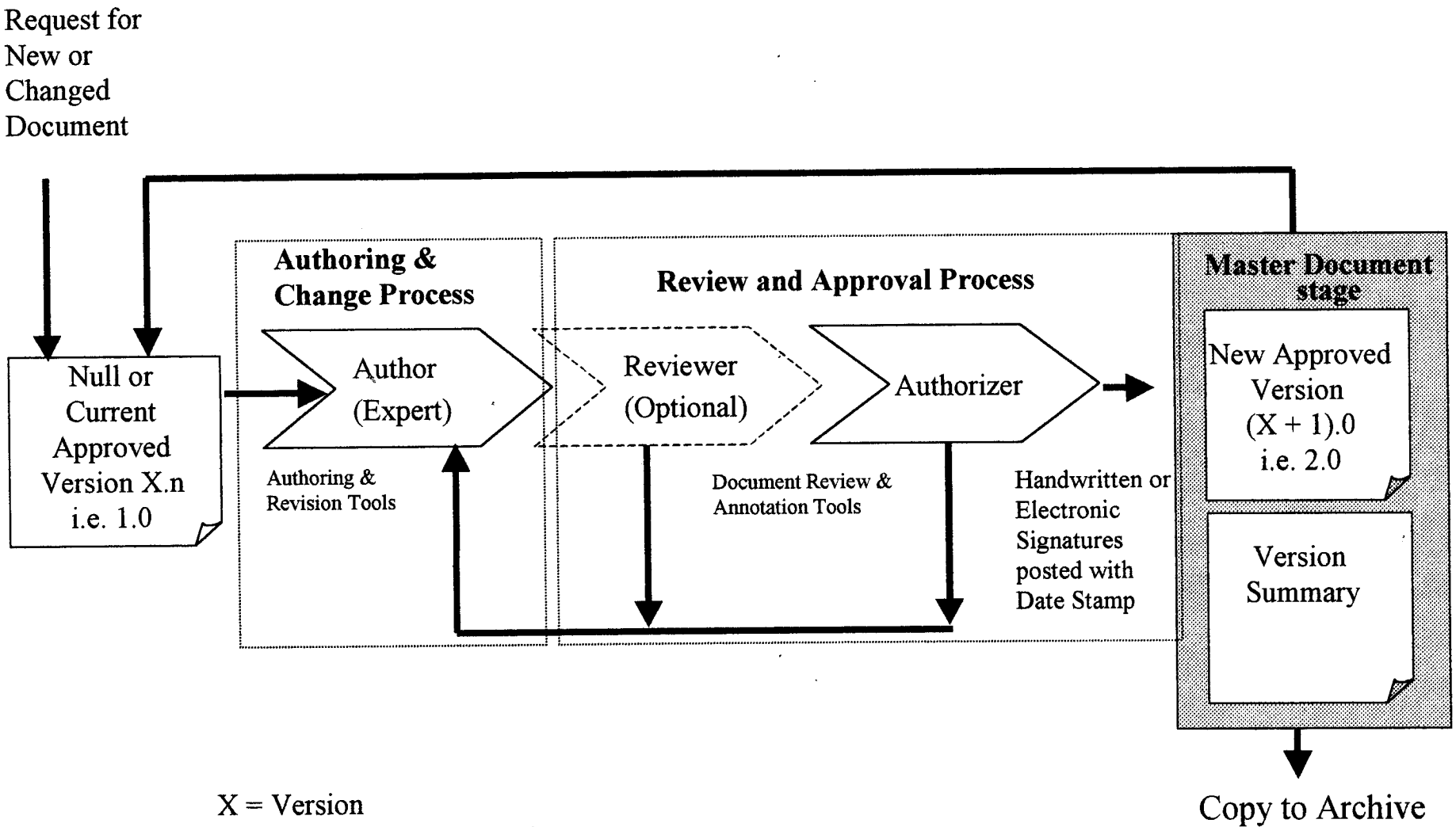
b) Documents:
Documents are identified by Version Numbers. Changes to documents are reflected by issuing a new version with a new number. New versions supercede all older versions. The interim changes, which are released only in a controlled manner for comment during the drafting of a new version, are not audit trailed. Only the new version is issued and recorded.

2) Guidance should be stated as explicitly as possible at a "user requirements" level and not on a "technical design" level as there are alternative designs that can achieve the requirement.

3) The Audit trail requirements apply to the scope of electronic records described in the Coalition input on Scope.

4) Hybrid processes (a combination of paper and computer based processes) and multiple highly integrated computer systems exist in industry and will use for the foreseeable future. Thus, an audit trail to reconstruct a regulated activity/event may require a combination of paper documents and electronic audit trails i.e.: Clinical Case Record Form, Adverse Event Reporting, SOP, Device History Records, etc.

Document Versioning Controlled Environment



X = Version
n = Revisions within Version