

FDA 21 CFR Part 11

Rule Number	Regulation	ensur Document Control Software
11.10a	Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	✓
11.10b	The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	✓
11.10c	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	✓
11.10d	Limiting system access to authorized individuals.	✓
11.10e	Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Records changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for the subject electronic records and shall be available for agency review and copying.	✓
11.10f	Use of organizational system checks to enforce permitted sequencing of steps and events as appropriate.	✓
11.10g	Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record or perform the operation at hand.	✓
11.10h	Use of device (e.g. terminal) checks to determine, as appropriate, the validity of the source of data input or Organizational Structure.	✓
11.10i	Determination that persons who develop, maintain or use electronic record/electronic signature systems have the education, training and experience to perform assigned tasks.	✓

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11.10j	The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	✓
11.10k	Use of appropriate controls over systems documentation including: <ol style="list-style-type: none"> 1. Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. 2. Revision and change control procedures to maintain and audit trail that documents time-sequenced development and modification of systems documentation. 	✓
11.50a	Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: <ol style="list-style-type: none"> 1. The printed name of the signer 2. The date and time of when signature was executed 3. The meaning (such as review, approval, responsibility, or authorship) associated with the signature 	✓
11.50b	The items identified in paragraphs (a) (1), (a) (2), and (a) (3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	✓
11.70	Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means.	✓
11.100a	Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	✓
11.100b	Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.	✓