

21 CFR Part 11 Requirements

Requirement	Regulation
System must be validated to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	Subpart B--Electronic Records Sec. 11.10(a) Controls for closed systems
System must generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying.	Sec. 11.10(b)
System must be able to protect records to enable their accurate and ready retrieval.	Sec. 11.10(c)
System must limit system access to authorized individuals only.	Sec. 11.10(d)
System must be able to use 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.	Sec. 11.10(e)
System must not allow record changes to obscure previously recorded information.	Sec. 11.10(e)
System must ensure audit trail documentation must be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.	Sec. 11.10(e)
System must use operational system checks to enforce permitted sequencing of steps and events.	Sec. 11.10(f)
System must use authority checks to ensure that only authorized individuals can use the system.	Sec. 11.10(g)
System must use authority checks to ensure that only authorized individuals can electronically sign a record.	Sec. 11.10(g)
System must use authority checks to ensure that only authorized individuals can access the operation	Sec. 11.10(g)
System must use authority checks to ensure that only authorized individuals can access the computer system input device	Sec. 11.10(g)