
21 CFR Part 11: Electronic Signatures, Electronic Records

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Background

- FDA
- Predicate requirements
- Electronic Signatures
- Electronic Records
- Open/Closed Systems

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General Provisions

- 11.1 Scope
 - Records in electronic form
- 11.2 Implementation
 - Electronic records must meet the requirements
- 11.3 Definitions

11.10 Controls for Closed Systems

“... employ procedures and controls designed to ensure the authenticity, integrity, and ... confidentiality of electronic records, and ensure that the signer cannot readily repudiate the signed record ...”

Basically, 11.10

- Ensures accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records
- Accurate and complete copies of records in both human readable and electronic form
- Protects records to enable their accurate and ready retrieval

Basically, 11.10

- Uses secure, computer generated, time stamped audit trails
- Uses operational checks to enforce sequencing of steps and events
- Uses authority checks to ensure users are authorized

11.20 Controls for Open Systems

11.10 “... from the point of their creation to the point of their receipt. ... and additional measures such as document encryption and ... digital signature standards to ensure ... record authenticity, integrity, and confidentiality”

11.50 Signature Manifestations

- Name of signer
- Date and time of signing
- Meaning (review, approval, author, etc.)
- Predicate controls

11.70 Signature Linking

- Electronic and handwritten signatures linked to electronic records
- Cannot be excised, copied, or transferred to falsify by ordinary means

11.100 Electronic Signatures

- Unique to one individual
- Cannot be reused or reassigned
- Person's identity has to be verified
- Agency has to be told of intention to use electronic signatures

11.200 Electronic Signature Components and Controls

- Biometrics
- or
- Two identification components
 - Used only by genuine owner
 - Administered so two or more people are required to impersonate

11.300 Controls of IDs/Passwords

- Unique combinations
- Periodic checks, recall, or revision
- Loss management to deauthorize and issue temporary replacements
- Detect and report unauthorized attempts