

## § 11.30

(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

### § 11.30 Controls for open systems.

Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in § 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary under the circumstances, record authenticity, integrity, and confidentiality.

### § 11.50 Signature manifestations.

(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following:

- (1) The printed name of the signer;
- (2) The date and time when the signature was executed; and
- (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.

(b) 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 Signature/record linking.

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.

## Subpart C—Electronic Signatures

### § 11.100 General requirements.

(a) Each electronic signature shall be unique to one individual and shall not

## 21 CFR Ch. I (4–1–04 Edition)

be reused by, or reassigned to, anyone else.

(b) 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.

(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures.

(1) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC-100), 5600 Fishers Lane, Rockville, MD 20857.

(2) Persons using electronic signatures shall, upon agency request, provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

### § 11.200 Electronic signature components and controls.

(a) Electronic signatures that are not based upon biometrics shall:

(1) Employ at least two distinct identification components such as an identification code and password.

(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.

(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.

(2) Be used only by their genuine owners; and

(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires

collaboration of two or more individuals.

(b) Electronic signatures based upon biometrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.

**§ 11.300 Controls for identification codes/passwords.**

Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include:

(a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.

(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).

(c) Following loss management procedures to electronically deauthorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.

(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.

(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.

**PART 12—FORMAL EVIDENTIARY PUBLIC HEARING**

**Subpart A—General Provisions**

Sec.

12.1 Scope.

**Subpart B—Initiation of Proceedings**

- 12.20 Initiation of a hearing involving the issuance, amendment, or revocation of a regulation.
- 12.21 Initiation of a hearing involving the issuance, amendment, or revocation of an order.
- 12.22 Filing objections and requests for a hearing on a regulation or order.
- 12.23 Notice of filing of objections.
- 12.24 Ruling on objections and requests for hearing.
- 12.26 Modification or revocation of regulation or order.
- 12.28 Denial of hearing in whole or in part.
- 12.30 Judicial review after waiver of hearing on a regulation.
- 12.32 Request for alternative form of hearing.
- 12.35 Notice of hearing; stay of action.
- 12.37 Effective date of a regulation.
- 12.38 Effective date of an order.

**Subpart C—Appearance and Participation**

- 12.40 Appearance.
- 12.45 Notice of participation.
- 12.50 Advice on public participation in hearings.

**Subpart D—Presiding Officer**

- 12.60 Presiding officer.
- 12.62 Commencement of functions.
- 12.70 Authority of presiding officer.
- 12.75 Disqualification of presiding officer.
- 12.78 Unavailability of presiding officer.

**Subpart E—Hearing Procedures**

- 12.80 Filing and service of submissions.
- 12.82 Petition to participate in forma pauperis.
- 12.83 Advisory opinions.
- 12.85 Disclosure of data and information by the participants.
- 12.87 Purpose; oral and written testimony; burden of proof.
- 12.89 Participation of nonparties.
- 12.90 Conduct at oral hearings or conferences.
- 12.91 Time and place of prehearing conference.
- 12.92 Prehearing conference procedure.
- 12.93 Summary decisions.
- 12.94 Receipt of evidence.
- 12.95 Official notice.
- 12.96 Briefs and argument.
- 12.97 Interlocutory appeal from ruling of presiding officer.
- 12.98 Official transcript.
- 12.99 Motions.

**Subpart F—Administrative Record**

- 12.100 Administrative record of a hearing.
- 12.105 Examination of record.