Guidance for Industry

21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms

Draft Guidance

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, room 1061, Rockville, MD 20852. All comments should be identified with the docket number 00D-1543.

For questions regarding this draft document contact Paul J. Motise, Office of Enforcement, Office of Regulatory Affairs, 301-827-0383, e-mail: pmotise@ora.fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs (ORA)
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)
Center for Devices and Radiological Health (CDRH)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
August 2001

Guidance for Industry

21 CFR Part 11; Electronic Records; Electronic Signatures

Glossary of Terms

Additional copies of this draft guidance document are available from the Office of Enforcement, HFC-200, 5600 Fishers Lane, Rockville, MD 20857; Internet http://www.fda.gov/ora/compliance_ref/part11.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs (ORA)
Center for Biologics Evaluation and Research (CBER)
Center for Drug Evaluation and Research (CDER)
Center for Devices and Radiological Health (CDRH)
Center for Food Safety and Applied Nutrition (CFSAN)
Center for Veterinary Medicine (CVM)
August 2001

Guidance For Industry

21 CFR Part 11; Electronic Records; Electronic Signatures

Glossary of Terms

Table of Contents

1. Purpose 1
2. Scope 2
2.1 Applicability 2
2.2 Audience 3
3. Definitions 3
4. References 6

Guidance For Industry[1]

21 CFR Part 11; Electronic Records; Electronic Signatures

Glossary of Terms

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

1. Purpose

The purpose of this draft guidance is to define terms that will be used in the Food and Drug Administration's (FDA's) guidances that describe FDA's current thinking on principles and procedures for creating, modifying, maintaining, archiving, retrieving, and transmitting electronic records and electronic signatures under the requirements of Part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures. It is intended to assist persons who are subject to the rule to comply with the regulation. It may also assist FDA staff who apply part 11 to persons who are subject to the regulation.

[1] This draft guidance was prepared under the aegis of the Office of Enforcement by the FDA Part 11 Compliance Committee. The committee is composed of representatives from each center within the Food and Drug Administration, the Office of Chief Counsel and the Office of Regulatory Affairs.

2. Scope

This draft guidance is one of a series of guidances about part 11. We intend to provide information with respect to FDA's current thinking on acceptable ways of meeting part 11 requirements to ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities.

In this draft guidance we define terms that will be used throughout other guidances in this series.

2.1 Applicability

This draft guidance applies to electronic records and electronic signatures that persons create, modify, maintain, archive, retrieve, or transmit under any records or signature requirement set forth in the Federal Food, Drug, and Cosmetic Act (the Act), the Public Health Service Act (PHS Act), or any FDA regulation. Any requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of part 11, are referred to in this document as predicate rules. Most predicate rules are contained in Title 21 of the Code of Federal Regulations. In general, predicate rules address the research, production, and control of FDA regulated articles, and fall into several broad categories. Examples of such categories include, but are not limited to: manufacturing practices, laboratory practices, clinical and pre-clinical research, adverse event reporting, product tracking, and pre and post marketing submissions and reports.

2.2 Audience

We intend this guidance to provide useful information to:

- Persons subject to part 11;
- Persons responsible for creating, modifying, maintaining, archiving, retrieving, or transmitting electronic records or electronic signatures;
- Persons who develop products or services to enable implementation of part 11 requirements; and,

This draft guidance may also assist FDA staff who apply part 11 to persons subject to the regulation.

3. Definitions

Definitions drawn from particular references are followed by a bracketed number to identify the reference. A listing of references appears in section 4.

Term	Definition
Biometrics	A method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable actions where those features and/or actions are both unique to that individual and measurable.[1]
Closed System	An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.[1]

Term	Definition
Computer Systems Validation	Confirmation by examination and provision of objective evidence that computer system specifications conform to user needs and intended uses, and that all requirements can be consistently fulfilled.
Digital Signature	An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.[1]
Electronic Record	Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.[1]
Electronic Signature	A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.[1]
Handwritten Signature	The scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.[1]
Off-the-Shelf Software (OTS software)	A generally available software component for which the user can not claim complete software life cycle control.[3]

Term	Definition
Open System	An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.[1]
Person	Includes an individual, partnership, corporation, and association. [4]
Predicate Rule	Requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of part 11.
Regression Analysis And Testing	A software verification and validation task to determine the extent of verification and validation analysis and testing that must be repeated when changes are made to any previously examined software products.[5]
Regression Testing	Rerunning test cases which a program has previously executed correctly in order to detect errors spawned by changes or corrections made during software development and maintenance.[5]
Reliability	The ability of a system or component to perform its required functions under stated conditions for a specified period of time.[2]

4. References

1 21 CFR Part 11; Section 11.3, Definitions
2 American National Standards Institute/The Institute of Electrical and Electronics Engineers, Inc. (IEEE) Std 610.12-1990, IEEE Standard Glossary of Software Engineering Terminology
3 FDA Center for Devices and Radiological Health, Guidance on Off-the-Shelf Software Use in Medical Devices, September 9, 1999
4 Federal Food Drug and Cosmetic Act, Chapter II, Section 201
5 Food and Drug Administration, Division of Field Investigations, Office of Regional Operations, Office of Regulatory Affairs, Glossary of Computerized System and Software Development Terminology

Doc ID Part11DraftGlossary_PostRES.doc
08/29/01