



Baxter Healthcare Corporation
One Baxter Parkway, DF3-1W
Deerfield, IL 60015-4633

December 19, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. OOD-1543: Draft Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms; Availability

I am writing on behalf of the Baxter Healthcare Corporation 21 CFR Part 11 Working Group.

We have reviewed the subject document in detail and have developed several comments, both general and specific. The general comments are addressed below, and the specific comments are contained in the attached table.

We believe that this document should be completely revised. Further development of the document will require both Agency and industry resources far beyond its potential value.

It is our understanding that the purpose of guidance is to clarify to Agency and industry personnel the Agency's expectations regarding appropriate compliance with a rule. We do not think that collecting relevant definitions into a document separate from the document providing the substantive guidance is useful.

We hope that our comments prove beneficial. Please contact me with any questions regarding these comments.

Sincerely,

Johnny Long
Director, Quality Systems
Baxter Healthcare Corporation

Attachments:

- 1) Table: Comments for Draft Guidance for Industry, Electronic Records; Electronic Signatures, Glossary of Terms
- 2) Line Numbered Copy of DRAFT Guidance for Industry, Electronic Records; Electronic Signatures, Glossary of Terms

OOD-1543

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Comment Form

				Date 10/25/01	Document Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms
Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale	
Baxter Healthcare Corp.	1. Purpose	7-9	Delete the last two sentences of the section: "It is intended to assist persons ... who are subject to the regulation."	This is duplicative information with section 2.2. This information is appropriately stated in section 2.2.	
	3. Definitions	42, 47, 57, 63, 68, 73, 88	Delete the following definitions: Biometrics, Closed System, Digital Signature, Electronic Record, Electronic Signature, Handwritten Signature and Open System.	<p>These definitions are already stated in the text of 21 CFR Part 11. Restating the same definitions adds no value. We suggest these definitions be deleted to avoid repetition of material and inefficient utilization of time in comparing this information. This duplicative information extends the volume and length of the glossary. However, clear, concise documents are most readily utilized by the regulated community.</p> <p>The terms "Biometrics" and "Handwritten Signatures" are NOT stated in the Validation Guidance Document. Adding additional definitions for terms which are not utilized in the Guidance Documents adds no value and creates unnecessary questions. These terms and definitions should be removed from the Glossary.</p> <p>The Glossary is designed to be perpetual and cover definitions of terms stated in all of the Guidance Documents.</p>	
		52-56	Delete the definition for: "Computer Systems Validation."	This is a new definition which is NOT consistent with definitions stated in references. This new definition adds no value and can contribute to misinterpretation and misunderstanding. Also, the term "Computer Systems" is not defined.	

				Date 10/25/01	Document Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures Glossary of Terms
Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale	
		98	Delete the wording "And Testing" in the term "Regression Analysis and Testing."	"Regression Analysis and Testing" is not a term which is stated in the content of the Validation Guidance Document. "Regression Analysis" is used and defined; "Regression Testing" is used and defined. However the term "Regression Analysis and Testing" is a new term which is not used in the Guidance Document. The words "And Testing" in the term "Regression Analysis and Testing" should be deleted in order to avoid misinterpretation and confusion.	
	4. References	NA	Standardize the format of the documents listed in the "References" section to agree with the format for documents listed as "References" in the Validation Guidance Document.	The format of the references is inconsistent with the format of the References in the Validation Guidance Document. The content of the references lack information which is included in the same references stated in the Validation Guidance Document.	
	4. References	NA	There appears to be no criteria for selecting definitions which are stated in the Glossary. We strongly suggest a consistent approach and criteria for selecting terms to be stated in the Glossary.	Some definitions are already stated in 21 CFR Part 11. Some definitions are for terms used in the Validation Guidance Document; other definitions are for terms which are not in the Validation Guidance Document. Also, the Glossary is missing some critical terms such as "Audit Trail" and "Metadata." There should be a defined, consistent approach and methodology for selecting terms to be stated and defined in the Glossary.	

Draft Guidance For Industry - Not For Implementation

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 OOD-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

Draft Guidance For Industry- Not For Implementation

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

Draft Guidance For Industry- Not For Implementation

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 Industry¹

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

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

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

2.1 Applicability

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

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2.2 Audience

31 We intend this guidance to provide useful information to:

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

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

3. Definitions

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

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

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51	<u>Term</u>	<u>Definition</u>
52	Computer Systems	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.
53	Validation	
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57	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]
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63	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]
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68	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]
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73	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]
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83	Off-the-Shelf Software	A generally available software component for which the user can not claim complete software life cycle control.[3]
84	(OTS software)	
85		

Draft Guidance For Industry- Not For Implementation

86	<u>Term</u>	<u>Definition</u>
87	88 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]
89	92 Person	Includes an individual, partnership, corporation, and association. [4]
90	94 Predicate Rule	Requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of part 11.
91	97 Regression Analysis 98 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]
100	102 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]
101	107 Reliability	The ability of a system or component to perform its required functions under stated conditions for a specified period of time.[2]
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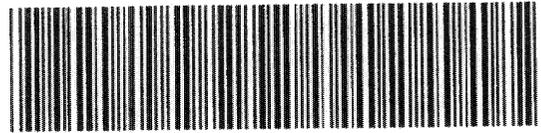
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4. References

- 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

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