1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

3066 '01 DEC 19 P4:21

AdvaMed
Advanced Medical Technology Association

December 18, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1060
Rockville, MD 20852

Re: Docket No. OO~~N~~D-15431: Draft Guidance for Industry; Electronic Records; Electronic Signatures, Glossary of Terms; Availability

Dear Sir or Madam:

I am writing on behalf of the AdvaMed Part 11 Issue Working Group, which represents a cross-section of our member companies affected by the rule. AdvaMed, the Advanced Medical Technology Association, (formerly the Health Industry Manufacturers Association) represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually.

We have reviewed the subject document in detail and have developed a number of 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We believe that this document should be withdrawn. Further development of the document will require both Agency and industry resources far beyond its potential value. In fact, we believe that its publication could create more confusion than clarification.

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. Thus, guidance is meant to increase understanding and simplify compliance. We do not think that collecting relevant definitions into a document separate from the document providing the substantive guidance is useful. It forces a novice to use at least two documents at

00D-1543

C4

once to develop functional understanding of how to comply. Many people will find this confusing rather than helpful.

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

Sincerely,

Bernie Liebler
Director
Technology and Affairs

AdvaMed Comments - Draft Glossary of Terms

Note: In our General Comment, we recommend that this document be withdrawn.
The comments in this table assume that the document will be published.

Date	Document
12/19/2001	**Glossary of Terms Draft Guidance**

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
AdvaMed	General		Delete definitions for which the Part 11 Final Rule already provides a definition within section 11.3 Definitions.	Terms that are defined within the Final Rule are already adequately defined and directly accessible. The rationale for a subsequent Guidance is to provide definitions for terms not otherwise covered within a predicate rule or for which the predicate rules of the various FDA centers provide differing, potentially conflicting, definitions. In addition, having to go to yet another document to determine the usage of a tem is contrary to the goal of guidance. We already have a general glossary, and it should be added to as needed. Putting the specific terms in the guidance where they are discussed will simplify usage.
AdvaMed		New	**Repudiate (11.10)** - for a person to claim that an electronic signature as not his or her own, or that the signed record had been altered. (Preamble #62)	A glossary should also explain words used in the regulation, the preamble or Part 11 training. The terms below are words used that are not commonly used or have a specific meaning for Part 11. By each term, its location in the rule or preamble is identified by Part 11 section number. After each definition, the contributing source from the Part 11 Final Rule preamble discussion is identified.
AdvaMed		New	**Nonrepudiation (Preamble #63)** - To prevent someone from successfully claiming that: (1) He or she did NOT, in fact, sign the record; (2) A given electronic record containing the individual's signature was NOT, in fact, the record that the person signed; or (3) The originally signed electronic record had been altered after having been signed. (Preamble #63)	A glossary should also explain words used in the regulation, the preamble or Part 11 training. The terms below are words used that are not commonly used or have a specific meaning for Part 11. By each term, its location in the rule or preamble is identified by Part 11 section number. After each definition, the contributing source from the Part 11 Final Rule preamble discussion is identified.
AdvaMed		New	**Audit trail (11.10)** - (ISO)(1) Data in the form of a logical path linking a sequence of events, used to trace the transactions that have affected the contents of a record. (2) A chronological record of system activities that is sufficient to enable the reconstruction, reviews and examination of the sequence of environments and activities surrounding or leading to each event in the path of a transaction from its inception to output of final results.	A glossary should also explain words used in the regulation, the preamble or Part 11 training. The terms below are words used that are not commonly used or have a specific meaning for Part 11. By each term, its location in the rule or preamble is identified by Part 11 section number. After each definition, the contributing source from the Part 11 Final Rule preamble discussion is identified.

Date	Document
12/19/2001	Glossary of Terms Draft Guidance

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
AdvaMed		New	Add the definition of "Computer System" from the existing FDA guidance on Computer and Software Terms: **Computer System** - (ANSI) a functional unit, consisting of one or more computers and associated peripheral input and output devices, and associated software, that uses common storage for all or part of a program and also for all or part of the data necessary for the execution of the program; executes user-written or user-designated programs; performs user-designated data manipulation, including arithmetic operations and logic operations; and that can execute programs that modify themselves during their execution. A computer may be a stand-alone unit or may consist of several interconnected units.	Completeness
AdvaMed		New	**Contemporaneously executed (11.200)** - to execute a signing at the same time as when an event takes place. For example a check is signed at the same time when the payee, amount and date are written on the check. If check is signed without filling in the rest of the information, you have a blank check! (No source)	A glossary should also explain words used in the regulation, the preamble or Part 11 training. The terms below are words used that are not commonly used or have a specific meaning for Part 11. By each term, its location in the rule or preamble is identified by Part 11 section number. After each definition, the contributing source from the Part 11 Final Rule preamble discussion is identified.
AdvaMed		New	**Controlled system access (11.200)** - (access session or logged-on period) (1) Requiring an individual to remain in close proximity to the workstation throughout the signing session; (2) use of automatic inactivity disconnect measures that would ``de-log" the first individual if no entries or actions were taken within a fixed short timeframe; and (3) requiring that the single component needed for subsequent signings be known to, and usable only by, the authorized individual. (Preamble #124)	A glossary should also explain words used in the regulation, the preamble or Part 11 training. The terms below are words used that are not commonly used or have a specific meaning for Part 11. By each term, its location in the rule or preamble is identified by Part 11 section number. After each definition, the contributing source from the Part 11 Final Rule preamble discussion is identified.

Date	Document
12/19/2001	**Glossary of Terms Draft Guidance**

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
AdvaMed	3	New	Add the Coalition remarks differentiating between **Data Records** and **Document Records**.	Requirements for these two record types differ significantly. Furthermore, the various FDA centers differ in the requirements contained in their predicate rules concerning these record types. For example, the medical device QSR has separate sections that address Records and Document Control. Finally, the approaches to appropriate validation vary depending on the record type.
AdvaMed		New	**Electronic Identification** - An "electronic identification" is a person's name or ID number that can be entered by anyone. Where FDA regulations do not require a record to include a signature, system requirements may be written to specify an "electronic identification" in lieu of specifying a an electronic signature. The electronic identification is not intended to be an electronic signature and therefore PART 11 requirements for electronic signature would not apply. For example, if a calibration technician notified an engineer of an out-of-spec condition of a calibration tool, the technician could record the identity of the engineer who received the notification in the calibration record. [DOCKET NO. 92N-0251] ER/ES Proposed Rule III. DEFINITIONS/STRATIFIED ACCEPTANCE APPROACH	This term was not used in 21 CFR Part 11 Final Rule. However, the concepts have been discussed in Part 11 training, the preamble and discussions of previous drafts.
AdvaMed		New	**Electronic Typewriter Exception** - An allowance described in comment #22 of the preamble that limits the applicability of Part 11 for computer systems that are merely incidental to the creation of paper records that are subsequently maintained in traditional paper-based systems. In such cases, the computer systems would function essentially like manual typewriters or pens and any signatures would be traditional handwritten signatures. Record storage and retrieval would be of the traditional ``file cabinet" variety. (Preamble #22)	This term was not used in 21 CFR Part 11 Final Rule. However, the concepts have been discussed in Part 11 training, the preamble and discussions of previous drafts.

Date	Document
12/19/2001	Glossary of Terms Draft Guidance

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
AdvaMed		New	**Hybrid System** - a combination electronic/paper based system where a document is an electronic record but the approval of the document is on paper. An example of a hybrid system is a document control system utilizing electronic storage for records but uses a paper change control process with traditional handwritten signatures for approval of changes. (Part 11 training)	This term was not used in 21 CFR Part 11 Final Rule. However, the concepts have been discussed in Part 11 training, the preamble and discussions of previous drafts.
AdvaMed	3	New	Add the following definition of "legacy system." **Legacy Systems** - Computer systems that were being used by an FDA regulated firm for compliance with GxP requirements before the enactment of Part 11 and which therefore may need to be replaced or upgraded with systems that meet business needs and are both GxP and Part 11 compliant.	The definition of Legacy System is not in the Final Rule, but is an important part of manufacturer's compliance planning and execution. It is an important component of the Part 11 Compliance Policy Guide and the Preamble to the Final Rule.
AdvaMed		New	Add a definition for **Metadata as follows:** **Metadata** - Data about data that can be used to establish source, format, context, location, authenticity, and similar characteristics of an electronic record without being part of the record itself.	Completeness
AdvaMed		New	Add definitions for **Raw data** and **durable media**.	These are terms that have caused great consternation among Industry members. The Agency needs to expressly address them in a way that clarifies expectations.
AdvaMed		New	Reference the FDA's Glossary of Computerized System and Software Development Terminology, August 1995.	There is little value in publishing a guidance document that merely restates definitions already provided in other documents, such as the Part 11 regulation and the Agency's own glossary of computer terminology. That being said, however, given the fact that FDA has published their draft glossary of terms for Part 11, they should formally acknowledge the full population of terminologies they have already endorsed by including the reference to their 1995 glossary of terms. When speaking to Part 11, any of these additional terms could come into play; particularly when considering the validation expectations embedded within Part 11 requirements.
AdvaMed	2.1	20	Add...persons <u>or systems</u> create,	Some records are automatically generated by the system or equipment, like audit trails.

Date	Document
12/19/2001	Glossary of Terms Draft Guidance

Commenter	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
AdvaMed	3	52-56	Delete the phrase "and intended uses."	Intended uses are a subset of the user requirements. If the phrase "intended use" is included, a definition would be needed for "intended use" in the context of an electronic records system (as contrasted with a finished medical product)
AdvaMed	3	52-56	Replace "specifications" with "performance."	As originally stated validation, would require only traceability of specifications to the user needs without performance testing.

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

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

Draft Guidance For Industry- Not For Implementation

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

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.

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 Term	Definition
42 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]
47 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