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AdvaMed
Advanced Medical Technology Association

April 23, 2003

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

RE: Docket Nos. 03D-0060, 99D-1458, 00D-1538, 00D-1543, 00D-1542, and 00D-1539; Draft Guidance for Industry on "Part 11, Electronic Records, Electronic Signatures- Scope and Application;" Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

Dear Sir/Madam:

I am writing on behalf of the AdvaMed Part 11 Working Group. AdvaMed, the Advanced Medical Technology Association, represents more than 1,100 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $71 billion health care technology products consumed annually in the United States, and nearly 50 percent of $169 billion purchased around the world annually.

We are pleased that FDA has issued this guidance and withdrawn the previous drafts. The approach espoused in the current document is, we believe, the only reasonable approach to this regulation. Part 11 compliance should be an outgrowth of compliance with the Quality System or Good Manufacturing Practices regulation rather than an end in itself, and in the medical device industry such compliance is driven by risk management principles.

We have attached a number of Specific Comments to locations in the draft document. However, there are some more general issuesthat we are going to cover in this letter.

We are concerned that it is not explicitly stated in the guidance that the risk-based approach should be applied to all Part 11 activities. Many people have interpreted the guidance as applying risk-based approaches only in the areas that are specifically singled out in the guidance for Validation, Audit Trail, and Record Retention We believe that the agency's intent is for manufacturers to apply arisk-based approach to their entire compliance effort for Partl 1, as it would make little sense to us to applysuch an approach selectively. We think that FDA must make this clearer than it is in the Draft Guidance.

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We are also concerned that other FDA guidances, particularly the Guidance on Computerized Systems Used in Clinical Trials (1999), reference Part 11 and in some instances exceed the requirements of Part 11. We believe that it is important that the FDA approach to electronic records be consistent across all interest areas. We urge you to include these related documents in your review of Part 11 and its associated guidances.

There are three additional areas that also suffer from a lack of clarity. We were not able to fully explore these areas in our specific comments, so we are presenting them in discussion format below.

1. **Enforcement Discretion -** Several of our members wanted to comment to the effect that the language stating that "FDA will not normally take regulatory action" is too vague. They suggested that we recommend a change to delete the word "normally." We understand that FDA cannot commit to taking no enforcement action on an existing regulation under any circumstances. We do believe, however, that in this case the agency should make an effort to explain the concept of enforcement discretion in greater detail than it might usually do.

Part 11 affects a broader constituency within the regulated industries than most FDA rules. Consequently, many parties unfamiliar with regulatory language and interpretation will be reading and implementing this guidance document. These parties will find the existing language to be vague, resulting in excessive or deficient implementation actions. These actions could result in additional expense, but will most surely result in confusion and unease. We believe it is worth some effort to explain the concept in detail to ensure that the guidance is understood and implemented according to agency expectations.

2. **Legacy Systems -** Legacy systems are another concept creating confusion. The simple definition that a Legacy System is one in service prior to the effective date of Part 11 is not practical. Most, if not all, such systems have been modified in some way since the inception of the regulation. Certainly, many were modified to address Y2k concerns. If one maintains that any modification to a system removes the legacy status, then there is no value to the guidance's exclusion of legacy systems.

There is a clear need for a broader definition of legacy system that takes into account the normal maintenance and changes to systems that are necessary to keep them running properly and satisfying the needs of the enterprise. We suggest the following as a starting point for FDA consideration and possible discussions with industry to refine a working definition that will satisfy the needs of all parties.

Legacy System:

> A Legacy System is a computer system or application in use prior to August 20, 1997 and in continuous use since that date. At this time, Legacy Systems

do not need to comply with all Part 11 requirements, but must comply with predicate rules—including validation, if applicable.

If a major change or radical change were made to a computer system or application since August 20, 1997, it would no longer be considered a Legacy System. One determining factor would be whether the changes were substantial enough that there was an opportunity to address Part 11 controls. (There must be a documented risk assessment addressing the controls that are in place for the Legacy System to ensure compliance with predicate rules and the justification for maintaining the system without addressing Part 11 controls.) If Part 11 controls could have reasonably been addressed during the change, the system should not be considered a Legacy System. If only changes to maintain the system operation have been made since August 20, 1997, it would be considered a Legacy System. Legacy Systems must comply with predicate rules and with those Part 11 controls that will ensure the system is fit for use as determined by risk assessment.

3. **Incidental Use of Computer Systems -** The final area of apparent confusion relates to when a computer system is in incidental use. It seems to us that the crux of this issue is whether the electronic record or the paper record is used for decision making and to demonstrate compliance. The introduction of the incidental use concept is confusing rather than clarifying. We will use the example of the SOP generated using a word processor. There are several possible cases that can be constructed. We will describe them and how we interpret them.

a. The SOP is developed, reviewed and approved electronically. Then it is printed and distributed on paper, and the users do not have access to the electronic version. *Since the electronic version is used for review and approval, it is a Part 11 record.*

b. The SOP is developed on a word processor, but paper copies are used for review, approval, and operations. The electronic copy is maintained for use in developing the next revision. *Since paper is used for all official purposes, it is the official record. There is no Part 11 involvement. The electronic copy maintained as a starting point for the next revision is just that and has no regulatory implications It is simply a means to simplify revision by avoiding starting from a "blank slate."*

c. The SOP is developed in a word processor, approved and distributed as paper, but the electronic copy is available for reference and for training. *The electronic copy is used for regulated activities and thus comes under Part 11.*

We can't guarantee that we have covered all possibilities, but we believe the above scenarios address a reasonable spectrum of possibilities. We also believe that this is the type of discussion that needs to appear in the guidance for the concept to become clear.

We appreciate the effort that FDA has put into this draft, and we also appreciate this opportunity to comment on it. We hope that our comments prove useful in completing the guidance. Please contact me at 202.434.7230 or bliebler@advamed.org, if you have any questions.

Sincerely,

Bernie Liebler
Director
Technology and Regulatory Affairs

AdvaMed Comments

Date	Document
04/04/03	Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures -- Scope and Application

	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
1.	Background	74 - 75	The guidance should clarify that use of local time as described in the Part 11 preamble is not mandatory.	Withdrawal of the Guidance document for Time Stamps leaves a problematic statement in the preamble that "... the signer's local time is the one to be recorded." Local time is generally taken from an individual user's workstation often making it the least accurate time available. An alternate source such as a centralized server should be acceptable for time stamps since this will generally be more reliable.
2.	III. A.	124	Replace, "FDA will enforce predicate rule requirements for records that are subject to Part 11," with "FDA will continue to enforce predicate rule requirements for all applicable records, including those records that are subject to Part 11."	The original sentence is confusing. It could be misinterpreted that predicate rule requirements apply only to Part 11 records or haven't previously applied to Part 11 records. The proposed change would help clarify that FDA will continue to enforce predicate rules and that Part 11 records must satisfy predicate rule requirements.
3.	III. A	135-137	From: Furthermore, persons must comply with applicable predicate rules, and records that are required to be maintained or submitted must remain secure and reliable in accordance with the predicate rules. To: The agency believes that these provisions of Part 11 afford firms considerable flexibility while providing a baseline level of confidence that records maintained in accordance with the rule will be of high integrity. We suggest that your implementation decisions be based on predicate rule requirements to ensure the accuracy and reliability of the records contained in the system. We recommend that you base your approach on a justified and documented risk assessment and a determination of the potential of the system to affect product quality and safety and record integrity.	It would be helpful for the agency to clarify the flexibility of the current rule and how that relates to the risk-based approach. This was addressed in the Preamble to the final rule: Preamble to 21 CFR Part 11); *C. Flexibility and Specificity 3.*

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	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
4.	III. B. 2.	163		Does this mean that electronic records required by predicate rule and records not required by predicate rule in the same system can be controlled differently?
5.	III. B. 2.	171	Please give examples and clarify.	We need to know when it is o.k. to use a paper versus an electronic record when an electronic record is created. Also, how does this apply to electronically generated reports printed and signed; and to paper approved document control records with electronic copies used for subsequent update?
6.	C		Add risk based approach to security (access controls)	Complements the NIST risk based reference. Generally such risk-based assessments are made regarding the degree to which security measures are applied.
7.	III. C. 1.	212 - 214	Insert the following sentence at the beginning of line 212: "*Validation guidance unique to Part 11 is not required.*	It would be useful to more clearly state that Part 11 validation guidance is not needed. This is because Part 11 is not intended to introduce unique software validation techniques. It is fully adequate to utilize existing general software validation guidance documents such as those referenced; CDRH General Principles of Software Validation and the GAMP 4 Guide.
8.	III. C. 2.	231	Move to 1st paragraph, line 222.	This is clarifying when audit trails are appropriate.
9.	III. C. 3.	234 - 241		Do the Part 11 requirements apply to the devices that the manufacturers produce for sale to the FDA regulated market (e.g. blood banks) when those devices are themselves systems that maintain records required by FDA regulations? Does the software contained on these devices require Part 11 functionality?
10.	III. C. 4.	246	From: As Is. To: Delete: "You should provide . . .during an inspection."	This passage should be eliminated to prevent misunderstandings regarding what is "reasonable" and "useful". Provisions regarding reviewing and copying of records are adequately discussed in lines 259 through 261.

Date	Document
04/04/03	Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures -- Scope and Application

	Section	Paragraph Figure/ Table Line No.	Proposed Change	Comment/ Rationale
11.	III. C. 4.	257-259	From: If you have the ability to search, sort, or trend Part 11 records, copies provided to the Agency should provide the same capability if it is technically feasible. To: deleted	The Part 11 regulation doesn't mandate the FDA to have the ability to manipulate the data (searching, sorting, trending). This guidance should not be adding requirements to the regulation. These statements in Lines 257-259 seem to conflict with lines 275-279, which allows for archiving of microfilm, microfiche and paper. These media are not searchable, sortable, or trendable.
12.	References	305	Consider removing the NIST document from the reference section or adding text to explain why it is included.	NIST Special Publication SP800-30: Risk Management Guide for Information Technology Systems appears in the References section although it is not mentioned in the body of the guidance. It may be misleading to include this document title in the References section since it addresses computer system risk and does not significantly add to an understanding of the nature of risk described in the guidance document; the potential to affect product quality and safety.