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Comments to FDA's Draft Guidance to Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application

The Society of Quality Assurance would like to present the following comments to the United States Food & Drug Administration on the above referenced Draft Guidance document.

Date: 2003-04-24

Society of Quality Assurance President

Laura Metzger

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Comments compiled by

Richard Siconolfi, CVIC & SAB

Note: Throughout this document the word "Guidance" refers to the Draft Guidance to Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application.

2365 Hunters Way, Charlottesville, VA 22911 • Telephone: 434/297-4772 • Facsimile: 434/977-0899
Website: www.sqa.org • E-mail: sqa@sqa.org

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2365 Hunters Way, Charlottesville, VA 22911 • Telephone: 434/297-4772 • Facsimile: 434/977-0899
Website: www.sqa.org • E-mail: sqa@sqa.org

General Comments

Number	Comment
1.	*We support the FDA's efforts to provide a reasonable approach to guidance addressing the difficult issues facing industry. The regulation, 21 CFR Part 11 (Part 11), continues to serve a useful purpose in improving practices within industry related to building, purchasing, and implementing quality systems for electronic records and signatures. It has also served to raise the industry's* ***awareness of the potential exposures that electronic data may be compromised****, especially without adequate controls.*
2.	*This draft Guidance provides a reasonable position and sufficient flexibility for organizations to determine appropriate approaches to:* • *Allow alternatives to fully automated audit trails, e.g., that will allow organizations to implement other controls for purchased systems that fill a very specialized need, yet may not have a completely Part 11 compliant automatic audit trail built-in.* • *Ensure long-term retention in electronic format has been one of the most challenging issues that organizations have struggled with in terms of effort and cost, since the interpretation to date has been that full processability and maybe even maintenance in the original format was required. This is quite problematic, with the rapid rate of technological change, not only for hardware and storage media, but also software required to read the records. The draft Guidance allows for companies to move to formats and/or media that will provide a better likelihood of accurate retrieval throughout the record retention period.*
3.	*The expectations of Part 11 may have been over-interpreted and applied too strictly in past years; however, this Guidance has backed off too far and may increase record integrity problems.*
4.	*There is no reference made to the Clinical Guidance Document issued in 1999. Is it also going to be rescinded?*

I. Introduction

Line Numbers	Draft Guidance
34-35	This guidance explains that, while this re-examination of Part 11 is under way, we will narrowly interpret the scope of Part 11.
	Comment: *How long does FDA believe this re-examination will last?*

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36-39	We will not normally take regulatory action to enforce compliance with the validation, audit trail, record retention, and record copying requirements of Part 11 as explained in this guidance. However, records must still be maintained or submitted in accordance with the underlying predicate rules.
	omments: . *How will FDA interpret the phrase "will not normally take regulatory action to enforce …"* . *Please clarify how FDA will enforce compliance for validation, audit trails, record retention, and copying of electronic records.*
46-50	FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.
	Comment *How can a guidance document, viewed only as recommendations, appear to have more authority than a regulation?*

II. Background

Line Numbers	Draft Guidance
81-82	Some statements by Agency staff may have been misunderstood as statements of official Agency policy.
	Comment: *Line 81 should be eliminated. The statement is not necessary and appears to be a criticism of certain FDA personnel.*

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III. Discussion

A. Overall Approach to Part 11 Requirements

Line Numbers	Draft Guidance
105-108	To avoid unnecessary expenditures of resources to comply with Part 11 requirements that may be revised through a rulemaking, we are issuing this guidance to describe how we intend to exercise enforcement discretion with regard to certain Part 11 requirements during the re-examination of Part 11.
	Comment: *Please define "enforcement discretion" and specify how and when it will affect the regulated industry.*

B. Details of Approach – Scope of Part 11

1. Narrow Interpretation of Scope

Line Numbers	Draft Guidance
149-156	Under the narrow interpretation of the scope of Part 11, with respect to records required to be maintained or submitted, when persons choose to use records in electronic format in place of paper format, Part 11 would apply. On the other hand, when persons use computers to generate paper printouts of electronic records, those paper records meet all the requirements of the applicable predicate rules, and persons rely on the paper records to perform their regulated activities, the *merely incidental* use of computers in those instances would not trigger Part 11. In such instances, FDA would generally not consider persons to be "using electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b).

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	Comments: 1. *Please explain the acceptance of paper records and the difference between those where the electronic source data would and would not trigger Part 11 compliance. If standard operating procedures (SOP) are printed and used in the lab, but the electronic file is kept for the next revision of the SOP; is the SOP considered electronic under Part 11 or would it be considered an "**incidental paper record**"?* 2. *This section is confusing, especially the phrase "**merely incidental use of computers**". It might be useful for FDA to provide additional examples to clarify this point of view.*

2. Definitions of Part 11 Records

Line Numbers	Draft Guidance
163-167	Records that are required to be maintained by predicate rules and that are maintained in electronic format *in place of paper format*. On the other hand, records (and any associated signatures) that are not required to be retained by predicate rules, but that are nonetheless maintained in electronic format, are not Part 11 records.
	Comment: 1. *If we create electronic records that are required by company SOPs, but not required by a predicate rule, are they subject to Part 11 rules?* 2. *Would the answer to this question be different if the company SOPs are required by a predicate rule?*
171-178	In some cases, actual business practices may dictate whether you are *using* electronic records instead of paper records under § 11.2(a). For example, if a record is required to be maintained by a predicate rule and you use a computer to generate a paper printout of the electronic records, but you nonetheless rely on the electronic record to perform regulated activities, the Agency may consider you to be *using* the electronic record instead of the paper record. That is, the Agency may take your business practices into account in determining whether Part 11 applies.

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	Comment: *The Guidance reiterates the concept of using computer systems which "**are merely incidental**" to the creation of paper records. This concept should be clarified. Systems such as word processors and perhaps document management systems that are used to create documents such as SOPs that are hand-signed and referenced on paper may not need to be Part 11 compliant. However, there are other systems, such as those in laboratories that ultimately generate paper yet perform significant processing and data manipulation prior to printing the paper copy of the record. In particular, where there is significant opportunity to manipulate or change records after initial raw data are collected, but before printing, additional controls, such as audit trails, should be in place to assist with identifying improper results or evaluation adjustments.*

C. Approach to Specific Part 11 Requirements

1. Validation

Line Numbers	Draft Guidance
198-201	The Agency intends to exercise enforcement discretion regarding the specific Part 11 requirements for validation of computerized systems (§ 11.10(a) and corresponding requirements in § 11.30). Persons must still comply with all applicable predicate rule requirements for validation (e.g., 21 CFR 820.70(i)).
	Comment: *Please add "21 CFR Part 58.63(a)" and all other predicate rules requiring validation.*
203-210	Even if there is no predicate rule requirement to validate a system in a particular instance, it may nonetheless be important to validate the system to ensure the accuracy and reliability of the Part 11 records contained in the system. We suggest that your decision to validate such systems, and the extent of validation, 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. For instance, a word processor used only to generate SOPs would most likely not need to be validated.
	Comment *This is a reasonable approach, and in fact has been the FDA's position since the*

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	mid 1980s when it was determined that system software tools do not require validation – only application software should be validated.

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2. Audit Trail

Line Numbers	Draft Guidance
218-222	The Agency intends to exercise enforcement discretion regarding the specific Part 11 requirements related to computer-generated, time-stamped audit trails (§ 11.10 (e), (k)(2) and any corresponding requirement in §11.30). Persons must still comply with all applicable predicate rule requirements related to documentation of, for example, date (e.g., § 58.130(e)), time, or sequencing of events.
	Comments 1. *If you do need an audit trail based on the predicate rule, will it need to be an automated audit trail?* 2. *Please explain. Part 11 requires automated audit trails as the most crucial mechanism to ensure long term data integrity for electronic records. This is a very legitimate requirement. What other mechanisms will the FDA require on a computer system for long period of time?*

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3. Legacy Systems

Line Numbers	Draft Guidance
236-240	The Agency intends to exercise enforcement discretion with regard to legacy systems that otherwise met predicate rule requirements prior to August 20, 1997, the effective date of Part 11. This means that the Agency will not normally take regulatory action to enforce compliance with any part 11 requirements. However, all systems must comply with all applicable predicate rule requirements and should be fit for their intended use.
	Comments: *1. While removing legacy systems from the scope of Part 11 will alleviate many of the difficulties industry has encountered. These systems **should not** be necessarily more reliable just because they are older. In fact, if Part 11 came about due to inadequate system controls and concern over electronic record integrity, then systems built before Aug. 20, 1997 would seem to be lacking. It would be more reasonable to allow alternative approaches to ensure record integrity objectives such as procedural controls, as opposed to an overall exemption. We are pleased to see the FDA still expects these systems to be "**fit for use**"; however, we would prefer to see the term "**validation**" here.* *2. If a system was validated prior to August 1997 but updated for Y2K issues in 1999, is it still considered a legacy system?* *3. Will upgrades and additions of new functionality cause it to fall out of the category of legacy system?*

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4. Copies of Records

Line Numbers	Draft Guidance
244-261	The Agency intends to exercise enforcement discretion with regard to the specific Part 11 requirements for generating copies of records (§ 11.10 (b) and any corresponding requirement in §11.30). You should provide an investigator with reasonable and useful access to records during an inspection. All records held by you are subject to inspection in accordance with predicate rules (e.g., §§ 211.180(c), (d) and 108.35(c) (3) (ii)). We recommend that you supply copies of electronic records by • Producing copies of records held in common portable formats where records are kept in these formats • Using established automated conversion or export methods, where available, to make copies in a more common format (including PDF) In each case, we recommend that you ensure that the copying process used produces copies that preserve the content and meaning of the record. 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. You should allow inspection, review, and copying of records in a human readable form, on your site, using your hardware and software, following your established procedures and techniques for accessing those records.
	Comment: *The last sentence in this section indicates that facilities should allow inspection, review, and copying of records in a human readable form, on your site, using your hardware and software.... By using the term "on your site," it appears FDA recognizes the technical difficulties that may be encountered in providing electronic copies for removal from the site by inspectors. Is this a correct interpretation of FDA's intention?*

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257-259	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.
	Comment: *The Part 11 regulation does not 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 allow for archiving microfilm, microfiche and paper. These media are not searchable, sortable, or trendable. Please comment.*

5. Record Retention

Line Numbers	Draft Guidance
275-281	FDA normally does not intend to object if you decide to archive required records in electronic format to non-electronic media such as microfilm, microfiche, and paper, or to a standard electronic file format, such as PDF. Persons must still comply with all predicate rule requirements, and the records themselves and any copies of the required records should preserve their content and meaning. In addition, paper and electronic record and signature components can co-exist (i.e., a hybrid situation) as long as predicate rule requirements are met and the content and meaning of those records are preserved.
	Comment *Please clarify what are the archival requirements in the predicate rule that could potentially proscribe archival to non-electronic format.*

References

Line Numbers	Draft Guidance
	No Comments to this section

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