

**Comment Form**

				Date	Document
				November, 2002	Maintenance
Comment By	Reference Section	Paragraph/ Figure/ Table Line No.	Proposed Change	Comment/ Rationale	
	General			Guidance should recognize that there are no guaranteed permanent technical solutions and limited commercially available solutions to meet the long-term retention requirement. Further, the guidance should include the FDA's current thinking on ways to achieve a migration without unnecessary costs to industry.	
	2. Intent of Part 11	99	"compatible with FDA's public health responsibilities" should be changed to "generally equivalent to paper records and handwritten signatures executed on paper."	No need to substitute new wording for the wording in the original rule. Does not confer clarity and introduces new areas of debate on interpretation. Stick with the original wording.	
	4.1 What Does part 11 Require	172	Change "Accordingly, the signature manifestation information, associated with an electronic record that is subject to this requirement, must be maintained for the duration of the record retention period." To ""Accordingly, the printed name of the signer, the date and time of signing and what the signature means, associated with an electronic record that is subject to this requirement, must be maintained for the duration of the record retention period."	It is constructive to describe what constitutes the "signature manifestation information" expected	
	4.1	181-2	Delete "authentic, and compatible with the FDA's public health responsibilities."	How is "authentic" different from "trustworthy". Why introduce a new term to be debated? Why the "compatible..." phrase that does not shed any more clarity and introduces a new subject of debate on interpretation?	

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	5.2, Factors That Might Affect The Reliability ..	210	Change "You should identify and control factors that could potentially affect the reliability of electronic records during their records retention periods." To: "You should identify and, to the extent possible, control factors that could potentially affect the reliability of electronic records during their records retention periods."	It is important to recognize that not all factors identified may be controllable.
	<i>5.3 Continued Availability And Readability Of Electronic Record Information Should Be Ensured.</i>	245	Add at end of last sentence "For the purpose of long term retention, electronic records may be retained in a format that differs from the original, which may include a format that offers dependence on technology and offers a broader probability for readability."	It is important to recognize the merits de-facto database standards and 'Technology Neutral Formats' offer for the long-term retention of required electronic records.
	5.5 The Ability To Process ..... Should Be Preserved.	258	Change "Throughout the records retention period, the ability to process information in an electronic record should not diminish.: To "Throughout the records retention period, electronic record should be maintained in a manner that allows the electronic record's information to generate copies in human and computer readable from that are suitable for FDA inspection, review, and copying."	Maintaining process capability of the old system is substantial expansion of scope of Part 11 functional requirements that should go through the proper FDA rule making process rather than being introduced via guidance. Further, this is unrealistic to achieve in some cases. For example, the ability to process information may be lost as systems are retired or become obsolete.

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	5.5 The Ability To Process ..... Should Be Preserved.	273	Change "For example, if you could automatically search for words in the text of an electronic record, sort or find values in a table, or perform calculations in a spreadsheet, you should be able to process information in a like manner for the electronic record over the entire records retention period. This ability (or functionality) derives largely from the hardware and software used to extract information from the electronic record, as well as the electronic record format itself. You should include this ability among your specifications in your procedures and controls." To "Throughout the records retention period, electronic record should be maintained in a manner that allows the electronic record's information to generate copies in human and computer readable from that are suitable for FDA inspection, review, and copying."	Maintaining process capability of the old system is substantial expansion of scope of Part 11 functional requirements that should go through the proper FDA rule making process rather than being introduced via guidance.  Acceptable alternatives are addressed in the predicate rules. For example in the GMPs section 211.180 (d) and the GLPs section 58.195 (g), the rule states "Records required by this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records." This clearly shows the intent to retain the information and does not require reprocessing." Requirement for reprocessing should be limited to those stated in a predicate rule and not introduced through Part 11 guidance(s).
	5.6 The Coping Process Should...	291	"Draft Guidance For Industry – Not For Implementation 12"	Appears to be extraneous text that is confusing

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	6.2.1.3 Electronic Record Integrity Attributes Should Be Preserved.	422	States "Where a migration, in effect, creates a new electronic record (by transforming the old electronic record) then, per section 11.10(e), the audit trail for the migrated electronic record would have to cover this creation."	Given the migration from the old and new systems is documented this appears to be an unnecessary step and one that is not typically supported by commercial software. Thus adding to the effort and cost of migration with limited incremental value.
	6.2.1.4 The Ability To Process Information In Electronic Records Should Be Preserved.	442	Change "In the migration approach, the new computer system should enable you to search, sort and process information in the migrated electronic record at least at the same level as what you could attain in the old system (even though the new system may employ different hardware and software). To "In the migration approach, the new computer system should be capable of making copies of the records in human and computer readable form which can be searched, sorted and processed by the FDA.	While there may be similarities, maintaining process capabilities of the old system(s) in a new is a substantial expansion of scope of Part 11 functional requirements that should go through the FDA rule making process rather than being introduced via guidance. Further and unrealistic to achieve in some cases. For example, the old system may not have the ability to search, sort or process information in the way desired. Further e-Records may not be migrated and the ability to process information may be lost as systems are retired or become obsolete.
	6.2.1.5 Unavoidable Differences And Losses Should Be Accounted For....	454	Insert sentence after "presented." "The fundamental objective of the migration is to preserve the essential meaning of the information as judged by experts in the field to be equivalent to the original in the context of its stated, actual or intended use.."	Migration to new systems may result in changes in appearance as well as analytical result calculation precision from the original system. Recognizing this it is important that the essential meaning of the information not change and that only that information relevant to essential meaning need be migrated.

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	6.2.1.5 Unavoidable Differences And Losses Should Be Accounted For....	471 - 473	Change: "Just prior to performing the electronic record migration a trusted third party from outside of the organization that has some responsibility for the electronic record verifies the digital signature using the old system methods:" To: "Just prior to performing the electronic record migration a trusted third party verifies the digital signature using the old system methods. The trusted third party should be independent from the organizational unit responsible for the electronic record and may be an independent service provider from outside the corporation regulated by the FDA.	Current sentence is confusing. Clarification is needed on who is an acceptable 3 <sup>rd</sup> party.	
	6.2.1.5	478	Replace line 478 with: "The migrated records must maintain the integrity of the association of signators (people) and records. The above trusted third party then applies a new digital signature (their own)	It must be clear that you are not migrating the signature itself, but rather migrating a representation of the fact of the signature and adding a new signature of testimony by a trusted third party.	
	6.2.1.5 Unavoidable Differences And Losses Should Be Accounted For....	495	States "An electronic record that supplements the migrated electronic record should explain the correlation between old and new color representations, so that the reader would correctly interpret the information"	Given the differences between the old and new systems are documented this appears to be an unnecessary step and one that is not typically supported by commercial software. Thus adding to the effort and cost of migration and offering limited incremental value.	

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		497-499	Replace the entire sentence "However... authenticity." With: "The text (that referred to the colors) may be altered to be consistent with the new colors."	<p>Transcribing of the text to refer to the new colors is required to preserve the essential meaning of the record in a manner that is easily understood. Requiring literal text be preserved and to be understood by humans in a convoluted fashion, especially after multiple migrations, could lead to human error of serious consequence. Migrations of text need not be any more literal than migrations of numbers that may change in literal representation from one system to the next. The key determining factor should be whether the migrated record preserves the essential meaning of the original record, i.e. judged by experts in the field to be equivalent to the original in the context of its stated, actual or intended use. Any such transcription can be documented as part of the migration process.</p> <p>Furthermore, this requirement is not typically supported by commercial software.</p>