AdvaMed Comments

Guidance for Industry
21 CFR Part 11; Electronic Records; Electronic Signatures
Maintenance of Electronic Records

Draft Guidance

December 6, 2002

(corrected 12/16/02)

	Commenter	Section	Paragraph Line No.	Proposed Change	Comment/ Rationale
1	AdvaMed	2	103-104 258-259 273-282	We intend this draft guidance to apply to the entire required retention period taking into account how the records are used or accessed.	The Medical Device Quality Systems Manual. A Small Entity Compliance Guide, HHS Publication FDA 97-4179, brings some common sense into the issue of records retention. It reads as follows: "Record Retention The QS regulation in section 820.180(b) requires that all records pertaining to a device shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than two years from the date of release for commercial distribution by the manufacturer. Manufacturers of longlife products should make prudent decisions as to how long to keep records. For example, there may be no value in keeping records for longlife devices such as stretchers, surgical tools, containers, etc., forever if the probability is low that any postdistribution remedial activity will occur. For devices that require repair or capital equipment devices that probably will be updated, appropriate records should be retained to support these repairs or modifications. Device master record requirements apply to devices modified in the field by the manufacturer's representatives after the devices are commercially distributed. Modification of a device is manufacturing and the QS regulation covers all manufacturing of devices where the result is placed into commercial distribution. In any case, a manufacturer should be prepared to provide a rationale for its decision to discontinue record-keeping." The longest lasting value of archival quality records is their ability to support postdistribution remediation activities. As records age, their value in supporting improvements in product quality, safety and effectiveness or other quality functions quickly diminishes. Accordingly, certain system functions are no longer needed nor desired as a record enters its archival phase. Therefore, instead of recommending that systems maintain a static level of functionality throughout the records lifecycle, there should be a risk-based approach in determining the system functions (e.g. retrieve, update, sort, search, compile, analyze, report, etc) for systems that maintain archived records.

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2	AdvaMed	2.1	121	Insert the following sentence as another sentence after the word "categories" in line 121 "Predicate Rules vary by FDA regulated industry " Then replace the wording "Examples of such categories include" with the wording "Depending on the industry, predicate rules categories may include", "	The phrase "Examples of such categories include, but are not limited to..." implies that all FDA regulated articles are subject to each of the categories enumerated. Large segments of the medical device industry do not have specific clinical research requirements or specific laboratory practices requirements (e g. Class1 Design control exempt and 501K exempt products). As currently worded, this guidance could be interpreted to expand the scope of predicate rules to apply across FDA divisions
3	AdvaMed	2.1	121-125	Change from: ...into several broad categories. Examples of such categories include but are not limited to... To: . into several broad categories. Predicate Rule requirements vary. Depending upon the regulated industry, Predicate Rules may include, but are not limited to...	To clarify the requirements for an Archive, the GLPs require not only retention of study records, but also: "There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations." "An individual shall be identified as responsible for the archives" "Only authorized personnel shall enter the archives" "Material retained or referred to in the archives shall be indexed to permit expedient retrieval" Clearly these requirements were written with paper in mind, but this is still the predicate rule so we cannot maintain electronic records on the computer or system on which they were generated. They must be 'archived' off to another system or media. This requirement seems to conflict with lines 243-245 which more or less suggests/recommends a separate archive to be 'prudent'. This guidance should not be interpreted in a manner that would expand the scope of Predicate Rules across FDA divisions.

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4	AdvaMed	4.1	152-182	Delete	This is redundant, as these requirements are already stated in the regulation.
5	AdvaMed	5.2 1	210-211	Change from: You should identify and control factors that could potentially affect the reliability of electronic records during their records retention period To. Factors that could potentially affect the reliability of electronic records during their record retention periods should be identified in the User Requirements Specification and Risk Assessment Process.	This has no meaning independent from what companies already do as a part of system validation. This is managed through the Risk Assessment process and User Requirements Definition
6	AdvaMed	5 3	227-235	Change Lines 227-229 (the first sentence in this section) From: You should periodically access a representative number of electronic records to ensure that record contents can still be read and evaluated throughout the records retention period. To: Continued availability of electronic record information should be addressed through periodic testing*. Also, delete lines 229-235. "For example, if...in this regard."	This is done on a process basis not a record basis. That is, tests are performed to determine if we can read records on a tape. We don't see if we can read specific records This is a very important distinction from a process point of view. In this same section is a reference to suppliers and producers of media. If you analyze history, the likelihood of the supplier outliving the e-record is unlikely. This also implies that suppliers may incur legal liability. To establish a system to periodically retrieve information (based on a time period) will require vast resources. What is meant by a representative number of electronic records? Is it a valuable utilization of resources to keep all the electronic files 'viable'? This is an area where a risk based approach would help considerably To put a process into place based upon guidance will require significant resources, but not reduce risk by a significant amount.
7	AdvaMed	5.3	236-245	Delete	This may be a good business practice; however, very little specific, concrete guidance is provided. Also, the terminology "most important electronic records" and "primary electronic records" is unclear and actually creates questions rather than providing guidance.

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8	AdvaMed	5.4	250	From: "You should monitor the conditions under which..." To: "You should consider the conditions under which..."	The recommendation in the guidance document to monitor the conditions under which the electronic records are stored (giving recommended parameters to measure such as temperature, humidity, dust, vibration, and sources of electromagnetic and radio frequency interference) adds unnecessary requirements for record storage and retrievability. Retrievability of the electronic records during their retention period should be verified; the monitoring of environmental records should be peformeed as needed
9	AdvaMed	5.5	258-259	Revise to read: "Throughout the records retention period, the ability to process information in an electronic record should be appropriate for the purpose(s) for which it is maintained A manufacturer should be prepared to provide a rationale for changes in record-keeping practices."	See Comment 1.
10	AdvaMed	5.5	271	Delete the sentence beginning with "the ability to process	It is already identified in the beginning of section 5.5 in a clearer manner. The minimal change by using the term "ability" in the last statement adds confusion.
11	AdvaMed	5 5	267-272	Remove text	This is an extension of the regulation and is not required in order to conform to the predicate rule requirement. This requirement can add unnecessary burden on industry for minimal to no benefit. Contrary to the implied contention in the draft guidance, the word "processability" does not appear in the regulation.
12	AdvaMed	5.5	273-276	Revise to read: Accordingly, where you could use computer technologies to search, sort, or manipulate information in an original electronic record, and where it is necessary to ensure the public's safety, you should be able to use computer technologies to perform the same kinds of processing on information in the maintained electronic record	See Comment 1.
13	AdvaMed	5 6	291	From: "...incomplete copy from Draft Guidance For Industry --Not For Implementation 12 being..." To: "incomplete copy from being "	Contains extraneous words that look as though they were once the footer for the document. Eliminate 'Draft. .12.'

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14	AdvaMed	6	294	Add a third approach ("Data Vault") to be used for data that are being retained for historical purposes only. In this approach, at the point when the system is being retired, the data would be converted to a common electronic format, thereby making it unnecessary to retain the originating system. All records in scope of Part 11 would then be available in common electronic format, thus eliminating the need for maintenance and upkeep on obsolete systems	Although the guidance identifies two approaches and makes the statement that, "you may use one or both approaches, or another approach. ", it would be valuable if the FDA would formally define a third approach to long-term data retention of records. This third approach may only be relevant if the FDA's stance on "processing" of old or archived records is relaxed (see comments about lines 256-282). The "Data Vault" approach would require that electronic records and audit trail information be available, without the requirement that the original system be placed in a time capsule or migrated. This approach would be most effectively applied where records are kept primarily for historical reasons and are not actively used or processed. The basis for this solution can be found in part 11 requirement 11.10 (b) "The ability to generate accurate and complete copies of records in both human readable and electronic form.. " If a business chooses to phase out a system or wants to archive the history of a system, this "Data Vault" method is another approach to meet all of the requirements of Part 11. Additional details could include the following: - Make accurate and complete copies of all in-scope records in human readable and electronic form. (This is a Part 11 requirement (11.10 (b)) that should be met by the original system already.) This assures the availability of information during the retention period. - Include in this 'accurate and complete copy of the record' other information such as audit trials, electronic signatures (if applic), and any other metadata, so that no information is lost and 'links' (such as those associated with electronic signatures or audit trails), are retained in all of the copied electronic data records. - Validate this copy process as well as the system used to retrieve the information during the retention period of the electronic records. In this way, a "data vault" could hold the historical information from many retired electronic systems in a format that can be more easily maintained over time. This approach would substantially reduce the maintenance and cost of preserving data.

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15	AdvaMed	6 2	334-336	Delete: "You should document the migration so that you have a traceable history of what systems were used throughout the records retention period."	A systems history is maintained via change control for validated systems. But once we migrate records to a "new" system, information about the old system is immaterial. We assume operating systems and other infrastructure items are not a part of the "systems" referenced here.
16	AdvaMed	6.2	337-354	Delete text.	Delete. "Old" e-records are deleted or purged when the record migration to a "new" system has been completed. Record migration is validated. The ability to process "old" e-records is not a viable option. This is the purpose of validating the migration process. The guidance offered in these sentences conflicts with the guidance in the section 6.1. The information adds no relevance to the overall regulated guidance, it is more business guidance.
17	AdvaMed	6.2	355 - 363	Remove lines 355 – 363.	In section 6.2, lines 355 to 363, the FDA references a number of specific system changes that we would consider merely enhancements that might require some level of risk assessment and revalidation. The FDA appears to consider these changes to be "migration" activities and would therefore expect far more validation than is reasonable or necessary. We feel, in general, that these items do not belong in this section as part of the discussion on migration.
18	AdvaMed	6.2.1	368-369	Remove text	The data migration plan should adequately address the ability to process information consistent with the overall level of data being migrated. To assume all data migration plans will continue to preserve all data processing capabilities is beyond the requirements of any predicate rule. Again this appears to be an expansion of the regulation without adequate process.
19	AdvaMed	6 2 1.2	397	The word "liability" should be changed to "reliability"	We assume this is a typing error in the document
20	AdvaMed	6.2 1 2	398	Starting with the word "even" on this line, replace the sentence with "even though metadata may have been transformed, the data element should be identified properly in the new system".	The current wording implies metadata has been transformed. However metadata has no unique function that requires it to be transformed as identified in the Part 11 guidance document
21	AdvaMed	6.2 1.3	413	Change the heading to be: "Electronic Record Change Control"	This better captures the essence of the contents in lines 414-438
22	AdvaMed	6.2.1 3	419	Move the sentence "This electronic record integrity information includes, but might not be limited to, audit trails and links between signatures and electronic records." to the beginning of the section.	By moving this sentence to the beginning it establishes the intention of the information in this section

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23	AdvaMed	6.2.1.3	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 that the migration from the old to the new system is documented, this appears to be an unnecessary step and one that is not typically supported by commercial software. This adds to the effort and cost of migration with limited incremental value.
24	AdvaMed	6 2.1.3	422 - 424	Rather than require a separate and new audit trail entry to reflect migration activity, it should be sufficient to document the migration in the system validation documentation.	The requirement to add information to the audit trail of each electronic record migrated seems overly prescriptive. We assume the FDA wants evidence that the migration occurred, as well as documentation of the migration process that was followed. We propose that the system documentation show the migration steps completed, the tools used and the validation activities conducted.
25	AdvaMed	6.2.1.3	427-429	Delete: "An audit trail itself may undergo...and/or deletion of an old electronic record."	Delete Adds no new guidance.
26	AdvaMed	6.2.1.4	439-440	Replace this section heading with the following "The Ability to Maintain Context and Meaning of the Migrated Data".	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
27	AdvaMed	6.2.1.4	441-449	Replace the contents of this section with· "In the migration approach, the new computer system should maintain the critical context and meaning of the information that was migrated to the new system." Delete everything else in this section	Maintaining process capability of the old system is a 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.
28	AdvaMed	6.2.1.5	458-461	Change the sentence beginning with the word "Generally" to read. "Generally, our view is that migrated electronic records could still reliably preserve and present the context and meaning of the information, despite some losses or modifications, provided that differences are appropriately accounted for, and explained in either the migrated record or readily available documentation."	The focus should be on preserving the appropriate meaning and context of the information not the process used to originally create the record

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29	AdvaMed	6 2.1.5	463-470	Change the structure of the sentence to read: "If the migrated electronic record is in a different file format or otherwise not identical, in every respect, the automated digital signature verification process will yield a failure outcome (indicating that the contents of the electronic record changed after the record was signed, or the signature is not genuine)."	Changing the structure clarifies the intent of the sentence.
30	AdvaMed	6.2.1 5	470	Replace the words "should perform" with "should consider performing"	The word "should" by itself is too prescriptive By adding the word "consider" to the statement it allows technical options to preserve the appropriate meaning and context of the record
31	AdvaMed	6 2 1 5	471-474	Change the bullet to read "Just prior to performing the electronic record migration a documented migration plan should be created and reviewed."	As it was originally written,"Trusted Third Party from outside the organization" establishes a standard of independence beyond the underlying predicate rules and adds an additional layer of cost. It should require rule making to establish this new standard.
32	AdvaMed	6.2.1 5	471-487	Delete this entire section: "Just prior to performing ..migrated electronic record and explanatory statement."	This entire section is confusing Migration is a validated process. There is no clarity as to what constitutes a "trusted third party." This concept adds additional process steps without a corresponding increase in data integrity from a risk management perspective.
33	AdvaMed	6 2 1 5	475-476	Change the bullet to read: "Under appropriate documented controls, the signed electronic record is migrated to the new system "	As it was originally written,"Trusted Third Party from outside the organization establishes" a standard of independence beyond the under laying predicate rules. It should require rule making to establish this new standard of care.
34	AdvaMed	6.2.1.5	478-487	Change the bullet to read; "A new digital signature is applied to the migrated record using technologies appropriate to the new system. Create a migration report detailing the activities and completion of the migration that demonstrates the appropriate review and approval process was followed."	As it was originally written,"Trusted Third Party from outside the organization establishes" a standard of independence beyond the relevant predicate rules. Rule making should be used to establish this new standard of care.
35	AdvaMed	6.2.1 5	463 - 487	Define "trusted third party".	There has been substantial confusion of what constitutes a "trusted third party" Should this third party be from outside the company, outside the division, or outside the department? What level of abstraction from the data migration process and/or business process is necessary to verify that a person can be considered a "third party"? And what level of expertise and/or experience with the company is necessary to determine that a person can be considered "trusted"?

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36	AdvaMed	6.2.1.5	463 - 487	Modify the language in this section to describe more clearly when the use of "trusted third party" is necessary. We would propose that this approach only be recommended when digital signature technology is applied to electronic signatures, rather than any time digital signature technology is used in a Part 11-relevant system.	In section 6.2.1.5, lines 471 to 487, the FDA discusses the use of a "trusted third party" to supervise the migration of digital signatures to a new system. The "trusted third party" is supposed to apply a new digital signature to the migrated electronic records. Upon initial review of this draft guidance, there was some confusion about the correct interpretation of this section. Some misinterpreted digital signature as electronic signature. Although we recognize this as a misinterpretation (because a digital signature is a specific type of technology and an electronic signature is an electronic representation of a signature), this distinction could be spelled out more clearly in the guidance document. There was also some confusion about when a "trusted third party" should be involved in the re-verification of signatures. The guidance can be interpreted as whenever digital signature technology is used, or, can be interpreted as only necessary when digital signature technology is applied to electronic signatures. Further clarification of this section is necessary to provide sufficient guidance to industry.