



## **Commentary on the “Durable Media” Issue**

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Ref: “Update on the “Durable Media” Debate, November 20, 2000, by J. McKenney

**SUMMARY:** FDA’s position on the concept that “an electronic record is not created until recorded on durable media” has changed since the early days of Part 11. A mounting body of evidence indicates that “durable media” will no longer be a factor in FDA inspections for Part 11 compliance. As a result, pharmaceutical companies should no longer use the lack of durable media as a criterion for exempting systems from Part 11 compliance. Instead, FDA will be focusing on whether or not the records are retrievable, and more importantly, can they be altered.

**BACKGROUND:** In the late 1990’s, following the publication of 21 CFR Part 11 in March of 1997, FDA was clear on the issue of durable media. Through public symposiums, private discussions and email, it was understood that FDA would consider systems that did not write electronic records to “durable media” to be exempt from Part 11. This view was further supported in FDA’s “Guidance for Industry, Computerized Systems Used in Clinical Trials, FDA, April 1999”, which stated in Section V.B.1.a., “A record is created when it is saved to durable media...”. The general understanding was that if a system did not write records to a hard drive, CD, or some other form of “durable media”, then as far as FDA was concerned, no record was created and Part 11 controls would not be required.

That view, however, has shifted as FDA has encountered increasing numbers and types of systems that do not have “durable media”, yet which contain important electronic records which may be intentionally or inadvertently modified or deleted. Examples include industrial programmable logic controllers (PLCs), personal digital assistants (e.g., Palm™ and iPAQ handhelds), and many others. This shift in FDA’s position is documented in a November, 2000 white paper by this author (referenced above).

The most recent and compelling documented evidence of FDA’s changing view on this matter is found in a “Memo of Meeting” on the FDA Dockets web site: (<http://www.fda.gov/ohrms/dockets/dockets/dockets.htm>). The following excerpt is from the Memo of Meeting with Ionics Instruments, dated September 6, 2001:

"The [Ionics] representatives asked if durable media was part of the definition of electronic record. We [FDA] said that it was not. We commented that people were using devices that recorded information to media such as flash memory and that as long as a human readable form of the electronic record could be generated the durability of the media was not a factor. We advised that this approach was consistent with the Electronic Signatures in Global and National Commerce Act."

While such comments in FDA memos do not represent official FDA regulations or policy, the above excerpt is nonetheless significant when taken in context with all of the other available

evidence of FDA's change in perspective on durable media. This is further reinforced by examining the list of FDA personnel in attendance at the above-referenced meeting (Tom Chin, James McCormack, Paul Motise, and Charles Snipes). Each of these FDA officials has been closely involved with Part 11 for many years, and it is unlikely they would allow such a statement to be published in the public memo if they did not support it.

**“DURABLE MEDIA” DEFINITION:** It is important to note that the term “durable media” is not used or defined in any of the following official FDA publications:

- 21 CFR Part 11
- The Preamble to 21 CFR Part 11
- The Glossary of Terms (Guidance for Industry 21 CFR Part 11; Electronic Records; Electronic Signatures, Draft Guidance)

The term “durable media” is used, but not defined, in:

- Guidance for Industry, Computerized Systems Used In Clinical Trials

It is precisely this lack of official definition and regulation concerning “durable media” that has made it possible for FDA to revise (if not eliminate) its interpretation of the term, in order to accommodate evolving technologies and federal legislation.

**IN CONCLUSION:** Based on the evidence discussed in this paper and elsewhere, it is this author's opinion that:

- There is sufficient evidence of FDA's “old view” of durable media to support many of the earlier system exemption decisions that were made, especially in the 1990's. However,
- Considerable evidence is mounting that viable, long-term Part 11 strategies should not include “durable media” in their definitions of electronic record or electronic record creation, nor should it be in the list of criteria for classifying “out of scope” systems; and
- FDA's attention has shifted away from media type and toward these important questions: (1) can the data be retrieved in perceivable form, and (2) can the data be altered? If the answer to either question (and especially to question 2) is “yes”, then the prudent approach would be to apply Part 11 controls to such a system.