



December 3, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
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Re: Comments on, "Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures; Maintenance of Electronic Records, Draft Guidance", Docket No. 00D-1539

Dear Sir or Madam:

SEC Associates, Inc. (SEC) is pleased to have the opportunity to provide comments on the above-referenced draft guidance. SEC is a regulatory compliance consulting and computer validation services firm, and as such, we have been heavily engaged in providing a range of services to FDA-regulated companies relating to both computer validation and 21 CFR Part 11.

In general, we believe that this draft guidance provides information that is both reasonable and helpful to industry. There are, however, a few points which we feel would benefit from further clarification or examples. In addition, we disagree with the proposed guidance on a couple of important issues. Our comments and recommendations are detailed on the attached pages.

Thank you once again for the opportunity to express our views.

Very truly yours,
SEC ASSOCIATES, INC.

A handwritten signature in cursive script that reads "John C. McKenney Sr.".

John C. McKenney, Sr.
President

00D-1539

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- 5.2 The list in Section 5.2 is helpful. It serves as a clear reminder that copies of data records (without associated meaning) and media life are not the only considerations for ensuring long-term readability of records.
- 5.5 An additional contrasting example may be helpful here. For instance, where the original system provides the capability to filter and select a subset of records for a report, being limited to search only for values in PDF representations of the records would not provide the same functionality.
- 6.2 This section states that migrations should be "documented" and "verifi[ed]". In our view, migrations should be validated, the process of which would generate the appropriate documentation and verification.
- 6.2.1.3 This section asserts that migration of a record to a new environment creates a new record, thus requiring that a new electronic audit trail entry or record must be created to capture the "creation" of the record in the new environment. We disagree with this interpretation. In our view, migration is not an act of creation; rather, it is an act of transforming and moving an existing record to a new environment. If a new audit trail entry were required, it would be due to record modification, not creation. There are, however, more important considerations regarding the need (or not) for an audit trail.

For one, migrations are normally performed via execution of automated utilities, rather than by manual transformation of digital data. This would fall outside the scope of 11.10(e), which specifies that the audit trail is limited to "operator entries and actions". Furthermore, record migration is generally recognized as a major event that requires validation, including careful documentation and testing. It tends to be done sparingly, and often never, during the life of an application. If done, it is a unique, and very likely to be a one-time event for a given system or application. Therefore, even if the argument is made that the automated transformation process must be initiated by an operator action, we would argue that this process should be exempt from the electronic audit trail due to (1) the thorough documentation and validation that should accompany the migration, and (2) the rare and unique nature of this operation.

- 6.2.1.5 This section requires that unavoidable losses or changes in migrated information be "explained in either the migrated record or readily available electronic documentation". In our opinion, thorough system documentation, with appropriate approvals - even in paper form - should be adequate to explain these situations. As stated in our comments for 6.2.1.3, record migration is a unique and rare process. In these one-of-a-kind processes, paper-based documentation will often be the most effective, efficient, and yet still reliable method for capturing the critical information about the process. Use of electronic records should not preclude the use of paper records in such instances.
- 6.2.1.5 The following comments all pertain to the example of digital signature verification, where the original digital signatures would fail after migration.
- a. The opening paragraph of this example concludes with the statement, "...you should perform the following sequence of procedures." We recommend that the procedures described be offered as only one possible approach that would be acceptable to FDA. With the speed of technological innovation and evolution, it is conceivable that entirely different, yet highly reliable, approaches to solving this

problem may come available. Thus, the scenario in this example should not be worded as if it is the only possible solution.

- b. The second bulleted paragraph refers to a trusted third party “from outside the organization...”. In order to avoid endless debate, please define “organization”.
 - c. The second bulleted paragraph refers to a trusted third party from outside the organization “that has some responsibility for the electronic record...”. What does “some responsibility” mean? Does this imply that the trusted third party must have some hand in developing the software, running the system, maintaining the records, or what? Why not leave it as “trusted third party from outside of the organization”? We tend to think that they cannot be a disinterested, trusted third party if they have a stake in the electronic records, any more than a Certified Public Accountant can serve as a trusted third party if they have a vested interest in the company they are auditing. Please clarify the intent of this phrase or delete it.
 - d. The fourth bulleted paragraph requires the trusted third party to digitally sign the migrated electronic record. What if the new environment does not support digital signatures? Should not any part 11 compliant electronic signature be acceptable? Furthermore, assume that the migration is done solely for the purpose of transforming the data into a format better suited for long-term retention and retrieval. In our opinion, it should be possible to achieve a reasonable degree of assurance of record integrity, authenticity, and reliability through a variety of means which may or may not include the use of digital signatures. For example, we should be able to place more trust in the trusted third party to witness and verify the transformation process and “locking” of the migrated data. Digital signature technology should not be the only means to achieve the desired goal.
 - e. In line with our previous comments, the requirement to have the trusted third party digitally sign the migrated electronic record, and then to digitally sign a separate electronic record (or addition to the migrated record) that explains the migration seems to go beyond reasonable measures for ensuring data integrity and trustworthiness. Corporate scandals notwithstanding, if we cannot trust the hand-signed word of a “trusted” third party to verify the conversion process and ensure the data is adequately “locked down” and protected; then we have passed the point where technology can protect us from ourselves. This level of technological complexity should not be required to provide a high degree of assurance that the records were properly migrated, verified, and protected after the migration.
- 6.2.1.5 This section states that any text explaining use of colors in displayed records should not be altered, even though the actual colors might have changed, due to the migration. We believe this could be confusing and could lead to misinterpretation of the data.

While somewhat extreme, the following examples illustrate the potential problem:

For example, in the original, colors are identified as:

<u>Actual Original color</u>	<u>Original Text</u>	<u>Becomes New Color</u>	<u>Text Still Reads</u>
PINK	PINK	RED	PINK
CYAN (turquoise)	BLUE	GREEN	BLUE
GRAY	GRAY	DARK BLUE	GRAY

Or...

BLUE = Low
RED = Out of range high
BLACK = Normal

And new colors are GREEN, BLUE, BLACK

Then an electronic record would have to be created to say:

OLD BLUE = NEW GREEN
OLD RED = NEW BLUE
OLD BLACK = NEW BLACK

Looking at the printout, blue values (which now represent "Out of range high") could be misinterpreted to represent "Low".

General Comments

- A. Because the question still arises, we recommend stating clearly in the guidance that copying electronic records to paper (even if "everything" is printed) is not an acceptable substitute for maintaining an electronic version of the records.
- B. Regarding the issue of long-term record retention with processability, we wonder if FDA is asking the pharmaceutical industry to implement a solution to a problem which, on a macro scale, has not yet been solved – either by industry (not just FDA-regulated), academia, or government (not just FDA)¹. While specialized pockets of research and applications have obtained limited success, there is no large-scale solution for long-term maintenance of processable e-records as envisioned by this guidance. While this is a very real problem that must be solved, we are concerned that FDA may be holding FDA-regulated industry accountable for a solution that has not yet been developed on a commercial scale. We respectfully recommend that FDA and industry hold one or more workshops to explore this issue further, and determine whether there is a workable solution that can be implemented until further technological and standards breakthroughs make it possible to achieve the level of control desired by this draft guidance.

¹ *Data Extinction*, MIT Technology Review, Volume 105/No. 8, Oct. 2002, pgs 37-42.