Guidance for Industry

21 CFR Part 11; Electronic Records; Electronic Signatures

Maintenance of Electronic Records

Draft Guidance

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July 2002

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Additional copies of this draft guidance document are available from the Office of Enforcement, HFC-200, 5600 Fishers Lane, Rockville, MD 20857; Internet http://www.fda.gov/ora/compliance_ref/part11/default.htm

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Maintenance of Electronic Records

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of applicable statutes and regulations.

1. Purpose

The purpose of this draft guidance is to describe the Food and Drug Administration's (FDA's) current thinking regarding principles and procedures for maintaining electronic records in electronic form in meeting the requirements of Part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures. It provides guidance to industry, and is intended to assist persons who are subject to the rule to comply with the regulation. It may also assist FDA staff who apply part 11 to persons who are subject to the regulation.

[1] This draft guidance was prepared under the aegis of the Office of Enforcement by the FDA Part 11 Compliance Committee. The committee is composed of representatives from each center within the Food and Drug Administration, the Office of Chief Counsel and the Office of Regulatory Affairs.

2. Scope

This draft guidance is one of a series of guidances about part 11. We intend to provide information with respect to FDA's current thinking on acceptable ways of meeting part 11 requirements to ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities. This draft guidance focuses on maintenance of electronic records.

When an FDA regulation requires that a record be maintained, generally the regulation specifies the period of time the record must be kept (referred to in this draft guidance as the records retention period). We intend this draft guidance to apply to the entire required retention period regardless of how actively the records are used or accessed.

This draft guidance presents key principles and practices and addresses some frequently asked questions, but it is not intended to cover everything about maintaining electronic records. The guidance provides two examples of approaches to electronic record maintenance.

This document includes some considerations that are also relevant to recording information in the first place. If information is inaccurately or incompletely recorded, record maintenance practices will not compensate for those shortcomings.

2.1 Applicability

Part 11 applies to electronic records and electronic signatures that persons create, modify, maintain, archive, retrieve, or transmit under any records or signature requirement set forth in the Federal Food, Drug, and Cosmetic Act (the Act), the Public Health Service Act (PHS Act), or any FDA regulation. Any requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of part 11, are referred to in this document as predicate rules. Most predicate rules are contained in Title 21 of the Code of Federal Regulations. In general, predicate rules address the research, production, and control of FDA regulated articles, and fall into several broad categories. Examples of such categories include, but are not limited to: manufacturing practices, laboratory practices, clinical and pre-clinical research, adverse event reporting, product tracking, and pre and post marketing submissions and reports. However, this draft guidance only applies to records that, by predicate rule, you are required to maintain.

2.2 Audience

We intend this draft guidance to provide useful information and recommendations to:

- Persons subject to part 11;
- Persons responsible for the maintenance of electronic records; and,
- Persons who develop products or services to enable implementation of part 11 requirements;

This draft guidance may also assist FDA staff who apply part 11 to persons subject to the regulation.

3. Definitions and Terminology

Unless otherwise specified below, all terms used in this draft guidance are defined in FDA's draft guidance document, "Guidance For Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Glossary of Terms," a document common to the series of guidances on part 11.

4. Regulatory Requirements

4.1 What Does Part 11 Require?

Part 11 has several requirements relevant to maintenance of electronic records. For example:

- Section 11.10 requires persons to "employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine." To satisfy this requirement persons must, among other things, employ procedures and controls that include "[P]rotection of records to enable their accurate and ready retrieval throughout the records retention period." See section 11.10(c).

Other part 11 requirements apply throughout the record retention period. Therefore, you should take the requirements below, among others, into account as you plan and implement your electronic records maintenance activities. Here are some examples:

- Section 11.10(a): “Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.”

- Section 11.10(b): “The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.”

- Section 11.10(d): “Limiting system access to authorized individuals.”

- Section 11.10(e): Use of secure, computer-generated, time-stamped, audit trails that, among other things, "shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying."

- Section 11.50: Signed electronic records shall contain information associated with the signing that clearly indicates the printed name of the signer, the date and time of signing and what the signature means. These items shall be "subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout)." 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.

- Section 11.70: "Electronic signatures and handwritten signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means."

Implementation of these and other part 11 controls will help to ensure that your maintained electronic records will be trustworthy, reliable, authentic, and compatible with FDA's public health responsibilities.

4.2 What Do Predicate Rules Require?

In addition to establishing records retention periods, predicate rules, among other things, establish record content and signing requirements. It is beyond the scope of this document to enumerate these requirements. However, keep in mind that electronic records must still meet predicate rule content and signing requirements, and they must be retained for as long as the predicate rule requires.

5. General Considerations For Electronic Records Maintenance

We believe it is very important that the factors unique to the maintenance of electronic records are controlled and work properly together so that people can accurately and readily retrieve and use the information that was originally intended to be preserved and presented. We believe the following principles and practices will help meet that objective.

5.1 Procedures For Electronic Records Maintenance Should Be Established and Followed.

As noted under Section 4 of this document, Section 11.10(c) requires that you employ procedures and controls for the protection of records to enable their accurate and ready retrieval throughout the records retention period. You should update the procedures and controls as conditions warrant. Procedures should describe:

- How electronic records will be maintained;
- Storage conditions and precautions;
- Retrieval and access restrictions;
- The technical approach to long term electronic record storage (e.g., electronic records migration, as described below); and,
- Personnel responsibilities for relevant tasks.

5.2 Factors That Might Affect The Reliability Of Electronic Records During the Required Retention Period Should Be Identified And Controlled.

You should identify and control factors that could potentially affect the reliability of electronic records during their records retention periods. These factors include, but are not limited to:

- Data encoded within an electronic record (e.g., computer readable representations of information);
- Metadata for an electronic record (e.g., information that gives the data meaning and context, such as data dictionaries for databases);
- Media (e.g., disk, tape, or flash memory devices) that record data and metadata;
- Hardware used to retrieve and display the electronic record;
- Software (both application programs and operating systems) used to read, process, and display electronic records; and,
- The processes of extracting and presenting information in human readable form.

If these factors are not controlled properly the information that the electronic records should convey might not be complete, accurate, or usable.

5.3 Continued Availability And Readability Of Electronic Record Information Should Be Ensured.

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. For example, if you store electronic records on reels of magnetic tape, you

should, on a pre-established schedule, rewind the tape and ensure you can still read the electronic records. We believe that suppliers and producers of electronic recording media have specific scientific information relating to the performance characteristics and limitations of the media. Therefore, those suppliers and producers should be a good source of information about how frequently you should try to access the electronic records. Literature searches may also provide useful information in this regard.

If you find that you are starting to have difficulty reading the electronic records we believe it would be highly advisable to subject them to data recovery procedures and/or transcribe them onto fresh electronic recording media before the degradation renders the electronic records unrecoverable.

Because electronic records are generally more perishable than traditional paper records, you should make back up electronic copies of your most important electronic records and store them separately from the primary electronic records. For example, we believe it would not be prudent to store both primary and backup electronic records on the same computer hard drive because both could be lost if the hard drive fails.

5.4 Electronic Records Should Be Stored Under Appropriate Environmental Conditions.

You should determine what storage conditions are appropriate for the specific electronic record media, and then maintain those conditions throughout the records retention

period. You should monitor the conditions under which the electronic records are stored. We believe that suppliers and producers of recording media can be a good source of information about specifications and precautions regarding such factors as temperature, humidity, dust, vibration, and sources of electromagnetic and radiofrequency interference. Literature searches might also provide useful information about these factors.

5.5 The Ability To Process An Electronic Record's Information Throughout Its Records Retention Period Should Be Preserved.

Throughout the records retention period, the ability to process information in an electronic record should not diminish. By being able to process the information, you would maintain the ability, for example, to effectively and efficiently reconstruct events, detect and investigate problems, detect trends and assess the need to modify procedures or specifications to improve product quality, safety, and effectiveness. Some FDA regulations require that records be maintained so that data in the records can be used for periodically evaluating product quality standards to determine the need for changes in product specifications, or manufacturing or control procedures – see 21 CFR 211.180(e), for example. In addition, maintaining an electronic record in a form that permits the record's information to be processed should help you to meet the part 11 requirement that you be able to generate electronic copies of electronic records that are suitable for FDA inspection, review, and copying. See section 11.10(b), as mentioned above in Section 4 of this document. The ability to process information in an

electronic record is a key aspect of whether certain electronic records are suitable for FDA inspection and review.

Accordingly, where you could use computer technologies to search, sort, or manipulate information in an original electronic record, you should be able to use computer technologies to perform the same kinds of processing on information in the maintained electronic record. 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.

5.6 Copying Processes Should Produce Accurate And Complete Copies.

You may find it necessary to copy electronic records from time to time during their records retention periods (e.g., from one type of disk to the same or different type of disk). One reason for this copying may be to compensate for wear and tear on media. We believe that it is very important that information not be lost or altered in the copy process. Some systems have a built-in copy verification mechanism, such as a cyclic redundancy check, that could be used to prevent an inaccurate or incomplete copy from

being made. A copy process that does not implement such a built-in error checking mechanism to prevent making an inaccurate or incomplete copy should be validated.

6. Approaches To Maintenance Of Electronic Records

You should use an approach to maintenance of electronic records that is best suited to your own circumstances, taking into account such factors as the durability of the electronic record media and how long you are required by predicate rule to maintain a particular electronic record. Below, we describe two approaches to maintaining electronic records. We recognize that, within a given organization, you may use one or both approaches, or another approach that meets applicable statutory and regulatory requirements.

6.1 The Time Capsule Approach

The electronic records time capsule approach involves preserving an electronic record on the same electronic media and computer system used to create the electronic record in the first place. During the records retention period the computer system might be in use or it might be inactive but still be capable of working. Throughout the records retention period, you would keep the computer system functional and make no changes to the computing environment. For example, you would not upgrade application and operating software, or hardware; upgrades would constitute a migration, an approach

explained below. In short, you would maintain systems as they were at the time the electronic records were created.

Under the time capsule approach, you should preserve system documentation, and ensure that personnel are proficient in system operation and routine upkeep. This means that personnel who are not familiar with a maintained older system should be trained accordingly.

This approach may be of limited practicality for long-term maintenance of electronic records due to the rapid pace of technology changes, such as the emergence of new storage media, revisions to application and operating software, and hardware modifications. In addition, companies that originally furnished systems used to create the electronic records might not elect or be able to support the systems in the long term. Nonetheless, the time capsule approach might be a viable option in some instances (e.g., where record retention periods are relatively short or the electronic record is created, modified, maintained, or transmitted, on a relatively low cost computing system that is dedicated to creating, modifying, maintaining, or transmitting the electronic record).

6.2 The Electronic Records Migration Approach

The electronic records migration approach involves moving electronic records (migrating them) from one computing environment (the source or "old" system) to another different computing environment (the destination or "new" system). You might perform several successive migrations during the records retention period. The outcome of the migration is an electronic record that continues to conform to established regulatory and statutory requirements, including those identified above in Section 4 of this document. You should document the migration so that you have a traceable history of what systems were used throughout the records retention period.

Upon completion and verification of a migration, you may elect to retire or discard the old electronic records and/or system, provided that the migrated records meet all requirements of the applicable predicate rules. However, you should carefully consider when it would be prudent to discard the old electronic records and/or system. The reason for this is that there is a risk that after the migration, a previously unknown problem with the old electronic record or system might come to light. The nature of the problem might adversely affect, among other things, the old electronic record's accuracy, completeness, or authenticity. Your ability to solve the problem might be hampered if you no longer have the old electronic record or system. (For example, solving the problem might involve installing modifications specifically intended to be made to the old system software, but not intended for the new system software.)

During a migration, one or more of the factors that enable an electronic record to reliably preserve and present information might differ between old and new systems. For example, a migration might typically involve transforming the digital sequence of information (e.g., bits) that comprises the original (old) electronic record. It is important to recognize differences between systems and how they might affect how reliably the migrated electronic record can preserve and present information.

Changes in factors that affect how reliably an electronic record can preserve and present information might not always be readily apparent. Examples of such changes include, but are not limited to, the following:

- Installing a new version of an application or operating system software program;
- Moving from one type of record storage media to a different one;
- Moving from one electronic file format to another;
- Changing from one type of video display unit or printer to another; and,
- Changing audio devices

6.2.1 Key Principles Of Electronic Records Migration

A migration generally involves a transformation of the original (old) electronic record. You should be aware that without careful control, information might be lost or altered in ways that impact such key factors as the electronic record's accuracy, completeness, authenticity, integrity, and (potentially) confidentiality. In addition, without careful

control, the ability to process information might be adversely affected. We therefore believe that it is extremely important that you plan and conduct the migration carefully, and maintain the electronic record's ability to reliably preserve and present information. Accordingly, you should carefully implement the principles set forth below in this section.

6.2.1.1 Information Continuity Should Be Preserved.

We believe it is extremely important that the migrated electronic record in its new computing environment conveys an accurate and complete representation of events, data, actions, and identification and signatures of people as required by the relevant predicate rule. Someone who reviews the migrated electronic record should be able to reconstruct events to determine if the predicate rule was followed (e.g., who did what, when, how, production values and conditions, study observations and findings). If you do not maintain this continuity of information you might be violating the predicate rule and you might not have sufficient information to detect, correct, and prevent problems (e.g., problems relating to production and control of a regulated product).

6.2.1.2 Factors In The New Computer System That Enable The Electronic Record To Reliably Preserve and Present Information Should Be Identified And Controlled.

These factors include, but are not limited to:

- Data; we consider it extremely important that information in the migrated electronic record be accurate and complete. For example, where an old system electronic record included the body weights for 100 laboratory animals, the migrated electronic record should contain the same information for the same number of animals.
- Metadata; the information in the migrated electronic record that gives context, meaning, and security attributes to the data should not lessen the reliability of the information the electronic record preserves and presents, even though the metadata may have been transformed so that it functions properly in the new system. For example, if a database is migrated to a new system, the new data dictionary might differ from the old, but it should, nonetheless, accurately and completely present the migrated information.
- Hardware; electronic record storage and display devices can affect the reliability of information preserved and presented. For example, it is possible for a new system video display that differs from the old system video display in resolution or color fidelity to alter the reviewer's interpretation of information (e.g., where graphics and text are color coded to convey meaning and differentiate information).
- Software; the operating system and application programs of the new system should maintain at least the same level of reliability in preserving and presenting information as did the operating system and application programs in the old system.

6.2.1.3 Electronic Record Integrity Attributes Should Be Preserved.

In designing and implementing an electronic record migration you should keep in mind requirements (from part 11 as well as applicable predicate rules) for preserving information that establishes record integrity. Electronic record integrity information might be separate from, but associated with, an electronic record, and therefore inadvertently overlooked if you only focused on migrating the electronic record itself. This electronic record integrity information includes, but might not be limited to, audit trails and links between signatures and electronic records. For example, section 11.10(e) of part 11 requires that audit trails record all operator entries and actions that create, modify or delete electronic records. 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. By adding this new creation step to the migrated audit trail carried over from the old electronic record you will help ensure a continuity of electronic record integrity.

An audit trail itself may undergo a transformation during a migration, but keep in mind that section 11.10(e) requires that the audit trail convey certain information, including information about the creation, modification, and/or deletion of the old electronic record.

With respect to the part 11 requirement that signatures be linked to their respective electronic records, the signature to electronic record links in the new electronic record

system might be created by a technology that differs from that used to create the links in the old system. However, to meet part 11 requirements, it is important that the new links "ensure that the signatures cannot be excised, copied, or otherwise transferred to falsify an electronic record by ordinary means." (See section 11.70.) By having reliable signature to electronic record links in the new computer system, you will help establish continuity of electronic record integrity.

6.2.1.4 The Ability To Process Information In Electronic Records Should Be Preserved.

The importance of being able to process information in an electronic record, using computer technologies, is explained above. 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). For example, if you could sort a table of values using the old system, you should be able to sort those values in the migrated electronic record using the new system, and achieve the same results. Some new systems can, by emulating older systems, process information in a very similar way.

6.2.1.5 Unavoidable Differences And Losses Should Be Accounted For and Explained In The Migrated Electronic Record Or New System Documentation.

When electronic records are migrated from one system to another, we recognize that there might be unavoidable losses or changes in certain information or record attributes that do not diminish the reliability of information that is preserved and presented. It should be clear that this caveat does not apply to losses or changes in information specifically mandated by predicate rules. In addition, we note that changing a record's content could undermine its authenticity. Generally, our view is that the migrated electronic record could still reliably preserve and present information, despite some losses or modifications, provided that differences are appropriately accounted for, and explained in either the migrated record or readily available electronic documentation. Here are some examples:

- Digital signature verification: current technical methods of verifying a digital signature depend upon maintaining the "as signed" electronic record in an unaltered state. 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 that the signature is not genuine) if the migrated electronic record is in a different file format or otherwise not identical in every respect. To account for this scenario, yet ensure continuity of record integrity, you should perform the following sequence of procedures:

- 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;
- Under supervision of the above trusted third party, the signed electronic record is migrated to the new system; and,
- The above trusted third party then applies a new digital signature (using technologies appropriate to the new system) to the migrated electronic record. The same third party also prepares and applies a digital signature to a new separate electronic record (or to an addition to the migrated electronic record) that explains the migration. In this situation, although you would no longer be able to verify the old digital signature directly, you should nonetheless be able to demonstrate continuity of record integrity by verifying the newly digitally signed migrated electronic record and explanatory statement.

- Color code changes; the electronic record in an old system includes a chart that uses colors to describe different groups of test animals, and the text accompanying the chart refers to the groups by those colors. The new system cannot replicate those colors; it uses a different set of colors to represent information. In this case, the migrated electronic record should use the new color representations to differentiate the groups so that the information and distinctions made in the old electronic record are maintained fully and

accurately. 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. However, text (that referred to the colors) in the migrated electronic record should not be altered because doing so would change the record content and authenticity.

7. APPENDIX -- References

You may find the following publications of interest with respect to electronic records maintenance.

Dr. Luciana Duranti, Principal Investigator, University of British Columbia, *"The Preservation of The Integrity of Electronic Records,"* March, 1997 (Internet address: http://www.slais.ubc.ca).

Alabama Department of Archives and History, *"Guidelines For The Use Of Digital Imaging Technologies For Long-Term Government Records In Alabama,"* April, 1997 (Internet address: http://www.archives.state.al.us/ol_pubs/digital.html).

National Institute of Standards and Technology, U.S. Department of Commerce, *"An Introduction to Computer Security: The NIST Handbook,"* Special Publication 800-12.

National Archives and Records Administration, *"Records Management Guidance for Agencies Implementing Electronic Signature Technologies"*, October 18, 2000.

Gregory S. Hunter, *"Preserving Digital Information, A How-To-Do-It Manual"*, How-To-Do-It Manuals For Librarians, Number 93, Neal-Schuman Publishers, Inc. 2000.

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