



November 27, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, Maryland 20852

NATIONAL
FOOD
PROCESSORS
ASSOCIATION

Re: Docket No. 00D-1539
*Guidance for Industry 21 CFR Part 11; Electronic Records;
Electronic Signatures Maintenance of Electronic Records*

Dear Sir or Madam:

The National Food Processors Association (NFPA) is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

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Overview

Addressing the 21 CFR Part 11 long-term retention requirements has proven to be every bit as challenging as expected to identify the key technical issues and considerations to achieve realistic and pragmatic solutions to the preservation of and access to e-Records. Ideally, the requirements and implementation of an e-Archive should make good business sense and address business, legal and regulatory needs leading to a holistic approach rather than fragmented solutions.

WASHINGTON, DC
DUBLIN, CA
SEATTLE, WA

The food industry understands and is fully committed to continued access to, and the preservation of accurate, complete and trustworthy e-Records for business, legal and regulatory needs for many years. The food industry also understands that while there are manageable steps that enable industry to make significant progress toward meeting the requirements today, we also recognize that the technology for permanent long-term solutions does not exist. Based on industry experience, we expect implementation to come at significant cost to the regulated industries.

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NFPA offers the following comments to FDA for the purposes of discussing the critical technical issues that will guide implementation, as technology evolves.

Phased-In Implementation

A phased-in implementation approach should be considered. Any one technical issue alone can be extremely challenging and complex in its own right, but the combination of key issues makes meeting the Part 11 long-term retention requirements very demanding and costly to Industry and subsequently the public. Industry's experience to date strongly suggests that the success of our meeting all of the business regulatory retention requirements, for the long term, will be very complex, problematic and extremely costly. Consequently, we question the cost-benefits of requiring all aspects of Part 11 being implemented at the same time, versus a phased-in approach. We urge you allow the industry the benefit of phasing in these new requirements.

Migration/Retention

The 21 CFR Part 11 Industry Coalition's work reaffirms the value of the emerging Technology Neutral File Formats (TNF) for electronic documents and de facto database standards from leading vendors. When the e-Record retention period is greater than the useful life of the technology, and the e-Records are not to be migrated to a modern platform, a TNF or leading vendor database format offers the greatest likelihood of long-term readability, but may not preserve all the technical attributes of the original e-Records. E-Record "Viewers" of the original format may overcome this issue, but are expected to be costly to develop and maintain.

Migration (recurrent transfers) of e-Records from one technology (hardware and/or software) to the next generation is the most common method known today to ensure that records are usable and trustworthy for as long as necessary and preserve processing capabilities. Where the need exists to provide only e-Copies in human or computer readable form, 'views' may be sufficient. Both are processes requiring continual reinvestment. Present experience indicates this required reinvestment to be typically in the 7 to 10 year range due to technical obsolescence, and at significant costs attributed to the necessary IT resources. Where only relatively short term (3-5 years) retention periods are required retaining the legacy environment, or subset, may provide a viable alternative.

NFPA endorses the use of mainstream technology products based on open standards or leading database vendors. For electronic documents there are two primary choices in focus today, PDF (portable document format) and XML (Extensible Markup Language). These are widely accepted practices with a large user base and are based on published specifications. For data, other than ASCII, which is limited, and possibly XML including its many extensions (e.g. SVG), de facto standards from leading database vendors prevail.

Long Term Retention

The issues of long-term retention have many inherent complexities, including the potential loss of usability for e-Records. The focus must be on the capability to securely retain and retrieve the content of the e-Records and to understand their context beyond the useful life of the technology in which any retained e-Record was created/maintained. The key issues that were developed concerning e-Record retention and retrieval are summarized below:

1. **No Guaranteed Solutions and Limited Commercially Available Solutions:** there is no known solution available today for permanent preservation of trustworthy e-Records. All require substantial ongoing efforts consistent with the retention periods. All current options require, in varying degrees, significant ongoing maintenance. These must be routinely maintained and periodically upgraded, typically in the 7-10+/- year range, to preserve the basic ability to create complete and accurate e-Copies in human and computer readable form. In cases where proprietary technology is used and vendor technical specifications are not available to the user, access may be limited to the life of the technology. It is clear that long-term retention and access will be a costly and a continually evolving process in order to satisfy both business and regulatory requirements. A range of solutions is likely to be applied case-by-case.
2. **Evolving e-Record Formats:** can be expected to continue as technology advances and may result in process incompatibility. TNF based on published "open standards" are expected to be very helpful. However, TNF are not considered the complete answer as preservation in these formats could yield loss of functionality, different "look and feel," possible loss of "meta data" and could become obsolete due to vendor dependence.
3. **Impact of Migration and/or System Retirement:** may result in the loss of readability and/or process capabilities. Some allowance should be made for processing variance (e.g., changes in data calculation at the nth decimal place) arising from the reprocessing in new/different software or hardware platforms due to migration or system retirement. The fundamental objective of the e-Archive is to secure and preserve the essential meaning of the information in the electronic records, in that it would be viewed by experts in the field as equivalent to the original in the context of its stated, actual or intended use. Companies and government agencies retire software and hardware through a documented process based on sound business decisions. As a result, functional capabilities that create/maintain/analyze e-Records may vary in the replacement computer systems or even be lost completely. NFPA agrees with FDA that it is unrealistic to retain obsolete hardware, software, media, skills, etc. and expect to be able to reconstruct the original functional environment. The ability to provide accurate and trustworthy electronic copies in human and computer readable form will prove to be an ongoing challenge.

4. Cost and Time to Comply: the costs and benefits as discussed in Part 11 did not seem to address the costs to maintain electronic records for long retention periods. Industry experience and belief is that these costs and time to comply are likely to be significant.

5. Impact on e-Signatures: Among several techniques for identification of an individual, the Part 11 rule recognizes the use of cryptographic methods of originator authentication that validate the identity of the signer. Over time, the use of encryption algorithms to revalidate the integrity of the data assumes that there is no change in the underlying bit streams of e-Records that are signed. Such changes do occur when e-records are migrated from an older format to a newer one. Thus, adequate documentation of the records' integrity, including trust certification and an audit trail of actions, created at or near the time of signing is recommended over maintaining the technical ability to revalidate digital signatures as far into the future as may be required.

Summary

NFPA values the effort that the Agency is putting toward clarification of 21CFR Part 11 and appreciates the opportunity to share the food industries main concerns so that a workable solution is achieved and the food safety and public health safety are preserved.

Thank you for providing this opportunity to comment.

Sincerely,


Sia Economides
Senior Scientist


Allen Matthys, Ph.D.
Vice President, Federal & State Regulations