Electronic Record Keeping

INTRODUCTION

The low cost and increased power of personal computers is making a significant impact on the business enterprise. One of the most exciting growth areas for computers is Computer Integrated Manufacturing. A recent nationwide survey conducted by the Computer Integrated Food Manufacturing Center (CIFMC) at Purdue University indicates that 94 percent of food manufacturers employ at least some Computer Integrated Manufacturing technology. This is in contrast to 42 percent of food manufacturers who used Computer Integrated Manufacturing in 1989 (Aly, 1989). A large part of this growth is in using computer systems to record crucial process information electronically. From the same CIFMC survey, it was determined that 94 percent of food processors currently use electronic record keeping in some aspect of the manufacturing process. The use of electronic record keeping is expected to grow.

The general trend is to move to a completely paperless manufacturing environment where all records are kept electronically. An electronic record is "any combination of text, graphics, data, audio, pictorial or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system" (FDA, 1997). Throughout the years, controls have been established to make paper records trustworthy and reliable.

One or more handwritten signatures are used to authenticate paper records. Recently, controls have been established to help assure the same level of trustworthiness to electronic records by means of an electronic signature. An electronic signature consists of "a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent or the individual's handwritten signature" (FDA, 1997).

The Electronic Records Regulation: An Implementation Guide for the Food Industry

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On March 20, 1997, the Food and Drug Administration published the Electronic Records: Electronic Signatures Rule in the Federal Register. This rule became effective on August 20, 1997. This new rule was codified as 21 CFR Part 11 and provides the criteria by which FDA will consider electronic records as equivalent to paper records and electronic signatures as equivalent to traditional handwritten signatures. It covers the creation and maintenance of electronic records and electronic signatures. This new regulation is important because it applies to food manufacturers who operate processes governed by federal regulations and want to generate, maintain, and use electronic records in association with those processes.

The electronic records and electronic signatures rule (ERESR) embodied by 21 CFR Part 11 applies to any records that are required by existing and new federal regulations. For example, 21 CFR Part 113 covers the thermal processing of low-acid foods and requires the retort operator to maintain records of specific information regarding retort process operations. If the operator uses a computer system to record these required observations electronically, then the resulting electronic records are subject to the regulations covered by the ERESR. However, the electronic records made by a production supervisor who uses a computer system to document yield and overhead expense would not be covered by the ERESR because that information is not mandated by any Federal regulation. Currently, the ERESR directly impacts food manufacturers who process low-acid shelf stable foods, seafood processors, and fruit juice processors who choose to maintain electronic records that document their compliance with Good Manufacturing Practice and HACCP regulations.

This document provides an overview of the ERESR and summarizes the controls required by FDA to comply with the ERESR.

OVERVIEW

The ERESR is considered a substantive rule and provides the minimal standards required by the FDA to generate and maintain trustworthiness and reliability of electronic records. Compliance with the rule permits food processors to use electronic records and signatures in place of paper records and handwritten signatures in all FDA regulated program areas.

Several guidelines were used in creating the ERESR. In general, these guidelines outline the government's expectations. Any implementation of a system used for electronic records and electronic signatures must:

- be compatible with commercial standards
- preserve original information and signatures reliably
- reduce fraud, error, misuse, and litigation problems
- minimize repudiation
- retain sufficient information to facilitate audits and resolve disputes
- provide archival benefits by preserving links and using time-stamped audit trails
- set standards for transaction terms and conditions
- accord a full legal effect for validity and enforceability
- keep privacy and confidentiality
- be technology neutral and allow migration to new technologies and standards.

It is important to understand that legacy systems are not exempt from the ruling. If an existing system is used to create regulated documents electronically and that system does not meet the requirements of the ERESR, then that system will need to be upgraded to meet the ruling. FDA understands that technical obstacles and challenges involved with legacy systems but expects manufacturers to take substantive steps toward compliance. Should an inspection by FDA find a food manufacturer not in compliance with the ERESR, then the FDA will take regulatory action on a case by case basis, depending on the nature of the violation and the effect of the violation on product quality and data integrity. The ERESR is part of an overall effort by the US Government to conform to the paperwork elimination act PL105-277. This act mandates all government agencies to use electronic records and signatures for document submission and maintenance by the year 2003. FDA's ERESR is being used as a model for other government agencies.

CONTROLS FOR ELECTRONIC RECORDS

FDA classifies electronic record keeping systems as either open or closed. A closed system is an environment in which system access is controlled by the persons who are responsible for the content of electronic records. An open system is an environment in which system access is not controlled by the persons who are responsible for the content of electronic records. Consider, for example, a food manufacturer that has purchased computer software to record, store, maintain, and generate records of HACCP inspections. If the food manufacturer does not have access to the contents of the data files generated by the HACCP software, the system is considered closed. If, however, the food manufacturer has access to the contents of the files generated by the HACCP software, the system is considered open. The distinction of whether a particular system is open or closed governs who is responsible for implementing the procedure and controls necessary to ensure the authenticity, integrity, and confidentiality of electronic records. If the system is closed, then the software manufacturer is responsible, otherwise, the food manufacturer is responsible.

The ERESR establishes specific procedures and controls. Food manufacturers who are subject to the ERESRs must be able to meet as a minimum the following FDA requirements. These items can be used as a checklist to assure compliance with the ERESR.

☑ *Validation*
Systems must be validated to ensure their accuracy, reliability, consistency, and ability to discern invalid or altered records. Food processors should use "The Guide For Validation of Automated Systems in Pharmaceutical Manufacture" (GAMP, 1998) or the National Food Processors Association's Bulletin 43-L (1990) for guidance on software validation.

☑ *Accurate copy*
Systems must be able to generate accurate and complete copies of records in human readable and electronic form suitable for inspection and review.

☑ *Protection*
Systems must contain an adequate means to protect records for accurate and ready retrieval throughout the record retention period. This may include systems to maintain appropriate backup records.

☑ *Access*
Systems must limit record access to authorized individuals.

☑ *Audit trail*
Systems must use secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Audit trail information must be retained throughout the record retention period and be available for FDA review and copying.

☑ *System checks*
Systems must allow use of operational checks to enforce permitted sequencing of steps and events.

☑ *Authority checks*
Systems must have some rigorously followed protocol or mechanism in place to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system, alter a record, or perform required operations.

☑ *Operator entry checks*
Systems must include some mechanism that determines and records the validity of the source of any data entered manually.

☑ *Education*
Persons who develop, maintain, or use electronic record and signature systems must have the education, training, and experience to perform their assigned tasks.

☑ *Policies*
Written policies must be established and adhered to that hold individuals accountable and responsible for actions initiated under their electronic signatures.

☑ *Systems documentation*
Systems must have adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. Revision and change control procedures to maintain an audit trail that documents the development and modification of systems documentation.

CONTROLS FOR ELECTRONIC SIGNATURES

Many records require identification of the person or persons who created the record. When performed electronically, this identification is termed an electronic signature. The following components and characteristics are required by FDA to be considered an electronic signature:

☑ *Manifestation*
The electronic signature must contain:
- the printed name of the signer
- the date and time executed
- the context (review, approval, responsibility, or authorship) in which the signature was used

☑ *Record linkage*
A mechanism must be in place to allow electronic signatures to be linked to their respective record(s)

☑ *Protection*
Sufficient controls must be in place to ensure that the electronic signature(s) and their link to the respective record cannot be removed, copied, or otherwise manipulated to falsify an electronic record.

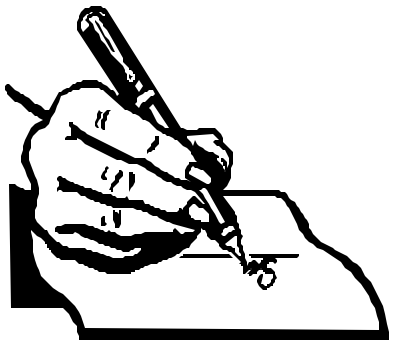
☑ *Uniqueness*
Each electronic signature must be unique to only one individual and must not be reused by or assigned to anyone else.

☑ *Identity establishment*
The identity of an individual must be established before assigning that individual an electronic signature.

☑ *FDA Notification*
Food manufacturers who desire to use electronic signatures as legally binding equivalent of traditional handwritten signatures must certify to FDA that they intend to do so by submitting a paper letter with a traditional handwritten signature to the agency.

☑ *Certification*
Persons using electronic signatures must be able to provide additional certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

Electronic signatures can be based on biometrics. Biometrics is a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are unique to that individual and measurable. Examples of biometrics include finger print identification, retinal scan, voice recognition, or combinations thereof. Systems based on biometrics must correctly identify the individuals for whom they are designed.



Systems not based upon biometrics must employ at least two distinct identification components such as an identification code (IC) and password (PW). In addition, a management system must be in place to ensure that:
- the issuance of IC and PW must be periodically reviewed
- the uniqueness of each combined IC and PW must be maintained such that no two individuals have the same combination
- a procedure must be in place to repudiate lost, stolen, missing, or otherwise potentially compromised methods that bear IC and PW information
- safeguards are present to prevent unauthorized use of IC and PW, and to detect and report in an immediate and urgent manner any attempts to those assigned to system management
- methods that bear or generate IC and PW information are validated, that they function properly and have not been altered in an unauthorized manner

When an individual executes a series of signings during a single continuous period of controlled system access, the first signing shall be executed using all electronic signature components: subsequent signings can be executed using at least one electronic signature component that is only executable by the individual. Otherwise, the individual must use all electronic signature components. Any attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals. The procedure and conditions under which such override takes place must be documented.

CONCLUSION

The ERESR is intended to provide safeguards to food manufacturers who choose to keep FDA regulated process records electronically. When properly implemented, electronic record keeping provides an equal or greater benefit to the business enterprise than using traditional paper records. However, developing a system that conforms to the ERESR requires significant material and manpower resources. Therefore, whenever possible, food manufacturers should acquire closed systems to minimize the outlay of such resources. However, not all commercial software meets the requirements of the ERESR. Food manufacturers that intend to use third-party software for electronic records and signatures must obtain written certification from the manufacturer that the product meets all of the provisions of the ERESR. Although the ERESR applies only to records associated with FDA regulated activities, it is prudent to require all electronic record keeping systems throughout the business enterprise to conform to the rigorous set of standards set forth by the ERESR.

In taking on this new initiative in the information age, FDA has committed to educate and help industry comply with the ERESR. All documentation and materials used to develop the ERESR are available for review. Furthermore, FDA provides presentations and meetings in trade and professional groups and to individual firms. Documents covering frequently asked questions and a video are also available.

The internet site: http://www.fda.gov/cder/esig/part11.htm contains the history of the ERESR as well as the final rule as published in the federal register.

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