

The Legal Need for Document Management

A host of industries have passed regulations that make getting information in order the law; non-compliance is not an option as companies risk stiff fines, and executives face the threat of personal liability.

By Melissa Reyen - 5/8/2003

In order for companies to stay in compliance with all of the recent industry-specific regulations, they need to make sure that their document management strategies are in order. The following is a list of some of the most recent regulations and how they will impact your company's document management strategy. This is just a summary, however; if you are worried that your company is not in compliance, at the very least you should look into each regulation more closely using the links provided. Non-compliance is a serious issue and could result in legal action against your company. According to Forrester Research, in December 2002, the SEC fined five Wall Street brokerages \$8.25 million for improperly storing e-mail communications.

21 CFR part 11

Adopted in 1997 for the healthcare and pharmaceutical industries, this law defines the recommendations for managing audit trails, access control and electronic records retrieval. On February 20, 2003, the FDA released a new draft--Draft Guidance for Industry; Part 11, Electronic Records; Electronic Signatures - Scope and Application--which changes the requirements for electronic records. It also withdraws many previous guidance documents on maintenance of records, e-copies of records, timestamps and validation.

For more information:

<http://www.21cfrpart11.com/>

http://www.fda.gov/ora/compliance_ref/part11/

<http://www.fda.gov/cber/gdlns/prt11elect.pdf>

Gramm-Leach-Bliley Act

Passed in 1999, this act requires financial services companies to implement safeguards for customers' current and legacy information. In essence, the act makes it illegal for a financial institution to share customers' "nonpublic personal information" with third parties unless the company first discloses its privacy policy to consumers and allows them to opt-out of that disclosure.

For more information:

<http://www.senate.gov/~banking/conf/>

<http://www.ftc.gov/privacy/glbact/>

HIPPA

The Health Insurance Privacy and Portability Act is a 1996 regulation provides national standards for the healthcare industry, in order to ensure consistency that makes it easier to process electronic claims. The law also enforces the security and privacy of personal health information.

For more information:

<http://www.hep-c-alert.org/links/hippa.html>

<http://www.hhs.gov/news/press/2002pres/hipaa.html>

Government Paperwork Elimination Act

Passed in 1998, this act requires federal agencies to accept electronic information and transactions. It also requires that they maintain electronic records. This work must be completed by October 21, 2003.

For more information:

<http://www.whitehouse.gov/omb/fedreg/gpea2.html>

http://www.archives.gov/records_management/policy_and_guidance/electronic_signature_technology.html

Sarbanes-Oxley Act

Adopted in 2002 for all public companies following the accounting debacles sparked by Enron, this act requires that all public companies keep audit papers for five years. It also makes altering, destroying or concealing relevant documents punishable by up to 20 years in prison and a fine.

For more information:

<http://www.sarbanes-oxley.com/>

http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_bills&docid=f:h3763enr.txt.pdf

<http://www.sec.gov/news/press/2002-128.htm>