Record Retention Management Policies: It’s All in the Timing

The good news is that electronic record retention tools and technologies give firms of all types and sizes unprecedented opportunities to improve their operational efficiencies, speed products to market, make regulators happy, and send black ink straight to the bottom-line. The bad news is that electronic record retention tools and technologies are arguably more advanced than some of the strategies and best practices employed by companies to try and ensure all of those benefits. Worse, some firms commit the well-meaning mistake of trying to be safe by hanging onto every electronic record until their systems are so slowed and clogged that it is hard to find the electronic records they need when you need them.

“The Food and Drug Administration (FDA) leaves it to the regulated company’s discretion to determine how long they should retain records and documents,” points out Eric June, chief software architect at AssurX. “The FDA does not expect records to be retained forever.”

Many firms have learned that the best way to approach record retention and compliance policies is to develop a well-reasoned program that balances the relative importance of an electronic record with the reality that saving everything all the time will actually make your records more cumbersome and less secure.

“Electronic record management is very important to our organization,” says Paul J. Fricke, Senior Quality Scientist, Compliance QA with Access Business Group (ABG). Fricke and ABG use Assurx’s CATSWeb for internal and external audit information among other workflow processes. “Once an audit process has been completed and records have reached a certain age, our record retention policy requires the records/information to be discarded,” Fricke explains. “Without this ability in CATSWeb, records would be retained past their business use and not in alignment with our corporate policy.” This way, ABG avoids wasting valuable database space and unnecessary exceptions to its retention policy.

Bottom-line, firms can choose either to control or to be controlled by their records, experts agree. “The impact of getting it right goes straight to the heart of the integrity and security of your operation,” says John McKenney, President of SEC Associates and co-author of “The ‘New’ Part 11 and Drug Development: A Q&A Reference Guide.”

The Bar Gets Higher

And the legal and regulatory bar for getting it right continues to get higher. In the financial arena, for example, the Securities & Exchange Commission (SEC) recently issued rules under the overarching Sarbanes-Oxley Act (SOX) that require accountants who audit or review an issuer’s financial statements to retain certain records relevant to that audit or review. Looking at the huge healthcare industry, while the FDAs 21 CFR Part 11 electronic record requirements have eased the agency’s demands on electronic record retention, the agency has made it clear that if the electronic record has a direct impact on patient safety or product efficacy that electronic record had better be accurate, defensible and accessible in a timely manner.
It is perhaps the SOX that has most raised awareness of the importance of wise electronic record retention policies. “It is very important for senior managers to understand the new implications of SOX,” says attorney Guy Lander, author of “What is Sarbanes-Oxley?” He notes that current and future requirements of the Act mandate that the company gather information, evaluate it and report it in a timely manner to the SEC and financial markets.

The importance of document retention and management programs will continue to grow at least as fast as the usage of technologies including BlackBerry’s, Instant Messaging and countless others expand.

There are many important electronic record-related issues that firms in most industries must consider, including:

- The importance of developing and adopting electronic record retention policies given the growing scrutiny of email trails and files of information as potential electronic evidence.

- The fact that sensible policies and plans regarding electronic evidence issues should be commonplace and yet still aren’t even in many Fortune 500 companies. However, you can learn from other corporations that are taking this seriously. For example, Lander applauds Pfizer’s leading-edge compliance work, including its decision to put a detailed corporate governance document on its webpage at http://www.pfizer.com/are/mn_investors.cfm.

- Intermingling of important and unimportant documents – At too many companies, too little distinction is made between confidential and non-confidential information. When attorney’s are trying to determine what is considered privileged information in a high-stakes litigation, the computer forensics team needs to sift through information with a fine tooth comb to ensure no privileged information is inadvertently handed over to the opposing team of attorneys.

- Intermingling of business and private use - Likewise, employees often use business computers for private use – a trend most analysts and HR experts suggest is only going to increase. In the same way that privileged information is intermixed with regular information and needs to be sifted out, so too does private information.

- Lack of distinction between disaster recovery back up and business archiving - Disaster recovery is meant to enable a corporation to get up and running in the two or three days after the disaster occurs. Business archiving is for the long-term and is important for regulatory obligations (e.g. broker-dealers must keep all client communications for seven years). Most corporations save absolutely everything, to cover for disaster recovery, and then regard that same mountain of information as their long term business archive. Corporations are saving too much unnecessary information for too long, again adding to inefficacies of information restoration and review.

- Back-up systems that cannot easily be restored - All too often, corporations update software and hardware with little regard to their existing back-up collection. Once faced with litigation, corporations are then obligated to pay for the cost of restoring and/or recreating data from an old legacy system.

“Doing nothing can be extremely dangerous,” says attorney Robert H. Feigenbaum, managing director of the forensic and litigation consulting practice with FTI Consulting, and founder and former president of U.S. Legal Solutions, a pioneer in delivering proactive solutions for corporate counsel to manage email, electronic records and other ediscovery issues.
Be Proactive

“Don’t wait any longer,” argue compliance attorneys Laurie Miller, Scott O’Connell and J.P. Ellison with Nixon Peabody LLP. If you haven’t already done so, now is the time to re-evaluate your company’s document retention policy.

Be prepared: You may not like what you find, many experts suggest. “Companies in highly litigious industries and/or ones that have heavy regulation are generally aware of the importance of strong electronic record retention programs,” says Mark R. Kindy, senior managing director of the forensic and litigation consulting practice with FTI Consulting. “Those companies are looking at this on a proactive basis.”

But other companies in other industries – perhaps because they have no regulators or laws breathing down their necks – have generally given their record retention programs short-shrift in terms of budget and personnel. That’s a mistake.

According to Cohasset Associates, electronic records pose a greater challenge to their paper counterparts when faced with legal proceedings where records must be admitted into evidence. This greater complexity in electronic records is that they must demonstrate accuracy, reliability and trustworthiness.

In their survey using a five-point scale of 1 – 5 (1 being “not at all confident”, 5 being “very confident”), only 5% indicated they were “very confident” in their electronic records management system, while an overwhelming 38% responded they were “not at all confident”.

Source: Cohasset Associates

“Getting it right transcends any regulatory climate,” says McKenney. “The importance of getting it right cannot be overstated.” In FDA-land, the old joke is that you don’t have to worry about electronic record retention as long as you don’t care about the security and integrity of your records. Even if you are in an industry that does not have such strict laws or rules, do you want to operate in a way that minimizes your performance and leaves you vulnerable to lawsuits or other charges of negligence?

“Document retention plans are no longer safely delegated to file clerks or facilities managers,” argue Miller, O’Connell and Ellison. “Untimely document destruction can have serious consequences for individuals and corporations, including, but not limited to criminal liability.”

Feigenbaum, who recently served as the electronic discovery consultant to the defendant and its outside counsel in the Zakre v. Norddeutsche Landesbank Girozentrale case, developed a unique native file production strategy which was specifically endorsed by the court over a motion to compel by the plaintiff. The strategy saved his client over $100,000 in electronic discovery costs and attorneys fees. Leading edge firms “understand the value of having quick access to their electronic records, including backing up tapes for archive purposes,” Feigenbaum says.
Ironically, the relative inexpensiveness of some electronic record storage solutions might end up costing companies more money and worry in the future. “Storage is so cheap that for some firms it adds to their inertia,” Feigenbaum says. Lacking a clear policy, these firms are afraid to get rid of anything. Consequently, they keep more electronic records than necessary and make it next to impossible to find and utilize those electronic records they truly need.

The time is now to take a hard, careful look at your record retention policy. The good news is that you don’t need to save everything. Instead, if you ask the right questions and make the technology work for you, you’ll end up saving money and not a few headaches by keeping the records you need and confidently getting rid of those you can more efficiently do without.

**FIVE IMPORTANT QUESTIONS TO ASK YOURSELF WHEN DEVELOPING A RECORD RETENTION POLICY:**

1. Does your policy meet or exceed legal requirements imposed at the federal and state level? If you are an FDA-regulated entity, this includes Part 11 requirements. If you are a public company, it includes Sarbanes-Oxley.

2. Have you had record retention problems before? Have you ever been audited? Was it difficult to retrieve the records sought by outsiders?

3. Do you have procedures and technologies in place to ensure that you do not inadvertently alter or destroy records you intended to keep?

4. Do you have a defensible policy that outlines what kind of records should be preserved and how they will be protected?

5. Do you maintain and enforce your record retention policy? Can you show evidence of that, including evidence that you have trained your employees adequately to do it right?

To find out how AssurX can help with your quality, compliance and records management needs, please call 408-778-1376, ext. 705.