

Whitepaper

RECOVERABILITY IN REGULATED INDUSTRIES: WHEN PROTECTING YOUR OS, APPLICATIONS AND DATA ISN'T OPTIONAL

Abstract

If you are on the consumer side of the thousands of regulations imposed by the U.S. government, just knowing they exist probably gives you some peace of mind. However, if you are on the compliance side of these complex and ever-changing regulations, you know that staying compliant is a constant tug-of-war between resources and regulation. Acting responsibly on behalf of your consumers and ensuring that your company avoids fines brought on by noncompliance means staying on top of regulatory legislation. By installing HEROware's "HERO" Backup Continuity Appliance (BCA), an all-in-one solution of server class hardware and software, small businesses deploying Microsoft Windows Small Business Server (SBS) can ensure that their systems remain compliant with all applicable regulations and that their entire SBS (OS, applications and data) will remain available 24-7-365.

Introduction

More than 8,500 U.S. state and federal regulations concern records management. If you are on the consumer side of these regulations – that is, if you are receiving health care, taking medication, have a bank account, credit card, investment accounts or will rely on any kind of government agency for benefits or protection, knowing these regulations exist probably gives you some peace of mind. However, if you are on the compliance side of these thousands of complex and ever-changing regulations, you probably have already had more than one sleepless night. Acting responsibly on behalf of your consumers and ensuring that your company avoids fines, or worse, brought on by non-compliance, means staying on top of regulatory legislation. If you are in any part responsible for compliance in your organization, you already know that federal regulations don't spell out what technology needs to be in place. For example, the Sarbanes-Oxley (SOX) Act doesn't ever mention the word "software"; but, for most regulated companies, necessary audit trails require some kind of record management software. Technology changes so quickly that specific requirements can't be legislated. In addition, legislators also assume that an organization will comprehend the requirements and implement a right-sized solution for their particular situation, service or product.

Compliance and Disaster Recovery

Just as SOX and all other federal regulations require an audit trail without defining the technology to be used, they all require a disaster recovery (DR) plan for certain kinds of data. Again, legislators urge steering members of the organization to read regulations for comprehension and then implement a solution that best reduces risk, protects privacy, ensures accountability, and in some cases, ensures business continuity in a disaster. Four major regulations, discussed below, require companies to safeguard information – and produce it on demand in an audit;

1) Sarbanes-Oxley Act

In 2002 the United States federal government passed the Sarbanes-Oxley Act (SOX) which establishes laws and standards for U.S. public company boards, management, and accounting firms. Provisions include a requirement that public companies evaluate, disclose and qualify (by independent auditor) the effectiveness of internal controls for financial reporting, a ban on personal loans to any executive or director, prohibition on insider trading during certain periods and accelerated reporting of insider trading, protections for whistle blowers and increased penalties for security violations. Because financial reporting in most companies is supported by electronic systems, IT is a large part of internal control.

SOX and DR Planning

Section 404, Management Assessment of Internal Controls pertains to disaster recovery requirements, stipulating that an organization should:

- State the responsibility of management for establishing and maintaining an adequate internal control structure.
- Contain an assessment, as of the end of the most recent fiscal year of the issuer, of the effectiveness of the internal control structure and procedures of the issuer for financial reporting. Translated, DR planning for SOX has two primary parts: implementing systems that completely protect all financial and other data required for reporting regulations³ and providing data on-demand, and clearly documenting those procedures so auditors can readily see that the plan protects regulated data as required.

2) FDA Title 21 Part 11

The U.S. Food and Drug Administration (FDA) is a public health agency that protects American consumers by enforcing laws that regulate the manufacture, storage, import and sale of food and medicine for humans and animals, as well as medical devices and cosmetics. CFR Title 21 Part 11 Electronic Records; Electronic Signatures (Part 11) is the rule regarding how all companies regulated by the FDA must maintain electronic records in order to remain compliant with Good Clinical, Laboratory and Manufacturing practices (GxP). Though finance and planning are excluded from Part 11, all other functional areas of FDA-regulated companies that involve GxP must comply or face legal sanctions and even criminal charges.

- **Title 21 Part 11 and DR Planning**

Part 11 has two basic requirements: a) that companies are able to generate accurate and complete copies of records for inspection and review during an audit, and b) that those records are protected so that they are readily retrievable throughout the required retention period. Data availability and protection at this level require a good business continuity plan that takes into consideration high availability, or "failover", and disaster recovery. The FDA realizes the potential impact of interruptions to critical business applications and therefore requires that electronic GxP applications must be always available – or at least quickly recoverable. For example, if a Windows-based application involved in the supply chain for a critical drug fails – interrupting the national supply of the drug – millions of lives are at risk. Another goal of continuous business operation is disaster recovery – the ability to restore critical data and operations, to new hardware at the original site or at a different physical site, after a disaster. In all regulations, e-mail is assumed to contain critical information and therefore must be retained. An electronic record is defined as "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."

3) Gramm-Leach-Bliley Act

The Gramm-Leach-Bliley Act (GLBA) governs consolidation of financial institutions and implements financial privacy rules and safeguards. The GLBA governs how customers' personal information is collected and disclosed and requires safeguards to protect this information. The regulations also apply to any company that receives this information, even if they are not financial institutions.

GLBA and DR Planning

The Safeguards Rule contained in the Gramm-Leach-Bliley Act requires regulated institutions to:

- Insure the security and confidentiality of customer records and information.
- Protect against any anticipated threats or hazards to the security or integrity of such records.
- To protect against unauthorized access to or use of such records or information which could result in substantial harm or inconvenience to any customer.



4) Health Insurance Portability and Accountability Act

The Health Insurance Portability and Accountability Act (HIPAA) make provisions for employees and their families to keep their health insurance when they change or lose their jobs. HIPAA also established national standards for security and privacy of electronic transmission of health care data.

- **HIPAA and DR Planning**

HIPAA's security rule states that each organization must determine its own risk in the event of an emergency (that would result in loss of operations). However, there are three things that companies must be able to substantiate in regards to DR planning:

- There has been a formal analysis of risk to data (physical and virtual access).
- A DR plan exists that covers backup, storage and recovery.
- The DR plan adequately addresses the risks outlined in the analysis.

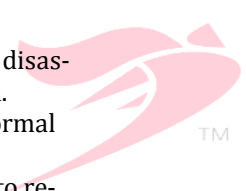
Data Protection and Availability

Data protection and data availability are the two major goals of a backup, availability and disaster recovery plan. The quantitative measures used are called Recovery Time Object (RTO) and Recovery Point Objective (RPO). Recovery Time Objective (RTO) and Recovery Point Objective (RPO) RTO represents the amount of time between the start of an outage and the resumption of normal business operations. The RTO for an outage that can be resolved by reloading from tape backup includes the time necessary to locate and mount the tape, the time required to restore the data from the tape, and any time necessary to post-process the restored data before restarting the downed applications. Recovery Point Objective (RPO) represents the point to which business data can be restored. This can be thought of as the latency between a production data set and its redundant or replicated copy. This latency may be expressed as a number of changes or a time interval; it measures how out-of-date the replicated copy will be compared to the original. For example, a nightly backup means that the RPO will be the time between when data was written to tape and when the failure occurs: a failure any time on Tuesday has an RPO of Monday night. Acceptable RTO and RPO must be evaluated by each enterprise individually. However, an RTO of less than 24 hours is usually necessary in order to ensure that supply of critical products or services to consumers is not interrupted. RPO can much more time-sensitive when it comes to compliance. If an application is saving time-stamped electronic signatures, there can be no gap in protection. While tape backup systems can be inexpensive and fairly reliable, the RPO and RTO they offer is not enough to remain truly compliant with any of the above mentioned regulations.

Loss Scenarios

Successful IT organizations evaluate their disaster recovery and business continuity options using these measures in the context of the types of loss for which they need to plan. There are four typical scenarios which should be evaluated when putting together a disaster recovery plan and selecting software or hardware solutions as part of that plan. Just as each system should have its own RPO and RTO goals based its criticality to the organization, each system should also be evaluated in terms of potential loss scenarios. By understanding RPO and RTO in the context of potential loss scenarios, an IT organization can more effectively plan for recovery of the system.

- **Loss of a single resource** – a single server supporting a regulated functional area fails or is interrupted. For example, losing the server that supports the document repository would seriously affect the ability to provide current documentation in an audit. It would also affect the ability to maintain the time-stamped electronic signature for document versions.
- **Loss of an entire facility** – an entire facility, and all of its resources, is unavailable due to natural disaster, power outages, failure of the facility's environmental conditioning systems, or terrorist action. Unless the facility in question is the primary production facility, the best response is to resume normal operations at another site.
- **Loss of user data files** – accidental or intentional loss of critical data files. The best mitigation is to restore the lost data from backup – normally, from the previous RPO. If there is a gap between backups, time-stamped data that is necessary to establish an audit trail can be lost.
- **Planned outages for maintenance or migration** – the need to restore or repair service. If this activity is not transparent to users and requires forced downtime, productivity will slow or stop during the outage.



Providing Effective Disaster Recovery

Depending on the crisis that drives the recovery, DR may take several different forms. In the most complex scenario the complete failure, destruction, or interruption of access to a data center might necessitate moving the company's operations and personnel to an alternate set of servers at another location. More simple recoveries might involve restoring operations after damage to the primary copy of critical data.

There are a number of strategies that can be employed to protect important data, and each has strengths and weaknesses. The most common method of storage protection is also the oldest: backing up to and restoring from magnetic tape. This method has been around for almost forty years and is still the bedrock of most recovery strategies. The cost per megabyte for tape storage is low; it's easy to move tapes to secure offsite storage, and the technology continues to scale well for many applications. However, tape backups have limitations, such as the amount of time required to back up and restore large volumes of data, the accompanying latency between when the data was protected and when the loss occurs, and the security involved in moving tapes to offsite storage. Accordingly, much attention is being focused on replication-based technologies. Replication-based technologies offer the promise of capturing a data set at a particular point in time with minimal overhead required to capture the data or to restore it later. HERO BCA integrates with the Windows® SBS operating system to copy data by capturing file changes as they pass to the file system. The copied changes are queued and sent to the HERO BCA while the original file operation is processed normally without impact to application performance. The result is cost-effective data protection.

Supporting your Compliance Strategy with HEROware

HERO from HEROware (powered by Double-Take® Software) can fulfill all the backup, disaster recovery and emergency mode operations that are required to ensure that clients deploying Microsoft Small Business Server remain in compliance with all applicable regulatory requirements. Hero is an All-In-One Backup Continuity Appliance (BCA) of server class hardware and software that provides unique, REAL-TIME byte level replication of a Microsoft SBS to the HERO BCA as transactions occur. All data and system information is replicated in REAL-TIME and stored on the HERO BCA while HERO is monitoring the production SBS for uptime. Should the production SBS server fail, the HERO BCA will send a failure notification or commence fail-over service automatically, depending on the client's desired configuration. Once the HERO BCA initiates fail-over, all the Microsoft SBS system's files and data are available for use on the HERO BCA. Productivity continues essentially without interruption. HEROware also offers secondary, concurrent replication over-the-cloud (HEROguard) so that if a customer's HERO BCA and physical location are completely destroyed in a catastrophic event, a full system restore is available from the secure HEROguard remote data center.

The HEROware Advantage

The unique replication technology leveraged by HEROware operates more efficiently than competitive solutions by only replicating the data that's changed. The approach of replicating data in real time offers a potential escape from the cost-versus-recoverability dilemma. The phrase "business continuity" covers a broad spectrum of technologies, processes and planning approaches. Evaluating the usefulness of replication for particular conditions requires us to examine three scenarios in which replication might lead to better business continuity and disaster recovery in support of an organization's compliance efforts: local/remote availability, disaster recovery and backup and restore.

Disaster Recovery

Disaster recovery is often assumed to be synonymous with business continuity. However, true disaster recovery is the ability to restore needed business data after a disaster. Many administrators and planners think of disaster recovery as the ability to quickly resume operations at a separate physical site; that's an overly broad and very expensive capability that's mostly relegated to very large organizations whose businesses are able to justify the cost and logistical complexity. HEROware gives you large-enterprise disaster recovery abilities at a fraction of the cost of large, dedicated "hot site" recovery operations. And, its easy set-up and administration makes HERO a business continuity/disaster recovery solution that is more afford-



able, easier to deploy, and simpler to operate than any other DR solution currently available the Microsoft Small Business Server Market.

Local/Remote Availability

One of the most common approaches to continuous business operations is that of "failover". The goal for these high availability (HA) solutions is to keep the users productive even when outages affect their entire server. HA is often thought of in terms of implementations of highly redundant hardware. However, HERO replicates, in real time, the entire Microsoft Small Business Server (OS, Applications, and Data) as and when transactions occur, while constantly monitoring the production SBS for uptime. Should the production SBS fail HERO will (depending on the users desired configuration) commence failover service immediately, send a failure notice and request authority to commence failover or be set to commence fail over regardless at a predestined time delay whether or not authority has been requested. Once the HERO appliance initiates failover all of the Microsoft SBS systems, files and data are available for use on HERO. Productivity continues essentially without interruption. There is no loss in data and virtually no downtime. And, if a customer chooses to enroll in the optional HEROGuard service, and their physical location is completely destroyed, they can recover and restore their system and all data created up to seconds before the catastrophic loss from HEROware's secure off-site data center and resume operations as soon as they can put a new production server in place.

Enhancing Backup and Restore

For a surprising number of companies, tape backup continues to be their only preparation for business continuity. The challenge with this approach is the ever-increasing restore times driven by the growth in data volume and change rates. Consider a typical scenario involving just offsite storage and assume that full backups are done every weekend, with nightly incremental backups. Off-site storage is used for continuity protection. A failure that occurs at 4 p.m. Tuesday must be recovered with the previous weekend's full backup and the Monday night incremental -but if that tape has already gone offsite, it must be retrieved which can add hours (if not days) to the recovery time. Even if the tape can be retrieved with only a four-hour lead time, that still means that users won't have access to the Monday version of their data until sometime on Wednesday (and Tuesday's data is completely lost). For many companies, this is not practical. Let's examine data protection strategies and their ability to address the inadequacy of existing tape-based backup solutions:

- Whole-file replication does provide a second copy for backup purposes within the latency parameters discussed earlier. However, most solutions do not properly handle a situation where the target data is being actively backed up. If the backup software locks files as it backs them up, replication may fail until the files are unlocked again.
- Similarly, most application replication tools do not deal well with the target data set being locked for backup.

As with disaster recovery, hardware and software replication offers approaches that are more flexible. Most hardware replication solutions offer various backup enhancements, including freezing one set of data while the other is given over to the backup (which may be host- or storage-attached) and making "snapshot" or point-in-time copies of the data. The only potential caveat is the re-synchronization time required for the frozen data set once it's thawed and updates are allowed to happen. Software replication via HEROware can offer similar benefits with a different twist. Unlike hardware solutions where one logical copy of the data exists in two arrays, the two data sets in software replication are only loosely coupled. This means that while the production data is locked and in use, the redundant copies are natively in a closed state (except of course when each file is actually being updated).



Summary

Major regulations such as SOX, GLBA, HIPAA and Part 11 of FDA rulings establish standards for storing, using and maintaining electronic data, but safeguarding information and producing it on demand in an audit is one of the biggest technology challenges that regulated small business organizations face. Replication-based technologies offered by HEROware offer small businesses the best strategy for maintaining critical data, with minimal overhead needed to capture the data and/or to restore it later. HERO from HEROware, (powered by Double-Take Software) can fulfill the backup, disaster recovery and emergency mode operations that are required for compliance. HERO is a real-time WHOLE SERVER replication and failover appliance that all small businesses running Microsoft SBS need today to meet all current regulatory requirements. For questions about HEROware, including pricing and product features call toll free 866-810-HERO (4376) or for quicker services see our "Partners" page at www.heroware.com for a reseller or distributor in your area.

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