

Blood Center Archival Records Management —A Radical Approach



Many blood centers across the U.S. are required to maintain donor record forms (DRF), resulting in the storage of literally hundreds of thousands to millions of pieces of paper for 10 years. Learn how IT staff at this blood center developed an optical records management system using off-the-shelf components and software at a fraction of the cost of vendor-supplied software and hardware solutions.

By John B. Holder

INTRODUCTION

Many blood centers across the nation are presented with the daunting task of maintaining and preserving Donor Record Forms (DRF) in accordance with Federal Regulatory Requirements. This requirement results in the storage of literally hundreds of thousands to millions of pieces of paper for 10 years and beyond to maintain compliance with those regulations. Many vendor solutions exist, but the costs are prohibitive in nature for most of the not-for-profit organizations that provide life-saving blood and blood products for patients in local hospitals in the areas that they serve.

The goal is to develop an optical records management system that will provide archival and online DRF retrieval to meet regulatory requirements by utilizing off-the-shelf components and software at a fraction of the cost of vendor-supplied software and hardware solutions. The number of optical records to be stored would range from 45-60 thousand per year (double-sided). A high-speed duplexing scanner would be required for the operation. The resulting system would need to have scalable properties, enhanced security, and offer a significant cost savings over physical storage methods. The planning stage Cost Benefit Analysis required that the system would have to provide the same functionality and record reproducible qualities as the old physical

storage method while demonstrating significant savings in terms of employee hours and storage fees.

BACKGROUND

The Northwest Florida Blood Center is one of the oldest community blood centers in the country. It was founded in 1948 in Pensacola, Florida, and it now serves 20 hospitals in the Northwest Florida Panhandle and Southeast Alabama. Over the years, paper records have been stored in an ever-growing cache in offsite storage facilities. In early 2001, it was decided to use optical, tape and online digital storage to eventually replace physical records storage. The discovery phase included a call for bids from vendors providing records storage solutions. This yielded several possibilities that ranged in cost from \$39,000 to well over \$100,000. With a limited IT budget, this cost presented a formidable hurdle for the organization. After the initial round of proposals, it was decided to attempt to develop an internal solution to meet the storage requirements that would:

1. Provide online access for at least 10 years of donor records.
2. Provide long shelf-life storage for digitally archived records.
3. Fit into the fiscal restraints of a not-for-profit organization.

4. Provide a redundant method of records retrieval in the event of a catastrophic loss of data stored on any one storage medium.
5. Provide a means for authorized personnel to access online records from multiple network workstations while maintaining access control and security.

PREPARATION

To achieve the goals set forth above, an aggressive research campaign was undertaken to identify commercially available off-the-shelf components that could achieve the desired results. In the search, several hardware vendors were presented with specifications and challenged to present quotes for the components of the proposed system.

The parts of the storage system were assembled with the following items:

1. Fujitsu M4097D Duplexing medium- to high-volume scanner (256 grey scale).
2. Maxtor 4100 (320GB) Network Attached Storage Device (NAS).
3. Seagate Scorpion 20/40GB DAT DDS4 ULTRA2/LVD Tape Drive.
4. Panasonic DVD-RAM/R 4.7GB ATAPI optical disk drive.
5. Adobe Acrobat 5.0 portable document creation software.

6. Athlon XP 1600+ workstation with 256MB RAM, and 60GB HD, Windows 2000 Professional Workstation as a client of a Windows 2000 Active Directory Domain.
7. Symbol LS 4004 Barcode Scanner (ISBT-128, and CODABAR enabled).

The installation cost of the hardware and software system was approximately \$9,000, all inclusive. Bids for off-the-shelf components used in this system were requested from multiple vendors to obtain the best overall pricing. We were prepared to split the orders with several different providers, to go with the lowest quotes, but we didn't have to in the end. Nearly all of the system components were obtained from CDW and Insight.

INITIAL TESTING

In the early stages of testing, each record was scanned individually. The time required to accomplish a 300-400 record daily data load was determined to be 8 hours by one technician. This effort was subsequently reduced to 2 hours or less by grouping records in a logical sequence into aggregate scans. Each group was scanned and saved by Donor ID Number sequence utilizing a Symbol LS 4004-IO49 Barcode Scanner in the file save step to eliminate operator error. This process was accomplished by reading the CODABAR or ISBT-128 barcode labels that are attached to the first and last DRF to build a file name.

The system utilized a Quality Assurance Model designed to ensure that each and every record is stored in a reproducible format that will satisfy stringent regulatory requirements. In this regard, careful consideration was given to ensure that the various colors of print, paper densities and paper sizes used by personnel generating the documents were properly imaged during scanning operations.

The validation process included several checks by IT and QA personnel to ensure that each stored document met quality standards. This initial validation model was later refined for actual production to involve detailed sampling of stored records while reducing employee interaction requirements.

SYSTEM IMPLEMENTATION

The original name chosen for the system was the "Optical Storage System" (OSS), and it has remained so for the production model. During implementation, several months'

worth of Donor Record Forms were scanned and categorized in the following manner:

1. Grouped in logical sequence by blood drive and location.
2. Stored in a master year folder.
3. Sub-grouped by two-month selections (to be archived on DVD-RAM/R).

DATA INTEGRITY PRECAUTIONS

DRF scans were protected by the following:

1. Daily backups to the DDS4 tape drive (stored nightly off-site).
2. Weekly archival burns to DVD-RAM/R that were then transported to off-site storage.
3. Monthly backups to DDS4 tape transported to off-site storage.

Note: Online records are protected by a RAID-5 disk storage NAS that provides speedy document retrieval and data integrity security.

REGULATORY CONSIDERATIONS

In a highly regulated environment (such as in blood collection centers), there exists a requirement to produce records or facsimiles of records that meet with digital signature requirements. Each DRF contains several signatory elements that chronicle the entire process of blood collection. The OSS faithfully records and can reproduce these signatures to meet all applicable requirements by printing stored images that contain facsimiles of the original signatures and initials of registration personnel, phlebotomists and reviewers. The Blood Bank Control System (BBCS) software environment that is housed on an AS/400 mid-range computer further augments this process by providing a master indexing component. Coupled with BBCS, the system provides online retrieval of pertinent blood donation information (donor information, testing results, shipping, and the reproduction of DRF in a completely digital realm).

RETRIEVAL AND REPRODUCTION

Retrieval of stored forms on both the online (NAS) and the offline medium (DVD-RAM/R) is provided by operating system directory file search facilities. Using the built-in features of Windows 2000, records are located

by initiating a file name search utilizing wildcard tokens on the current year (or year and month grouping) storage folders. Typical access times are less than 2 seconds in the current configuration. Records can be viewed interactively using Adobe Acrobat 5.0 Reader, and they can be printed to any off-the-shelf inkjet or laser printer that is compatible with the system, further reducing the requirement for proprietary hardware. Since indexing of records and data is provided by the BBCS system on the AS/400, there was no requirement to add to the overhead of the retrieval process. All blood donations are assigned a unique unit identification number (UID), and once the UID is determined, it is utilized as a file pattern in the search. Since records are grouped by UID within the system and the group scans are saved in this manner, it is a quick and cost-effective retrieval method using BBCS and the Windows 2000 file search built-in facility on the OSS workstation or any other network workstation with the appropriate access permissions.

SYSTEM VALIDATION

Validation of the system entailed a comprehensive plan to ensure accuracy of stored records and faithful reproduction of it through a documented QA process. A sampling of several months of scans was utilized. Each DRF is reviewed at several steps in the process from creation to scan, and it undergoes several quality assurance checks before and after archival storage prior to physical records destruction. There are data processing, history, pre-scan, post-scan, and post-archival QA spot checks conducted. The end result is a fully reproducible document that meets with current federal guidelines for retrieval and reproduction.

SYSTEM SECURITY

The OSS data storage NAS is part of a Windows 2000 Active Directory Network, and all access permissions are assigned utilizing individual and group permissions. In this manner, only the OSS operators are given read/write access. All other employees with the need to retrieve specific records are granted read-only permissions based on access levels assigned to the various types of records being stored.

Using the security model provided by the underlying operating system further simplifies maintenance of access to the OSS data store. With the active directory model, access to a given portion of the stored records can be centrally managed and modified from a single

console. Access auditing can also be accomplished by the operating system. With the old physical storage model, the retrieval of these records involved action by several employees, and in many cases, travel to an off-site storage facility was required.

Central management of file access, security and records integrity is the key element of the system. The overall benefit is a significant increase in availability of information and increased productivity for employees.

COST SAVINGS AND ARCHIVAL RECORDS STORAGE REQUIREMENTS REDUCTION

The reduction of physical storage requirements for paper records has had a significant

impact for Northwest Florida Blood Center. In a 10-year period, the number of documents that must be cataloged, stored and archived for retrieval is well over one million images (front and back side, and accompanying documents). Now these archival records are stored on small form factor media (DVD-RAM/R and DDS4 Tape) that are maintained at an off-site branch location with minimal associated storage fees. Utilizing commercially available off-the-shelf hardware components and storage media reduces future expansion and cross-archival transfer costs.

The online NAS capacity can be readily expanded using evolving and inexpensive hard disk technology. An operation that once required tens of thousands of dollars annually in employee time and archival records storage

fees has been reduced to a fraction of the original costs. The cost per image set has been reduced to a few cents each from what once equaled as much as \$1.00 or more to process, store, maintain and retrieve. The rapid retrieval of the online records has provided the added benefit of increased employee productivity and efficiency.

As originally envisioned, the OSS now contains over one year's worth of stored records, and the NAS is only filled to approximately 10 percent of overall capacity. Without the implementation of this system, Northwest Florida Blood Center would have needed to increase storage facilities in the past year to accommodate an ever-growing cache of records. In fact, off-site storage requirements have actually decreased during that time, and the off-site facilities for physical records storage will be phased out entirely in upcoming years.

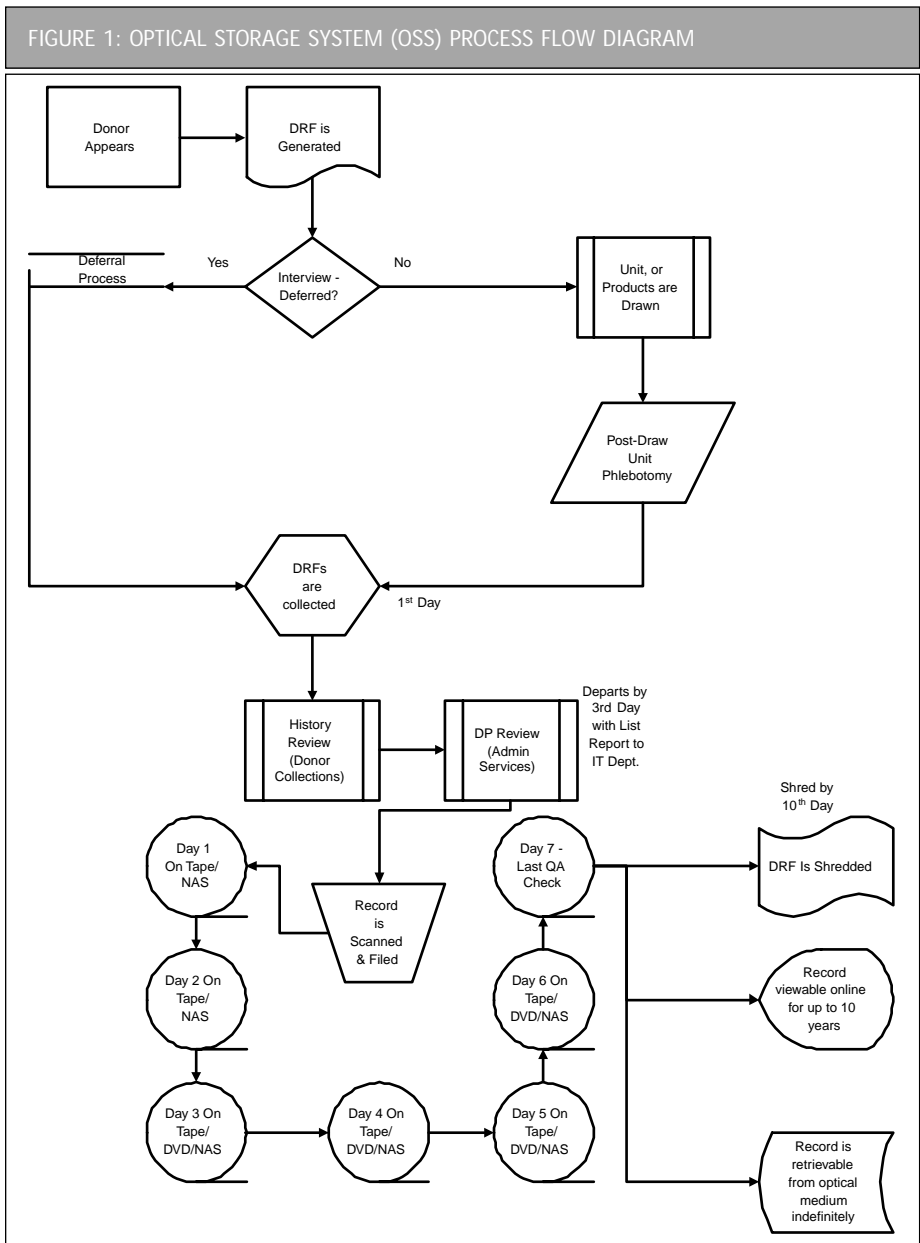
POST-IMPLEMENTATION DEVELOPMENTS

Since the validation of our own system, a discussion with one of our sister blood centers (Shepard Community Blood Center, in Augusta, GA) has resulted in another organization utilizing our model of archival records storage. In their case, they were able to construct the system for the cost of approx. \$7,000 by substituting a RAID-5 server assembly for the NAS portion of the system. They, too, have maximized the availability of low-cost off-the-shelf components to reduce overall costs.


FUTURE EXPANSION

Many records require long-term or indefinite storage to satisfy current regulatory requirements. The OSS provides for this expansion in a user-friendly software portable manner. This document storage and retrieval system is positioned for eventual expansion, and is cost-effective when there is a commercial indexing records management software system in place. In our case, this expansion has already begun with the archiving of other records to the NAS and DVD-RAM. Phase II of the expansion will include storage of records from the QA Department and Laboratory. Records requiring long-term or indefinite storage are in the process of being added to the system.

The OSS is being expanded to include a second high-speed duplexing scanner that will



double the overall scanning capacity of the system, and provide for continuity of operations in the event of equipment failures. This addition will permit scanning of other physical records currently maintained at one of several off-site storage facilities without impacting current operations.

FIGURE 1 demonstrates the document process flow of the OSS. 

NaSPA member John B. Holder is the Director of Information Technology at the Northwest Florida Blood Center, Inc. in Pensacola, Florida. He has over 18 years of experience as a commercial software developer and 24 years of experience as a network security and operations specialist. John is also the Vice President of Development at Marathon Computer Press in Atlanta. You can reach him via e-mail at jholder@nfbcblood.org, or VP-Development@marcompres.com.

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The Northwest Florida Blood Center is a Not-for-profit Community Support Organization located in Pensacola Florida.

Our Mission Statement:

Our mission is to serve our donors, hospitals, and community to the utmost of our ability and to protect our community blood supply. The Blood Center Board of Directors and staff support and promote a quality program consistent with the standards of its accrediting agencies. In this endeavor, we pledge to:

Treat our donors in a gentle, caring, and professional manner worthy of the life saving contribution they voluntarily make to our community.

Serve our hospitals and our community in the most professional and efficient manner possible, and to convey at all times an attitude that is worthy of their trust.

Please visit our web site at www.nfbcblood.org

