

Is Your Document Control Out of Control? Complying with Document Control Regulations

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Clinical laboratories, faced with new or changing regulations and shortages in trained laboratory staff, may find it difficult to comply with guidelines related to document control, upkeep of standard operating procedure manuals, and documentation of quality programs or competency reviews. Now, more than ever, it is critical to keep documents, procedures, and training material organized and accessible to busy laboratory staff and inspectors. The key may be the ability to use existing software programs available to industry for similar compliance issues. The laboratory's ability to change and update quickly with limited staffing may depend on electronic solutions to the complexities of document control. Several software programs have merit and can be integrated into a clinical laboratory.

INFORMATION OVERLOAD

In today's rapidly changing laboratory environment, most medical laboratory scientists know that overworked, overloaded feeling all too well. Often, change occurs at a frightening pace and challenges our ability to keep pace with the deluge of information that we process each day—operating procedures, policies, memos, practice guidelines, new regulations and laboratory inspection requirements, procedural updates, revisions, and new bacterial nomenclature. The list goes on. How can we keep pace? How can we rise to the challenge and position our laboratory operation for the future? How can we get our documents under control? Our laboratory sought help from business software established to provide document control that meets ISO Quality Standards Regulations. It is a perfect match for a health-care laboratory that is trying to

automate or standardize their paper document control system. Help is on the way!

DESCRIPTION

Our laboratory is a part of the Diagnostic Service Line at the Southern Arizona Veteran's Affairs Health Care System (SAVAHCS) located in Tucson, Arizona. Fully accredited by the Joint Commission on Accreditation of Healthcare Organization services are provided in a tertiary care medical center with 306 patient beds, a full complement of medical subspecialty clinics, four primary care and outpatient clinics, and five community-based outpatient clinics with their associated network of physician office laboratories located throughout the state of Arizona. The laboratory also serves as a reference laboratory for several community hospitals and for the Veteran's Integrated Service Network (VISN 18). In addition, the laboratory is active in education and research and part of the network of teaching affiliates that support the University of Arizona College of Medicine. The laboratory supports pathology training programs, internships for medical laboratory scientists, and clinical laboratory infrastructure for research initiatives based at the university and at the VA.

Historically, our document control system was composed of electronic documents on various computer drives and floppy disks, or available in hard copy only. Duplicate paper copies were maintained if more than one lab section or site was involved. Retired documents were stored in file cabinets and boxes. Despite the best of intentions to review some documents each month, we, like many other laboratories, typically reviewed documents each year *en mass*, straining our supervisory

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staff to race to review completion by year's end. Our system was adequate and sufficient for its time, but change was on the way.

DOCUMENT CONTROL NEEDS FOR THE SAVAHCS LABORATORY

In December 1998, the SAVAHCS clinical laboratory underwent a reorganization to create a core laboratory system. Management duties and positions were reassigned, core instruments were added, diagnostic reference ranges were changed, and outpatient test volumes were substantially increased. Because of the reorganization, the technical staff had extensive cross-training issues for Chemistry, Hematology, Blood Bank, and Microbiology. Workflow optimization was constant and necessitated many changes to policies and protocols. Accurate and reliable Standard Operating Procedures became more important, as gaps in our document control process became more apparent. These stresses were coupled with changes to College of American Pathology (CAP) requirements, first issued in 1994, checklists that required compliance with standard formats for procedures. In addition, CAP now references ISO 9000 standards related to the quality program of the American Association of Blood Banks, and there may be further references as the CAP integrates the National Committee for Clinical Laboratory Standards (NCCLS) documents that related to quality standards for laboratories (1). The International Organization for Standardization (ISO) is planning documents that detail quality and competency in medical laboratories (<http://www.iso.ch/iso/en/ISOOnline.frontpage>) so more changes may follow.

Table 1
Document categories

Seven broad document categories were chosen for the document classification system at SAVAHCS

- **Personnel:** Training, competency, qualifications, job/position descriptions
- **Organization:** Organizational charts, definitions, responsibilities and relationships, inspection and accreditation records, Provision of Service Plan, Quality Plan
- **Safety:** Accidents reports, Chemical Hygiene Plan, Biohazardous Waste Disposal Plan, Shipping and Handling of Biologicals, Infectious Control Plan
- **Audits:** Internal and external
- **Performance:** Quality assurance records, performance improvement records, faults, reporting errors and accidents, root cause analysis records and corrective action plans
- **Supplies and Equipment:** Identification, inventory list, validation records, operation/maintenance checks, and quality control records
- **Manuals:** Policies, processes, and standard operating procedures

In September 2001, the laboratory had more than 800 documents, 35 manuals, six research protocols, hundreds of online VA policies and memos, and many educational modules to track. We organized documents in seven different broad categories (Table 1) with approximately 23 subcategories related to medical specialties or topics.

“Why must we have all of these documents?” Like many health-care systems, we are subject to the three Rs of clinical/medical laboratories: regulations, requirements, and recommendations (Table 2). Review of these seemingly endless descriptions outlined what we needed to accomplish to create a complete set of laboratory manuals and a document control system (Table 3), but gave very few suggestions about how to accomplish it.

Our laboratory was much like other laboratories across the United States in that document control deficiencies were our number one perpetrator of CAP deficiencies. In fact, 40% were document related. Nationally, the top three laboratory deficiencies in the years 1998–2001 were related to document control items. Joint Commission on Accreditation of Healthcare Organization inspection of laboratories yields similar results; non-compliance to document control standards account for most of the laboratory deficiencies, especially when off-site or multi-site laboratories are involved.

Although no real solutions were found in our review of regulations, it was clear that change was essential for us. Technical staff expressed concerns about the rapid pace of changes and training requirements to support the changes. Other issues emerged as we attempted to comply with the new quality system essentials (1) and document control regulations (2). In addition, plans for a new Molecular Diagnostic and Research Laboratory were underway and would further challenge the system to comply with Good Laboratory Practice regulations (3, 4) needed for certain academic research and ISO standards from industry (5).

Review of the latest document control and quality system recommendations served two purposes: to overwhelm us and to reinforce our sense of commitment to document control. We aimed to facilitate:

- standardized procedure formats with complete and accurate information to enable performance and/or documentation of laboratory methods or policies
- competency-based training of personnel who perform, verify, and manage all laboratory activities according to standard operating procedures
- standardized and timely calibration, maintenance, and monitoring of equipment
- provision of consistent high quality critical materials and services from contracted suppliers
- provision of safe and adequate environmental conditions in the workplace
- compliance for regulatory requirements
- control of all processes.

Table 2

Regulations, guidelines, and information with application to documents in a clinical laboratory

A listing of relevant regulations grouped according to the regulatory agency from which they are issued. (Because information changes rapidly, the information depicted is representative of information available in February 2003.)

1. Food and Drug Administration (FDA)**21 CFR 11, Electronic Records; Electronic Signatures**

Subpart B—Electronic records

21 CFR 58, Good Laboratory Practice for Non-clinical Laboratory Studies (GLP)

58.185 Reporting of non-clinical laboratory study results

58.190 Storage and retrieval of records and data

58.195 Retention of records

21 CFR 211, Current Good Manufacturing Practice for Finished Pharmaceuticals

Subpart J—Records and reports (211.180–211.198)

21 CFR 600, Biological Products, General

600.12 Records

21 CFR 606, Current Good Manufacturing Practice for Blood and Blood Component

606.100 Standard operating procedures

Subpart I—Records and reports (606.160–606.171)

21 CFR 640, Additional Standards for Human Blood and Blood Products

640.72 Records

21 CFR 803, Medical Device Reporting of Adverse Events and Certain Malfunctions

803.17–803.18 Written MDR procedures, files

21 CFR 820, Good Manufacturing Practice, Quality System Regulation

Subpart M—Records (820.180–820.198)

2. Department of Labor: Occupational Safety and Health Administration (OSHA)**29 CFR 1904, Recording and Reporting Occupational Injuries and Illnesses**

1904.6 Retention of records

1904.9 Falsification or failure to keep records or reports

29 CFR 1910 Occupational Safety and Health Standards

Appendix C to 1910.120

4. Training (records)

8. Medical Surveillance Program (records)

3. Department of Health and Human Services: Center for Medicare and Medicaid Services (CMS)**42 CFR 493, Laboratory Requirements (CLIA 88)**

493.1107 Test—Records

493.1201(b) Written quality control procedures

493.1202(c)(2) Procedure manual, moderate-complexity testing

493.1211 Procedure manual, high-complexity testing

493.1221 Quality Control—Records

493.1721 Quality Assurance—Records

4. Department of Health and Human Services, Public Health**42 CFR 72, Interstate Shipment of Etiologic Agents****5. Department of Transportation****49 CFR 171-7 Shipment of Hazardous Materials****6. Department of Labor****29 CFR 71—Protection of Individual Privacy and Access to Records Under the Privacy Act of 1974****7. Miscellaneous Sources (specifics not listed)**

Multiple *Federal Register* sources

FDA Guidelines, Guidances, and Memoranda

Various CDC Guidelines

FDA Compliance Program Guidance Manual

8. Veterans Health Administration (VHA)

Pathology and Laboratory Medicine Service Procedures—Directive 1106 and Handbook 1106.1 (February 12, 1998)

Chapter 2 Quality Improvement

2.04 Required Elements for Quality Improvement in Major Divisions of the Laboratory and Ancillary Testing Sites

2.08 retention of Samples, Slides, and Records

VA Records Control Schedule (RCS) 10-1, Section VIII, “Laboratory Service,” (February 14, 2002)

9. American Association of Blood Banks (AABB)

Standards for Blood Banks and Transfusion Services (21st edition)

6.0 and 6.1.1 through 6.1.6—Documents and records; policies, processes, and procedures to ensure that documents are identified, reviewed, approved, and retained

10. College of American Pathologists (CAP)

Standards for Laboratory Accreditation (1999 edition)

continued on page 258

CAP Laboratory Accreditation Program Checklists for Inspection of Laboratories (2002 edition)
Requirements under checklists (too numerous to count!)

Example: Gen. 41480 Are laboratory records and materials retained for an appropriate time?

11. Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Comprehensive Accreditation Manual for Pathology and Clinical Laboratory Services (2001–2002)

IM.7 Laboratory–Specific data and information; the laboratory develops tools for communication. For example:

- IM.7.1 Written procedures
 - IM.7.1.1 Procedure approval
- IM.7.6 Required records and reports are maintained
- IM.7.10 Current descriptions and instructions for all analytical methods and procedure

LD.2 Directing Services–The laboratory director is responsible for developing, implementing, and maintaining policies and procedures

IM.8 Aggregate data and information

IM.10 Comparative data information; defined, collected, analyzed, transmitted, reported, and used

QC.1 Each specialty/subspecialty has a documented Quality Control program

12. National Committee for Clinical Laboratory Standards (NCCLS)

GP2-A4 Clinical Laboratory Technical Procedure Manuals (4th edition)

GP26A A Quality System Model for Health Care Approved Guidelines (October 1999)

Part 4.6, Quality System Essentials, Documents and Records

13. International Organization for Standardization (ISO)

ISO 9001 (3rd edition; December 15, 2000)

Section 4. Quality Management System

4.2 Document requirements

4.2.1 General; documented procedures to control all documents and data

4.2.2 Quality manual

4.2.3 Control of documents

4.2.4 Control of records

DEFINITIONS

There are two major components to a document control system:

1. Documents must be identified, reviewed, approved, and retained.
2. Records must be created, reviewed, stored, and archived.

Elements of the document control process include:

- a master list of documents, including policies, processes, procedures, labels, and forms
- use of a standardized format for all policies, processes, and procedures
- review and approval of new and revised documents before use
- annual review of each policy, process, and procedure by an authorized individual
- use of current and valid documents
- identification and appropriate archiving of obsolete documents.

TEAM, ROLES, RESOURCES, AND SCHEDULES

Like many laboratories, the SAVAHCS document control system was working, but the system was very difficult to manage and to monitor. Concerns about our current system gave rise to the Document Control Workgroup. After employees expressed concern over recent changes and training requirements, Dr. Ronald Schiffman, Chief of the Diagnostic Service Line, appointed a team to assess current compliance to document control regulations and to outline future laboratory needs. The

following team was assembled and composed of four representatives:

1. regulatory representative, VA Regional Commissioner’s Office, Region 6
2. ADPAC (Automated Data Package Application Coordinator), Computer specialist/LIS representative
3. blood bank manager
4. laboratory director/researcher/faculty member.

Notably missing from our group was a Laboratory Quality Control/Quality Assurance Specialist, which, in retrospect, would have been very useful to our process. Each of the four members performed some of the duties for this missing position.

The following list represents the group’s composite skill sets, experience, or affiliations:

- Veteran’s Health Administration Directives and the VA Regional Commissioner’s Office
- U.S. Federal Law, Code of Federal Regulations, *Federal Register*
- College of American Pathology Standards and Inspection Requirements
- Joint Commission on Accreditation of Healthcare Organization Standards
- American Association of Blood Banks guidelines
- NCCLS guidelines
- Good Laboratory Practice Regulations (GLP)
- laboratory information systems and computer software
- management, health administration, organizational behavior
- laboratory operations

- education
- research

The team was organized as a self-directed workgroup, with each member contributing his or her specific skill sets with meeting times established on a weekly basis to plan strategy and review progress. A document control email list was established to foster communication and to track the project process by keeping a temporal log of events. The team interfaced with laboratory supervisors

Table 3

**What the regulations say about document control
(February 2003)**

CAP and Manufacturer's Manuals

"A manufacturer's procedure manual for an instrument/reagent system may be acceptable as a component of the overall departmental procedures. Any modification to or deviation from the procedure manual must be clearly documented."

"The use of inserts provided by manufacturers is not acceptable in place of a procedure manual. However, such inserts may be used as part of a procedure description, if the insert accurately and precisely describes the procedure as performed in the laboratory. Any variation from this printed procedure must be detailed in the procedure manual. In all cases appropriate reviews must occur."

CAP and the Use of an Electronic Document System

Note 4: Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. Such electronic versions must be subjected to proper document control (*i.e.*, only authorized persons may make changes, changes are dated/signed [manual or electronic], and there is documentation of periodic review). Current paper copies of electronically stored procedures should be available at the time of the CAP inspection, or rapidly generated at the request of the Inspector.

One Discrepancy/Between CAP and NCCLS GP2-A4

NCCLS GP2-A4: "Annual review is unnecessary if a document control process is followed utilizing review of the SOP when it is new and at each change request."

CAP: "Is there documentation of at least annual review of all policies and procedures in the automated (chemistry) laboratory section by the current Laboratory Director or designee?" Note: As of September 17, 2002, CAP plans to keep the more stringent statement in their checklist.

Addressing Another Lab Perception Regarding Employee Signatures

CAP: "Does the laboratory have a system documenting that all personnel are knowledgeable about the contents of procedure manuals (including changes) relevant to the scope of their testing activities?" "NOTE: This does not specifically require annual procedure sign-off by testing personnel. The form of this system is at the discretion of the Laboratory Director."

at the onset of the process to gather information and assess the current status of the laboratory protocols and policies.

To begin the process, a time schedule and project management list were established for the following topics:

1. Resource Assessment

- What documents do we have? Where are they located?
- Is the document format NCCLS compliant?
- Is the document available in a computerized word processing format?
- Who writes and revises existing documents?
- What is the laboratory capacity for clerical support needed for document control activity?

2. Needs Assessment

- Who needs access to the documents and for what reason?
- Where will documents need to be accessed?
- What are the existing and future recommendations and guidelines related with quality system essentials and, specifically, document control?
- When will improvements in the current document control system be required?

Gap Analysis was performed with the following observations:

- Improvements in process were necessary: staff requested increased communication about content of paper SOPs
- Increased control was required: Off-site testing and physician office outreach clinics make paper difficult to control
- Existing workforce had little capacity to devote resources to compliance with new regulations:
- Minimal support was available for clerical activity
- Time was limited: Non-compliance existed for document control processes.

POSSIBLE SOFTWARE SOLUTIONS AND ASSESSMENT

Existing organizational software, such as Microsoft Office Suite, Visio for Flow Charting, and Front Page software for web-based links of Microsoft documents, were examined and were determined to be capable of fulfilling certain document control needs. Each had a very specific application with many merits. None was thought to provide our laboratory with the standardization and flexibility that we sought. Likewise, phone calls, emails, and inquiries to other laboratories proved to be of limited help. It became clear that we needed to expand our search and we looked to the Internet for help. Although it took hours of searching on the Internet, eventually several software programs, designed for industry to fulfill ISO Quality Standards, were identified. This software appeared to have the potential to fit our document control needs. Several web-links that listed various document control vendors were identified, including:

Table 4
Comparison of vendors

Software	Supplier	Desktop	Intranet	Internet	Web site
Documentum	Documentum, Inc.		×	×	www.documentum.com
Integrum	Trinity Consultants, Inc.		×	×	http://www.integrumonline.com/index.htm. http://www.trinityconsultants.com/
Proquis	Proquis, Inc.	×	×	×	www.proquis.net
Sharepoint	Microsoft, Inc.		×	×	http://www.microsoft.com/frontpage/share/point/ http://www.microsoft.com/solutions/msi/
Net-it Central				×	http://sample.netit.com/healthcare/
Adobe	Adobe Systems, Inc.	×	×	×	http://www.adobe.com/products/acrobat/main.html

- www.qualitydigest.com/feb01/html/docbg.html
- www.documantmanagement.org.uk/pages/vendors.html
- www.pdmic.com/vendors/docimage1.html

We reviewed numerous web sites from individual vendors, made numerous phone calls to assess the applicability of business software to health care, and finally selected three vendors for comparison (Table 4). Table 4 is not all-inclusive, but it provides a place to start your search.

SELECT SOLUTIONS AND PREPARE JUSTIFICATION

Although all the programs had much merit, after our review of software and options, Proquis was selected for our system. We chose a program with a web-based overview and online demonstrations of the software prior to purchase. Its modular flexibility to expand from a simple document control module to a software module suite that would encompass many of the new quality system essential requirements was of particular interest. In addition, familiar document types such as Word and Excel could be used within software. The program is based on a Microsoft Access integrated database so changes in one section can be designed to trigger corresponding changes to other areas automatically. For example, a fault log (error) that was generated as the result of a faulty procedure generates an automatic review of that procedure. The software can be used on PC or thin clients and a web-based version is also available.

The first modules purchased were document control, equipment control, and the fault log. The software is delivered with the application software, such as a Document Viewer, Personnel and Training modules, software for making flow charts, and reports software to produce reports for elements such as Quality Assurance and competency-based training. Other optional modules include: Vendor Control, Customer Care, FMEA Design Control, Audit and Management, and Health and Safety.

PLAN FOR IMPLEMENTATION

Once selected, a pre-implementation planning phase was initiated and intended to prepare us for installation

and make the best use of our allotted training time. The following list may help you prepare for software installation, no matter which program you choose to purchase.

- Documents were localized onto one network drive with folders designated for each specialty or procedure manual.
- Scanning technology needs were assessed to provide a means to import documents, which were not computer based. Extra scanners were purchased.
- Employee information was assembled and included the technologist's name, employee number (used as the software access code), title, work areas, and email.
- Organizational charts were prepared to outline chain of command and guide document approval chain.
- Laboratory organization charts were analyzed to identify document authorizers and sub-authorizers, and personnel responsible for writing and reviewing documents for each laboratory section. In the software, these responsibilities are designated for each procedure, (singly or in batch format).
- Templates for each document type were defined with organizational headers and footers to include mandatory information as per NCCLS format.
- A complete document control policy was drafted to include terminology and protocols for categorizing and naming things like SOPs, forms, and policies.
- Gaps in systems were identified.
- Regarding system information, network server availability and computer technical specifications were assessed, and the ability to integrate with existing LIMS databases was reviewed.
- Technical specifications and computer licensing policies were reviewed.
- Web links were identified for common policies.

Critical check point: the plan to purchase was re-assessed.

- Prepare on-site training room.
- Other software modules such as fault logs, reports, and equipment modules were explored.

- Timeframe and training schedule were established.
- A document control policy, document change request policy, document retirement, storage, and destruction policy were drafted.

When the staff was prepared for software installation, training was scheduled. A 1-day training course was provided free with the software purchase, but the 2-day training is optional and well worth the extra cost for a software representative to spend more time with your team for setup.

After the core workgroup was trained, the workgroup was expanded and test designed to challenge the team's ability to use the software. Two extra backup computer LIS ADPACs (the BACPACs) were chosen to help install and set up the software on network PCs for every member of the laboratory. The BACPACs also were assigned duties, such as scanning documents and importing scanned and Microsoft Word documents into the document control software. The selected individuals performed these tasks as collateral duty. Weekly meetings continued to finalize document templates and redefine the laboratory sections and procedure groupings. Each week the process was reviewed to assess problems, impediments, and successes.

After several weeks, the team felt ready to select extra staff to help with laboratory implementation and training for each employee. The workgroup and BACPACs expanded their group to include members defined as the Proquis Implementation Team (PIT) Crew. Each member of the PIT Crew was trained by original team members and given a PowerPoint slide presentation that would help with training needs for bench technologists. An implementation sequence and timeline was defined so that all staff members, supervisors, and directors could be trained to maximize their particular software responsibilities. As with any change, education was crucial and basic information about the rationale for purchase and the benefits the software offers to the laboratory were reviewed and shared with staff members.

ASSESSMENT

The software has proven to be very beneficial to the document control process in our laboratory. It provides for improved control, easier maintenance, and improved processes as follows:

Control of:

- the document distribution list
- access controls for each document
- distribution
- changes
- authorizations
- confirmations
- key duties of authorizers and sub-authorizers
- automatic document history.

Maintenance of:

- history of changes to documents
- documents that have been superseded and retired.

Improves:

- Security of the controlled document. No unauthorized changes to documents can occur.
- Communication. Employees receive an internal email when a new document has been released or changes made to existing documents. Employees can review documents and changes online and even request a change to occur by email to the document authorizer.
- Access. Online look-up adds a search capability so that documents can be found easily by keyword or section. Each employee simultaneously can review documents and provide easy access to related documents through web links or links to other SOPs.
- Archiving capabilities and retrieval of archived documents.
- Review process. Automatic notification of review dates. Documents are assigned a review date and a diary of actions to be completed is generated for the appropriate authorizers to notify them of upcoming events.
- Change request process: maintains authorship and authorization for each document and records approvals and confirmations.

WHAT COULD HAVE BEEN DONE DIFFERENTLY?

Roadblocks

- Although an unlimited number of viewers can review documents, the edit function is limited by the number of concurrent users on a software license. Our original one-user license soon became inadequate to meet our need for concurrent users so that several supervisors can edit documents at the same time.
- One scanner was not enough for us to quickly meet the needs of scanning and editing the documents that were not already in Microsoft Word format.
- Web links are still not functional in the program and would be very useful for linking to online VA documentation.

Unexpected Issues

- Encryption of electronic signatures became a difficult issue to resolve for electronic documentations of reviews and revisions.
- Not all laboratory employees use Outlook email and the system does not directly link with our VA standard email to report changes in documents to laboratory staff. What should be an automatic

function is now manual because of the type of email that is the norm in the VA system.


CURRENT STATUS

At present, implementation of software for online document control is nearly complete. Phase I of our process involves placing all current documents into the document control software system via import or scanning where they will be available for viewing and editing by laboratory employees. Phase II of implementation will begin when documents are placed on their yearly review cycle, with a subset of documents to be reviewed each month. Once in place, the review process will be subsequently triggered automatically by software. Phase III and beyond will explore the automatic reminders for the review process and use of other software modules, beginning with equipment control, fault logs, and training records for employees. Software modules fit in nicely with a formal review of our quality system, and plans exist to make full use of the software to automate most of our quality practices. Purchase of the web-based version of the software would allow the entire organization to share the software package as needed.

SUMMARY AND FUTURE APPLICATIONS

Because we have just scratched the surface of the iceberg called quality systems, there are many opportunities for us to move forward with adapting the software to enable us to automate other laboratory quality practices. Applications for competency-based training exist and will be helpful for training, re-training, and documentation of

employee skill sets and competencies. The software has the ability to place QA projects online for availability and review in real time. Fault logs also can be generated and tracked along with solutions and problem resolutions. In addition, there are modules to automate record keeping for equipment maintenance.

One thing is for certain. Today's laboratories are fast-paced, multi-tasking, and constantly changing. We have advanced laboratory informatics and electronics in our laboratories and yet many of us still struggle with manual review of documents, signatures, and massive paper files that contain revisions and archived documents. Isn't it time we follow our own lead and go electronic? No matter what software system you choose, there certainly will be a learning curve. This is one investment, however, that is well worth consideration. 

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