Electronic Documentation for Policies and Procedures

Document Management in the Modern Laboratory
Pathology Informatics 2011

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Goal and Objectives

- Define document management
- Understand requirements for document management
- Review process for selection of document management software
- Describe requirements for selection
- Discuss implementation process
- ISO 15189
- Show software
What is Document Management?

- Somewhat confused term currently
  - Many vendors are focused on document scanning software, not “electronic” policy and procedure workflow management
- Generic: a defined process for managing documents related to business processes
- What I will discuss is software for computer based management of laboratory policies and procedures
- Our labs have a huge number of such documents!
  - How about Yours?
Why do you Need Document Management?

- The process of managing documents is daunting and time consuming
  - Clinical laboratories have thousands of policies and procedures
  - Electronic systems provide efficient, effective, cost saving approach
- CAP accreditation requires a document management process/policy to handle laboratory policies and procedures
  - Not yet an electronic requirement
- A key component of ISO 15189 accreditation focuses on highly controlled management of documents
What is Document Management?

Paper

- Procedure and policy binders
- Annual review of policy and procedures
- Complicated process of circulating paper documents
  - Keeping them up to date
  - Documenting review and understanding by staff
- Manual sign off of each policy and procedure
- Access to paper binders across laboratories
- Updates by inserting new document versions to binders
- A policy governing how this will all be managed
What is Document Management?

Electronic

- Procedures and policies managed online in “organizers”
- Annual review managed online
- Electronic creation and sign-off
- Updates by electronic versioning
- Simplified process for circulating documents and keeping them up to date
  - Email notification
  - On line quizzes to documenting review and understanding by staff
- Access to online documents for laboratory and non-laboratory personnel
  - PDF’s, Word Documents
- Inherent electronic governance, dating and naming enforces document management policies
System Selection
Selection Process
RFI and RFP Process

- Formal RFI and RFP process
  - Used the Internet and personal references to identify 10-15 systems that may be applicable
  - Formed lab working group to identify requirements
- Submitted RFI (Request for Information) to these vendors
  - Based on responses we identified 4 vendors that were most feasible
- Submitted an RFP (Request for Proposal) based on system selection criteria developed by the working group
- Defined an evaluation form to rate the various proposal
- Carefully reviewed offerings
Selection Process

- Evaluated possible vendors who responded to the RFP
  - Demonstrations
    - Live and web based
    - Product literature and specifications
  - Cost
  - Contract review
  - Ratings and outcomes were reviewed and vetted with the workgroup, laboratory leadership team, and informatics leadership

- This took months!
  - Well worth the effort and wait based on the final selection

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Selection Analysis

- Vendor list
- Specification Analysis Excel
- Assessment of Finalists
Vendor list

- Policy Technologies
  - http://www.policytech.com
- Policy Medical
  - http://www.policymedical.com/
- Zequel, Dynamic Policy 4.0
  - http://www.zequel.com
- Soft Tech Health
- EZ Content Manager

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Vendor list

- Knowledge tree
  - http://www.knowledgetree.com
- Master Control Documents
- Chem SW
- Innovative Data Solutions (IDS): PowerDMS
Vendor List

- Policy IQ
  - http://www.policyiq.com

- Intelex

- Policy Manager
<table>
<thead>
<tr>
<th>Number</th>
<th>Section</th>
<th>Query</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Technology Platform</td>
<td>Do you consider your software to be a turnkey solution?</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Is the software designed to be deployed at a department level?</td>
</tr>
<tr>
<td>1.1</td>
<td></td>
<td>Specify hardware, operating system and database requirements</td>
</tr>
<tr>
<td>1.2</td>
<td></td>
<td>Does the system require a dedicated server?</td>
</tr>
<tr>
<td>1.3</td>
<td></td>
<td>Specify networking requirements to implement and use your software.</td>
</tr>
<tr>
<td>1.4</td>
<td></td>
<td>What database management systems are supported?</td>
</tr>
<tr>
<td>1.5</td>
<td></td>
<td>Client application: thick or thin?</td>
</tr>
<tr>
<td>1.6</td>
<td></td>
<td>How scalable is your system?</td>
</tr>
<tr>
<td>1.7</td>
<td></td>
<td>What routine maintenance is required?</td>
</tr>
<tr>
<td>1.8</td>
<td></td>
<td>Is there an archiving application built into the software?</td>
</tr>
<tr>
<td>1.9</td>
<td></td>
<td>Does archiving happen in real-time or does the system need to be offline?</td>
</tr>
<tr>
<td>1.10</td>
<td></td>
<td>Do you provide toll-free technical support within the USA?</td>
</tr>
<tr>
<td>1.11</td>
<td></td>
<td>What is the current version of the software?</td>
</tr>
<tr>
<td>1.12</td>
<td></td>
<td>Are new versions currently under development?</td>
</tr>
<tr>
<td>1.13</td>
<td></td>
<td>When upgrades occur, will existing documents and security parameters be automatically</td>
</tr>
<tr>
<td>2.0</td>
<td>Security</td>
<td>Is Active Directory supported for security</td>
</tr>
<tr>
<td>2.1</td>
<td></td>
<td>Is your system Novell™ compatible?</td>
</tr>
<tr>
<td>2.2</td>
<td></td>
<td>Can specific activities be assigned and audited?</td>
</tr>
<tr>
<td>2.3</td>
<td></td>
<td>Does the software allow for multiple facilities/locations with similar divisions?</td>
</tr>
<tr>
<td>2.4</td>
<td></td>
<td>Can user data be imported directly from third party products like Peoplesoft™, Novell™ and Active Directory™?</td>
</tr>
<tr>
<td>2.5</td>
<td></td>
<td>Can user information/permissions be easily modified?</td>
</tr>
<tr>
<td>2.6</td>
<td></td>
<td>How is security applied to individual users and groups?</td>
</tr>
</tbody>
</table>

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### Specification Analysis

**Administrative**

- Does the software support assessment of target audience on the content - current and updates? (Quiz)
- Does the system support automated notification for document updates at pre-defined or user-defined periods?
- Is there an online help system (within the application)?
- Has your application been used in a diagnostic medical laboratory?
- What specific feature(s) would be to particular advantage in the diagnostic medical laboratory setting?

**Documentation Features**

- Can pre-existing documents be imported en-masse or individually from another source?
- Does your system support MS Word as the word processing software?
- If not, what is the text editor used by your system? (E.g. Word Perfect or Native Editors)
- Can it support incorporation of tables, flowcharts, images? (E.g. Visio charts)
- Can document templates be employed?
- Can documents be scanned into the system?
- Can a date/time stamp be put on a document?
- Is key wording or tagging supported?
- Is electronic searching supported?
- Is hyperlinking supported - intradocument, interdocument and interdepartment?
- Can a single document be created/edited at one location and shared with multiple locations? How would review and approval process work for these documents?
- Does your system support E signatures?
- Will electronic signatures be permanent linked to and displayed on the documents?
- Will electronic signatures follow document through various software upgrades?
- Does the system have an automated page numbering facility?
- Can an index be created automatically?
- Are table of contents be created automatically?
- Will the TOC adjust automatically if a section is added/removed?
- Can a specific policy, procedure, or entire manual be selected and printed?
- **Can the document be printed out as an indexed book with a table of contents?**
- Can a quiz be generated to test that targeted end-users have reviewed a new policy or...
## Specification Analysis

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>67</td>
<td>5.0</td>
<td><strong>Version control</strong></td>
</tr>
<tr>
<td>68</td>
<td>5.1</td>
<td>What is the system for assigning unique identification name/number for each individual documents?</td>
</tr>
<tr>
<td>69</td>
<td>5.2</td>
<td>What is the process for tracking the lifecycle of a document?</td>
</tr>
<tr>
<td>70</td>
<td>5.3</td>
<td>Does the system use a document check-in/check-out system?</td>
</tr>
<tr>
<td>71</td>
<td>5.4</td>
<td>Can modifications be made to active documents and re-submitted for review?</td>
</tr>
<tr>
<td>72</td>
<td>5.5</td>
<td>How are updates to documents tracked?</td>
</tr>
<tr>
<td>73</td>
<td>5.6</td>
<td>Is versioning the only way to modify a document?</td>
</tr>
<tr>
<td>74</td>
<td></td>
<td></td>
</tr>
<tr>
<td>75</td>
<td>6.0</td>
<td><strong>Finance</strong></td>
</tr>
<tr>
<td>76</td>
<td>6.1</td>
<td>What is the cost of the system?</td>
</tr>
<tr>
<td>77</td>
<td>6.2</td>
<td>What is the licensing arrangement?</td>
</tr>
<tr>
<td>78</td>
<td>6.3</td>
<td>What are maintenance costs per annum?</td>
</tr>
<tr>
<td>79</td>
<td>6.4</td>
<td>Are upgrades included in the system costs?</td>
</tr>
<tr>
<td>80</td>
<td>6.5</td>
<td>Is the database included in the cost?</td>
</tr>
<tr>
<td>81</td>
<td></td>
<td></td>
</tr>
<tr>
<td>82</td>
<td>7.0</td>
<td><strong>Company Information</strong></td>
</tr>
<tr>
<td>83</td>
<td>7.1</td>
<td>What is the age of your company?</td>
</tr>
<tr>
<td>84</td>
<td>7.2</td>
<td>Provide a minimum of five(5) customer references; name, address, phone, email?</td>
</tr>
<tr>
<td>85</td>
<td>7.3</td>
<td>Provide any references related to healthcare, specifically those related to the diagnostic medical laboratory on a similar scale?</td>
</tr>
<tr>
<td>86</td>
<td>7.4</td>
<td>Provide evidence of positive financial performance?</td>
</tr>
<tr>
<td>87</td>
<td>7.5</td>
<td>What is the future vision of your company?</td>
</tr>
<tr>
<td>88</td>
<td>7.6</td>
<td>What is the future direction of the product we are discussing?</td>
</tr>
<tr>
<td>89</td>
<td>7.7</td>
<td>Do you accept enhancement requests from customers?</td>
</tr>
</tbody>
</table>

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is_your_product_ISO_certified?
Selection of Finalists

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Selection of Finalists

Radar Summary

- Technology Platform
- Company Information
- Finance
- Version control
- Document Features
- Administrative
- Security

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Final Selection

MasterControl Document Management Suite
v. 6.0
Salt Lake City, UT
MasterControl

Features

- Suite of applications for laboratory management
- Uses MS Word as text editor and all of Word’s features
  - Tightly integrated with MS office application’s including PowerPoint, Excel, Visio etc.
- Web based (Thin Client) workflow application manages interaction with documents
- Hardware requirements within our limitations
- Email notification
- Flexible document management process
  - Organizers
  - “Info Cards”
  - Allowed sharing of documents between user groups
  - Flexible workflow
MasterControl Features

- Ease of document import
- External web publication to non lab users
  - Documents can be hyperlinked and provided to non lab users
    - PDF publishing module
- Vendor responsiveness
  - User group
  - Updates/enhancements
  - We have driven several modifications
    - “Binder”
    - Version 8.2 is now implemented
MasterControl
Features

- Training Module
  - Verification and documentation of employee review of documents
  - Uses quizzes to assure understanding of document content
  - Meets CAP and ISO 15189 requirements for annual employee review
Implementation
How to Get Started

- Go slow
  - This is a project that runs over years
- Select correct vendor
- Purchase and implement system
- Import current documents
- Design a new template that will address ISO/CAP requirements
  - CLSI standard is a good point of departure
- Examine current file, document nomenclature to assess whether redesign
- Examine inspection cycle relevant to implementation timeline
Technical Requirements

- Technical requirements link
  - Hardware and software requirements
- Implemented on VM cluster
  - Web server MS Internet Information server
    - Combined with PDF publisher
  - “Polyserve” MS SQL cluster
- Supported on HFHS data center
  - Tape Backup, snapshots, EMC NAS storage
Current Status at Henry Ford

- Most documents have been imported in their original form (over 3000)
  - Some laggards of course!
- Standard template for documents designed and implemented
- A standard nomenclature for document naming and numbering has been designed and implemented
- Imported documents are now being placed into “organizers”
  - This is the first step to activating a division or customer group
Current Status at Henry Ford

- Training for customers has been accomplished with laboratory divisions
  - Now proceeding across other hospital locations
- Documents for each completed organizer are placed on our intranet replacing prior document
- Migrated to enterprise hardware
- Upgraded to version 8.2
- Implemented ISO compliant templates
Current Status at Henry Ford

- Backup systems in place
  - Networked PC in core lab area
- Documents in MasterControl linked to our intranet website
- Controlled copies implemented
# Document Structure: Relationship of Quality Documents

<table>
<thead>
<tr>
<th>Document Type</th>
<th>Description</th>
</tr>
</thead>
</table>
| **Policy**    | • Statement of intent  
                • Derived from  
                               - Established requirements, or  
                               - organizational mandate  
                • Describes “what is done” |
| **Process**   | • Description of “who does what and when”  
                • Provides information on “how it happens here.” Typically a flow chart or table. |
| **Procedure** | • Instructions for how to do a task within the larger process |
| **Forms/ Records** | • Data, information, or results captured from performing a procedure, recorded on a form, label, or tag, or entered into a computer |
| **Standard Work** | • The current one best way to safely complete an activity with the proper outcome and the highest quality  
                           • Each step in the process should be defined and must be performed repeatedly in the same manner identifying work components: Content, Sequence, Timing, Location and Outcome |
### ISO Document Naming Convention

**DOCUMENT**

**TITLE**

LABEL (prefix)

**NAME**

#### Abbreviation: QSE

<table>
<thead>
<tr>
<th>Quality System Essentials (QSE)</th>
<th>Abbreviation</th>
<th>QSE Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization</td>
<td>ORG</td>
<td>1.0</td>
</tr>
<tr>
<td>Personnel</td>
<td>PER</td>
<td>2.0</td>
</tr>
<tr>
<td>Equipment</td>
<td>EQM</td>
<td>3.0</td>
</tr>
<tr>
<td>Purchasing and Inventory</td>
<td>PUR</td>
<td>4.0</td>
</tr>
<tr>
<td>Process Control</td>
<td>PRC</td>
<td>5.0</td>
</tr>
<tr>
<td>Documents and Records</td>
<td>DOC</td>
<td>6.0</td>
</tr>
<tr>
<td>Information Management</td>
<td>INF</td>
<td>7.0</td>
</tr>
<tr>
<td>Occurrence Management</td>
<td>OCC</td>
<td>8.0</td>
</tr>
<tr>
<td>Assessments: External And Internal</td>
<td>ASM</td>
<td>9.0</td>
</tr>
<tr>
<td>Process Improvement</td>
<td>PRI</td>
<td>10.0</td>
</tr>
<tr>
<td>Customer Service</td>
<td>CUS</td>
<td>11.0</td>
</tr>
<tr>
<td>Facilities and Safety</td>
<td>SAF</td>
<td>12.0</td>
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</table>

#### Abbreviation: QSE

<table>
<thead>
<tr>
<th>Type of Document</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy</td>
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</tr>
<tr>
<td>Process</td>
<td>prs</td>
</tr>
<tr>
<td>Procedure</td>
<td>pro</td>
</tr>
<tr>
<td>Standard Work</td>
<td>stw</td>
</tr>
<tr>
<td>Checklist</td>
<td>chk</td>
</tr>
<tr>
<td>Flow chart</td>
<td>flc</td>
</tr>
<tr>
<td>Form</td>
<td>frm</td>
</tr>
<tr>
<td>Photograph</td>
<td>pho</td>
</tr>
<tr>
<td>Power point</td>
<td>ppt</td>
</tr>
<tr>
<td>Screen shot</td>
<td>scr</td>
</tr>
<tr>
<td>Scanned document</td>
<td>scn</td>
</tr>
<tr>
<td>Table</td>
<td>tab</td>
</tr>
<tr>
<td>Video</td>
<td>Vid</td>
</tr>
</tbody>
</table>
# ABBREVIATIONS IN DOCUMENT CONTROL

## Hospital & Division Level Detail

<table>
<thead>
<tr>
<th>HOSPITAL</th>
<th>DIVISION</th>
<th>ABBREVIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>PALM = System-wide</td>
<td>PALM</td>
<td>PALM</td>
</tr>
<tr>
<td>HFH Henry Ford Hospital</td>
<td>Anatomic Pathology</td>
<td>ANP</td>
</tr>
<tr>
<td>HFMCT Macomb Clinton</td>
<td>Clinical Pathology</td>
<td>CLP</td>
</tr>
<tr>
<td>HFMWC Warren Campus</td>
<td>Point of Care Testing</td>
<td>POC</td>
</tr>
<tr>
<td>HFWBH West Bloomfield</td>
<td>Microbiology</td>
<td>MIC</td>
</tr>
<tr>
<td>HFWH Wyandotte Hospital</td>
<td>Transfusion Medicine</td>
<td>TRM</td>
</tr>
<tr>
<td>HFCH Cottage Hospital</td>
<td>Chemistry</td>
<td>CHM</td>
</tr>
<tr>
<td>HFMG HF Medical Group</td>
<td>Coagulation</td>
<td>COA</td>
</tr>
<tr>
<td></td>
<td>Core Lab</td>
<td>COR</td>
</tr>
<tr>
<td></td>
<td>Cytopathology</td>
<td>CYP</td>
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<tr>
<td></td>
<td>Hematology</td>
<td>HEM</td>
</tr>
<tr>
<td></td>
<td>Immunology- Transplant</td>
<td>IMM</td>
</tr>
<tr>
<td></td>
<td>Laboratory Service Center</td>
<td>LSC</td>
</tr>
<tr>
<td></td>
<td>Laboratory Support Services</td>
<td>LSS</td>
</tr>
</tbody>
</table>
Title: ALL CAPS (Document Prefix: Document Name + Type of Document)

I. Purpose or Principle:
(Principle: The theory, reasons and background for the policy Purpose: Description of the reason the policy was created)

II. Scope ( Defines the laboratory, division, section or staff members that the policy applies to and will be responsible for the performance and/ or working knowledge of the policy)

III. Policy (Documented statement of overall intent derived from either established requirements or organizational mandate, providing a description of “what is done” and endorsed by management)

IV. Materials and Equipment (Listing of supplies, reagents and equipment necessary to perform this procedure)
A.

V. Forms, Labels and Definitions (optional) (Any associated forms, labels or definitions that are necessary to perform this procedure)
A.

VI. Procedure (Step by step directions for how the procedure is to be performed)
A.

VII. Monitoring (This section will describe the processes for ensuring that the associated forms and processes are properly reviewed)
A.

VIII. References
• Documents and materials used to create this policy
• List the CAP checklist question that it complies with if applicable- (e.g. LAB GEN .2034)
A.

IX. Supporting Documents (Policy, process or the individual procedures that support but are not linked to this policy)
A.

X. Attachments (Any other items that are used in the creation of or are otherwise important to the policy/procedure [that are linked to this policy/procedure] e.g. Standard Work, Flow chart, Power point, Screen shot, Table or Video)
A.
Demonstration

Screen shots from master control
MasterControl Collaboration Task

Task Name: For Dr. Tuthill's Review
Step Name: Collaboration
Task Instructions: There are no instructions for this item.
Task Contents: Fake Document #7 Doc-007 010
Task Actions: Sign Off on this Task
Open Collaboration Task in MasterControl
This document is used to test the Master Control system.

9/18/2008

☐ Testing the one step approval process.
☐ This is my added content with track changes on. Jackie
☐ This content is edited with Tuthill's track changes
☐ What is the next step? Let's check in then accept all the changes in
the next round.
☐ My second round of changes.
☐ Here are mine as well....can we sign off now?
☐ Next edit
☐ Testing upload

Testing scheduled tasks
Here are the changes I am adding to the document

- One
- Two
- Three
- Four
- Five
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J. Mark Tuthill, MD, Henry Ford Hospital
J. Mark Tuthill, MD, Henry Ford Hospital
Task Details: Review: 002 1

View instructions and contents for the selected task.

Sign Off

Instructions
There are no instructions for this item.

Contents

<table>
<thead>
<tr>
<th>Document Number</th>
<th>Title</th>
<th>File Name</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>002</td>
<td>testing web page review</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Sign Off Task: Review: 002 1
Enter your comments (if any) and approve the selected task.

Comments
Looks good now.

Sign Off
Review
*Electronic Signature

*Status
Reviewed

Save
### MasterControl Documents > Document InfoCard

#### Version Information
- **Document Number**: HFH-PIN-Policies-019
- **Title**: PRC-PALM-PIN-S.10-pcl PATHOLOGY INFORMATICS PROJECT REQUESTS POLICY
- **Notes**: Pathology Informatics Policies GEN.43022

#### Other Information
- **Author**: Michele A. Westcott (MWESTCO1)
- **Owner**: Michele A. Westcott (MWESTCO1)

#### Data Information
- **Created**: 4 Jan 2010
- **Effective**: 6 Jan 2010
- **Expires**: 6 Jan 2010
- **Released**: 6 Jan 2010

#### Main File
- **File Name**: PRC-PALM-PIN-S.10-pcl PATHOLOGY INFORMATICS PROJECT REQUESTS POLICY.doc
- **File Size**: 182.00 KB

### Standards

<table>
<thead>
<tr>
<th>Standard</th>
<th>Section</th>
</tr>
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<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>
J. Mark Tuthill, MD, Henry Ford Hospital
Questions?