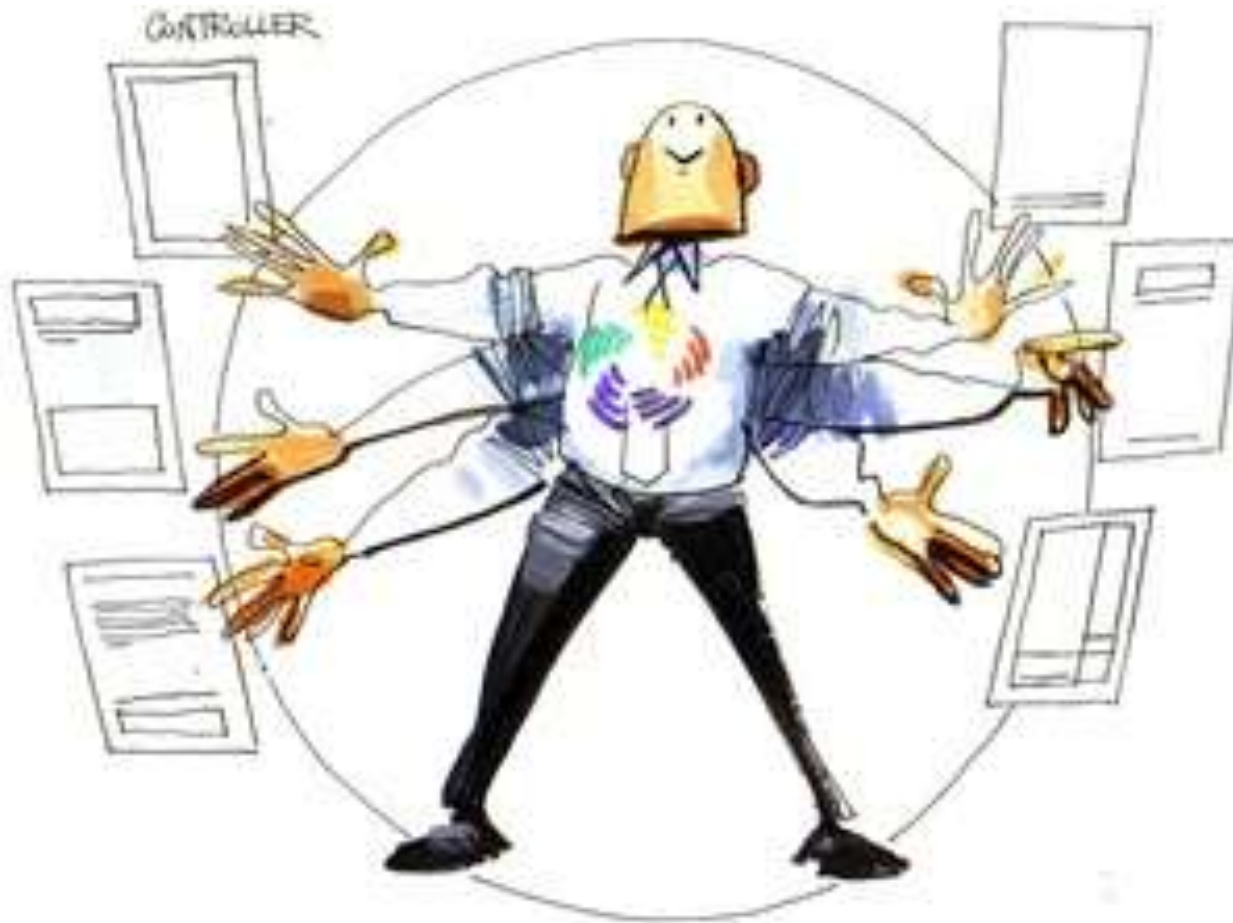


CONTROLLING YOUR DOCUMENTS AND RECORDS



Presentation Objectives

- Upon completion, the participant will be able to:
 - Explain the relationship of document/records control to the **Quality Management System (QMS)**
 - State the benefits of effective document/records control
 - Describe some of the current issues in document/records management
 - Evaluate the adequacy of his/her organization's document/records control system

Definitions

- Accrediting Agency
 - A professional or nongovernmental agency that grants recognition to an entity for the demonstrated ability to meet predetermined criteria for established standards
- Regulatory Agency
 - An agency, organization, or body of a federal, state, or local government that creates, promulgates, and enforces rules concerning delivery of a product or service

Definitions

- **ISO – International Organization for Standardization**
 - Adopted 9000 series of standards in 1987
 - **ANSI -American National Standards Institute** adopted standards in U.S. & endorsed by **American Society for Quality (ASQ)**
 - Standards undergo updates to reflect current worldwide requirements
- **FDA CFR 21 Part 820 – Federal Code of Regulation**
 - Also known as the **Quality System Regulations (QSR)**
 - Outlines **current Good Manufacturing Practices (cGMPs)** regulations that control aspects in manufacture of finished devices intended for human use

Premises of Document Control Standards, Regulations

- Document & supporting medium is considered information
 - Dark Ages
- Implies over time new information supersedes old; change must be managed
- Documents are active and dynamic
- Essential preventive measure to ensure only current, approved documents in use



Document Control -a QMS Cornerstone



4.2.1 “General Documentation Requirements” states QMS documentation shall include:

- Documented statements of a quality policy & quality objectives
- A quality manual
- Documents needed by the organization to ensure the effective planning, operation, & control of its processes
- ISO required documented procedures and records

Hierarchy in ISO

- 4 Quality Management System

- 4.1 General requirements

- 4.2 Documentation requirements

- 4.2.1 General

- 4.2.2 Quality Manual

- 4.2.3 Control of documents

- 4.2.4 Control of records



Hierarchy in 21CFR820

- Part 820_Quality System Regulation
 - Subpart D_Document Controls
 - 820.40 Document controls
 - Subpart M_Records
 - 820.180 General requirements
 - 820.181 Device master record
 - 820.184 Device history record
 - 820.186 Quality system record
 - 820.198 Complaint files

Importance of Document Control

- Helps ensure compliance with audits
 - Document control generates most nonconformance in ISO 9001 QMS
 - Some of most common reasons for FDA 483 Observation and Warning Letter Citations (2007)
- Essential to risk management



History of Document Media

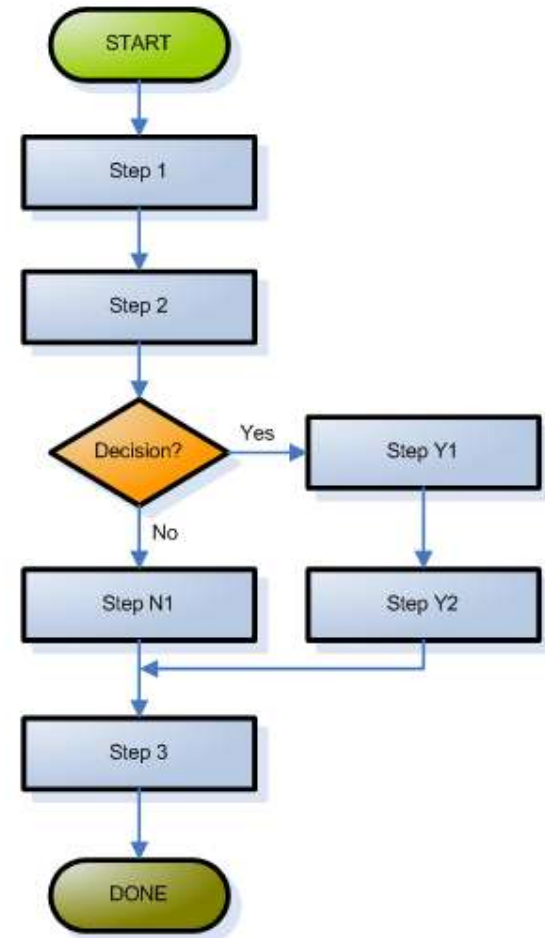


Cave painting, Lascaux, France, 15,000 to 10,000 B.C.

- European prehistoric cave paintings carbon date to 32,000 years ago
- Moses and 10 commandments – 1250 BC
- 300 AD invention of papermaking in China
- Declaration of Independence - 1776

MEDIA ON WHICH DOCUMENTS MAY BE PRESENTED

- Hard copy (paper or similar material)
- Laminated cards at work stations
- Print on the reverse side of a form
- Process map displayed over work area

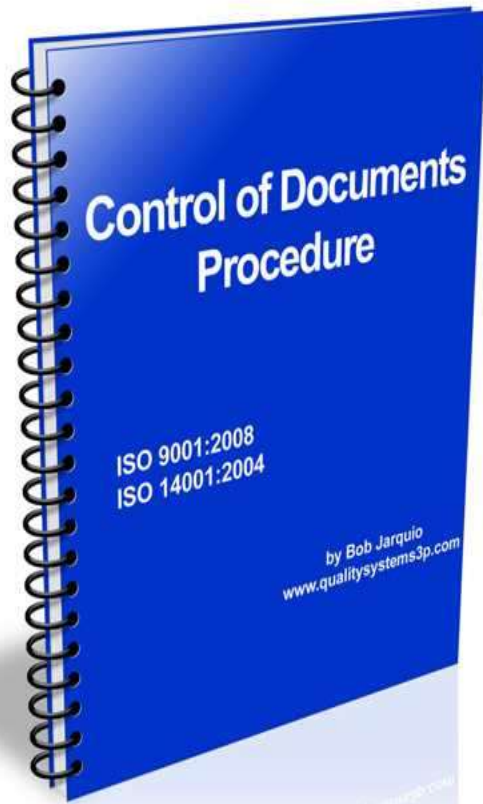


MEDIA ON WHICH DOCUMENTS MAY BE PRESENTED



- Computer screen
- Video stream or clips
- Embedded in work order

DOCUMENTS REQUIRING ESTABLISHMENT, MAINTENANCE, CONTROL



- Quality policy/objectives & manual
- Operational procedures
- Work instructions
- Specifications
 - Device
 - Production process
 - Packaging and labeling
- QA procedures/specifications

DOCUMENTS REQUIRING ESTABLISHMENT, MAINTENANCE, CONTROL

- Installation, maintenance, and servicing procedures/methods
- Forms and records
- Any company documents affecting quality or customer satisfaction



PROCEDURES AND WORK INSTRUCTIONS

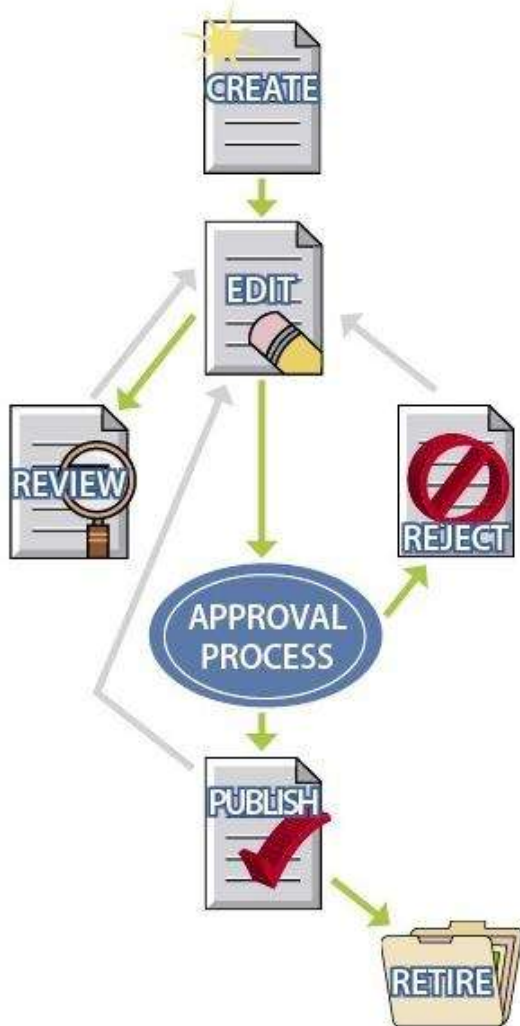
- Organizations have managed processes without much formal documentation, record keeping
- Major changes (global marketing, mergers, time pressures, etc.) causing/forcing companies to document systems, processes, practices



ADVANTAGES OF GOOD DOCUMENTED PROCEDURES

- IDs preferred/required approach to follow
- Provides basis for measuring performance
- Emphasizes consistent method of doing work
- Supports training
- Captures “one best way” of combination of methods
- Serves as job aid guiding, refreshing performer
- Provides baseline for assessment and improvement
- Has positive impact on quality, cost, customer satisfaction, productivity

DOCUMENT CONTROL



- Must account for complete document life cycle
 - Creation
 - Classifying
 - Storing
 - Securing
 - Harvesting (retrieval) of content for reuse
 - Destruction/disposal

Document Control

- Your mandatory, written document control procedure must define how you:
 - Review and approve documents (eg procedures, flow-charts, process maps, etc.) prior to use
 - Review, update and re-approve amended documents
 - Identify changes and current revisions of documents
 - Make relevant and current documents available at points of use

Continued.....

- Your mandatory, written document control procedure must define how you:
 - Ensure that documents are legible and identifiable
 - Identify and control the distribution of documents of external origin
 - Identify retained obsolete documents and prevent their unintended use
 - *** Obsolete-but-still-in-use is single most common non-compliance

Essential Design Criteria for Effective Document Control

- Begins with document design and creation
- Ask authors to:
 - Be concise
 - Make documents multi-purpose when possible
 - Use a standardized template
 - Use frequently used or required language



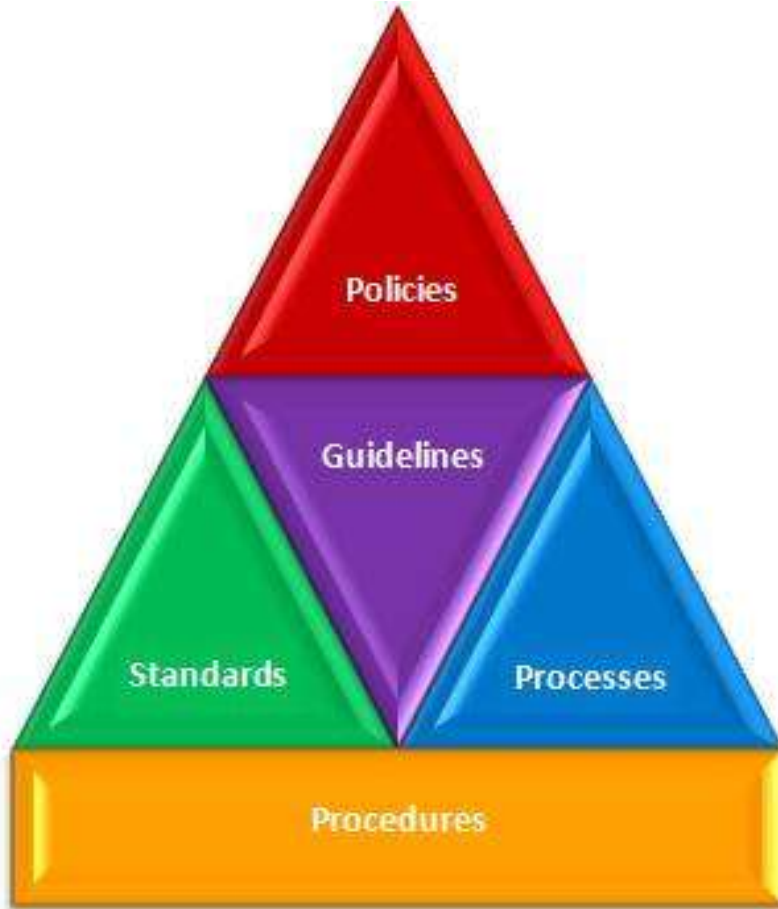
Essential Design Criteria for Effective Document Control

- Incorporate a hierarchy & structure for easy navigation
- Scheme should:
 - Make the most sense to organization
 - Meet requirements of applicable standards
- Two basic approaches prevalent for structure
 - Documentation follows the process flow of the product or service provided
 - Documentation is keyed to specific paragraphs of the applicable standard

A Layered Structure to Documentation

- Helps users find what they're looking for
- An ISO 9001 structure typically organizes into 4 levels:
 - Policy
 - Procedure
 - Work instructions
 - Forms and records

Logical Document Arrangement



- Clarifies authority, scope and interrelationship of each document
- Lower level documents agree with requirements of higher level documents
- Higher level documents reference lower level documents



QUALITY SYSTEM MANUAL

Revision: d
Effective Date: 09/29/10

4.2 Documentation Requirements

Page 1 of 3

Responsibility: Quality Documentation Coordinator
Approved by: Director of Quality

4.2.1 The Quality Management System Documentation includes:

- 4.2.1.1 A Quality Policy and Quality System Goals
- 4.2.1.2 Department Quality Goals
- 4.2.1.3 The Quality System Manual
- 4.2.1.4 Standard Operating Procedures and Work Instructions, where applicable
- 4.2.1.5 Records

4.2.2 The Quality System Manual includes:

- 4.2.2.1 The Scope of the Quality Management System in a Key Process flowchart (Section 1.1), which includes the interaction between the processes of the quality management system.
- 4.2.2.2 Documented procedures established for the Quality Management System.

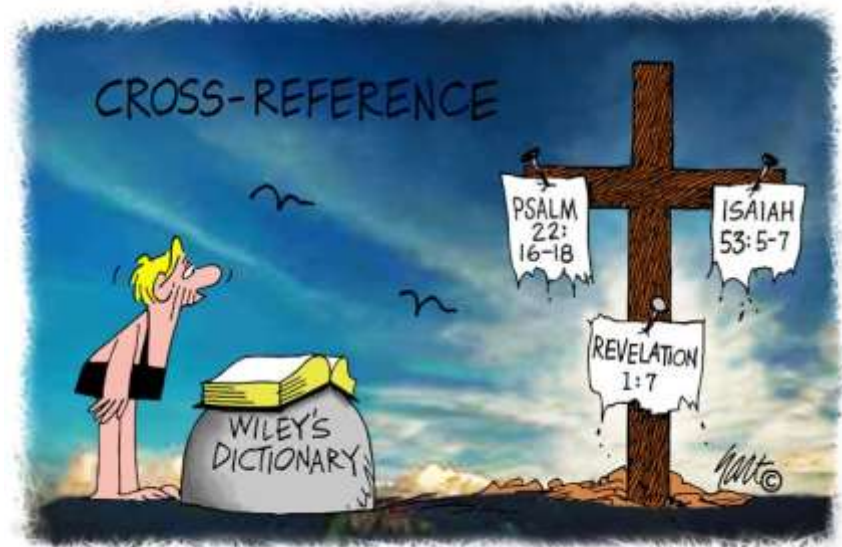
4.2.3 Control of Documents

Note: On occasion, Pierce Appleton SOP's, WI's and QSD are utilized at the Florida branch.

<u>Title:</u>	ALARM CHECKS FOR REFRIGERATORS AND FREEZERS - QUARTERLY FOR EQUIPMENT NOT ON A CENTRAL MONITORING SYSTEM
<u>System:</u>	Quality Management
<u>Critical Control Point(s):</u>	Process Control and Calibration
<u>Reason for Change:</u>	Add "Daily Freezer Temperature and Inspection Record – Offsite Hospitals" (FBS-2469). Delete flowchart.
<u>Principle:</u>	Refrigerators and freezers used to store blood and blood components must have the alarm system challenged on a quarterly basis to ensure they are working properly. This is performed by trained personnel, in CTL, Ref, IDC and DTL.
<u>Computer Programs:</u>	None
<u>Forms Needed:</u>	Alarm Check - Refrigerator, Quarterly (FBS-0393) Alarm Check - Freezer, Quarterly (FBS-0392) Daily Refrigerator Temperature and Inspections – Offsite Hospitals (FBS-0750) Daily Freezer Temperature and Inspection Record – Offsite Hospitals (FBS-2469)
<u>Training Documents:</u>	Alarm Checks for Refrigerators and Freezers - Quarterly for Equipment Not on a Central Monitoring System (FBS-0208-Checklist)
<u>Specimens:</u>	None
<u>Materials:</u>	<u>Refrigerators:</u> Container large enough for probe housing Styrofoam Cups Water

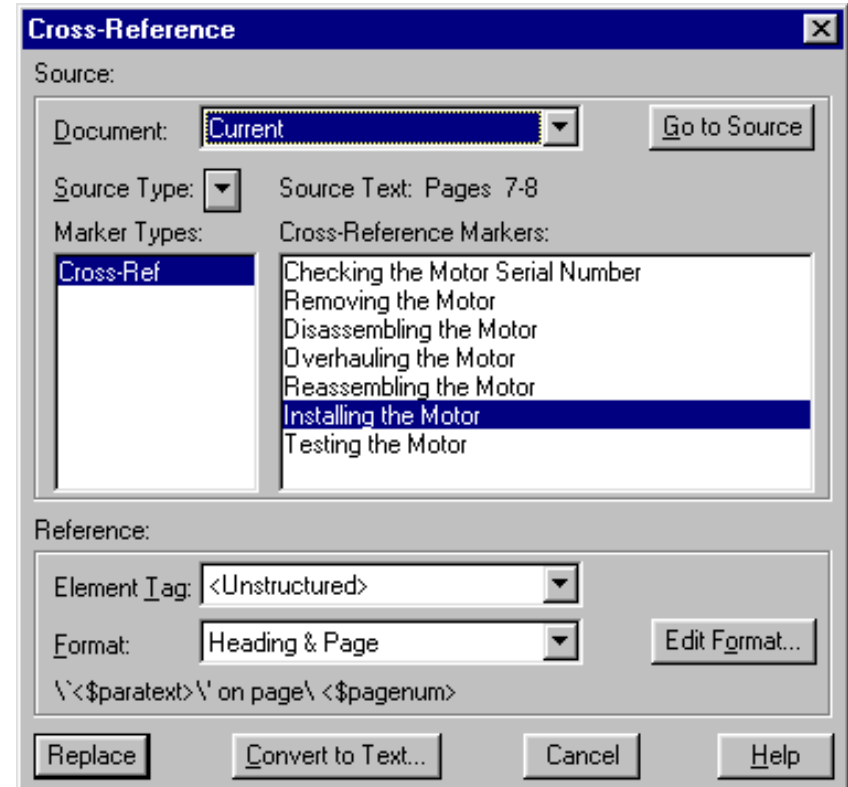
Cross-referencing

- Common to add references to related documents within body of document
 - Reader can quickly find additional info on topic
 - Difficult to maintain/update



Cross-referencing

- Alternatives
 - Carefully designed doc. numbering systems
 - Master list showing parent-child relationships between documents
 - Electronic document management system that allows for easy searching



Essential Criteria for Effective Document Control

- Reviewers & approvers
 - Future users of document
 - Managers responsible for the activity
 - Workers affected by the activity
 - Other interested individuals
- How to decide – balance:
 - Desire for gaining buy-in and accountability
 - Efficiency of document control process

Change Role Help Go To Logout

Document No.	FBS-0037-SOP [M]	Status	DRAFT
Type	SOP	Current Approval Status	PARTIALLY APPROVED
Title	Early Donation Approval	Phase	ROUTED FOR REVIEW

Review Approval Routing Signature Checklist Attachment

Review	DS-R	Seq.	1
Review Purpose	Draft Building Review Process		

Escalation		Approval Status	PARTIALLY APPROVED
Rule			

Stop

		+Level	+Role	+Actor	+Actor Name	Note To Approver	Substitute Option
<input type="checkbox"/>	10	EMAIL		EMAIL	SS EMAIL		Anyone Within Same Role
<input type="checkbox"/>	20	DS		1114 - GOENS, M	MARA GOENS		Anyone Within Same Role
<input type="checkbox"/>	30	DS		0278 - PORTER, C	CATHLEEN PORTER		Anyone Within Same Role
<input type="checkbox"/>	40	UNIVERSAL REQUIREMENT ROLE		0976 - WILLIAMS, D	DEBORAH WILLIAMS		Anyone Within Same Role
<input type="checkbox"/>	50	QA		0937 - MILETO, K	KERRY MILETO		Anyone Within Same Role
<input type="checkbox"/>	60	DS		1114 - GOENS, M	MARA GOENS		Anyone Within Same Role

✖ ✖ Show Top 6 / 6

Essential Criteria for Effective Document Control

- Approving Documents
 - Must be done prior to release of document
 - Approvals may be written signatures or password-protected electronic approvals; must be dated
 - Dates of approvals must precede document's release date
 - Also applies to temporary documents
 - Must be clearly identified, signed, and dated
 - Advisable to include an expiration date

Document No.	FBS-0152-SOP [L]	Status	DRAFT
Type	SOP	Current Approval Status	PARTIALLY APPROVED
Title	Component Preparation Supplies and Equipment	Phase	ROUTED FOR REVIEW

- Review
- Approval Routing
- Signature
- Checklist
- Attachment

Review	IDC-R	Seq.	1
Review Purpose	Draft Building Review Process		

Escalation	Rule
------------	------

[View](#)

	+Level	+Role Name	+Actor	+Actor Name	Note To Approver	Note From Approver	+Approval Status	+Sign-off By	Sign-off Date	
<input type="checkbox"/>	10	EMAIL	EMAIL	SS EMAIL		SOP attach ...	APPROVED	1477 - WHISLER, E	10/19/2010 8:13 AM	View Attachment
<input type="checkbox"/>	20	IDC	0976 - WILLIAMS, D	DEBORAH WILLIAMS		ok	APPROVED	0976 - WILLIAMS, D	10/19/2010 9:25 AM	View Attachment
<input type="checkbox"/>	30	IDC	1537 - SMITH, K	KENTON SMITH		ok	APPROVED	0976 - WILLIAMS, D	10/19/2010 9:25 AM	
<input type="checkbox"/>	50	QA	0890 - REY, ALEJANDRO	ALEJANDRO REY		ok	APPROVED	0890 - REY, ALEJANDRO	10/19/2010 1:32 PM	View Attachment
<input type="checkbox"/>	60	IDC	0976 - WILLIAMS, D	DEBORAH WILLIAMS			READY			
<input type="checkbox"/>	65	EMAIL	EMAIL	SS EMAIL			NOTREADY			
<input type="checkbox"/>	70	IDC	0976 - WILLIAMS, D	DEBORAH WILLIAMS			NOTREADY			

Show Top 7 / 7

[Search](#)

Essential Criteria for Effective Document Control

- Review, update, re-approve documents
 - As necessary
 - On periodic basis tied to company's internal audit process, management review, or set schedule:
 - To detect redundancies or documents no longer needed
 - As an opportunity to consolidate documents to keep your QMS document lean
- Record of the review must be kept

Essential Criteria for Effective Document Control

- Changes to documents
 - Must identify, record, and maintain the reason for and nature/description of the changes (ISO & CFR)
 - Shall be (CFR):
 - Approved by individuals in same function that performed the original review/approval
 - Dated and signed
 - Approved changes must be communicated to appropriate personnel in timely manner (CFR)
 - Record shall include when changes become effective (CFR)



Essential Criteria for Effective Document Control



- Must keep record of the current revision status including (ISO):
 - Date of revision level (number or letter) identifying current version of document
 - Current development stage (draft, review, approval, etc.)

Essential Criteria for Effective Document Control



- Relevant versions of applicable documents must be available at points for which they are designed, used, or otherwise necessary (ISO & CFR)
 - Make storage and access to documents easy
 - Consider if you want:
 - To establish designated controlled locations for documents
 - To allow short-term reference copies of controlled documents

Essential Criteria for Effective Document Control

- Ensure format and storage protect documents from deterioration, being rendered unreadable due to wear/damage, or loss
- Ensure every document can be identified through a title, document number, or other suitable identification
- Ensure electronic records are backed up



Essential Criteria for Effective Document Control



- External documents must be controlled if they are necessary for:
 - Ensuring quality
 - Meeting customer requirements
- Include customer, supplier, industry documents
- Extent of control limited to clear identification & controlled distribution

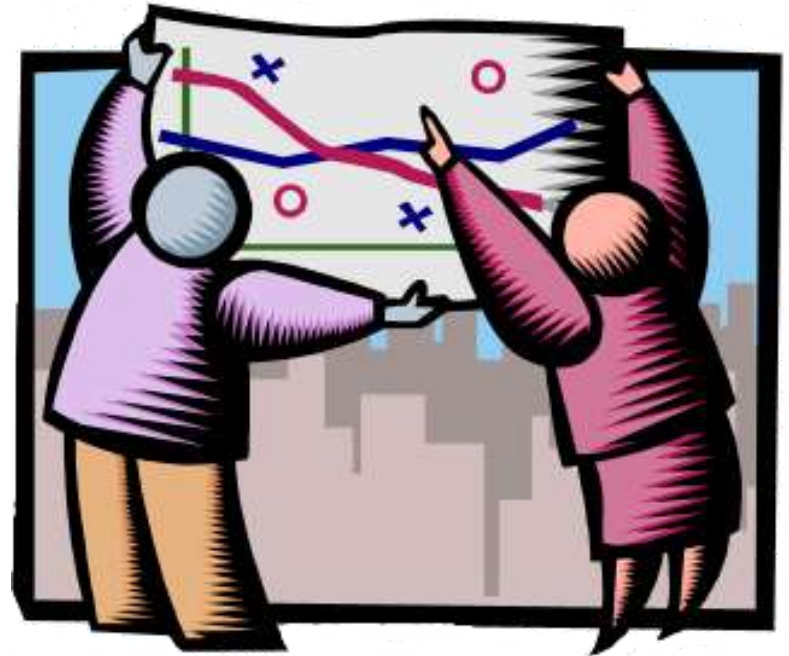
Essential Criteria for Effective Document Control

- Prevent the unintended use of obsolete documents through:
 - Segregation
 - Disposal
- Obsolete documents kept for reference or any purpose must be:
 - Clearly identified through markings
 - Stored separately



Measure the Performance of Your Document Control Process

- Suggested metrics:
 - User satisfaction – survey employees regarding usability of documentation
 - Document errors – track # of document revisions due to information mistakes
 - Up-to-date – count # of document revisions stemming from a document that is out-of-date



Measure the Performance of Your Document Control Process



- Cycle time – Measure time it takes to develop a document, or revise it from initial draft to release
- Cost – track costs through entire document life cycle

EXTERNAL AUDITS LOOK FOR

- Are quality policy and objectives documented? Where?
- Is there a quality manual? Operational procedures?
- Are drawings, specifications, work instructions and orders, control orders, etc. issued & maintained as controlled documents?
- Are electronic documents (computer files) backed up?



What an Audit Looks For



- Is there a written procedure for the control of documents?
- Are controlled documents reviewed & approved?
 - How is the approval evidenced (signature)?
- Is there a process for reviewing, updating and re-approving documents?

What an Audit Looks For

- Are documents identified with their revision level?
- How are changes identified?
- What measures ensure relevant and current documents are available at points of use?
- Are documents uniquely identified and legible?



What an Audit Looks For



- Is there a process for receiving, reviewing, approving for use, and distributing documents of external origin?
- Are obsolete documents clearly marked to distinguish them from current revisions?
- What other measures prevent the use of obsolete documents?

What is a Record?

- ISO defines **records** as “information created, received and maintained as evidence and information by an organization or person, in pursuance of legal obligations or in the transaction of business.”
- Records management – “field responsible for efficient and systematic control of creation, receipt, maintenance, and disposition of records, including the process of capturing and maintaining evidence of and information about business activities and transactions in the form of records.”

Managing Physical Records

- Identify and authenticate
- Storing records
 - Typical paper document in file cabinet
 - Environmentally controlled rooms (temp. & humidity)
 - Disaster-proofing vital records
- Circulating records
- Disposal of records



Managing Electronic Records



- More difficult to ensure content, context, structure preserved, protected when record does not have a physical existence
- Functional requirements to manage electronic records produced
- Research under heading of digital preservation addressing concerns
- Electronic tax records

Who's Been Good as of 2005



- Industries with strong historical records management discipline
 - Legal
 - Healthcare
 - Government
- Corporate records poorly standardized, implemented
 - Enron/Andersen scandal
 - Morgan Stanley records-related mishaps
 - Mortgage industry debacle

Current Issues in Records Management

- Increased interest due to new compliance regulations, statutes
- Privacy, data protection, and identity theft
- Implementing required change to individual & corporate culture
- Adoption of Electronic Document and records Management Systems (EDRMS)
- Impact of social media, such as wikis, facebook, and twitter on records management practice, principles, concepts

Conclusion

- Document and records management often seen as an unglamorous, unnecessary, or low priority administrative task
- Publicized events have demonstrated that it is in fact the responsibility of all individuals within an organization



References

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