Learning Objectives

• Describe the CAP LAP checklist requirements for document control
• List how policies, procedures, records and forms come under the document control requirements
• Discuss strategies and issues in implementing a rigorous document management system.
Document Control Is…

• The process by which the instructions in use can be assured to be current, correct and available.
  – Instructions for tasks (procedures)
  – Instructions for behaviors (policies)
  – Instructions for organization (processes)
  – And any associated material related to these instructions
Document Control Is Not…

• The storage of data (records)
  – Caution: under CLIA and CAP guidelines, specific requirements exist for record retention
• Limited to paper (hardcopy)
• Impossible to do with electronic documents
Terminology (For This Talk)

• Must:
  – Required for compliance

• Should:
  – Recommended, often as a way to satisfy a “must” requirement
  – Best practice under the current “state-of-the-art”
  – The laboratory may not feel that the recommendation is necessary
Does the laboratory have a document control system?
"... any information or instructions including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans, documents of external origin such as regulations, standards, examination procedures."

—ISO/IEC 15189:2007, Section 4.3.1 Note
NOTE: The laboratory should have a document management or control system to assure that:

1. All copies of policies and procedures are current;
2. Personnel have read the policies/procedures relevant to their job activities;
3. All policies/procedures have been authorized by the laboratory director or designee before implementation;
4. Policies and procedures are reviewed at least annually by the laboratory director or designee;
5. Discontinued policies/procedures are quarantined in a separate file for a minimum of 2 years after the date of discontinuation (5 years for Transfusion Medicine).
Are all quality management procedures, forms and records maintained under document control?

Quality management documents are considered equivalent to bench-level documents and subject to the same document control requirements.
Life Cycle of a Document

- Initiation/implementation
- Use
- Review/revision
- Retirement

Ideally, a policy that outlines processes, responsibilities and delegations, and compliance requirements should be available and followed.
Initiation/Implementation

• Elements:
  – Title
  – Purpose/Principle
  – Process Flowchart/Procedure Instructions
  – References
  – [Optional]: Related Documents
  – Appendixes or Attachments

• Author

• Approval Signatures/Authorized

—Modified from CLSI GP2-A5
Document Authorization

• CLIA’88: 42CFR493.1251
  – “(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.”

• Under laboratory director responsibilities (42CFR493.1445), the director may designate responsibilities, but
  – “(b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.”
Document Authorization

• For many laboratories, the director (as named on the CLIA license) does not have the expertise to evaluate documents for all sections
  – The appropriate section head may do so if this individual meets the CLIA qualifications for a director

• Authorization may be on every document or on a summary document but each document must be authorized individually
Electronic Signature

• Two distinct identification codes should be used to identify the signer
  – Commonly, user name and password

—21 CFR 11.200 *Electronic signature components and controls*
Electronic Signature

• Signage of a single document during a period of access requires entry of both codes to validate the signature
• Signage of multiple documents during a period of access requires entry of both codes for the first document and entry of at least one of the identification codes for each subsequent document

—21 CFR 11.200 Electronic signature components and controls
Electronic Signature

• The electronic signature must contain:
  – Printed name of the signer
  – Date and time when the signature was executed
  – The meaning (authorship, authorization, review, revision) of the signature

—21 CFR 11.50 Signature manifestations
Document Use

• Training and review by personnel
  – The degree of direct training should be determined by the director or designee
  – Review (and retraining if indicated) must be recorded

• The document must be readily available at the bench
  – Primary hardcopy or current [controlled] copy
  – For electronic documents, access must not be lost due to system failure
    • Backup access does not necessarily need to be easy or convenient, just possible and timely
Document Use

• All versions of the document in use must be current, including:
  – Photocopies/printed versions of electronic documents
  – Outlines or card file summaries
  – Personal notes
Document Review

• Delegated responsibility
• Ideally, should be done by someone actively using the document
• Changes should follow revision process
  – The specifics for revisions should be described in the document control policy
Document Review

• Occurs on an annual basis
  – There is no specific statement as to how long “annual” is
  – Should be explicitly stated in the policy
  – May be based on the date of authorization
  – May specify a window for completion
  – Checklist recommendation is to divide the documents into twelve groups, each group designated for review during a specific month
## Northfield Hospital Laboratory

Bird in Hand, PA 17505

Whole Blood Maggolin
Parker Brothers Outla 2000

### Annual Review

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### Revisions

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<td>Specimen type changed from heparinized whole blood to EDTA whole blood per revised package insert</td>
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## Northfield Hospital Laboratory
Bird in Hand, PA 17505

### Multicon® 500
Procedure Manual Annual Review

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</table>

## Refer to Attachment B
Document Review

• GEN.20375:
  “Electronic versions of procedures must be subjected to proper document control. Documentation of review of electronic procedures may be accomplished by including statements such as “reviewed by [name of reviewer] on [date of review]” in the electronic record. Alternatively, paper review sheets may be used to document review of electronic procedures. Documentation of review by a secure electronic signature is NOT required.”
Document Retirement

GEN.20375:

“…

5. discontinued policies/procedures are quarantined in a separate file for a minimum of 2 years after the date of discontinuation (5 years for Transfusion Medicine).”

• The discontinued document must state the date it was retired from use

• If replaced by a new document, there should be a reference to the prior, retired document
“Appendices”

• Documents are legal material and need to fully represent the instructions that were to be followed on each given day
  – Documents may reference package inserts; since these change over the lifetime of the document, the information in previous versions of the package inserts should be traceable
  – Documents may reference tables or graphs in textbooks; the original sources should be retained in a specific location
“Appendices”

• Some documents specify the use of certain forms
  – Generic/self-explanatory forms do not need to be under document control
    • LIS worksheets
    • Blank templates for recording maintenance/temperature data
  – Specific forms, especially those with task-specific instructions, should be either part of the parent document or retained in a specific location
    • Instrument-specific maintenance forms
    • Laboratory-designed forms with instructions for corrective action
“Appendices”

• These supplemental documents need to be referenced or reviewed for appropriateness as part of the annual document review.
• The document control policy should state explicitly when signed review is required
  – Manufacturer’s current package insert
  – Explicitly identified vs free-standing supplemental document
Stepping Beyond the Basics

• Document revision
  – It should be possible to reconstruct the contents of the document in effect on any given day, in spite of later revision
  – Possible approaches:
    • List each revision with effective date of implementation, prior text and revised text
    • Maintain the earlier version as if it were “retired”
Document Control Log

• A formal listing of current, valid copies of all documents and their location
  – Should also list location of previous revisions (if retained) and retired documents during the appropriate retention time

• “Non-controlled documents” are all copies or transcriptions that are not maintained in the document control log
Handling Non-Controlled Documents

• Forbid
• Disavow
  – “Official” copies
  – Make each person responsible for any copies they maintain within the laboratory
Handling “Ephemera”

• Documents contain standard operating procedures which need to be deviated from at times
  – Temporary unexpected situations
  – Permanent changes that cannot wait for revision of the document before implementation
PHLEBOTOMIST
PAGER
860-6095 - Main Reeder
864-2847 - KT
864-2108 - Karen

HEP PN LC
HEP PN LAN
T3 T4 TOTAL CORTISOL
FSH
Pink Top
Plain Red
“Ephemera”

- A record should be maintained of:
  - The deviation
  - The person initiating the deviation
  - All individuals affected (and, ideally, acknowledgement)
  - *Expiration date* of the deviation
  - This should be explicitly stated in the initial deviation
  - The deviation can be continued by re-authorizing if the conditions have not resolved by the expiration date (with a new expiration date)
“Ephemera”

- The document control policy should specify how such deviations should be handled
  - Who can initiate
  - How do the affected individuals acknowledge the change
  - How is the deviation documented and retained
Summary

• Document control ensures that the information in use at any given day (of record) is authorized, current, known by personnel, and reviewed for changes on an ongoing basis.

• Although the design of the program is up to the laboratory, it should be formalized in a policy or procedure.
Summary

• Best practices ensure:
  – “Official” copies are tracked and kept consistent
  – It is possible to reconstruct the instructions in place at any time for any activity
    • Forms
    • Revisions
    • Supportive material
  – A process is in place to control and record deviations from SOP
References

Technical Assistance

• http://www.cap.org
• E-mail: accred@cap.org
• 800-323-4040, ext. 6065
Thank You

Questions and Answers