Document and Record Control in a Hospital Clinical Laboratory

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Linda A. Chambers, MD
Nothing to disclose
Definitions and Concepts

• Document (noun)
  - Written or electronic information relied on as the basis of a work function. Includes manuals, policies, procedures, training materials, job aids, forms, and outside materials such as operator manuals and test kit package inserts.

• Record (noun)
  - Information captured in writing or electronically that provides objective evidence of activities that have been done or results that have been achieved. A completed “form” is a “record.”

You “create a document” or “make a record.”
Document Types: The Big 3

• Policy
  - A general principle that guides present and future decisions

• Process
  - A series of actions, usually by several different people, to complete a piece of work
    • Often written in the form of a process diagram or table

• Procedure
  - The written instructions that describe how a work task is performed

Policy Example:
1. “The laboratory participates in a CLIA-approved proficiency testing program (PT) as part of its quality program.”

Process Examples:
1. The PT material is received and logged in by the department administrative assistant, who brings it to the relevant section supervisor.
2. The section supervisor designates the technologist who will perform and record the PT testing.

Procedure Example:
Document Hierarchy

Applicable to more and more staff

Provides more and more detail

POLICIES

PROCESSES (maps/tables)

PROCEDURES (and forms, job aids, etc.)

RECORDS
Operational Activities
- Testing procedures
- Reagent preparation
- Quality control (QC) testing
- Blood inventory procedures
- Sample receipt and processing
- Result reporting
- Troubleshooting

Manufacturer’s Instructions focused here
You Are Not an Island: Operational/Clinical

- Laboratory sample collection and labeling
- Patient registration and wrist banding
- Transfusion administration
- Surgical specimen handling in the operating room
- Physician order documentation
- Massive transfusion protocol

Develop a mechanism to ensure that the laboratory and hospital policies and procedures are compatible. Arrange to have input where it matters. Keep a list in the laboratory that procedure owners and process designers can easily locate.
Definitions and Concepts

• Document and record control is a program to direct the way you create, maintain, use, and archive the documents and records in your facility that affect the quality of your work.
  – These are (should be) “controlled documents”:
    » Written policies
    » Process maps or tables
    » Procedures
    » Forms and job aids
    » Outside materials and source documents
    » Records
    » Training materials

Quality:
• Accuracy
• Timeliness
• Safety
• Efficacy
How Do Documents Affect Quality?

• Policies
  – Explain the current “rules” and answers “why”?
  – Guide future decisions; ensure consistency over time.
  – Define management’s expectations.

• Process Maps/Tables
  – Put procedures into workflow context.
  – Explain the relationship between the people and tasks in the process.
  – Serve as a resource during training and annual competency exercises.

• Procedures
  – Serve as work instructions for staff.
    » Support proper consistent execution.
    » Support compliance.
  – Provide a reference for questions.
  – Serve as resources for setting up or fixing processes.

• Records
  – Capture work output for patient result reporting.
  – Serve as a resource to investigate and fix problems.
  – Prove regulatory compliance.
Definitions and Concepts

- Document and record control is a part of your quality plan:
  - Personnel
  - Equipment
  - Purchasing and Inventory
  - Facilities and Safety
  - Documents and Records
  - Nonconforming Event Management
  - Assessments
  - Continual Improvement
Document Hierarchy (cont’d)

Operational Activities
- Testing procedures
- Reagent and equipment preparation
- Blood inventory management
- QC testing
- Sample receipt and processing
- Result reporting
- Troubleshooting

Quality Plan
- Equipment
- Personnel
- Materials and Supplies
- Facilities and Safety
- Process Management
- Document and Record Control
- Process Management
- Nonconforming Event Management
- Assessments
Develop a mechanism to ensure that the laboratory and hospital policies and procedures are compatible. Arrange to secure input. Keep a list in the laboratory that procedure owners and process designers can easily locate.

- IT policies regarding information security
- Job descriptions
- Purchasing and materials management standard operating procedures (SOPs)
- Contracting with suppliers
- Facilities management
Individuals who perform tasks that affect quality are qualified by education, training, and experience. Each associate is responsible for maintaining current licenses and certifications required for continued performance of job tasks.

Associate records are maintained and include records of qualifications, position description, orientation, competency assessments, certification/licensure, and disciplinary action. Files may also include a copy of the resume, application, and color blindness testing. The Human Resources department maintains all employment-related files. A copy of the associate’s annual assessment is retained online for use by the Human Resources department and laboratory management or in paper copies retained in the Human Resources department and in the associate’s departmental file.

Position descriptions, specifying key job responsibilities and necessary qualifications for individuals performing tasks that affect quality, are available for each job code.
Example From Riverside Methodist Hospital

DEPARTMENT PROCEDURES

Staffing plan (QUA-PR-01)
Administrative/technical competency policy (QUA-PR-02)
Continuing education (QUA-PR-03)
Documentation of Associate Identification (QUA-PR-04)
Medtraining Systems (MTS) (QUA-PR-04)

HOSPITAL and CORPORATE PROCEDURES

Employee/Human Resources records (HR-701.050)
Orientation of new associates (HR-701.150)
Introductory period (HR-701.250)
Performance management (HR-702.100)
Performance review (HR-702.300)
Staff competency and assessment (HR-702.400)
Mandatory education of staff (HR-702.600)
Position description and pay grades (HR-704.400)
Anxious?

You’re making me nervous. This is too abstract. Where do I begin?
Document and Record Control: 
Pretend You’re at the Beginning…

1. Create your tools; gather your materials.
   • Document master list
   • Master files
2. Set your policies.
3. Make your basic decisions.
   • How are you going to accomplish the jobs of creating, reviewing, authorizing, distributing, modifying, and retiring documents and records?
   • What formats are you going to use?
   • What are you going to archive? Where and how long?
4. Write the policies, process diagrams, and procedures that capture your decisions.
5. Bring your operational documents into compliance.
   • Create missing documents, especially process maps.
   • Update existing documents.
Document and Record Control:

Pretend You’re at the Beginning…(cont’d)

1. Create your tools, gather your materials, and get ready.
   - Document master list
   - Master files
2. Set your policies.
3. Make your basic decisions.
   - How are you going to accomplish the jobs of creating, reviewing, authorizing, distributing, modifying, and retiring documents and records?
   - What are you going to archive?
   - Where are you going to archive and how long?
Use of a Master List
(Think Spreadsheet)

• Comprehensive table of contents for all laboratory document binders
  - Name and version in use
  - Associated job aids, forms, outside documents, and training
  - Owner/responsible manager(s)
  - Last reviewed date
    » Can generate a reminder to the owner when the review date is within two months or one month, or has passed.
  - Locations of copies

• Apply to coordination of annual reviews and transfer of ownership, as necessary.
1. Create your tools, gather your materials, and get ready.
   - Document master list
   - Master files
2. Set your policies.
3. Make your basic decisions.
   - How are you going to accomplish the jobs of creating, reviewing, authorizing, distributing, modifying, and retiring documents and records?
   - What formats are you going to use?
   - What are you going to archive? Where and how long?
Concept of Master File
Paper or Electronic

• Collect current and previous versions of a given document into a master file.
  – Allows access, if needed, to reconstruct SOP as part of a problem investigation
  – Makes it easy to identify when and what has changed

• The following items may be included
  – Implementation authorization sign-off sheets/electronic pages
  – Records of staff training on that procedure.
  – Associated forms, job aids, training materials, source documents
Document Development and Maintenance:

History Record? Master Files? Master List?

- Title and ID Number
- Where it is being used
- Owner/who to contact with issues
- History: dates of origin and modification
- Validation records
- Approvals for implementation—initial, and for each modification
- Annual review records, last and next review dates
- Source documents used for its creation, including version dates
- Relevant certification and accreditation requirements
1. Create your tools, gather your materials, and get ready.
   - Document master list
   - Master files

2. Set your policies.

3. Make your basic decisions.
   - How are you going to accomplish the jobs of creating, reviewing, authorizing, distributing, modifying, and retiring documents and records?
   - What formats are you going to use?
   - What are you going to archive? Where and how long?
Sample Document and Record Control Policies for Documents (Standard Operating Procedures)

- Instructions for all tasks that affect quality are captured in written SOPs.
  - Staff have read the SOPs relevant to their assigned work.
  - SOPs are followed as written.
    - Exceptions are approved in advance and recorded.
  - Current SOPs are readily available to all staff who perform the involved tasks.
    - Obsolete SOPs (and forms and job aids) are taken out of use and retained according to a written document retention policy.

» NOTE: You must have a mechanism to get outdated versions off the wall, out of the drawer, out of the manuals, and out of the briefcases and back seats.
• SOPs are maintained under document control.
  • SOPs are written using approved format(s).
  • SOPs are validated, reviewed, and approved before implementation.
    – **NOTE:** This must include the CLIA laboratory director and cannot be delegated.
  • SOPs are reviewed and updated annually.
  • A document master list is maintained.
  • Documents are proprietary and protected from unauthorized use or modification.
Sample Document and Record Control Policies for Records

• Records are:
  - Created concurrent with the related task
  - Legible, accurate, and complete
  - Sufficient to reconstruct the history of a service or test
  - Confidential and protected from unauthorized access or modification
  - Retained for a defined period and retrievable within a reasonable amount of time
  - Discarded with approval in a manner that protects confidentiality
• Forms and job aids are linked to the process or procedure to which they relate, and are reviewed and updated along with the linked process or procedure.
Document Hierarchy

POLICIES

PROCESSES
(maps/tables)

PROCEDURES
(and forms, job aids, etc.)

RECORDS

Quality Program for Document and Record Control

(Policies for documents and records – can’t write down yet; don’t know standardized format)

Master document list
Master document files
Document history sheets
Document and Record Control:
Pretend You’re at the Beginning…(cont’d)

1. Create your tools, gather your materials, and get ready.
   • Document master list
   • Master files

2. Set your policies.

3. Make your basic decisions.
   • How are you going to accomplish the jobs of creating, reviewing, authorizing, distributing, modifying and retiring documents and records?
   • What formats are you going to use?
   • What are you going to archive? Where and how long?
Design Standard Formats

Benefits:
• Users will know where to find needed information.
• Format will not “get in the way of” usability.
• Templates can be used.
  - Define the expectations for content.
  - Lock in the font, organization, coding, etc.
  - Remind the developer to address certain issues.
  - Speed up word processing.
Standard Operating Procedure
Format(s) to Address

• Title and numbering convention
• Version and implementation date
• Outline
  - 2-column table vs active verb sentence
  - Outline sequence: A/1/a/l, l/A/1/a
• Hospital name/logo and address location
• Pagination and headers/footers
• Margins
• Font/font size
Standard Operating Procedure Format(s) to Address (cont’d)

• **Standard sections** (use as applicable)
  - Principle, Policy, Definitions, Purpose, Procedure, References, Attachments, Forms and Records, etc.

• **Standard content in technical procedures** (use as applicable)
  - Patient Preparation, Samples, Solutions, Reportable Range, Controls, Reference Intervals, Critical Results, Calibration, Calibration Verification, etc.

• **Job aids and forms**
  - Attach them to the related SOP so they are reviewed and updated in concert.

• **Record of annual reviews, procedure owner(s), authorizing committee, etc.**
  - Is it part of the procedure, in the master file, or on the master list?
Pointers and Tips

• References

- What are the right “references” for an automated complete blood count (CBC)? (Not the same as for a publication.)

- List “source documents” for the content of the procedure.
  » Operators manual
  » Package inserts
  » CAP standards

- Create a bibliography to provide articles for supplemental learning.
Pointers and Tips (cont’d)

• For multianalyte automated testing, consider focusing on the procedure on operation of the equipment and information about each analyte included on attachments.

• Avoid retyping manufacturers’ instructions into your procedures. Where appropriate, write the instructions for steps that occur before and after the testing, and provide the manufacturer’s information as an attachment.
TIP: Pretend you are already up and running and fully in compliance with your policies, when you write the policy statements.

“All associates will be trained in the performance of their job responsibilities and will be found to be competent before performing those tasks without direct oversight or supervision.”

Is better as:

“All associates are trained in the performance of their job responsibilities and found to be competent before performing those tasks without direct oversight or supervision.”
PURPOSE:
To define the format for written laboratory procedures and policies.

POLICY:
As part of document control, procedures and policies are written in a defined format, appropriately authorized for implementation, reviewed on a regular basis, and updated as processes and policies are modified. All forms, job aids, templates, teaching tools, and similar documents that support the procedure or policy accompany the applicable document as attachments, and are reviewed in conjunction with the document. For procedures and policies that provide instructions for both laboratory and clinical staff, a second copy of the document is formatted for and kept with the clinical/nursing procedures.

DEFINITIONS:

Document (noun): The written descriptions of the way an organizational function is achieved. Documents include written descriptions of work steps (procedures), the way that the procedures occur in sequence to achieve a particular function (process maps), the reasons behind the way the work is performed (policies), how the work is recorded (forms), and other activities that make the set of work happen.

Policy: A statement of the underlying principle, value, objective, or goal that applies to a particular set of work. Policies guide decision-making and process development.
DOCUMENT REVIEW and APPROVAL TO IMPLEMENT
Preparer/Owner Linda Chambers, MD
Manager/Director ______________________________ Date _________________
Section Medical Director ______________________________ Date _________________ □ NA
CLIA Laboratory Director ______________________________ Date __________

Annual Reviews

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<thead>
<tr>
<th>Date</th>
<th>Signature</th>
<th>Title</th>
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</tbody>
</table>

Document History
Originated: Document Control, October 2007
Retired:

Electronic copy: G:\Grant\Dept\Lab\SOPs - Current\ Quality Plan\Developing Documents.doc
Quality Program for Document and Record Control
Policies developed and written down

Document standard format

Master document list
Master document files
1. Create your tools, gather your materials, and get ready.
   - Document master list
   - Master files
2. Set your policies.
3. Make your basic decisions.
   - How are you going to accomplish the jobs of creating, reviewing, authorizing, distributing, modifying, and retiring documents and records?
   - What formats are you going to use?
   - What are you going to archive? Where and how long?
Document Development and Maintenance

• Who can develop document?
  – Required input (e.g., compliance, laboratory director)
• What checking is done before sending for authorization?
  – Validation process and technical reviews
• Who authorizes implementation?
  – Order of authorization, method and location of documentation
• Where and how are SOPs distributed?
  – Recipients, and method of delivery/replacement, for updated SOPs
• When to review existing documents, who reviews them, and how are they recorded?
• What is the plan for the use of outside documents to develop SOPs?
  – Process for identifying whether information has changed
• How long should retired procedures be retained?
Tips and Pointers

• If you store and access your procedures electronically, be sure you protect the documents from unauthorized changes (eg, read only, .pdf) or maintain an untouchable separate copy (eg, with the author/owner, or in the master file).
PURPOSE:
To define the process for preparing written procedures, policies, process maps, and other work documents. The term “documents” includes all technical procedures for test performance; policies; process maps; all administrative and safety procedures; all quality plan procedures and policies; and any forms, job aids, teaching materials, or other written or electronic materials intended to support the proper performance of a process.

POLICY:
Written procedures are made readily available to staff who perform the work. Documents are protected from accidental or unauthorized changes, and approved before implementation. New and updated documents are approved by the CLIA Laboratory Director. Each document is reviewed annually and updated as needed to keep it current. Staff is presented with new and changed documents at the time of initial approval and during orientation for new employees. Staff read the documents related to the work that they do and initial a sign-off sheet. Mandatory review of certain policies and procedures whether or not changes have been made (eg, Safety, Infection Control) occurs annually and is documented as part of the individual’s performance evaluation.
The signed paper printout of the document is the official current version. Locations that retain working copies of documents ensure that their copies are updated whenever the master copy is reissued.
Any document that has been discontinued is stored electronically in a segregated file for a minimum of two years after being taken out of service, according to the procedure on document retention.

PROCEDURE:
1. New Procedures, Policies and other Process Documents
Preparer/Owner:
Prepare the document using Microsoft Word according to the...
Record and Material Retention Policy and Procedure

• Identify all the various records you create and input materials you use (tubes of blood, surgical pathology specimens, glass slides, etc).
• Decide what to keep according to a meaningful algorithm plus requirements of AABB, CAP, CLIA, state.
• Build your table; write your procedure.
PRINCIPLE:
It is critical to retain specimens, slides, reports, and data for a minimum period of time in order to recall the information when needed and to support process improvements.

POLICY:
Laboratory specimens, documents, slides, reports, and data are retained for a specified period of time, depending on their source and viability, and in accordance with accrediting and regulation requirements.
If the hospital and/or laboratory cease operations, arrangements shall be made to continue retention of laboratory records, slides, blocks, and tissues until the required period has passed.

PURPOSE:
To establish minimum requirements that comply with regulatory agency standards for the retention of records and materials within the laboratory. (Attachment 1)

PROCEDURE:
Retain records, specimens, slides, reports, and data in a reasonably accessible form and location, according to the following table:

<table>
<thead>
<tr>
<th>Area</th>
<th>Record/Material</th>
<th>Period of Retention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimens</td>
<td>Serum/Plasma Blood Bank</td>
<td>16 Days</td>
</tr>
<tr>
<td></td>
<td>Serum and EDTA Plasma</td>
<td>7 Days</td>
</tr>
<tr>
<td></td>
<td>EDTA Whole Blood for CBC/A1C</td>
<td>3 Days</td>
</tr>
<tr>
<td></td>
<td>Citrated Plasma</td>
<td>16 Hours</td>
</tr>
<tr>
<td></td>
<td>Urine, Random</td>
<td>24 Hours</td>
</tr>
<tr>
<td></td>
<td>24 hour Urine (Aliquot)</td>
<td>7 Days</td>
</tr>
</tbody>
</table>
**Quality Program for Document and Record Control**

**POLICIES**
Developed and written down

**PROCESSES**
Document development, approval, and distribution
Document review, updating, and archiving

**PROCEDURES**
Standardized format for documents
Writing and updating documents
Record and material retention

**RECORDS**
Master document list
Master document files
Document history records
Staff sign-off sheets

Educate staff about new document and record control program.
How Document and Record Control Supports Quality

• Policies
  – Explain the current “rules” and answers “why”?
  – Guide future decisions; ensure consistency over time.
  – Define management’s expectations.

• Process Maps/Tables
  – Put procedures into workflow context.
  – Explain the relationship between the people and tasks in the process.

• Procedures
  – Serve as work instructions for staff.
    » Support proper consistent execution.
    » Support compliance.
  – Provide a reference for questions.
  – Serve as resources for setting up or fixing processes.
  – Serve as a resource during training and annual competency exercises.

• Records
  – Capture work output for patient result reporting.
  – Serve as a resource to investigate and fix problems.
  – Prove regulatory compliance.
What is it all for?

Quality:

• Staff know how to follow their procedures correctly because they are properly qualified, selected, trained, and directed.

Training Materials; Competency checks
Operational policies; process maps and procedures
Job descriptions
Candidate evaluation forms; initial competency checks

COMING SOON FROM CLSI:

Questions or comments, or stories from the battlefield?