



Laboratory Quality Management System

Module 5: Documents and Records

Venue:

Presenter:

Date:

1. INTRODUCTION



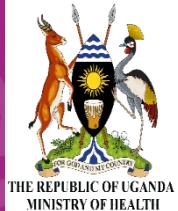
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2

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The Quality Management System



Learning Objectives

At the end of this module, participants will be able to:

- explain the difference between documents and records;
- describe the hierarchy of documents and the role of each level;
- outline the content that should be included in a standard operating procedure;
- explain the important steps, or elements, of a laboratory document management system;
- outline the contents of a quality manual;
- describe methods and tools to properly store documents and records.



Module Outline

- Difference between Documents and Records
- Hierarchy of documents
- Quality Manual
- Standard Operating Procedures
- Job aids
- Document control
- Documents of external origin



Laboratory records

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Activity 5 - 1

Scenario - Differentiating Documents from Records

Purpose: Allow participants to discuss whether laboratory information

is part of a document or a record

Time: 5 minutes



Scenario

You have found all these papers lying on a desk. Which of these are documents and which are records?

- testing algorithm
- safety manual
- client test results
- standard operation procedures (SOPs) for an approved HIV rapid test
- manufacturer test kit inserts
- summary of findings from on-site evaluation visit



- report of corrective actions
- temperature log (blank form)
- quality control record (blank form)
- daily maintenance log (completed)
- stock cards and stock book (completed)
- EQA specimen transfer log (completed)

Assessment

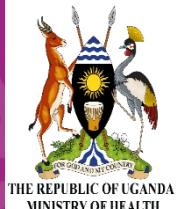
You have found all these papers lying on a desk.
Which of these are **documents** and which are **records**?

- testing algorithm
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- stock cards and stock book (completed)
- EQA sample transfer log (completed)



Why do laboratories need to manage documents and records?

To find information whenever it is needed!



Documents and Records—How do they differ?

Documents

- communicate information via policies, processes, and procedures
- need updating

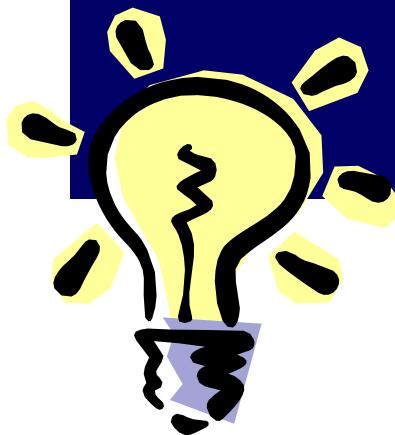


Records

- capture information on worksheets, forms, labels, and charts
- permanent, do not change



Information is the major product of the laboratory



2. DOCUMENTS

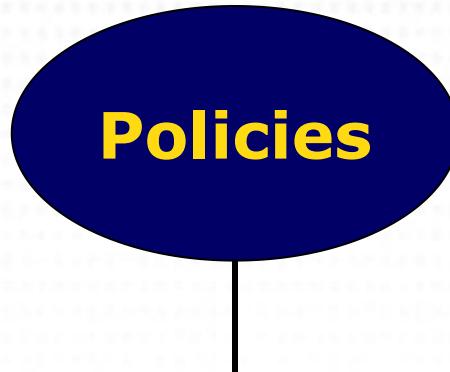
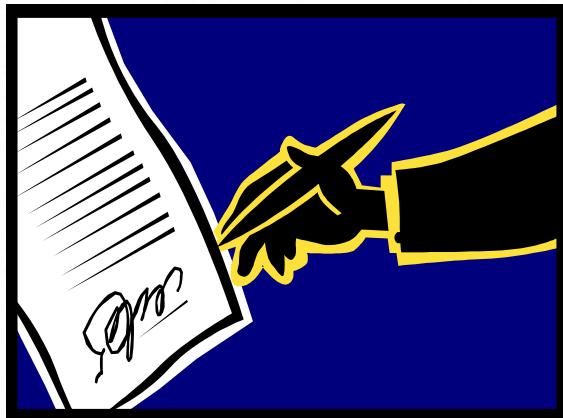


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12

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Laboratory Documents



Policies - The “WHAT TO DO”

“A written statement of overall intentions and directions defined by those in the organization and endorsed by management.” (CLSI HS1-A3)

Policies:

- ❑ tell “what to do” in a broad and general way
- ❑ include the organizational mission, goals, and purpose
- ❑ serve as the framework for the quality system
- ❑ should always be specified in the quality manual

Processes - The “HOW IT HAPPENS”

A “set of interrelated or interacting activities that transform inputs into outputs.” (ISO 9000 4.3.1)

Processes:

- describe the steps involved to carry out quality policies
- easily represented in flow charts
- involve a series of steps, usually occurring over a period of time



Procedures - The “HOW TO DO IT”

Standard operating procedures (SOP)

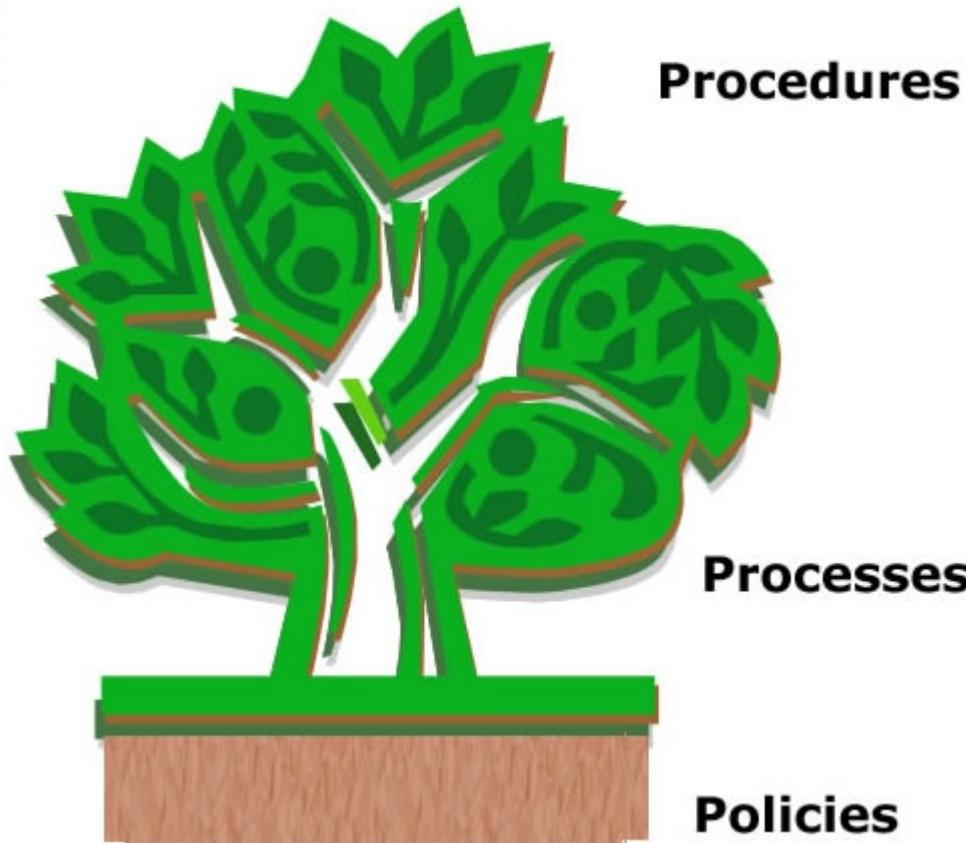
- ❑ step-by-step instructions for performing a single activity

Job aid

- ❑ a shortened version of the SOP
- ❑ does not replace the SOP



3. HIERARCHY OF DOCUMENTS



“How to do it”

“How it happens”

“What to do”

Why are documents important?

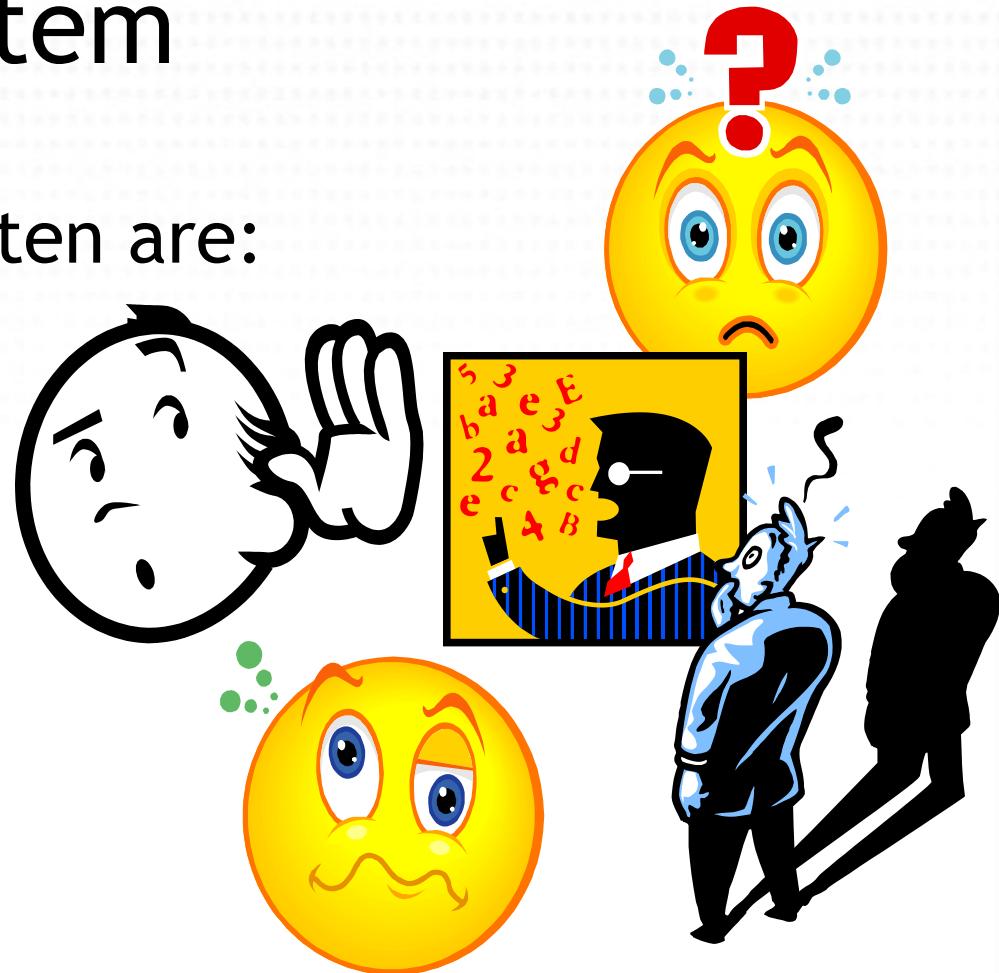
- essential guidelines for laboratory
 - quality manual
 - SOPs
 - reference materials
 - required by formal laboratory standards



Documents are the communicators of the quality management system

Verbal instructions often are:

- not heard
- misunderstood
- quickly forgotten
- difficult to follow



Test Questions



Microsoft Word
7 - 2003 Document

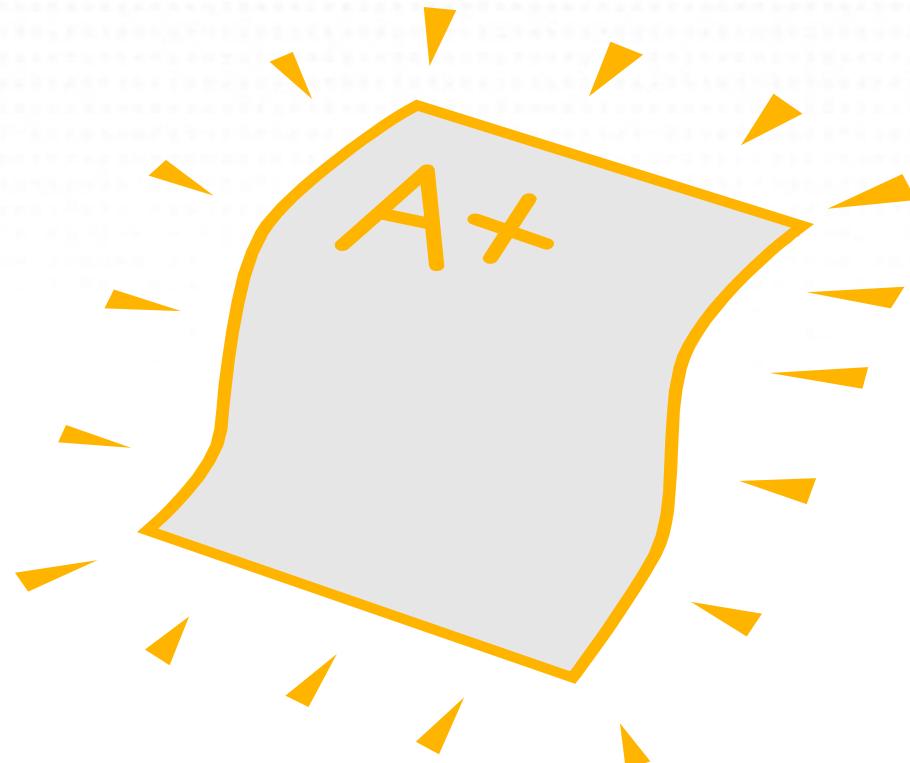


Documents are a reflection of the laboratory's organization and its quality management.

A good rule to follow is:
“Do what you wrote and write what you are doing.”

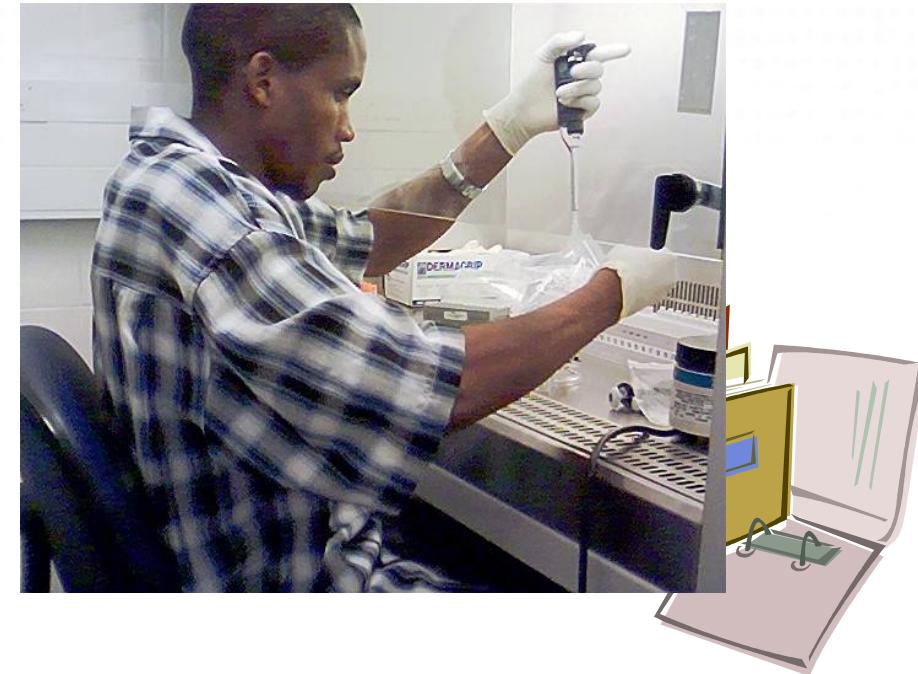
Good Documents are:

- clear
- concise
- user-friendly
- explicit
- accurate
- up-to-date



Documents for work processes should be accessible to staff at the work site :

- instructions on handling incoming samples
- SOPs for each test
- quality control charts and trouble-shooting instructions
- Equipment SOPs
- safety manuals and precautions
- Quality Manual



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4. QUALITY MANUAL

The Quality Manual is a document
describing the quality management
system of an organization
(ISO 15189)



Activity 5 -2 : The Quality Manual

Purpose: To present a laboratory scenario, demonstrating the importance of the quality manual.

Suggested time: 5 minutes

Scenario:

“A new laboratory manager was hired by Laboratory X. The laboratory has not had a quality manual in the past, but the new manager wants to develop one.”



- Why do you think a quality manual is important?
- Who should the laboratory manager involve in the process?
- How can the laboratory manager ensure that all of the details are included? Would this result in increased costs for patient management, and what would increase the cost?
- List some of the content required for a quality manual and what that they think should be included in a quality manual.



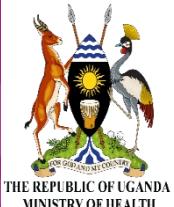
Who should be responsible for writing the quality manual?

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26

Quality Manual

- Communicates information
- Serves as a framework or roadmap for meeting quality management system requirements
- Demonstrates management commitment to quality



Writing a Quality Manual

Style and structure are flexible;
make to best meet the needs of
the laboratory and its customers



Writing a Quality Manual

Form a Steering Committee

Set policy for
12 QS
essentials

Organization
Personnel
Equipment
Quality Control
Information Management
Assurance
Facilities & Safety

Describe how
the related
quality
processes occur

Reference
procedures



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Key Points: Quality Manual

- Only ONE official version
- Never “done”, always being improved
- Read and accepted by everyone
- Use the best-adapted language

Very big job, but very useful

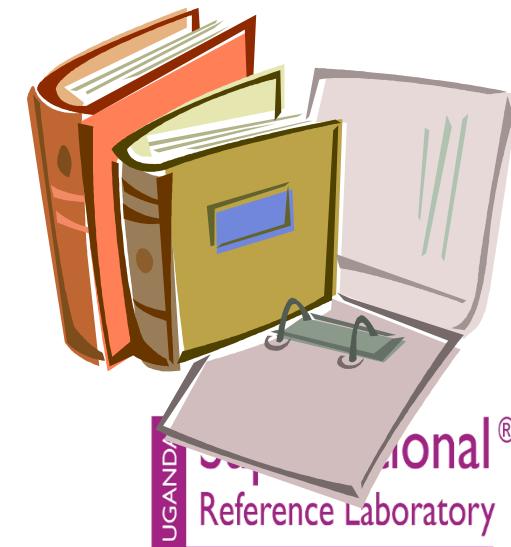


5. STANDARD OPERATING PROCEDURES(SOP)

are documents that:

- ☛ describe how to perform a test using step-by-step instructions

- ☛ written SOPs help ensure:
 - consistency
 - accuracy
 - quality



A Good SOP

- provides detailed, clear, and concise direction for testing techniques
- is easily understood by new personnel
- is reviewed and approved by management
- is updated on a regular basis



Standardized SOP Format

Version 1.0	METHYLENE BLUE STAINING	Application Date 01/06/2003
Reference : VPD-Lab-QAM		Page : 1/1
Chapter : 5-3		
Author: J Johnson, Reader: RB Smith QA Valid	Ishvili on	
Recipient:	All the laboratory technical staff	
Modifications:	Initial version	26/05/2003

Principle : Methylene blue is a simple stain that is particularly useful in the identification of *Corynebacterium* species.

The metachromatic granules of *C.diphtheriae* readily take up Methylene blue dye and appear deep blue. Although some authors have stated that the cytoplasmic granule formation characteristic of *C.diphtheriae* is rarely seen with saprophytic species of *Corynebacterium*, this criterion is unreliable and cannot be used for definitive identification of *C.diphtheriae* without further studies.

Procedure

1. Heat-fix the smear. Flood the surface of the smear with the Methylene blue-staining solution for 1 minute. Wash the slide with water and blot dry.
2. In the past it was necessary to add alkali to the above solution before use. However, Methylene blue dyes prepared in recent years do not require this additional step because acid impurities found in older stains have been removed.

Results

Interpretation

The corynebacteria are pleomorphic bacilli that range in size from 0.5 to 1.0 µm in width and from 2 to 6 µm in length and appear as straight, curved, or club-shaped rods. Characteristic for the micro-organisms are metachromatic granules that take up Methylene blue stain and appear dark blue. Although this finding is characteristic of the corynebacteria, species of the



- Computerized procedure
- Standardization:
 - Header
 - Version/chapter/reference
 - Author/reader/validator
 - Recipients
 - Version date/Application date
 - Typical outline
- Updating and storage of different versions is easy

Complete Standardized Header

TML\MSH Microbiology Department Policy & Procedure Manual	Policy # MT\RESP\11\v05	Page 1 of 5
Section: Respiratory Tract Culture Manual	Subject Title: SPUTUM (Including Endotracheal Tube and Tracheostomy Specimens)	
Issued by: LABORATORY MANAGER	Original Date: September 25, 2000	
Approved by: Laboratory Director	Revision Date: September 14, 2006 Annual Review Date: August 13, 2007	



Reduced Standardized Header

TML\MSH Microbiology Department Policy & Procedure Manual	Policy # MI\RESP\11\v05	Page 2 of 5
Respiratory Tract Culture Manual		

- other pages of every procedure
- use at the top of all other pages



When Preparing SOPs

**determine
procedure
to use**

**establish
means for
updating**



**assess
scientific
validity**

**gather all
documents**

**include
each step**

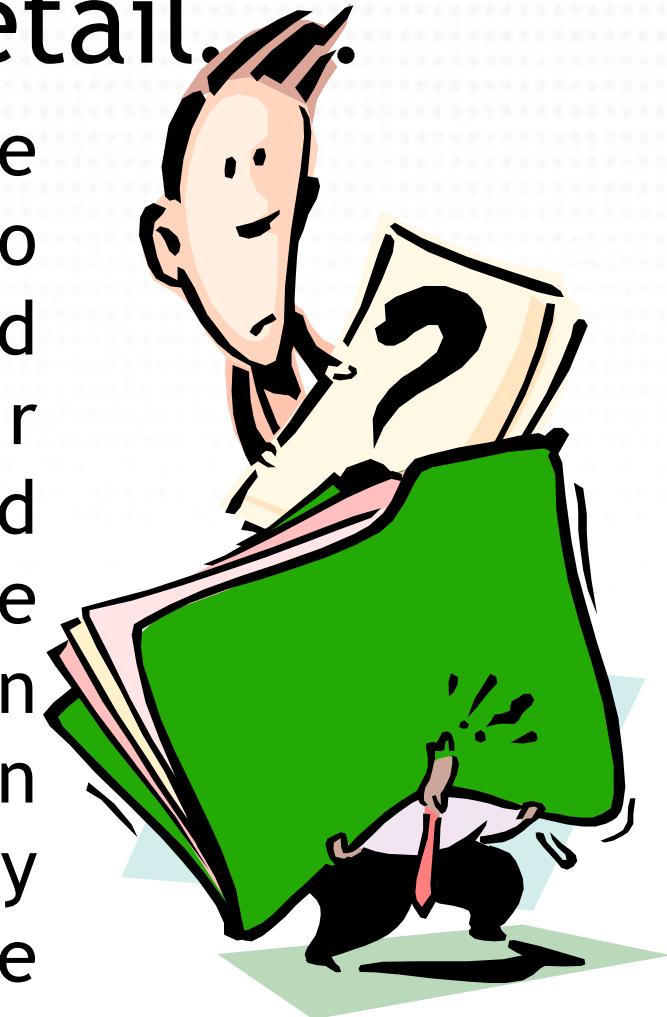
Suggested Outline for SOPs

- Title: Name of Test
- Purpose: Medical use
- Instructions:
 - Pre-examination
 - Examination
 - Post examination
- References to verify the method is established
- Author's name
- Approval signature(s)-initial and date



Avoid Drowning in Detail.

- BAD EXAMPLE: “The purpose of this procedure is to document the aforementioned activities, herein after referred to as the prescribed tasks in terms that preclude their execution in an inconsistent manner, wherein such inconsistency may potentially result in the prescribed tasks delivering a result that is not repeatable or reproducible”...



Do not rely solely on manufacturer product inserts

Inserts do not provide specific information for test sites,
such as:

- materials required, but not in kit
- specific safety requirements
- external quality control requirements

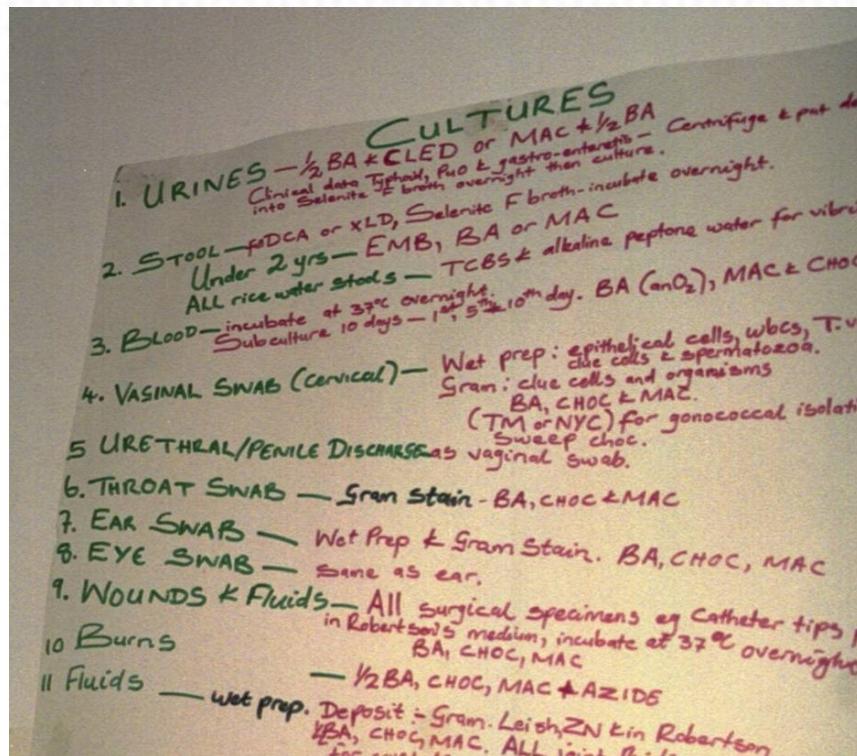


6. JOB AIDS

- shortened version of SOPs
- hand written or printed
- visible location at testing site
- useful tool to assure all testing steps are correctly performed



Job Aids



AFB SMEAR STAINING

1. Always use new, grease free, and clean slides. Correctly label slides with stylus or lead pencil.
2. Fish out yellowish portion from sputum container and place on slide with the rough end of the stick.
3. Spread material evenly in an approximate area of 2mm X 1cm so that newsprint is readable on drying.
4. Air dry smear completely and then heat fix smear in a flame.
5. Place slides on the staining rack without touching each other. Always add Positive and Negative control slides.
6. Cover slides with freshly filtered carbolic fuchsin.
7. Heat gently with a torch until steam rises from the slides. Stain for five minutes.
8. Wash briefly with water.
9. Drain the water.
10. Cover slides with decolorizing solution for three minutes.
11. Wash thoroughly with water. If slide is not decolorized properly repeat step 10 for additional 1-3 minutes. Rinse thoroughly with water.
12. Drain the water.
13. Cover with counter stain Methylene blue for one minute.
14. Drain the counter stain.
15. Wash with water. Wipe the back side of slides with tissue paper.
16. Air dry the slides in a rack.
17. View the smear under oil immersion. AFB: Fine, red rods against blue background.

AFB Counts Recording/Reporting

No AFB or less than 100 AFBs	All negative
1 to 9 AFBs in 100 fields	Actual AFB count
10 to 99 AFBs in 100 fields	-
100 to 100 AFB per field	-
> 100 AFB per field or less than 100 fields	-

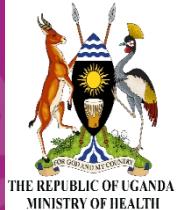
Report the findings as per WHO and WHO/TD recommendations.

A joint effort of:

The illustrations 1 and 5-17 are used with the permission of RIT/JICA from "TB Technology Transition to Step II by Akira Fujita"



Job Aids



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42

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7. DOCUMENT CONTROL

Assures that the most current version is used



ensures availability when needed



organizational tool

Document Control Elements

- System for organizing, such as numbering or coding system
- Approval, distribution, and revision process
- Master log that describes which documents are in circulation
- Accessibility of documents at the point of use
- System for archiving



regulations
and
standards

SOPs

Controlled documents

equipment
service
manuals

texts,
articles,
reference
books



8. DOCUMENTS OF EXTERNAL ORIGIN

- Include in the laboratory document control system:
 - instrument service manuals
 - industry regulations
 - ISO standards
 - references used for documentation

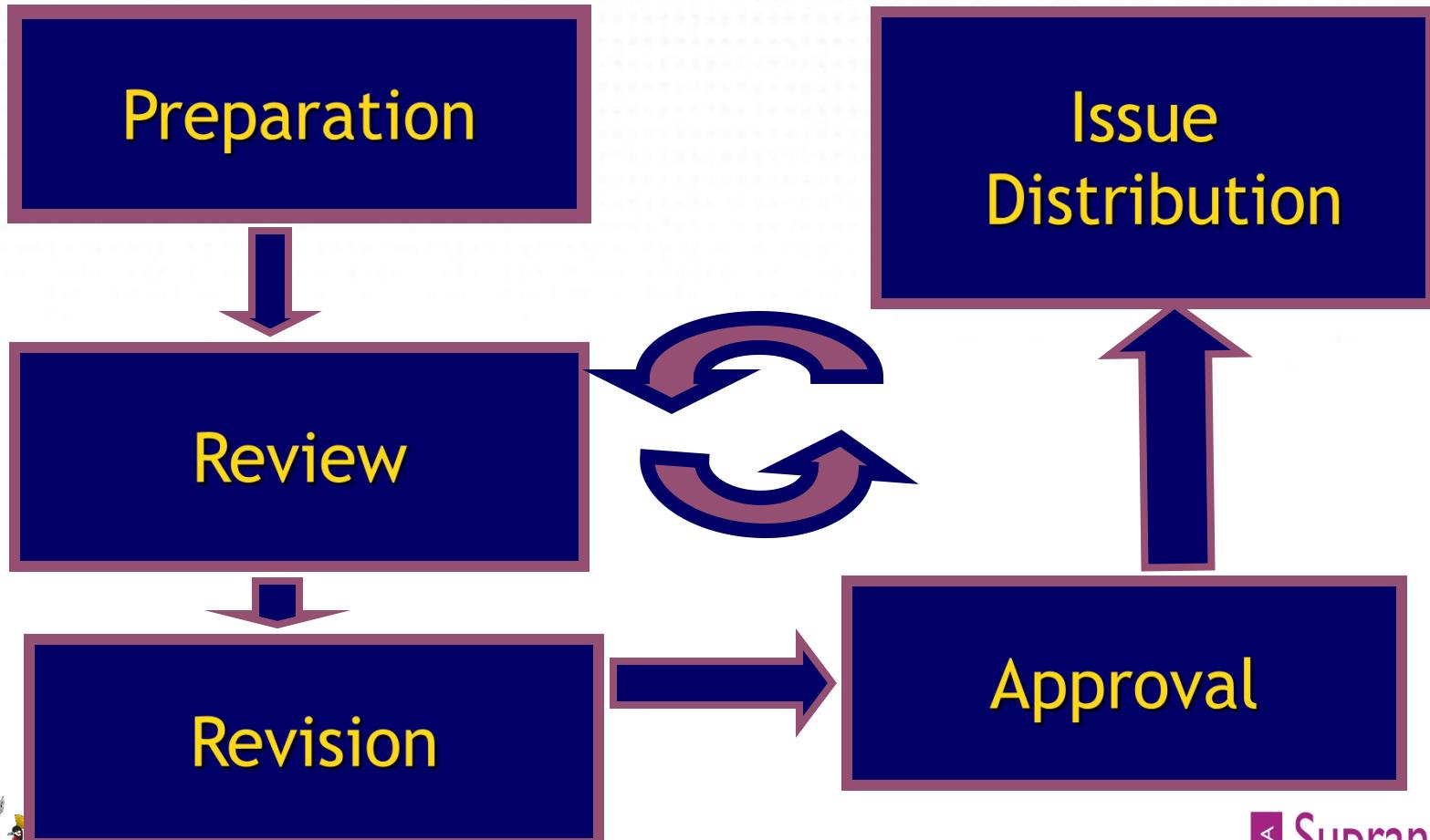


Numbering System

- need uniform numbering system
- do not change a current system that works
- one system: letter for the type of document and then an incremented number: B1, B2, B3 for books and T1, T2 for official texts
- number all pages of document
- reference by document code, pages, location code: Book number 2, pages 188-200, on bookshelf 1: B2,188-200, BS1



Document Preparation and Control Process



Implementing Document Control

- collect existing documents
- review and update
- determine additional needs
- develop or obtain documents, forms, worksheets, logbooks, reports
- involve stakeholders



Common Document Control Problems

- outdated documents
- too many documents are distributed and the system cannot be maintained
- lack of control of documents of external and internal origin





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9. RECORDS

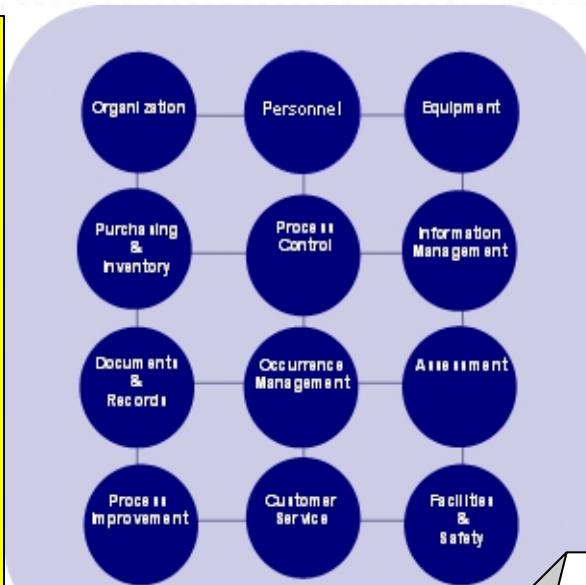


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Why are records essential?

Continuous monitoring of quality system



Management tool

Sample trace throughout the process



Identify problems

Laborator y Records

Patient
test reports

Sample
log book
or register

Workbooks
Worksheets

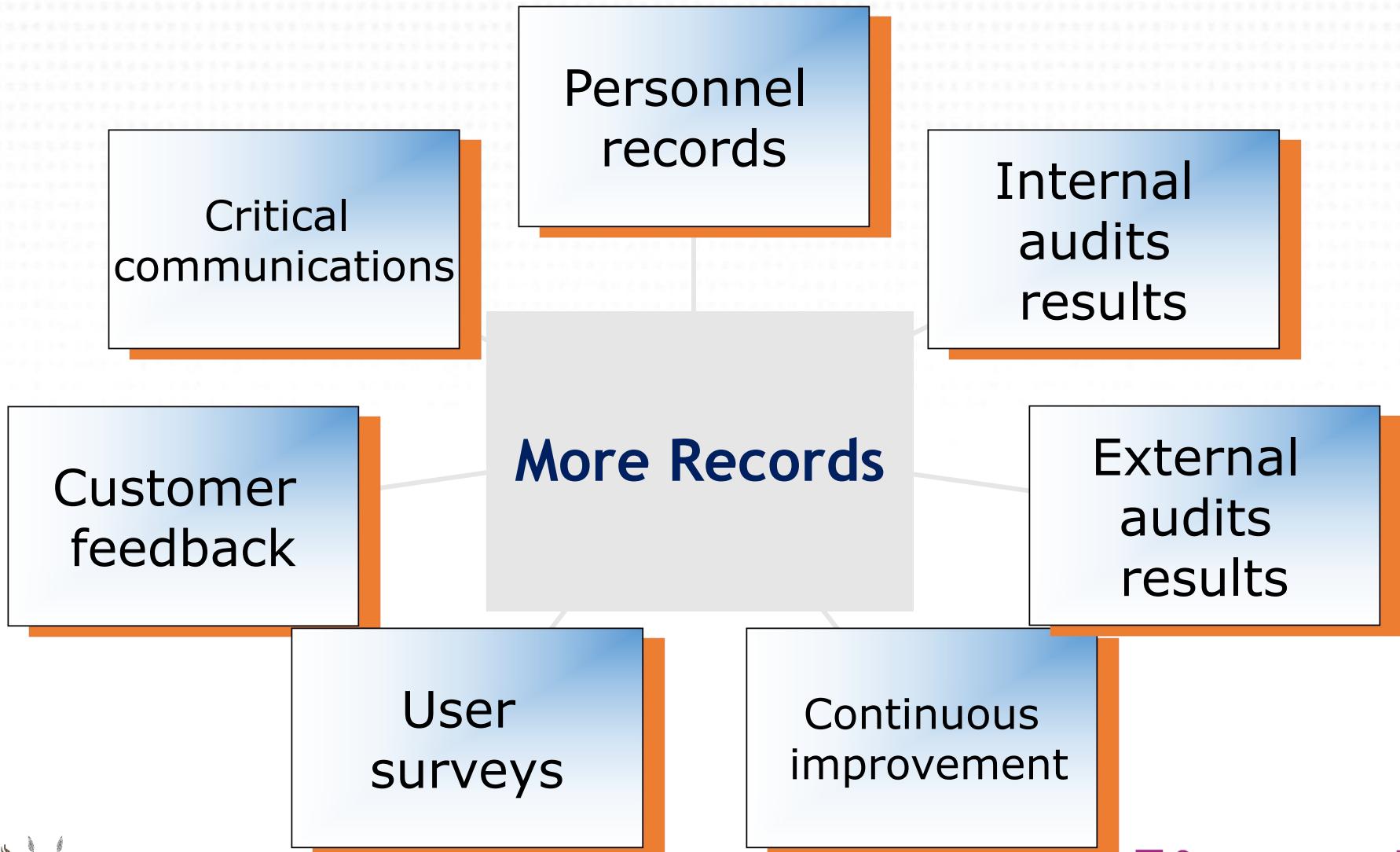
EQA /
PT records

Instrument
printouts

Quality
control
data

Maintenance
records





Keep the Things You Might Forget!

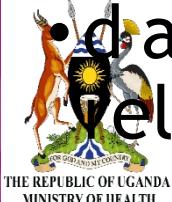
- disposition of rejected samples
- referral of samples to another laboratory
- records of adverse occurrences or problems
- inventory and storage records
- equipment purchase data, preventive maintenance, and troubleshooting



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Test Report Contents ISO 15189

- test identification
- laboratory identification
- patient unique identification and location
- name and address of requestor
- date and time of collection
- time of receipt in lab
- date and time of release of report
- primary sample type
- results (SI units)
- biological reference intervals
- interpretive comments
- person authorizing release, with signature when possible
- note if reporting a corrected result



Paper Systems

Permanence

- bind books
- number pages
- use permanent ink
- control storage

Accessibility

- use system that will allow ease of access



Security

- maintain confidentiality
- keep safe from environmental hazards

Traceability

- allow for tracking of a specimen throughout all processes



Electronic Systems

- permanence
 - computer system maintenance, backups
- security
 - access
 - confidentiality
- traceability



National
legislation
and
regulation

Testing
process
review

Factors
affecting
retention
times

Research
purposes

Time
between
assessments
-audits



Assessment

- Explain the difference between documents and records;
- Describe the hierarchy of documents and the role of each level;
- Outline the content that should be included in a standard operating procedure;
- Explain the important steps, or elements, of a laboratory document management system;
- Outline the contents of a quality manual;
- Describe methods and tools to properly store documents and records.



Summary

Documents:

- include written policies, processes, and procedures
- need to be updated and maintained

Records:

- include information captured in processes
- are permanent, do not require updating

A good document control program:

- most current version used

availability and ease of access

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Key Messages

- Information is our product.
- Documents are essential for assuring accuracy and consistency in the laboratory.

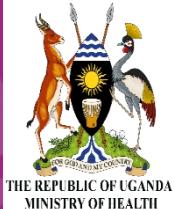


Reference

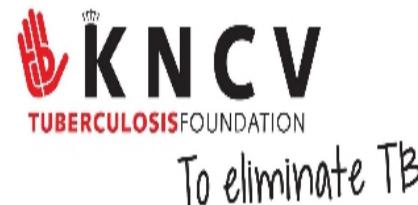
ISO 15189:2012 Medical Laboratories -
Requirements for Quality and Competence
« Clause 4.3, 4.13»

CLSI

ASLM



Acknowledgement



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