Laboratory Management of a Quality System

Module 6: Document Control and Record Management

ACKNOWLEDGEMENT

- Ministry of Health and Social Welfare – Tanzania
- Muhimbili University of Health and Allied Sciences
- World Bank
- ECSA- HC

Learning Objectives

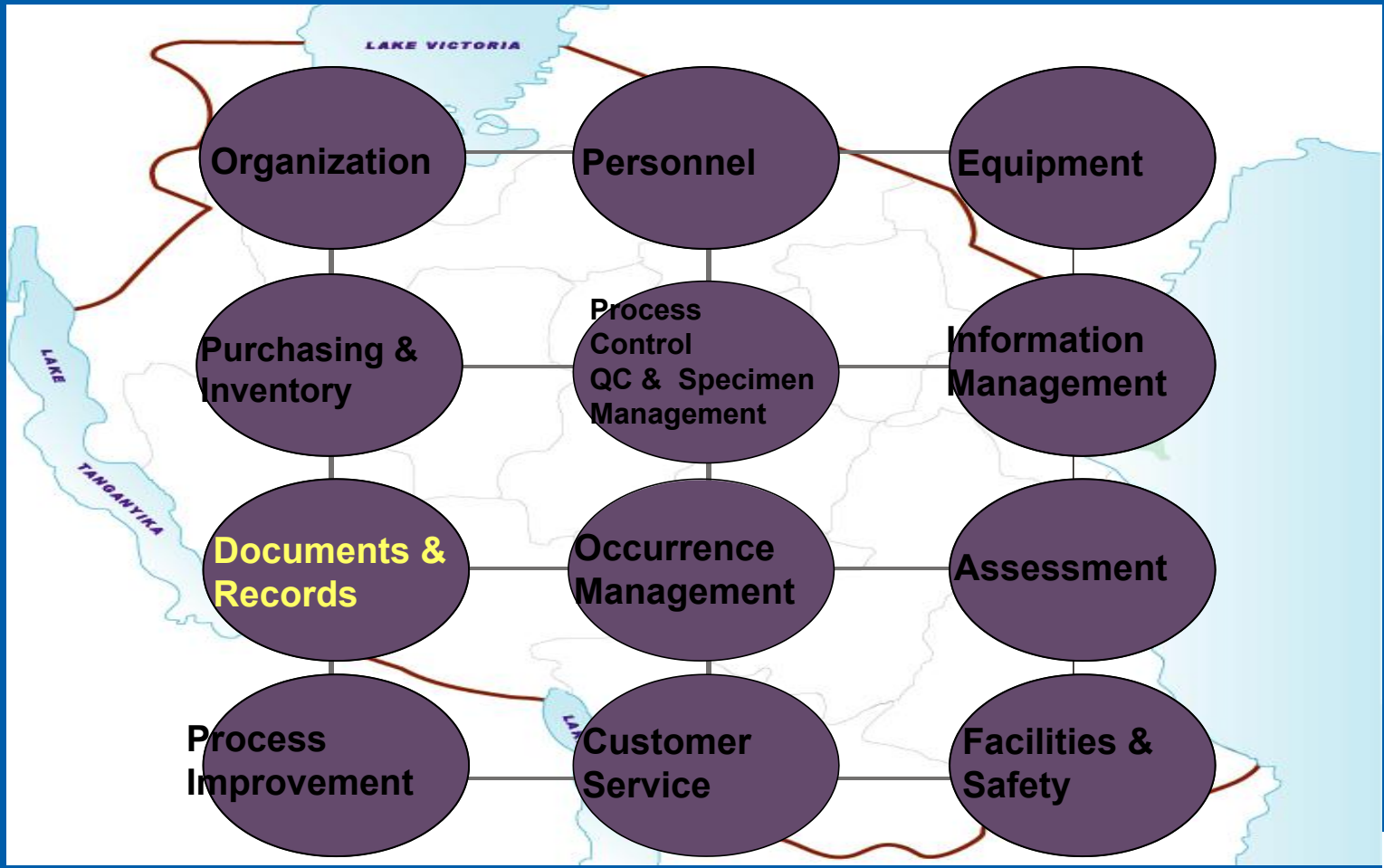
- Define document control and its purposes
- Differentiate between documents and records
- Define policies, processes, and procedures
- List the features of a well-written standard operating procedure
- Flowchart a laboratory process and create a process table and supporting procedures
- Describe the elements of a record

Today's Agenda

The Quality System

- Document Control
  - Standard Operating Procedures (SOPs)
  - Process-Based SOPs
  - Implementing SOPs
- Records Management
- Module Summary

The Quality System



The Laboratory Documentation

- Quality depends on having a good document and record control system in place for:
  - Formatting and maintaining various versions of documents
  - Assuring well written standard operating procedures
  - Assuring proper record retention

Documents vs. Records

Documents describe what is to be done

- Document types
  - Policies
  - Procedures
  - Forms
  - Checklists
- Documents must be created and controlled

Records describe the result of what was done

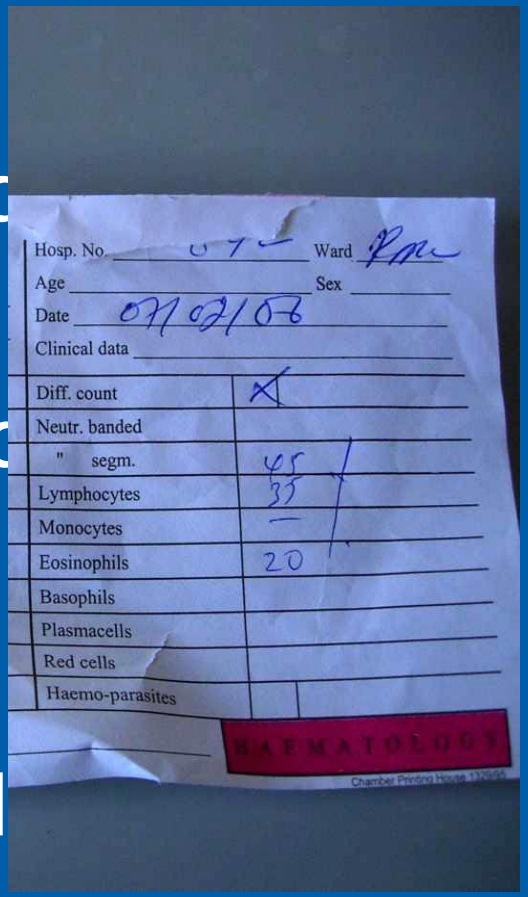
- Record types
  - Any data or information recorded by the laboratory
  - Instrument printouts
- Records must be created and retained

Why Document and Record Control is Important to Quality?

- Assures a standardized format for all documents and records (procedures, results, forms)
- Establishes change controls for revising documents
- Assures all departments have the most accurate, current, and approved documents

Why Document and Record Control is Important to Quality? (Continued)

- Establishes a record retention system for patient records and other documents to assure records are stored for defined period
- Assures easy retrieval of all documents and patient records



Does anyone have a question?

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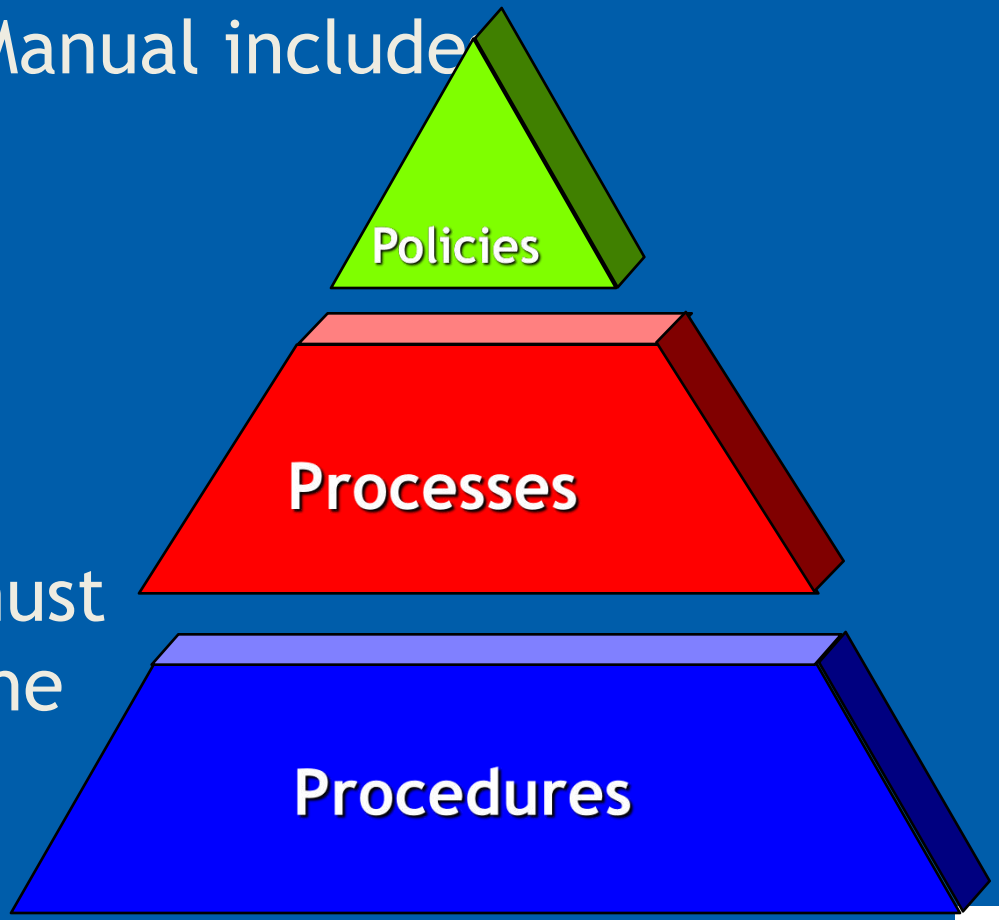
Document Control

- The Lab Quality Manual include
  - Policies
  - Processes
  - Procedures
- All are controlled documents and must be approved by the head of Lab.



Document Control: Policies

- Policies define “What to do”
- Defined in broad terms usually written in compliance with standards of laboratory practice

Document Control: Processes

- Processes describe "How it happens"
- Sets of interrelated activities that transform inputs into outputs such as
  - Specimen collection
  - Specimen accessioning
  - Instrument calibration

Document Control: Procedures

- Standard Operating Procedures (SOPs) define “How to do it”
- Provide step-by-step instructions that laboratory staff must follow carefully

Document Control: Numbering

- All controlled documents and corresponding forms must be numbered uniformly
- A standard cover sheet must be used for reviews, approvals, and document control information
- All pages must be numbered (1 of 3, etc.)

What questions do you have about controlled documents?

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Standard Operating Procedures

- Give management and customers an assurance of quality
- Provide laboratory staff with written instructions on how to perform testing
- Identify all reagents and supplies needed for inventory

Standard Operating Procedures
(Continued)

- Serve as a guide for new staff training
- Help to assess employee competence and identify retraining needs
- Prevent unauthorized modifications to procedures

Standard Operating Procedures
(Continued)

- Good SOPs are:
  - Clear and concise
  - Accurate and updated
  - Understood easily by staff
  - Accessible to staff
- Define the required elements in a template for consistency

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Process-Based SOPs

Analyte Procedures

- Detailed
- Procedure manual
- Very detailed
  old CLSI format
- Large binders on a shelf

Process-Based Procedures

- Simple, new CLSI format
- Process manuals for each process and instrument
- Easy to read format for each step in the process
- Readily available at the bench or instrument

Why Process-Based SOPs?

- All work is a process of interrelated activities that transform inputs into outputs
- Processes may involve more than one person or area of the laboratory
- Processes can be mapped to identify component procedures that need staff instructions for performance
- Process-based procedures make training and competency assessment much easier

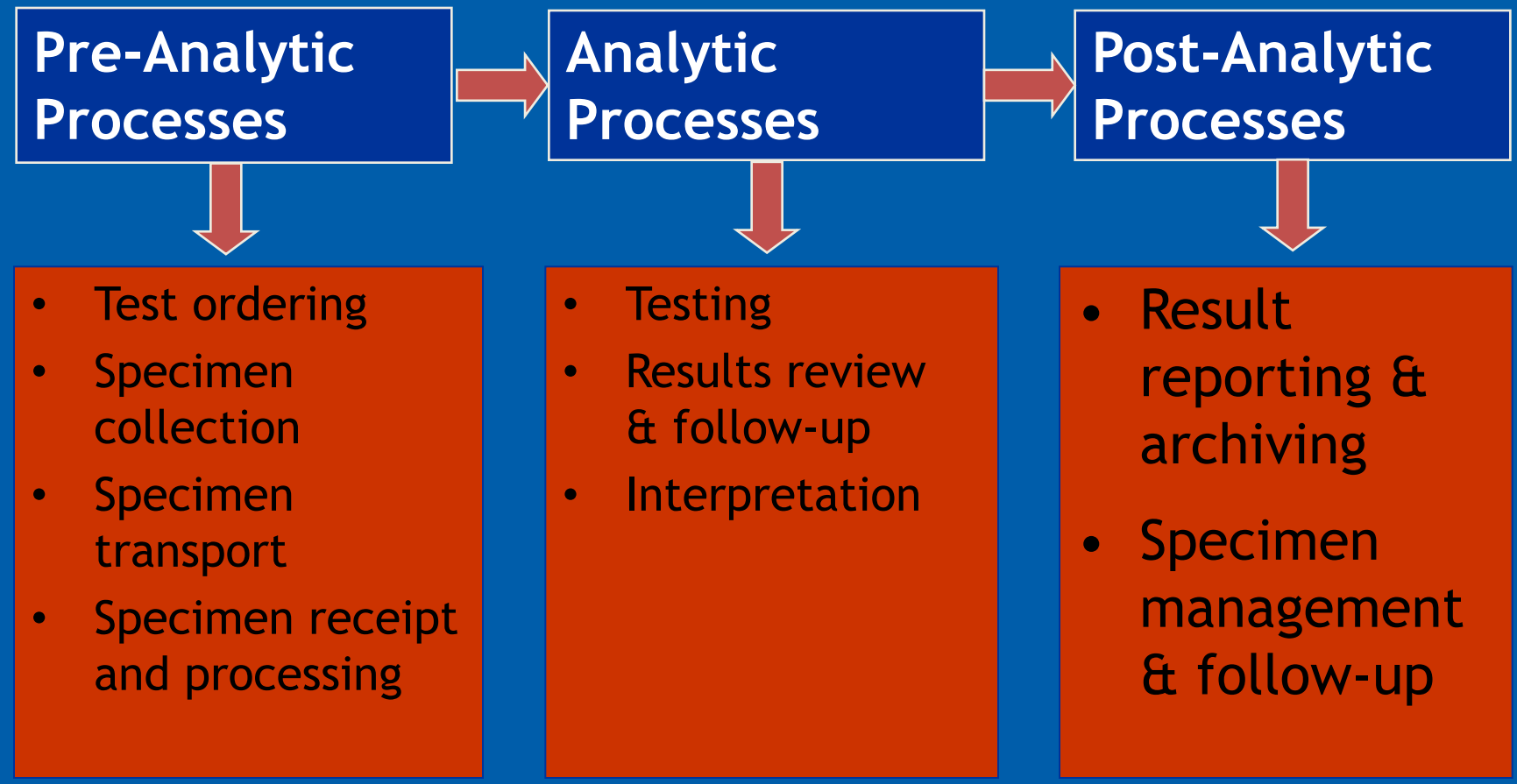
How to Create Process-Based SOPs

- Identify key processes in the lab workflow
- Draw basic flowchart of each process
- Create process table
- Write the required procedures in the process
- Create the Process Manual
- Write the analyte procedures for a separate method-based manual

Step 1: Identify Key Processes

- The laboratory workflow consists of:
  - Pre-analytical, Analytical, and Post-analytical processes
- SOPs must be defined for pre-analytical, analytical, and post-analytical processes in the laboratory workflow
- Approximately 9 major processes exist in the laboratory workflow

Laboratory Workflow Processes



Step 2: Draw Basic Flowchart of Each Process

- A workflow can be drawn using 3-4 symbols

- For example, each automated analyzer process can be flowcharted to identify the important procedures that must be written for the analyzer operation

Automated Analyzer Flowchart

Samples received analyzer

Sample acceptability is evaluated

Is analyzer ready for samples

Yes: Samples are loaded & tested

No: Perform start-up, daily maintenance and QC

Is analyzer functioning properly?

No: Perform troubleshooting

If Yes

Repeat examination

If No

Yes: Results are evaluated

Results are verified

Alerts or critical notified

Samples are unloaded & stored

End

What questions do you have about drawing process flowcharts?

Example: Accessioning Process Map

- A process map for accessioning would include the following steps with written procedures:
  - Specimen and request received and entered into specimen log
  - Specimen and request are evaluated for adequate labeling and adequacy
  - Inadequate specimens are rejected
  - Specimens are centrifuged, aliquotted, or prepared for shipment out of the laboratory
  - Specimens are distributed to the testing area

Step 3: Create Process Table

- Define what happens at each step in the process
- Identify who is responsible
- Identify what procedures are needed for each step

Example Process Table for Automated Analyzer

What Happens?	Who's Responsible	Procedures Needed
Sample evaluated for acceptability	Technologist	Evaluating Sample Acceptability for Abx Pentra Clot Checking Procedure
Analyzer ready procedures performed	Technologist	Checking required reagents Performing daily start-up Performing daily maintenance Performing daily function checks Performing and evaluating QC
Samples are loaded and run	Technologist	Programming samples on the analyzer Generating pending test list Loading routine and STAT tests on the analyzer
Troubleshooting performed for instrument problems	Technologist	Troubleshooting procedures

Example Process Table for Automated Analyzer (Continued)

What Happens?	Who's Responsible	Procedures Needed
Results are entered and evaluated	Technologist	Evaluating patient results Identifying and interpreting codes, flags, and histograms Correcting WBC for nRBC Entering and releasing results
Results are reported to wards and archived	Technologist	Reporting results on request form Notifying doctor on unusual or critical results Archiving/filing patient results
Samples are unloaded and stored	Technologist	Storing patient samples

Step 4: Write Required Procedures

- Write basic instructions for components of the process
- Group procedures by process

  Ex. Specimen labeling

Example – Specimen Labeling Rejection Procedure

- Specimens are rejected if inadequately labeled as follows:
  - Unlabeled
    - Any specimen is unlabeled if the container holding the specimen (evacuated tube, urine container, slide, etc.) does not have the patient's last and first names, and identification number directly affixed to it.
    - Labels must be placed on the container themselves rather than the lids

Example – Specimen Labeling Rejection Procedure (Continued)

- Specimens are rejected if inadequately labeled as follows:
  - Mislabeled
    - A specimen is mislabeled if its patient identification differs from the patient identification on the request form associated with it
    - A specimen is mislabeled if the specimen does not belong to the patient on the label

Example – Specimen Labeling Rejection Procedure (Continued)

- Improperly/Incompletely Labeled
  - The patient's first name, last name, and the identification/file number are the minimum acceptable patient demographic data required on the specimen
  - Certain types of specimens must also have an accurate date and time of collection on specimen labels
  - Blood Bank specimens require a date drawn and first initial and last name of the blood collector clearly printed on the pilot tube

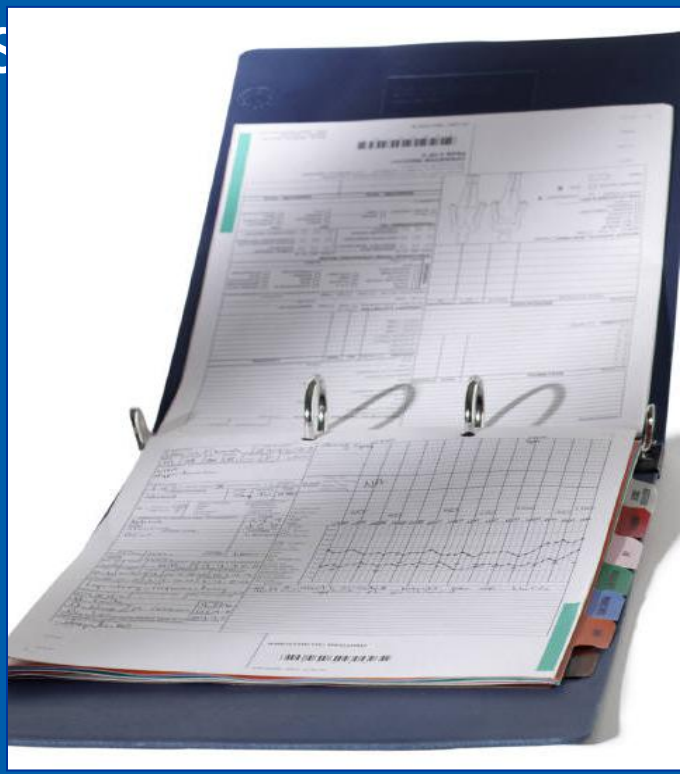
Example – Specimen Labeling Rejection Procedure (Continued)

- Specimen rejections will be documented on the laboratory request form and sent to the ward
- The ward or clinician will be notified of the need to recollect

What questions do you have about creating process tables and writing procedures?

Step 5: Create Process Manuals

- One manual for each proces
and instrument
- Process manual becomes your training, competency assessment, and procedure manual.



Step 5: Create Process Manuals

- Process Manuals include:
  - Flowchart of the processe
  - Procedure instructions in order of performance
  - Related documents
  - References

Step 6: Write Analyte Procedures

In addition to process procedures from the process table, one single page procedure would exist for each analyte on the analyzer. These are included in a separate procedure manual by analyte and would include elements not needed for daily use.

Elements of Analyte Procedures

- Principle and purpose of the test
- Sample requirements
- Equipment and materials
- Reagent lists
- Special safety precautions
- Maintenance procedures
- Quality control details
- Calculations
- Reference ranges
- Interpretation of results
- Linearity/dilutions

Elements of Analyte Procedures

(Continued)

- Interferences and procedural limitations
- Any alert/critical values
- References
- Approval sheet with signatures
  - Author(s)
  - Persons reviewing and approving
  - Employee review
  - Implementation and revision dates

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Implementation of SOPs

- Why don't personnel follow SOPs?
  - SOPs do not exist
  - Too complex and detailed
  - Not readily available in user-friendly format
  - SOP developed at a higher level or at another lab
  - Old SOP versions are in use
  - Adherence to SOPs is not a job requirement
  - Poor or absent supervision of compliance
  - Difficulty in dealing with change
    - "We have always done it this way" attitude

Implementation of SOPs (Continued)

- Organization and management must have a commitment to implement SOPs
- Perform a needs assessment
  - Prioritize simple process based procedures first for higher volume procedures at local site
- Establish central QA unit to develop, disseminate, and update analyte based SOPs
- Provide orientation, training and continuing education programs on contents

Implementation of SOPs (Continued)

- Have sufficient qualified personnel with documented training and experience to carry out laboratory work to the required standard
- Make knowledge and adherence to SOPs a job requirement and include in the standard performance appraisal system

What questions do you have about implementing standard operating procedures?

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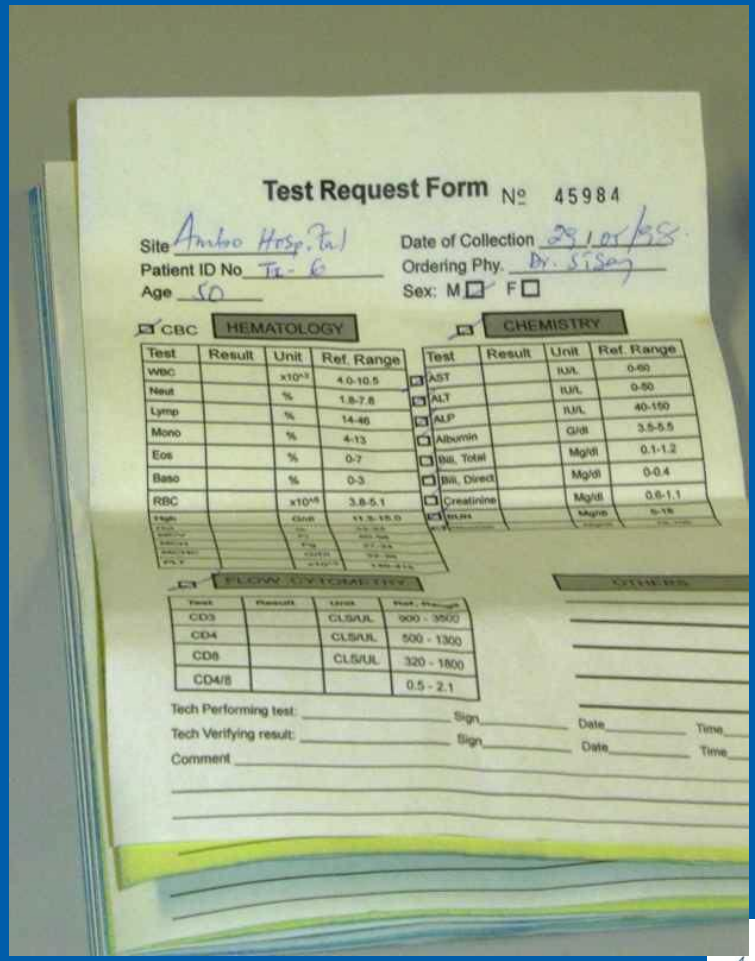
Important Laboratory Records

- Records are any data or information recorded by the laboratory including:
  - Test requisition forms
  - Patient result forms (may be the same as requisition) initial and corrected/amended
  - Accession logs
  - Instrument print-outs (function checks etc.)



Important Laboratory Records

(Continued)

- Records are any data or information recorded by the laboratory including:
  - Maintenance logs
  - Temperature checks
  - QC and QA records
  - Specimen rejection logs
  - Result worksheets with calculations

Format of Records

- Forms should include at minimum:
  - Title
  - Date
  - Results
  - Tolerance limits/acceptable range
  - Comments
  - Performing staff initials/date

Exercise – Record Design Review

- Review Record Design (pick one for each group)
  - Investigation Request
  - Accession book/log
  - Result register
  - Temperature chart

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Record Storage Systems

- Record system must allow one to reconstruct the entire process from beginning to end
- Paper Storage Systems
  - Data entry on manual records must be accurate, legible, permanent ink, and complete
  - File cabinets organized alphabetically and by month/year
  - Bound books of records
- Electronic Storage Systems

Electronic vs. Paper Systems

- Electronic record-keeping provides the following advantages over paper systems:
  - Permanence
  - Security
  - Ease of storage and retrieval
  - Traceability
  - Legibility

Record Retention

- Records should be maintained on-site if possible to provide easy retrieval for 5 years
- Records must be organized, secure, and easily retrievable
- Records must be traceable to performing staff and reviewing supervisor
- Records should be retained in secure, water-resistant boxes according to date, type of record and disposal date

Record Retention (Continued)

- Manual records of testing and QC should be retained for at least 5 years
- The period of retention depends on:
  - Clinical needs for retrieval of patient records
  - Government or accrediting requirements
  - Storage capacity
  - Auditing and assessment needs

What questions do you have about laboratory records, storage systems, and record retention?

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Summary: Documents vs. Records

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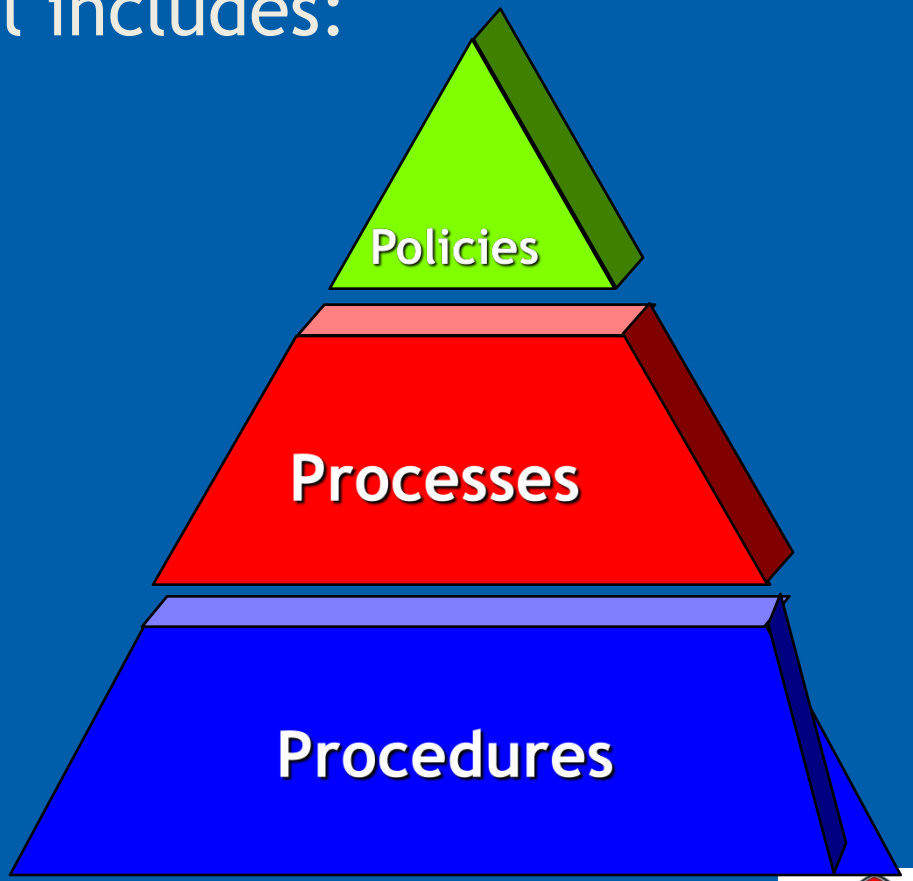

What questions do you have about document and record control for the laboratory?

Thank you