Welcome to the Documents and Records Module
Module 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.
12 QSEs for Quality Management
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)
Documents

- Communicate information via policies, procedures and working instructions (SOPs);
- Need updating.

Records

- Capture information on worksheets, forms, labels, and charts;
- Permanent, do not change.
Approach to Laboratory Documentation

- Policies
- Procedures
- Working Instructions (SOP)
- Forms and Reports
Approach to Laboratory Documentation (continued ...)

**Policies**
Provide a statement of intent that you will follow a particular course of action
States the intent and reason, e.g. WHY

**Procedures**
Practical way in which a policy is translated into action
States HOW and not only WHY
Provide information to carry out an intent
Called SOPs

**Working instructions**
Procedures can refer to/include working instructions
Practical day to day instructions
i.e. the procedural instructions/step-by-step instructions in an SOP

**Forms and reports**
Provide evidence of fulfillment of intent
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.
What makes a good document?

- Clear
- Concise
- User-friendly
- Explicit
- Accurate
- Up-to-date
Life Cycle of a Document

- Initiation/implementation
- Use
- Review/Revision
- Retirement (Obsoletion)
Types of Documents

- Two classes described by ISO guidelines: technical and quality records;

What is the difference between a procedure (quality record) and a technical record?

- Technical records are generated as a product of quality records. E.g. following a test SOP will generate raw data, equipment maintenance records and patient request forms.
<table>
<thead>
<tr>
<th>Quality</th>
<th>Technical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality manual</td>
<td>Raw data</td>
</tr>
<tr>
<td>Policies</td>
<td>Patient request forms</td>
</tr>
<tr>
<td>Study guidelines</td>
<td>Temperature log sheets</td>
</tr>
<tr>
<td>Organograms</td>
<td>Equipment log sheets</td>
</tr>
<tr>
<td>Personnel records</td>
<td>Laboratory workbooks</td>
</tr>
<tr>
<td>SOPs</td>
<td>Patient results and reports</td>
</tr>
<tr>
<td>Test and equipment validations</td>
<td>Corrective actions</td>
</tr>
<tr>
<td>Internal and external audit reports</td>
<td>Preventative actions</td>
</tr>
<tr>
<td></td>
<td>Internal QC records</td>
</tr>
<tr>
<td></td>
<td>EQA records</td>
</tr>
</tbody>
</table>
The Quality Manual is a document describing the quality management system of an organization. (ISO 15189)

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

Form a Steering Committee

Set policy for 12 QS essentials

Describe how the related quality processes occur

Reference procedures

WHO: Training Toolkit
Key Points: Quality Manual

- Only ONE official version;
- Never “done”, always being improved;
- Read and accepted by everyone;
- Use the best-adapted language;
- Signed and dated by management.
1. Introduction
2. Organization and management
3. Quality policy
4. Personnel (staff education and training)
5. Document control, including records, maintenance and archiving
6. Accommodation and environment
7. Instruments, reagents, consumables management
8. Safety
9. Research and development (optional)
10. Pre-examination procedures
11. Examination procedures
12. Post-examination procedures
13. Quality control
14. Laboratory information system
15. Handling of complaints–occurrence management
16. Communications and other interactions
17. Preventive and corrective action, internal audit
18. Ethics
1 Introduction

- Laboratory history
- Activities
- Manual’s field of application
- Manual updates:
  - Who
  - What
  - Where
  - When
  - How
  - Why
2 Organisation and Management

- Description of laboratory organization
- Legal identity
- Resource requirements
- Assignment of responsibility /authority

3 Quality Policy

- Official declaration of a quality policy by appropriate laboratory management
- Assures that the laboratory director will designate a quality manager
- Defines the laboratory:
  - Missions
  - Objectives
  - Roles / Responsibilities
4 Personnel

- Job descriptions, including qualifications needed
- Personnel list
- Laboratory organizational chart
- Recruitment conditions
- Intern and student management
- Confidentiality Agreements
- Training/Competency Records

5 Quality Policy

- Management approval
- Finalizing document: verification, printing, signature, transmission
- Confidentiality management
- Storage, archiving
- Producing reports
- List of reference documents:
  - Manuals
  - Books
  - Articles
6 Accommodation and Environment

- Map of the laboratory premises
- Restricted points of access
- Laboratory signs or other identification
- Environmental requirements for the laboratory (size, temperature, water, electrical, airflow)
  - Verification
  - Tolerated uncertainties
7 Instruments, Reagents, and Consumables Management

- Specify that each instrument requires written procedures, maintenance, quality control
- Reagents
  - Ordering and receipt
  - Quality control
  - Validation
  - Storage
- Consumables or supplies – define management
8 Safety
- Handling of samples and materials
- Disinfection
- Fire instructions
- Hazardous chemical instructions
- Waste disposal
- Sterilization
- Product labelling
- Risk Assessment

9 Pre-examination Procedures
- Equipment used
- Patient preparation
- Identification of samples
- Aliquoting and pre-treatment of samples
- Storage
- Transport
10 Examination Procedures

- Equipment used
- Reagents used
- Calibration / quality control
- Analysis/testing procedure
- Validation technique

11 Post-examination Procedures

- Analysis of results
- Final biological validation
- Printing/copying report of results
- Transmission of report
- Filing (archiving) report
- Relationships with disease surveillance authorities
12 Quality Control

- Reminder of commitment to quality
- Link to control procedures:
  - Equipment
  - Reagents
  - Personnel competencies.
- Summary of all quality control procedures and links to the appropriate sections in quality manual

13 Corrective/Preventive Actions, Internal Audits

- Continuous improvement
- Reviewing and understanding all problems and errors
- Internal audits are required under the ISO 15189 scheme
Standard Operating Procedures

- 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
Standardised SOP Format

WHO: Training Toolkit
<table>
<thead>
<tr>
<th>TML\MSH Microbiology Department Policy &amp; Procedure Manual</th>
<th>Policy # MT\RESP\11\v05</th>
<th>Page 1 of 5</th>
</tr>
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<tbody>
<tr>
<td>Section: Respiratory Tract Culture Manual</td>
<td>Subject Title: SPUTUM (Including Endotracheal Tube and Tracheostomy Specimens)</td>
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<tr>
<td>Issued by: LABORATORY MANAGER</td>
<td>Original Date: September 25, 2000</td>
<td></td>
</tr>
<tr>
<td>Approved by: Laboratory Director</td>
<td>Revision Date: September 14, 2006</td>
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</tr>
<tr>
<td></td>
<td>Annual Review Date: August 13, 2007</td>
<td></td>
</tr>
</tbody>
</table>

Use at the top of the first page only
Steps to keep in mind when preparing to write a standard operating procedure document.

- Determine the procedure that should be used;
- Use reliable reference sources (assess and collect);
- Include all steps and details explaining how to properly perform the procedure;
- Collect any additional information;
- Establish a mechanism for keeping SOPs updated.
Suggested Outline for SOP

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

Avoid drowning in detail and do not rely solely on manufacturer product inserts as they do not provide specific information for test sites
What is a Job Aid

- Shortened version of SOPs
- Hand written or printed
- Visible location at testing site
- Useful tool to assure all testing steps are correctly performed

Click on the image to view an example of a Job Aid
Your lab is using a procedure for the daily maintenance of their Abbott m2000sp. There has been a major update from the manufacturer and this has been added to the SOP.

One of the staff members responsible for training has trained new staff on the instrument, but he preferred to use his copy of the SOP with notes to train the staff, and didn't use the new version of the SOP.

**What would be the impact of this on the instrument and other staff using the instrument?**
Why Manage / Control Documents and Records?

- The main aim of keeping documents and records is to **find information whenever it is needed**.
- ISO15189:4.3. The lab shall establish and maintain procedures to control all documents that form part of its quality system.
- Ensures that the information available is consistent throughout.
- A register of controlled documents is available at QAU.
- Ensures that staff are aware of necessary documents and that they have read the documents.
Why Manage Documents and Records?

- “Uncontrolled” documents are difficult to manage.
- Ensuring the same document is used throughout ensures compliance.
- If it’s not written down, it didn’t happen
- Also – if it’s now written down, no-one can claim “that they didn’t know”!
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
Implementing Document Control

**Preparation**
- Collect existing documents and records;

**Review and Revision**
- Review and update;
- Determine additional needs;
- Develop or obtain documents, forms, worksheets, logbooks, reports;

**Approval**
- Involve stakeholders for approval and sign off;

**Issue Distribution**
- Distribute documentation.
Storage of Documents

- Follow a logical storage method for documents
- Ensure files have indexes so that documents can be found
- Ensure files are labelled to indicate contents
Accessibility to Documents

- Documents must be easy to retrieve and be available for use at instruments etc.
- Make sure that the filing system is understood by all staff – any person should be able to find an SOP if asked to do so.
- Sometimes difficult in labs with multiple areas to make SOPs available at the instruments – define central area where documents are available.
- SOP’s accessible to all staff.
For “uncontrolled” copies of documents, lab must decide how they will handle this.

Either not allowed at all or each person is responsible for the copy they have.

Must have a way to notify all staff of changes and new version of documents – persons must then make sure that their copies match these.
Obsolete Documents

- Obsolete documents must be removed from circulation and destroyed;
- QAU has master copies of obsolete versions and documents and it is sufficient to destroy all copies in your lab and refer queries to QAU;
- Obsolete documents are stamped “OBSOLETE”;
- Ensures that staff don’t refer to old documents.
Clinical and Laboratory Standards Institute
Revision of SOPs

- Reviewed periodically or as described in your policy
- Done by authorized and qualified personnel
- Laboratory should have a system in place to notify reviewers
- **Possibility of 3 outcomes:**
  - Keep – Retain document as is
  - Change – Document needs changes
  - Retire / obsolete
- Proof of document reviews shown
- **May also be reviewed:**
  - When there are changes to test methods
  - As a result of NC identified
  - Findings from an internal / external audit
Revision of SOPs (continued…)

- When major changes have been made to an SOP staff must read the SOP again as soon as possible – especially if it impacts test procedures or instrument operation

- Retraining of staff

- Good idea to discuss changes at lab meetings and have staff acknowledge changes by signing forms
When amending data, the following procedures should be followed:

- Draw a single line through the original entry – the original data must always be visible
- Write legibly
- Record the correct value
- Sign and date the change
- Document the reason for the change (if required)
- Do not use white out/correction fluid
- Do not use pencil
An archive is a collection of historical records, as well as the place they are located.

Archives contain primary source documents that have accumulated over the course of an individual or organization's lifetime.

Document QSP-GEN-006 defines how long documents should be archived for.

Some studies could require longer.

Archive must:
- Ensure that risk of damage is minimized, i.e. fire, vermin, water
- Have a register of records stored
- Record retrieval and return of any records
- Ensure all records are clearly identified
As laboratories change, so does the format in which they generate data.

This includes electronic patient results, raw data, equipment maintenance and service.

Much of the data generated is electronic, and this data must adhere to the same rules as quality and technical documents.

Laboratories must ensure that they have data backup procedures in place.
Electronic Archiving (continued…)

- If data backup is managed by other source (IT), the lab must ensure that they know what is being done.

- Formats for electronic data:
  - CDs, DVDs
  - External hard drives (HDD)
  - Tape drives

- Lab must ensure that whichever format is used, that is stable over time and that data can be retrieved.
Document control is an important part of the quality system in the lab.

Ensures that the information at any given time is authorized, current, known by personnel and reviewed for changes on an ongoing basis.

Best practices will ensure that:
- “Official copies” are tracked and kept consistent.
- It is possible to reconstruct the instructions in place at any time for any activity through forms, revisions and supportive documentation.
- A process is in place to control and record deviations from SOP.

Information is the laboratory’s product.

Documents are essential for assuring accuracy and consistency in the laboratory.
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
References

- WHO: Quality Management Toolkit
- ISO 15189:2012: Quality management in the clinical laboratory
- Guidance for Laboratory Quality Manuals (Ontario Laboratory Accreditation Division)
Participants are now able to:

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Questions