PANDORA
Pan-African Network For Rapid Research, Response and Preparedness for Infectious Diseases Epidemics

CANTAM
Central Africa Clinical Research Network

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THE GLOBAL HEALTH NETWORK

Laboratory Quality Control workshop

TGHN online workshop

21st to 22nd October 2020

DOCUMENTATION

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Learning Objectives

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

- Define Good Documentation Practice and purpose of Laboratory documentation as foundation of Quality Management System (QMS)
- Cite Essential documents required for QMS
- Know the document control process and the importance of master list
- Complete laboratory records in compliance with good documentation practice (GCP) guidance
- Understand the Compliance with documentation in audits
- Understand the format of Standard Operating Procedure (SOP) and Master list Index

What is Good Documentation Practice?

- Document is information (meaningful data) and its supporting medium, in form of paper, CD, Computer file, microfilm, x-Ray film etc
- Documents provides information or evidence or may serve as an official record.
- Record is a document stating results achieved or provide evidence of activities performed.
- Guidelines are documents that provide recommended practices and instructions.
- Policy is a plan or adopted course or principle of action intended to influence and determine the decisions or actions of an organization.
- Procedures (or Standard Operating Procedure (SOP)) are documents that specify the way to carry out an activity or a process

What constitutes Good Documentation Practice (GDP)

- **Legible:** everyone should be able to read what is written regardless of who, where or what has been written.
- **Concise:** the document must provide clear information that is understood by all customers
- **Traceable:** who recorded it, where and why
- **Contemporaneous:** the information should be documented at the correct time frame along with flow of events
- **Enduring:** Long lasting and durable
- **Accessible:** Easily available for review.

Purpose of Laboratory Documentation

- Documentation is the foundation of the QMS
- All aspects of the laboratory function MUST be documented
- To provide the basic guide for good document practices with regard to creation, approval, review, maintenance, correction or errors, verification and archiving etc
- Ensures documented evidence, traceability, provide records and audit trails for investigation
- Ensures availability of data for validation, review and statistical analysis.
- Control of Process - Ensures all staff knows what to do, how to do it and when to do it.
- To improve performance
- Regulatory requirements.

Essential documents required for QMS

- Quality Manual and Quality Policy
- Standard Operating Procedures
- Laboratory Analytical Plans
- Laboratory Reference Standards
- Laboratory Note Books
- Temperature charts
- Equipment service and maintenance records
- Corrective Action Preventive Action (CAPA)
- Lab staff training records
- Quality Control records (e.g. Levey-Jennings chart)

Structure of documentation applicable to all organisations

Figure describes a typical QMS documentation hierarchy with different document types at each level

Document control process

- The ISO15189 (Medical Laboratories- requirements for quality and compliance)standards (4.3) requires that

  "The laboratory shall control documents required by the quality management system and shall ensure that unintended use of obsolete documents is prevented"

- All controlled documents must be identified to include:
  - A title
  - Unique identifier on each page
  - Date of the current version and/or the version number
  - Page number to total number of pages (e.g. page 1 of 2)
  - Authority of issue
- Current authorised versions and their distribution should be identified by a means of a Master List Index

Example of SOP template

SOP Cover page

REPUBLIQUE DU CAMEROUN Paix – Travail – Patrie		REPUBLIC OF CAMEROON Peace – Work – Fatherland
	Laboratory for Tuberculosis Research and pharmacology *Biotechnology Center, Nkolbisson* *University of Yaoundé 1*	
STANDARD OPERATING PROCEDURE		
Lab Section/Unit: General	**Title of the SOP**	Document Code: **LTR-SOP-N°** Control Copy N°.: Version N°.: Revision N°.: **Page 1 of 1**

	Written by:	**Reviewed by:**	**Approved by:**
Name			
Designation			
Signature			
Date			

SUPERSEDES DOCUMENT:			
REVIEW & REVISION HISTORY			
Date Reviewed	**Date Revised**	**Done by: (Name & Signature)**	**Date of Next Review**
Distribution/Location:		**Number of Copies:**	
Date of Discontinuation			

Example of SOP template

SOP content

STANDARD OPERATING PROCEDURES			
	Procedure Type		
	Analytical		
Section	Quantitative	Qualitative	Non-analytical (Organizational/Managerial SOPs)
Title/Cover and signature pages	X	X	X
Introduction	As Needed	As Needed	As Needed
Purpose	X	X	X
Principle	X	X	As needed
Scope & Applicability	X	X	X
Authority/Roles and Responsibilities	X	X	X
Definitions	As Needed	As Needed	As Needed
Abbreviations	X	X	X
Materials/Disposables	X	X	As needed
Equipment/Reagents	X	X	As needed
Specimen (Type of container & Additive)	X	X	As needed
Precautions & Safety	X	X	As needed
Calibration	X	As needed	As needed
Quality Control	X	X	As needed
Performance Specifications	As Needed	As Needed	As Needed
Procedural Steps/Method	X	X	X
Interpretation/Reporting Results	X	X	As needed
Procedural Notes	X	X	As needed
Limitations/Interferences and Cross Reactions	X	X	As needed
Biological Reference Interval	X	As Needed	As Needed
Alert/Critical Values	As Needed	As Needed	As Needed
Storage conditions for samples	As Needed	As Needed	As Needed
Related Documents	X	X	X
References	X	X	X
Appendices	As used	As used	As used

Example of Master list Index

Laboratory for Tuberculosis Research and pharmacology
Biotechnology Center, Nkolbisson
University of Yaounde 1

Effective Date: 04 Nov. 2014 **Controlled Copy Number:** 01 **Document Code:** LTR-FRM-01
Revision Number: 00 **Date Revised:** (Not yet revised) **Page** 1 of 4

DOCUMENT MASTER LIST

Control Copy Number	Document Code	Document Name /Title POLICY STATEMENTS	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	GENERAL /ORGANIZATIONAL/MANAGERIAL PROCEDURES/TASKS	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	FORMS (FICHES)	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	BIOSAFETY PROCEDURES (SOPs)/ PROCEDURES SPECIFIQUES SUR LA BIOSECURITE	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	EQUIPMENT SPECIFIC SOPs/ PROCEDURE SPECIFIQUE (EQUIPEMENT)	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES

Example of Master list Index

Control Copy Number	Document Code	TEST SPECIFIC SOPs	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	GRAPHS/ REPRESENTATION GRAPHIQUE	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	FLOW CHARTS/ORGANIGRAMME	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	JOB AIDS/ OUTILS DE TRAVAIL	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	REGISTERS/ REGISTRES	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	DRAWINGS & PLANS	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	POSTERS	Version Number	Effective Date	Date of last	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES

Example of Master list Index

					Review/Revision		
Control Copy Number	Document Code	MATERIAL SAFETY DATA SHEETS (MSDS)	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	MANUALS	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	CALIBRATION TABLES	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	BIOLOGICAL REFERENCE INTERVALS	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	BIBLIOGRAPHY (DOCUMENTS EXTERNES)	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	SERVICE NOTES / NOTE DE SERVICE	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENTS & NUMBER OF COPIES

Example of Master list Index

Control Copy Number	Document Code	REAGENT INSTRUCTION LEAFLETS/ NOTICE DES REACTIFS	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	AGREEMENTS /AGREMENT (CONVENTION)	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	SOFTWARES (ELECTRONIC DOCUMENTATION)/ DOCUMENTS ELECTRONIQUES et LOGICIEL	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
Control Copy Number	Document Code	REPORTS /RAPPORT	Version Number	Effective Date	Date of last Review/Revision	Next Review Date	LOCATION OF DOCUMENT & NUMBER OF COPIES
		RAPPORT GENERAL (eg RAPPORT AUDIT INTERNE, EXTERNE, REUNIONS, ETC)					

Document control process

- Approve documents for adequacy prior to issue by authorised staff;
- Review and update documents as necessary and re-approve;
- Ensure that changes and the current revision status of documents are identified;
- Ensure that current relevant versions of applicable documents are available at points of use;
- Ensure that documents remain legible and readily identifiable;
- Ensure that documents of external origin are identified and their distribution controlled; and
- Prevent the unintended use of obsolete documents and apply suitable identification to them if they are retained for any purpose.

What is required for "control"?

The whole point of controlling documented information is to make sure it is "available, current and suitable for use" and also "protected”

- **Identification:** How is documented information identified?
- **Format:** What is the best format for this information?
- **Review and approval:** When a new document is found, or is created, how is it approved for release?
- **Distribution, access, retrieval and use:** How will you provide access to released documents everywhere they are needed?

What is required for "control"?

- **Storage and preservation:** How do you protect the documented information from unauthorised changes, or loss?
- **Control of changes:** When changes are made, how do you identify them?
- **Retention and disposition:** How do you prevent the use of obsolete documents?
- **External documents:** How do you find and control documents from external sources?
- **Document master copy**
  Each controlled document has one master copy. This is the copy to which all changes are initially made and from which further copies are made and issued as required. The location of the master copy is recorded on the Document Master List.

Common Documentation Errors when completing records

- Missing signature and dates at the time the activity is performed
- The write-over
- Non-uniform date and signature entry
- Writing a note that activity was performed on one day and signed for on other day.
- Blank spaces
- Illegible writing
- Too many corrections

Principles of Good Documentation Practice (GDP) for compliance

- A document bearing original signatures should never be destroyed
- Never falsify information
- Never you a White-out and cover-over-tapes
- Never obliterate information or record
- Never over-write a record
- Never use pencil – all information should be completed in permanent Black or Blue ink
- No spaces, lines or fields are to be left blank
- Never use symbols e.g. ditto marks or arrows to indicate repetitive and consecutive

Benefits of Good Documentation

- Build confidence in the Laboratory Quality System
- Reduce efforts to compliance with regulatory bodies
- Allows for achievements of required results
- Correct, complete, current and consistent information effectively meets customers and stakeholders' requirements
- Enables the Laboratory activities to be arranged into functional patterns for specific action

Benefits of Good Documentation

- Create structures so that staff can systematically coordinate to conduct business
- Training of Laboratory staff
- Solve complicated problems
- Reduce or eliminate assumptions and second-guessing.
- Eliminate the need to re-ask the same questions
- Specify clear instructions for staff

THANK YOU FOR YOUR ATTENTION!