

**10-Laboratory Document Control**

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**ANNUAL REVIEW:**

<b>REVIEWED</b>	<u>Sanford H. Bailey, M.D.</u>	<u>July-15-2025</u>
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**SUPERSEDES:** Procedure titled **Purpose:**

This Standard Operating Procedure (SOP) outlines the document control procedure for MMCCCL, which is a crucial component of quality assurance in the laboratory setting. The SOP aims to provide clear guidance on the creation, review, revision, approval, and retention of all laboratory documents, including Standard Operating Procedures (SOPs), forms, and records, to ensure accuracy, consistency, and completeness. The objective of this SOP is to establish a framework that promotes compliance with regulatory requirements, facilitates effective communication, and enables staff to access current and relevant laboratory documents easily. This SOP

serves as a tool for achieving consistent and reliable results, reducing errors, and maintaining the highest standards of laboratory practice, ultimately enhancing patient care and safety.

### **Scope:**

This SOP applies to all laboratory documents, including Standard Operating Procedures (SOPs), forms, and records, generated and maintained by the Clinical Laboratory. It covers the entire document control process, from document creation to archiving, and applies to all laboratory staff involved in the creation, review, approval, implementation, and maintenance of laboratory documents. This SOP applies to all laboratory activities, including testing, quality control, quality assurance, and management, and is applicable to all laboratory locations. This SOP is a critical component of the Clinical Laboratory's Quality Management System (QMS) and supports the laboratory's commitment to quality, safety, and compliance with regulatory requirements.

### **Abbreviations:**

MMCCCL- Meharry Medical College Clinical Consolidated Laboratory  
QMS-Quality Management System  
SOP- Standard Operating Procedure  
PPE-personal protective equipment

### **Health and Safety considerations:**

MMCCCL is committed to ensuring the health and safety of its staff and clients. All laboratory activities must comply with applicable health and safety regulations and guidelines. All laboratory staff are required to be familiar with and follow the laboratory's safety policies and procedures. The laboratory will provide personal protective equipment (PPE), appropriate training, and regular safety inspections.

### **Policy:**

MMCCCL is committed to maintaining accurate and up-to-date documentation that supports the delivery of high-quality laboratory services and compliance with regulatory requirements. The laboratory recognizes the importance of effective document control in achieving this goal and has established a Document Control Procedure to ensure that all laboratory documents are created, reviewed, approved, and retained in a consistent and controlled manner. The Document Control Procedure applies to all laboratory documents, including Standard Operating Procedures (SOPs), forms, and records, and applies to all laboratory activities,

including testing, quality control, quality assurance, and management. The laboratory will regularly review and update the Document Control Procedure to ensure its continued effectiveness and compliance with regulatory requirements. The laboratory will provide training to all staff involved in the document control process to ensure their understanding and compliance with the procedure. The laboratory expects all staff to follow the Document Control Procedure and to raise any concerns or suggestions for improvement with their supervisor or the Quality Manager.

### **Procedure:**

Only controlled document/procedure to be used. Controlled document to be approved by laboratory director and make easily accessible for laboratory staff.

In case-controlled document retired, Copy should be kept separate/locked for 2 years

If controlled document revised, /supersede this should be traceable with what and when changes happened and also need to approved by lab director.

If major changes, a new version should be approved by lab director

### **References**

CAP all common checklist 2023  
COLA accreditation manual 2022