ADM 102 ADM 102 - Document Control

Copy of version 3.0 (approved and current)

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Comments for version 3.0
Added Section 5 "General Guidelines" which includes documentation techniques from use of blue or black indelible pen to correcting laboratory records with strikethrough and date and initials per CAP **GEN.20450** Correction of Laboratory Records

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	5/3/2023	3.0	Ali Mousa Ramadan MD	
Approval	Quality Assurance Manager	5/2/2023	3.0	Lydia Seifu	
Approval	Lab Director	3/16/2023	2.0	Ali Mousa Ramadan MD	
Approval	Quality Assurance Manager	3/13/2023	2.0	Lydia Seifu	
Approval	Lab Director	6/15/2022	1.0	Ali Mousa Ramadan MD	
Approval	Laboratory Operations Manager	6/15/2022	1.0	Wendell McMillan (108860)	
Approval Captured outside MediaLab	Lab Director	6/15/2022	1.0	Wendell R. McMillan II	Recorded on 6/15/2022 by Wendell McMillan (108860) when document added to MediaLab (previous system of record: Paper Copy)
Periodic review Captured outside MediaLab	Designated Reviewer	6/15/2022	1.0	Wendell R. McMillan II	Recorded on 6/15/2022 by Wendell McMillan (108860) when document added to MediaLab (previous system of record: Scanned)

Approvals and periodic reviews that occurred before this document was added to the MediaLab Document Control system may not be listed.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
3.0	Approved and Current	Major revision	5/2/2023	5/3/2023	Indefinite
2.0	Retired	Major revision	3/13/2023	3/16/2023	5/3/2023

1.0	Retired	First version in Document Control	6/15/2022	6/15/2022	3/16/2023

HOWARD UNIVERSITY HOSPITAL
DEPARTMENT OF PATHOLOGY AND LABORATORY MEDICINE

STANDARD OPERATING POLICY AND PROCEDURE MANUAL

POLICY: DOCUMENT CONTROL AND RECORD RETENTION POLICY
No. ADMIN/102/2004/2

I. PRINCIPLE:

Document control and retention are critical components of the Department of Pathology and Clinical Laboratory Quality Plan. This policy addresses the processes for controlling, distributing, and archiving laboratory documents and records. The laboratory has a document control system to manage policies, procedures, and forms that are subject to CAP accreditation (in accordance with College of American Pathologists General Checklist GEN.20375). This includes documents relating directly to laboratory testing, such as quality management, safety, specimen collection, personnel, and laboratory information systems. The document control system utilized by the Department of Pathology is MediaLab. MediaLab document control solution guides to full compliance with all laboratory standards, regulations, and best practices. Document Control provides an automated, centralized platform for all document approvals, workflows, edits, and sign-offs, audits, and more.

II. DEFINITIONS:

- **Document**- approved information that describes to the user what needs to be done and how; this is generally documented in the form of SOPs.
- **Record**- process or procedure data captured on forms (test requisition, log forms, etc.)
- **Policy**- a description of what will be done.
- **Procedure**- a set of work instructions that describe how to perform a specific task.
- **Document Identification -** All documents will be identified using a standardized document identification number- laboratory section abbreviation/function/number/date/version.

III. OVERVIEW OF MEDIA LAB DOCUMENT CONTROL:

A. The MediaLab Document Control system is designed to ensure all copies of policies and procedures are current, reviewed, and readily available and that obsolete documents have been removed from use. Additionally, the system helps ensure that all personnel have read the policies and procedures relevant to their job activities and that all policies and procedures have been authorized by the laboratory director or designee before implementation. It can also be utilized to ensure that documents are reviewed at least every 2 years by the laboratory director, supervisor, or designee.

B. All current policies and procedures are kept as 'read-only' documents in the MediaLab Document Control system and can only be modified or printed by authorized personnel defined in the permissions section of the MediaLab system

C. All discontinued policies and procedures are removed from operations by authorized personnel using the "retire this document" link within the MediaLab system. Retired procedures in the MediaLab document control system are kept indefinitely**.** They may be permanently deleted subject to defined regulations for 2 years after the date of discontinuation.

IV. MEDIA LAB DOCUMENT CONTROL PROCESS

A. **Manuals and Sub-Manuals**: Document Control includes a system of manuals to organize documents and to manage access to those documents. Manuals are either top-level manuals (also called parent manuals) or sub-manuals.

Manuals and sub-manuals are identified below:

1. Administrative Policy
2. Anatomic Pathology (Sub manuals: Surgical Pathology, Histology Manual)
3. Autopsy
4. Chemistry (Beckman DXI 600, Beckman DXC700 AU, Abbott Architect 1000i, Fetal Fibronectin, Geenius HIV ½)
5. Coagulation
6. Cytology
7. Hematology
8. LIS
9. Microbiology (Sub manuals: Molecular, Bacteriology, Immunology and Rapid Tests, Quality, Worksheets, and Training Checklists
10. Point of Care
11. Quality Assurance for Core Lab
12. Transfusion Services
13. Urinalysis

B. **Approval and Review Workflows**: Site administrators and document administrators over a particular manual can create the following types of workflows / processes for their documents:

1. Editing / collaboration workflows: a structured process for reviewing, editing, collaboration, or input that new documents, minor revisions, and major revisions must follow before they can start their approval process (this workflow is optional)
2. Approval processes for new documents and major revisions: an approval process to tell the system who needs to approve a new document or a major revision to an existing document.
3. Periodic review processes: a periodic review process to tell the system who needs to review a document every two years or every year and determine if it is still current, correct, and up-to-date.

C. **Staff Notification/Training**- Department of Pathology staff members are given sign in access to the Document Control system, by visiting www.medialab.com. Each employee will have their own unique access to Document Control. Once the site is accessed, employees will have task items shown as "documents requiring your sign-off as a performing employee". This is an important task that ensures compliance with employee review of new documents and revised documents. MediaLab will send automated emails when a new/revised document requires your sign off. Assignments are set-up by the Quality Assurance Manager (Primary Site Administrator) based on tasks trained on.

D. **Record Retention**: The laboratory complies with applicable national, federal, state, and local laws and regulations. Records are retained for the following appropriate time:

Type of Record	Retention Period
General Records	
Specimen requisitions (including the patient chart or medical record if used as the requisition)	2 years
Accession records	2 years
Quality management records	2 years
Test method validation/verification records	Length of time the test is in use, plus 2 additional years
Proficiency testing records	2 years
Policies and procedures	At least 2 years following discontinuance
Quality control records	2 years
Individualized Quality Control Plan (IQCP) including risk assessment and supporting data, and approval of quality control plan	Length of time the test is in use, plus 2 additional years
IQCP ongoing quality assessment data	2 years

Instrument/equipment maintenance* and function check records (including temperature charts)	2 years
Chain-of-custody collection, receipt, accessioning, and handling records	2 years (or longer as applicable)
Personnel Records	
Competency assessment records	2 years
Training records	2 years

Testing Records	
Instrument printouts (not interfaced with the laboratory computer system) and worksheets***	2 years
Patient test results and reports, including original and corrected reports, and referral laboratory reports	2 years
Direct-to-consumer testing results, including reference intervals	10 years
Laboratory Computer Services	
Computer system validation records	2 years beyond the life of the system
Records of changes to software, the test library, and major functions of laboratory information systems	2 years beyond the life of the system
Autoverification rules	At least 2 years following discontinuance
Ongoing computer system checks (eg, calculation verification)	2 years

E. **Copies of Records**: Copies of approved policies and procedures may be kept in the Laboratory for easy access to employees, but **must** be destroyed once a new revision is available. The laboratory also must ensure that laboratory records (e.g. patient reports, worksheets, quality control records) being converted onto another medium

for storage and retention are verified for accuracy, legibility, and completeness before the original record is destroyed.

F. **Archival of Documents-** Withdrawn policies and procedures and obsolete documents are archived when they are updated with a new version of the document, and they are removed as an official document. All archived files will be placed in the archived in MediaLab for life. Archived discs may also be maintained in the Laboratory Manager's office for at least 5 years.

V. GENERAL GUIDELINES FOR LABORATORY RECORDS

A. General Guidelines

1) **Always use permanent ink (blue or black indelible ink).** Laboratory record entries need to be in permanent ink, **NEVER** pencil. This ensures that data observed is never falsified or modified. Different color ink is allowed when a second person is marking on a document. Examples include use of red ink when grading training/competency questions or colored ink when reviewing antigrams.
2) **Write Down everything immediately.** A common mistake is to think that you will remember things to write down later.
3) **Be complete, yet concise, and write clearly.**
4) **Avoid use of highlighters which obscures information if copied or faxed.**
5) **Do not use self-affixing notes or small pieces of paper stapled, paper-clipped or otherwise attached to the technical record. If necessary, create a formal referenced attachment.**
6) **Never leave cells empty.** If data is not applicable, rows not used, etc... Ensure a "N/A" is written. For example in cases where logs are monthly, multiple unused rows can have a large strikethrough to demarcate that no further entries will be added to log, along with a date and initial of the individual closing the log out.
7) **Correction of Laboratory Records.** Laboratory records and changes to such records must be legible and indelible. The techniques used must meet the following:
   - Original (erroneous) entries must be visible (i.e. erasures and correction fluid or tape are unacceptable) or accessible (e.g. audit trail for electronic records)
   - Corrected data, including the identity of the person changing the record and when the record was changed must be accessible to audit.

- Simplest method is to have a clear strikethrough the erroneous entry by drawing a line through it. Adjacent to the correction write legibly the initials and date of the individual correcting the data.