

Department:	Laboratory and Blood Bank		
Document:	Departmental Policy and Procedure		
Title:	Documents and Records Management (Records Retention)		
Applies To:	All Laboratory and Blood Bank Staff		
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1. PURPOSE:

- 1.1 To provide guidelines for the uniform retention and storage of laboratory records.

2. DEFINITONS:

- 2.1 N/A

3. POLICY:

- 3.1 Laboratory records shall be retained in accordance with the CBAHI standards.

4. PROCEDURE:

- 4.1 The laboratory implements a general laboratory records retention system that ensures the following:
 - 4.1.1 Laboratory test request forms, specimen accessioning logs, instrument printouts, reported results, records of quality control, proficiency testing records, and quality management reports (Quality indicators, Audits, Process improvement projects) are retained for three years.
 - 4.1.2 Method / instrument validation records are retained for the entire period of using the method / instrument and three years after discontinued.
 - 4.1.3 Maintenance records are retained for the life time of the instrument and three years after retirement.
 - 4.1.4 Employees identification records (signature, initials, identification code, and inclusive date of hiring) are retained for the entire period of hiring and three years after departure.
- 4.2 The implemented blood bank and transfusion services records retention system ensures the following:
 - 4.2.1 Inspection records (blood, blood components and critical supplies). Proficiency testing records and Quality management reports (Quality Indicators, Audits, and Process Improvement Projects) are retained for five years.
 - 4.2.2 Whole blood collection, aphaeresis collection, therapeutic phlebotomy, therapeutic aphaeresis, component preparation, component modification, quality control, and normal pre-transfusion testing records are retained for ten years.
 - 4.2.3 Donation history, donor testing, donor notification, deferred donors, final deposition of blood / blood components and look back records are retained permanently.
 - 4.2.4 Abnormal patients testing records (records of patients with antibodies, transfusion reactions, or special requirements), patient's transfusion history, transfusion reaction, and transfusion transmitted diseases investigation records are retained permanently.
- 4.3 Discontinued (retired) blood bank and transfusion controlled documents are retained for five years after the retirement date.
- 4.4 Discontinued (retired) general laboratory controlled documents are retained for three years after the retirement date.

Records Retention Storage Guidelines

Section	Records	Retention Period
General Laboratory	Laboratory test request forms, specimen accessioning logs, instrument printouts, reported results, records of quality control, proficiency testing records and quality management reports (quality indicators, audits, process improvement projects)	Retained for 3 years.
	Method/instrument validation records.	Retained for the entire period of using the method/instrument and 3 years after discontinued.
	Maintenance records.	Retained for the life time of the instrument and 3 years after retirement.
	Employee identification records (signature, initials, identification code and inclusive dates of hiring).	Retained for the entire period of hiring and 3 years after departure.
Blood Bank	Inspection records (blood, blood components and critical supplies), proficiency testing records and quality management reports (quality indicators, audits, process improvement projects).	Retained for 5 years.
	Whole blood collection, aphaeresis collection, therapeutic phlebotomy, therapeutic aphaeresis, component preparation, component modification, quality control and normal pre-transfusion testing records.	Retained for 10 years.
	Donation history, donor testing, donor notification, deferred donors, final disposition of blood/blood components and look back records.	Retained permanently.
	Abnormal patients testing records (records of patients with antibodies, transfusion reactions or special requirements), patient's transfusion history, transfusion reaction and transfusion transmitted diseases investigation records.	Retained permanently.
Histopathology	Surgical pathology reports, outside consultation reports.	Retained for 10 years.

4.5.1 Records shall be stored/maintained in a manner to allow retrieval when necessary.
 4.5.2 Boxes will be labelled with sections, type of record, inclusive dates of records and discard date.

4.5.3 In order to avoid congestion in the record storage area, every six months sections will make arrangements to discard records from the area for incineration.

5. MATERIAL AND EQUIPMENT:

5.1 N/A

6. RESPONSIBILITIES:

- 6.1 Laboratory Director
- 6.2 Chief Laboratory Technician
- 6.3 Laboratory Quality Assurance Officer
- 6.4 Section Heads and Senior Technologist of all sections of the laboratory department

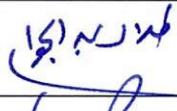
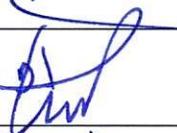
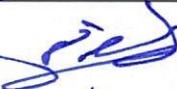
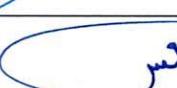
7. APPENDICES:

7.1 N/A

8. REFERENCES:

- 8.1 Guidelines for Good Clinical Laboratory Practices, ICMR, New Delhi, 2008.
- 8.2 Quality management system: qualifying, selecting, and evaluating a Referral laboratory; approved guideline -2ed.

9. APPROVALS:

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