Medical Laboratory Science Council of Nigeria

Guideline on Documents and Records Retention

Plot 1166, Muhammad N. Umar lane,
Durumi Phase II,
Garki, Abuja
Email – info@mlscn.gov.ng
Website – www.mlscn.gov.ng

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Policy Statement	The MLSCN Guidelines on Document and Records Retention refers to the retention and destruction of documents and records both in hard copy and electronic media. The purposes of this guideline includes the following: I. To promote the practice of retention and maintenance of Documents and Records necessary for proper laboratory function and in compliance with applicable national legal requirements and Medical Laboratory – Requirements for Quality and Competence. ISO 15189: 2012 (E), 17025 and 17043. II. To provide guidance on retrieval and access for documents and records. III. To provide guidance on the disposal of documents and records which no longer need to be retained. It may be appropriate for laboratories to retain records and/or materials for a longer period of time when required for patient care, education, quality improvement, or for sundry needs.

ACRONYMS

EQA	- External Quality Assurance
ISO	- International Organization for Standardization

DEFINITION TERMS

Documents include written policies, processes and procedures, and provide a framework for the quality system. They need to be updated and maintained.

Records include information captured in the process of performing and reporting a laboratory test. This information is permanent and does not require updating.

Worksheets Documentation to allow full traceability of all blood components, whether used or discarded.

Current something generally or commonly in use. That which is in general circulation or a matter of common knowledge or acceptance.

	DOCUMENT AND RECORD TYPE	RETENTION TIME (MIN)	REFERENCE/REMARKS
A.	**Documents, electronic and paper records**		
	Request forms	3 years (unless otherwise stated)	
	Medical laboratory register (Patient/Specimen)	30 years	
	Daily work logs (day books and electronic equivalents) and other records of specimens received by a laboratory	5 years	
	Mortuary registers	30 years	
	Current standard operating procedures (SOP)	2 years	
	Worksheets	1 year	
	Medical Laboratory bench books	10 years	
	Medical laboratory results register	30 years (unless otherwise stated)	
	Duplicates of patients test reports	7 years (unless otherwise stated)	
	Chemical Pathological reports (Neonatal screening and in-born error of metabolism)	25 years	
	Haematological reports (Bone marrow, Haemoglobin analysis, Special coagulation tests-e.g. factors, platelets assay etc, Special tests- e.g. Osmotic fragility, Sickling, Ham's, Sucrose lysis tests, immuno-phenotyping)	20 years	
	Records of result communication	1 year	
	Records of telephoned or faxed reports	5 years	
	Report copies (physical or electronic, print-outs)	3 years	

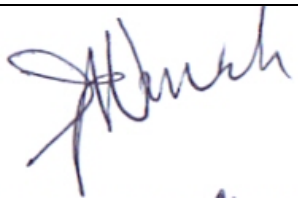
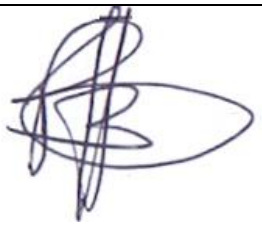
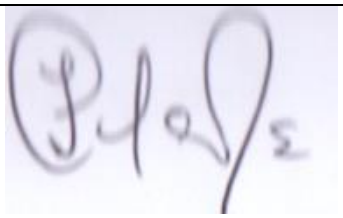
	Correspondence on patients	30 years	
	Reportable Infectious Diseases Reports	10 years	
	Point-of-care test data	7 years or lifetime of the instrument (whichever is longer)	ISO 17025 (point-of-care testing)
	Bound copies of reports and records (if made)	30 years	
	Records of Surveillance communications	10 years	
	Record of ethical approvals for research	5 years	
	Medical Laboratory archive and museum materials	20 years	
	Photographic records	30 years	
	Batch-to-batch verification records	5 years	
	Internal quality control records	5 years	
	External quality assessment records	5 years	ISO 17043 (proficiency testing)
	Accreditation documents and records of inspections	5 years	ISO 15189
	Temperature records for refrigerators, freezers, water-baths, incubators, environmental monitoring etc	2 years	
	Equipment Calibration Records-e.g. Thermometers, Balances, Pipettes etc)	2 years	
	Equipment maintenance logs	Life span of equipment plus 3 years after.	
	Records of daily, weekly and monthly maintenance	1 year	
	Records of service inspections and instrument maintenance	Lifetime of instrument plus 4 years	
	Records relevant to production of diagnostic products or equipment	5 years	

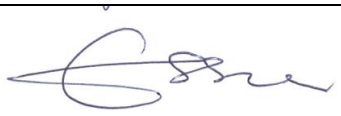
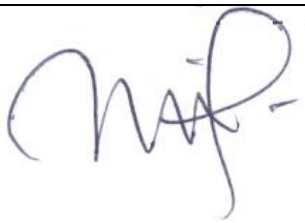
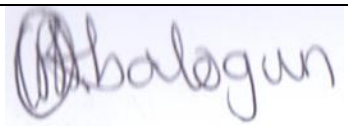
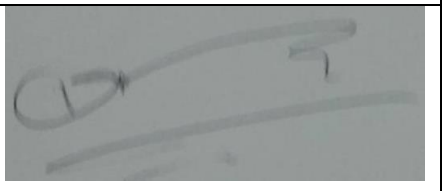
	Records of assay validation and verification	5 years	
	Discontinued laboratory methods/procedures (SOP, Manuals)	3 years after discontinuation	
	Research data		
	Records relating to cell/tissue transplantation	30 years	
	Records relating to semen, spermatozoa, oocytes and tissues for fertility assessment and use in assisted reproduction	30 years	
B.	**Documents and records for transfusion laboratories**		
	Documents and records		
	Request forms for grouping, antibody screening	10 years	
	Request forms for cross-matching and transfusion	20 years	
	Results of grouping, antibody screening and other blood transfusion-related tests	20 years	
	Medical laboratory records of blood donations and administration of blood and blood products	20 years	
	Records of indefinitely deferred donors, permanently deferred donors, or donors placed under surveillance for the recipient's protection (e.g., those donors that are hepatitis B core positive once, donors implicated in a hepatitis positive recipient)	Indefinite	
	Transfusion results and report duplicates for children	Until child reaches 25 years	

	Blood Bank Register, blood component audit trail and fates	20 years	
	Blood bank refrigerator and freezer charts	2 years	
	Records of Incidences and occurrences	5 years	
	Annual reports for transfusion laboratory services	10 years	
C.	**Documents and records for Molecular Diagnosis and Genetic analysis**		
	Request forms for Genetics (Human Testing Services)	Indefinite	
	Results and reports duplicates for Genetics (Human Testing Services)	Indefinite	
	Results and reports associated with analysis and interpretations of molecular diagnostic tests	30 years	
D.	**Quality Improvement Records**		
	Management Review Records	5 years	
	Training, Qualifications and Competency	3 years after last day of employment	
	Signature/ID Traceability	3 years after last day of employment	
	Duty Roster	2 years	
	Records of complains, suggestions and feedback	5 years	
	Software Application Validation Records	Life of instrument plus 2 years	
	Supplier Qualification Records	5 years	
	Specimen referral register	5 years	
	Referral Lab Arrangements and Contracts	Duration of Contract plus 2 years after	
	Specimen rejection register	1 year	
	Records of retrieval and access	Indefinite	

	Records of disposal of documents and records	Indefinite	
	Retention of documents and records of external quality assessment		
	Records by EQA providers	1 year	
	Records of Participation in EQA	5 years	
	Medicolegal documents and records	Indefinite	
	Documentations and records for teaching	5 years	
	Research data and records	1 year after publication of findings	

Contributors

S/N	Participant Name	Organization	Signature
1	ERHABOR, Tosan	Medical Laboratory Science Council of Nigeria	
2	AZEEZ, M. M.	Medical Laboratory Science Council of Nigeria	
3	UDO, Stella N.	Medical Laboratory Science Council of Nigeria	
4	NWOKAH, Easter G.	Rivers State University, Port Harcourt	
5	BARDE, Joshua B.	NEQAL Laboratory/ Medical Laboratory Science Council of Nigeria	
6	ADEOYE, Felix (Col.)	HIFASS	
7	UCHUNO, Gregory	Medical Laboratory Science Council of Nigeria	

8	AIKPITANYI- IDUITUA, G. A.	Medical Laboratory Science Council of Nigeria	
9	RUBAINU, Manason G.	Peak Medical Laboratories Ltd.	
10	ESSIEN, Victor	Medical Laboratory Science Council of Nigeria	
11	OFFUTALU, Paulinus N.	PHIVDS Laboratory, Medical Laboratory Science Council of Nigeria	
12	IFEANYI, CASMIR I. C. (Dr.)	University of Abuja	
13	IBANG, Livinus	Nigerian Biological Safety Association (NIBSA)	
14	BALAGUN. Oyebimpe	Institute of Human Virology, Nigerian	
15	ELENDU, Humphrey Ndubueze	Medical Laboratory Science Council of Nigeria	
16	AKINWALE, Abayomi Air Cdre (Rtd.)	USDOD Nigeria	

17	Tubi Abiola	NTBLCP	

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