National Department of Health

Title: Required retention durations for records, documents and specimens

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Developed by:	**R Cole (PPTC), J Ferguson**
Reviewed by:	**S Mabone**
Authorized by:	**W Porau**
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Version	Date issued	Changes
A	5/7/22	New document

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NB. Printed copies of this document for local laboratory use require endorsement on the front page and recording on the Printed Document Logsheet.

1. Purpose & Scope

This SOP defines the required retention durations for records, quality documents and patient specimens.

It has been developed with permission from a model document provided by the Pacific Pathology Training College.

2. Principle & Clinical application

Retention of records and documents is an essential part of quality management, allowing retrospective review of data, compliance and practice.

Retention of key specimens and materials/isolates derived from laboratory analyses allows for retrospective reassessment / re-testing of specimens and provides an historical archive that is extremely valuable for future research.

3. Responsibilities

Role	Responsibility
Lab bench scientist/ technician	Awareness of this SOP Compliance with filing of records, specimens and derived materials
Head of section/ laboratory manager	Develops the logistics and storage system required to comply with this SOP
Quality officer/manager	Ensures that all staff are aware of this SOP and have signed the read acknowledgement sheet. Oversees compliance and provides reminders to staff at staff meeting

4. Specimen

Various as per Table below.

5. Equipment & Materials

- Storage buckets/trays for fridges
- Slide stores
- Storage vials for microbiological isolates
- Other storage equipment as required

6. Procedure

The Table below specifies the minimum retention times.

6.1 Test records

- All records must be tidy and legible and include sufficient information so that they may be readily interpreted by staff other than those responsible for their generation.
- Corrections or amendments to test records must be done by crossing out the data in a manner that is traceable and obvious. Initials and authorisation must be shown.
- The use of correction tape or sticky labels to cover amendments to test data is not permitted.

6.2 How Records are Stored:

- The majority of paper records are retained in cardboard boxes, filing systems or Hard copy exercise books, to be found in respective areas of the laboratory.
- Electronic copies, scanned request forms, test data, QC records and quality documentation for the Laboratory are all acceptable forms of retained records to supplement hard copies.
- Electronic records in LIMS are retained from the day the LIMS was created indefinitely. The LIMS needs to show that records are backed up regularly and that data cannot be tampered with or erased.

6.3 Security information

- It is the responsibility of all laboratory staff members to ensure no unauthorised persons can obtain information from the computer system or laboratory records.

6.4 Confidential paper

- Confidential paper records are either shredded on-site prior to disposal or sent to a commercial contractor for destruction.

Table: Type of Records, Documents, Specimens and Minimum Retention Periods

Record Type	Record File	Minimum Retention
Personnel records	Job description, training and competency records. HR files.	Period of employment + 4 years
ll quality control records including reagent QC sheets, kit QC, pipette calibration, AST QC weekly records, equipment performance & validation records	Include summaries with management review	4 years
All Quality Management system records & documentation	Quality Manual policies LQMS records, audits & reviews Complaints.	4 years
Laboratory methods and SOPs	Section SOP manuals	4 years
Equipment maintenance	Maintenance records, evaluations.	Life of equipment + 4 years
Request forms, lab. records of analysis & calculations *	Scanned images are alternative to original documents.	4 years
All diagnostic reports & results		7 years for adults 7 years from the age of majority (18 years) for minors
Employee incident or accident records		7 years after last date of action
All specimens, unless otherwise department specified	**Store at 2-8°degC** **Daily buckets required**	**7 days from receiving specimen**
Haematology	a. Blood films - significant	1 year
	b. Not clinically significant	1 month
	c. Blood samples	7 days; note that repeat testing not reliable after 2 days
	d. Special Plasma Coagulation	1 month at -20°degC
	e. BM slides & reports	20 years
Blood Transfusion and serology	a. Lab records of all Immuno-haematology testing	20 years
	b. Records of blood products received & issued.	20 years

Record Type	Record File	Minimum Retention
	c. BS forms & worksheets	20 years
	d. infectious diseases serum sample including antenatal (positive or negative)	12 months
Clinical Biochemistry	Therapeutic drug levels	1 month
Microbiology	a. CSF/Aspirates/Sterile sites	1 month
	b. Urine specimens	1 day
	c. Significant isolates from blood, CSF and defined AMR isolates	1 year (indefinite preferred) at -70°degC
	d. Other significant isolates from other sites (non-AMR)	1 month at -20°degC
	e. Contaminant blood isolates	2 weeks (store positive BACTEC bottles 20°degC)
	f. Slides – Grams, other stains	1 month
	g. EQA isolates, EQA records and reviews	4 years
	g. AFB slides	6 weeks
	g. PCR (nucleic acid) samples	1 month
Cytology	a. Gynaecological (cervical) slides b. Non-gynae cytology/FNA/Cell blocks c. Specimens in liquid based fixative d. Digital images, pap screen images	10 years 10 years 1 month 6 years
Anatomical Pathology	a. Reports & records b. Slides -fixed tissue in medium c. Fixed tissue by fluorescence FISH d. Blocks in paraffin wax e. Frozen section	10 years 10 years 6 months 10 years 10 years

***** Availability of storage space within the hospital facilities is a major factor in determining the retention time for high volume items such as Requisition forms (Hard copy). A minimum of 48 months is dependent on the practical space limitations. Scanned electronic copies are a favourable alternative.

7. **Results Recording - not applicable**
8. **Interpretation - not applicable**
9. **Safety - not applicable**

10. Related documents – available from https://path-png.org/lqm-associated-documents/

Bacterial Isolate Preparation for Storage and or Transport	G_90_SOP_5
Bacterial isolate Referral List	G_90_J_10

11. References

- Australian NPAAC, National Pathology Accreditation Advisory Council (Australia) 2022, 9th Edition Guidelines on retention of Laboratory Records and Diagnostic Material.
- NZS 8153:2002 New Zealand Standard for Retention of Health Records.
- Retention of Health Information Guidelines 1996, SR 1996/343.