AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

Tier 3B document

Requirements for the retention of laboratory records and diagnostic material

Ninth Edition 2022

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Contents

National Pathology Accreditation Advisory Council

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to consider and make recommendations to the Australian, state and territory governments on matters related to the accreditation of pathology laboratories and the introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia. A function of NPAAC is to formulate standards and initiate and promote education programs about pathology tests.

Publications produced by NPAAC are issued as accreditation material to provide guidance to laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a risk to public health and patient safety.

Australian Commission on Safety and Quality in Health Care

The Australian Commission on Safety and Quality in Health Care (the Commission) leads and coordinates national improvements in health care safety and quality. The Commission works in partnership with patients, carers, clinicians, the Australian state and territory health systems, the private sector, managers, healthcare organisations, colleges and professional organisations to achieve a safe, high-quality and sustainable health system.

The Commission's statutory functions include formulating model national schemes that provide for the accreditation of organisations that provide health care services and relate to healthcare safety and quality matters.

The Commission is responsible for the administration of the National Pathology Accreditation Scheme on behalf of the Australian Government Department of Health (the Department). The Department retains responsibility for the regulation and funding of pathology in Australia.

Scope

The *Requirements for the retention of laboratory records and diagnostic material (Ninth Edition 2022)* is a Tier 3B NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for medical pathology services*. The latter is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

Whilst there must be adherence to all the Requirements in the Tier 2 document, reference to specific Standards in that document are provided for assistance under the headings in this document.

The *Requirements for the retention of laboratory records and diagnostic material* represents the minimum standards for retention of laboratory records and materials. These principles are important for medical pathology services. Individual laboratories may choose to exceed these minimum requirements based on local circumstances and historical practice.

This document does not address tissue banking, biobanking or issues related to research records and specimens in research laboratories.

Abbreviations

Abbreviation	Description
AS	Australian Standard
ISO	International Organization for Standardization
NPAAC	National Pathology Accreditation Advisory Council
NATA	National Association of Testing Authorities, Australia
NIP	Non-invasive Prenatal Testing
TGA	Therapeutic Goods Administration

Definitions

Term	Definition
Requirements for medical pathology services (RMPS)	means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

Introduction

Pathology reports form part of the patient's medical record, and may also be retained in, or remain accessible from, the laboratory information system. In addition, laboratories are required to maintain a number of records that substantiate the validity of testing done for the production of results for patient records.

Retaining specimens has two primary purposes: to ensure there is a physical audit trail, in case the integrity or identification of the specimen needs to be established; and to allow additional testing to be done on the original specimen, if required. In some cases, the original specimen may be consumed, exhausted or be otherwise unsuitable for any additional testing; however, retention is still required for audit and traceability purposes.

If a specimen subject to retention requirements is requested by another laboratory (e.g. for a second opinion or additional testing), both original and reference laboratories have an obligation to track the location of the specimen and ensure its safe return to the source laboratory.

The *Requirements for the retention of laboratory records and diagnostic material* outlines the minimum best practice standards for retention of laboratory records and materials. These principles have been developed with a risk-based approach and are important for medical pathology services to assure they provide high quality pathology services.

The overarching priority in the development of NPAAC Standards is patient welfare. However in relation to the issue of retention of specimens and laboratory records, a balance needs to be achieved between the possible requirement to retrieve materials to inform health decisions for a patient and/or their family (clinical utility), and issues related to prolonged storage. Material with implications for the long-term health of an individual or their family members (such as records relating to germline genetic testing) may be required to be stored for longer.

Representation has been made to NPAAC by various advocacy groups that are particularly concerned at the reduction in minimum storage times for histology blocks from adult patients from 20 years to 10 years in the previous version of the *Requirement for the retention of laboratory records and diagnostic material (Sixth Edition 2013)*. The issue has been considered by the Drafting Committee, with input sought from professional groups, researchers and consumer representatives, and a decision has been made to not reverse the previous reduction in minimum storage times for histology specimens from adults. The reasoning behind this decision is as follows:

- This NPAAC Standard relates to minimum storage times for routine specimens; individual laboratories may choose to exceed these storage times if the capacity to do so and clinical justification exists. It should be noted that the Standard has not altered the requirement to retain histology specimens from a paediatric patient at least until the age of 25 (majority plus 7 years) or until the minimum period has elapsed (whichever is greater), thus for practical reasons, laboratories may choose to retain all specimens as if they were of paediatric origin.

- The Standard does not address issues relating to research laboratories or Tissue Banking, which are covered by other documents.[1,2] Tissue specimens that may have been sub optimally fixed, processed or stored, and that lack detailed clinical and follow-up information are of limited value as research material.[3]

- Despite recent advances in the ability to extract meaningful genetic information from archival tissue specimens through the use of using next generation sequencing techniques, similar techniques have highlighted tumour heterogeneity and clonal evolution during tumour progression. Testing of an archival specimen (although theoretically possible) is not necessarily a reliable predictor of the therapeutic response of disease recurrence, which in nearly all cases would be amenable to biopsy for accurate biomarker assessment and individualised treatment planning. Therefore, assessment of archival tumour material becomes largely a matter of academic interest rather than clinical utility, and the value of comparing previous with current tumour samples in very occasional cases must be weighed against the impost of retaining all adult histology samples for prolonged periods.

- Triage of cases for prolonged retention on the basis of diagnosis alone cannot be justified; the requirement for review and retesting is not limited to tumour samples, and indeed, in very antiquated samples, a request for retrieval is more likely to be related to other indications such as identity/paternity testing.

With the introduction of NPAAC *Requirements for use of digital images as an alternative to direct microscopy*, the issue of retention of high-resolution digital images as opposed to glass slides has been considered as a minor amendment to this Retention Standard. It has been determined that if a diagnosis was made on glass slides, the slide should be retained for the minimum retention period (currently 10 years for an adult patient). If the diagnosis was made on a digital image, an accessible high-resolution image must be retained for at least the equivalent time period; the minimum retention period for the slide from which the image was digitised has been reduced to 4 years. If a case has been used to validate digital imaging technology within a laboratory, comparing diagnoses made on glass slide/s and digitised images, the slide/s should be retained in accordance with minimum slide retention requirements.

It should be noted that advances in sequencing technologies are such that molecular diagnostics can be performed on tissue retrieved from glass slides which represent a “specimen of last resort” when the block has cut out. Loss of this resource, as expanding numbers of tests are required on increasingly smaller biopsies, may negatively affect patient care.

The Standards also address requirements for the retention of digital images or graphical output integral to diagnosis. These include scatter plots used in flow cytometric analysis, FISH images, histological images subject to image analysis and tiled annotated images from semi-automated cervical cytology screening. The slightly longer retention time for the latter relates to the 5 year screening interval for the new National Cervical Screening Program. It is not intended that this requirement apply to the graphical output of routine haematology autoanalysers.

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[1] *Therapeutic Goods (Manufacturing Principles) Determination No. 1 of 2013*. Available from: https://www.legislation.gov.au/Details/F2017C00967

[2] *Therapeutic Goods Act 1989* (Cth) s 10 *Therapeutic Goods Order No. 8*. Available from: https://www.legislation.gov.au/Details/F2013L00854

[3] Grizzle WE, Bell WC, Section KC. Issues in collecting, processing and storing human tissues and associated information to support biomedical research. Cancer Biomarkers. 2010;9(1–6):531–549. Available from: doi:10.3233/CBM-2011-0183

These Requirements do not override the minimum retention periods mandated by commercial contracts, agreements or jurisdictional requirements governing retention of records or specimens. Laboratories should have well documented procedures for ensuring that the longer period of retention is observed in such circumstances.

In addition, these Requirements do not stipulate detailed requirements for disposal of specimens, however this should be undertaken in accordance with relevant State and Territory legislation.

Guidance is provided on returning specimens to patients upon request (**Appendix A**), which once again must be undertaken in accordance with relevant State and Territory legislation, particularly as it pertains to health and safety issues. A summary of current legislation relevant to retention and disposal of laboratory specimens and records is provided in **Appendix C**.

These Requirements are intended to serve as minimum Standards in the accreditation process and have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization including:

AS ISO 15189 *Medical laboratories—Requirements for quality and competence*.

These Requirements should be read within the national pathology accreditation framework in conjunction with the current versions of the following NPAAC documents:

All Tier 2 and Tier 3 Documents

Tier 4 Documents

- *Requirements for laboratories reporting tests for the National Cervical Screening Program*

In each section of this document, points deemed important for practice are identified as 'Standards' or 'Commentaries'.

- A Standard is the minimum requirement for a procedure, method, staffing resource or laboratory facility that is required before a laboratory can attain and maintain accreditation – Standards are printed in bold type and prefaced with an 'S' (e.g. **S2.2**). The word **'must'** in each standard within this document indicates a mandatory requirement for pathology practice.

- A Commentary is provided to give clarification to the Standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a Standard or not. Note that when comments are expanding on a Standard or referring to other legislation, they assume the same status and importance as the Standards to which they are attached. As a general rule, where a Commentary contains the word **'must'** then that Commentary is considered to be **normative**.

Please note that any appendices attached to this document may be either **normative** or **informative** and should be considered to be an integral part of this document.

Please note that all NPAAC documents can be accessed at Department of Health.

From 1 July 2021, the Australian Commission on Safety and Quality in Health Care (the Commission) is responsible for administering the National Pathology Accreditation Scheme and supporting NPAAC and its subcommittees in their work to develop and maintain the pathology standards.

Comments from users are appreciated and can be directed to:

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1. Conditions of specimen storage

> Refer to Standard 7 in *Requirements for medical pathology services*

S1.1 Specimens **must** be stored under appropriate storage conditions that permit reliable retrieval.

S1.2 Laboratories **must** demonstrate storage conditions are fit for purpose and retain supporting documentation, including records of storage temperatures.

C1.2(i) Recommended general storage temperatures are as follows:

(a) Refrigeration 2 to 8°C

(b) Freezer −20°C or lower

(c) Deep freezer −70°C or lower.

C1.2(ii) Some types of refrigerators and freezers involve “freeze/thaw” cycles as part of their auto-defrost features. Specimens stored in these types of refrigerators/freezers should not be intended for later testing of analytes that are degraded by such freeze/thaw cycles.

S1.3 Storage of blood and blood products **must** be in accordance with *AS 3864 Medical Refrigeration Equipment – for the storage of blood and blood products*.[4]

S1.4 Specimen refrigerators and freezers **must** not be used for storage of food or drink.

S1.5 Use of specimen refrigerators and freezers for storage of tissue specimens intended for transplantation or use as a therapeutic device requires that the laboratory **must** comply with the regulatory requirements of the TGA[5] and other relevant regulatory codes.

[4] SAI Global. Australian Standard AS3684: Medical refrigeration equipment – For the storage of blood and blood products. Sydney (AU): Standards Australia; 1997

[5] Therapeutic Goods Administration. Australian Regulatory Guidelines for Biologicals (ARGB) [Internet]. Canberra (AU): TGA; 2017 [viewed 17 January 2018]. Available from: https://www.tga.gov.au/publication/australian-regulatory-guidelines-biologicals-argb

2. Minimum retention times

> Refer to Standard 8 in *Requirements for medical pathology services*

Discipline variations

While preparing this document, a common set of requirements for retention across all disciplines was acknowledged as an ideal; however, there are valid practical reasons for some discipline-to-discipline variations. Every effort has been made to minimise these and where they exist, ensure consistency of approach to comparable situations in the different disciplines.

The minimum duration of retention of records relating to laboratory equipment has been adjusted in consideration of a number of issues, such as the recent changes to the NATA surveillance cycle from 3 to 4 years and an additional margin for records relating to Quality Assurance.

Table 1: General minimum retention times

	Record/material	Minimum retention time
1.1	Personnel records	Period of employment + 4 years
1.2	All quality control, quality assurance and quality management records	4 years
1.3	Equipment maintenance	Life of equipment + 4 years
1.4	Laboratory methods/procedures (manuals)	4 years[EN1]
1.5	Referring doctor's request, laboratory records such as records of analysis, calculations and observations from which the result is derived	4 years[EN2]
1.6	Digital images or graphical output used in diagnosis[EN3]	4 years

[EN1] The retention time of 4 years refers to the circumstance where a laboratory method/procedure/in-vitro diagnostic (IVD) device has been superseded or replaced by a new and unrelated methodology. However, where a laboratory method/procedure/IVD has simply been modified, the full history of all earlier versions/modifications of that particular IVD must continue to be retained.

[EN2] Storage of scanned facsimile images and associated records of these intermediary documents is a satisfactory alternative to retention of the original document. For those areas where material is retained for longer than 4 years, the laboratory may wish to consider retaining the associated records for a corresponding period. See also **Appendix B** for electronic storage requirements of pathology request forms. Although there is no minimum retention time for paper request forms after validated scanning has been performed, it would be prudent to retain them for as longs as is necessary to exclude the possibility of scanning failure.

[EN3] Except where specific guidelines for image retention are made in the following Tables (see EN8).

	Record/material	Minimum retention time
1.7	All specimens, unless otherwise specified under the separate disciplines given in Tables 2 to 11	7 days from date of receipt or until 2 days after the final report is issued (whichever date is later)
1.8	Copy of original report, or ability to reprint the information content of an original report unless a longer period is specified in Tables 2 to 11	7 years for adults 7 years from the age of majority for minors

Table 2: Minimum retention time for anatomical pathology

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 2**.

	Record/material	Minimum retention time
2.1	Copy of original report, or ability to reprint the information content of an original report	10 years or 7 years from the age of majority for minors (whichever is the greater)
2.2	Slides:	
	(i) Sections of fixed tissue preserved in mounting medium	10 years (where the diagnosis is made on the slide); otherwise 4 years if the diagnosis is made on a digitized image
	(ii) Sections of fixed tissue assessed by FISH (fluorescence in situ hybridization	6 months
	(iii) Sections of unstained, fixed tissue not in permanent mounting medium (unstained spares)	1 month
	(iv) Sections of unfixed tissue not in permanent mounting medium (including immunofluorescence slides)	See General 1.7 in **Table 1**
2.3	Digital images used for diagnostic analysis	10 years (where diagnosis is made solely on the image); otherwise see General 1.6
2.4	Blocks: Tissue embedded in paraffin wax or any other permanent embedding medium, including for ultrastructural study	10 years[EN4]
2.5	Specimens for intra-operative frozen section diagnosis:	10 years[EN4]
	(i) The original sections used for diagnosis, preserved on slides in permanent mounting medium	
	(ii) Residual tissue from which the frozen sections were prepared, embedded in paraffin blocks	
	(iii) All other blocks of paraffin-embedded tissue from the same specimen/s from which tissue has been selected for frozen section examination	

[EN4] Where the report or specimen relates to a pediatric patient, the retention period for anatomical pathology and cytology specimens should be the greater of 10 years or 7 years from the age of maturity.

	Record/material	Minimum retention time
2.6	(i) Frozen tissue blocks, including specimens for immunofluorescence studies	1 month at −70°C or lower
2.7	(ii) Containers with no residual tissue	1 month from date of issue of report
	(iii) Unblocked wet tissue from specimens removed at surgery	1 month from date of issue of report
2.8	Non-coronial autopsy:	
	(i) Registers, report duplicate, blocks and slides, records of tissue and organ disposal	10 years
	(ii) Unblocked tissue from histological samples retained at autopsy, or	3 months from date of issue of report unless a limitation is imposed, such as the need to reunite retained specimens with the body before a funeral has been stipulated by next-of-kin
	(iii) Organs retained at autopsy with consent	

Table 3: Minimum retention times for chemical pathology

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified in **Table 3**.

	Record/material	Minimum retention time
3.1	Serum, plasma, other body fluid and tissue specimens	See General 1.7 in **Table 1**

Table 4: Minimum retention times for cytology

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 4**.

	Record/material	Minimum retention time
4.1	Copy of original report, or ability to reprint the information content of an original report	10 years or 7 years from the age of majority for minors (whichever is the greater)
4.2	Exfoliative non-gynaecological cytology and fine needle aspiration (FNA) slides and cell blocks	10 years[EN5]
4.3	Gynaecological (cervical) cytology slides	10 years
4.4	Residual specimens of sputum, urine and other body fluids following preparation of cytology slides	See General 1.7 in **Table 1**
4.5	Specimens received in liquid-based fixative	1 month[EN6]
4.6	Digital images used for diagnostic analysis e.g. semi-automated Thin Prep screening images	6 years

[EN5] Where the report or specimen relates to a pediatric patient, the retention period for anatomical pathology and cytology specimens should be the greater of 10 years or 7 years from the age of maturity.
[EN6] Unless otherwise stated in the *Requirements for laboratories reporting tests for the National Cervical Screening Program*.

Table 5: Minimum retention times for forensic pathology

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 5**.

	Record/material	Minimum retention time
5.1	Forensic and medico-legal autopsy: (i) Registers, report duplicate, blocks and slides, records of tissue and organ disposal, gross photographs, or (ii) Unblocked tissue from histological samples retained at autopsy, or (iii) Organs retained at autopsy with consent, or (iv) Body fluids and tissues for toxicology, or (v) Representative tissue suitable for DNA analysis	In accordance with jurisdictional requirements or indefinitely if not specified
5.2	Clinical Forensic Medicine Clinical Forensic Medicine materials including, but not limited to: biological samples for toxicology, body swabs and slides, foreign material and trace evidence, biological evidence, fingernails, representative/reference DNA samples, clothing and photographs	In accordance with jurisdictional requirements or indefinitely if not specified

Table 6: Minimum retention times for genetics (including biochemical genetics, cytogenetics, molecular genetics and newborn screening)

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 6**.

	Record/material	Minimum retention time
6.1	Copy of original report, or ability to reprint the information content of an original report	
	(i) Constitutional genetic testing	100 years (effectively indefinite)
	(ii) Somatic genetic testing	10 years[EN7]
6.2	Cytogenetics:	
	(i) Analysis records/karyotypes/digital images including FISH images	4 years
	(ii) Stained microscope slides in permanent mounting medium	4 years
	(iii) Fixed chromosome cell suspension or FISH slides	6 months
	(iv) Original specimens and containers	1 month from date of issue of report
6.3	Cytogenetics/biochemical genetics/molecular genetics: Tissue cultures/cell culture lines	
	(i) Rare clinically significant variants	For indefinite cryopreservation
	(ii) Common clinically significant variants or clinically non-significant	As for General 1.7 in **Table 1**
6.4	Biochemical genetics: Specimens of plasma, serum and urine	
	(i) Original container	7 days
	(ii) Analytic aliquot	3 months after date of issue of report
6.5	Neonatal screening (dried blood spot):	
	(i) Specimen (Guthrie) cards	2 years
	(ii) Records	see Genetics 6.1 in **Table 6**
6.6	Molecular genetics: (i) Nucleic acid extracts for somatic or constitutive testing	3 months from date of issue of the report for an individual, or from completion of a family study where the proband's sample is required as a control, or from completion of testing; whichever of the three periods is the longest
	(ii) Nucleic acid extracts or frozen plasma for NIPT	12 months

[EN7] Where the report relates to a pediatric patient, the retention period should be the greater of 10 years or 7 years from the age of maturity.

	Record/material	Minimum retention time
6.7	Bioinformatic genetic data:	
	(i) Read data (e.g. FASTQ) or aligned reads (e.g. BAM)	4 years from date of issue of report
	(ii) Variant call files	10 years
	(iii) Microarray analysis files	4 years

Table 7: Minimum retention times for haematology

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 7**.

	Record/material	Minimum retention time
7.1	Blood films[EN8]	
	(i) Clinically significant	1 year
	(ii) Not clinically significant	1 month
7.2	Plasma for special haemostasis testing	1 month at −20°C or lower
7.3	Blood specimens, other than 7.1–7.2	As for General 1.7 for purpose of identification and traceability, noting that repeat testing may not be technically reliable after 2 days
7.4	Bone marrow, slides and reports	10 years for adults 7 years from the age of majority for minors
7.5	Flow cytometry	
	(i) Reports	10 years for adults 7 years from the age of majority for minors
	(ii) Graphical outputs used in diagnosis such as gated dot plots and histograms	see General 1.6 in **Table 1**

[EN8] This includes images created in the context of automated digital screening of blood films.

Table 8: Minimum retention times for immunohaematology (blood transfusion)

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 8**.

	Record/material	Minimum retention time
8.1	Laboratory records of blood products received and issued[EN9]	20 years
8.2	Laboratory records of all immunohaematology testing[EN9]	20 years

Table 9: Minimum retention times for immunology

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 9**.

	Record/material	Minimum retention time
9.1	Serum, plasma, other body fluid and tissue specimens	See General 1.7
9.2	Frozen tissue blocks, including specimens for immunofluorescence studies	1 month at −70°C or lower
9.3	Immunofluorescence slides	See General 1.7 in **Table 1**
9.4	Digital images used for diagnostic analysis	see General 1.6 in **Table 1**

[EN9] Should be done in accordance with the *Requirements for transfusion laboratory practice*.

Table 10: Minimum retention times for microbiology

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 10**.

	Record/material	Minimum retention time
10.1	Slides	
	(i) Wet preparations	Nil (discard)
	(ii) Immunofluorescence slides	7 days
	(iii) Gram stains	2 weeks
	(iv) Ziehl-Neelsen stains	6 weeks
	(v) Other stained slides	2 weeks
10.2	Isolates[EN10]	
	(i) Clinically significant[EN11]	5 days
	(ii) Not clinically significant	Discard
10.3	Serum/plasma for infectious disease serology	
	(i) All sera unless specified below	4 months
	(ii) Antenatal sera	12 months
	(iii) Reactive syphilis sera	12 months
	(iv) Source and recipient sera from body fluid exposure (needle-stick), where this has been notified to the laboratory	12 months
10.4	Urine specimen for microbiological examination	3 days from date of issue of report, under refrigeration
10.5	(i) Nucleic acid for diagnostic microbiological examination – extract or original specimen	1 month from date of issue of report[EN12]
	(ii) Nucleic acid for screening examination – extract or original specimen	1 month from date of issue of report[EN13]

[EN10] Unless addressed by the Security Sensitive Biological Agent (SSBA) legislation.
[EN11] Clinically significant isolate is considered to be all blood culture and sterile isolates, plus any cultured isolate which is reported by the laboratory as a potential pathogen (in contrast to contaminants and commensal flora).
[EN12] Except during the period of the COVID-19 pandemic where the retention period for both positive and negative COVID-19 test samples is reduced to one week after results are released. See also fact sheet on retention period for COVID-19 test samples on the Commission website.
[EN13] Unless otherwise stated in the *Requirements for laboratories reporting tests for the National Cervical Screening Program*.

Table 11: Minimum retention times for other material

Please refer to **Table 1:** General minimum retention times for both record and material retention times, unless otherwise specified below in **Table 11**.

	Record/material	Minimum retention time
11.1	Semen for fertility analysis	2–3 days from date of issue of report for purpose of identification and traceability noting that repeat testing may not be technically reliable after 1 day.
11.2	Cell therapy – tissue transplantation	Refer to relevant TGA regulations and NPAAC Requirements that may be applicable.
11.3	Flow cytometry on non-haematological samples (e.g. tissue, cerebrospinal fluid) – graphical outputs used in diagnosis, such as gated dot plots and histograms of other specimens	See General 1.6 in **Table 1**.

3. Tracking of referred and received specimens

Refer to Standard 9 in *Requirements for medical pathology services*

S3.1 Laboratories **must** have policies and procedures in place regarding the tracking of specimens which are referred into or out of the laboratory, for the purposes of traceability.

S3.2 Laboratories that refer a specimen with prolonged retention requirements to a second laboratory **must** document the release and return of the specimen.

C3.2(i) This requirement relates specifically to stained histological, cytological and bone marrow slides and/or blocks referred or requested for second opinion or additional testing.

C3.2(ii) Laboratories **must** not retain referred materials with prolonged retention requirements without the consent of the original/referring pathologist.

C3.2(iii) Laboratories that receive a referral specimen with prolonged retention requirements **must** ensure its safe and prompt return to the original laboratory at the completion of review or additional testing. This does not apply to spare slides or recut slides upon which additional testing was performed, which should normally be retained according to Guidelines above in the laboratory performing the additional testing.

S3.3 Laboratories performing additional review or testing on any referral specimen **must** provide a copy of any report to the original laboratory to ensure continuity of the medical record.

4. Disposal of specimens and records

Refer to Standard 8 in *Requirements for medical pathology services*

S4.1 Laboratories **must** dispose of specimens and patient records in accordance with relevant state/territory legislative requirements (refer to **Appendix C**).

C4.1(i) Documents with identifying patient details should be shredded or disposed of in another secure manner.

C4.1(ii) Any organs retained at autopsy with consent of next-of-kin, should be disposed of as outlined in the *National Code of Ethical Autopsy Practice*[6] unless otherwise stipulated by the next-of-kin.

S4.2 Laboratories **must** have a policy to address patient requests for returned specimens, including instructions for the disposal of specimens (refer to **Appendix A**).

[6] Australian Health Ministers' Advisory Council Subcommittee on Autopsy Practice. The National Code of Ethical Autopsy Practice. Adelaide (AU): Australian Government; 2002

5. Impact of amalgamation, mergers or change of ownership

Refer to Standard 3 and Standard 4 in *Requirements for medical pathology services*

S5.1 When pathology practices amalgamate or merge, the data from both systems **must** be maintained with integrity, and information from both systems must remain accessible.[7]

S5.2 Retention times for records and diagnostic materials outlined in this document **must** be maintained regardless of changes in ownership or governance of the laboratory.

C5.2(i) Retention times for records and diagnostic materials **must** be maintained regardless of changes in the information technology systems that result from such changes of ownership or governance.

[7] National Pathology Accreditation Advisory Council. Requirements for medical pathology services [Internet]. Canberra (AU): Australian Government Department of Health; 2018. Standard 4, Clinical Governance. Available from: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-medpathserv-2018

Appendix A — Returning a specimen or body part to a patient (Informative)

> Refer to Standard 1 in *Requirements for medical pathology services*

Returning a specimen to a patient or next-of-kin

Although a pathology practice may own the container in which a patient's specimen is held, in most jurisdictions it does not legally own the specimen itself. However, the laboratory must consider its duty of care to the patient before agreeing to release a specimen to the patient or next-of-kin. This involves confirming the identity of the applicant and assessing the reason for the applicant's request for an early release or return of the specimen and using this information to judge whether the request is reasonable. The laboratory must be particularly aware of the possibility of an unauthorised third party trying to obtain access to a patient's specimens (e.g. for paternity testing or other litigation). In rare cases, the laboratory may wish to seek legal advice about an unusual request.

In some jurisdictions (e.g. New South Wales), where the application is made on behalf of an Indigenous Australian, there is some legal extension of the concept of who can act as the agent for the patient, or in the case of a deceased person, for the next-of-kin.

If the specimens are returned to the patient, then Retention times are not applicable.

It should be noted that microbiological isolates derived from patient specimens do not fall under the *Human Tissue Act 1983* and are not considered to be the property of the patient.

These guidelines do not relate to the return of a specimen, organ, body part or tissue specimens removed in the context of coronial/forensic autopsy.

Returning a body part

A 'body part' may be a whole organ removed at autopsy or at surgery (e.g. kidney or uterus); however, at present most requests are for the return of a 'pre-viable fetus' for burial or cremation. A pre-viable fetus is a fetus that is too early in gestation for it to be classified as a stillbirth for which a special type of cause of death medical certificate must be issued. Such fetuses, under current definitions of a stillbirth, are of less than 20 weeks gestational age; however, in practice, determining exact gestational age between ~18 and ~22 weeks is difficult and generally done on the best available evidence from the features of the fetus and any clinical information about the pregnancy.

Jurisdictional regulations may constrain ownership of human tissue to prevent trading in tissues and organs for transplantation. Infectious agents may be transmitted by tissues (especially if unfixed), so the laboratory must comply with relevant regulations, and must be satisfied that the applicant will dispose of the fetus, organ or other body part lawfully and in a way that meets community standards.

The laboratory must maintain appropriate records of the return or disposal to the applicant of a fetus, organ or other body part, and must obtain a signed receipt from the applicant, which notes the above undertaking to dispose of the tissue lawfully.

Advice can be sought from the state/territory Public Health Authority.

Returning a processed specimen

The general principles outlined above for returning body parts also apply to returning processed specimens such as histopathology blocks or slides. However, because such specimens are processed tissues, the 'ownership' of the material is less clear. For this reason, although a laboratory is free to follow the above guidelines relating to a body part, it may prefer to be less flexible when responding to requests for returning processed specimens for unspecified purposes.

If the request for returning the material is to obtain a second opinion for a patient's care, the laboratory will normally comply. The patient's interests should be considered paramount, and permission not unreasonably refused. The laboratory may, however, require that the patient's consent be provided in writing, that the specimen is sent directly to the person providing the second opinion[8] and that, unless specifically agreed otherwise, all of the material is returned to the original laboratory after the second opinion has been provided, along with a copy of the second opinion.

[8] Royal College of Pathologists of Australasia. Provision of second opinions with particular reference to morphological examination [Internet]. Sydney (AU): RCPA; 2017. Available from: https://www.rcpa.edu.au/getattachment/7ed4de8f-d708-4dc4-9df3-f4ef17c97685/Provision-of-Second-and-Subsequent-Opinions-Histop.aspx

Appendix B — Notice of Information Technology (IT) Requirements under the Electronic Transactions Act 1999 for scanning and storage of referrals and requests (Normative)

1. Authority

1.1 This Notice is made pursuant to sections 9, 10, 11 and 12 of the *Electronic Transactions Act 1999*.

2. Scope

2.1 This Notice specifies Medicare Australia's information technology requirements (**Medicare Australia's IT requirements**) for electronic scanning and storage of certain referrals and requests[1].

3. Date of Effect

3.1 1 October 2009

4. Replaces

4.1 This Notice replaces the *Notice of Information Technology (IT) standards under the Electronic Transactions Act 1999 for electronic and paper:*

Referrals to Consultant Physicians or specialists

Requests and Confirmation of Requests for Pathology Services to Approved Pathology Practitioners

Requests for Diagnostic Imaging Services

which is repealed with effect from 30 September 2009.

5. Definitions

5.1 A 'request' means any request for diagnostic imaging or pathology Medicare Benefits Schedule items. Any reference to a 'request' for a Medical Pathology Service includes a confirmation of that request.

[1] The term 'request' includes 'combined requests and assignments.

5.2 A 'referral' means any referral for Medicare Benefits Schedule claimable items.

6. Scanning of paper referrals or requests for electronic storage

6.1 Clause 6 applies where a referral or request is required to be given to, or can be requested by, Medicare Australia and an image of a paper referral or request is scanned for electronic storage.

6.2 The scanning and storage system must ensure that:

(a) the scanned image is unaltered and unalterable from the moment scanning is finished;

(b) the date and time the image was converted to digital form be recorded; and

(c) the image be retrievable in a legible form.

7. Storage of electronic transmitted referrals or requests

7.1 Clause 7 applies where a referral or request is required to be given to, or can be requested by, Medicare Australia and the referral or request has been electronically transmitted and stored.

7.2 The storage system must ensure that:

(a) the store electronic transmission is unaltered and unalterable;

(b) the date and time the electronic transmission was received be recorded; and

(c) the stored electronic transmission be retrievable in a legible form.

8. Security and access

8.1 A system that electronically stores referrals or requests, whether scanned or electronically transmitted, must provide reasonable measures to prevent any loss, improper disclosure or destruction of the stored information.

Appendix C — Legislation relating to the retention and disposal of laboratory records and diagnostic materials (Informative)

This table is a summary of various relevant legislation that may affect retention requirements. The references in this table are extensive, but are not intended to be exhaustive. In all cases, the relevant jurisdictional legislation takes precedence over these Requirements in terms of mandating retention times different from those specified in these requirements. Readers are encouraged to review the current regulations available from the Federal Register of Legislation, noting that the legislation may be subject to amendment from time to time.

Jurisdiction	Legislation and Guidelines
New South Wales	*Health Practitioner Regulation (NSW) Regulation 2016* *Public Health Regulation 2012* *State Records Act 1998* Health Care Records – Documentation and Management (Policy Directive 2012), Document Number PD2012_069 *Human Tissue Act 1983*
Queensland	Queensland Health (Pathology Laboratory Records) Retention and Disposal Schedule 2006 *Coroner's Act 2003* *Transplantation and Anatomy Act 1979* *Public Records Act 2002*
Northern Territory	Northern Territory Governments Record Disposal Schedule, Medical Pathology Services, Department of Health (2017/8)
Australian Capital Territory	*Health Records (Privacy and Access) Act 1997* *Public Health Act 1997* *Medical Treatment (Health Directions) Act 2006* *Health Act 1933*
Victoria	*Health Services Act 1988* *Public Records Act 1973*
South Australia	*Freedom of Information Act 1991* *South Australian Health Commission Act 1976* *State Records Act 1997* *Transplantation and Anatomy Act 1983*

Jurisdiction	Legislation and Guidelines
Tasmania	*Anatomy Examinations Act 2006* *Health Act 1997* *Human Tissue Act 1985* *Public Health Act 1997*
Western Australia	Patient Information Retention and Disposal Schedule version 4, 2014 *State Records Act 2000*

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