NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS FOR THE RETENTION OF LABORATORY RECORDS AND DIAGNOSTIC MATERIAL

(Sixth Edition 2013)

NPAAC Tier 3B Document

Print ISBN: 978-1-74241-948-0

Online ISBN: 978-1-74241-949-7

Publications approval number: 10207

Paper-based publications

Internet sites

First published	1987
Second edition	1998
Third edition	2002
Fourth edition	2007 (formerly titled: *Retention of Laboratory Records and Diagnostic Material*)
Fifth edition	2009 reprinted with amendments
Sixth edition	2013 reprinted and reformatted to be read in conjunction with the *Requirements for Medical Pathology Services*

Australian Government Department of Health

Contents

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.

Scope

The *Requirements for the Retention of Laboratory Records and Diagnostic Material* 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 document *Requirements for the Retention of Laboratory Records and Diagnostic Material* represents the *minimum* standards for retention of records and materials. Individual Laboratories may choose to exceed these minimum requirements based on local circumstances and historical practice.

Abbreviations

AS	Australian Standard
ISO	International Organization for Standardization
NPAAC	National Pathology Accreditation Advisory Council
TGA	Therapeutic Goods Administration

Definitions

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. The standard headings are set out below – Standard 1 – Ethical Practice Standard 2 – Governance Standard 3 – Quality Management Standard 4 – Personnel Standard 5 – Facilities and Equipment A – Premises B – Equipment Standard 6 – Request-Test-Report Cycle A – Pre-Analytical B – Analytical C – Post-Analytical Standard 7 – Quality Assurance

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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 which 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.

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 version of the following NPAAC document:

Tier 2 Document

- *Requirements for Medical Pathology Services*

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.

The format of these Requirements currently remains substantially the same as the 5th Edition. It is anticipated that the Requirements will be presented in a more standardised form following the next document review.

The following information addresses specific areas relating to retention of Laboratory records and diagnostic material and is reproduced from that document.

NPAAC uses terms such as 'significant finding' or 'not clinically significant', while recognising that these terms can have different meanings to different people. The terms have been retained in these Standards, without attempt at definition. Similarly, some recommendations apply only if 'appropriate'. Interpretation of these terms is left to the professional judgement of the Laboratory supervisor, taking into account the intention and context of the terms as they are used here.

Please note that all NPAAC documents can be accessed at www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm.

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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Specific retention options for paediatric paraffin blocks, slides and reports

(Refer to Standard 1 in *Requirements for Medical Pathology Services)*

Earlier editions of these Standards proposed one retention time for adults and another for children, until the child reached the age of 25 (i.e. age of majority [18 years], plus seven years). In many cases, to comply with these Standards, all paraffin blocks, slides and reports had to be retained for the extended period, even though this may have exceeded reasonable requirements for non-paediatric paraffin blocks, slides and reports retention. The fourth edition of the retention requirements proposed a reduction to 10 years for anatomical pathology Specimens; however, note that the requirement for extended retention of *paediatric* paraffin blocks, slides and associated reports was *not* waived. Laboratories now have the option to devise a system to ensure that such paraffin blocks and slides are flagged at the time they are created so they are retained for more than the default minimum of 10 years at the time of disposal of non-retained Specimens.

Returning a Specimen to a patient

(Refer to Standard 1 in *Requirements for Medical Pathology Services)*

While 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.

The Laboratory must consider its duty of care to the patient before agreeing to release a Specimen. 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.

Returning a body part

(Refer to Standard 1 in *Requirements for Medical Pathology Services)*

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.

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

[*] 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 medical certificate of the cause of death 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.

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 also obtain a signed receipt from the applicant, which notes the above undertaking.

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.

Returning a processed Specimen

(Refer to Standard 1 in *Requirements for Medical Pathology Services)*

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, while 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, a Laboratory will normally comply. The Laboratory may, however, require that the patient's consent be provided in writing, agreement that the Specimen is sent directly to the person providing the second opinion, and that, unless specifically agreed otherwise, all of the material is returned to the original Laboratory after the second opinion has been provided.

Impact of amalgamation, mergers or change of ownership

(Refer to Standard 2 in *Requirements for Medical Pathology Services)*

When health care organisations or pathology practices amalgamate or merge, those involved must ensure that the integrity of both systems of documentation and record keeping is maintained. Information from both systems must remain accessible.

The retention times for records and diagnostic materials outlined in this document must be maintained regardless of changes of ownership or governance of the Laboratory. Similarly, the retention times for records and diagnostic materials must be maintained regardless of changes in information technology systems that result from such changes of ownership or governance.

Health service providers are responsible for retaining or providing storage for health records upon closure of their practice. Health service providers are also obliged to make health information available to another health service provider at the request of a patient, or where requested by an appropriately authorised health professional acting for, or on behalf of, the patient. Current relevant state and territory legislative requirements **must** be implemented.

Minimum retention times

(Refer to Standard 6 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.

Table 1 General minimum retention times

	Record/material	**Minimum retention time**
1.1	Personnel records	Period of employment + 3 years
1.2	All quality control and quality assurance records	3 years
1.3	Equipment maintenance	Life of equipment + 3 years
1.4	Laboratory methods/procedures (manuals)	3 years[‡]
1.5	Referring doctor's request, Laboratory records such as records of analysis, calculations and observations from which the result is derived	3 years[§]
1.6	All Specimens, unless otherwise specified under the separate disciplines given in the tables that follow	7 days from date of receipt or until 2 days after the date of the issued report (whichever date is later), under appropriate storage conditions and reliable retrieval †
1.7	Copy of original report, or ability to reprint the information content of an original report	7 years for adults 7 years from the age of majority for minors[**]

[‡] The retention time of 3 years refers to the circumstance where a 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.

[§] 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 3 years, the Laboratory may wish to consider retaining the associated records for a corresponding period. See also Appendices A & B for electronic storage requirements of pathology request forms.

†Appendix C is a guide to suggested storage temperatures.

[**] Where the report pertains to a Specimen collected from a paediatric patient, see page 3 indicating retention until the person reaches the age of 25, except for genetics, where the retention time is 100 years.

Table 2 Minimum retention times for anatomical pathology

Please refer to Table 1 (General minimum retention times) for both record and material retention times, unless otherwise specified below.

	Record/material	Minimum retention time
2.1	Slides: Sections of fixed tissue preserved in mounting medium Sections of unfixed tissue not in permanent mounting medium (including immunofluorescence slides)	 10 years[††] See General 1.6
2.2	Blocks of tissue embedded in paraffin wax or any other permanent embedding medium	10 years[††‡‡]
2.3	Specimens for intra-operative frozen section diagnosis: (i) The original section(s) used for diagnosis, preserved in permanent mounting medium (ii) Residual tissue from which the sections in (i) were prepared, embedded in paraffin (iii) All other blocks of paraffin-embedded tissue from the same Specimen or Specimens from which tissue has been selected for frozen section examination	10 years[8]
2.4	Frozen tissue blocks, including Specimen for immunofluorescence studies	1 month at -70°C or lower
2.5	(i) Containers with no residual tissue (ii) Unblocked tissue from Specimens removed at surgery (iii) Unblocked tissue from Specimens retained at autopsy	1 month 1 month from date of issue of Specimen report 3 months after autopsy 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
2.6	Autopsy — registers, report duplicate, blocks and slides, records of tissue and organ disposal	10 years for autopsy other than forensic or other medico-legal autopsy
2.7	Forensic and medico-legal	In accordance with jurisdiction requirement or 20 years if not specified

[††] Where the report pertains to a Specimen collected from a paediatric patient, see page 2 indicating retention until the person reaches the age of 25, except for genetics, where the retention time is 100 years.

[‡‡] Where the report pertains to a Specimen collected from a paediatric patient, see page 2 indicating retention until the person reaches the age of 25, except for genetics, where the retention time is 100 years.

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 below.

	Record/material	Minimum retention time
3.1	Serum, plasma, other body fluid and tissue Specimens	See General 1.6

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.

	Record/material	Minimum retention time
4.1	Exfoliative cytology and fine needle aspirations (FNAs) including slides and cell blocks	10 years
4.2	Gynaecological (cervical) cytology slides	10 years
4.3	Specimens of sputum, urine and other body fluids	See General 1.6
4.4	Specimens received in liquid-based fixative	1 month

Table 5 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.

	Record/material	Minimum retention times
5.1	Copy of original report, or ability to reprint the information content of an original report	100 years (effectively indefinite)
5.2	Cytogenetics: Analysis records/karyotypes Microscope slides	 3 years 3 years
5.3	Cytogenetics/molecular genetics: Fixed chromosome cell suspension	 6 months
5.4	Cytogenetics/molecular genetics: Original Specimens and containers	 1 month from date of issue of report
5.5	Cytogenetics/biochemical genetics/molecular genetics: Tissue cultures/cell culture lines	 Clinically significant: for cryopreservation Not clinically significant: as for General 1.6
5.6	Biochemical genetics: Specimens of plasma, serum and urine	 Original container: 7 days An aliquot: 3 months after date of issue of report
5.7	Molecular genetics: DNA extracts for molecular genetics	3 months from date of issue of the report for an individual or for completion of a family study or for completion of testing; whichever of the three periods is the longest
5.8	Neonatal screening (dried blood spot) Cards	Specimens: a minimum of 2 years Records: see Genetics 5.1

Table 6 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.

	Record/material	Minimum retention time
6.1	Blood films	Clinically significant: 1 year Not clinically significant: 1 month
6.2	Plasma for special haemostasis testing	3 months at -20^{o}C or lower
6.3	Blood Specimens, other than 6.1–6.2	As for General 1.6 for purpose of identification and traceability, noting that repeat testing may not be technically reliable after 2 days
6.4	Bone marrow — slides and reports	10 years

Table 7 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.

	Record/material	Minimum retention time
7.1	Laboratory records of blood products received and issued	20 years

Table 8 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.

	Record/material	Minimum retention time
8.1	Serum, plasma, other body fluid and tissue Specimens	See General 1.6
8.2	Frozen tissue blocks, including Specimens for immunofluorescence studies	1 month at -70^{o}C or lower
8.3	Immunofluorescence slides	See General 1.6

Table 9 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.

	Record/material	Minimum retention times
9.1	Slides	Wet preparations: discard Immunofluorescence slides: 7 days Gram stains: 2 weeks Ziehl-Neelsen stains: 6 weeks Other stained slides: 2 weeks
9.2	Isolates	Clinically significant: 5 days Not clinically significant: discard
9.3	Serum/plasma for infectious disease serology	All sera (unless specified below): 4 months Antenatal sera: 12 months Syphilis (reactive): 12 months
9.4	Urine Specimen for microbiological examination	3 days from date of receipt: under refrigeration

Table 10 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.

	Record/material	Minimum retention times
10.1	Semen for fertility analysis	2-3 days from date of receipt for purpose of identification and traceability noting that repeat testing may not be technically reliable after 1 day.
10.2	Cell therapy	Refer to relevant TGA regulations and NPAAC Requirements that may be applicable

Appendix A 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 Confirmations 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 electronically 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 stored 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 B State and territory legislation relating to the retention of Laboratory records and diagnostic materials (Informative)

This table is intended to assist Laboratories by consolidating reference to various relevant legislations that may affect retention requirements. The references in this table, while extensive, are not intended to be exhaustive. In some cases, the relevant jurisdictional legislation may take precedence over these requirements in terms of mandating retention times different from those specified in these requirements. The content of the table was correct at the time of preparation; changes may be implemented by states and territories in the future that may affect the legislative requirements.

State	**Legislation**
New South Wales	Medical Practice Regulation 1998 Private Hospital Regulation 1996 Public Hospital Regulation 1996 *State Records Act 1998* Circular 96/88 Retention of Medical Records *Human Tissue Act 1983*
Queensland	Queensland Health (Pathology Laboratory Records) Retention and Disposal Schedule *Coroner's Act 2003* *Transplantation and Anatomy Act 1979* *Queensland Public Records Act 2002*
Northern Territory	There is no current relevant legislation in place specifically for pathology results and Specimens. A general disposal schedule for medical records is currently in draft form.
Australian Capital Territory	*Health Records (Privacy and Access) Act 1997* *Public Health Act 1997* *Medical Practitioners Act 1930* *Medical Treatment Act 1994* *Health Act 1933*
Victoria	*Health Services Act 1988* *Medical Practice Act 1994* *Public Records Act 1973*
South Australia	*Freedom of Information Act 1991* *Health Act 1935* *South Australian Health Commission Act 1976* *State Record Act 1997* *Transplantation and Anatomy Act 1983*
Western Australia	Patient Information Retention and Disposal Schedule v2 2000 *State Records Act 2000*
Tasmania	*Medical Practitioners Registration Act 1996* *Anatomy Act 1964* *Health Act 1997* *Hospitals Act 1918* *Human Tissue Act 1985* *Public Health Act 1997*

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Appendix C Recommended storage temperatures (Informative)

Type of storage	Temperature
Immunohaematology	
Storage of blood and blood products	See AS 3864 *Medical refrigeration equipment – For the storage of blood and blood products* Standards Australia
General	
Refrigeration	2-8°C
Freezer	-20°C or lower
Deep freezer	-70°C or lower

Note 1: Laboratories may choose to use temperature ranges other than the above recommendations for Specimen storage. In such cases, the use of ranges other than the above must be supported by Laboratory documentation and (where appropriate) validation.

Note 2: Use of Specimen refrigerators/freezers for storage of other products (e.g. reagents) requires that consideration must be given the storage requirements of these other products stored with the Specimens.

Note 3: Use of Specimen refrigerators/freezers for storage of food/drink is not permitted, for reasons of occupational and environmental health and safety.

Note 4: Use of Specimen refrigerators/freezers for storage of tissue Specimens intended for transplantation or use as a therapeutic device requires that the Laboratory complies with the regulatory requirements of TGA and other relevant regulatory codes.

Note 5: Some types of refrigerator/freezer 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.

Further information

Other NPAAC documents are available from:

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