AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

NPAAC

Requirements for medical pathology services

Draft Edition for public consultation

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2013 First published.

2018 Second edition published. Revised and reprinted.

2018 Third edition published. Revised definition for medical pathology network and reprinted.

202X Fourth edition published. Supersedes the following six NPAAC Standards:

- *Requirements for medical pathology services (Third Edition 2018)*
- *Requirements for supervision in the clinical governance of medical pathology laboratories (Seventh Edition 2023)*
- *Requirements for the communication of high-risk pathology results (First Edition 2020)*
- *Requirements for the estimation of measurement of uncertainty (2007 Edition)*
- *Requirements for quality control, external quality assurance and method evaluation (Sixth Edition 2018)*
- *Guidelines for Approved Pathology Collection Centres (Requirements for medical pathology specimen collection) (Third Edition 2013)*

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 and Aged Care (the Department). The Department retains responsibility for the regulation and funding of pathology in Australia.

Scope

The Requirements for medical pathology services (Fourth Edition 2024) is the overarching governance document for medical pathology practice in Australia. The primary consideration is patient safety through quality testing, where the needs and expectations of patients, the pathology workforce and medical professionals are satisfactorily met.

Medical pathology laboratories are obligated to comply with the Requirements for medical pathology services (Fourth Edition 2024) and all other relevant national pathology accreditation standards issued by the National Pathology Accreditation Advisory Council (NPAAC) to ensure safety, efficacy and quality in all medical pathology testing.

The Requirements for medical pathology services (Fourth Edition 2024) covers areas of governance within a medical pathology laboratory. There are five sections within the Requirements for medical pathology services (Fourth Edition 2024) covering leadership, safety and quality roles and responsibilities, ethical practice, risk management, quality improvement, patient testing, incident management, communication and reporting, patient populations, safety in the pathology environment including supervision and partnering with consumers.

The Requirements for medical pathology services (Fourth Edition 2024) provide a nationally consistent statement about the standard of medical pathology testing consumers can expect from pathology laboratories.

Definitions

Term	Definition
Critical results	Results requiring immediate medical attention and action because they indicate a high risk of imminent death or major patient harm.[1]
High risk results	A collective term used to denote results that require communication in a timely manner, i.e., critical risk results, significant risk results and results of critical tests.
Risk	the chance of something happening that will have a negative impact. Risk is measured by the consequences of an event and its likelihood.[1]
Risk management	the design and implementation of a program to identify and avoid or minimise risks to patients, employees, volunteers, visitors and the organisation.[1]
Quality improvement	the combined efforts of the workforce and others – including consumers, patients and their families, researchers, planners and educators – to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development. Quality improvement activities may be undertaken in sequence, intermittently or continually. [2]

Introduction

Medical Pathology Services play a key role in the diagnosis and delivery of health care in Australia. Medical pathology testing is an important function in ensuring appropriate diagnosis, management, and treatment of diseases. By utilising medical pathology testing, value-based care can be enhanced.

The Requirements for medical pathology services (Fourth Edition 2024) was developed by the Australian Commission on Safety and Quality in Health Care (the Commission) in collaboration with the National Pathology Accreditation Advisory Council (NPAAC), Australian Government, states and territories, the private sector, pathology experts, patients and carers. The Requirements for medical pathology services is the overarching document that outlines the minimum standards acceptable for good laboratory practice that are applicable to all medical pathology testing. The primary aims are to protect the public from harm and to improve the quality of pathology testing. They provide a quality assurance mechanism that tests whether relevant systems are in place to ensure that expected standards of safety and quality are met.

The Requirements for medical pathology services require the implementation of organisation-wide systems for clinical governance, safety in the pathology environment, performance management and partnering with consumers.

The fourth edition of the Requirements for medical pathology services is a consolidation of six national pathology accreditation standards from Tiers 2, 3A and 3B. This revision streamlined the requirements medical pathology services must comply with. Duplication has been removed across six standards, the language simplified, and a risk-based approach incorporated. A risk-based approach requires medical pathology service to assess and manage risks unique to their service through a dynamic and active risk management system. This approach allows flexibility in the way medical pathology service can address their risk areas which enhances safety and quality rather than a blanket approach that may not be fit-for-purpose in all medical pathology service in Australia.

Similar implementation strategies apply to multiple actions across the Requirements for medical pathology services. It is important to identify the links between actions. This will help medical pathology service to ensure that their safety and quality systems are integrated and reduce the duplication of effort in implementing the actions separately. The guide to support medical pathology service in implementing the Requirements for medical pathology services provides information about how the actions are linked.

The Commission and NPAAC has worked closely with partners to review the national pathology accreditation standards to determine the standards most appropriate for consolidation to provide value to medical pathology service and maintain the highest level of safety and quality in pathology testing.

These are minimum standards considered acceptable for good laboratory practice.

NPAAC documents can be accessed at the Australian Commission on Safety and Quality in Health Care website.

Comments on this document from users can be directed to:

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Governance, leadership and culture

Item	Action	
Governance, leadership and culture	1.01	The governing body: a. Provides leadership to develop a culture of safety and quality improvement and satisfies itself that this culture exists within the pathology laboratory. b. Sets priorities and strategic directions for safe and high-quality laboratory services and ensures that these are communicated effectively to the workforce and the community. c. Endorses the organisation's clinical governance framework. d. Ensures that roles and responsibilities are clearly defined for the governing body, management, designated person and workforce. e. Monitors the action taken as a result of analysis of pathology incidents. f. Endorses the laboratory's risk management framework. g. Reviews, reports and monitors the laboratory's progress on safety and quality performance including involvement in relevant external quality assurance programs
	1.02	The governing body ensures any commercial, financial or other influences that could adversely affect the provision of services, the quality of the services or the integrity of the laboratory are addressed and routinely monitored
Organisational leadership	1.03	The Pathology Service establishes and maintains a clinical governance framework, and uses the processes within the framework to drive improvements in safety and quality
	1.04	The Pathology Service consider the safety and quality of health care for patients in its business decision-making and its business continuity plan
Clinical leadership	1.05	The Pathology Service nominates the designated person and includes in their roles and responsibilities: a. That they hold current qualifications as a pathologist or medical practitioner b. Clinical governance and delegations c. The recruitment of a qualified workforce d. The supervision of all testing conducted by pathologists and medical practitioners within their scope of practice. e. That supervision arrangements are appropriate for the range, volume and complexity of testing. f. That selected referral laboratories meet required levels of quality and safety. g. That a consultation service can be provided as and when required by a referring doctor
	1.06	The Pathology Service supports the designated person, its pathologist's workforce to: a. Understand and perform their delegated safety and quality roles responsibilities. b. Operate within the clinical governance framework to improve the safety and quality of services
Ethical practice	1.07	The Pathology Service has policies and procedures that address: a. Respectful treatment of patients, their specimens and body parts including of deceased patients b. The duty of care by the healthcare workforce to patients c. Conflict of interest

Safety and quality systems

Item	Action	
Risk management	2.01	The Pathology Service has processes to: a. Identify and document organisational risks including safety and quality risks. b. Uses clinical and other data collections to support risk assessments. c. Acts to reduce risks. d. Regularly reviews and acts to improve the effectiveness of the risk management system. e. Report on risks to the governing body, the workforce and consumers f. Plans for, and manages, internal and external emergencies and disasters, including cyber security risks and threats
Policies and procedures	2.02	The Pathology Service uses a risk management approach to: a. Set out, review, and maintain the currency and effectiveness of policies, procedures and protocols. b. Monitor and take action to improve adherence to policies, procedures and protocols. c. Review compliance with legislation, regulation, and jurisdictional requirements
Measurement and quality improvement	2.03	The Pathology Service uses its quality improvement systems to: a. Identify safety and quality measures, including specimen integrity, traceability and turnaround times. b. Involve its workforce in the review of safety and quality performance and systems and report performance and outcomes to its governing body, workforce, consumers and other relevant organisations. c. Improve the safety and quality of its Service
	2.04	The Pathology Service has processes for internal quality controls that: a. Apply to all analytical processes. b. Specify the criteria for the acceptance of a quality control and action to be taken when results are unacceptable. c. Specify alternative quality control mechanisms to ensure validity of testing when internal quality controls are not available. d. Include the performance of “send away testing”
	2.05	The Pathology Service has processes to report adverse events involving equipment, devices, and in-house in vitro diagnostics to the Therapeutics Goods Administration: a. Within the specified time frames b. In the required format c. In line with regulatory requirements
Patient testing	2.06	The Pathology Service has processes to ensure unambiguous identification of a patient’s sample
	2.07	The Pathology Service has processes to identify, analyse and address failures or risks that occur with patient testing within the laboratory
	2.08	The Pathology Service: a. Participates in external quality assurance programs for pre- and post-analytical functions for the tests it conducts. b. Establishes equivalent documented internal quality assurance processes where external quality assurance programs are not available.

Item	Action	
	2.09	Where results are produced by different methods and on different instruments, the laboratory has processes to confirm the comparability of patient results in a laboratory or network of laboratories
	2.10	The Pathology Service has processes to verify the performance of assays: Meet the Therapeutic Goods Administration's requirements and on the Australian Register of Therapeutic Goods are industry best practice
	2.11	The Pathology Service has a process to validate the clinical accuracy of its in-house in vitro diagnostic medical devices in line with the Requirements for the development and use of in-house in vitro diagnostic medical devices (IVDs)
	2.12	The Pathology Service has an estimation of the measurement uncertainty process that: Is used to demonstrate that assays meet the acceptable performance goal. Identifies tests where an estimation of measurement of uncertainty is not possible and minimises potential risks.
	2.13	The Pathology Service sets out, reviews and maintains procedures associated with the: a. Assessment of assays b. Introduction of new assays or procedures c. Selection of targets and ranges for quality control samples d. Acceptance criteria for quality control results
Incident management systems and open disclosure	2.14	The Pathology Service has an organisation-wide incident management and investigation system that: a. Supports the workforce to recognise and report incidents. b. Ensures significant incidents are escalated to the designated person. c. Facilitates patients, carers and families to communicate concerns or report incidents. d. Involves the workforce in the review of incidents. e. Provides timely feedback on the analysis of incidents to the workforce and governing body. f. Uses the information from the analysis of incidents to improve safety and quality. g. Is regularly reviewed and acts to improve the effectiveness of the incident management and investigation system
	2.15	The Pathology Service: a. Uses an open disclosure program consistent with the Australian Open Disclosure Framework b. Monitors and acts to improve the use and effectiveness of open disclosure processes
Feedback and complaints management	2.16	The Pathology Service: a. Has processes to seek or enable regular feedback from referrers, patients, carers and families about their experiences and outcomes. b. Has processes to regularly seek feedback from the workforce on their understanding and use of the safety and quality systems. c. Uses this information to improve safety and quality systems
Communication	2.17	The Pathology Service has processes to: a. Provide services in response to a documented request that identifies the patient, the requesting practitioner, contact details for reporting critical results, the tests requested and relevant clinical information. b. Inform the clinician, and the patient about relevant pre- analytical and post-analytical procedures
	2.18	The Pathology Service has processes to ensure its 'direct to the consumer' testing is performed within a documented risk management framework

Item	Action	
	2.19	The Pathology Service has processes to: a. List tests where critical results can occur. b. Define the criteria for results to be termed critical. c. Publish its list of critical results on its website. d. Ensure these results are reliably identified during the testing process. e. Communicate critical test results to the designated person and requesting practitioner as a matter of urgency. f. Communicate critical test results to the patient when the referrer or delegate cannot be contacted and encourage them to seek medical care. g. Review and improve the procedures for the notification of high-risk results
Reporting of results	2.20	The Pathology Service has processes to ensure reports: a. Are provided in a clear, secure and timely manner to the requesting practitioner and to other persons delegated by the requesting practitioner. b. Comply with its reporting policy
	2.21	The Pathology Service has processes to ensure report results that are amended are documented in the reporting system and traceable to the original report
	2.22	The Pathology Service has processes to document and report notifiable diseases in accordance with jurisdictional requirements and disease registries
Healthcare records	2.23	The Pathology Service has healthcare record systems that: a. Make the healthcare record available to the authorised members of its workforce when testing, reporting and for historical review. b. Support the workforce to maintain accurate and complete healthcare records. c. Comply with security and privacy regulations. d. Support systematic auditing of clinical information. e. Integrate multiple information systems, where they are used. f. Provides for backup of electronic systems, to recover and restore patient data files. g. Provides for the storage of pathology records in the event of amalgamation or merger or closure of a laboratory in accordance with jurisdictional legislation.
	2.24	The Pathology Service contributing to My Health Record has processes to: a. Comply with legislative requirements. b. Use national healthcare identifiers for patients and practitioners. c. Use standard national terminologies. d. Support the laboratory workforce to use My Health Record to optimise the safety and quality of patient health care. e. Ensure the accuracy and completeness of the information uploaded
Referral laboratories	2.25	The Pathology Service engaging referral laboratories has processes to inform itself and set requirements for: a. Accreditation status of the destination medical pathology service b. Logistics of specimen transportation to ensure specimen integrity and traceability. c. Comprehensive documentation at handover(s) d. Turnaround times e. Receipt of the report by the referring Medical Pathology Service f. Receipt of the report by the referring medical practitioner g. The responsibility for the notification of critical (high risk) results h. Reviewing and improving the service arrangements

Performance and effectiveness

Item	Action	
Safety and quality roles and responsibilities	3.01.	The Pathology Service has processes to support the workforce to understand, perform, and meet their roles and responsibilities for safety and quality
	3.02	The Pathology Service ensures supervision: a. Is provided by a pathologist and or medical practitioner with the appropriate skills and experience working within their scope of clinical practice. b. Complies with regulation and guidance published by the National Pathology Accreditation Advisory Council c. Supports the workforce to fulfil their roles and responsibilities. d. Is available for after-hours advice. e. Arrangements reflect the laboratory's service plan for the range, volume and complexity of testing conducted
	3.03	Supervising pathologists and medical practitioners are: a. Routinely present when testing is conducted. b. When not present, are readily available and able to attend the laboratory
Safety and quality training	3.04	The Pathology Service includes in its workforce orientation information on their safety and quality roles and responsibilities
	3.05	The Pathology Service sets out its training requirements and uses its training systems to: a. Support the workforce to maintain and update the skills required to fulfil their individual safety and quality responsibilities. b. Support its medical practitioners and clinical scientists to complete mandatory continuing professional development and participate in quality assurance activities. c. Implement a mandatory training program to meet its requirements arising from these standards. d. Provide access to training to meet its safety and quality, security, privacy and cyber risk training needs and e. Monitor the workforce's participation in training
Performance management and development	3.06	The Pathology Service has reliable performance review processes that: a. Require workforce members to regularly take part in a review of their performance. b. Support pathologists and clinical scientists to participate in peer review assessment processes
Credentialing	3.07	The Pathology Service: a. Conducts processes to ensure that its workforce is credentialed, where relevant b. Monitors and improves the effectiveness of its credentialing process
Evidence-based care	3.08	The Pathology Service: a. Provides its workforce with ready access to best-practice guidelines, integrated care pathways, and decision-support tools relevant to their practice. b. Supports the workforce to use the best available evidence, including relevant resources published by the National Pathology Accreditation Advisory Council

Safety in the pathology environment

Item	Action	
Safe environment	4.01	The Pathology Service maximises safety and quality of care: a. Through the design of the environment b. By maintaining buildings, equipment, consumables, utilities, devices and other infrastructure that are fit for purpose.
Collection centres	4.02	The Pathology Service has a process to ensure collection centres: a. Have space to enable patients and carers to be present. b. Have space for patients to be seated or recumbent. c. Have a fit-for-purpose workstation for the collection staff. d. Comply with all applicable regulations where collections are in temporary locations
	4.03	Where the Pathology Service operates a collection service, it identifies patient areas in its facilities where there is a high risk of unpredictable behaviours and develop strategies to minimise the risks of harm for patients, carers, families, consumers and the workforce
	4.04	The Pathology Service has strategies to improve the cultural safety of its collection centres to meet the needs of its Aboriginal and Torres Strait Islander patients

Partnering with consumers

Item	Action	
Healthcare rights and informed consent	5.01	The Pathology Service has processes to ensure. a. Its contact information is clearly identifiable to the requester and the patient. b. The identification of the patient is confirmed at the point of collection, including when requests are transmitted electronically. c. The requesting practitioners and patients are provided with information about the test, including any prerequisites. d. Where there is direct patient contact a charter of rights is used that is consistent with the Australian Charter of Healthcare Rights3
	5.02	The Pathology ensures that: a. Its informed consent processes including financial consent comply with legislation and best practice. b. Health information is available to other health service providers at the request of the patient or the request of a health professional acting with the consent of the patient. c. Patients collecting their own specimens are provided with instructions in accordance with the collection manual. d. Collection centres have a charter of rights that is consistent with the Australian Charter of Healthcare Rights and easily accessible for patients, carers, families and consumers
Communication that supports effective partnerships	5.03	The Pathology Service uses communication mechanisms that are tailored to the diversity of the consumers who use its services

References

1. From RACP 'Consensus statement for the Management and Communication of High Risk Laboratory Results (https://www.rcpa.edu.au/getattachment/14432ea0-123b-42d7-882f-8ed87f272886/Consensus-Statement-for-the-Management-and-Communi.aspx)

Reference for critical results - White GH, Campbell CA, Horvath AR. Is This a Critical, Panic, Alarm, Urgent, or Markedly Abnormal Result? Clin Chem. 2014 Sep 4. pii: clinchem.2014.227645.

2. Australian Commission on Safety and Quality in Health Care. National Safety and Quality Health Service Standards. 2nd ed. – version 2. Sydney: ACSQHC; 2021.

3. Australian Commission on Safety and Quality in Health Care: Australian Charter of Healthcare Rights. Sydney: ACSQHC: 2008.

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