

NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS FOR MEDICAL PATHOLOGY SERVICES

(Second Edition 2018)

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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 on minimum Standards considered acceptable for good Medical Pathology Service practice.

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

Scope

The *Requirement for Medical Pathology Services (Second Edition 2018)* is the overarching document outlining the standards for good medical pathology practice, where the primary consideration is patient welfare, and where the needs and expectations of patients, Medical Pathology Service staff and referrers (both for pathology requests and inter-Medical Pathology Service referrals) are safely and satisfactorily met in a timely manner. Providers of Medical Pathology Services must adhere to these and all other NPAAC Requirements in order to achieve accreditation and to ensure the safety, efficacy and quality of all medical pathology testing.

These Tier 2 Requirements are supported by, and must be read in conjunction with, the other NPAAC publications as listed in Tiers 3 and 4 within the NPAAC document hierarchy published on the NPAAC website. Failure to meet these Requirements may pose a risk to the health and safety of the users of the Medical Pathology Service.

Abbreviations

| Abbreviation | Description |
|--------------|--|
| ACSQHC | Australian Commission on Safety and Quality in Health Care |
| APA | Approved Pathology Authority |
| APL | Accredited Pathology Laboratory |
| ARTG | Australian Register of Therapeutic Goods |
| AS | Australian Standard |
| EQA | External Quality Assurance |
| ISO | International Organization for Standardization |
| IVD | In Vitro Diagnostic Device |
| NPAAC | National Pathology Accreditation Advisory Council |
| NSQHSS | National Safety and Quality Health Service Standards |
| OH&S | Occupational Health and Safety |
| QA | Quality Assurance |
| RCPA | Royal College of Pathologists of Australasia |
| TGA | Therapeutic Goods Administration |

Definitions

| Term | Definition |
|--|---|
| Clinical Governance | <p>means a systematic and integrated approach to assurance and review of clinical responsibility and accountability that continually improves quality and safety of services provided to patients resulting in optimal patient outcomes.</p> <p>Clinical governance extends across the boundaries of functions and organisation delivering services along with whole patient care cycle. An interface in, or split responsibility for, delivering patient care are considered points of increased risk.</p> |
| Clinical Handover | <p>means the transfer of professional responsibility and accountability for some or all aspects of a patient's care to another person or professional group on a temporary or permanent basis.</p> |
| Designated person | <p>means a registered medical practitioner with appropriate qualifications, competence and relevant scope of practice who has responsibility for the clinical governance of the Medical Pathology Service and provides oversight and management of staff and processes to ensure ethical patient care and the provision of accurate and timely test results</p> |
| Equipment | <p>means instruments, reference materials, consumables, disposables, reagents, cabinets (incubators, refrigerators), analytical systems and electronic information systems.</p> |
| External Quality Assurance | <p>means a program in which multiple specimens are periodically sent to laboratories for analysis and/or identification, in which each Medical Pathology Service's results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating Medical Pathology Service and others.</p> <p>Such a program may also compare an individual's results with those of their peer group.</p> |
| Informative (as applied to Commentaries and Appendices) | <p>means the material is presented to assist in the application or interpretation of the Standard(s) to which it is attached.</p> |

| Term | Definition |
|---|--|
| Laboratory | <p>means premises where Medical Pathology Services are performed. A Medical Pathology Service may be stand alone or be part of a network of laboratories.</p> <p>A Medical Pathology Service may be in the same healthcare precinct where pathology services in more than one group of pathology services are performed, or it may be a part of such a Medical Pathology Service in which pathology tests in a specific discipline or group of pathology services are performed. The premises include all locations in the same healthcare precinct, where pathology services are performed.</p> <p>Thus a Medical Pathology Service may be a medical device in a medical practice or it may be for example a chemical pathology Medical Pathology Service in a large teaching hospital, which is part of a pathology Medical Pathology Service network.</p> |
| Medical Laboratory Network | means a network of laboratories that operate under a single Approved Pathology Authority (APA). |
| Medical Pathology Service | <p>means any service whereby pathology testing provides information for –</p> <ul style="list-style-type: none"> • diagnosis, exclusion and monitoring of disease processes and their treatment • health screening • epidemiological purposes. |
| Normative (as applied to Commentaries and Appendices) | means prescriptive or mandatory. The material carries the same weight as the Standards to which it is attached. |
| Quality Assessment | means a measurement and monitoring function of quality assurance for determining how well health care is delivered in comparison with applicable standards or acceptable bounds of care. |
| Quality Assurance | means a part of quality management focused on providing confidence that quality requirements will be fulfilled. |
| Quality System | means those management activities involved in the direction and control of the organisation regarding quality. |
| Reference Standards | means standards developed to meet a certain requirement. |

| Term | Definition |
|---------------------------|---|
| Request-Test-Report Cycle | <p>means the process of the initiation of pathology requests, most commonly by a medically qualified individual for the purpose of patient diagnosis or management (Requester), the informed cooperation of the patient, the performance of the requested pathology tests by a pathologist and/or pathology provider (Pathology Provider), and the reporting of the test results and/or professional opinions back to the Requester or their nominated delegate.</p> <p>Request means pre-analytical Test means analytical Report means post-analytical</p> |
| Specimen | <p>means any tissue or fluid from a patient that is submitted to the Medical Pathology Service for testing.</p> |

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Introduction

The first set of National Pathology Accreditation Advisory Council (NPAAC) pathology accreditation standards and guidelines were referenced within the *Health Insurance Act 1973* in 1986, with the introduction of a compulsory accreditation system in relation to Medicare benefits for pathology. The NPAAC accreditation framework has continued to evolve since that time.

The *Requirements for Medical Pathology Services (Second Edition 2018)* (RMPS Requirements) is a Tier 2 document and is the overarching document that outlines the minimum standards acceptable for good laboratory practice that are applicable to all medical pathology testing.

The RMPS Requirements have been reviewed to reflect a risk based approach and current best practice. They aim to ensure the safe performance of pathology testing and delivery of quality results for the benefit of patient outcomes.

While developing and revising these Requirements, existing NPAAC publications (including those being reviewed at the time) were used as source material. Additional sources of materials included the *AS ISO 15189*, National Safety and Quality Health Service Standards and the RCPA's [Pathology Request-Test-Report Cycle – Guidelines for Requesters and Pathology Providers](#).^{*1}

NPAAC Requirements apply to all pathology laboratories seeking accreditation and must be applied in conjunction with jurisdictional and other regulatory requirements.

NPAAC recognises that medical pathology testing is also performed outside the traditional laboratory and therefore outside of the pathology accreditation framework. However, the Requirements should be followed to guide best practice wherever medical pathology services are provided.

The RMPS Requirements serve as minimum standards in the pathology accreditation process and where possible, are aligned with relevant international standards and the Australian Commission on Safety and Quality in Health Care (ACSQHC) [National Safety and Quality Health Service Standards](#).^{†2}

These Standards have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardization (ISO) including:

AS ISO 15189 Medical laboratories – Requirements for quality and competence

In each section of the 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 facility that is required before a Medical Pathology Service can attain 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.

* [RCPA Pathology Request-Test-Report-Cycle Guidelines](#)¹

† [National Standards and Accreditation](#)²

- 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](#).

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

| | | |
|---|----------|--|
| NPAAC Secretariat | Phone: | (02) 6289 4017 |
| Diagnostic Imaging and Pathology Branch | Fax: | (02) 6289 4028 |
| Medical Benefits Division | Email: | NPAAC@health.gov.au |
| Department of Health | Website: | www.health.gov.au/npaac |
| GPO Box 9848 (MDP 951) | | |
| CANBERRA ACT 2601 | | |

All providers of Medical Pathology Services must be familiar with and have access to, the current international standard AS ISO 15189 *Medical laboratories– Requirements for quality and competence* and to the National Safety and Quality Health Service Standards developed and maintained by the Australian Commission on Safety and Quality in Healthcare.

NPAAC Requirements have been developed with consideration of other national and international standards and endeavour to minimise any duplication of standards where possible.

1. The Role of Standards in the Australian Pathology Accreditation Framework

Pathology services are a vital clinical service that underpins Australia's high performing healthcare system. The important role of pathology was recognised with the introduction of a mandatory regulatory framework in 1986. The legislation under which NPAAC was established is aimed to ensure the safety of Australians undergoing pathology testing and to promote a consistent standard of practice through the development of quality standards for the purpose of accreditation.

NPAAC Standards are applicable within the Australian legal and regulatory framework and recognise the settings and models of service that exist in Australia. They also reference other national and international standards where they are suitable for application in the Australian context.

NPAAC applies a risk based approach to the pathology accreditation framework. This approach calls for a focus on areas of high potential risk and on the prevention of harm to patients and to the Australian public more broadly, and support of better health outcomes. The Standards are intended to provide minimum, evidence based standards for best practice in pathology.

NPAAC Standards reference other relevant national and international standards, such as those developed by the ACSQHC, and relevant ISO standards, in particular *AS ISO 15189: Medical Laboratories, requirements for quality and competence*.

Australian pathology laboratories **must** meet NPAAC accreditation standards that are specified in the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017* to achieve pathology accreditation and be eligible to receive Medical Benefits Schedule rebates for pathology services. Pathology laboratories are assessed to the NPAAC requirements by an independent assessing body.

S1.1 Where an NPAAC Standard exists, it must be met for the purposes of accreditation.

S1.2 In the absence of an explicit NPAAC or referenced standard, the AS ISO 15189 Standard must be met for the purposes of accreditation.

C1.2 A referenced standard has been developed to meet a special requirement in a field on medical testing by for example a pre-eminent specialist society. An example of this is seen in *Requirements for Transfusion Laboratory Practice* at C14.1(i).

2. Ethical Practice

S2.1 The wellbeing of patients and their rights must be primary consideration.

C2.1 The patient **must** be given the opportunity to provide and to be provided with information for the pre-analytical and post-analytical phases of the Request-Test-Report Cycle, for example the provision of information to the patient regarding the test process, associated costs, or when to expect [results](#).^{‡3}

S2.2 Medical Pathology Services must have an open disclosure policy and procedure that allows for a discussion with a patient (and/or their support person(s)) about a patient safety incident that did result or may have resulted in harm to that patient.

S2.3 Patients, their specimens and body parts must be treated with respect.

C2.3 This Standard also applies to the deceased.

S2.4 Policies and procedures that define ethical standards of the Medical Pathology Service must be in place.

C2.4(i) These policies and procedures **must** address any commercial, financial or other influences that could adversely affect the provision of services, the quality of the work or bring into question the integrity of the Medical Pathology Service.

C2.4(ii) Conflicts of interest **must** be assessed, managed and documented through a risk management tool.

S2.5 There must be a policy regarding informed consent and this must be consistent with jurisdictional requirements.

C2.5(i) Apart from autopsies ordered by the Coroner, written consent **must** be obtained from the next of kin, or relevant authority, for autopsy and specimen/body part retention. The patient may also give consent ante-mortem.

C2.5(ii) Consent and/or ethical approval may be required for specimen/body part retention for research, quality activities, and education purposes. In this context it is recognised that de-identified specimens are retained and used for quality assurance purposes.

C2.5(iii) It is inferred that informed consent has been obtained from the patient by the referring practitioner when the patient allows the collection or procedure to be carried out. For some tests specified in technical documents, it is the requesting practitioner's responsibility to obtain written informed consent.

C2.5(iv) Consent should also include informed financial consent.

[‡] [Medical Board of Australia Good Medical Practice: A Code of Conduct for Doctors in Australia](#)³

- S2.6** The privacy and confidentiality of patients' personal information must be maintained at all times.
- S2.7** The designated person is responsible for implementing procedures to ensure the ongoing availability and integrity of materials and records in the event of closure of their practices' in accordance with current relevant state and territory legislation.
- S2.8** The designated person is responsible for ensuring the on-going availability and integrity of materials and for providing storage for pathology records in the event of amalgamation or merger of a Medical Pathology Service in accordance with current relevant state and territory legislation.
- S2.9** Medical Pathology Service providers must make health information available to another health service provider at the request of the patient, or the request of a health professional acting for, or on behalf of, the patient.
- C2.9(i) In the event of closure of a Medical Pathology Service or death of the proprietor, the receiver or estate **must** ensure compliance with the relevant state and territory legislation in relation to retention of records and [materials](#).[§]
- C2.9(ii) The designated person **must** develop a contingency plan for the retention of materials and records in the event of future closure or amalgamation.

[§] [Requirements for the Retention of Laboratory Records and Diagnostic Material \(Seventh Edition 2018\)](#)

3. Risk Management

Contemporary international governmental regulatory practice supports a risk based approach to regulation. This approach calls for a focus on preventing harm and promoting better health outcomes. This is done by prioritising a review of processes that are not compliance focussed. This approach supports the attainment of the overall objectives of the legislative mandate. It also acts as a tool for prioritisation and the allocation of resources by the regulated entity and the accrediting body.

S3.1 Medical Pathology Services must identify key risks to patient safety, collect data and monitor the performance of the Medical Pathology Service in managing these risks (see *Appendix A*).

S3.2 Medical Pathology Services must demonstrate that there is a regular review of potential risks, and adverse incidents to patients generated by failures in the pathology request-test-report cycle and that a proactive approach is taken to prevent harm and promote better outcomes.

C3.2 Compliance with a particular standard is not required, however, there are many resources, including [ISO 31000](#)^{**}, outlining the elements of a risk management framework. Successful risk management depends on the application of the risk management process to individual decisions.

S3.3 The Medical Pathology Service must demonstrate that evidence based measures are used to identify and address any failures, including in morphological disciplines that could potentially harm patients.

C3.3 Medical Pathology Services **must** monitor the durability and success of these evidence-based measures.

S3.4 The risk management framework must include, or form part of, a Quality Management system.

^{**} [ISO 3100: Risk Management](#)

4. Clinical Governance

These Requirements **must** be considered in conjunction with the Tier 3A document *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories*.

Regardless of the organisational structure, the clinical governance structure must demonstrate clear accountability for the responsibility for supervision, and clear criteria and processes for the escalation and communication of incidents that may affect patient safety.

- S4.1 The Medical Pathology Service must have a process of clinical governance that ensures patient safety and quality in the delivery of its services.**
- S4.2 The Medical Pathology Service delivering the service must be able to be clearly identified by the requester and the patient.**
- S4.3 All Medical Pathology Services must have a delegation procedure in place that clearly communicates delegated responsibilities.**
- S4.4 The Medical Pathology Service must have an escalation protocol that defines significant events whereby the delegate notifies the designated person.**
- S4.5 The designated person(s), who is a medical practitioner, under whose direction and control the Medical Pathology Service operates must be clearly identifiable and accessible, provide leadership to promote safe and ethical practice and must have the authority and competence to ensure and take active responsibility for:**
 - (a) clinical governance**
 - (b) policy setting and implementation**
 - (c) the identification and management of risk**
 - (d) the implementation and maintenance of the quality management system**
 - (e) compliance with all NPAAC and jurisdictional requirements**
 - (f) operational practices and staffing (including training)**
 - (g) determining the range of tests provided, their methods and procedures while considering that the numbers processed are sufficient to maintain competence**
 - (h) determining the suitability of referral laboratories**
 - (i) regular review of the quality management systems, proficiency testing data, reports, and all aspects of performance**
 - (j) provision of medical and scientific consultation**
 - (k) procedures used and the tests performed being within the scope of the education, training, continuing professional development and experience of individual staff members**
 - (l) determining work suitable to be performed outside normal working hours and that such work is performed by staff who are qualified, trained and competent to work in the absence of an on-site supervisor**
 - (m) provision of a clearly defined process for contacting a supervisor who is not currently on site**

- (n) ensuring the ongoing availability and integrity of materials and for providing storage for pathology records in the event of amalgamation or merger of a Medical Pathology Service.**

5. Quality Management

Medical pathology services contribute to patient safety and improved clinical outcomes.

- S5.1 The Medical Pathology Service must have a documented and monitored Quality System in place which ensures the safety of patients and contributes to improved patient outcomes.**
- S5.2 The Medical Pathology Service must have a designated quality manager who shall have delegated responsibility and authority that includes:**
- a) ensuring that the quality management system is established, implemented and maintained
 - b) reporting to management of the Medical Pathology Service, at the level at which decisions are made on Medical Pathology Service policy, objectives, and resources, on the performance of the quality management system and any need for improvement
 - c) ensuring awareness of user requirements throughout the Medical Pathology Service.
- S5.3 The effectiveness of the Quality System must be audited.**
- S5.4 The pathology services provided by laboratories must be evaluated.**
- C5.4(i) Where practicable, performance measures such as incident and error rates and turn-around times **must** be used for evaluation and improvement purposes.
 - C5.4(ii) There **must** be protocols to facilitate feedback from patients and referrers and for the feedback to be used for evaluation and improvement purposes.
 - C5.4(iii) There **must** be protocols for the redress of valid complaints. Complaints and the response to the complaint **must** be sighted by the delegated person in **S4.4**. Relevant events **must** be reported and escalated to designated person in **S4.4**.

6. Personnel

- S6.1 There must be sufficient medical, scientific, technical and support staff who have the qualifications, training and competence to provide Medical Pathology Services consistent with the scope of accreditation.**
- C6.1(i) Laboratories **must** ensure an appropriate scope of practice for Pathologists and Clinical Scientists for the scope of testing performed in the Medical Pathology Service and maintain such documentation.
 - C6.1(ii) All qualified staff involved in the provision of Medical Pathology Services **must** provide documented evidence of participation in continuing professional development commensurate with their role and responsibilities.
 - C6.1(iii) Staff **must** undertake relevant professional activities to enable them to maintain and update the skills required to undertake their individual responsibilities.
 - C6.1(iv) Where maximum workload measures are specified in technical documents, these **must** not be exceeded.
 - C6.1(v) Medical and scientific staff **must** participate in relevant peer review and assessment processes.
 - C6.1(vi) Medical Pathology Services **must** provide sufficient time and support for staff to undertake relevant professional development activities.
- S6.2 The Medical Pathology Service must have a policy for the reporting of critical (high risk) results to the requesting practitioner.**
- S6.3 The requesting practitioner must be able to obtain advice from the Medical Pathology Service on issues such as:**
- (a) **patient preparation, the importance of clinical information and the adequacy of the specimen submitted**
 - (b) **the precision and accuracy of methods used**
 - (c) **the significance of results in relation to the Medical Pathology Service's reference values**
 - (d) **the scientific basis of the results**
 - (e) **any further investigations that may be helpful.**
- S6.4 The Medical Pathology Service must have a policy outlining the escalation processes in relation to consultation by relevant clinical staff.**

7. Facilities and Equipment

A. Premises

S7A.1 Medical Pathology Service premises must be clearly identified and suitable for all activities undertaken.

C7A.1 Approved Collection Centres **must** meet the NPAAC *Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection)*.

S7A.2 There must be designated space and facilities sufficient for the safe provision of the medical pathology services. This applies to all sectors of the Medical Pathology Service including testing areas, specimen collection, administrative and mortuary areas.

S7A.3 Access to adequate and up to date educational resources for all staff in the individual pathology disciplines must be provided at the Medical Pathology Service.

C7A.3 These resources may be textbooks, journals and electronic resources.

B. Equipment

The Tier 3 and Tier 4 NPAAC Requirements identify specific items of equipment. Laboratories must comply with the [TGA's IVD regulatory framework](#)^{††4} and ensure that commercially supplied IVDs and in-house Class 1-3 IVD's are registered on the ARTG and report any adverse events.

S7B.4 Information about an adverse event resulting from the use of an IVD, including an in-house IVD, must be reported to the Medical Pathology Service designated person and to the TGA as soon as practicable but within the timeframes [specified](#).^{‡‡5}

S7B.5 Equipment must be “fit for purpose” and must be maintained to ensure functionality.

C7B.5 Reagents **must** not be used outside their expiry dates unless extension of their use has been validated.

S7B.6 Electronic information systems must be protected to ensure and maintain integrity of data and to prevent unauthorised access, alteration or destruction of data.

C7B.6 Laboratories **must** mitigate the risk of electronic data becoming inaccessible due to software obsolescence.

^{††} [Federal Register of Legislation](#)⁴

^{‡‡} [TGA Adverse Event Reporting](#)⁵

8. Request-Test-Report Cycle

Clinical handover is the transfer of information, accountability and professional responsibility for the care of a patient or group of patients. Failure in handover is a major source of preventable patient harm and appropriate clinical handover will maximise patient safety. It is acknowledged that a key feature of effective clinical handover is a process that is standardised through effective, concise and comprehensive communication.

A. Pre-Analytical

It is recognised that not all specimen collections are done within the control of the Medical Pathology Service.

SA8.1 The Medical Pathology Service must ensure that pre analytical procedures and post analytical processes are part of the clinical handover between the Medical Pathology Service and the [clinician](#).^{§§2}

SA8.2 Specimens within the request test report cycle must be traceable at all times.

SA8.3 Sufficient information must be available for requesting practitioners and patients about the services provided and both parties must be advised about any prerequisites for testing.

SA8.4 Provision of Medical Pathology Services must be in response to a documented request identifying the patient, the requesting practitioner, the tests requested and any relevant clinical information provided (e.g. any medication history, family history, ancestry).

CA8.4(i) Where there are several different identifiers for the one patient (e.g. baby of . . . , unknown patients, change of maiden to married name, multiple medical record numbers), there **must** be a policy relating to the merging or linkage of the patient data.

CA8.4(ii) A request may be made verbally by a requestor for further testing when the specimen is already present in the laboratory. In these cases, the nature and time of the request **must** be recorded. A confirmatory documented request **must** be received.

CA8.4(iii) Where a Medical Pathology Service offers direct-to-consumer testing, the testing **must** be performed within a documented risk management framework.

Accurate patient identification and specimen labelling are crucial to patient safety. Failure to comply with these requirements is a significant cause of patient morbidity and occasionally mortality.

^{§§} [Australian Commission on Safety and Quality in Health Care Standards - Communicating Patient Safety Standard²](#)

SA8.5 Specimen collection must be performed with accurate identification of the patient and labelling of specimens in accordance with written protocols.

- CA8.5(i) Where the request has been transmitted electronically, there **must** be a documented protocol indicating how the patient is to be identified at the point of collection.
- CA8.5(ii) The identity of the person collecting the primary sample **must** be traceable in the Medical Pathology Service records.
- CA8.5(iii) When identifying the patient, three identifiers **must** be used on the request form. This also applies to unidentifiable and unconscious patients who will need a unique medical record number and two other descriptors e.g. head injury and motorbike accident.
- CA8.5(iv) When labelling the patient's specimen, two identifiers **must** be used or three identifiers where practicable.
- CA8.5(v) If there is discordance between the identifiers on the request form and the specimen label there **must** be a documented process for reconciliation and managing of potential risks to patient safety.
- CA8.5(vi) The specimen **must** be labelled in the presence of the patient and, if possible, the patient identifiers should be confirmed by the patient.
- CA8.5(vii) The identifiers **must** include the patient's full name and at least one of either date of birth or unique record number. Additional identifiers may be the unique accession number or patient address. Alternative identifiers may be used in special circumstances, such as when patients are to remain anonymous.
- CA8.5(viii) Where patients collect their own specimens, they **must** be provided with instructions in accordance with the collection instructions manual.
- CA8.5(ix) Where the Medical Pathology Service accommodates requests for patient de-identification, coding for identification processes **must** remain unique for the patient and must encompass at least a two-part system (similar to the patient's name and date of birth currently used); for example, a coded 'name' plus the correct date of birth. The same 'code' **must** be used for each patient at subsequent consultations.
- CA8.5(x) If a coded name is used, Standard Australian English alphabet and Arabic numerals should be used in codes, with no spaces between letters or numbers (as spaces may get moved or left out, creating difficulties in finding a person's code in the Laboratory Information System). Non-standard alphabetical letters should be avoided. Symbols should be avoided in patient coded identities. Arabic numbers should be written clearly to avoid confusion (e.g. O and 0, 1 and 7, Z and 2).

SA8.6 The Medical Pathology Service records must include:

- (a) **three patient identifiers**
- (b) **sex**
- (c) **date and time of collection (where supplied)**
- (d) **date and time of receipt in the Medical Pathology Service**
- (e) **anatomical site of tissue specimens**
- (f) **type of specimen (e.g. urine, joint aspirate)**
- (g) **clinical status of patient (e.g. fasting), where required**
- (h) **specimen characteristics that may provide information relevant to interpretation of results (e.g. haemolysis)**
- (i) **informed consent where required by legislation or NPAAC requirements**
- (j) **the name of the requester and provider number or practice address.**

SA8.7 The Medical Pathology Service must have a written policy for the management of inadequately labelled specimens and incomplete request forms.

SA8.8 Pathology specimens must be packaged and transported in a manner that ensures the integrity of the specimen and safety of the public.

SA8.9 The integrity of the specimen must be ensured before testing and before the release of test results.

CA8.9 Examples of compromised integrity include haemolysis, partial clotting of anti-coagulated specimens, absence of or inadequate fixative for tissue specimens or leaking specimen containers.

B. Analytical

SB8.1 Validated and/or verified recognised procedures must be used.

CB8.1(i) Validation and verification records **must** be available.

CB8.1(ii) Tests that cannot be fully validated **must** only be performed where dictated by clinical necessity or public risk and where there is no reasonable access to an alternative validated test. For certain tests laboratories may need to seek advice from the relevant regulatory authority on how to access an unapproved in vitro diagnostic medical device.

SB8.2 There must be evidence to confirm comparability of patient results in a Medical Pathology Service or network of laboratories when results are produced by different methods and on different instruments.

SB8.2 The analytical performance must meet the requirements for the clinical application of the assay.

SB8.3 Test procedures must be documented, authorised, and available in the work area in which they are used.

- SB8.4 Acceptable test performance must be confirmed by the ongoing use of internal quality control material.**
- CB8.4(i) There **must** be documented criteria for the acceptance of quality control. Any results and any action to be taken when these are unacceptable **must** be documented.
- CB8.4(ii) Where internal quality control material is available, it **must** be included in the test system in a manner as close to a patient specimen as possible.
- CB8.4(iii) Where internal quality controls are not available, alternative mechanisms to ensure validity of testing **must** be carried out.
- SB8.5 The Medical Pathology Service must be enrolled, participate and perform to an acceptable standard in EQA programs that cover all testing methods performed where such programs are available.**
- CB8.5(i) Where EQA programs do not exist for a test method, the validity of the test results **must** be demonstrated by methods such as inter-laboratory comparisons or the analysis of reference material.
- CB8.5(ii) All staff performing Medical Pathology Services **must** participate in EQA programs in accordance with Medical Pathology Service's policy and according to their responsibilities. The policy **must** include frequency of participation.
- CB8.5(iii) To minimise risk across the entire test cycle, quality assurance includes extension beyond the analytical aspects of pathology testing into pre- and post-analytical areas.
- SB8.6 Non-concordant results must be investigated and the possible ramifications for patient specimen testing must be considered and appropriate actions taken.**
- SB8.7 Staff must be aware of factors that may give rise to uncertainty about a test result.**
- CB8.7 There may be pre-analytical sources, software limitations, measurement uncertainty within numerical analytical processes, and post-analytical sources.
- SB8.8 Measurement uncertainty must be estimated for each test procedure where relevant and possible.**
- CB8.8 Where an estimation of uncertainty is not possible, then areas of uncertainty should be identified to minimise any potential risks.
- SB8.9 The Medical Pathology Service must have evidence that its measurement uncertainties meet clinical requirements.**
- SB8.10 Estimates of measurement uncertainty must be made available to requesters upon request.**

C. Post-Analytical

Breakdown in the transfer of information or communication has been identified as one of the contributing factors in serious adverse events and is a major preventable cause of patient harm.

SC8.1 There must be a documented policy for results from test procedures and specimen examinations.

- CC8.1(i) The results **must** be verified to ensure that they are correct, evaluated against internal quality control, timely, clear and unambiguous, clinically relevant and traceable to the request form.
- CC8.1(ii) If a clinically non-validated test has been performed, the report **must** clearly indicate that the diagnostic validity has not been established.
- CC8.1(iii) Interpretative and additional comments may be added by identifiable authorised persons.

SC8.2 Pathology reports must contain:

- (a) **patient demographic data (e.g. name, sex, age)**
- (b) **tissue or fluid tested (e.g. blood, serum, plasma) and, where relevant, its state (e.g. fresh, frozen, fixed)**
- (c) **validated result data**
- (d) **identity of the Medical Pathology Service issuing the report**
- (e) **unique identifier for each sample episode such as accession number or other unique identifier to allow traceability**
- (f) **identity of any referral Medical Pathology Service that performed part or all the testing**
- (g) **all interpretive comments provided by the referral Medical Pathology Service**
- (h) **date and time of report release.**

- CC8.2(i) Provisional/interim reports **must** be issued according to documented policy and indicate their provisional nature.
- CC8.2(ii) Structured reporting **must** be used where appropriate.
- CC8.2(iii) Reports may be paper based or electronically submitted.
- CC8.2(iv) Test reports should not be copied or reproduced except in their entirety.

SC8.3 Reports must be communicated in a clear, secure and timely manner to the requesting practitioner and to others delegated by the requesting practitioner responsible for the patient's immediate care and management.

- CC8.3(i) Verbal reports **must** be given according to documented policy, which must include the name of the person providing and the person receiving the report, the date and time of the communication and a requirement for reading back the verbal report.

- CC8.3(ii) Verbal reports **must** be followed up with an electronic or hard copy as soon as possible.
- CC8.3(iii) The Medical Pathology Service **must** develop, in consultation with relevant referrers, a list of critical test results to be provided to those referrers.
- CC8.3(iv) Where clinically significant results have the potential to have a serious immediate effect on the patient's safety and where the requesting practitioner or proxy cannot be contacted, then every effort **must** be made by the medical director, relevant pathologist or most senior responsible person to contact the patient to arrange management. Referring practitioners should be encouraged to provide after-hours contact numbers. A register of such after-hours contact details should be established.
- CC8.3(v) Where clinically significant results have been verbally communicated to a requesting practitioner directly or through a third party, such as a practice nurse or receptionist, the urgency or significance of the results **must** be made clear.

SC8.4 Medical Pathology Services must have procedures for:

- (a) **the reporting of notifiable diseases in accordance with jurisdictional requirements**
- (b) **reporting to disease registries.**

SC8.5 Medical Pathology Services must have documented procedures for the provision of test results directly to patients.

SC8.6 Retention of patient data, specimens, test procedures and equipment records must comply with [NPAAC Requirements](#)^{*} and jurisdictional requirements.**

SC8.7 Disposal of biological material from pathology testing must comply with jurisdictional regulations and the organisation's waste management policy.

^{***} [Requirements for the Retention of Laboratory Records and Diagnostic Material \(Seventh Edition 2018\)](#)

9. Send away tests

It is recognised that the practice of referring patient specimens, in full or in part, from the original receiving Medical Pathology Service, to other testing Medical Pathology Service, within the same network, outside the same network or to other national jurisdictions or across borders, is associated with an increased risk of an error that may cause patient harm.

S9.1 The referral laboratory performing testing on behalf of a referring laboratory must provide the referring laboratory with a copy of the results of the requested testing in a timely manner

C9.1 The referring laboratory is responsible for providing the results of testing by the referral laboratory to the original requesting medical practitioner.

S9.2 The Medical Pathology Service must have a policy and procedure in its Quality System to document and manage referred specimens.

C9.2(i) Measures of the performance of the send away testing **must** be monitored and actions taken to identify and reduce potential risks to patient safety.

C9.2(ii) The quality system should address:

- (a) quality assurance of the logistics process
- (b) documentation of handover(s)
- (c) specimen integrity
- (d) specimen traceability
- (e) accreditation status of the destination Medical Pathology Service
- (f) turnaround times
- (g) receipt of the report by the referring Medical Pathology Service
- (h) receipt of the report by the referring medical practitioner
- (i) the notification of critical (high risk) results.

Appendix A Risk Assessment – Risk Points (Normative)

The following risk points **must** be considered as part of a Medical Pathology Service’s risk assessment to mitigate potential risks to the delivery of quality pathology services and patient safety.

- 1. Governance:** Clear governance structures will facilitate prompt corrective action where the accuracy, clinical utility or timeliness of testing has been compromised. They will also promote early notification to the referring doctor about test results or clinically significant events in the management of the patient.
- 2. Competency of staff:** Demonstrated ability to perform a task successfully and efficiently.
- 3. Patient identification:** Clear processes to allow unequivocal identification of the patient and promotes safe and timely testing.
- 4. Specimen integrity:** Processes that address common pre analytical issues, in particular specimen haemolysis, and promote safe and timely testing.
- 5. Specimen traceability:** Processes that enable the traceability of samples and promote the safety and timeliness of testing.
- 6. Specimen analysis:** Processes that address failures of Quality Control and promote safe and timely testing.
- 7. Verification, validation and documentation of methods:** Verification is the process of demonstrating the performance criteria to which the method has been validated can be met by the facility, prior to introducing into routine use. Method validation is the process of establishing the performance characteristics and limitations of a method, and the identification of the influences that may change these characteristics, and to what extent.
- 8. Quality Assurance:** Participation in Quality Assurance Programs, performance reviews and corrective actions where performance is unsatisfactory.
- 9. Reporting results:** Unambiguous reports, current best practice reporting, promote the safety of testing by facilitating timely and appropriate clinical interventions.
- 10. Turnaround times:** Turnaround times that allow timely decision-making promote good patient outcomes from testing.
- 11. Communication:** Processes that allow the communication of critical (high risk) results to clinicians, the management of confidential results, and privacy, promote the safety of testing.
- 12. Send away tests:** Risk management processes that address transport, handovers, specimen integrity, the quality of testing in the referral Medical Pathology Service, turnaround times and the delivery of reports to the referring doctor and the referring Medical Pathology Service improve the safety of testing.
- 13. Reviews of incidents:** Processes that investigate incidents with real or potential adverse outcomes for patients, take corrective actions, monitor the efficacy of these actions, and improve the safety of testing. Processes to identify, track and reduce diagnostic errors.

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