REQUIREMENTS FOR MEDICAL PATHOLOGY SERVICES
(First Edition 2013)
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 purpose of these Requirements is to provide an overarching document broadly outlining the 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. **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 both the providers and users of the Laboratory.
# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ACSQHC</td>
<td>Australian Commission on Safety and Quality in Health Care</td>
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<td>AS</td>
<td>Australian Standard</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>NPAAC</td>
<td>National Pathology Accreditation Advisory Council</td>
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<td>NSQHSS</td>
<td>National Safety and Quality Health Service Standards</td>
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<td>OH&amp;S</td>
<td>Occupational Health and Safety</td>
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<td>RCPA</td>
<td>Royal College of Pathologists of Australasia</td>
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## Definitions

<table>
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<tr>
<th>Term</th>
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<tr>
<td>External Quality Assessment</td>
<td>means a program in which multiple Specimens are periodically sent to Laboratories for analysis and/or identification, in which each Laboratory’s results are compared with those of other Laboratories in the group and/or with an assigned value, and reported to the participating Laboratory and others. Such a program may also compare an individual’s results with their peer group.</td>
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<tr>
<td>Informative</td>
<td>means the material is presented to assist in the application or interpretation of the Standards to which it is attached.</td>
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| Laboratory                                | means a facility for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination, including genetic testing, of materials for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of pathology investigation including the interpretation of results and advice on further appropriate investigation.  

This definition is adapted from AS ISO 15189 Medical laboratories – Requirements for quality and competence.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Medical Pathology Service                 | means any service whereby pathology testing provides information for –  

  - diagnosis and monitoring and exclusion of disease processes and their treatment  
  - health screening  
  - epidemiological data.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Normative                                 | means prescriptive or mandatory and the material carries the same weight as the Standards to which it is attached.                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

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*Requirements for Medical Pathology Services*
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<tr>
<th><strong>Quality Assessment</strong></th>
<th>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.</th>
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<tr>
<td><strong>Quality Assurance</strong></td>
<td>means a part of quality management focused on providing confidence that quality requirements will be fulfilled.</td>
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<td><strong>Quality System</strong></td>
<td>means those management activities involved in the direction and control of the organisation with regard to quality.</td>
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| **Request-Test-Report Cycle** | means 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.  
  
  Request means pre-analytical  
  Test means analytical  
  Report means post-analytical |
| **Specimen**           | means any tissue or fluid from a patient that is submitted to the Laboratory for testing. |
| **Users**              | means referrers, patients and healthcare workers who have a “need to know”.  
  
  Wherever the word patient is used it encompasses carers and guardians. |
Introduction

The first set of National Pathology Accreditation Advisory Council (NPAAC) pathology accreditation standards and guidelines were adopted as part of the Health Insurance Act 1973 in 1986. The NPAAC accreditation framework has continued to evolve since that time.

At its 55th meeting in 2010, NPAAC perceived a need for an overarching document to be applied to all medical pathology testing, which would provide a clear framework to improve consistency and reduce duplication between NPAAC documents. The Requirements for Medical Pathology Services is the Tier 2 NPAAC document that outlines minimum Standards acceptable for good medical pathology practice in Australia and should be read within the context of the national pathology accreditation legislative framework. The Requirements detail core requirements from existing NPAAC publications and from AS ISO 15189 Medical laboratories – Requirements for quality and competence, and must be read together with all other NPAAC Requirements.

Whilst developing these Standards existing NPAAC publications (including those being reviewed at the time) were used as source material. Additional sources of materials included AS ISO 15189, National Safety and Quality Health Service Standards and RCPA Chain of Custody for the Pathology Request-Test-Report Cycle Guidelines1.

NPAAC Requirements apply to all 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 thus these NPAAC Requirements address this extended setting when seeking accreditation. The Requirements should be used for guidance where services are provided outside the accreditation framework.

These Requirements are intended to serve as minimum Standards in the pathology accreditation process and are consistent with the National Safety and Quality Health Service Standards (published in 2011) which were developed by the ACSQHC2.

These Standards have been developed with reference to current and proposed Australian regulations and other standards from the International Organization for Standardisation (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 Laboratory 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.
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 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:

The Secretary
NPAAC Secretariat
Department of Health
GPO Box 9848 (MDP 951)
CANBERRA ACT 2601

Phone: (02) 6289 4017
Fax: (02) 6289 4028
Email: npaac@health.gov.au
Website: www.health.gov.au/npaac

All providers of Medical Pathology Services must be aware of, 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 as set down by the Australian Commission on Safety and Quality in Healthcare. It is inevitable that there still may be some duplication between standards.
1. Ethical Practice

S1.1 The wellbeing of patients and their rights must be primary considerations.

C1.1 There must be provisions to enable User participation in 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. The patient should be given the opportunity to provide additional relevant information.

S1.2 Patients, their Specimens and body parts must be treated with respect.

C1.2 This Standard also applies to the deceased.

S1.3 Policies and procedures that define ethical standards of Laboratory practice must be in place.

C1.3 These policies and procedures must address any commercial, financial or other influences which could adversely affect the provision of services, the quality of the work or bring into question the integrity of the Laboratory.

S1.4 There must be a policy regarding informed consent consistent with jurisdictional requirements.

C1.4(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.

C1.4(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 for quality assurance purposes.

C1.4(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 e.g. genetic testing, HIV testing.

C4.1(iv) Consent should also include informed financial consent.

S1.5 The privacy and confidentiality of patients must be maintained at all times.
2. Governance

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

S2.1 The Laboratory must have a system of governance that actively manages patient safety and quality risks in the delivery of its services.

C2.1 When healthcare organisations or pathology practices amalgamate, merge or cease operations, the integrity of documents and records must be maintained.

S2.2 The Laboratory must be able to be clearly identified by its Users.

S2.3 The designated person(s) under whose direction and control the Laboratory operates must be clearly identifiable and accessible, show leadership to promote safe and ethical practice and must have the authority and competence to ensure and take responsibility for:

(a) policy setting and implementation
(b) compliance with all NPAAC and jurisdictional requirements
(c) operational practices and staffing (including training)
(d) determining the range of tests provided, their methods and procedures taking into account that the numbers processed are sufficient to maintain competence
(e) determining the suitability of referral Laboratories
(f) regular review of the quality systems, proficiency testing data, reports, and all aspects of performance
(g) provision of medical and scientific consultation
(h) procedures used and the tests performed being within the scope of the education, training, continuing professional development and experience of individual staff members
(i) 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
(j) provision of a clearly defined process for contacting a supervisor not currently on site.

C2.3(i) Selected tasks may be delegated but must comply with the governance system, as outlined above.

C2.3(ii) Documentation must be available to support all of the above.

C2.3(iii) The specific requirements for governance and supervision will differ according to the complexity of testing and category of Laboratory.
3. **Quality Management**

S3.1 The Laboratory must have a documented and monitored Quality System in place that addresses such issues as:

(a) policies and procedures relating to risk management that ensure the safety of patients, staff and visitors

(b) test procedures, including reference intervals, source, internal quality control and External Quality Assessment

(c) defined procedures to monitor the traceability of Specimens throughout the Request-Test-Report cycle

(d) protocols to ensure continued integrity of Specimens throughout the Request-Test-Report cycle

(e) policies, protocols and procedures for infection control and surveillance

(f) timely reporting that contributes to safe patient care

(g) responsiveness to consumer input and needs, e.g. requests for information

(h) a waste management policy

(i) a contingency plan for continued operations in the event of equipment and other failures

(j) policies, protocols and procedures to control all documents and information that form the Laboratory’s quality documentation.

S3.2 The Quality System and its documentation must be reviewed and updated on a regular basis.

S3.3 The operations of the Laboratory must be audited as part of the Quality System.
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4. Personnel

S4.1 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 Laboratory’s Quality System.

C4.1(i) There must be documentation demonstrating that the education, training and competence of individual staff members and their trainers is appropriate and adequate for the tests and procedures being performed. There must be a documented staff induction program and documentation that the staff have taken part in the program.

C4.1(ii) All qualified staff involved in the provision of Medical Pathology Services must provide documented evidence of participation in continuing professional development to ensure maintenance and updating of the skills required to undertake their individual responsibilities.

C4.1(iii) Staff must be given time, and should be supported, to attend relevant professional meetings to enable them to maintain and update the skills required to undertake their individual responsibilities.

C4.1(iv) Where maximum workload measures are specified in technical documents, these must not be exceeded.

C4.1(v) Staff working outside normal working hours must be sufficiently trained and experienced to operate without on-site supervision.

C4.1(vi) Medical and scientific staff should be afforded sufficient time to participate in peer review and assessment processes.

S4.2 The Laboratory must offer a consultative service and staff with the necessary competence must be readily available to advise on the interpretation of results. The requesting practitioner must be able to obtain advice 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 Laboratory’s reference values
(d) the scientific basis of the results
(e) the clinical significance of the requested procedure and its suitability to assist in solving any clinical problem
(f) which further investigations may be helpful.
S4.3 Access to adequate and up to date educational resources for all staff in the individual pathology disciplines must be provided at the Laboratory.

C4.3 These resources may be textbooks, journals and electronic resources.

S4.4 Staff health, safety and a suitable work environment must be assured. There must be compliance with all OH&S and public health jurisdictional requirements.

C4.4(i) Staff must not be subjected to harassment or bullying.

C4.4(ii) There must be policies regarding sharps, biohazard spills and infection control

C4.4(iii) A suitable work environment should include consideration of such factors as adequate interval breaks and noise levels.
5. Facilities and Equipment

A. Premises

S5.1 Premises must be clearly identified, suitable for activities undertaken therein and must comply with building regulations as well as local government, jurisdictional and OH&S requirements.

S5.2 There must be sufficient designated space and facilities for the safe and satisfactory provision of the Medical Pathology Service. This applies to all sectors of the Laboratory including testing areas, Specimen collection, administrative and mortuary areas.

C5.2 Aspects to be considered should include:

(i) reception and handling of Specimens
(ii) handling of hazardous substances, sharps and waste disposal
(iii) performance of all testing
(iv) functioning and maintenance of equipment
(v) storage of reagents
(vi) storage of blood and blood products
(vii) storage of Specimens and records
(viii) storage of food, drinks and pharmaceuticals
(ix) undertaking of administrative duties
(x) safety equipment including safety cabinets, personal protective equipment, specific hand basins, emergency eye wash and shower
(xi) ventilation, lighting and noise levels
(xii) security
(xiii) communication facilities for the testing area, the collection centre, the collectors and the administration between those areas and with patients and referrers
(xiv) designated areas for patient reception, waiting and collection areas with wheelchair access
(xv) toilet amenities for staff, patients and visitors
(xvi) electricity supply for equipment (including critical back-up for emergencies, as required)
(xvii) water supply and outlets.

B. Equipment

For the purpose of these Standards, instruments, reference materials, consumables, disposables, reagents, cabinets (incubators and refrigerators), analytical systems, and electronic information systems are considered to be “Equipment”.

The Tier 3 and Tier 4 NPAAC Requirements identify specific items of equipment.

S5.3 Equipment must be “fit for purpose”, and must be maintained to ensure functionality. Associated documents must form part of the Quality System.
C5.3(i) Instruments **must** comply with specifications, **must** achieve required performance characteristics, **must** be uniquely identified and, where relevant, **must** be calibrated.

C5.3(ii) Reagents **must** not be used outside their expiry dates unless extension thereof has been validated.

C5.3(iii) First aid material **must** be available.

**S5.4** Electronic information systems must be protected to ensure and maintain integrity of data and to prevent unauthorised access, alteration or destruction of data.
6. Request-Test-Report Cycle

It is recognised that not all Specimen collections are done within the control of the Laboratory.

A. Pre-Analytical

SA6.1 Sufficient information must be available for requesting practitioners and patients about the Medical Pathology Services provided and both parties must be advised about any prerequisites for testing purposes.

SA6.2 Medical Pathology Services provided must be in response to a documented request identifying the patient, the requesting practitioner, the tests requested and required clinical information (e.g. any medication history, family history, ancestry).

CA6.2(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 data.

CA6.2(ii) At times 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 documented. A confirmatory documented request must be received.

SA6.3 Collection of Specimens must be performed with accurate identification of the patient and labelling of Specimens in accordance with written protocols.

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

CA6.3(i) Where the request has been transported electronically, there must be a documented protocol indicating how the patient is to be identified at the point of collection.

CA6.3(ii) 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.

CA6.3(iii) When labelling the patient’s Specimen, three identifiers should be used where practicable (two must be used if three cannot be accommodated).

CA6.3(iv) There must be concordance between the identifiers on the request form and the Specimen label.

CA6.3(v) The Specimen must be labelled in the presence of the patient and, if possible, the patient identifiers should be confirmed by the patient.

CA6.3(vi) The identifiers must include full name and at least one of either date of birth or unique medical record number. Additional identifiers may be
the unique accession number or patient address. Alternative identifiers may be used in special circumstances such as patients who wish to remain anonymous.

CA6.3(vii) Where patients collect their own Specimens, they must be provided with instructions in accordance with the collection instructions manual.

CA6.3(viii) Where requested to accommodate 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.

CA6.3(ix) 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, for example O and 0, 1 and 7, Z and 2.

SA6.4 The Laboratory 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 Laboratory
(e) anatomical site of tissue Specimens
(f) type of Specimen (e.g. urine, joint aspirate)
(g) person collecting (desirable for all records, but essential for blood grouping, cross matching, tissue typing and genetic testing)
(h) clinical status of patient (e.g. fasting), where required
(i) Specimen characteristics which may provide information relevant to interpretation of results (e.g. haemolysis)
(j) informed consent where required by legislation or NPAAC documents
(k) the name of the requester.

SA6.5 The Laboratory must have a written policy for the management of inadequately labelled Specimens and/or incomplete request forms.

CA6.5 In order to minimise risk to patients, the staff should endeavour to obtain the relevant details during the pre-analytical phase by advising and educating requesting practitioners about the importance of providing the necessary information. Examples of these risks are inadequate labelling leading to wrong patient results, paediatric Specimen where no age is provided and reference intervals are given for adults, and lack of clinical information leading to erroneous conclusions.
SA6.6  Pathology Specimens must be packaged and transported in a manner that assures the integrity of the Specimen and safety of the public.

SA6.7  The integrity of the Specimen must be ensured prior to testing.

CA6.7  Examples of compromised integrity include haemolysis, partial clotting of anticoagulated Specimens, absence of fixative for tissue Specimens or leaking Specimen containers.
B. Analytical

SB6.1 Validated and/or verified recognised procedures must be used, if available.

CB6.1(i) Non-validated tests must only be performed where dictated by clinical necessity or public risk.

CB 6.1(ii) Validation and verification records must be available.

SB6.2 The analytical performance must meet the requirements for the clinical application of the test results.

SB6.3 Authorised test procedures must be documented and available in the work area in which they are used.

CB6.3 Documentation of test procedures must include the source or reference for the procedure, the date it was last reviewed, the calibration standards and controls required, and instructions for handling Specimens and issuing results. The manufacturer’s package insert must be included in the documentation, where available.

SB6.4 Testing must be validated by the use of internal quality control material. Where this is not available, alternative mechanisms to ensure validity of testing must be carried out, such as Specimen exchange with an alternate Laboratory.

CB6.4(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.

CB6.4(ii) Where internal quality material is available, it must be included in the test system in a manner as close to patient Specimens as possible.

SB6.5 Staff must be aware of factors which may give rise to uncertainty about a test result.

CB6.5 There may be pre-analytical sources, software limitations, measurement uncertainty within numerical analytical processes, and post-analytical sources.

SB6.6 Measurement uncertainty must be estimated for each test procedure where relevant and possible.

SB6.7 The Laboratory must have evidence that its measurement uncertainties meet clinical requirements.

SB6.8 Estimates of measurement uncertainty must be made available to requesters upon request.
C. Post-Analytical

The 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.

SC6.1 There must be a documented policy for results from test procedures and Specimen examinations. The results must be validated to ensure that they are correct, evaluated against internal quality control, timely, clear and unambiguous, clinically relevant and matched to the request form.

CC6.1(i) If a clinically necessitated non-validated test has been performed, the report must clearly indicate that the diagnostic validity has not been established.

CC6.1(ii) Interpretative and additional comments may be added by identifiable authorised persons.

CC6.1(iii) Structured reporting should be used where appropriate.

SC6.2 The reports must contain:

(a) patient demographic data (e.g. name, sex, age),
(b) tissue or fluid tested and, where relevant, its state (e.g. fresh, frozen, fixed)
(c) validated result data
(d) identity of the Laboratory issuing the report
(e) identity of any referral Laboratory that performed part or all of the testing
(f) all interpretive comments provided by the referral Laboratory, and
(g) date and time of report release.

CC6.2(i) Provisional/interim reports must be issued according to documented policy and indicate their provisional nature.

CC6.2(ii) Reports may be paper based or electronically submitted.

CC6.2(iii) Test reports should not be copied or reproduced except in their entirety.

SC6.3 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. Verbal reports must be given according to documented policy, which must include the name of the person providing and the name of the person receiving the report, and the date and time of the communication.

CC6.3(i) Verbal reports must be followed up with an electronic or hard copy as soon as possible.
CC6.3(ii) Where clinically significant results with the potential to have a serious immediate impact 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.

CC6.3(iii) Where there are clinically significant results and these 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.

SC6.4 There must be policies for:

(a) the reporting of notifiable diseases in accordance with jurisdictional requirements

(b) reporting to disease registries

SC6.5 Results provided directly to patients must be given according to the Laboratory’s established policy.

SC6.6 Retention of patient data, Specimens, test procedures and equipment records must comply with NPAAC Requirements and jurisdictional requirements.

SC6.7 Disposal of biological material from pathology testing must comply with jurisdictional regulations and the organisation’s waste management policy.
7. Quality Assurance

S7.1 Compliance with the Laboratory’s quality system must be audited.

C7.1 Prior to the introduction of a new test into routine clinical service, the analytical validity and clinical utility of the test must be documented in sufficient detail to enable external review.

S7.2 The Laboratory must be enrolled, participate and perform to an acceptable standard in external proficiency testing programs that cover all test methods performed where such programs are available.

C7.2(i) Where External Quality Assessment 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.

C7.2(ii) All staff performing Medical Pathology Services must participate in External Quality Assessment programs in accordance with Laboratory policy and according to their responsibilities. The policy must include frequency of participation.

C7.2(iii) In order 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.

S7.3 Specimens within the test cycle must be traceable at all times.

S7.4 Non-concordant results must be investigated and the possible ramifications for patient Specimen testing must be considered and appropriate actions taken.

S7.5 The services that the Laboratory provides must be evaluated.

C7.5(i) Where practicable, performance measures such as incident and error rates, turn-around times etc, must be used for evaluation and improvement purposes.

C7.5(ii) There must be protocols to facilitate feedback from patients and referrers and the feedback used for evaluation and improvement purposes.

C7.5(iii) There must be protocols for the redress of valid complaints. Complaints and the response must be sighted by the person designated in S2.3 under the Governance section in this document.
References


Bibliography


Acknowledgements

Dr Eva Raik AM (Chair)

Mr Mike Ralston

Associate Professor Peter Stewart

Dr Janney Wale

Members of the National Pathology Accreditation Advisory Council (NPAAC)

Members of the NPAAC Document Review and Liaison Committee (DRL)
Further information

Other NPAAC documents are available from:

NPAAC Secretariat
Primary Care, Diagnostics & Radiation
Oncology Branch
Department of Health
GPO Box 9848 (MDP 951)
CANBERRA ACT 2601

Phone: (02) 6289 4017
Fax: (02) 6289 4028
Email: npaac@health.gov.au
Website: www.health.gov.au/npaac