

## Module overview

Please note: This module must be read in conjunction with the Fundamentals of the Framework (including glossary and acronym list).

A patient requiring pathology services does not usually need to be near the pathology equipment or facility. There are some time-limited tests that require the patient to be nearby; however, even in these cases, the patient's specimen may be taken off-site. Therefore, the location of the specimen processing facility is not usually a relevant factor for pathology services.

Point of Care Testing (PoCT) has become increasingly important, particularly in same-day procedural centres, community alternatives to hospitals, and in rural and remote locations. PoCT includes blood gas analysers with parameters for electrolytes, haemoglobin, glucose and other measurements. PoCT may also be a useful strategy to shorten the length of a patient's hospital stay, move care to the outpatient setting, and as a central feature in clinical decision-making.

The levels of pathology services provided by a health facility reflect the acuity of the patient and the number of acutely ill patients treated at that facility. Where there is infrequent acute activity, a non-urgent sample request can be collected and sent off-site for processing, and the report returned. If urgent, the patient may be transferred to a facility with access to a higher level pathology service.

In a small number of health facilities with very high patient acuity, and where a rapid response is required, pathology services are available on-site 24 hours a day. Trauma, emergency, oncology and maternity volumes are key variables in the level of pathology service required, due to the frequency of urgent requests.

Pathology laboratories and suppliers of external assessment programs are required to establish and maintain a quality system appropriate to the functions of their respective organisations. These standards outline the general features an external quality assessment program must meet in order to effectively monitor the various pathology disciplines. It is important for a laboratory to be able to select a quality assessment program compatible with the particular service it provides. The ongoing participation—to an acceptable standard—in appropriate external quality assessment programs is an essential aspect of good laboratory practice.

All laboratories should be accredited by the National Association of Testing Authorities (NATA)<sup>1</sup> acting in collaboration with the Royal College of Pathologists of Australasia (RCPA).<sup>2</sup> Five laboratory categories are specified in Section 17 of the Health Insurance Act (Accredited Pathology Laboratory – Approval) Principles 2002.<sup>3</sup> These are:

- category GX or GY (general)—providing services in one or more groups of pathology disciplines in either a single or a number of collocated laboratories:
- category B (branch)—is an integral part of a GX or GY laboratory, or part of a regional pathology service
- category M (medical practice)—provides a limited number of tests and is situated within a medical practice
- category S (specialised)—provides a limited range of particular tests.

Several clinical diagnostic services are performed in each category of laboratory. Staffing and supervisory requirements differ for each of the five categories. The range of tests performed by each laboratory category must be approved by the accrediting agency.

**These tests include, but are not limited to:**

<b>Anatomical pathology</b>	<ul style="list-style-type: none"> <li>• Histology and cytopathology</li> </ul>
<b>Haematology</b>	<ul style="list-style-type: none"> <li>• Routine haematology</li> <li>• Bone marrow pathology</li> <li>• Blood transfusion and related services</li> <li>• Coagulation</li> <li>• Cytogenetics</li> <li>• Haemolytic anaemia</li> <li>• Megaloblastic anaemia</li> <li>• Molecular genetics</li> <li>• Routine biochemistry</li> </ul>
<b>Chemical pathology</b>	<ul style="list-style-type: none"> <li>• Therapeutic drug monitoring</li> <li>• Endocrinology</li> <li>• Protein investigations</li> <li>• Metabolic markers</li> <li>• Neonatal screening</li> <li>• Toxicology</li> <li>• Trace elements</li> <li>• Tumour markers</li> </ul>
<b>Microbiology</b>	<ul style="list-style-type: none"> <li>• Bacteriology</li> <li>• Mycobacteriology</li> <li>• Molecular microbiology</li> <li>• Serology</li> <li>• Virology</li> </ul>

- Allergy testing
- Autoimmune investigations
- Immunobiology
- Tissue typing

The relevant policies for participating in external quality assessment programs by both the laboratory and the program supplier should include:

- the aims and criteria for program selection
- the range of services
- documented procedures for participating in the selected program
- reporting procedures, suitability of data analysis and interpretation of results
- a review of mechanisms.

Participation in external quality assessment is a mandatory requirement for meeting acceptable laboratory performance standards. These are described in the Australian Standard 4633 (International Standards Organisation [ISO] 15189), National Association of Testing Authorities (NATA) Field Application Document: Medical Testing Supplementary Requirements for Accreditation, and in the laboratory's Quality Manual. Quality assessment may also include measuring key performance indicators for the range of testing available. These include turnaround times used by the relevant hospital and external proficiency programs.

## Service networks

In addition to the requirements outlined in the Fundamentals of the Framework, specific service network requirements include:

- documented processes, at each service level, with an accredited public or private laboratory for referral and transfer of specimens to ensure safe, ongoing management of complex tests
- the requirement to meet the National Pathology Accreditation Advisory Council (NPAAC) Requirements for the Packaging and Transport of Patient Specimens and Associated Material.<sup>4</sup>

## Service requirements

In addition to the requirements outlined in the Fundamentals of the Framework, specific service requirements include:

- provide relevant clinical indicator data to satisfy accreditation and other statutory reporting obligations.

# Workforce requirements

In addition to the requirements outlined in the Fundamentals of the Framework, specific workforce requirements include:

- laboratories staffed in accordance with relevant NPAAC standards
- supervisory roles for each of the laboratories defined as per laboratory categories.

The definitions of disciplines of staff that may be found in pathology laboratories are listed below and are in accordance with the *Health Insurance Act 1973*.

**Table 1: Definitions of pathology laboratory disciplines**

Discipline	Definition
<b>Pathologist</b>	A medical practitioner who has been recognised for the purposes of the <i>Health Insurance Act 1973</i> as a specialist in one of the pathology specialties listed in Item 113 of Schedule 4 of the Health Insurance Regulations 1975. <sup>5</sup>
<b>Supervising pathologist</b>	A pathologist who has had training to allow him/her to supervise a medical testing laboratory.
<b>Scientist</b>	A person who possesses one of the following qualifications: <ol style="list-style-type: none"> <li>A degree in science or applied science with subjects relevant to the field of pathology awarded after not less than 3 years full-time study, or an equivalent period of part-time study, at a university in Australia, which provides for direct entry or following examination to a professional class of membership of the Australasian Association of Clinical Biochemists,<sup>6</sup> Australian Institute of Medical Scientists,<sup>7</sup> Australian Society for Microbiology,<sup>8</sup> Australian Society of Cytology,<sup>9</sup> or the Human Genetics Society of Australasia.<sup>10</sup></li> <li>An associate qualification conferred by the Australian Institute of Medical Technologists<sup>11</sup> before 1 December 1973.</li> <li>A qualification that the Minister determines, pursuant to the definition of 'scientist' in subsection 23DNA(4) of the Health Insurance Act 1973, to be equivalent to a qualification referred to in paragraph (a) or (b) of this definition.</li> </ol>
<b>Supervising scientist</b>	On-site staff at a category B laboratory must include an on-site supervisor who is a laboratory scientist with appropriate qualifications plus a minimum of 2 years supervised relevant experience for the work being performed in the specified laboratory. The on-site supervisor must be present at the laboratory during normal working hours. Where more than one person provides this supervision, a designated person must ensure the continuity of overall onsite supervision.

Discipline	Definition
<b>Senior scientist</b>	<p>A scientist who has had not less than 10 years full-time relevant laboratory experience and who possesses one of the following qualifications:</p> <ul style="list-style-type: none"> <li>(a) A Doctorate of Philosophy in a subject relevant to the field of pathology</li> <li>(b) A Fellowship of the Australasian Association of Clinical Biochemists</li> <li>(c) A Fellowship of the Australian Institute of Medical Scientists</li> <li>(d) A Fellowship of the Australian Society for Microbiology (medical/clinical microbiology)</li> <li>(e) A Fellowship of the Human Genetics Society of Australasia</li> <li>(f) A qualification that the Minister determines, pursuant to the definition of 'scientist' in subsection 23DNA(4) of the Health Insurance Act 1973, to be equivalent to a qualification referred to in paragraph (a), (b), (c), (d) or (e) of this definition.</li> </ul>

## Pathology services

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service description	<ul style="list-style-type: none"> <li>no on-site laboratory, but may have access to PoCT as well as competent operators to use this equipment.</li> <li>no frozen sections performed, and pathology testing services provided remotely by laboratory staff in facility accredited by NATA and RCPA.</li> </ul>	<ul style="list-style-type: none"> <li>no on-site laboratory, but has access to PoCT.</li> <li>qualified staff available to collect and transport specimens to nearest laboratory.</li> <li>may have on-site blood storage, but cross-matched blood—managed by off-site laboratory—is available locally, where this is applicable to the facility.</li> </ul>	<p>As per Level 2, plus:</p> <ul style="list-style-type: none"> <li>will usually provide limited range of approved tests and has ability to manage emergency pathology specimens until transfer to higher level available.</li> <li>more complex testing usually accessible via higher level pathology services, mainly through electronic distributions, which return results promptly to requesting laboratories / practitioner.</li> </ul>	<ul style="list-style-type: none"> <li>part of service network with some specialist diagnostic services available.</li> <li>more complex testing usually accessible via higher level pathology services mainly through electronic distributions, which return results promptly to requesting laboratories / practitioner.</li> </ul>	<ul style="list-style-type: none"> <li>provides more complex testing, including additions noted below.</li> </ul>	<ul style="list-style-type: none"> <li>includes superspecialty services and provides highly complex pathology services such as clinical investigations, transplantation services and blood banking.</li> <li>services provided by on-site NATA / RCPA accredited.</li> <li>on-site collection and processing capabilities available, as well as laboratory and medical staff.</li> <li>some or all Level 6 services may be provided by Level 5</li> </ul>

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
						laboratories, also accessible to Level 3, 4 and 5 pathology laboratories by referral of samples where relevant to patient care.
<b>Service requirements</b>	<p>As per module overview, plus:</p> <ul style="list-style-type: none"> <li>access to pathology services via ambulatory access or home collection of samples.</li> </ul>	<p>A Level 2 service requires:</p> <ul style="list-style-type: none"> <li>access to approved specimen and blood collection service.</li> <li>access to courier / transport service for specimen and blood product transfer to laboratory for processing, available for facility operating hours.</li> <li>collection services provided on-site</li> </ul>	<p>As per Level 2, plus:</p> <ul style="list-style-type: none"> <li>services provided on-site (access to laboratory will meet on-site requirement statement).</li> <li>NATA / RCPA accredited laboratory access to NATA / RCPA accredited laboratory with collection services where: <ul style="list-style-type: none"> <li>laboratory scientists / health professionals on duty /</li> </ul> </li> </ul>	<p>As per Level 3, plus:</p> <ul style="list-style-type: none"> <li>laboratory scientist / health professional must be available for high-use periods, including weekends and public holidays. or</li> <li>service can be provided by on-site NATA / RCPA accredited pathology laboratory.</li> </ul>	<p>As per Level 4, plus:</p> <ul style="list-style-type: none"> <li>services from NATA / RCPA accredited laboratory with: <ul style="list-style-type: none"> <li>on-site collection and processing capabilities</li> <li>laboratory and medical staff</li> <li>blood product storage and cross-matching capabilities</li> </ul> </li> </ul>	<p>As per Level 5, plus:</p> <ul style="list-style-type: none"> <li>blood product storage and cross-matching capabilities, fine needle aspiration and frozen section services provided with following additions: <ul style="list-style-type: none"> <li>access to specialised pathology services such as microbiological virology investigation</li> </ul> </li> </ul>

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
		by suitably qualified laboratory staff, or facility / unit staff.	<p>available in laboratory</p> <ul style="list-style-type: none"> <li>- supervision from NATA / RCPA accredited laboratory (NATA / RCPA accreditation to NPAAC Standards for Pathology)</li> <li>- pathologists from laboratory available 24 hours</li> <li>- frozen sections may be performed if cryostat is on-site</li> <li>- access to full haematology (including coagulation and manual</li> </ul>		<ul style="list-style-type: none"> <li>- fine needle aspiration</li> <li>- frozen sections services.</li> <li>• pathologists present accessible at laboratory during business hours and accessible 24/7.</li> <li>• scientist present at laboratory during business hours and accessible 24/7.</li> <li>• laboratory staff present 24 hours.</li> <li>• access to comprehensive suite of anatomical pathology, cytopathology, chemical pathology, haematology (including blood banking), immunopatholog</li> </ul>	<p>ns and advice</p> <ul style="list-style-type: none"> <li>- cytogenetics service, with flow cytometry / cytochemistry, chromosome analysis and immunophenotyping carried out within 18 days</li> <li>- cell culture facilities and cryopreservation</li> <li>- same-day therapeutic drug level results</li> <li>- comprehensive facilities for molecular as well as serological techniques</li> </ul>

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
			<p>differential full blood count), routine biochemistry and transfusion service with laboratory tests and blood products available 24 hours</p> <ul style="list-style-type: none"> <li>– access to cross-matched blood managed by other off-site laboratories and available locally</li> <li>– routine microbiology services (including culture of blood, urine, stool)</li> </ul>		<p>y and microbiology general and specialist services 24 hours.</p>	<p>of tissue for typing and matching.</p> <ul style="list-style-type: none"> <li>• where applicable to haematological transplantation services: <ul style="list-style-type: none"> <li>– access to accredited laboratory services with appropriate quality controls in collection, processing and storage of bone marrow and peripheral blood stem cells</li> <li>– cryopreservation for autologous transplantation</li> <li>– procedures in place to</li> </ul> </li> </ul>

	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
			undertaken or samples referred as per laboratory protocols. <ul style="list-style-type: none"> <li>– routine anatomical pathology available within 96 hours.</li> </ul>			ensure clonogenic capacity and sterility of stem cell preparations by specific clinical scientists.
<b>Workforce requirements</b>	As per module overview	As per module overview	As per module overview	As per module overview	As per module overview	As per module overview
<b>Specific risk considerations</b>	Nil	Nil	Nil	Nil	Nil	Nil

# Legislation, regulations and legislative standards

In addition to what is included in the Fundamentals of the Framework, pathology services must comply with the following:

- Australian Government Department of Health and Ageing. Requirements for quality management in medical laboratories (2007 Edition). Canberra: Department of Health and Ageing; 2007. <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-dhaquality.htm>
- National Association of Testing Authorities, Australia. AS4633 (ISO15189) Field application document: Medical testing. NATA; 2013. [http://www.nata.com.au/phocadownload/publications/Accreditation\\_criteria/ISO15189-Medical/MEDFAD.pdf](http://www.nata.com.au/phocadownload/publications/Accreditation_criteria/ISO15189-Medical/MEDFAD.pdf)
- Standards Australia/Standards New Zealand. AS/NZS 2243: Safety in Laboratories, Parts 1-9. <http://infostore.saiglobal.com/store2/results2.aspx?keyword=safety%20in%20laboratories&Db=AS&searchType=simple&Status=all&publisher=AS&Max=15&Search=Proceed>

## Non-mandatory standards, guidelines, benchmarks, policies and frameworks

(not exhaustive & hyperlinks current at date of release of CSCF v3.2)

As per the Fundamentals of the Framework, plus:

- National Association of Testing Authorities, Australia. [www.nata.asn.au/](http://www.nata.asn.au/)
- National Pathology Accreditation Advisory Council. Standards for Pathology. [www.health.gov.au/npaac](http://www.health.gov.au/npaac)
- Royal College of Pathologists of Australasia. <http://www.rcpa.edu.au/>

## Reference list

1. National Association of Testing Authorities (NATA). [www.nata.asn.au/](http://www.nata.asn.au/)
2. Royal College of Pathologists of Australasia (RCPA). [www.rcpa.edu.au/](http://www.rcpa.edu.au/)
3. Australian Government. Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002 HS/11/2002. Canberra: Australian Government; 2002. <https://www.legislation.gov.au/Details/F2017C00258>
4. National Pathology Accreditation Advisory Council. Requirements for the packaging and transport of pathology specimens and associated materials. Canberra: Department of Health and Ageing; 2013. <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-docs-PackTransPathSpecimens.htm>

5. Australian Government: Health Insurance (Pathology Services Table) Regulation 2013 2016. <https://www.legislation.gov.au/Details/F2016L01304>
6. Australasian Association of Clinical Biochemists. [www.aacb.asn.au/](http://www.aacb.asn.au/)
7. Australian Institute of Medical Scientists. [www.aims.org.au/c/](http://www.aims.org.au/c/)
8. Australian Society for Microbiology. [www.theasm.com.au/](http://www.theasm.com.au/)
9. Australian Society of Cytology. [www.cytology-asc.com/](http://www.cytology-asc.com/)
10. Human Genetics Society of Australasia. [www.hgsa.com.au/](http://www.hgsa.com.au/)
11. Australian Institute of Medical Technologists. <http://www.aims.org.au/>