Pathology Services

Government of South Australia
SA Health

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. Many pathologists also have specialized clinical roles (e.g. Haematology, Immunology, Infectious Diseases, Metaboloic Medicine) and these pathologists need proximity to the relevant patients. For intraoperative consultations, such as frozen sections, where turn-around-time is critical proximity of the pathology service, including pathologist, technical staff and equipment to the hospital facility is essential.

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. PoCT must be subject to quality control and this and the requirements for equipment selection, servicing and calibration, training/supervision of users of the equipment and delivery of results to Laboratory Information Systems are important considerations that benefit from involvement of a GX or GY laboratory. PoCT may involve greater costs than processing through an automated laboratory but cost efficiency needs to take account also of impact of PoCT on clinical workflow.

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 7 days a week. Trauma, emergency, oncology and maternity volumes are key variables in the level of pathology service required, due to the frequency of urgent requests. Access to expert pathologist input for optimum test requesting and result interpretation is a key requirement for tertiary services.

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)[1] acting in collaboration with the Royal College of Pathologists of Australasia (RCPA).[2] Five laboratory categories are specified in Section 17 of the Health Insurance Act (Accredited Pathology Laboratory – Approval) Principles 2002.[3] 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:

Anatomical pathology	Histology, cytopathology and autopsy pathology
Haematology	Routine haematology
	Bone marrow pathology
	Blood transfusion and related services
	Coagulation
	Cytogenetics
	Tissue typing
	Haemolytic anaemia
	Megaloblastic anaemia
Molecular genetics	
Chemical pathology	Therapeutic drug monitoring
	Endocrinology
	Protein investigations
	Metabolic markers
	Neonatal and antenatal screening
	Toxicology
	Trace elements
	Routine biochemistry
	Tumour markers
Microbiology	Bacteriology
	Mycobacteriology
	Molecular microbiology
	Serology
	Virology
Immunology	Allergy testing
	Autoimmune investigations
	Primary Immunodeficiency investigation
	Immunochemistry
	Flow cytometry
	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 by which the laboratory reviews its outcomes in external quality assessment and when indicated, takes corrective action and follows up on the results of those corrective actions.

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 and associated data including data relating to patient and requesting clinician identity and clinical notes relevant to the request.
- the requirement to meet the National Pathology Accreditation Advisory Council (NPAAC) Requirements for the Packaging and Transport of Patient Specimens and Associated Material.[4]

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.
- compliance with SA Health policy directives and guidelines that are referenced at:
  - SA Health Policy Directives
  - SA Health Policy Guidelines
  - SA Health Clinical Directives and Guidelines

Workforce Requirements

The CSCF does not prescribe staffing ratios, absolute skill mix, or clerical and/or administration workforce requirements for a team providing a service, as these are best determined locally and in accordance with relevant industrial instruments. Where minimum standards, guidelines or benchmarks are available, the requirements outlined in this module should be considered as a guide only. All staffing requirements should be read in conjunction with the *Health Care Act 2008*, Awards and relevant Enterprise Agreements including, but not limited to:

- SA Health Salaried Medical Officers Enterprise Agreement 2013
- SA Health Visiting Medical Specialists Enterprise Agreement 2012
- SA Health Clinical Academics Enterprise Agreement 2014
- Nursing/Midwifery (South Australian Public Sector) Enterprise Agreement 2013
- SA Ambulance Service Enterprise Agreement 2011
- SA Public Sector Wages Parity Enterprise Agreement Salaried 2014

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
Pathologist	A medical practitioner who has been recognised for the purposes of the *Health Insurance Act 1973* as a specialist in one of the pathology specialties listed in Item 113 of Schedule 4 of the Health Insurance Regulations 1975.[5]
Supervising pathologist	A pathologist who has had training to allow him/her to supervise a medical testing laboratory.
Scientist	A person who possesses one of the following qualifications: (a) 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,[6] Australian Institute of Medical Scientists,[7] Australian Society for Microbiology,[8] Australian Society of Cytology,[9] or the Human Genetics Society of Australasia.[10] (b) An associate qualification conferred by the Australian Institute of Medical Technologists[11] before 1 December 1973. (c) 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.
Supervising scientist	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.
Senior scientist	A scientist who has had not less than 10 years full-time relevant laboratory experience and who possesses one of the following qualifications: (a) A Doctorate of Philosophy in a subject relevant to the field of pathology (b) A Fellowship of the Australasian Association of Clinical Biochemists (c) A Fellowship of the Australian Institute of Medical Scientists (d) A Fellowship of the Australian Society for Microbiology (medical/clinical microbiology) (e) A Fellowship of the Human Genetics Society of Australasia or (f) A Fellowship of the Faculty of Science of the RCPA (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.
Senior clinical scientist	Similar to Senior scientist with qualifications requiring a masters or equivalent and also Fellowship of the Faculty of the Science of the RCPA

Pathology Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service description	As per module overview, plus: > no on-site laboratory, but may have access to PoCT as well as competent operators to use this equipment. > no frozen sections performed, and pathology testing services provided remotely by laboratory staff in facility accredited by NATA and RCPA.	As per Level 1, plus: > no on-site laboratory, but has access to PoCT. > qualified staff available to collect and transport specimens to nearest laboratory. > 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. > initial operating theatre frozen sections performed.	As per Level 2, plus: > will usually provide limited range of approved tests and has ability to manage emergency pathology specimens until transfer to higher level available. > more complex testing usually accessible via higher level pathology services, mainly through electronic distributions, which return results promptly to requesting laboratories / practitioner.	As per Level 3, plus: > part of service network with some specialist diagnostic services available. > more complex testing usually accessible via higher level pathology services mainly through electronic distributions, which return results promptly to requesting laboratories / practitioner.	As per Level 4, plus: > provides more complex testing, including additions noted below.	As per Level 5, plus: > includes superspecialty services and provides highly complex pathology services such as clinical investigations, transplantation services and blood banking. > services provided by on-site NATA / RCPA accredited category GX or GY laboratory. > on-site collection and processing capabilities available, as well as laboratory and medical staff. > some or all Level 6 services may be provided by Level 5 laboratories, also accessible to Level 3, 4 and 5 pathology laboratories by referral of samples where relevant to patient care.

Pathology Services	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Service requirements	As per module overview, plus: > access to pathology services via ambulatory access or home collection of samples.	A Level 2 service requires: > access to approved specimen and blood collection service. > access to courier / transport service for specimen and blood product transfer to laboratory for processing, available for facility operating hours. > collection services provided on-site by suitably qualified laboratory staff, or facility / unit staff.	As per Level 2, plus: > services provided on-site (access to category B laboratory will meet on-site requirement statement). > NATA / RCPA accredited category B laboratory with collection services where: - laboratory scientists / health professionals on duty / available in laboratory - supervision from NATA / RCPA accredited category G laboratory (NATA / RCPA accreditation to NPAAC Standards for Pathology) - pathologists from category G laboratory available 24 hours - frozen sections may be performed if cryostat is on-site - access to full haematology (including coagulation and manual differential full blood count), routine biochemistry and transfusion service with laboratory tests and blood products available 24 hours - access to cross-matched blood managed by other off-site laboratories and available locally - routine microbiology services (including culture of blood, urine, stool) undertaken or samples referred as per laboratory protocols. - routine anatomical pathology available within 96 hours.	As per Level 3, plus: > laboratory scientist / health professional must be available for high-use periods, including weekends and public holidays. **or** > service can be provided by on-site NATA / RCPA accredited category GX or GY pathology laboratory.	As per Level 4, plus: > services from NATA / RCPA accredited category GX or GY laboratory with: - on-site collection and processing capabilities - laboratory and medical staff - blood product storage and cross-matching capabilities - fine needle aspiration - frozen sections services. > pathologists onsite at laboratory during business hours and accessible 24/7. > laboratory staff onsite 24 hours. > access to comprehensive suite of anatomical pathology, cytopathology, chemical pathology, haematology (including blood banking), immunopathology and microbiology general and specialist services 24 hours.	As per Level 5, plus: > blood product storage and cross-matching capabilities, fine needle aspiration and frozen section services provided with following additions: - access to specialised pathology services such as microbiological virology investigations and advice - cytogenetics service, with flow cytometry / cytochemistry, chromosome analysis and immunophenotyping carried out within 18 days - in diagnosis of primary immune deficiency in neonates or diagnosis of Haematological malignancy, flow cytometry results are often needed within a few hours - cell culture facilities and cryopreservation - same-day therapeutic drug level results - comprehensive facilities for molecular as well as serological techniques of tissue for typing and matching. > where applicable to haematological transplantation services: - access to accredited laboratory services with appropriate quality controls in collection, processing and storage of bone marrow and peripheral blood stem cells - cryopreservation for autologous transplantation - procedures in place to ensure clonogenic capacity and sterility of stem cell preparations by specific clinical scientists.

Palliative Care	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Workforce requirements	As per module overview.	As per module overview.	As per module overview.	As per module overview.	As per module overview.	As per module overview.
Specific risk considerations	> 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

> 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

As per the Fundamentals of the Framework, plus:

> National Association of Testing Authorities, Australia. www.nata.asn.au/

> National Pathology Accreditation Advisory Council. Standards for Pathology. 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/
2. Royal College of Pathologists of Australasia (RCPA). www.rcpa.edu.au/
3. Australian Government. Health Insurance (Accredited Pathology Laboratories — Approval) Principles 2002 HS/11/2002. Canberra: Australian Government; 2002. http://www.comlaw.gov.au/Details/F2014C00026
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. www.health.gov.au/
5. Australian Government: Health Insurance (Pathology Services Table) Regulation 2013. http://www.comlaw.gov.au/Details/F2014C00003
6. Australasian Association of Clinical Biochemists. www.aacb.asn.au/
7. Australian Institute of Medical Scientists. www.aims.org.au/c/
8. Australian Society for Microbiology. www.theasm.com.au/
9. Australian Society of Cytology. www.cytology-asc.com/
10. Human Genetics Society of Australasia. www.hgsa.com.au/
11. Australian Institute of Medical Technologists. http://www.aims.org.au/

For more information

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Public I1-1A

Interpreter

Acknowledgement: Used and adapted with the permission of Queensland Health

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