

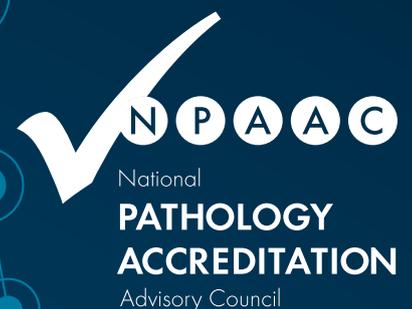


Australian Government
Department of Health

NPAAC TIER 3A DOCUMENT

REQUIREMENTS FOR SUPERVISION IN THE CLINICAL GOVERNANCE OF MEDICAL PATHOLOGY LABORATORIES

(Sixth Edition 2021)



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Contents

Scope	v
Abbreviations	vi
Definitions.....	vii
Introduction.....	1
1. Supervision of Medical Pathology Services	3
2. Categories of Medical Pathology Laboratories.....	5
3. Supervision Requirements	7
4. Supervision of Category S Laboratories (Specialised).....	12
5. Supervision of Category M Laboratories (Medical).....	15
6. Consultation.....	16
Appendix A Required Supervisory Activities and Conditions (Normative)	17
Appendix B Specific Restrictions Relating to Category M Laboratories (Normative).....	19
Appendix C Pathology disciplines with national workforce shortages (Informative)	20
References.....	21
Bibliography	22
Acknowledgements	23

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 *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)* is a Tier 3A NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services*. The latter is the overarching document broadly outlining 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.

The *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)* describes the role and responsibilities of the *Designated Person* described in the Tier 2 document *Requirements for Medical Pathology Services*. This person is the key medical practitioner leading a Medical Pathology Service. The current legislative framework mandates that for a pathology service to be rebated under Medicare, it must be supervised by a Pathologist or medical specialist.

This document describes the categories of pathology laboratories and the competencies and roles of key staff, including, Pathologists, Clinical Scientists, Scientists and Technical Officers. It is the intention of the Requirements that all tests are supervised by competent persons who are working within their Scope of Practice and that they will be able to demonstrate effective clinical governance to the accrediting body.

To ensure best practice in pathology and to ensure optimal patient safety, clinical governance frameworks should be embedded in an organisation's structure. These standards for governance must be met in order for pathology services to be approved in accordance with the *Health Insurance Act 1973* and the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017*. Demonstrated and ongoing compliance with this document is mandatory for any medical pathology laboratory providing services eligible for Medicare Benefits from the Australian Government for the provision of pathology services within Australia.

Abbreviations

Abbreviation	Description
AEI	Australian Education International
APA	Approved Pathology Authority
AQF	Australian Qualifications Framework
ART	Assisted Reproductive Technology
ARTG	Australian Register of Therapeutic Goods
CPD	Continuing Professional Development
FTE	Full-Time Equivalent
ISO	International Organisation for Standardization
IVD	In Vitro Diagnostic Medical Device
IVF	In Vitro Fertilisation
NATA	National Association of Testing Authorities, Australia
NOOSR	National Office of Overseas Skills Recognition
NPAAC	National Pathology Accreditation Advisory Council
QS	Quality System
PoCT	Point of Care Testing
RCPA	Royal College of Pathologists of Australasia
RTAC	Reproductive Technology Accreditation Committee
TGA	Therapeutic Goods Administration

Definitions

Term	Definition
Clinical Scientist	<p>means a person with the training and competence to perform the functions required, who has at least 5 years' relevant medical laboratory experience and possesses one or more of the following qualifications by examination:</p> <ul style="list-style-type: none"> (a) a Fellowship of the Australasian Association of Clinical Biochemists (b) a Fellowship of the Australian Institute of Medical Scientists (c) a Fellowship of the Australian Society for Microbiology (medical microbiology or clinical microbiology) (d) a Fellowship of the Human Genetics Society of Australasia (biochemical genetics, cytogenetics or molecular genetics) (e) a Fellowship of the Faculty of Science of the Royal College of Pathologists of Australasia (f) a Fellowship of the Australian Society of Cytology <p><i>Or</i></p> <p>A Doctorate of Philosophy, Australian Qualifications Framework level 10^{*1} or equivalent doctoral level degree, in a subject relevant to the scope of diagnostic testing of the laboratory they are supervising</p> <p><i>Or</i></p> <p>For ART laboratories, the Clinical Scientist must meet the criteria in the RTAC code of practice for scientific directors.</p> <p><i>Or</i></p> <p>For Bone Marrow Transplant laboratories, the Clinical Scientists must meet the requirements of the Bone Marrow Transplant Scientists Association of Australasia (BMTSAA).</p> <p><i>Or</i></p> <p>For American Society of Histocompatibility and Immunogenetics accredited</p>

* <https://www.aqf.edu.au/aqf-second-edition-january-2013>

Term	Definition
	laboratories, the Clinical Scientist must meet the requirements for a General Supervisor. [†]
Competence	means a person who has the education, training, experience and demonstrated ability to apply skills and knowledge in a particular area.
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 organisations delivering services along the whole patient care path. Interfaces in, or split responsibility for, delivering patient care are considered points of increased risk.</p>
Credentialing Body	means the formally constituted committee of practitioners and managers who collectively analyse and verify the information submitted by an applicant, consider credentials and make a determination on the scope of clinical practice for a health practitioner. The membership of the credentialing committee should include, and preferably be led by, representatives from the professional group whose scope of clinical practice is being <u>determined</u> . [‡]

[†] American Society for Histocompatibility and Immunogenetics. Standards for Accredited Laboratories 2020 – http://cdn.ymaws.com/www.ashi-hla.org/resrouce/remmgr/docs/standards/2021/clean_2020_1030_2020_ashi_pdf

[‡] Australian Commission on Safety and Quality in Health Care [Credentialing health practitioners and defining their scope of clinical practice](#)²

Term	Definition
Delegation	means the same as 2.1 of the Health Insurance (Approved Pathology Undertakings) Approval 2017 .
Designated Person	means a registered medical practitioner with appropriate qualifications, competence and relevant Scope of Practice who has responsibility for the clinical governance of the laboratory and provides oversight and management of staff and processes to ensure ethical patient care and the provision of accurate and timely test results.
Group of Pathology Testing	means a group (and subgroup) of tests that is performed in a Medical Pathology Service as defined in the Pathology Services Table of the Medicare Benefits Schedule.
Laboratory	<p>means premises where Medical Pathology Services are performed. A laboratory may be stand alone or be part of a pathology network of laboratories.</p> <p>A laboratory 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 laboratory in which pathology tests in a specific discipline or group of pathology services are performed. The premises include all locations in the same health care precinct, where pathology services are performed.</p> <p>Thus a laboratory may be a medical device in a medical practice or it may be a chemical pathology laboratory in a large teaching hospital that is part of a Pathology Network.</p>
Medical Practitioner	means a person as described in subsection 3(1) of the Health Insurance Act 1973 .
Medical Pathology Service	<p>means any service whereby pathology testing provides information for –</p> <ul style="list-style-type: none"> • diagnosis and monitoring and exclusion of disease processes and their treatment • health screening • epidemiological data.

Term	Definition
Normal Working Hours	<p>means the hours during which the laboratory is operating and during which supervision needs to be provided onsite.</p> <p>It should be noted that access to pathologists for consultations may need to be provided outside of <i>normal working hours</i>.</p>
Onsite Manager of a Category B or SB laboratory	<p>means a Scientist with appropriate qualifications and a minimum of two (2) FTE years relevant experience in the testing performed in the laboratory they are supervising who is deployed by the Category GX laboratory and is delegated to manage the Category B laboratory by the Designated Person at the Category GX laboratory.</p>
Onsite Operator	<p>means a person who has undergone training and is assessed as competent to operate a PoCT or other pathology testing device.</p>
Open Disclosure	<p>means an “open discussion with a patient (and/or their support person(s)) about a patient safety incident which could have resulted or did result in harm to that patient while they were receiving health care.</p> <p>Essential elements of Open Disclosure are:</p> <ul style="list-style-type: none"> • an apology • a factual explanation of what happened • an opportunity for the patient to relate their experience • a discussion of the potential consequences • an explanation of the steps being taken to manage the event and prevent recurrence.” §3
Pathologist	<p>means a Specialist in a discipline of the specialty of pathology as defined in Schedule 4 Health Insurance Regulations 1975, or regulations made to replace those regulations.</p>
Pathology Network	<p>means, for the purpose of this document, more than one laboratory operating under the same governance structure.</p>

§ [Australian Commission on Safety and Quality in Health Care Australian Open Disclosure Framework, 2013](#)³

Term	Definition
Point of Care Testing (POCT)	means pathology testing performed in close proximity to a patient by a healthcare worker and usually outside the precincts of a traditional laboratory. This is usually undertaken at the time of and for use during a consultation or episode of care.
Quality Manager	means a member of staff appointed with delegated authority to ensure that processes needed for the Quality System (QS) are established, implemented and maintained.
Scientist	means a person with competence to perform the functions required and who is authorised to perform these functions This person must possess one of the following qualifications: <ul style="list-style-type: none"> <li data-bbox="810 808 1385 1137">(a) a degree at Australian Qualifications Framework level 7 with subjects relevant to the field of pathology, as determined by the person responsible for the scientific management of the laboratory and/or person responsible for the clinical governance of the laboratory, awarded from a university in Australia; or <li data-bbox="810 1144 1385 1585">(b) a degree at Australian Qualifications Framework level 7 with subjects relevant to the field of pathology awarded by an overseas tertiary institution if the qualification is assessed as equivalent to a degree accredited by the Australian Institute of Medical Scientists, according to their authority approved by Australian Education International via the National Office of Overseas Skills Recognition (AEI-NOOSR); or <li data-bbox="810 1592 1385 1742">(c) an associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973.
Scope of Practice	means the discipline and/or areas of testing in which a person has been trained and successfully examined or assessed as competent by the relevant College, professional society, or credentialing body and in which they have met current Continuing Professional Development and recency of practice requirements.

Term	Definition
Specialist	means the same as the definition in subsection 3(1) of the <i>Health Insurance Act 1973</i> .
Technical Officer	<p>means a person with relevant training and competence, and who is authorised to perform laboratory functions. This person must possess one of the following:</p> <p>(a) a qualification in the field of pathology awarded by a tertiary-level Australian institution, following successful completion of a course of at least 2 years' full time study or an equivalent period of part time study; or</p> <p>(b) a qualification at Australian Qualifications Framework level 5 or 6 with subjects relevant to the field of pathology awarded by an overseas institution accredited by the Australian Institute of Medical Scientists, according to their authority approved by Australian Education International via the National Office of Overseas Skills Recognition (AEI-NOOSR).</p>
Risk assessment	means a technique that helps decision makers understand the risks that could affect the achievement of objectives as well as the adequacy of controls already in place . ^{**4}
Risk management	means coordinated activities to direct and control an organisation with regard to risk . ^{††5}

** [ISO/IEC Guide 51 Safety aspects – Guidelines for their inclusion in standards](#)⁴

†† [ISO 31000 Guide 73: 2009 Risk Management - Vocabulary](#)⁵

Introduction

The *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Sixth Edition 2021)* requires a governance system whereby the *Designated Person*^{##} is accountable for the provision of accurate and timely results of pathology investigations. Accountable governance minimises potential risks to patient safety and improves patient health outcomes.

The provision of quality pathology services relies on the collaborative working relationship between Pathologists, Clinical Scientists, Scientists, Technicians and other laboratory staff. Although all laboratory staff have an important role and responsibilities in the performance of pathology testing, the *Health Insurance Act 1973* attributes the responsibility for ensuring that there is proper supervision for the rendering of the pathology service to the Approved Pathology Practitioner.

The *Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories* (formerly the *Requirements for the Supervision of Medical Pathology Laboratories*) takes a risk-based approach to the provision of laboratory supervision. It recognises that contemporary practice in many Pathologist-led pathology laboratories is to provide services through a pathology network, using a hub and spoke model. The clinical governance arrangements in these organisations can be complex and pose a risk to the effective supervision of testing. These Requirements intend to require a clearly documented and understood governance structure that ensures that all testing is supervised by persons who are appropriately qualified, competent and operating within their Scope of Practice and who are accountable for the conduct of their Designated Person responsibilities.

The Designated Person must make risk-based decisions about the provision and supervision of tests based on the complexity of the tests performed, the number of tests performed, the qualifications and experience of scientific staff and the level of Pathologist supervision required.

During the implementation of this Standard it became apparent that there were Australia wide workforce shortages in some pathology disciplines and that credentialing processes for laboratories led by non-pathologists were difficult to access. In addition, the Australian Red Cross LifeBlood Laboratories which collect, and supply Australia's blood supply required a set of arrangements which reflected its unique model of service. A limited review has led to provisions being included to address these circumstances so that where testing can be demonstrated to be safe, access is not curtailed. The value that a team comprising long serving personnel brings to safe testing is recognised in these provisions. The provisions to address workforce shortages apply for a finite period.

These Standards have been developed with reference to current and proposed Australian regulations and particularly the following Australian Standard:

AS ISO 15189 *Medical laboratories – Particular requirements for quality and competence*

^{##} [NPAAC Requirements for Medical Pathology Services](#)

These Requirements should be read within the national pathology accreditation legislative framework and in conjunction with the current version of the following NPAAC Requirements:

Tier 2 Document

All Tier 3 and 4 Documents

In each section of this 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 laboratory facility that is required before a laboratory can attain and maintain 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 Commentaries 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, comment from users would be appreciated and can be directed to:

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1. Supervision of Medical Pathology Services

Supervision is a key responsibility of Medical Practitioners for controlling the risks to patient safety and welfare that may arise while providing Medical Pathology Services. A key principle of supervision is that all tests will be personally supervised by a person with the appropriate skills, experience and current Scope of Practice. 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 affect patient safety.

S1.1 Every laboratory must be under the direction and control of a Designated Person who is a medical practitioner and who is responsible for and accountable for the clinical governance of the Medical Pathology Services provided by the laboratory.

C1.1 The Designated Person may delegate to another medical practitioner with a relevant Scope of Practice to personally supervise the rendering of pathology services in a Category GX, GY or related Category B laboratory.

S1.2 The overarching clinical governance structure and individual laboratory supervision delegation arrangements for every laboratory must be clearly defined, documented and regularly reviewed.

S1.3 The Designated Person is responsible for the establishment, implementation and operation of the risk management plan for the Medical Pathology Services under their direction and control. This plan must be documented as part of the laboratory Quality System.

C1.3(i) The risk management plan **must** document major patient safety risks, the strategies proposed to mitigate those risks, and the implementation status of each mitigation strategy.

C1.3(ii) Operation of this plan **must** be monitored and supported by compliance and reporting processes so that any material breach, non-compliance or failure of operation is notified to the Designated Person. This plan **must** be reviewed regularly for effectiveness and whenever there is a material change to the operation of the laboratory. The scope of the risk management plan required for the purposes of these *Requirements* is restricted to supervision arrangements

S1.4 The Designated Person must perform a risk assessment of supervision arrangements that includes an assessment of the complexity of the tests performed, the number of tests performed, the qualifications and experience of scientific staff and the level of Pathologist supervision required when assessing potential risks to patient safety and resourcing of supervision within the laboratory.

S1.5 The laboratory must have a documented clinical incident management system that includes requirements and processes for reporting, investigating and following up of clinical incidents, including open disclosure.

C1.5(i) Responsibility and timeframes for actions arising from investigations **must** be clearly designated with actions commensurate with the level of risk to patient safety.

S1.6 The Designated Person and all Pathologists and Clinical Scientists who are appointed as delegates must meet Continuing Professional Development requirements applicable to their Scope of Practice.

C1.6(i) Medical Practitioners **must** meet the Medical Board of Australia's requirements for CPD.

C1.6(ii) Clinical Scientists **must** provide evidence of their participation in CPD relevant to the field of testing of the laboratory.

2. Categories of Medical Pathology Laboratories

For the purposes of accreditation, pathology services are allocated one of the categories of accreditation specified in the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002*.

The categories are summarised as:

1) Category GX (General)

A Medical Pathology Service comprising a laboratory, or a number of co-located laboratories, performing services in one or more Groups of Pathology Testing:

- (a) under the full time supervision and clinical governance of a Designated Person who must be a Pathologist, and
- (b) where responsibility for full time onsite supervision of pathology testing may be delegated to other Pathologists with relevant Scope of Practice. These Pathologists may further delegate supervision of specific testing to Clinical Scientists with the relevant Scope of Practice.

2) Category GY (General)

A Medical Pathology Service comprising a laboratory, or a number of co-located laboratories, performing services in one or more Groups of Pathology Testing:

- (a) under the full time supervision and clinical governance of a Designated Person who must be a Pathologist residing in the related GX laboratory, and
- (b) where supervision of one or more disciplines (Groups of Tests), but not all disciplines, is provided by onsite full time, in aggregate, pathologist(s) with relevant Scope of Practice;
- (c) the GY laboratory must be related to a GX laboratory. In that case the Designated Person is located at and also responsible for the supervision and clinical governance of that GX laboratory.
- (d) the supervision arrangements for tests or Groups of Tests for which there is not full time onsite pathologist supervision with relevant scope of practice are described in Section 3.3. These supervision arrangements must be reviewed by the Designated Person to ensure that there is a documented risk assessment which includes taking into account the complexity of the tests performed, the number of tests performed, the qualifications and experience of scientific staff and the level of Pathologist supervision.

3) Category B (Branch)

A Medical Pathology Service comprising a laboratory performing services in one or more Groups of Pathology Testing, being a laboratory related to an accredited Category GX or GY laboratory:

- (a) a branch, integrated (except in its location) with the Category GX or GY laboratory in the same pathology network; and
- (b) operating under the direction and control of the Designated Person or delegate
- (c) the Designated Person may delegate responsibility for supervision of pathology tests outside of their own Scope of Practice to a Pathologist with the relevant Scope of Practice.

This category includes laboratories that only provide PoCT services that belong to a Pathology Network under the control of a Pathologist.

4) Category S (Specialised)

Medical Pathology Services comprising a laboratory performing a limited range of pathology tests, for a target patient population, under the supervision of a Medical Practitioner with specialist qualifications and competency in the field of those tests and who is not a Pathologist. The tests performed must be restricted to the field of testing directly related to the qualifications and competencies and current Scope of Practice of the Medical Practitioner. If the laboratory proposes to undertake a wider scope of pathology testing the operator must apply for accreditation as a Category GX or GY laboratory.

5) Category M (Medical)

Medical Pathology Services comprising a laboratory performing a limited range of pathology services under the supervision of a Medical Practitioner being services only for the patients of the medical practice operated by, or that employs or engages the Medical Practitioner, where the medical practice is co-located with the laboratory.

3. Supervision Requirements

(Refer to Standards 2, 3 and 4 in *Requirements for Medical Pathology Services*)

3A. Supervision of Category GX or GY Laboratory (General)

S3.1 Category GX Laboratories must operate under the direction and control of a Designated Person who must be a Pathologist:

- (i) the Designated Person can supervise only one Category GX laboratory, but may provide supervision where not provided on site, at other Category GY and B laboratories related to that GX laboratory**
- (ii) the Designated Person can only supervise testing within their Scope of Practice**
- (iii) if the laboratory offers testing outside the Scope of Practice of the Designated Person, the Designated Person must delegate to another Pathologist(s) with the relevant Scope of Practice to personally supervise the rendering of those pathology services in the Category GX laboratory and any related Category GY or Category B laboratories.**

S3.2 There must be at least one full time equivalent, in aggregate, onsite Pathologist with the relevant Scope of Practice for each pathology test offered by a Category GX laboratory.

S3.3 For a Category GY laboratory, supervision must be provided by the onsite Pathologists who have relevant Scope of Practice.

C3.3 For those tests where there is no full time onsite pathologist supervision with relevant Scope of Practice, provided that there is full time onsite pathologist supervision in the same scope of practice at the related Category GX laboratory, supervision at the Category GY laboratory may be delegated to an onsite Pathologist with the relevant scope of practice. Otherwise supervision **must be provided by Pathologists from other Category GX, GY or B laboratories in the same Pathology Network.**

S3.4 When the delegated Pathologist at the GX laboratory is on bona fide absences (e.g. annual leave, sick leave, conference leave) then the GX laboratory can operate as a GY laboratory, for periods up to 4 weeks but not exceeding 8 weeks in total any one calendar year, by requiring a Pathologist with relevant Scope of Practice from another site to attend on-site, 1 day per week during the period of absence of the usual supervisor, but recognising that this is a bona fide absence of that person from their own onsite supervision obligation at their “home” base laboratory, i.e. it should not count against their log of absence from their normal site.

S3.5 Where efforts to recruit a full time Pathologist with a particular scope of practice to a laboratory fail because of a recognised national workforce shortage, (*Appendix C*), the designated person must undertake a risk assessment of the provision of this group of tests. If, in the view of the Designated Person, a satisfactory risk management plan can be established, supervision may be delegated to a Pathologist with relevant Scope of Practice who must:

- (a) provide part-time on-site supervision and be available for consultation with the laboratory and referrers during normal working hours and out of hours as required
- (b) in the event that S3.5(a) cannot be met, provide supervision by on site and virtual attendance (Australia based) and be available for consultation with the laboratory and referrers during normal working hours and out of hours as required
- (c) in the event that S3.5(a) and S3.5(b) cannot be met, the designated person for an accredited pathology service, existing at the time of the issue of this Standard, may delegate supervision of testing to an onsite Clinical Scientist with a relevant scope of practice.
- (d) in the event that S3.5(a), S 3.5(b), S3.5(c) cannot be met, the Designated Person for an accredited pathology service existing at the time of the issue of this Standard and with long serving personnel, may elect to supervise testing. Significant failures in external quality assurance exercises which, if seen in patient testing would impact upon patient safety, must be notified to the accreditation body on receipt of the report, together with proposed remedial actions
- (e) Whenever a pathologist with Scope of Practice is not on site in S3.5(a), S3.5 (b), S3.5 (c), S3.5(d), the designated person or their delegate Pathologist must provide on site supervision.
- (e) S3.5(a)(b)(c)(d) are temporary measures. The Designated Person must be able to demonstrate active recruitment strategies and regular advertisement of the position.
- (f) Standard 3.5 applies until this Standard is re-issued or 2 years from the publication of this edition of the Standard, whichever occurs first.

3B. Supervision of Category B Laboratories (Branch)

S3.6 The laboratory must have a documented clinical governance structure identifying the person or persons who supervise the Medical Pathology Service(s).

- C3.6(i) The Designated Person or their delegate (who is a Pathologist) **must** visit the laboratory at least once a year in order to discharge the governance roles as outlined in S4.5 of the *Requirements for Medical Pathology Services*.
- C3.6(ii) The Quality Manager or their delegate **must** visit the laboratory at least once a year.
- C3.6(iii) Provided that there is full time onsite pathologist supervision in the same scope of practice at the related Category GX laboratory, supervision may be delegated to an onsite Pathologist with the relevant scope of practice, otherwise supervision **must** be provided by Pathologists from other Category GX, GY or B laboratories in the same Pathology Network..

S3.7 If the supervision of pathology testing is not provided by an onsite Pathologist it must be delegated by the Designated Person to Pathologists, who may further delegate supervision responsibilities to Clinical Scientists or Scientists, with the relevant Scope of Practice from another laboratory in the same Pathology Network with remote and onsite access to the Laboratory Information System and Quality System of the Category B laboratory:

- (a) The supervising Pathologist(s), Clinical Scientists or Scientists must spend at least two (2) FTE days per year, in aggregate, at the Category B laboratory, and all supervisory duties related to the testing performed at the Category B laboratory, as outlined in *Appendix A*, are discharged.**
- (b) The Onsite managers from the Category B laboratory must spend a minimum of two (2) days per annum of supervised training or professional development at another laboratory operated in the same Pathology Network.**
- (c) Documented videoconference or teleconference meetings with a formal agenda relevant to management of the Category B laboratory must be performed on a monthly basis.**

S3.8 If central monitoring of the Quality System and Quality Control at the Category B laboratory by the Category GX or GY laboratory and video/teleconference management meetings as specified in S3.6 do not occur then the following alternative supervision visits must be performed and documented:

- (a) in addition to above, Pathologists, Clinical Scientists, or Scientists, with relevant competence, must spend at least twenty (20) additional FTE days per year, in aggregate, at the Category B laboratory**
- (b) the visits must be at least quarterly and formal management activities that occur must be documented.**

S3.9 The laboratory must have an Onsite Manager, who is a Scientist with appropriate qualifications and a minimum of two (2) FTE years relevant experience in the testing performed in the laboratory they are supervising.

C3.9 In the event of exceptional circumstances, a person who is a Scientist of more than one (1) but less than two (2) years' experience, or a Technical Officer with more than five (5) years' experience, may be deemed an interim onsite manager of a Category B laboratory, provided that bona fide efforts, such as requiring the organisation to demonstrate active recruitment strategies and regular advertisement of the position every six (6) months, are being made by the laboratory to recruit a manager. This clause applies for up to two (2) years, after which time the circumstances will require further review as part of an accreditation assessment.

S3.10 The Onsite Manager must be present at the laboratory during Normal Working Hours.

C3.10 The Designated Person **must** delegate responsibility for the on-site management of the laboratory to another suitable scientist or Technical Officer when the manager is absent.

3C. Supervision of Category B Laboratories providing PoCT services only

- S3.11** A Category B laboratory providing PoCT services only must have the PoCT device(s) continually monitored through an online system that provides continual performance monitoring of the device and must meet the following requirements:
- a) there must be a supervision by a pathologist with a relevant Scope of Practice
 - b) the supervising pathologist may further delegate supervision responsibilities to Clinical Scientists or Scientists with the relevant scope of practice
 - c) there must be documentation to demonstrate the competency of the Onsite Operators to perform the limited range of testing being carried out by the laboratory
 - d) there must be a clearly documented procedure in place identifying all of the responsibilities of the Onsite Operators. The Pathology Network must be able to provide documented evidence that these responsibilities are being met
 - e) the Category B laboratory providing PoCT services only must be visited by the Designated Person, or their delegate, or the supervising pathologist's Clinical Scientist or Scientist delegate, at least once (1) per year, during which visit all Designated Person duties outlined in *Appendix A* are discharged.

3D. Supervision of Australian Red Cross Lifeblood laboratories.

This section applies specifically to the supervision of both patient and donor testing by ARCBS Lifeblood which operates as a national blood service and is regarded, in toto, as a Category GX laboratory network. It must be read in conjunction with the other requirements set out in this Standard.

- S3.12** The Lifeblood laboratory must operate under the direction and control of a Designated Person who must be a pathologist:
- (i) the Designated Person can only supervise testing within their Scope of Practice
 - (ii) if the laboratory offers testing outside the Scope of Practice of the Designated Person, the Designated Person must delegate to another Pathologist(s) with the relevant Scope of Practice to personally supervise the rendering of those pathology services in laboratories in the Lifeblood network.
- S3.13** There must be at least one full time equivalent, in aggregate, onsite Pathologist with the relevant Scope of Practice for each pathology test offered within the ARCBS Lifeblood network.
- C3.13** These Pathologists may further delegate supervision of specific testing to Clinical Scientists or Scientists with the relevant Scope of Practice.

- S3.14** Where efforts to recruit a full time pathologist with a particular scope of practice to a laboratory fail because of a recognised national workforce shortage, (*Appendix C*), the Designated Person must undertake a risk assessment of the provision of this group of tests. If, in the view of the designated person, a satisfactory risk management plan can be established, supervision may be delegated to a pathologist with relevant scope of practice who must:
- (a) provide part-time on-site supervision and be available for consultation with the laboratory and referrers during normal working hours and out of hours as required
 - (b) in the event that S3.14(a) cannot be met, provide supervision by on site and virtual attendance (Australia based) and be available for consultation with the laboratory and referrers during normal working hours and out of hours as required
 - (c) in the event that S3.14(a) and 3.14(b) cannot be met, the Designated Person for an accredited pathology service, existing at the time of the issue of this Standard, may delegate supervision to a Clinical Scientist with scope of practice.
 - (d) in the event that S3.14(a), S3.14(b), S3.14(c) cannot be met, the Designated Person for an accredited pathology service existing at the time of the issue of this Standard and with long serving personnel, may elect to supervise testing. Significant failures in external quality assurance exercises which, if seen in patient testing would impact upon patient safety, must be notified to the accreditation body on receipt of the report, together with proposed remedial actions
 - (e) S3.14(a)(b)(c)(d) are temporary measures. The Designated Person must be able to demonstrate active recruitment strategies and regular advertisement of the position or must be able to demonstrate currently employed pathologists are actively working towards gaining the relevant extension of their scope of practice to supervise the testing.
 - (f) S3.14 applies until this Standard is re-issued or 2 years from the publication of this edition of the Standard, whichever occurs first.

4. Supervision of Category S Laboratories (Specialised)

(Refer to Standard 2, Standard 3 and Standard 4 in the *Requirements for Medical Pathology Services*)

4A. S Laboratories

S4.1 The laboratory must have a full time Designated Person who is responsible for the clinical governance of the laboratory and who is a specialist Medical Practitioner, other than a Pathologist, with relevant qualifications or skills and with a current Scope of Practice in the field of medicine directly related to the specialised tests performed.

C4.1(i) The laboratory **must** have an onsite Clinical Scientist with the relevant Scope of Practice during normal working hours.

C4.1(ii) The Designated Person may also delegate to another Medical Specialist, Clinical Scientist or Scientist with the relevant Scope of Practice to personally supervise the rendering of pathology services in the Category S or any related Category SB laboratory.

S4.2 The Designated Person is responsible for the clinical governance of the laboratory and must ensure that the supervision requirements set out in *Appendix A* are all fulfilled.

S4.3 The laboratory must only perform tests that are directly related to the relevant qualifications and skills of the person responsible for the clinical governance of the laboratory.

C4.3(i) The tests performed **must** be restricted to the field of testing directly related to those qualifications and competencies and current Scope of Practice of the specialist Medical Practitioner. If the laboratory proposes to undertake a wider scope of pathology testing the operator **must** apply for accreditation as a Category GX or GY laboratory.

S4.4 Where the Designated Person of an accredited pathology service which exists at the time of publication of this Standard and which provides services in a discipline with a recognised workforce shortage (*Appendix C*), has not yet met the requirements of a credentialing process, the Designated Person, who is accountable for the service, may elect to continue to offer testing under the following conditions:

- (i) A Clinical Scientist with scope of practice and five years of relevant experience must be in place**
- (ii) The pathology service must meet a clinical need for access to testing and develop a comprehensive risk management plan.**
- (iii) Significant failures in external quality assurance exercises which, if seen in patient testing would impact upon patient safety, must be notified to the accreditation body on receipt of the report, together with proposed remedial actions**

- (iv) **S 4.4 is a temporary measure. The Designated Person must be able to demonstrate active progress to satisfactory credentialling**
- (v) **S4.4 applies until this Standard is re-issued or 2 years from the publication of this edition of the Standard, whichever occurs first.**

4B. SB Laboratories

An SB laboratory is a branch, integrated (except in its location) with the Category S laboratory under the control of the same proprietor (APA).

- S4.5 The SB laboratory must have the same APA as the associated Category S laboratory.**
- S4.6 The laboratory must have a documented clinical governance structure identifying the person or persons who supervise the Medical Pathology Service(s).**
- C4.6(i) The Designated Person or their delegate (who is a medical specialist) **must** visit the laboratory at least annually in order to discharge the governance roles as outlined in **S2.3** of the *Requirements for Medical Pathology Services*.
 - C4.6(ii) The Quality Manager or their delegate **must** visit the laboratory at least once a year.
 - C4.6(iii) An onsite medical specialist can supervise pathology testing within their Scope of Practice, where delegated by the Designated Person.
- S4.7 If the supervision of pathology testing is not provided by an on-site medical specialist it must be delegated to Medical Specialist, Clinical Scientists or Scientists with a relevant Scope of Practice from another laboratory operated by the same Network with remote and onsite access to the laboratory Information System and Quality System of the Category S laboratory:**
- (a) **the supervising medical specialist(s), Clinical Scientists or Scientists must spend at least two (2) FTE days per year, in aggregate, at the Category SB laboratory, during which all supervisory duties related to the testing performed at the laboratory outlined in *Appendix A* are discharged.**
 - (b) **the Onsite Managers from the Category SB laboratory must spend a minimum of two (2) days per annum of supervised training or professional development at another laboratory operated by the same APA.**
 - (c) **documented videoconference or teleconference meetings with a formal agenda for management of the Category SB laboratory must be performed on a monthly basis.**
- S4.8 If central monitoring of the Quality System and Quality Control at the Category SB laboratory by the Category S laboratory and video or teleconference management meetings as specified in S4.6 do not occur then the following alternative supervision visits must be performed and documented:**
- (a) **in addition to above, Medical Specialists, Clinical Scientists, or Scientists, with relevant competence must spend at least twenty (20)**

additional FTE days per year, in aggregate, at the Category SB laboratory; and

(b) the visits must be at least at quarterly.

S4.9 The laboratory must have an On-Site manager, who is a Scientist with appropriate qualifications and a minimum of two (2) FTE years relevant experience in the testing performed in the laboratory they are supervising.

C4.9 In the event of exceptional circumstances, a person who is a Scientist of more than one (1) but less than two (2) years' experience, or a Technical Officer of more than five (5) years' experience, may be deemed an interim Onsite Manager of a Category SB laboratory, provided that bona fide efforts, such as requiring the organisation to demonstrate active recruitment strategies and regular advertisement of the position every six (6) months, are being made by the laboratory to recruit a manager. This clause applies for up to two (2) years, after which time the circumstances will require further review as part of an accreditation assessment.

S4.10 The Onsite Manager must be present at the laboratory during Normal Working Hours.

C4.10 The Designated Person must delegate responsibility for the on-site management of the laboratory to another suitable scientist or Technical Officer when the manager is absent.

4C. S(FC) Laboratories

S4.11 An S(FC) laboratory must have a full time Designated Person who is responsible for the clinical governance of the laboratory and who is a specialist Medical Practitioner, other than a Pathologist, with relevant qualifications or skills and with a current Scope of Practice in the field of medicine directly related to the specialised tests performed.

C4.11(i) The laboratory **must** have an onsite Clinical Scientist with the relevant Scope of Practice during normal working hours.

C4.11(ii) Where a Clinical Scientist with relevant scope of practice cannot be engaged, the Designated Person for an accredited pathology service existing at the time of the issue of this Standard and with long serving personnel, may elect to supervise testing if it meets a clinical need for access to testing and they can develop a comprehensive risk management plan. Significant failures in external quality assurance exercises which, if seen in patient testing would impact upon patient safety, **must** be notified to the accreditation body on receipt of the report, together with proposed remedial actions.

C4.11(iii) C4.11(ii) is a temporary measure. The Designated Person **must** be able to demonstrate active recruitment strategies and regular advertisement of the position.

C4.11(iv) C4.11(iii) applies until this Standard is re-issued or 2 years from the publication of this edition of the Standard, whichever occurs first.

5. Supervision of Category M Laboratories (Medical)

(Refer to Standard 1 in the *Requirements for Medical Pathology Services*)

- S5.1** The laboratory must have a Designated Person who is and is a Medical Practitioner with relevant qualifications or skills and with a current Scope of Practice that is relevant to the pathology tests performed.
- S5.2** The Designated Person of the laboratory is responsible for the clinical governance of the laboratory (refer to *Appendix A*). When the Designated Person is not available, they must appoint a delegate medical practitioner who is available and able to be contacted.
- S5.3** The Designated Person must be able to demonstrate:
- (a)** competence to provide the limited groups of pathology testing performed in the laboratory
 - (b)** completion of a training program in the operation, monitoring and use of the equipment as set down in manufacturers manuals, laboratory manuals and any relevant legislative requirements
 - (c)** additional scientific knowledge and experience in the methodology, equipment and analytical (including quality monitoring) procedures in use in the laboratory
 - (d)** a knowledge and understanding of all relevant NPAAC requirements relevant to Category M laboratories.
- S5.4** The laboratory must only perform tests from the Groups of Pathology tests that are outlined in *Appendix B* under the direction, control and supervision of a medical practitioner for patients of the co-located medical practice.
- S5.5** If the Designated Person has delegated testing to an Onsite Operator, the Onsite Operator must be present at the laboratory during normal working hours.
- S5.6** The Designated Person must assess the competence of any one Onsite Operator every two years.

6. Consultation

(Refer to Standard 4 in *Requirements for Medical Pathology Services*)

Appendix A Required Supervisory Activities and Conditions (Normative)

Supervision of a laboratory must include at least the following activities:

- a) at least yearly performance review of the immediate reporting senior staff and discussion of issues arising from their performance review of their staff
- b) documented review of incidents revealed by the quality system with corrective action and further follow-up to ensure that the problem has been corrected by the action
- c) documented review of the risk management plan, including the identification of changes in the levels of risks and where new mitigating strategies have had to be deployed.
- d) documented review of all external quality assurance program participation to ensure full participation, review of results and corrective actions when discordant results are obtained
- e) documented review of internal quality control results including audits and any corrective actions e.g. documented review of customer feedback including complaints and their corrective actions
- f) documented review of safety records, incidents and corrective actions
- g) discussion with staff regarding any proposed new tests or equipment
- h) physical inspection of the laboratory
- i) documented evidence of staff meetings with educational components
- j) review of continuing education both internal and external, including its extent and relevance
- k) where the laboratory provides services to a hospital or is sited in a hospital, documentary evidence of liaison with clinical and administrative staff of the hospital.

Operational Requirements

- a) supervision of all areas of testing in a laboratory must be able to be mapped to a medical practitioner with relevant qualifications and competency
- b) medical practitioners and Clinical Scientists with responsibility for supervision must demonstrate that they have been provided sufficient time to execute their duties including review of methods and assay performance
- c) supervisors must demonstrate that they have implemented systems to monitor quality measures including review of QC and QA and the issuing of reports
- d) supervisors must demonstrate that they have implemented systems for the communication of laboratory process issues with potential adverse clinical impact that require escalation to the Designated Person
- e) supervisors must demonstrate that they have implemented systems for the communication and escalation of enquiries from clinicians or patients that have potential adverse clinical impact to the Designated Person
- f) supervisors must demonstrate that they have implemented systems to record the evidence of the effectiveness of clinical governance – e.g. nature and timeliness of Pathologist or Clinical Scientist response to the escalated issue, recording of any complaints, compliments from clinicians and patients

- g) supervisors must be available for telephone consultations except for bona fide absences
- h) supervisors must be available in person or via telecommunications for any accreditation visits.

Appendix B Specific Restrictions Relating to Category M Laboratories (Normative)

A Category M laboratory is confined to a restricted set of services covered under the following groups and subgroups of pathology testing and where all the tests in that restricted set of services that have been accredited for that laboratory and TGA approved:

Group P1 - Haematology

- A. Haematology (Items 65060,65070,65120,65123,65126,6519)

Group P2 - Chemical Pathology

- A. General chemistry

Group P3 - Microbiology

- A. Microbiology

Group P4 - Immunology

- A. Immunology

Appendix C Pathology disciplines with national workforce shortages (Informative)

1. Genomics (including cytogenetics and biochemical genetics)
2. Immunology
3. Chemical Pathology

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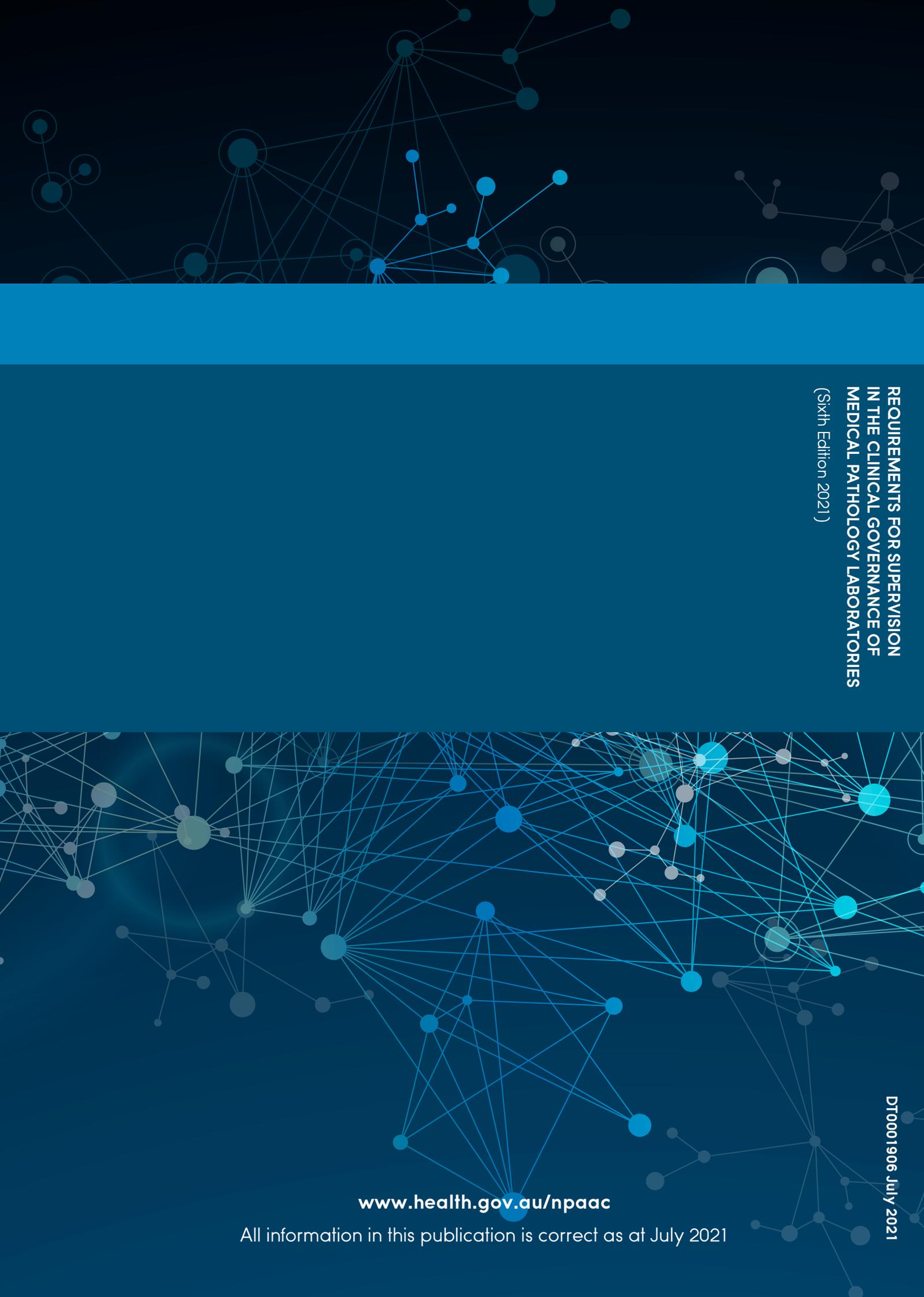
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