NSW Health Pathology Supervision Policy

Policy

Supervision

NSWHP_PD_019

Contents

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1. Purpose

The purpose of this Policy is to provide an organisational framework for the supervision of laboratories in NSW Health Pathology (NSWHP). This document is intended to provide consistent interpretation, understanding, practical application and recording of meaningful supervision activities at or above minimum requirements.

To ensure best practice in pathology and optimise patient safety, clinical governance and supervisory structures are embedded within NSWHP's operations. This Policy describes the supervision governance structures and the roles and responsibilities of all staff involved in supervision activities.

This Policy must be read in conjunction with the National Pathology Accreditation Advisory Council (NPAAC) Tier 2 document Requirements for Medical Pathology Services (Third Edition 2018) and NPAAC Tier 3A document Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018) effective 1 August 2019.

2. Background

Laboratory supervision is critical to the maintenance of clinical governance standards. Accreditation of laboratories requires demonstrated adherence to NPAAC requirements, which describe the minimum requirements for supervision and the responsibilities of supervising pathologists, clinical scientists, and other supervisory staff.

All laboratories are required to adhere to the mandatory NPAAC Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018), superseding the Requirements for the Supervision of Pathology Laboratories (2007 Edition).

3. Abbreviations

NSWHP:	NSW Health Pathology
LPD:	Local Pathology Director
FTE:	Full Time Equivalent
NATA:	National Association of Testing Authorities, Australia
NPAAC:	National Pathology Accreditation Advisory Council
QAP:	Quality Assurance Program
RCPA:	Royal College of Pathologists of Australasia
RMPS:	Requirements for Medical Pathology Services

4. Definitions

Clinical Governance: 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. 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.

Clinical Scientist: Means a person with the training and competence to perform the functions required, who has at least 5 years' relevant medical laboratory experience and who is responsible for supervising a laboratory and possesses one or more of the following qualifications by examination:

(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. Or

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. Or

For ART laboratories, the Clinical Scientist must meet the criteria in the RTAC code of practice for scientific directors. Or

For Bone Marrow Transplant laboratories, the Clinical Scientists must meet the requirements of the Bone Marrow Transplant Scientists Association of Australasia (BMTSAA).

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. For NSWHP laboratories the Designated Person must be a Pathologist, and a Local Pathology Director residing in a GX laboratory.

Director of Operations: Means a member of NSWHP senior staff responsible for clinical governance and supervision at the regional operational level.

On-site Manager of a Category B laboratory: 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.

Local Pathology Director (LPD): Means a Senior Pathologist within a NSWHP Local Pathology Team organisational structure with responsibility for clinical governance and to ensure that supervision requirements are being adhered to at the sites where they have responsibility. A LPD based at a Category GX laboratory acts as the Designated Person for that Category GX laboratory and the Category GY and B laboratories related to that Category GX laboratory.

Normal Working Hours: Means the hours during which the laboratory is operating and during which supervision needs to be provided on-site. It should be noted that access to pathologists for consultations may need to be provided outside of normal working hours.

Operations Manager: Means a member of NSWHP senior staff responsible for clinical governance and supervision at the operational level.

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.

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.

Risk Management Plan: The Risk Management Plan describes the risk management response to ensure risks are being managed and controlled at acceptable levels.

Supervising Pathologist: Means a pathologist with a relevant scope of practice who has been delegated supervision responsibilities by the Designated Person.

5. Policy Statement

From 1 August 2019 all laboratories must adhere to the Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018) published by NPAAC. This Policy builds on the minimum regulatory requirements for laboratory supervision and provides a clear standard for how supervisory responsibilities should be discharged and recorded within NSWHP.

This Policy provides NSWHP's interpretation of the NPAAC requirements and how supervision must be addressed within NSWHP. In circumstances where the appropriateness of the supervision activity or the method for determining supervision time is unclear, the Director of Quality and Patient Safety or a local Quality Manager should be consulted.

6. Supervision Activities and Accountability

For further clarification of supervision activities and tasks please refer to Section 17 Supervision Activities and Tasks Table A.

6.1. Supervision Accountability Matrix

A balance of activities covering the items in the matrix below should be attained over time.

Activity	Designated Person, Supervising Pathologists, Clinical Scientists or Scientists	Quality Manager	Directors of Operations, Operations Managers	On-site Manager of Cat B Laboratory (Laboratory Manager)
Review previous visit record and outstanding corrective actions	✓		✓	✓
Documented review of external QAP	✓			✓
Documented internal QC review	✓			✓
Workforce review	✓		✓	✓
Yearly performance review of immediate reporting staff	✓	✓	✓	✓
Documented review of incidents and complaints	✓	✓	✓	✓
Documented review of risk management plan	✓	✓	✓	✓
Documented meetings or discussions with staff regarding new tests or equipment	✓		✓	✓
Documented staff meetings with educational components	✓	✓	✓	✓
Review of internal and external continuing education	✓		✓	✓
Documented review of safety records, incidents and corrective actions	✓	✓	✓	✓
Documented evidence of liaison with LHD management regarding pathology services	✓		✓	✓
Physical inspection of the laboratory and equipment	✓		✓	✓
Documented audits, outcomes and corrective actions	✓	✓	✓	✓

6.2. NSWHP Exclusion of Supervision Actvities

Activities that are not supervision activities for the purpose of NPAAC supervision compliance include:

a) Finance meetings

b) Social occasions or events

c) Staff Specialist clinics or clinical activities

d) Travel time.

7. NSWHP Documentation of Supervision Activities

The following section provides a framework and a NSWHP organisational standard for meaningful supervision.

7.1. Agenda Items and Minutes

Staff meetings counted towards supervision activities must include agenda items relevant to supervision. Minutes must document the supervisor in attendance, the scope of practice (i.e. discipline) of the supervisor in which the supervisory hours will be counted. Documentation of agendas and minutes support supervisory visit records. Relevant agenda items include:

a) Laboratory process issues and corrective actions

b) Review of incidents (IIMS) and complaints

c) Review and update of the risk register/risk management plan

d) Quality control and assurance review

e) Review of patient safety records

f) Upcoming supervisory visits, reciprocal visits and review of compliance with required supervisory visit needs

g) Educational activities.

7.2. Senior Medical Officer Leave Forms

Leave forms for Pathologists with supervisory responsibilities must be submitted to the Local Pathology Director for approval, detailing arrangements for alternative cover of supervision responsibilities. The Local Pathology Director must notify the Operations Manager and Laboratory Manager of all laboratories affected by the change in supervision arrangements.

7.3. Accountability Structures

Details of supervision arrangements, including the names and contact numbers of supervisors, and tools and templates related to supervision activities must be easily accessible within each laboratory.

A notice detailing current supervision arrangements must be displayed and be clearly visible to staff in every laboratory. Please complete the NSW Health Pathology Supervising Pathologist Contact Details Template NSWHP_F_032.

7.4 Risk Assessment

The Designated Person is responsible for ensuring that a risk assessment is completed and documented using the NSW Health Pathology Risk Assessment Template. The Designated Person is also responsible for overseeing and monitoring the assessment and management of laboratory supervision risk.

7.4. Risk Management Plan

Every laboratory is required to have a risk management plan as part of their Quality System detailing risks related to the services they provide. These plans must document major patient safety risks, the strategies proposed to mitigate those risks and the implementation status of each mitigation strategy.

The risk management plan must be monitored regularly and supported by compliance and reporting processes so that any material breach, non-compliance or failure of operations is notified to the Designated Person or Local Pathology Director.

Risks will be continuously monitored and reviewed to ensure:

a) Changing circumstances do not alter risk priorities

b) That risk management plans are appropriate and risk control processes are effective

c) The overall risk management approach remains relevant and

d) The resources invested in the risk management strategy are commensurate with the level of return for the organisation.

The risk assessment and risk management plan are to be recorded in the electronic statewide risk register for monitoring and reporting purposes.

7.5. Supervision Activity Record

Supervision activities are required to be documented as supporting evidence that an activity has taken place. This documentation should address the following:

a) Name and position undertaking supervision activity

b) Specialty/scope of practice

c) Date and time spent undertaking supervision

d) Details of nature and findings of supervision activity

e) Any corrective and preventative actions requiring follow-up should also be recorded in the Quality System as a non-conformance or opportunity for improvement.

A central tool for documenting supervisory activity will be implemented. In the interim the NSW Health Pathology Supervisory Visit Record NSWHP_F_034 must be used for documenting supervisory activities. Once complete, the form should be forwarded to the on-site Laboratory Manager at the supervised laboratory for central record keeping. The Supervision Activity Record Template should also be used to record visits by Category B laboratory on-site managers to another NSWHP laboratory for supervised training or professional development.

7.6. Summary of Supervision Activities and Hours

A centralised summary record of the current status of compliance with the NPAAC Standard for supervision is required for each laboratory. Designated Persons, Local Pathology Directors, Directors of Operations, Operations Managers and Laboratory Managers are responsible for the maintenance of the information in this centralised record. The NSW Health Pathology Supervision Compliance Record NSWHP_SD_036 must be used for the summarised recording of supervision activities compliance. All records of supervision activities must be readily accessible for inspection and auditing purposes at all times.

7.7. Supervision Record Management

Documentation relating to supervision must be regularly updated and maintained within each laboratory. It is the responsibility of the Laboratory Manager or on-site supervisor to ensure that accountability structures, risk management plans and record of supervision visits are easily accessible and staff are aware of all supervision arrangements.

8. Operational Supervisory Requirements

The following operational requirements must be demonstrated to be in place:

a) Supervision responsibilities for each area of testing in a Category GX, GY and B laboratory are mapped to a Designated Person via a Pathologist with relevant qualifications, current scope of practice and competency

b) Staff with supervision responsibilities be allocated sufficient time to discharge these duties

c) Local Pathology Directors and supervisors have implemented systems to monitor and measure quality including QC and QA and the issuing of reports

d) Systems for the communication of issues that require escalation to the Local Pathology Director and/or the Designated Person due to potential adverse clinical impact have been implemented and work effectively

e) Systems for the communication and escalation of enquiries or complaints from clinicians or patients that have potential adverse clinical consequences to the Local Pathology Director and/or the Designated Person

f) Systems to record the evidence of the effectiveness of clinical governance eg nature and timeliness of response to escalated issues.

For further information and clarification of supervision activities please refer to the Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018).

8.1. Supervising Pathologist

Responsibility for supervising a discipline at a GX laboratory may be delegated by the Designated Person, to one or more Pathologists who in aggregate can ensure full time on-site supervision of all testing performed by the laboratory. Supervising Pathologists must only provide supervision within their scope of practice. Supervising Pathologists may further delegate supervision of specific testing to Clinical Scientists and Scientists with the relevant scope of practice.

8.2. Delegation of Supervision Responsibilities

If the supervision of pathology services is not provided by an on-site pathologist at a GY or B laboratory it must be delegated by the Designated Person in consultation with the Local Pathology Director (where relevant) to a Pathologist with relevant scope of practice from another Category B, GY or GX laboratory with access to the supervised laboratory's Information and Quality Systems.

8.3. On-Site Laboratory Manager of Category B Laboratory

All Category B laboratories must have an on-site manager who is a scientist with appropriate qualifications and a minimum of 2 FTE years relevant experience in the testing performed in the laboratory they are supervising.

The on-site manager must be present at the laboratory during normal working hours. During absences of the on-site manager, the Designated Person must delegate responsibility for the on-site manager's duties to another suitable Scientist or Technical Officer (see NPAAC Requirements for suitability).

9. Minimum Supervision Activity Time Requirements

Supervision is limited to scope of practice and supervision hours are therefore generally pathology specialty specific ie discipline specific.

The minimum supervision time required where:

a) Testing is not provided under the full time in aggregate supervision of on-site pathologists and

b) Access to the Laboratory Information System and central monitoring of the Quality System and quality control at the laboratory by the supervisors can and does occur, is:

Position	Minimum Time	Modality
Designated Person or their Pathologist delegate (Supervising Pathologist)	At least one visit per year to discharge responsibilities	On-site supervision
Supervising Pathologists, Clinical Scientists or Scientists	16 hours per annum in aggregate for each specialty	On-site supervision
On-site supervisor (Laboratory Manager)	16 hours per annum	Supervised training or professional development at another GX, GY or B laboratory
Quality Manager or their delegate	At least one visit per year to discharge responsibilities	On-site supervision
Any of the above attendance at a monthly laboratory management meeting	1-hour monthly meetings	On-site, teleconference or videoconference with formal agenda

Where supervision is provided by a Pathologist who does not have access to central monitoring of the Laboratory Information System (LIS), Quality System and Quality Control at the laboratory and video/teleconference management meetings do not occur, the following alternative supervision visits must occur in addition to the above:

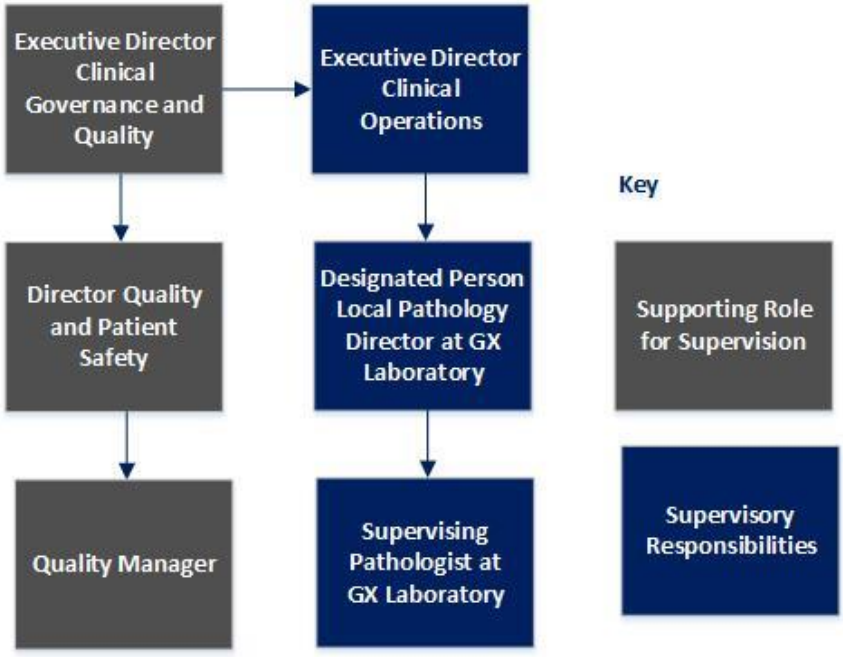
Position	Minimum Time	Modality
Supervising Pathologist, Clinical Scientist, Scientist	160 hours per annum for each specialty with at least quarterly visits	On-site supervision

Note: In addition to minimum time requirements for supervision, all supervisory duties related to the testing performed at the laboratory must be discharged.

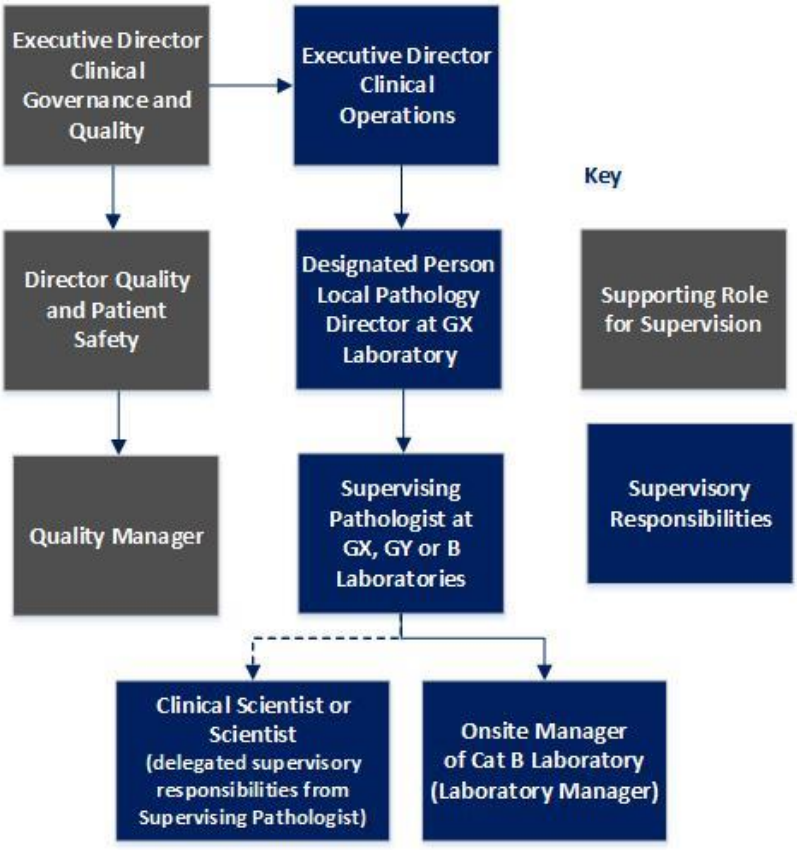
Please refer to Section 17 Supervision Activities and Tasks Table A.

10. Supervision Governance Structure

10.1. Supervision Governance Structure at GX Laboratory



10.2. Supervision Governance Structure at GY and B Laboratories



11. Roles and Responsibilities

11.1. Executive Director Clinical Governance and Quality

a) Accountable for the standard of meaningful supervision that must be practiced

b) Sets the vision and standard for meaningful supervision

c) Provides advice and guidance for interpretation of NPAAC requirements

d) Monitors consistency of interpretation and delivery of meaningful supervision throughout the organisation

e) Provides tools and an organisational framework for supervision

f) Identifies anomalies in compliance and advises on options for corrective action

g) Reports to the Chief Executive and relevant NSWHP executive committees on the status of compliance with supervision requirements.

11.2. Executive Director Clinical Operations

a) Ensures NPAAC and NSWHP requirements for laboratory supervision are implemented and maintained

b) Ensures appropriate identification and management of major risks to patient safety across Clinical Operations

c) Champions and communicates supervision requirements and roles and responsibilities of staff

d) Ensures appropriate resourcing and operational capabilities for supervision requirements to be met

e) Monitors compliance to the requirements and addresses shortcomings or deviations to ensure Standards are met

f) Escalates supervision risks and issues requiring attention.

11.3. Designated Person

As defined in the NPAAC Tier 2 RMPS document the Designated Person must have the authority and competence to ensure and take active responsibility for:

a) Clinical Governance

b) Policy setting and implementation

c) Identification and management of risk (noting Appendix A of RMPS)

d) Escalating supervision risks and issues requiring attention

e) Implementation and maintenance of the quality management system

f) Compliance with NPAAC and jurisdictional requirements

g) Operational practices and staffing including training

h) Determining the range of tests provided, their methods and procedures while considering that the numbers processed are sufficient to maintain competence

i) Determining the suitability of referral laboratories

j) Regular review of the quality management systems, proficiency testing data, reports and all aspects of performance

k) Provision of medical and scientific consultation

l) Procedures used and the tests performed being within the scope of the education, training, continuing professional development and experience of individual staff members

m) Determining work suitable to be performed outside normal working hours and that such work is performed by staff who are qualified, trained and competent to work in the absence of an on-site supervisor

n) Provision of a clearly defined process for contacting a supervisor who is not currently onsite

o) Ensuring the ongoing availability and integrity of materials and for providing storage for pathology records in the event of amalgamation or merger of a Medical Pathology Service.

11.4. Local Pathology Director

a) Operates as the Designated Person if credentialed and resides in a Category GX laboratory as per NPAAC requirements

b) Ensures local supervisory arrangements are documented, in place and are effective

c) Delegates supervisory responsibilities in consultation with the Designated Person (where this is a different person) to Pathologists and Clinical Scientists with a relevant scope of practice, ensuring clear documentation of arrangements in an accountability structure that is easily accessible in each laboratory

d) Ensures interpretation of NPAAC supervision requirements aligns with this Policy

e) Monitors documentation of supervisory status for Laboratories

f) Approves Leave for Supervising Pathologists and ensures that backup arrangements are in place

g) Escalates supervision risks and issues requiring attention

h) Makes 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.

11.5. Supervising Pathologist or Clinical Scientist

a) Undertakes discipline specific supervisory visits and activities evidenced by supervisory visit records

b) Discharges the supervision responsibilities as set out in the NPAAC requirements and Supervision Requirements

c) Documents and maintain records of supervisory visit details and shares information with the on-site laboratory manager (on-site supervisor) for recording keeping of activities into a central register

d) Delivers meaningful supervisory visits for local laboratory staff as outlined in activities listed in the NSW Health Pathology Supervisory Visit Record NSWHP_F_034.

e) Provides notification of leave as set out in the relevant Award or Policy to Local Pathology Director with documented backup arrangements for supervisory responsibilities that will be covered by another pathologist with the required scope of practice

f) Fulfils requirements of all annual site visits and supervision activities as per scope of practice and allocated site responsibility determined by the Designated Person

g) Escalates supervision risks and issues requiring attention

h) Refer to the Section 6.1 Supervision Accountability Matrix.

11.6. Director Quality and Patient Safety

a) Provides advice, guidance and support for the management of quality assurance/improvement activities and patient safety initiatives.

11.7. On-Site Manager of Category B Laboratory (Laboratory Manager)

a) Prepares and plans reciprocal visits and supervisory visits in conjunction with the Supervising Pathologist and/or Clinical Scientist

b) Monitors compliance with supervisory requirements against NPAAC standards and NSWHP Policy

c) Maintains centralised documentation of the laboratories supervision activities

d) Responsible for real-time records management of supervision activities in conjunction with Supervising Pathologists, Clinical Scientists and others

e) Escalates supervision risks and issues requiring attention

f) Refer to Section 6.1 Supervision Accountability Matrix.

11.8. Director of Operations

a) Assists Local Pathology Director and/or Designated Person in being assured that required arrangements are in place and operating effectively within their region

b) Escalates supervision risks and issues requiring attention

11.9. Operations Manager

a) Ensures records management practices are in place, easily accessible and up-to-date

b) Escalates supervision risks and issues requiring attention

c) Refer to Section 6.1 Supervision Accountability Matrix.

11.10. Quality Manager

a) Ensures that processes needed for the Quality System are established, implemented and maintained

b) Provides advice, guidance and support for the management of quality assurance/improvement activities and patient safety initiatives

c) Refer to Section 6.1 Supervision Accountability Matrix.

12. Legal and Policy Framework

The requirements for supervision are mandated by the National Pathology Accreditation Advisory Council (NPAAC) in the:

a) Requirements for Medical Pathology Services (Third Edition 2018)

b) Requirements for Supervision in the Clinical Governance of Medical Pathology Laboratories (Fifth Edition 2018)

Related Legislation

a) NPAAC Requirements

b) *Health Insurance Act 1973*

c) Health Insurance Regulations 1975

Related Policy Document Suite and Supporting Documents

a) NSW Health Pathology Critical Incident Procedure NSWHP_PR_021

b) NSW Health Risk Management – Enterprise-Wide Risk Management Policy and Framework PD2015_014

c) NSW Health Pathology Enterprise Risk Management Procedure NSWHP_PR_026

d) NSW Health Pathology Risk Assessment Template NSWHP_F_011

e) NSW Health Pathology Supervising Pathologist Contact Details Template NSWHP_F_033

f) NSW Health Pathology Supervisory Visit Record NSWHP_F_034

g) NSW Health Pathology Supervision Compliance Record NSWHP_SD_036

13. Review

This policy will be reviewed by 1 August 2020.

14. Risk

Risk Statement	Supervision of pathology services supports the delivery of quality pathology services, enables management of risks to patient safety and improves patient health outcomes.
Risk Category	Clinical Care and Patient Safety

15. Further Information

For further information, please contact:

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16. Version History

The approval and amendment history for this document must be listed in the following table.

Version No	Effective Date	Approved By	Approval Date	Policy Author	Risk Rating	Sections Modified
1.0	01/08/19	Chair, Clinical Gov, Quality & Risk Committee	31/07/19	Executive Officer, Clinical Operations	High	New Policy.

17. Supervision Activities and Tasks

Table A

Activity	Task
Review previous visit record and outstanding corrective actions	View the record of the previous supervisory visit for outstanding issues and follow-up. View Corrective Action log and records, assist with resolution, monitor sign-off.
Documented review of external QAP	A record of what was reviewed, any actions required and follow-up of those actions. Tick off discipline(s) reviewed. This includes review of results and corrective actions when discordant results are obtained
Documented internal QC review	A record of what was reviewed, any actions required and follow-up of those actions. Tick off discipline(s) reviewed. Includes inter-laboratory samples. For example, audits and corrective actions e.g. review of customer feedback.
Workforce review	Review training records. Perform competency based assessments. Discuss training needs, review call-back and overtime issues. Attendance at workforce related meetings.
Yearly performance review of immediate reporting senior staff	Documented performance review record for Supervising Pathologists, Clinical Scientists and on-site supervisor (on-site Laboratory Manager).
Documented review of incidents and complaints	Review of IMMS incidents, investigation of incidents, follow-up on implementation of recommendations to ensure problem has been corrected by the action.
Documented review of risk management plan	Review and update of risk management plan detailing risk levels and mitigation strategies in line with the NSWHP Enterprise Risk Management Procedure.
Documented meetings or discussions with staff regarding new tests or equipment	Meeting minutes detailing supervisor in attendance and discipline the activity will be counted towards, file notes detailing outcome of discussions with staff, completion of supervision record.
Documented staff management meetings with educational components	Meeting minutes detailing supervisor in attendance and discipline the activity will be counted towards, completion of supervision record.
Review of internal and external continuing education	Case study, QAP morphology, journal review, current topics, etc. ensure continuing education register is updated with topic and attendance record.
Documented review of safety records, incidents and corrective actions	Review work, health and safety documentation, workplace related incidents and follow-up on corrective actions.
Documented evidence of liaison with LHD management regarding pathology services	Follow through on clinical issues, incidents, complaints and queries. Liaise with hospital management in relation to service requirements and performance, collaboration, and new or changed services.
Physical inspection of the laboratory and equipment	Documented inspection of the laboratory. May involve equipment issues such as maintenance, replacement, and method discussion such as clinical utility.
Documented audits, outcomes and corrective actions	Targeted audits to determine compliance with the Quality System and Accreditation.