

# Compliance Management Framework



Health  
Pathology

# Compliance Management Framework

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## 1. Introduction

NSW Health Pathology recognises that an important part of achieving our strategic direction is to have an effective system of governance. This includes conducting our activities in accordance with applicable laws, regulations, professional codes, industry standards and NSW Health and NSW Health Pathology policy documents.

NSW Health Pathology commits to maintaining high standards of diligence in all areas of public accountability, including by implementing a compliance management system and promoting a culture of integrity and compliance.

## 2. Purpose

This Framework establishes the state-wide compliance management system that ensures NSW Health Pathology's operations are conducted in accordance with our Compliance Obligations.

The Framework stipulates the key principles that guide compliance management within NSW Health Pathology, consistent with our [purpose](#), [values](#), [strategy](#) and [risk appetite](#).

The Framework assists NSW Health Pathology to:

- a) Demonstrate our commitment to the highest standards of ethics and compliance;
- b) Embed a culture of integrity and compliance;
- c) Integrate effective policy, systems, controls and delegations of authority necessary to ensure compliance;
- d) Inform staff of mechanisms to facilitate compliance; and
- e) Establish and maintain an assurance program to monitor and report on compliance activities.

## 3. Background

The Framework is aligned with:

- a) [International Standard AS ISO 37301:2021 Compliance Management Systems – Requirements with guidance for use](#)
- b) [International Standard AS ISO 15189: 2012 Medical laboratories – Requirements for quality and competence](#)
- c) [National Pathology Accreditation Advisory Council \(NPAAC\)](#)
- d) [National Safety and Quality Health Service Standards](#)
- e) [NSW Health Code of Conduct PD2015\\_049](#)
- f) [NSW Health Corporate Governance and Accountability Compendium](#)
- g) [NSW Health Legal Compendium](#)
- h) [NSW Health Pathology Enterprise Risk Management Policy NSWHP\\_PD\\_024](#)
- i) [NSW Health Pathology Policy Framework NSWHP\\_CG\\_003](#)
- j) [Health Services Act 1997 \(NSW\)](#)
- k) [NSW Health Significant Legal Matters and Management of Legal Services PD2017\\_003](#)
- l) [NSW Treasury Internal Audit and Risk Management Policy for the NSW Public Sector \(TPP20-08\)](#).

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## 4. Definitions

**Audit and Risk Management Committee** means the Audit and Risk Management Committee of the Board established pursuant to section 33 of the Board's Instrument of Constitution dated 8 October 2018.

**Board** means the NSW Health Pathology Board established in 2012 under section 126C of the *Health Services Act 1997 (NSW)*.

**Compliance Obligations** means applicable laws, regulations, professional codes, industry standards and NSW Health and NSW Health Pathology policy documents.

**Compliance Officer** means the nominated officer occupying the role of Legal Counsel.

**Compliance Coordinator** means the nominated officer occupying role of Senior Legal Counsel.

**Compliance Owner** means the nominated officer (generally a member of the Strategic Leadership Team) responsible for maintaining compliance with each Compliance Obligation allocated to them.

**Compliance Register** means the register referred to in section 7.

**Compliance Report** means the [compliance report](#) described in section 9.4.

**Controls** means the policies, procedures, processes and other systems put in place to manage compliance with Compliance Obligations and associated risk of non-compliance.

**Disclosures Coordinator** means the nominated officer occupying role of Director, Legal & Corporate Governance.

**Framework** means this Compliance Management Framework.

**Personnel** means NSW Health Pathology employees, students, Board members, agents, contractors, visitors, volunteers, contractors and consultants performing work within or using NSW Health Pathology facilities.

Other terms used in the Framework are, where applicable, consistent with the definitions in the [International Standard AS ISO 37301:2021 Compliance Management Systems – Requirements with guidance for use](#).

**Strategic Leadership Team** means the NSW Health Pathology's senior leadership team.

## 5. Scope

The Framework is mandatory and applies to all Personnel and encompasses all Compliance Obligations.

## 6. Key Components of Compliance Management System

The key components of NSW Health Pathology's compliance management system are:

- a) This Framework;
- b) A Compliance Register – an accurate and complete record of key Compliance Obligations and associated Controls and risks of non-compliance;
- c) Allocation of accountability for assessing, monitoring and ensuring compliance to members of the Strategic Leadership Team based on their respective functional areas;
- d) A clear process for escalating identified instances of potential or actual non-compliance;
- e) Annual attestation of compliance;
- f) An embedded compliance culture led by the Strategic Leadership Team that is committed, proactive, visible and consistent;

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- g) Staff awareness and training on specific compliance responsibilities; and
- h) Continual review of compliance risk.

## 7. Compliance Register

A Compliance Register will be maintained by NSW Health Pathology's Corporate Governance portfolio. The Compliance Register will record:

- a) Key Compliance Obligations that impact on the operations of NSW Health Pathology;
- b) The Compliance Owner for each Compliance Obligation;
- c) A summary of Controls for each Compliance Obligation as well as any additional Controls required to improve compliance; and
- d) A [risk assessment](#) for each Compliance Obligation, determined on the basis of the likelihood and the consequences of non-compliance. The risk rating will inform the priority of compliance activities. Identified risks must be managed and reported in accordance with the NSW Health Pathology Enterprise Risk Management Policy NSWHP\_PD\_024

It must be noted that all legislative and regulatory obligations are *mandatory* regardless of the risk rating.

The Compliance Officer will be responsible for updating the Compliance Register regularly to incorporate relevant changes to Compliance Obligations and Controls and ensuring that the Compliance Register is made available to relevant Personnel.

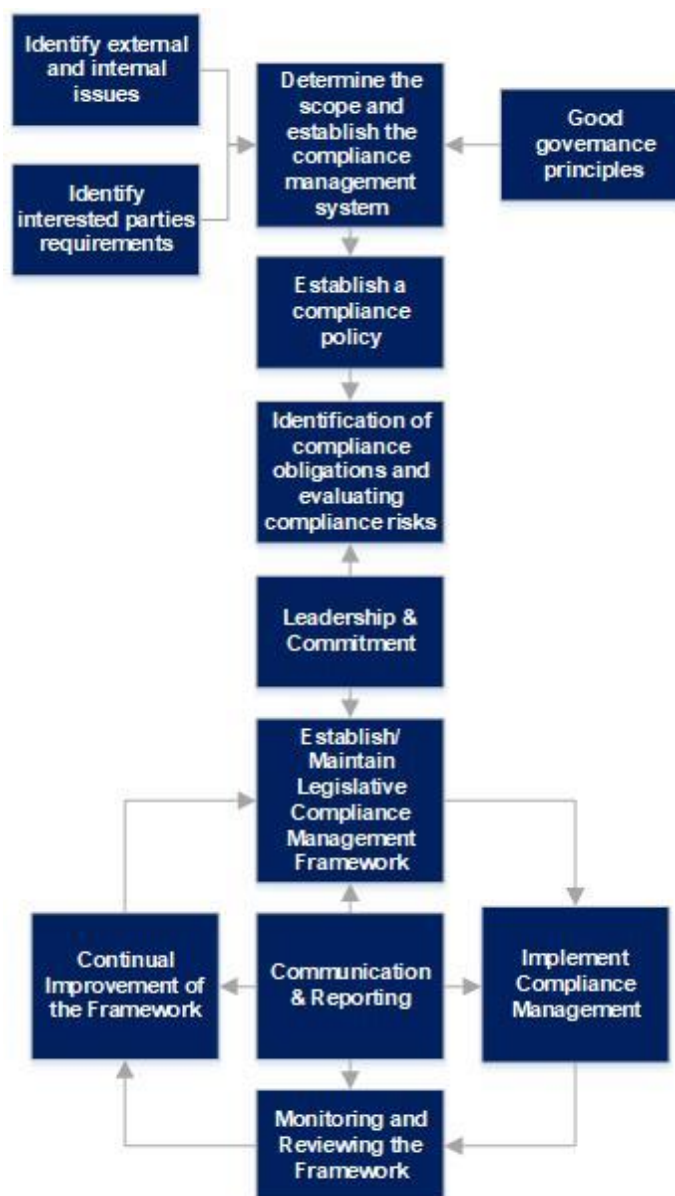
Compliance Owners (with assistance from the Compliance Officer and Compliance Coordinator) will be responsible for ensuring that any changes to Compliance Obligations for which they are responsible are identified, communicated to affected areas and reported to the Compliance Officer so that they may be incorporated into the Compliance Register.

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## 8. Flowchart: Compliance Management System

The flowchart below details NSW Health Pathology's compliance management system and is based on the principle of continual improvement. The objective is to establish a system that facilitates the development, implementation, evaluation and maintenance of Controls to promote a culture of integrity and compliance.



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## 9. Monitoring and Reporting

### 9.1 Monitoring

The Compliance Owner must be familiar with Compliance Obligations within their area of functional responsibility and must ensure that there are adequate Controls in place to continually monitor and review compliance with those obligations, and that any Control gaps or instances of actual or potential non-compliance are promptly identified and, where possible, resolved. This includes ensuring that:

- a) Risk ratings remain accurate; and
- b) Controls remain appropriate and effective,

notwithstanding any changes in the operational or regulatory environments.

### 9.2 Reporting Compliance Issues or Incidents

Actual or potential non-compliance may be a result of:

- a) Changes to Compliance Obligations which have not been pre-empted;
- b) Missed regulatory deadlines;
- c) Activities that are undertaken without the required accreditation, licence, permit or regulatory authorisation or which are otherwise prohibited by law;
- d) Regulatory compliance audit findings (internal or regulatory audits);
- e) Notices, directives or fines issued by regulators; and
- f) Pending prosecutions, regulatory investigations or other legal enforcement actions.

In accordance with the [NSW Health Code of Conduct PD2015\\_049](#), all Personnel must comply with all Compliance Obligations relevant to their role and responsibilities. Behaviour that compromises compliance will not be tolerated and, in addition to disciplinary action, a failure to comply with Compliance Obligations may also be punishable by law.

Personnel are required to proactively identify and, as soon as possible, report to their line manager any actual or potential non-compliance. The line manager must escalate the matter in a hierarchical fashion to the responsible Compliance Owner, who must report it to the Compliance Officer or Compliance Coordinator as soon as practical.

If Personnel are not comfortable reporting the non-compliance to their line manager, they should report the matter directly to the relevant Compliance Owner. Alternatively, they may anonymously report it to the Compliance Coordinator via the [legal email account](#).

Upon receipt of a reported non-compliance, the Compliance Officer is responsible for updating the Compliance Register and reporting the non-compliance to the Disclosures Coordinator. The non-compliance must also be recorded in the NSW Health Pathology Risk Register and reported in accordance with the [NSW Health Pathology Enterprise Risk Management Procedure NSWHP\\_PR\\_026](#).

The Disclosures Coordinator will report instances of non-compliance to the Chief Executive, the Strategic Leadership Team, the Audit and Risk Management Committee and other officers or committees, as appropriate, within timeframes determined according to the assessed risk rating of the applicable non-compliance.

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In some instances, such as allegations of corruption, there is a mandatory requirement to report matters to external agencies. Such instances should be reported to the [Disclosures Coordinator](#) immediately, who will ensure that the matter is reported to the responsible agency.

Instances of non-compliance that constitute a 'Significant Legal Matter' must also be notified to NSW Health in accordance with the [NSW Health Significant Legal Matters and Management of Legal Services Policy Directive PD2017\\_003](#).

Complaints alleging compliance breaches should be handled in accordance with the [NSW Health Complaints Management Policy PD2020\\_013](#) and [NSW Health Complaint Management Guidelines GL2020\\_008](#).

NSW Health Pathology is committed to protecting any person who raises concerns about a breach of a Compliance Obligation from retaliation or reprisal. Any attempt to take detrimental action against a person who legitimately reports an actual or potential breach of a Compliance Obligation will be treated seriously and may result in disciplinary action.

## 9.3 Resolving Compliance Issues or Incidents

Once an instance of potential or actual non-compliance has been identified and reported, the relevant Compliance Owner will:

- a) Implement appropriate corrective action in consultation with the Compliance Coordinator;
- b) Assess, document and monitor the timeframe and implementation of corrective actions; and
- c) Continue to report on non-compliant matters and address issues raised by the Chief Executive, the Strategic Leadership Team, the Audit and Risk Management Committee and other officers or committees in response to the reported non-compliance until the issue or incidence is rectified.

Any residual risks remaining after corrective action has been taken will be assessed and managed in accordance with the [NSW Health Pathology Enterprise Risk Management Procedure NSWHP\\_PR\\_026](#).

## 9.4 Annual Attestation

The Board and the Chief Executive are required to report to the Ministry of Health in the annual [Corporate Governance Attestation Statement](#) that NSW Health Pathology has complied with the relevant legislation and regulations in the preceding twelve (12) months. To facilitate this, and verify compliance more generally, Compliance Owners will be required to complete a [Compliance Report](#) and provide it to the Compliance Coordinator by 31 July each year.

The [Compliance Report](#) is designed to provide reasonable assurance to the Board and the Chief Executive that NSW Health Pathology has appropriate mechanisms in place to ensure that all facilities and units comply with all relevant Compliance Obligations.



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## 10. Continual Improvement

NSW Health Pathology will continually assess and seek to improve the suitability, adequacy and effectiveness of the Framework by:

- a) Keeping abreast of compliance best practice;
- b) Reviewing the Framework at least every two (2) years to ensure currency, including by identifying opportunities for improvement;
- c) Encouraging staff to provide feedback on the Framework to the Compliance Coordinator.

## 11. Training and Awareness

The Compliance Owner is responsible for promoting understanding and awareness and ongoing reinforcement of Compliance Obligations within their area of functional responsibility through:

- a) Referencing obligations in relevant policy documents and position descriptions;
- b) Incorporating compliance as a component of the on-boarding process;
- c) Incorporating compliance training and promoting a culture of integrity in appropriate staff developmental activities;
- d) Facilitating targeted compliance training to staff with specific responsibilities affected by legislative changes;
- e) Conducting annual audits of professional registrations where relevant; and
- f) Ensuring NSW Health Pathology's commitment to compliance is visible and ongoing.

The Compliance Coordinator will arrange training sessions on legislative compliance management on an as needs basis.

## 12. Performance Measures

The Disclosures Coordinator, with the assistance of the Compliance Coordinator, will report annually to the Audit and Risk Management Committee on NSW Health Pathology's overall compliance performance for the preceding twelve (12) months. NSW Health Pathology's compliance performance will be assessed by measuring:

- a) % of policy documents that are reviewed by the specified review date;
- b) % of reported breaches where the investigation has been completed within the period required by the [NSW Health Incident Management Policy PD2020\\_047 \(as applicable\)](#);
- c) Completion of annual review of Compliance Obligations including a risk assessment; and
- d) Mandatory training completion rates.

The Audit and Risk Management Committee will review this report and provide timely feedback aimed at improving the future assessment of NSW Health Pathology's overall compliance performance.

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## 13. Roles and Responsibilities

To ensure that NSW Health Pathology achieves its intended compliance outcomes, the Framework establishes key responsibilities for Personnel as follows:

### 13.1 Board

It is the responsibility of the Board to:

- a) Oversee the development, implementation and monitoring of the Framework;
- b) Promote a positive culture of integrity and compliance; and
- c) Review and monitor compliance.

### 13.2 Chief Executive

It is the responsibility of the Chief Executive to:

- a) Oversee the effective management of the Framework;
- b) Provide leadership for, and actively support, compliance;
- c) Promote, monitor and uphold a positive culture of integrity and compliance;
- d) Embed compliance into the operational processes of NSW Health Pathology by ensuring that Personnel are aware of their responsibilities pursuant to the Framework;
- e) Ensure NSW Health Pathology complies with all Compliance Obligations;
- f) Approve correspondence with regulators in relation to the resolution of non-compliance as required; and
- g) Attest annually to the Ministry of Health that the legal and policy obligations of NSW Health Pathology are identified and understood and the responsibilities for compliance are allocated in accordance with the [Corporate Governance and Accountability Compendium for NSW Health](#).

### 13.3 Audit and Risk Management Committee

It is the responsibility of the Audit and Risk Management Committee to:

- a) Ensure that the Framework contributes to enterprise-wide risk management processes;
- b) Determine whether management has appropriately considered legal and compliance risks as part of NSW Health Pathology's risk assessment and management arrangements;
- c) Review the effectiveness of the Framework in ensuring NSW Health Pathology's compliance with Compliance Obligations;
- d) Review and provide timely feedback on the annual report detailing NSW Health Pathology's overall compliance performance for the preceding twelve (12) months.

### 13.4 Compliance Owners (Strategic Leadership Team)

It is the responsibility of the Compliance Owners to:

- a) Adopt the Framework and promote, monitor and uphold a positive culture of integrity and compliance;

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- b) Maintain an awareness of Compliance Obligations (including changes to existing Compliance Obligations) relevant to their area of operational responsibility and notify the Compliance Coordinator and affected Personnel of any new Compliance Obligations or changes to existing Compliance Obligations;
- c) Identify and assess compliance risks to manage compliance risk in their area of operational responsibility;
- d) Ensure that Personnel within their area of operational responsibility are aware of their responsibilities in relation to compliance;
- e) Effectively manage and monitor compliance with all Compliance Obligations within their area of operational responsibility;
- f) Report annually that the Compliance Obligations within their area of operational responsibility have been identified and are understood and (except as otherwise indicated) complied with, and that appropriate Controls are in place;
- g) Review the Compliance Obligations allocated to it in the Compliance Register at least annually, including by reviewing the Controls and risk rating and prioritising any strategies to minimise the risk of non-compliance;
- h) Allocate appropriate resources for compliance management within their area of operational responsibility;
- i) Encourage Personnel to raise compliance concerns and actively participate in managing and resolving compliance issues or incidents; and
- j) Report, manage and where possible resolve (including by seeking legal advice where appropriate) actual or potential non-compliance in accordance with this Framework.

## 13.5 Compliance Officer

The Compliance Officer is located in the Corporate Governance portfolio of NSW Health Pathology, with a direct reporting line to the Compliance Coordinator. It is the responsibility of the Compliance Officer to:

- a) Maintain the Compliance Register;
- b) Report to the Compliance Coordinator on compliance matters, the effectiveness of the compliance management system and compliance trends or issues as required;
- c) Compile an annual report on overall compliance performance, in consultation with the Compliance Coordinator;
- d) Prepare a consolidated compliance statement each year for the Chief Executive and Board incorporating individual compliance reports from Compliance Owners;
- e) Maintain appropriate systems or processes for recording instances of reportable non-compliance in consultation with the Compliance Coordinator; and
- f) Identify systemic issues arising from instance of reportable non-compliance and report such issues to the Compliance Coordinator and Disclosures Coordinator.

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## 13.6 Compliance Coordinator

The Compliance Coordinator is located in the Corporate Governance portfolio of NSW Health Pathology, with a direct reporting line to the Disclosures Coordinator. It is the responsibility of the Compliance Coordinator to:

- a) Ensure a coordinated and consistent approach is adopted across NSW Health Pathology to meeting its Compliance Obligations;
- b) Develop, implement, communicate and review the Framework;
- c) Report to the Compliance Coordinator on compliance matters, the effectiveness of the compliance management system and compliance trends or issues as required; and
- d) Identify systemic issues arising from instance of reportable non-compliance and report such issues to the Disclosures Coordinator.

## 13.7 Disclosures Coordinator

It is the responsibility of the Disclosures Coordinator to:

- a) Receipt anonymous reports of non-compliance;
- b) Report matters of non-compliance to external agencies as required;
- c) Report to the Strategic Leadership Team and the Audit and Risk Management Committee on compliance matters, the effectiveness of the compliance management system and compliance trends or issues as required;
- d) Report annually to the Audit and Risk Management Committee on over-all performance compliance; and
- e) Report systemic issues arising from instances of reportable non-compliance to the Strategic Leadership Team, Chief Executive and Audit and Risk Management Committee as appropriate.

## 13.8 All Personnel

It is the responsibility of all Personnel to:

- a) Comply with all relevant Compliance Obligations within the scope of their roles; and
- b) Identify and report any concerns in relation to non-compliance to their line manager (or otherwise in accordance with this Framework).

## 14. References and Links

### 14.1 Legislation

[Federal Register of Legislation](#)

[NSW Legislation](#)

[State Records Act 1998 \(NSW\)](#)

[Health Services Act 1997 \(NSW\)](#)

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## 14.2 Standards

[International Standard AS 37301:2021-04 Compliance Management Systems – Requirements with guidance for use](#)

[International Standard AS ISO 9001 Quality Management Systems](#)

[International Standard ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories](#)

[International Standard AS ISO 15189: 2012 Medical laboratories – Requirements for quality and competence](#)

[National Pathology Accreditation Advisory Council \(NPAAC\)](#)

[National Safety and Quality Health Service Standards](#)

[SAI Global \(NSW Health Pathology access to International and Australian Standards\)](#)

## 14.3 Policies

[NSW Health Code of Conduct PD2015\\_049](#)

[NSW Health Corporate Governance and Accountability Compendium](#)

[NSW Health Complaint Management Guidelines GL2020\\_008](#)

[NSW Health Complaint Management Policy PD2020\\_013](#)

[NSW Health Pathology Delegations Manual CG\\_001](#)

[NSW Health Patient and Clinical Quality Program PD2005\\_608](#)

[NSW Health Incident Information Management System](#)

[NSW Health Incident Management Policy PD2020\\_047](#)

[NSW Health Legal Compendium](#)

[NSW Health Pathology Clinical Governance Framework](#)

[NSW Health Pathology Enterprise Risk Management Policy NSWHP\\_PD\\_024](#)

[NSW Health Pathology Policy Framework CG\\_003](#)

[NSW Health Risk Management – Enterprise-Wide Risk Management Policy and Framework PD2022\\_023](#)

[NSW Health Significant Legal Matters and Management of Legal Services Policy Directive PD2017\\_003](#)

[NSW Treasury Internal Audit and Risk Management Policy for the NSW Public Sector \(TPP20-08\)](#)

## 14.4 Regulatory

[National Association of Testing Authorities, Australia](#)

[Royal College of Pathologists of Australasia Quality Assurance Programs](#)

[Therapeutic Goods Administration](#)

## 15. Review

The framework will be reviewed by 31/12/2024.

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## 16.Risk

<b>Risk Statement</b>	Compliance with relevant legislative and regulatory obligations will mitigate the risk of: <ul style="list-style-type: none"><li>- Loss of funding given the legislative compliance conditions in the <i>Health Services Act 1997 (NSW)</i>;</li><li>- Complaints, penalties, fines, litigation, investigations, inquiries, loss of services and management time, injuries and adverse outcomes;</li><li>- Reputational damage.</li></ul>
<b>Risk Category</b>	Leadership and Management

## 17.Further Information

For further information, please contact:

<b>Policy Contact Officer</b>	Position: Compliance Coordinator (Senior Legal Counsel)
	Email: NSWPATH-Legal@health.nsw.gov.au

## 18.Version History

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

Version No	Effective Date	Approved By	Approval Date	Policy Author	Risk Rating	Sections Modified
V1.0	24/10/18	Transformation Governance Committee	10/10/2018	Samantha Brookes Senior Policy Officer and Compliance Coordinator	High	New framework.
V2.0	19/04/21	Director, Corporate Governance	19/04/2021	Stephanie Campbell Senior Legal Counsel	High	Updates throughout document.
V3.0	10/10/23	Director, Legal & Corporate Governance	10/10/2023	Senior Legal Counsel	High	Updated references to Standards, policies and procedure and new role at section 13.5

## 19.Supporting Documents

[Compliance Report](#)