

- **Summary** This Policy Directive addresses clinical care and patient safety risks associated with clinical procedures; improve matching of the patient to the correct procedure; improve communication within the procedural team, and between the patient and the procedural team; and reduce the number of clinical procedure related incidents.
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 - **Distributed to** Ministry of Health, Public Health System, Divisions of General Practice, Government Medical Officers, NSW Ambulance Service, Private Hospitals and Day Procedure Centres
 - Audience All Clinical Staff;Operating Theatres and Emergency Departments;Nursing Staff;Medical;Diagnostic Imaging Depts and Business Units;Clinical Staff Working in Perioperative Environments;Surgical;Anaesthesia



Policy Statement

NSW Health aims to address clinical care and patient safety risks associated with clinical procedures by improving matching of the patient to the correct procedure; improving communication within the procedural team, and between the patient and the procedural team; and reducing the number of clinical procedure related incidents.

This Policy Directive aligns with the <u>National Safety and Quality Health Services</u> <u>Standards</u> requirements for communicating for safety, in particular correctly matching patients with their care.

Summary of Policy Requirements

All staff involved in clinical procedures must adhere to the requirements of this Policy Directive. There are multiple related documents including NSW Health policy directives that are directly applicable to the implementation of this Policy Directive.

All staff must comply with the pre-procedure and post-procedure requirements for all procedures which are listed in the Policy Directive, including:

- Level 1 procedures: patient identification, procedure verification, allergy / adverse reaction check, preparation for anticipated events, and post-procedure documentation and handover.
- Level 2 procedures: performing a Team Time Out, patient identification, procedure verification, site / side / level marking, allergy / adverse reaction check, medication administration, preparation for anticipated events, and post-procedure documentation, handover and testing.
- Level 3 procedures: patient identification, procedure verification, site / side / level marking, Sign In and related checks, Team Time Out and related checks, and Sign Out and related checks, documentation and post-procedure documentation.

Health services must complete audits to assess compliance with this Policy Directive.



NSW Health Policy Directive

Revision History

Version	Approved By	Amendment Notes
PD2025_006 February-2025	Deputy Secretary, People, Culture and Governance	Revised following review. Includes consideration for the use of blood products and Child Safe Standards. Replaces PD2017_032.
PD2017_032 September-2017	Deputy Secretary, People, Culture and Governance	Revised following review. Replaces PD2014_036.
PD2014_036 October 2014	Deputy Secretary, Governance, Workforce & Corporate	Revised following review. Replaces PD2007_079.
PD2007_079 October-2007	Director General	Revised following review. Replaces PD2005_380.
PD2005_380 January-2005	Director General	New policy.

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NSW Health

Clinical Procedure Safety

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1. Background

1.1. About this document

This Policy Directive addresses clinical care and patient safety risks associated with performing clinical procedures; improve matching of correct patient to the correct procedure and the correct site; improve communication within the procedural team and between the patient and the procedural team; and reduce the number of clinical procedure related incidents.

This Policy Directive also aligns with the National Safety and Quality Health Service Standards, focusing on the need for effective communication to accurately align patients with their care.

1.2. Clinical procedure safety principles

The following principles apply to clinical procedures:

- The NSW Health Policy and Procedure Manual *Consent to Medical and Healthcare Treatment Manual* (Consent Manual) provides operational guidance and procedures to support compliance with the NSW law on obtaining consent to medical treatment from patients or their substitute consent providers. This is mandatory for all people who work within the NSW public health system [1].
- Per the Consent Manual, consent is generally not required where the patient lacks capacity and immediate treatment is necessary to save a person's life or prevent serious injury to their health [1].
- Implement the <u>Child Safe Standards</u> when children or young people are undergoing clinical procedures. Children should be involved in decisions that affect them and should be encouraged to contribute, considering their age, development, maturity and understanding.
- The manager / departmental head is responsible for ensuring the processes for clinical procedure safety are followed.
- Every clinician involved in a procedure whether as an individual proceduralist or as a member of a procedural team is responsible for ensuring the processes for clinical procedure safety are followed.
- Active involvement and effective communication between the proceduralist (and procedural team members where appropriate) and the patient or their person responsible must occur.
- Use patient-centred communication techniques. For example, when communicating with children, a staff member experienced in communicating with children should provide an explanation of the procedure, in consultation with the person responsible, using language that can be understood by the child. The use of toys such as dolls or teddy bears may assist with explanations.
- In general, where a child is undergoing the procedure the person responsible is encouraged to stay with their child where clinically appropriate.



- Proceduralists and clinicians should be aware that some patients including children, because of previous experience, will require trauma-informed care including principles of safety, collaboration and empowerment.
- Obtained consent must be documented for the procedure including the use of Health Care Interpreters when applicable [1].
- Confirm and document the patient's consent or refusal to the <u>use of blood products</u> [1, 3].
- To the extent possible, involve the patient and/or their person responsible, at all points in the patient identification and procedure verification processes, including marking of the procedure site where appropriate.
- The care provided should be culturally responsive. This includes the recognition of the cultural values of Aboriginal people and acknowledgement of Kinship relationships [4]. Health services should involve Aboriginal Liaison Officers, Aboriginal Health Practitioners and/ or Aboriginal Health Workers in discussions with patients where appropriate and provide culturally appropriate resources.
- The appropriate clinical setting must be selected for the procedure to be performed. This includes considering clinical space, access to resources and environment sterility.
- Patient identification [2], and verification of the correct procedure and correct site (where appropriate) must occur prior to the procedure commencing.
- The proceduralist (and procedural team members where appropriate) is responsible for confirming patient identification [2], procedure verification and where appropriate the correct site / side / level for the procedure. The proceduralist carries ultimate responsibility for the patient identification and procedure verification.
- Site marking must be completed where there is the potential for error involving multiple structures (fingers, toes, or lesions), left / right distinction, or levels (spine).
- Confirm and document the patient's known allergies / adverse reactions to substances. Ensure flagged substances are not used during the procedure.
- If pre-procedure imaging or pathology data are to be used, the proceduralist is responsible for ensuring the data is available and correctly identified before the patient receives procedural sedation / anaesthesia.
- If prostheses, implants, sterile equipment, or special equipment are required, they must be available and, where appropriate, confirmed they are functional and appropriate for use, such as left / right, before the patient receives procedural sedation / anaesthesia.



1.3. Key definitions

Airway management	Includes oxygen therapy via face mask, management of airways obstruction including the use of common devices such as oro-pharyngeal and naso-pharyngeal airways, single handed and 2 handed mask ventilation using Bag and Mask, insertion and management of Laryngeal Mask Airways and intubation of the trachea using standard laryngoscopy equipment and monitoring of the patient for the effects of hypoxia with basic monitoring such as ECG (electrocardiogram), NIBP (non-invasive measurement of blood pressure), Pulse Oximetry and CO ₂ waveform analysis for deep sedation.
Assisting clinicians	Staff engaged in assisting the proceduralist as part of the procedure.
Clinical handover	The effective transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis [5].
Clinician	A person authorised by a facility to provide clinical care to a patient.
Clinician airway monitor	A dedicated clinician (who is not the proceduralist) with appropriate training, whose primary responsibility is to ensure the patency of the patient's airway and monitor the patient's cardio-respiratory status and level of consciousness a during the procedure.
Incident	Any unplanned event resulting in, or with the potential for, injury, damage or other loss. This includes a near miss [6].
Must	Indicates a mandatory action that is required to be complied with.
Patient	A person receiving health care. Also known as consumer or client.
Patient identification	The active process of confirming a patient's identity using 3 approved patient identifiers to ensure the correct patient is matched to their planned procedure [2, 7].
Person responsible	For the purpose of this Policy Directive, a person who can provide consent for a patient's clinical procedure to be performed [1].



Proceduralist	A clinician who is performing or assisting in the procedure. There may be more than one proceduralist involved in a procedure. The senior proceduralist takes overall responsibility for the case.		
Procedural Team	Includes all clinicians participating in the delivery of care during the procedure.		
Procedure	For the purpose of interpreting this Policy Directive, procedure is defined as follows.		
	Loval 1 procedure		
	Level 1 procedure		
	Usually requires a single proceduralist		
	 Usually does not require written consent 		
	 Does not involve procedural sedation or general / regional anaesthesia 		
	 Exception - Dental procedures involving dental nerve blocks are classified as Level 1 procedures 		
	 Usually performed in wards, emergency departments, clinics and imaging departments on a defined bed or treatment location 		
	Requires pre-procedure stop.		
	Level 2 procedure		
	 Requires a proceduralist, often supported by an assisting proceduralist/s 		
	Usually requires written consent		
	 Does not involve procedural sedation or general / regional anaesthesia 		
	 Usually performed in wards, emergency departments, clinics, imaging departments and interventional suites or in a clinically appropriate space, such as procedure room. 		
	Requires Team Time Out.		
	Level 3 procedure		
	 Requires at least one proceduralist and a procedural team 		





	 Always requires written consent 	
	 Involves procedural sedation or general / reg anaesthesia 	ional
	 Usually performed in formal procedural suites operating theatres, emergency departments, suites, interventional imaging suites, birthing cardiac catheterisation laboratories 	endoscopy
	 Requires Team Time Out 	
	Requires procedure Sign In and Sign Out.	
Procedure verification	The active process of verifying the procedure by complanned procedure and the site / side / level for the	
Sedation and anaesthesia [8]	Procedural sedation implies that the patient is in a drug-induced tolerance of uncomfortable or painful or interventional medical, dental or surgical procedu	diagnostic
	 Conscious sedation is defined as a drug-ind depression of consciousness during which pa able to respond purposefully to verbal comma light tactile stimulation. 	atients are
	• Deep levels of sedation is where conscious and patients only respond to painful stimulati associated with potential loss of the ability to patent airway, inadequate spontaneous venti or impaired cardiovascular function. Deep lev sedation may have similar risks to general an and may require an equivalent level of care.	on, are maintain a lation and / /els of
	For the purpose of interpreting this Policy Directive:	
	Use of opioids	
	The use of opioids for analgesia is not conside procedural sedation.	lered
	Use of nitrous oxide	
	 If the primary intent is analgesia, then considered procedural sedation. 	it is not
	 If the primary intent is sedation, then it considered procedural sedation and th procedures must be classed as Level procedures. 	nese
	Procedural sedation does NOT include premedication reduce anxiety or provide pain relief.	on to
	Regional anaesthesia includes major nerve blocks	, epidural
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	blocks and spinal blocks. Excludes dental nerve blocks. It involves the injection of local anaesthetic in the vicinity of major nerve bundles supplying body areas. Regional anaesthesia may be used on its own or combined with sedation or general anaesthesia.	
	General anaesthesia is a drug-induced state characterised by absence of purposeful response to any stimulus, loss of protective airway reflexes, depression of respiration and disturbance of circulatory reflexes. General anaesthesia is sometimes indicated during diagnostic or interventional medical or surgical procedures and requires the exclusive attention of an anaesthetist, or other appropriately trained and credentialed medical specialist within their scope of practice.	
Should	Indicates a recommended action that is the correct or most reasonable course to be followed unless there are sound reasons for taking a different course of action.	
Sign In	Procedural documentation completed in the period immediately before preparing the patient for their procedure by the procedural team.	
Sign Out	Procedural documentation completed in the period after the procedure and before the patient / procedural team leaves the procedural area.	
Team Time Out	The period immediately before commencing the procedure to undertake a final verification of the patient's identity and the procedure. Team Time Out applies to Level 2 and Level 3 procedures.	
Venous thromboembolism (VTE) prophylaxis	Treatment, either pharmacological or mechanical, provided to a patient to reduce the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) [9].	



1.4. Related documents

This Policy Directive is to be read in conjunction with the following related documents.

Related documents

Organisation / Document Number	Document Title	
NSW Health, ISBN: 978-1-76023- 628-1	Consent to Medical and Healthcare Treatment Manual	
NSW Health, GL2021_007	Emergency Surgery Guidelines and Principles for Improvement	
NSW Health, Agency for Clinical Innovation, ISBN 978-1-74187-006- 0	Minimum standards for safe procedural sedation	
NSW Health, PD2023_002	Accountable Items used in Surgery and Other Procedures	
NSW Health, PD2024_045	Prevention of Venous Thromboembolism	
NSW Health, PD2019_020	<u>Clinical Handover</u>	
NSW Health, PD2021_033	Patient Identification Bands	
NSW Health, PD2011_003	Electroconvulsive Therapy: ECT Minimum Standard of Practice in <u>NSW</u>	
NSW Government Office of the Children's Guardian, ISBN 978-0- 6451877-0-0	Guide to the Child Safe Standards	
Australian Commission on Safety and Quality in Health Care (ACSQHC)	National Safety and Quality Health Service Standard Communicating for Safety	
World Health Organization (WHO)	Guidelines for safe surgery: 2009: safe surgery saves lives	
WHO	Surgical Safety Checklist	
Royal Australasian College of Surgeons'	Surgical Safety Checklist	



2. Level 1 Procedures

Definition	Examples ¹	Requirements	
		Pre-procedure	Post procedure
 Single proceduralist Usually does not require written consent Does not involve procedural sedation or general/regional anaesthesia, except for dental procedures involving dental nerve blocks Usually performed in wards, emergency departments, clinics, imaging departments on a defined bed or treatment location 	 Insertion of intravenous (IV) cannula Insertion of indwelling catheter (IDC) Insertion of nasogastric tube (NGT) Taking blood samples Diagnostic Radiology Diagnostic Nuclear Medicine Routine dental procedures, such as dental extraction, fillings Dental procedures involving dental nerve blocks Superficial skin lesions / biopsies Non operative obstetrics, such as fetal scalp blood sampling, perineal repair with local anaesthetic, Artificial Rupture of Membranes, fetal scalp electrode² 	STOP and confirm the following before commencing the procedure: - Patient identification - Procedure verification - Allergy / adverse reaction check - Anticipated critical events	 Document procedure in patient's health care record Advice for clinical handover Specimens / images labelled correctly Post procedure tests where clinically relevant

¹ The examples provided do not cover all possible procedures. The examples may be escalated to a higher level. For example, Level 1 procedures may be classified by a health service as Level 2 or Level 3 procedures. Health services should consider development of local lists of examples for Level 1, Level 2 and Level 3 procedures consistent with the requirements of this Policy Directive.

² Where the procedure is a non-operative obstetric procedure and patient identification has occurred at the commencement of labour, the obstetric team that has cared for the patient during labour should confirm the patient's identification immediately before commencing the procedure if appropriate, for example if the patient is moved to a new room or a new member joins the obstetric team caring for the patient during the procedure.

2.1. Pre-procedure

For Level 1 procedures the proceduralist, and assisting proceduralist/s, where relevant, must STOP and confirm the below minimum requirements (see sections 2.1.1 - 2.1.4) immediately before commencing the procedure.

Where 2 or more staff members are involved, they must introduce themselves to each other and to the patient, as appropriate before the procedure commences. This must include their preferred names and their clinical roles.

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2.1.1. Patient identification

The patient's identity must be confirmed before any procedure commences.

Staff must confirm that they have the correct patient by asking the patient, and/or their person responsible, to state the patient's full name and their date of birth. Staff must not state the patient's name or date of birth before asking.

The response must be confirmed against the details on the request form / referral / treatment plan and the patient's identification band or other approved patient identification tool (including unique patient identifier), as appropriate [2].

Where patient details on the request form / referral / treatment plan are incomplete or there is a discrepancy with the information received from the patient, or their person responsible, the correct information must be verified before commencing the procedure. The actions taken are to be documented in the patient's health care record.

If the patient is unable to participate in the patient identification step or is a child and their person responsible is not present, then the patient's identification band or other approved patient identification tool (including unique patient identifier) should be used to confirm the patient's identification.

2.1.2. Procedure verification

Consent must be obtained for procedures as required by the NSW Health Policy and Procedure Manual <u>Consent to Medical and Healthcare Treatment Manual</u> [1], and obtained consent must be documented in the patients' health care record.

Consent must be documented for high-risk radiology and nuclear medicine procedures [10]. The level of risk associated with imaging procedures or examinations should be determined locally based on the risk factors of the individual patient and the risk of the procedure.

Written consent is not required for Level 1 (minor) procedures performed under local anaesthesia.

Request forms / referrals / treatment plans for procedures must include the patient's:

- name
- date of birth
- sex
- unique patient identifier (where appropriate)
- reason for the procedure
- details of the test/s required
- the date the test/s were ordered, and
- the exact anatomical location for the test/s including the procedure site, laterality and level.

The proceduralist must ask the patient, and/or their person responsible, to state what procedure they understand will be performed, and to state the site / side / level for the

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procedure (where relevant) and verify this matches the planned procedure and consent / request form / referral / treatment plan.

Where procedure details on the request form / referral / treatment plan are incomplete or there is a discrepancy, the requesting clinician or a member of their team must be contacted to clarify the information before commencing the procedure and the response is to be documented.

2.1.3. Allergy / adverse reaction check

The proceduralist must ask the patient, and/or their person responsible, if they have a known allergy / adverse reaction and if the answer is yes, what the allergy / adverse reaction was, and what effect they experienced. The response must be documented [2, 11]

2.1.4. Anticipated critical events

The proceduralist must consider the planned procedure, critical steps, anticipated events, equipment requirements and anticipated response should an event occur.

2.2. Post procedure

Following completion of the procedure:

- 1. The name of the proceduralist/s must be documented in the patient's health care record.
- 2. Document the name of the procedure and outcome/s in the patient's health care record.
- 3. Provide clinical handover advice (verbal and documented) to the staff caring for the patient or post procedure destination, as appropriate, and discuss with the patient and/or person responsible where possible.
- 4. Specimens / images must be labelled correctly, and labels checked with the patient or person responsible, or checked with another clinician where possible.
- 5. Referral for post procedure tests must be discussed with the patient (and/or their person responsible) where clinically appropriate and arranged.



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3. Level 2 Procedures

Definition	Examples ³	Requirements	
		Pre-procedure (including Team Time Out)	Post procedure
 Proceduralist often supported by an assisting proceduralist/s Usually requires written consent Does not involve procedural sedation or general / regional anaesthesia Usually performed in wards, emergency departments, clinics, imaging departments, interventional suites or in a clinically appropriate space, such as procedure room 	 Lumbar puncture Insertion of chest tube Ascitic tap Stress test Diagnostic interventional procedures Nuclear Medicine therapies Non-superficial biopsies Intravenous (IV) or intrathecal administration of chemotherapy IV administration of contrast Centrally inserted central venous access device [8] 	 STOP and confirm the following before commencing the procedure: Proceduralist / assisting proceduralist/s introductions Patient identification Procedure verification - procedure + site / side / level, where appropriate, matches consent Patient position Essential imaging reviewed Allergy / adverse reaction check Confirmation of pregnancy status for women of childbearing age Special medication/s administered Antibiotics Implants and special equipment Anticipated critical events 	 Document procedure in the patient's health care record Advice for clinical handover Equipment problems / issues Specimens / images labelled correctly Post procedure tests where clinically relevant, such as chest x-ray post insertion of chest tube

³ The examples provided do not cover all possible procedures and the examples may be escalated to a higher level. For example, Level 1 procedures may be classified by a health service as Level 2 or Level 3 procedures. Health services should consider development of local lists of examples for Level 1, Level 2 and Level 3 procedures consistent with the requirements of this Policy Directive.

3.1. Pre-procedure (including Team Time Out)

For Level 2 procedures, the proceduralist and other members of the procedural team, must **STOP** and confirm the following minimum requirements immediately before commencing the procedure.

Where 2 or more staff members are involved, they must introduce themselves to each other, to the patient and their person responsible where appropriate, by their preferred names and roles before the procedure commences.



3.1.1. Patient identification

Process is the same as in <u>section 2.1.1</u>.

3.1.2. Procedure verification

Process is the same as in <u>section 2.1.2</u>.

Consent must be documented for high-risk radiology and nuclear medicine procedures [10]. The level of risk associated with each imaging procedure should be determined locally based on the risk factors of the individual patient and the risk of the procedure.

When contrast is used, the computed tomography (CT) contrast administration checklist (*State Form CT contrast administration checklist NHSIS70046*) (or eMR based digital equivalent form) must be completed prior to the scan.

3.1.3. Site / side / level marking

- The site / side / level must be marked where there is the potential for error involving multiple structures (fingers, toes, or lesions), left / right distinction, or levels (spine).
- Non-procedure sites / sides / levels must not be marked.
- Marking occurs before the patient enters the procedural room, except in an emergency.
- The method of marking should be consistent throughout the organisation. Initials must not be used in marking.
- Marking takes place with the patient involved, awake and aware, where appropriate. Note some patients (such as paediatric, psychiatric, or intellectually impaired patients) may find this distressing and marking may be done after these patients are anaesthetised. For this group of patients, it may be appropriate to have a person responsible or support person present.
- The mark must be visible and sufficiently permanent, so it remains visible following skin preparation and draping.
- The marking must be documented in the patient's health care record by the person marking the site / side / level.
- The mark should be on or near the incision site or radiotherapy site. The site / side / level marking for radiotherapy treatments involve the following:
 - For certain treatments, the immobilising device may be marked.
 - Site / side / level marking is not required in the following circumstances:
 - For multiple fractions of radiotherapy, where the site is usually only marked before the first fraction and reapplied as necessary, and
 - where markings are applied to the immobilisation device rather than on the patient's skin.





3.1.4. Patient position

The positioning of the patient must be verified as correct for the planned procedure.

The appropriate equipment for positioning must be working and available for use during the procedure.

3.1.5. Essential imaging reviewed

If imaging data are to be used to verify the procedure or site / side / level of the procedure, the proceduralist must verify in conjunction with the assisting proceduralist/s, as appropriate, that:

- The patient's identity, the site of the procedure and the date of the image in relation to the procedure all match.
- The images are for the correct side of the body, oriented correctly, and correctly labelled with the patient's name and date of birth.

3.1.6. Allergy / adverse reaction check

The proceduralist must:

- Ask the patient, and/or their person responsible, if they have a known allergy / adverse reaction and if the answer is yes, what the allergy / adverse reaction was and what effect they experienced. The response must be documented [2, 11].
- Check for any other source that may provide further information on allergies / adverse reactions the patient might have, such as treatment plan, progress notes.
- Check that allergies / adverse reactions are noted on the allergy / adverse reaction section of the *National Inpatient Medication Chart* or other relevant section of the patient's health care record.
- Note that when contrast is used for procedures or examinations the allergy / adverse reaction check must be included in the *State Form CT contrast administration checklist NHSIS70046* (or eMR based digital equivalent form).
- Ensure the assisting proceduralist/s is aware of all identified allergies / adverse reactions.

3.1.7. Confirmation of pregnancy status

For women of child-bearing age, the proceduralist must confirm the patient's pregnancy status.

3.1.8. Special medications administered

The proceduralist must confirm that any special medications required have been administered.



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3.1.9. Antibiotics

Antibiotic prophylaxis may be indicated and should be given in accordance with the Therapeutic Guidelines: *Antibiotic* [12] prior to the procedure commencing, except when antibiotics are withheld to obtain specimens for microbial testing.

3.1.10. Anticipated critical events

The proceduralist must consider, and discuss with the assisting clinician/s, the planned procedure, critical steps, anticipated events, equipment requirements and anticipated response should an event occur.

The proceduralist, and the assisting proceduralist/s, must verbally confirm sterility, implants and equipment requirements.

3.2. Post procedure

3.2.1. Document the name of the proceduralist/s

The name of the proceduralist/s must be documented in the patient's health care record.

3.2.2. Document the name of the procedure

The proceduralist must confirm the exact procedure performed, any expected or unexpected adverse events and patient outcomes, and document in the patient's health care record.

Where a procedure varies from initial plans the rationale must be documented with reason/s why.

3.2.3. Advice for clinical handover

Provide clinical handover advice (verbal and documented), including the patient's management plan post procedure, for the clinicians at the post procedure destination and discuss with the patient and/or their person responsible where possible [5].

Document and communicate any altered calling criteria on the relevant observation chart.

3.2.4. Equipment problems / issues documented and advised to relevant staff

Malfunctioning equipment and instruments should be accurately identified to prevent them from being used again until the problems are resolved. Any equipment or instrument problems arising during the procedure must be documented, and raised with the relevant staff so they can be resolved as soon as possible.

If an adverse event has occurred as a result of equipment / instrument malfunction, this must be notified in the incident management system (see <u>section 5</u>).

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3.2.5. Specimens / images labelled correctly

The proceduralist, and assisting proceduralist/s, must ensure the correct labelling of any pathology specimen / images obtained during the procedure by verifying the patient's name, specimen / image description and any orienting marks.

3.2.6. Test required

Referral for test/s post procedure must be discussed with the patient and/or their person responsible where clinically appropriate and arranged.



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4. Level 3 Procedures

Definition	Examples ⁴	Requirements	
 At least one proceduralist 	 Surgical procedure 	1. Pre-procedure	2. Sign In
 Always requires written consent Always requires written consent Involves procedural sedation or general / regional anaesthesia Usually performed in formal procedural suites such as operating, theatres, emergency departments, endoscopy suites, interventional imaging suites, birthing suites, cardiac catheterisation laboratories 	 electroconvulsive therapy (ECT) Colonoscopy Bronchoscopy Interventional imaging procedure, including: Angiography Cardiovascular Coiling Stenting Interventional Neuroradiology 	 Patient identification Consent / refusal of blood products Procedure verification – planned procedure + site / side / level, where appropriate, matches consent Site / side / level marking, where appropriate Confirmation of pregnancy status for women of child-bearing age 	 SIGN IN ONE Patient identification Procedure verification – planned procedure + site / side / level, where appropriate, matches consent Allergy / adverse reaction check Sedation / anaesthetic equipment checked Patient sedation risk / anaesthetic assessment Significant airway or aspiration risk Clinician airway monitor identified Clinician skilled to manage airway identified Pulse oximeter working Risk of major bleeding Consent / refusal of blood products SIGN IN TWO Essential imaging available Site marking (exemptions) Implants and special equipment Proceduralist available to complete procedure



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⁴ The examples provided do not cover all possible procedures. The examples may be escalated to a higher level (for example Level 1 procedures may be classified by a health service as Level 2 or Level 3 procedures). Health services should consider development of local lists of examples for Level 1, Level 2 and Level 3 procedures consistent with the requirements of this Policy Directive.

Procedures involving procedural sedation / anaesthesia must always be classified as Level 3 procedures.

4.1. **Pre procedure requirements**

The following must be undertaken before the patient is transferred to the procedural suite:

4.1.1. Patient identification

Process is the same as in <u>section 2.1.1</u>.

Patients undergoing Level 3 procedures must be wearing a patient identification band [2]. Ensure the band is not attached to any limb that is for removal.

Confirm and document the patient's consent or refusal to the use of blood products [1, 3].

4.1.2. Procedure verification

Process is the same as in <u>section 2.1.2</u> and <u>section 3.1.5</u>.

Other relevant clinical information including documentation recorded electronically must be available prior to the planned procedure.

Verification must be documented in the patient's health care record, including a record of individuals involved in the verification process.

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4.1.3. Side / side / level marking

Site / side / level marking

Site / side / level marking must be completed where there is the potential for error involving multiple structures (fingers, toes, or lesions), left / right distinction, or levels (spine). In these cases, where appropriate, the site / side / level must be marked.

The site / side / level must be marked by one of the proceduralists (except for intra-ocular surgery):

- Process is the same as in <u>section 3.1.3</u>.
- For some procedures (such as those that involve ovaries and fallopian tubes), side detection may be unreliable preoperatively. In these circumstances, side verification is not recommended.

Exception: For intra-ocular surgery where pre-operative mydriatic drops have been ordered, the correct side may be marked by a registered nurse, and the marking checked by a second member of the clinical team before the drops are given, in conjunction with confirmation of the patient's identity, checking of the consent, and verbal confirmation by the patient, or their person responsible, of the side to have surgery. The mark must be subsequently checked as the correct side for the procedure as required by Sign In One, Sign In Two and Team Time Out.

Site / side / level marking exemptions

Site / side / level marking is not required in the following circumstances (although it can be used):

- To avoid confusion, for example if a procedure requires a regional anaesthetic, then only the procedure site must be marked.
- For single organ cases, such as cardiac surgery, caesarean section.
- Where the site of surgical entry is unambiguous, for example midline incisions, cystoscopies, laparoscopies.
- If the site is obvious, such as open trauma wound, large tumour.
- For endoscopies.
- For procedures where the catheter / instrument site is not predetermined, for example cardiac catheterisation, epidural / spinal analgesia / anaesthesia.
- For radiology procedures where marking the site could add to the ambiguity of subsequent procedures.
- Where intra-procedure imaging for localisation, such as radiological, magnetic resonance imaging (MRI), stereotaxis, ultrasound, radiation detection will be used.
- Where the procedure site cannot be marked, for example teeth, the site / side must be clearly recorded in the patient's health care record.
- For premature infants, and some oral and maxillofacial surgery, where marking may cause permanent marking of the tissues.



- Where the patient refuses marking. Such refusal must be documented in the patient's health care record.
- In a life-threatening emergency where the patient enters the procedural room directly. This must be documented in the patient's health care record.

4.1.4. Confirmation of pregnancy status

For women of child-bearing age, the proceduralist must confirm the patient's pregnancy status.

4.2. Requirements for a Level 3 procedure checklist

There are 3 distinct stages to Level 3 procedure checklists with each stage corresponding to a specific time period in the patient's procedure.

Sign In	The period before commencing procedural sedation or general / regional anaesthesia that is, immediately before the procedural team prepares the patient for their procedure. Sign In is further divided into 2 parts - Sign In One and Sign In Two
Team Time Out	The period immediately before commencing the procedure to undertake a final patient identification and procedure verification.
Sign Out	The period before the patient / procedural team leaves the procedural area.

A checklist must be used for every Level 3 procedure, and must include Sign In, Team Time Out and Sign Out (see sections 4.3 to 4.6 below).

Sign In One and Two may be combined with the agreement of sedationists / anaesthetists and proceduralists.

The name of the clinician/s responsible for each section of the checklist (as below) must be clearly documented.

Section	Clinician responsible for leading and ensuring completion of checklist	
Sign In One	Sedationist / Anaesthetist	
Sign In Two	Proceduralist	
	Where Sign In One and Sign In Two are combined , the names of both clinicians responsible must be documented - that is the name of the Sedationist / Anaesthetist and the name of the Proceduralist	
Team Time Out	Senior proceduralist	
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Sign Out Proceduralist / Nurse / Midwife

The checklist is part of the patient's health care record.

The checklist must include confirmation of the patient's identification, procedure verification and consent or refusal of blood products.

The checklist should comply with the requirements of sections 4.3 to 4.6 of this Policy Directive.

For procedures performed outside an operating suite, Local Health Districts / Specialty Health Networks (LHD / SHNs) may remove items included in a Level 3 procedure checklist, as set out in sections 4.3 to 4.6, based on a risk management approach considering issues such as the type of procedure and the procedural setting. This would only apply when the items removed have no relevance to the procedure being performed (for example, for electroconvulsive therapy (ECT) procedures the checklist might remove the items about blood loss or imaging).

If modified checklists are created, they must be clearly labelled with the location the checklist will be used in or, if a procedure specific checklist, then the procedure must be included in the title (such as ECT Procedure Safety Checklist).

Additional items not covered by this Policy Directive may be added as required.

Checklists for Level 3 procedures must be approved by the LHD / SHN Chief Executive or their delegate/s (such as Executive Directors of Clinical Governance, Medical Services, Nursing & Midwifery) or the LHD / SHN's quality and safety committee. The approval must be documented.

4.3. Sign In One: Sedationist / anaesthetist responsible

Sign In One must be completed before commencing procedural sedation or general / regional anaesthesia.

Sign In One is completed by the sedationist / anaesthetist in conjunction with another member of the procedural team, such as the anaesthetic nurse / circulating nurse. Where there is no sedationist / anaesthetist then a proceduralist must complete this check.

In procedural suites where a formal, documented verification check is performed prior to entering the procedural suites, such as in an airlock, theatre holding bay or reception area, the Sign In One is an additional step that must occur in a room or area immediately adjacent to the procedural room, for example in the anaesthetic room if available, or in the procedural room.

Sign In One must be completed before the patient enters the procedural room, except in emergency situations, where an anaesthetic room does not exist or where the patient enters the procedural room directly. In these cases, Sign In One should be completed inside the procedural room.

4.3.1. Patient identification

Process is the same as in <u>section 2.1.1</u>.

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Patient identification must occur before any treatment / intervention is initiated except if a lifethreatening emergency exists.

4.3.2. **Procedure verification**

The consent form is the primary source of information about the patient's planned procedure. The procedure to be performed must match what has been written on the patient's signed consent form. Details on the consent form must be clear and correct; and must match the health care record, the request / referral letter, the patient's or their person responsible's understanding of the procedure to be undertaken, and imaging data, where appropriate.

A final consent check with the patient, or their person responsible, before sedating / anaesthetising the patient gives the patient the opportunity to identify any mistakes. If the planned procedure and consent do not match, the proceduralist must resolve the matter before the patient receives procedural sedation / anaesthesia.

If the planned procedure information on the consent form is incorrect, this must be documented in the patient's health care record as well as the actions taken to resolve the discrepancy.

4.3.3. Site / side level matches consent

The relevant team member must ask the patient, or their person responsible, to state their site / side / level for the planned procedure. The team member must not state the site / side / level for the planned procedure and then ask the patient, or their person responsible, if this information is correct.

For some procedures (such as those involving ovaries and fallopian tubes), side detection may be unreliable preoperatively⁵. In these circumstances, side verification is not recommended.

4.3.4. Allergy / adverse reaction check

Process is the same as in section 3.1.6.

4.3.5. Sedation / anaesthetic equipment check

When procedural sedation or anaesthesia is planned, a formal check of the necessary sedation / anaesthetic equipment must be completed prior to each procedure to ensure the equipment is available and working [8].

Continuous pulse oximetry and blood pressure monitoring must be commenced on the patient prior to commencing procedural sedation or anaesthesia and continued until the patient is adequately recovered from this.

⁵ Gynaecology surgery for adnexal masses: it is not uncommon for a patient to be consented for a right sided procedure, based on clinical examination or imaging (usually ultrasound) and to find at operation that the pathology is left sided (and vice versa). This is due to the fact that the tubes and ovaries are lateral and posterior to the uterus and fall towards the midline of the pelvis, making it easy to get the wrong side.



4.3.6. Patent sedation risk / anaesthetic assessment done

When procedural sedation or anaesthesia is planned a medical assessment must be completed prior to commencement of the procedure (except in a life-threatening emergency) [8]. This must include documentation of the patient's medical condition/s and their sedation risk / anaesthetic assessment. When a non-anaesthetist plans to give procedural sedation, an assessment must be made as to whether an anaesthetist is required to assess and manage the patient. This decision must be documented in the patient's health care record.

4.3.7. Significant airway risk

When procedural sedation or anaesthesia is planned, the sedationist / anaesthetist must formally assess the patient's airway and document this in the patient's health care record prior to commencing procedural sedation / anaesthesia [8]. If this assessment indicates a significant airway risk, then an anaesthetist must be present before sedation is given.

When a significant airway risk is identified the procedural sedation / anaesthesia must not commence until all required special equipment needed is present and functional, and anaesthesia and procedural team members needed are present.

Functioning and clean suction equipment must always be immediately available when procedural sedation / anaesthesia is given.

4.3.8. Significant aspiration risk

The risk of aspiration should also be evaluated and documented [8]. If the patient has symptomatic active reflux or a full stomach, the sedationist / anaesthetist must consider what additional steps might be taken to reduce the increased risk of aspiration.

When a significant aspiration risk is identified the procedural sedation / anaesthesia must not commence until all required special equipment needed is present and functional, and the appropriate procedural team members are present.

Functioning and clean suction equipment must always be immediately available.

4.3.9. Identification of clinician airway monitor and availability of skilled personnel

When procedural sedation is to be used, and where an anaesthetist is not present to care exclusively for the patient, a clinician airway monitor other than the proceduralist must be nominated whose primary responsibility is to monitor the patient's level of consciousness and to monitor and provide the initial management of cardio-respiratory status of the patient during the procedure.

There must be present a clinician skilled in airway management and cardio-pulmonary resuscitation relevant to the patient's age.

4.3.10. Risk of critical bleeding

If there is a risk of critical bleeding:

• The procedural team must confirm there is a valid group and screen available, and where indicated, appropriate compatible blood components are available to support



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critical bleeding. Where the laboratory indicates there may be a delay in the provision of cross matched red blood cells, a local risk assessment must be undertaken in consultation with the laboratory to ensure compatible blood components will be available.

- The procedural team should ensure the laboratory is notified of the best telephone extension number to ensure communication of time critical information.
- The patient should have large bore venous access.
- Intra-procedure blood loss should be measured and documented, and the patient monitored for signs of hypovolaemia.

4.4. Sign In Two: Proceduralist responsible

Sign In Two must be completed before commencing procedural sedation or general / regional anaesthesia.

Sign In Two must be completed by a proceduralist who is required to confirm the following:

4.4.1. Essential imaging available

Process is the same as in <u>section 3.1.5</u>.

4.4.2. Site marked

A proceduralist must confirm that the site has been marked or that marking is not required (Refer to section 4.1.3).

4.4.3. Implants and special equipment

If any implant (type / side / size / power) and/or special equipment is required, its availability and function where possible to check, must be checked by 2 team members.

A proceduralist must be present prior to commencement of procedural sedation / anaesthesia to confirm that sterile instrumentation, implants and/or any special equipment required are present and functional.

Where an implant is used the product's label, code reference and serial number must be recorded in the patient's health care record.

4.4.4. A proceduralist who can complete the procedure is immediately available

Confirm that a proceduralist who can complete the procedure is immediately available before the patient receives procedural sedation / anaesthesia and before moving to the Team Time Out stage.

4.5. Team Time Out: Senior proceduralist responsible

Team Time Out is the final patient safety check and must occur immediately before the procedure commences in the room where the procedure is to be conducted. Usually this will be after procedural sedation / anaesthesia has commenced. The senior proceduralist present



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must lead the Team Time Out. The proceduralist, sedationist / anaesthetist and other members of the procedural team must **ALL** confer and agree on all aspects of the Team Time Out section of the checklist.

During Team Time Out, all other activities are stopped / paused so that full attention can be given to the Team Time Out.

Success of Team Time Out is reliant on active communication amongst all members of the procedural team. It is the responsibility of the senior proceduralist present to ensure that Team Time Out is completed. The procedure must not commence until all team members are satisfied that the patient identification and procedure verification processes have been completed and patient identification and procedure verification are correct.

Each member of the procedural team is responsible for ensuring Team Time Out occurs and for raising any concerns they may have during Team Time Out.

Where discrepancies are noted or disagreements occur at Team Time Out, the procedure must be delayed until the issues are resolved. Only for reasons of clinical urgency should the procedure commence. The justification for proceeding in the presence of such discrepancies must be documented by the proceduralist in the patient's health care record as soon as the procedure is completed, and an incident report completed.

Where previous identification / verification steps have occurred satisfactorily but a discrepancy in information or disagreement in identification / verification occurs at Team Time Out, an incident report should also be completed even if the issues are resolved satisfactorily.

If disagreement occurs in an extreme emergency, the senior member of the procedural team is responsible for the care of the patient and should decide the most appropriate course of action.

Only after Team Time Out has been completed should the procedure commence.

4.5.1. Procedural team member introductions

All procedural team members must introduce themselves to each other by their preferred names and roles before the procedure commences. Team members may change frequently, and it is important in effective management that all team members understand who each member is and their role.

In situations where multiple patient procedures are undertaken consecutively and there is no change in team members during the list, then this action can occur at the commencement of the list.

In addition, teams may adopt local strategies such as documenting the name and role of team members on a whiteboard.

4.5.2. Patient identification

The patient's identity must be confirmed against approved patient identifiers, including the patient identification band/s, consent and documentation [1, 2]. The identification band/s used for confirmation must be accessible after positioning and draping.



4.5.3. Procedure verification

The consent form is the primary source of information about the patient's planned procedure. The planned procedure must be matched against the patient's consent form and imaging data, where appropriate.

The processes described in this Policy Directive should not preclude the use of discretion by the treating proceduralist to alter the procedure for reasons of clinical judgement. However, significant changes to the documented procedure must be communicated to all members of the procedural team and must be recorded in the patient's health care record.

4.5.4. Site / side / level marking

The site / side / level mark must be consistent with the site / side / level documented in the consent and imaging.

For some procedures (such as those involving ovaries and fallopian tubes), side detection may be unreliable preoperatively⁶. In these circumstances, side verification is not recommended.

4.5.5. Patient position

The positioning of the patient must be confirmed as correct for the planned procedure and site / side / level.

The appropriate equipment for positioning must be working and available for use during the procedure.

4.5.6. Essential imaging reviewed

Process is the same as in <u>section 3.1.5</u>.

If essential images are not available, the proceduralist must decide if it is safe to proceed and document this decision in the patient's health care record.

4.5.7. Allergies / adverse reactions

Confirm any known allergies / adverse reactions. This will raise the team's awareness of precautions that may need to be taken during the procedure to avoid allergies / adverse reactions.

4.5.8. Special medications administered

Confirm that any special medications required (for example eye drops, steroids, mannitol) have been administered.

⁶ Gynaecology surgery for adnexal masses: it is not uncommon for a patient to be consented for a right sided procedure, based on clinical examination or imaging (usually ultrasound) and to find at operation that the pathology is left sided (and vice versa). This is due to the fact that the tubes and ovaries are lateral and posterior to the uterus and fall towards the midline of the pelvis, making it easy to get the wrong side.



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4.5.9. Antibiotics

Surgical antibiotic prophylaxis is recommended for specific procedures. Refer to the Therapeutic Guidelines: *Antibiotic* for indications and recommended regimens [12].

Surgical antibiotic prophylaxis must be administered before surgical incision. For short-acting antibiotics, such as cefazolin, the dose should be administered no more than 60 minutes before incision.

An exception is when antibiotics are withheld in order to obtain specimens for microbial testing.

4.5.10. Venous thromboembolism (VTE) prophylaxis

All patients must have their VTE risk assessed and prescribed prophylaxis where indicated prior to the procedure [9].

VTE prophylaxis can be pharmacological (anticoagulants) and mechanical (including graduated compression stockings, anti-embolic stockings, intermittent pneumatic compression and/or food impulse devices).

Anticoagulants are high-risk medicines. They have a narrow therapeutic index and over or under anticoagulation can result in significant adverse patient outcomes. Refer to the NSW Health Policy Directive *High-Risk Medicines Management* (PD2024_006) and associated High-Risk Medicine Standard: <u>Anticoagulants</u>.

Not all VTE prophylaxis methods will commence pre-procedure. For example, anticoagulants may be withheld pre- and during procedure, and commence at a specified time post procedure. Ensure the plan for commencement of anticoagulants is clearly documented in the patient's healthcare record.

4.5.11. Anticipated critical events

Effective team communication reduces error, prevents major complications and supports efficient teamwork. To ensure the procedural team has a common understanding of the planned procedure and expected outcomes / issues:

- The proceduralist must verbally brief the team on the planned procedure, critical steps, anticipated events and equipment requirements.
- The sedationist / anaesthetist must verbally identify any specific patient or procedure concerns they have.
- The nurse / midwife verbally confirms that:
 - o All required equipment is available and, where possible to check, functional
 - Any required items or implants are available and, if necessary, sterilised / disinfected.

4.6. Sign Out: Proceduralist / nurse / midwife responsible

Sign Out should occur before the patient / procedural team leave the procedural area.



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Sign Out is designed to ensure that all relevant patient documentation is completed, and that appropriate clinical handover can be conducted. The nurse / midwife is responsible for Sign Out and should complete this section before the patient / procedural team leave the procedural area. The proceduralist or sedationist / anaesthetist could also complete this section.

Responsibility for documentation must be consistent with the requirements in NSW Health Policy Directive Accountable Items used in Surgery and Other Procedures (PD2023_002) which states "while documentation is primarily completed by the circulating nurse / midwife, the instrument nurse / midwife is ultimately responsible for ensuring the completion and accuracy of all documentation relating to the surgery/procedure. The anaesthetic nurse is responsible for documenting the anaesthetic nursing care provided."¹³

The nurse / midwife confirms the following:

4.6.1. Name of the procedure is recorded

The proceduralist must document the procedure that was carried out in the patient's health care record. Where a procedure has varied from what was planned, the rationale must be also noted in the health care record.

4.6.2. Count / tray list checks

Refer to NSW Health Policy Directive Accountable Items used in Surgery and Other Procedures (PD2023_002) [13].

4.6.3. Specimens / images labelled correctly

Process is the same as in <u>section 3.2.5</u>.

4.6.4. Equipment problems / issues documented and advised to relevant staff

Process is the same as in section 3.2.4.

The procedural team confirms the following:

4.6.5. Blood loss documented; ongoing blood loss discussed

To ensure that early warning signs of blood loss can be assessed, the blood loss (if any) during the procedure should be documented and any anticipated post procedure bleeding discussed.

If significant post procedure bleeding is anticipated, blood loss criteria for notifying medical staff must be documented.

4.6.6. Advice for clinical handover

The following advice for clinical handover (verbal and documented) must be provided to staff at the post procedure destination [5]:

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- The procedural team has discussed the patient management plan for recovery, post procedure investigations and communication. This is expected to include any key messages that should be relayed to the patient and/or their person responsible.
- Any altered calling criteria documented if patient is not being recovered in a Post Anaesthetic Care Unit (PACU) or Recovery.
- Post procedure VTE prophylaxis has been ordered, if required [9].
- Post procedure care should be discussed with the patient, and/or their person responsible, where possible.

5. Incidents

In the event of an incident:

- If the patient's condition permits, an immediate plan to rectify the error/s should be made by the senior member of the procedural team. Wherever possible, the patient and their person responsible should be involved in the management plan.
- Manage incidents as required by NSW Health Policy Directives:
 - o Incident Management (PD2020_047) [14]
 - Open Disclosure (<u>PD2023_034</u>)
- Report the incident to the Special Committee Investigating Deaths Under Anaesthesia (SCIDUA) and or / Collaborating Hospitals' Audit of Surgical Mortality (CHASM) as appropriate. Additional information on Mortality Review (Authorised Committees) is available on the <u>CEC website</u>.

6. Auditing and Reporting

Auditing compliance with this Policy Directive must be undertaken by each Local Health District / Specialty Health Network (LHD / SHN). The frequency of audits should be determined by each LHD / SHN risk assessment.

Observational audits should be completed at the point-of-care, in real time, and be undertaken by a clinician with a good understanding of this Policy Directive.

Performance indicators may be included in reporting to LHD / SHN governance bodies.



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7. References

- [1] Consent to Medical Treatment and Healthcare Treatment Manual at <u>www.health.nsw.gov.au/policies/manuals/Pages/consent-manual.aspx</u>
- [2] Patient Identification Bands, PD2021_033 https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2021_033
- [3] Blood Management, PD2024_024 at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2024_024
- [4] Communicating Positively: A Guide to Appropriate Aboriginal Terminology, GL2019_008 at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=GL2019_008
- [5] *Clinical Handover is defined in Clinical Handover Policy, PD2019_020 at* <u>https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2019_020</u>
- [6] Incident is defined in Incident Management Policy, PD2020_047 at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2020_047
- [7] *Client Registration Policy, PD2007_094* https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2007_094
- [8] Australian and New Zealand College of Anaesthetists, 2023, PG09(G) Guideline on procedural sedation, at <u>https://www.anzca.edu.au/getattachment/c64aef58-e188-494a-b471-3c07b7149f0c/PG09(G)-Guideline-on-procedural-sedation-2023</u>
- [9] Prevention of Venous Thromboembolism, PD2024_045 at https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2024_045
- [10] Diagnostic Imaging Accreditation Scheme Standards 2016, Australian Commission on Safety and Quality in Health Care, 2016, <u>https://www.safetyandquality.gov.au/publications-and-resources/resourcelibrary/diagnostic-imaging-accreditation-scheme-standards</u>
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- [13] Accountable Items used in Surgery and Other Procedures, PD2023_002 https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2023_002
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