SESLHD PROCEDURE COVER SHEET

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SUMMARY	Procedures to optimise patient, carers and comforters, and fetal exposure to radiation from diagnostic and interventional x-ray procedures.

1. POLICY STATEMENT

The South Eastern Sydney Local Health District (SESLHD) is committed, through a risk management approach, to protecting employees, contractors, students, volunteers, patients, members of the public and the environment from unnecessary exposure to radiation arising from systems and processes which use radiation apparatus and radioactive substances, whilst maintaining optimum diagnostic and therapeutic quality, therapeutic efficacy, and patient care.

This document provides procedures necessary to ensure compliance with this policy in relation to optimisation of protection of patients, relatives and carers/comforters in departments performing diagnostic or interventional radiology procedures.

2. BACKGROUND

Optimisation of exposure is maximising the benefit-risk ratio of the medical exposure for a given patient. It is the responsibility of all staff groups involved in the patients' medical exposure to implement procedures of optimisation within the scope of parameters under their control and their detailed responsibilities.

Once clinically justified, each examination should be conducted so that the dose to the patient is lowest necessary to achieve the clinical aim. The quality of the images and the complexity of the examination must be sufficient for the intended clinical task. It is also crucial that the procedure is performed safely and as prescribed.

Since patients may accrue direct benefits from medical exposures, it is not appropriate to impose limits on the doses received from clinically justified examinations. However, patient dose surveys indicate significant variations in delivered dose to achieve satisfactory image quality, indicating that there is scope for the implementation and optimisation of patient protection, as well as for relatives and carers or comforters.

3. RESPONSIBILITIES

3.1 The Radiological Medical Practitioner (The Radiologist):

The Radiological Medical Practitioner (RMP) is responsible for the clinical management of the patient undergoing a diagnostic or interventional radiology procedure.

As per the Australian Radiation Protection and Nuclear Safety Agency's (ARPANSA) Radiation Protection Series C-5 [10], the Radiological Medical Practitioner must:

- decide to proceed with a diagnostic or interventional radiology procedure based on the specialist's knowledge of the potential risks and benefits of the procedure, considering the clinical information, and the sensitivity and specificity of the procedure.
- ensure all radiation exposures are justified.
- only authorise a procedure if a written referral is provided, which contains all the information necessary to be able to justify the exposure.

- make information on the benefits and risks associated with the procedure available to the patient (or their person responsible), including risk to embryo/fetus for pregnant patients undergoing procedures likely to result in more than 1 mSv to the embryo or fetus.
- ensuring that protection of the patient is optimised within the scope of parameters under the RMP's control, and in accordance with section 4.2.
- liaise with the referrer and the patient (where relevant), following an interventional radiology procedure where the patient is identified as likely to experience radiation-induced skin effects to ensure follow-up of the patient (refer to section 4.2.3).

3.2 The Operator:

The Operator is typically the radiographer but for interventional radiology cases can be the interventionalist.

As per ARPANSA's Radiation Protection Series C-5 [10], the Operator is responsible for:

- ensuring that a person is not exposed to ionising radiation unless the procedure (i) has been authorised by the Radiological Medical Practitioner or, (ii) is in accordance with written protocols (either site-specific or generic) endorsed or established by the Radiological Medical Practitioner or an acknowledged professional college or authority.
- following the established protocol for the procedure.
- ensuring that protection of the patient is optimised within the scope of parameters under the Operator's control, and in accordance with section 4.2.
- correct identification of patient, site, and prescribed procedure prior to performing the procedure.
- ensuring that valid consent is obtained for all radiological procedures.
- taking reasonable steps to establish the pregnancy status of patients of childbearing capacity where an authorised procedure is conducted in accordance with (ii) or seek confirmation from the Radiological Medical Practitioner that the pregnancy status of the patient has been established (see section 4.2.2).
- ensuring that only persons necessary to the procedure are present when performing exposures, and exposure of persons other than the patient is minimised.
- reporting any instance of accidental, abnormal, or unplanned exposure to the RSO, and where required also in accordance with SESLHDPR/558 - Handling, Investigation and Reporting of Radiation Incidents.
- ensuring that following any fault or error of the equipment or system, or unusual operating behaviour that the immediate use of the equipment is ceased until the issue is rectified, that record is made, and that the chief radiographer is notified.

3.3 The Radiation Safety Officer (RSO):

The RSO (see SESLHDPD/296 Section 4 Contact Details of the Sector RSOs) will oversee and provide advice on radiation safety within departments performing diagnostic or interventional radiology

3.4 The Medical Physicist:

The Medical Physicist is required to be available for consultation on optimisation of medical exposures, including patient and fetal dosimetry and quality assurance, and to give advice on matters relating to radiation protection. The Medical Physicist works in collaboration with the Radiological Medical Practitioner and Operator in the optimisation of diagnostic and interventional radiology procedures.

In addition, a medical physicist is required to provide Human Research Ethics Committees with a radiation dose estimation and risk assessment for any research studies that involve the research participants receiving an exposure from ionizing radiation, in accordance with the requirements of RPS8 Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes [11].

4. PROCEDURE

4.1 Procedures for the correct identification of the patient, procedure, and sites prior to commencing procedure

4.1.1 Identifying the Patient, Procedure and Site

All staff must comply with NSW Health Policy Directive PD2017_032 - NSW Health Policy Directive: Clinical Procedure Safety [1].

PD2017_032 defines three levels of clinical procedures, grouped according to risk and complexity. For each level, requirements for pre-procedure checks, patient identification checks, and post procedure actions are described.

Different **procedure levels** are assigned to procedures with different invasiveness / risk. The higher levels carry additional responsibilities:

Level 1: Diagnostic Radiology

Level 2: Diagnostic Interventional procedures

Level 3: Interventional procedures, including: angiography, cardiovascular, coiling, stenting, interventional neuroradiology.

The proceduralist (and procedural team members where appropriate) is responsible for:

- confirming patient identification
- procedure verification and,
- where appropriate, the correct site / side / level for the procedure.

The following procedures for ensuring correct patient, procedure and site in Radiology are common across NSW:

Step 1 - Referral Document

The referral document must be legible and must contain:

- patient's full name, date of birth, sex, and patient identifier (where appropriate).
- name of the procedure, anatomical location including procedure site (where appropriate), clinical history and clinical indication/question.
- contact details of the referrer for consultative processes; if the Radiological Medical Practitioner authorising the procedure is also the referrer, then the information detailed must be recorded in the patient record.
- dated signature, for any written imaging request.

There may be exceptions to the above in the cases of a patient involved in a health screening program, undergoing an emergency radiological procedure or an individual involved in an approved research study.

Inappropriate or incomplete referrals must be queried with the referrer, or member of their team, and clarified before the procedure can be carried out.

Step 2 – Patient Identification (Regardless of the procedure level)

- Patient identification must be confirmed prior to the procedure commencing.
- Patient identification process **must be documented**.

Staff must confirm that they have the correct patient by asking the patient, or their person responsible, to state (not confirm) the patient's full name and date of birth. Questions should be asked in an open-ended way, such as 'I need to check your details again; could you please tell me your name and date of birth.' The response must be confirmed against the details on the request form / referral and patient identification band, where appropriate.

- Where patient details on the request form / referral are incomplete or there is a discrepancy, the patient, or their person responsible, must provide the correct information before commencing the procedure and actions taken documented.
- If the patient is unable to participate in the patient identification step, for example due to physical incapacity, language issues, 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.

Step 3: Confirm Procedure and gain consent (regardless of the procedure level)

1. Request form - 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 requested, and (when appropriate) the exact anatomical location for the test/s including the procedure site, laterality, and level.

2. The operator must ask the patient or their person responsible, to state what procedure they understand will be performed and to state the site / side / level for the procedure (where relevant) and verify this matches the request form / referral. Where procedure details on the request form / referral 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.

3. If relevant, the operator must ascertain the pregnancy status of the patient prior to commencing the procedure (see section 4.2.2)

4.1.2 Consent

Staff must comply with the NSW Health Consent to Medical and Healthcare Treatment Manual [14]:

Express consent specifically granted either verbally or in writing.

Implied consent "implied" from a person's conduct, for example a patient may hold out their arm to receive an injection.

Level 1 procedures - Verbal (preferred) or implied consent is adequate – must be documented.

Level 2 procedures – Usually requires written (express) consent.

Level 3 procedures - Written (express) consent is required and must be obtained by a medical officer.

Consent must be:

- **obtained for all procedures** prior to commencing the procedure.
- **documented** for radiology and nuclear medicine procedures for Diagnostic Imaging Accreditation Scheme accreditation.
- **Informed** - Patients must be provided with sufficient information about investigation options, treatment options, benefits, possible adverse effects or complications, and the likely result if treatment is not undertaken, in order to be able to make their own decision about undergoing a procedure or treatment.
- **Valid**
    - Patient must be able to understand [1]
    - Freely given (uncoerced, unforced, unrushed).
    - Specific – only for the procedure explained.
    - Obtained by a medical practitioner **if in writing**.

Exposure of Carers and Comforters

[1] Challenges: children < 14, people affected by mental illness, dementia, brain damage or intellectual disability, and some people who are temporarily or permanently impaired by drugs or alcohol.
Solutions: consent from parent, guardian, "person responsible". Does not include language, deafness, or other special communication needs – professional, accredited interpreters are required.

As per the definition of ARPANSA's Radiation Protection Series C-5 a carer or comforter is "a person who willing and voluntarily help (other than their occupation) to care, support and comfort of patients undergoing a radiological procedure for medical diagnosis or in the course of their medical treatment" [10].

Where it is clinically justified for a carer or comforter to be present during a radiological procedure, the carer or comforter must give consent to receiving an exposure and consent must be documented. They must receive, and have indicated understanding of, the risks and benefits of being present during the exposure to radiation. A person should not be a carer or comforter if it is possible that they may be pregnant. Any radiation protection procedures that the carer or comforter must follow during the exposure must also be explained by the Operator at this point. A dose constraint of 1 mSv must be used in the optimisation of protection and safety in radiological procedures where an individual is acting as a carer or comforter [10]. The carer or comforter should be provided with a lead-equivalent radiation protection apparel for the procedure.

Step 4 - "Time Out" (Level 2 and 3 procedures only)

Immediately prior to the start of the procedure the proceduralist, and any assisting proceduralist/s present, must stop and confirm that the patient identification matches that on the request form and that the procedure and site are verified and correct.

4.2 Procedure for Optimisation of Exposures, Protection and Safety of Patients

Optimisation should be a collaborative approach between the Radiological Medical Practitioner, the Operator, and the Medical Physicist (and other relevant staff groups as required i.e., manufacturer applications specialists). The group must take particular consideration of exposures to:

- Paediatric patients
- Individuals undergoing health screening.
- Volunteers in medical research
- Pregnant patients (fetal exposures)

4.2.1 Exam technique and protocols for all diagnostic and interventional radiology procedures

Clinical protocols for all diagnostic and interventional radiology procedures must be reviewed and verified by the RMP and senior radiographer of the modality, for all new radiation apparatus and following modifications of those for existing equipment. Exam technique and exposure factors must also be verified to confirm their appropriateness for the clinical task/procedure and that they are in line with current professional body guidance or recommendation on best practice where available. Consideration of balance between minimisation of patient dose and acceptable image quality to answer the clinical task must be considered.

Thereafter, routine periodic review of clinical protocols and exam technique/exposure factors must be conducted. Record of current clinical protocols and exposure factors, as well as their review must be documented locally.

4.2.2 Pregnancy and Protection of the Embryo/Foetus

4.2.2.1 Radiation Effects on Embryo/Fetus

The risk to the embryo or fetus from exposure to ionising radiation is related to the dose received and to the stage of pregnancy at which the exposure occurs.

There are two types of possible effects from radiation exposure to the embryo or fetus [6]:

- Stochastic effects (induction of cancer and hereditary disease to their offspring)
- Deterministic effects (fetal death, malformation, grow retardation, abnormal brain development)

Table 1 provides typical fetal doses, and associated risk of childhood cancer, for common radiological procedures.

Table 1: Typical fetal doses and associated risk for common radiology procedures † [6] [2]:

Examination	Typical fetal dose range	Risk of childhood cancer (from radiation exposure)
Greater than 1 mSv		
Interventional fluoroscopy	>1 mSv	>1 in 10 000
CT: Chest/Abdo/Pelvis		
CT: Abdo and/or Pelvis		
CT: Lumbar Spine		
CT: Chest with portal phase		
Fluoroscopy: Intravenous urography		
Fluoroscopy: Barium meal		
Fluoroscopy: Barium enema		
X-ray: Lumbar spine		
X-ray: Abdomen		
X-ray: Pelvis		
Less than 1 mSv		
CT: Chest (pulmonary embolism)	0.01 to 1 mSv	1 in 1 000 000 to 1 in 10 000
CT: Chest (without portal phase)		
CT: Head/Brain and/or Neck	<0.01 mSv	<1 in 1 000 000
Fluoroscopy: PICC		
X-ray: Cervical spine		
X-ray: Thoracic spine		
X-ray: Chest		
X-ray: Dental/teeth		
X-ray: Skull		
X-ray: DEXA		
X-ray: Extremities		
X-ray: breast (mammography)		

†Table is reproduced from *Protection of Pregnant Patient during Diagnostic Medical Exposure to Ionising Radiation* (RCE-9). Health Protection Agency, The Royal College of Radiologists and College of Radiographers. [6], and includes additional examinations taken from Annex A of 'Safety Guide: Radiation Protection in Diagnostic and Interventional Radiology', Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Radiation Protection Series 14.1 (2008) [2] **Note:** the fetal doses are based on doses to the uterus and therefore only apply to early stages of pregnancy when the fetus is small.

The life-time cancer risk following intra-uterine exposure is assumed to be similar to that following irradiation in early childhood.

For procedures that result in radiation dose to the embryo/fetus of up to 1 mSv, the associated risks of childhood cancer are very low (below 1 in 10 000) and considered

acceptable in comparison to the natural risk of childhood cancer of approximately 1 in 500 [6].

There is evidence of a slightly increased risk of induction of childhood cancer or leukaemia for doses of more than 10 mSv. Interventional radiology procedures involving extended fluoroscopy times and CT scans of the abdomen or pelvis may result in a radiation dose to embryo/fetus exceeding 10 mSv.

Malformations, growth retardation, abnormal brain development and fetal death are not expected to occur at fetal doses less than 100 mSv [6]. Diagnostic and most interventional procedures should not result in fetal/embryo doses in excess of 100 mSv if the exposure is performed as expected [6]. Termination of pregnancy at fetal doses less than 100 mSv is not justified solely upon the basis of radiation risk to the unborn child [6].

4.2.2.2 Pregnancy Warning Signs

Signs must be displayed in prominent places (including patient waiting rooms, reception area/desk, changing cubicles and examination rooms) throughout each department where x-rays are used advising patients to notify staff if they may be pregnant. Signs must be written in several languages, relevant to the community. An example of wording might read as follows:

IF IT IS POSSIBLE THAT YOU MIGHT BE PREGNANT,
NOTIFY THE PHYSICIAN OR RADIOGRAPHER
BEFORE YOUR X-RAY EXAMINATION

Displayed signs do not replace the responsibilities (outlined the section 4.2.2.3 of this procedure) of the Operator or Radiological Medical Practitioner to enquire about and ascertain the pregnancy status of patients of child-bearing capacity.

4.2.2.3 Confirming Pregnancy Status

The Radiological Medical Practitioner must take reasonable steps to ascertain the pregnancy status of a patient of child-bearing capacity if the procedure to be performed is likely to result in a radiation dose of **more than 1 mSv** to an embryo or fetus [10]. Pregnancy status must be ascertained prior to carrying out the procedure. The following procedures should be assumed to result in a radiation dose of **more than 1 mSv** [2]:

- Conventional radiography/fluoroscopic procedures of the abdomen and/or pelvis, or
- Computed Tomography procedures of the chest (where the fetus or part thereof may be included in the scan range/primary beam) and/or abdomen and/or pelvis regions, or

- Interventional fluoroscopy procedures

Note it can be assumed that the fetus will not be included in the primary beam if the procedure excludes the area between the lower extent of the diaphragm and the pelvic floor.

Typical fetal doses of common radiological procedures are detailed in Table 1.

Typically, the Operator will confirm the pregnancy status of the patient prior to carrying out the examination. Pregnancy status must be confirmed verbally by asking the patient about the possibility of being pregnant or by seeking confirmation from the Radiological Medical Practitioner (where applicable) that pregnancy status has been established. Record of confirmation of pregnancy status from the patient must be documented on the local RIS system.

Consideration of a patient's age, sexual orientation, gender identity, religious views and cultural background should be made when the pregnancy question is asked, regarding person(s) present and the privacy of the location.

NSW Health interpreter services should be sought in cases where a language barrier is present.

For cases where there is uncertainty about the pregnancy status of a patient, and the procedure is likely to result in radiation dose to the fetus or embryo of **more than 1 mSv**, the Radiological Medical Practitioner must consider serum β-HCG testing before conducting the procedure. The Radiological Medical Practitioner should consider delaying the procedure (if appropriate) if the test result is ambiguous, till pregnancy can be excluded.

4.2.2.4 Procedure for a Patient with Confirmed Pregnancy

Radiological procedures that are likely to result in radiation dose **of less than 1 mSv** to the embryo or fetus can be carried out on a pregnant, or possibly pregnant patient, without concern.

For procedures that are likely to result in a radiation dose of **more than 1 mSv** to the embryo or fetus, the Radiological Medical Practitioner must be consulted to justify the procedure on an individual basis prior to the procedure being carried out [10]. The Radiological Practitioner must include an assessment of risk to the embryo or fetus from the radiation exposure and to patient if the procedure is not carried out [10]. The Radiological Medical Practitioner must obtain an estimate of expected radiation dose to the fetus/embryo from a medical physicist before the procedure is carried out [10]. A record of the estimate must made in the patient's record with signed confirmation as to whether the procedure is clinically justified.

The following procedures should be assumed to result in a radiation dose to the embryo or fetus of **more than 1 mSv** [2]:

- Conventional radiography/fluoroscopic procedures of the abdomen and/or pelvis, or
- Computed Tomography procedures of the chest (where the fetus or part thereof may be included in the scan range/primary beam) and/or abdomen and/or pelvis regions, or
- Interventional fluoroscopy procedures

Note: it can be assumed that the fetus will not be included in the primary beam if the procedure excludes the area between the lower extent of the diaphragm and the pelvic floor.

For procedures where justification is given, the Radiological Medical Practitioner must fully explain the risks to the pregnant patient (or patient's legal authorised representative) and the referrer prior to the procedure being performed [10]. Where clinically practicable written consent must be obtained [10].

Alternative non-ionising radiation modality options must first be considered.

4.2.2.5 Procedure for Special Cases (Life Threatening cases and Out-of-hours)

For urgent life-threatening situations that involve patients of child-bearing capacity, the immediate clinical management should be equivalent to that for a non-pregnant patient and radiological procedure can be carried out after it is justified as per that of a non-pregnant patient.

Pregnancy status must be ascertained (as per section 4.2.2.3) as soon as possible. For urgent life-threatening cases, this typically will only be practical after treatment or imaging. If pregnancy is confirmed, then the steps in section 4.2.2.4 should be followed as soon as possible and the Operator or RMP must complete and submit a pregnancy notification form to Medical Physics to obtain an estimate of radiation dose to the fetus or embryo from the exposure.

During out of hours cases (non-life-threatening situations), the steps outlined in section 4.2.2.3 and 4.2.2.4 must still be carried out for procedures that are likely to result in radiation dose to the embryo or fetus of **more than 1 mSv**. In cases where a medical physicist is not immediately available to provide an estimate of radiation dose, a fetal radiation dose and risk information sheet approved by a medical physicist (refer to Appendix 1) should be used as a guide of expected dose and for discussion of risk with the patient and referrer prior to the procedure being conducted. The Operator or RMP must complete and submit a pregnant patient radiation notification form to Medical Physics as soon as possible so an estimate of dose and risk can be made and follow-up discussion of risk with referrer and patient can be conducted as required.

A flowchart summarising the workflow for patients undergoing radiological procedures, who are or may be pregnant, is given in Appendix 2.

4.2.2.6 Techniques to minimise fetal dose.

Procedures (once justified as per 4.2.2.4) that are to be conducted on pregnant or possibly pregnant patients, and where the radiation dose to the embryo or fetus is likely to be **greater than 1 mSv**, must have their exam technique and exposure parameters optimised (including consideration of collimation) to lower the dose to the embryo/fetus as low as reasonably achievable (ALARA).

Procedures on pregnant patients that will result in a radiation dose of **less than 1 mSv** to embryo/fetus can be carried out without need for concern. Application of lead protection to shield the lower abdomen is not recommended provided appropriate collimation is used and the radiation apparatus itself is adequately shielded [7]; the primary contribution to fetal exposure is from internal scatter. If a pregnant patient requests contact shielding, the operator should use their professional judgment to consider the psychological impact on the patient if their request is refused. The Operator may offer lead protection but only if it can be ensured that shielding will not mask any clinically required anatomical/physiological information or encroach on AEC chambers.

4.2.2.7 Inadvertent exposure of pregnant patient

All cases of accidental or unintentional irradiation of a fetus or embryo must be referred to the Radiation Safety Officer for investigation and assessment. The RSO must be provided with an SESLHD Radiation Accident Incident Reporting form for the incident. An IMS form must also be completed.

The RSO will request an estimate of the radiation dose to the fetus or embryo from a medical physicist so that the patient and their clinician/referrer can then be better advised as to any possible risk.

The RSO is responsible for completing the required regulatory actions.

4.2.3 Exposures from Interventional procedures

Complex interventional procedures involving prolonged irradiation of the same skin site can result in radiation-induced skin injuries if the absorbed dose to the patients' skin exceeds the deterministic threshold of skin effects. The threshold for skin effects is 2 Gy.

Acute radiation doses, delivered to tissues during a single interventional fluoroscopic procedure or closely spaced procedures, may cause:

a) Transient erythema and epilation between 2 and 5 Gy

b) Possible partial permanent epilation and dermal atrophy and induration between 5 and 10 Gy

c) Possible permanent epilation and desquamation between 10 and 15 Gy

d) Acute ulceration and delayed skin necrosis at > 15 Gy.

To help avoid, limit, and monitor for radiation-induced skin injuries, the following procedures should be followed.

4.2.3.1 Clinical Protocols for Interventional Procedures

Local clinical protocols, for each type of interventional procedure, should contain a statement of anticipated radiographic images (including projections, number, and technique factors) and nominal values for fluoroscopy times, air kerma rates, and resulting cumulative skin doses at skin site exposed (values should related to fluoroscopy equipment installed at facility [2]. Each protocol should be used as a demonstrative baseline of the interventional procedure at that facility, recognising that actual procedures will vary considerably due to the complexities of the specific case [2]. Local protocol provides the interventionalist baseline levels for patient skin dose that permits comparison to irradiation conditions and resulting skin doses occurring during actual procedures as a means to minimise the potential for skin injury [2].

Clinical protocols and exam technique/exposure factors for interventional procedures should also follow the requirements detailed in section 4.2.1 of this procedure.

4.2.3.2 Techniques for minimisation of skin-injury

Interventionalist/operators must be trained to use information, displayed at the operator's position, to monitor the 'patient skin dose' during an interventional procedure. The displayed cumulative air kerma (in mGy or Gy) can be used as a surrogate for entrance dose to the patient's skin up to a given point in the procedure. This value should be monitored by the interventionalist/operator throughout the procedure and used to limit the cumulative absorbed dose to the skin during the procedure where clinically appropriate.

The displayed air kerma rate (in mGy per minute), the total fluoroscopy time (in minutes) and the pulse/frame rate can also be taken into consideration when monitoring skin dose.

The interventionalist/operator must consider the following when optimising and limiting cumulative absorbed dose to the skin:

- Number of single shot or pulsed radiographic exposures used.
- Length of fluoroscopy screening time
- Number of oblique angles used.
- Use of low dose or pulsed fluoroscopy modes
- Use of low frame or pulsed rates
- Restrictive collimation to the anatomical region interest
- Distance of entrance of patient to x-ray tube

4.2.3.3 High Skin Dose Notification Procedure

For cases, where the cumulative displayed air kerma (surrogate value for absorbed dose to the skin) exceeds:

- **3 Gy** for any one procedure or
- **1 Gy** for procedures that may be repeated within 3 months,

a high skin dose notification form must be completed and provided to Radiation Safety/Medical Physics, as soon as possible following the procedure. A Medical Physicist must complete an individual skin dose assessment including:

- An estimate the expected peak skin dose.
- Location of site on the skin where peak skin dose was received.
- Possible radiation-induced skin effects the patient is likely to experience following the procedure.

For cases where absorbed dose to skin is confirmed as **> 3 Gy**, the assessment must be reported to the interventionalist of the procedure for liaison with the referrer/patient's clinician to ensure patient follow-up. Skin dose assessments and patient follow-up should occur within 14 days of the patient's procedure (where practicable) to ensure patients are counselled on any potential radiation-induced effects prior to their presentation.

4.2.4 Patient Dose Surveys and Diagnostic Reference Levels

Diagnostic reference levels (DRLs) are defined as dose levels for medical exposures applied to groups of standard-sized patients or standard phantoms for common types of examination and broadly defined types of equipment [15]. ARPANSA's states that DRLs are "an indicative measure which can be used to determine whether, in routine conditions, the amount of radiation used is unusually high (or low) for a specified procedure" and act as "a benchmark that when exceeded triggers review" of practice and imaging protocols [8].

Departments must conduct patient dose surveys for those diagnostic and interventional procedures for which ARPANSA have established National DRLs. Comparison of local doses to national DRLs is a requirement of both ARPANSA C-5 and Diagnostic Imaging Accreditation Scheme. It is recommended that imaging departments participate in ARPANSA's NDRL service to meet this requirement.

The local median dose for a specified procedure is an appropriate value for comparison to the national DRL. The dose metric used must be equivalent to that used for the national DRL, and will typically be the following:

- Radiographic examinations; Entrance Skin Dose (ESD) or the Kerma-area Product (KAP)
- Diagnostic and Interventional Fluoroscopic examinations; KAP or cumulative air kerma at the patient entrance reference point (K_a)

- CT examinations; Volumetric Dose Index ($CTDI_{vol}$) and Dose Length Product (DLP).

DRLs for adults are usually defined for a standard size (about 60 to 80 kg) [8] and therefore, the sample of patients selected for survey must be within a standardised weight range (unless specified otherwise by ARPANSA). For paediatric exams, it must be ensured that the sample of patients selected matches the same weight and/or age bands used for ARPANSAs NDRLs.

The sample sizes recommended for patient dose surveys are (unless specified otherwise by ARPANSA) [8]:

- General Radiographic: 20 standard sized patients
- CT Examinations: 20 standard sized patients (however preferably 30 patients)
- Fluoroscopy examinations: 30 standard sized patients

If a national DRL is consistently and substantially exceeded a local review must be conducted to establish whether there is clinical justification or whether review and optimisation/modification of practice or imaging protocol/technique/exposure factors is required. The process of review and optimisation must be a collaborative approach between the Radiological Medical Practitioner, the senior radiographer, the Medical Physicist, and any other relevant groups as required (i.e., manufacturer applications specialist). The review, including outcomes and any corrective action taken, must be recorded, and documented.

Following the introduction of any optimised or modified imaging protocols, a review of image quality must be conducted to ensure that adequate image quality is maintained for the diagnostic task. A follow-up dose survey to verify that typical patient dose for the facility is now in line with national DRL should also be conducted.

Where the local median dose is consistently and substantially below the national DRL, a review of image quality must be conducted to ensure that patient images are providing adequate image quality for the diagnostic task. It is recommended that, where available, professional body image quality audit tools or criteria is used i.e., RANZCR CT Image Review Self Audit protocol and the European Commission guidelines on Quality Criteria for Diagnostic Radiographic images [9].

For procedures for which national DRLS do not exist, it is recommended that sites conduct local routine patient dose surveys and compare to any established facility reference levels or suitable national DRLs from other countries.

4.3 Patient Radiation Doses for Common Procedures

When considering the justification for a medical exposure, the benefit is weighed against the detriment, including radiation effects. For diagnostic and interventional radiological procedures, the potential detriment is the risk of inducing cancer. This risk is greater in children and decreases with age. For effective doses greater than 100 mSv the overall lifetime risk of fatal cancer is estimated to be 5% per Sv. Whilst there is no epidemiological evidence of an increased risk below about 100 mSv, using the LNT hypothesis it is possible to extrapolate the risk to lower doses although there is

uncertainty in such estimates. An approximate guide is given by age-specific mortality risk factors in a general population. For an effective dose of 20 mSv, the nominal risk is about 1 in 1200 for adults aged 30 to 60 years at the time of exposure.

For adults aged 70 or more the risk falls to less than 1 in 3000. However, for children up to 10 years old the risk is about 1 in 450.

The tabulated numbers below are typical patient effective doses from common radiological examinations; they are guides only as the actual dose that an individual receives may vary substantially depending on the:

- patient's anatomy
- equipment used
- exact type of examination undertaken.

Table 2: Approximate effective doses arising from common radiological examinations in adults.

Effective Dose Range (mSv)	Radiological Examinations
0 – 0.1	Extremities Skull Cervical spine Chest Bone densitometry
0.1 – 1.0	Thoracic spine Lumbar spine Abdomen Pelvis Pelvimetry Mammography (2 view)
1.0 – 5.0	Intravenous pyelogram (IVP) Barium swallow Barium meal CT head CT cervical spine CT chest (without portal liver phase)
5.0 – 10.0	Barium enema Angiography – coronary Angiography – pulmonary Angioplasty –coronary (PTCA) CT chest (with portal liver phase) CT renal (KUB) CT abdomen/pelvis – single- phase CT thoracic spine CT lumbar spine
>10	Angiography – abdominal Aortography – abdominal Trans-jugular intrahepatic portosystemic shunt (TIPS) RF cardiac ablation CT chest/abdomen/pelvis CT abdomen/pelvis – multi-phase studies

5. DOCUMENTATION

- Protocols for CT procedures
- Clinical protocols for interventional procedures.

6. AUDIT

The following records should be available for audit:

- Records of exposure of pregnant patients
- Survey of doses against the Diagnostic Reference Levels.

7. REFERENCES

[1] NSW Ministry of Health Policy Directive - PD2017_032 - Clinical Procedure Safety

[2] Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (RPS 14.1), ARPANSA 2008

[3] European Society of Radiation, Clinical Decision Support

[4] IAEA Radiation Protection of Patients

[5] Pregnancy and Medical Radiation. ICRP Publication 84. Ann. ICRP 30 (1), ICRP 2000

[6] Protection of Pregnant Patient during Diagnostic Medical Exposure to Ionising Radiation (RCE-9). Health Protection Agency, The Royal College of Radiologists and College of Radiographers, 2009

[7] Guidance on using shielding on patients for diagnostic radiology applications, BIR 2020

[8] Diagnostic reference levels in medical imaging. ICRP Publication 135. Ann. ICRP 46 (1), ICRP 2017.

[9] European Guidelines on Quality Criteria for Diagnostic Radiographic Images, European Commission 1996

[10] Code for Radiation Protection in Medical Exposure. Radiation Protection series C-5, ARPANSA 2019

[11] Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes RPS-8, ARPANSA 2005

[12] SESLHDPR/558 - Handling, investigation and reporting of radiation incidents

[13] The Royal Children's Hospital Radiation and Pregnancy Procedure V2.0, The Royal Children's Hospital, Melbourne, Victoria, 2020

[14] NSW Health Consent to Medical Healthcare Treatment Manual

[15] Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-ray Examinations. Report 88, IPEM 2004

[16] Radiology- Imaging Pregnant Patients Procedure, Government of Western Australia WA Country Health Service 2017

8. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
June 2010	draft	Richard Smart, Area Radiation Safety Officer in conjunction with the Area Radiation Safety Committee
February 2011	0	Approved by Combined Clinical Council
January 2016	1	Periodic Review
November 2016	1	Review and updates approved by Executive Sponsor
December 2019	2	Review and updates approved by Executive Sponsor
26 April 2024	3.0	Major review: Updated to follow ARPANSA C1 and C5; added Appendices 1 and 2 to address pregnant patient and foetal exposures in radiological exams. Approved by SESLHD Clinical and Quality Council.

Appendix 1: Out of hours Fetal Dose and Risk Information Sheet

1. GUIDANCE

In out-of-hours (non-life threatening), it may be clinically necessary for a pregnant patient to undergo a procedure that is likely to result in a radiation dose to the fetus/embryo of greater than 1 mSv. In cases where a medical physicist is not readily available to provide an estimate of radiation dose and risk to the fetus from the exposure to the Radiological Medical Practitioner, Table 1 can be used as guide to inform the required risk assessment for justification and to discuss associated risks with the patient and referrer prior to the procedure.

All doses must be treated as indicative only, as individual doses can differ from tabulated values by as much as a factor of 10 [2].

This appendix is an accompanying document to SESLHDPR/551 Radiation Safety – Optimisation of Medical Radiation Exposures in Diagnostic and Interventional Radiology and therefore must be used in conjunction with the requirements outlined in the procedure.

Medical Physics must be provided a pregnant patient notification form as soon as possible following the procedure so that a patient-specific estimate of radiation dose and risk to the fetus can be performed.

2. APPROXIMATE FETAL EFFECTIVE DOSES AND ASSOCIATED RISK

Table 1 provides guidance as to likely effective dose received by the fetus as function of gestational age. The exams included are common radiological exams that may result in a radiation dose to the fetus/embryo of **more than 1 mSv** [2].

The uterus and upper large intestine organs have been used as surrogates for the fetus in 1st and 3rd trimesters, respectively. Values for 2nd trimester will be between those tabulated for the 1st and 3rd trimesters [2].

The values in Table 3 are only indicative values and should be used with the knowledge that individual doses can differ from tabulated values by a factor of 10 [2].

Table 3: Approximate fetal effective dose (mSv) arising from common radiology examinations of pregnant patients¥ and the associated excess risk of childhood cancer.

	Approximate Fetal Dose (mSv)	Risk of childhood cancer***	Approximate Fetal Dose (mSv)	Risk of childhood cancer***
Exam	1st trimester		3rd trimester	
Conventional Radiography*				
Pelvis	1	1 in 12 500	2	1 in 6 200
Abdomen	1.5	1 in 8 300	2.5	1 in 5 000
Lumbar spine	2	1 in 6 200	6	1 in 2 000
Intravenous pyelogram (IVP)	2	1 in 6 200	10	1 in 1 200
Barium meal	1	1 in 12 500	6	1 in 2 000
Barium enema	7	1 in 1 700	25	1 in 500
Computed Tomography (CT)**				
Chest w/ portal phase	1	1 in 12 500	7	1 in 1 700
Lumbar spine	10	1 in 1 200	25	1 in 500
Chest/Abdo/pelvis	12	1 in 1 000	13	1 in 900
Abdo/pelvis single phase	12	1 in 1 000	12	1 in 1 000
Abdo/pelvis multiple phase	15	1 in 800	30	1 in 400

* Based on data from Sharp et al. 1998 and simulation using PCXMC code
** Obtained using ImPACT dose calculator and typical technique factors
*** Based on risk coefficient for excess risk of cancer in first 15 years of 8 $x10^{-5}$ per mSv [6]
¥ Table reproduced from Annex A of 'Safety Guide: Radiation Protection in Diagnostic and Interventional Radiology', Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Radiation Protection Series 14.1 (2008) [2]

3. CONTEXTUALISED RISK

Immediately post conception, when the number of cells is small, the most likely effect is death or failure to implant.

The risks for developing embryo/fetus are increased risk of cancer and tissue reactions (such as nervous system abnormalities, malformations, growth retardation and fetal death).

Nervous system abnormalities, malformations, growth retardation and fetal death, as a result of radiation exposure, occur at doses above the threshold of 100 milligray (mGy) [6]. Diagnostic and most interventional radiology procedures are not expected to breach this level [6] Termination of pregnancy at fetal doses less than 100 mGy is not justified solely upon the basis of radiation risk to the unborn child [6].

The excess risk of cancer in the first 15 years of life following irradiation in utero is about 1 in 13 000 ($8x10^{-5}$ mGy^{-1}) [6]. The risk of childhood cancer tabulated in Table 1 is based on the product of the approximate effective dose for that exam and the risk coefficient ($8x10^{-5}$ mGy^{-1}). Note: risk has been rounded to the nearest 100. Note the natural baseline risk of childhood cancer of about 1 in 500 [6].

Radiation doses to the embryo/fetus resulting from diagnostic procedures in pregnancy present negligible risk of causing radiation-included hereditary disease in the descendants of the unborn child [6].

Note: In the context of diagnostic and interventional radiological procedures 1 mGy is equivalent to 1 mSv.

Appendix 2: Workflow Summary for Imaging Pregnant Patients