SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Radiation Safety - Optimisation of Radiation Exposures in Nuclear Medicine
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/552
DATE OF PUBLICATION	March 2020
RISK RATING	Medium
LEVEL OF EVIDENCE	Standard 1: Governance for safety and quality in health service organisations
REVIEW DATE	March 2023
FORMER REFERENCE(S)	SESLHNPD/49 Radiation Safety – Optimisation of Radiation Exposures in Nuclear Medicine
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KEY TERMS	Radiation safety; ionising radiation; Nuclear Medicine; gamma rays; radionuclide; radioactive; PPE
SUMMARY	Procedures to optimise patient, foetal, carer, staff and general public exposure to radiation from Nuclear Medicine procedures.

Radiation Safety - Optimisation of Radiation Exposures in Nuclear Medicine

SESLHDPR/ 552

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 the optimisation of protection of patients, relatives and carers, staff and general public in departments performing diagnostic or therapeutic Nuclear Medicine.

2. BACKGROUND

Once clinically justified, each examination should be conducted so that the dose to the patient is the lowest necessary to achieve the clinical aim. It is also crucial that the procedure is performed safely and exactly as prescribed.

Since patients may accrue direct benefits from medical exposures, it is not appropriate to impose strict limits on the doses received from fully justified examinations. However, patient dose surveys demonstrate significant variations in delivered dose to achieve satisfactory image quality indicating that there is scope for the implementation and optimisation of patient protection. Once the radiopharmaceutical has been administered, there is also significant scope for optimising radiation dose for relatives and carers.

3. RESPONSIBILITIES

3.1 The Radiation Medical Practitioner (The Nuclear Medicine Specialist):

The Nuclear Medicine Specialist is responsible for the clinical management of the patient undergoing a diagnostic or therapeutic nuclear medicine procedure. This includes the decision to proceed with a Nuclear Medicine procedure based on the specialist's knowledge of the potential risks and benefits of the procedure, taking into account the clinical information, and the sensitivity and specificity of the procedure.

3.2 The administering person:

Before any procedure is undertaken, the administering person needs to comply with the centre's operating procedures on how to identify the patient (See 4.1 - Procedures for correct identification of the patient, procedure and sites prior to commencing the treatment).

The administering person needs to:

- be trained in intravenous injection and cannulation
- use protective equipment designed to reduce radiation exposure (eg, syringe shields, lead pots) and wear an approved personal radiation monitoring device when handling radioactive materials

- ensure that only persons necessary to the procedure are present when performing administrations
- report 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).

3.3 The Nuclear Medicine Technologist:

The nuclear medicine technologist is responsible for performing nuclear medicine procedures as prescribed by the nuclear medicine specialist in accordance with the centres written standard protocols.

This will include one or more of the following duties:

- prepare, dispense and administer radiopharmaceuticals
- follow imaging and in vitro protocols to ensure optimal data acquisition and analysis
- perform quality assurance procedures for radiopharmaceuticals, instrumentation and image quality.

The nuclear medicine technologist's role may include the responsibilities of the administering person and the person preparing radiopharmaceuticals.

3.4 The person responsible for radiopharmaceuticals:

The person responsible for radiopharmaceuticals needs to develop systems for the:

- procurement of radionuclides/radiopharmaceuticals
- storage and waste management of radionuclides/radiopharmaceuticals
- in-house reconstitution of radiopharmaceuticals
- development of safe procedures and practices for the preparation and manipulation of radiopharmaceuticals, in consultation with relevant staff
- implementation of a quality assurance program for radiopharmaceuticals.

The radiopharmacist/radiochemist, plays, in addition to the above duties, a central role in the:

- in-house manufacture of radiopharmaceuticals
- production of cyclotron radionuclides and derived radiopharmaceuticals
- implementation of a comprehensive quality assurance program for radiopharmaceuticals
- provision of advice on the safe and efficacious use of radiopharmaceuticals.

3.5 The Nuclear Medicine Physicist:

A Nuclear Medicine Physicist is required to be available for consultation on optimisation of medical exposures, including clinical dosimetry and quality assurance, and to give advice on matters relating to radiation protection.

The nuclear medicine physicist works closely with the nuclear medicine specialist and technologists in the optimisation of clinical studies – through image acquisition, analysis and display optimisation and ongoing oversight of the quality control of equipment.

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, (see protocol section 14).

3.6 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 the Nuclear Medicine Department.

4. PROCEDURE

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

4.1.1 Identifying the Patient, Procedure and Site

All staff must comply with NSW Health Policy Directive PD2017_032 - *Clinical Procedure Safety.*

PD 2017_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 Nuclear Medicine

Level 2: Therapeutic Nuclear Medicine

Cardiac stress testing associated with cardiac imaging

Level 3: Procedural sedation or General Anaesthesia

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 patient clinical safety in Nuclear Medicine are common across NSW:

Step 1 - Referral Document

The referral document must be legible and must contain the patient's full name, date of birth and the name of the procedure.

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 ordered, and (when appropriate) the exact anatomical location for the test/s including the procedure site, laterality and level.
2. The proceduralist 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 administering person should also ask about pregnancy status and confirm the absence of breast-feeding

4.1.2 Consent

NSW Health PD2005_406 *Consent for medical treatment - patient information*

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

Consent must be:

- **Obtained for all procedures**
- **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**.

Step 4 - "Time Out"

Immediately prior to the administration of the radiopharmaceutical the administering person should confirm that the patient identification matches that on the request form; and that the radiopharmaceutical (form and activity) and route of administration are appropriate for the study requested. At least one suitably trained and qualified person should verify the form and activity of the dispensed radiopharmaceutical. For a therapy procedure a second such person is required to verify the measurement of the dispensed activity.

Additional documentation and checks

The member of staff administering the dose to the patient must:

- attach the printout from the dose calibrator for the patient's dose to the Request Sheet, complete and sign the printout (indicating pregnancy status and site of injection and other procedural checks), which must stay in the patient's Scan Bag
- for in-patients, complete the yellow Radiopharmaceutical Administration sticker and attach this to the clinical notes section of the patient's medical record
- Ask the patient if they have a known allergy / adverse reaction and if yes, what the allergy / adverse reaction was and what effect they experienced.

Anticipated critical events

The proceduralist must consider the planned procedure, critical steps, anticipated events and equipment requirements.

[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.

Post procedure

The proceduralist must document that the procedure was completed as planned, or document any unexpected adverse events and patient outcomes.

4.2 Procedures to avoid unintentional irradiation of embryo/foetus, or child (from breast-feeding)

Radiation effects and risks to foetus in Nuclear Medicine

The risk from radiation is related to the foetal dose and to the stage of pregnancy at which the exposure occurs. Doses above thresholds of 100 mGy or more can cause failure to implant (conceptus up to week two or three of gestation), developmental abnormalities (embryo week three to eight) or neurological effects (foetus weeks eight to 25). There is evidence of a slightly increased risk of induction of childhood cancer or leukaemia for doses of more than 10 mGy. This latter risk is considered to be uniform throughout the pregnancy after the first three to four weeks of gestation. The life-time cancer risk following intra-uterine exposure is assumed to be similar to that following irradiation in early childhood. In addition to carcinogenesis, radioiodinated compounds can also cause subsequent hypothyroidism in the infant.

Absorbed dose coefficients for the uterus and embryo/foetus from various radiopharmaceuticals administered to a woman in early pregnancy are listed in ARPANSA Safety Guide RPS 14.2 *Radiation Protection in Nuclear Medicine*.

The doses associated with diagnostic nuclear medicine procedures are much lower than the levels where developmental and neurological effects are known to occur. The main physical risk, although very low, may be a slight increased risk of childhood cancer or leukaemia.

Most diagnostic nuclear medicine procedures pose little risk to the mother or foetus compared to other risks during pregnancy. However, anxiety or even distress can occur if a woman has had radiation to the pelvis and subsequently finds that she was pregnant.

Radionuclide therapy procedures can exceed the threshold doses for direct harm to an embryo/foetus.

Sometimes CT is used in combination with radionuclide scanning i.e. with SPECT or PET. The radiation doses from the CT component depend upon the settings used and upon the region of the body scanned.

Confirming Absence of Pregnancy (Diagnostic Procedures)

Illustrated signs are required to be posted in prominent places within the nuclear medicine department, advising patients to notify staff if they may be pregnant. An example might read as follows:

IF IT IS POSSIBLE THAT YOU MIGHT BE PREGNANT,
PLEASE INFORM THE STAFF *BEFORE* YOU HAVE YOUR INJECTION
FOR YOUR NUCLEAR MEDICINE EXAMINATION.

In addition to the signage, staff have a responsibility to enquire about the possibility of pregnancy in all female patients of childbearing age. It is required that reasonable steps be taken immediately before the commencement of the procedure to establish whether the patient is pregnant. When asking the patient about the possibility of pregnancy it is also important to indicate to the patient why there is a need to know, to avoid the patient taking offence and not answering fully.

In every case, the patient's pregnancy status must be recorded with a signature on the dose printout or worksheet by the injecting technologist or supervising physician.

When doubt exists about pregnancy status, the nuclear medicine specialist should be consulted to make a decision about whether to defer the nuclear medicine study until after the next menstrual period, or to perform a pregnancy test (urinary or serum β-HCG) to confirm absence of pregnancy, or to proceed with the study.

If a β-HCG test is performed and the test is positive, or the result is equivocal, the nuclear medicine specialist should be consulted. If the β-HCG test is equivocal it may be advisable to defer the nuclear medicine procedure for a few days and repeat the test. If a woman whose pregnancy status is uncertain declines β-HCG testing before the nuclear medicine procedure, the offer and refusal should be documented.

Confirming Absence of Pregnancy (Therapeutic Procedures)

All female patients of childbearing age who are to be administered therapeutic radionuclides need to have pregnancy excluded by a definitive biochemical test, eg, serum or urinary β-HCG, within 24 hours before the commencement of the treatment. However, a clinical history is necessary in all cases in order to facilitate accurate interpretation of these laboratory investigations (RPS 14.2).

Nuclear Medicine Procedures involving pregnant patients (Diagnostic Procedures)

Pregnancy is not an absolute contraindication to radionuclide studies and in many situations, eg, confirmation or exclusion of pulmonary embolus, may provide essential diagnostic information.

If a diagnostic radiation study is medically indicated the risk to the mother and foetus from not performing the study is usually greater than the risk from the radiation associated with the procedure. If a nuclear medicine study is justified and will be performed, the administered activity should be minimised, provided it is sufficient to supply the required diagnostic information. Prior to the procedure the nuclear medicine specialist should assess the potential dose and communicate the risks to the mother in a meaningful manner. Individual foetal radiation dose estimates may require the services of a nuclear medicine physicist.

The fact that the patient is pregnant must be clearly marked on the consultation form.

Avoidance of conception following Therapeutic Nuclear Medicine Procedures

The ICRP has recommended that a woman receiving a therapeutic dose of a radionuclide not become pregnant until sufficient time has passed that the potential foetal dose would not exceed 1 mGy (ICRP Publication 84). The female patient should be advised to avoid

pregnancy for a time period which depends on the isotope and activity administered. These time periods are listed in ARPANSA Safety Guide *Radiation Protection in Nuclear Medicine*, RPS 14.2. Additional advice should be sought from the RSO.

Inadvertent exposure of a foetus

All cases of accidental or unintentional irradiation of a foetus or embryo must be referred to the Radiation Safety Officer for investigation and assessment.

The RSO should estimate the radiation dose to the foetus so that the patient and their obstetrician can then be better advised as to any possible risk. In many cases there is little risk as the irradiation will have occurred in the first three weeks following conception. In rare cases the foetus will be older and the dose involved may be significant. It is however extremely rare for the dose to be large enough to warrant advising the patient to consider termination.

Breastfeeding or caring for an infant

Illustrated signs are required to be posted in prominent places within the nuclear medicine centre requesting the patient to inform the staff if they are breast-feeding, or caring for, an infant. An example might read as follows:

IF YOU ARE BREAST-FEEDING OR CARING FOR A YOUNG CHILD, PLEASE INFORM THE STAFF *BEFORE* YOU HAVE YOUR INJECTION FOR YOUR NUCLEAR MEDICINE EXAMINATION.

Additionally, before commencing a nuclear medicine procedure, every female patient of childbearing age should be asked by the administering person whether she is breast-feeding or caring for a young child. Steps can then be taken (if necessary) to minimise the external radiation dose to the child during periods of close contact with the patient, and the internal radiation dose from ingested breast milk.

A patient who is breast-feeding a child should be advised of the risks of continued breast-feeding before any therapeutic or diagnostic nuclear medicine procedure.

ARPANSA Safety Guide *Radiation Protection in Nuclear Medicine* (RPS14.2) gives advice about the possible need to restrict breast-feeding. The advice to be given to the patient will depend on the radiopharmaceutical and its activity, and should ensure that the infant will receive a total effective dose of no more than 1 mSv. Advice should be sought from the RSO.

Breast-feeding should be stopped before commencing therapy with any unsealed radionuclide.

Where interruption of breast-feeding is necessary it may be possible to express some milk prior to the study and to store at least one feed in a refrigerator or freezer. During any period of interruption the mother should regularly express and discard her milk.

ARPANSA Safety Guide *Radiation Protection in Nuclear Medicine* (RPS14.2) also gives advice on the length of time for which a patient caring for a child may need to restrict close contact with the child in order to minimise the external irradiation of the child. This

advice ensures that the child receives an effective dose of no more than 1 mSv. Advice may be sought from the RSO.

4.3 Patient related considerations for Radionuclide therapy

Medical supervision

It is important that the nuclear medicine specialist consults with the patient so that clinical issues and possible side-effects of the radiopharmaceutical are discussed. The specialist must supervise the checking of the activity and the administration of the dose.

The ARPANSA publication *Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances*, RPS-4, provides guidance on the conditions which should be met for the discharge from a hospital or clinic of a patient who is undergoing treatment with a radioactive substance, and the conditions for treatment as an outpatient. The recommendations take into account the dose rate external to the patient; and the potential for the spread of contamination from an unsealed radioactive substance excreted by the patient. The effective dose received by the carer should be unlikely to exceed 5 mSv per treatment episode and the dose to children and members of the public should be unlikely to exceed 1 mSv per annum. Carers are individuals who are not normally occupationally exposed and who are appropriately informed of the radiation risks. Carers may be relatives and friends over the age of 18 years who are not pregnant.

After Radiopharmaceutical Administration

The patient and/or their carer should receive written information on:

- the type and radioactivity of the radiopharmaceutical administered
- the date of administration
- any specific radiation safety precautions
- any restrictions on activities including travel home
- how long the restrictions or precautions should last.

Further information is available in RPS 14.2 - Safety Guide *Radiation Protection in Nuclear Medicine*.

4.4 Review of administered activities and comparison with diagnostic reference levels (DRLs)

DRLs for common nuclear medicine procedures have been obtained from a survey of practices in Australia. Reference activities for adult and paediatric patients, together with the corresponding effective doses, are available on the ANZSNM website.

The activity of radiopharmaceuticals administered to patients must be recorded and periodically compared to diagnostic reference levels (DRLs).

DRLs are advisory, allowing for flexible application to individual patients on the basis of sound clinical judgment by the nuclear medicine specialist. However, if a DRL is consistently and substantially exceeded, the usual administered activity should be re-examined to ensure that the activity administered has been optimised.

Technical matters relating to DRLs that should be borne in mind are:

- DRLs are defined as the 75th percentile of the distribution of median values reported by the facilities that have been included in the DRL survey.
- The DRLs for adults are usually defined for a person of average size, which is taken to be about 60 to 80 kg. When performing dose surveys patients within this weight range should be selected, especially where the number of surveyed patients is less than 50.
- The local median is the appropriate value to compare to the DRL.
- Recommended values for DRLs are chosen from a substantive survey of the distribution of the activities administered to patients. They do not represent best practice, so that the ultimate target for any institution should be to lower their doses to a level regarded as achievable. For any procedure, an achievable activity is one which maximises the ratio of benefit and risk without compromising the clinical purpose of the examination. This means that exceeding a DRL is not necessarily a problem, however the local doses must be able to be justified in light of the DRL.
- Nuclear Medicine DRL values are reviewed and adjusted from time to time by the ANZSNM.

4.5 Patient radiation doses from common procedures

When considering the justification for a medical exposure, the benefit is weighed against the detriment, including radiation effects. For diagnostic 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 approximate radiation dose range to adults from common diagnostic nuclear medicine procedures is as follows:

Effective Dose Range (mSv)	Procedures
< 1 mSv	GIT motility, lymphoscintigraphy, cystogram, GFR
1-5 mSv	Biliary system, liver/spleen, lung V/Q, renal, thyroid, parotid imaging with ^{99m}Tc
5 – 10 mSv	Bone, parathyroid, GHPS, infection, blood pool, brain or tumour imaging with ^{99m}Tc; tumour imaging with ^{123}I-MIBG

10 – 20 mSv	Myocardial perfusion imaging with all ^{99m}Tc stress/rest protocols; PET/CT , SPECT/CT
> 20 mSv	Infection or tumour imaging with ^{67}Ga; tumour imaging or myocardial perfusion with ^{201}Tl

5. DOCUMENTATION

- SOPs for preparing and dispensing radiopharmaceuticals
- SOPs for administration of radiopharmaceuticals for diagnostic or therapeutic purposes.

6. AUDIT

The following records should be available for audit:

- Records of patient identification process
- Administered activities for diagnostic and therapeutic procedures
- Radiopharmaceutical inventory (receipts, usage, disposal)
- Quality assurance of radiopharmaceuticals.

7. REFERENCES

[1] PD2017_032 NSW Health Policy Directive: Clinical Procedure Safety
[2] SESLHNPR/558 Handling, investigation and reporting of radiation incidents.
[3] SESLHNPD/296 Radiation Safety - Ionising Radiation Safety
[4] ARPANSA RPS-4 Recommendations for the Discharge of Patients Undergoing Treatment with Radioactive Substances (2002)
[5] ARPANSA RPS-8 Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005)
[6] ARPANSA RPS-14.2 Safety Guide for Radiation Protection in Nuclear Medicine (2008)
[7] ICRP Publication 84 Pregnancy and Medical Radiation, Annals of the ICRP, Vol. 30, No. 1 (2000).

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
May 2010	draft	Richard Smart, Area Radiation Safety Officer in conjunction with the Area Radiation Safety Committee
November 2010	Revised draft	Richard Smart, incorporating comments received
February 2011	0	Approved by Combined Clinical Council
October 2012	1	Broken hyperlink to RPSA 8 fixed
January 2016		Periodic Review

November 2016	1	Review and updates approved by Executive Sponsor
March 2020	2	Review and updates approved by Executive Sponsor