SESLHD PROCEDURE COVER SHEET

Health
South Eastern Sydney
Local Health District

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SUMMARY	Procedures to optimise patient exposure to radiation from radiotherapy procedures.

1. POLICY STATEMENT

The South Eastern Sydney Local Health District (SESLHD or the LHD) 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 the procedure necessary to ensure compliance in relation to the protection of patients undergoing radiation therapy procedures.

2. BACKGROUND

Once clinically justified, each radiation therapy procedure should be performed such that the dose to the patient is the lowest necessary to achieve the desired therapeutic effect (Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) RPSC-5, 2019). To achieve optimisation of protection in radiotherapy, the dose to the target tissue must be sufficient while maintaining protection of those tissues outside the target volume.

3. RESPONSIBILITIES

3.1 The Radiological Medical Practitioner:

- is responsible for the safety and protection of the patient in the prescription and delivery of radiotherapy
- is required to ensure that the radiation dose to the patient is justified and optimised.

3.2 Persons administering radiation (Operator):

- administers ionising radiation for radiation therapy purposes. This will usually be a qualified radiation therapist, but in some cases such as brachytherapy and intraoperative radiotherapy (IORT), this may be a physicist or a radiological medical practitioner
- will deliver radiation in accordance with the radiation treatment plan approved by the radiological medical practitioner
- will adhere to all relevant department operating procedures and provide continuous oversight of the radiation-producing equipment during radiation dose delivery.

3.3 Radiation Therapist:

- will be involved in both the planning and treatment aspects of radiation therapy
- in addition to the responsibilities outlined in 3.2 above, will typically calculate and document the relevant treatment parameters for treatment planning and delivery, participate in the department's quality assurance program, manage quality control for patient-related treatment and planning activities, and adhere to safe practice procedures for operating radiotherapy equipment.

3.4 Qualified Expert (Radiation Oncology Medical Physicist):

- will give advice on optimisation of medical exposures and matters relating to radiation protection
- is responsible for performing or supervising radiotherapy calibration, dosimetry and quality assurance.

3.5 Radiation Safety Officer:

- will oversee and provide advice on radiation safety within radiation therapy departments.

4. PROCEDURE

4.1 Procedures for dose calculation quality control

The ARPANSA code of practice, RPS C-5, requires a written prescription from the Radiological Medical Practitioner and approval of the treatment plan before treatment commences. All SESLHD facilities shall comply with Section 8 of Radiation Oncology Practice Standards (RANZCR, 2023), which includes mandatory data items to be collected and verified by NSW Health Radiation Oncology Treatment Centres during the prescription, planning and treatment stage for megavoltage, superficial and orthovoltage radiation therapy.

The ARPANSA code of practice, RPS C-5, prescribes that all dosimetry data used for treatment planning:

- shall be clearly documented
- have a reference trace to the original data source.

It must be ensured that:

- the treatment planning procedures are followed
- all treatment planning equipment is tested
- the basic data for each available treatment planning computer program are verified by a Radiation Oncology Medical Physicist (ROMP):
  - on initial acceptance
  - after any change or upgrade
- patient specific independent calculations of monitor units or treatment time are performed.

A local quality assurance program should be designed that complies with the tolerances and frequencies of quality control procedures specified in the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) Position Paper: Recommendations for the Safe Use of External Beams and Sealed Brachytherapy Sources in Radiation Oncology (1997). Reference should also be made to the International Atomic Energy Agency (IAEA) Technical Report Series No. 430 (IAEA, 2004) and the Radiation Oncology Practice Standards (RANZCR 2023). To ensure accurate and safe clinical usage of all radiotherapy equipment, calibration and performance testing according to the tendered specifications, should be undertaken at the initial commissioning stage, after a source change, and after major repairs or modifications that may affect the accuracy of patient dose delivery.

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

The NSW Ministry of Health Policy Directive PD2017_032 Clinical Procedure Safety shall be adhered to by all SESLHD sites. To help staff comply with this policy, posters relating to correct patient, procedure, and site before simulation, and radiation therapy treatment are available from NSW Health.

4.3 Procedures for the delivery of radiotherapy

Each person administering radiation must have the appropriate authorisation from the relevant regulatory authority, in the form of a NSW Radiation User Licence. No person may use or operate the equipment unless they have undertaken training according to local business rules.

As outlined in the ARPANSA code of practice, RPS C-5, the operator must not expose a person to radiation unless the procedure has been approved or prescribed by the Radiological Medical Practitioner. The operator must ensure that the protection of the patient is optimised, within the scope of the parameters under their control and ensure that the radiation exposure of persons other that the patient is minimised.

In the case of radiotherapy, the operator must ensure that:

- the radiation treatment plan has been approved by the Radiological Medical Practitioner
- the radiation dose to the patient is delivered in accordance with the radiation treatment plan
- there is a continuous oversight of the operating parameters of radiation-producing equipment during the radiation dose delivery
- the exposure from radiation-producing equipment is immediately terminated if there is any concern that the equipment will not deliver the correct patient radiation dose.

For external beam radiotherapy and intra-operative photon and electron radiotherapy, the person who administers radiation should

- create a document for the delivery of the prescribed radiotherapy treatment to the patient
- ensure that a double-check of the prescription has been performed and recorded; and
- ensure that the record includes the following details:
    - date of treatment
    - treatment site and field size(s)
    - total radiation dose at the reference point
    - number of fractions
    - radiation type and quality
    - doses received by critical normal tissues (OARs).

A radiotherapy record and verify (R&V) system should be able to compare the predetermined treatment setting recorded for an individual patient treatment with the actual treatment settings of each treatment. The planning Radiation Therapist should enter the treatment parameters into the R&V system, preferably by electronic transfer, directly from the planning computer. Manual transfer of the treatment parameters should be avoided where possible as errors are more likely. All parameters should then be checked independently by a second Radiation Therapist before treatment commences. The predetermined treatment parameters should be assigned appropriate tolerances to allow for daily set up inconsistencies. Only a designated Radiation Therapist should be authorised under departmental protocol to override the predetermined treatment verification settings when they exceed the R&V tolerance values. The Radiation Therapist and overridden parameters should be identified and recorded in the patient treatment record for audit purposes.

Each LHD Radiation Oncology department will have a document which addresses the issues outlined above and this document will be reviewed annually.

4.4 Prevention of erroneous administration

To optimise treatment delivery and check the dose delivered to the patient, direct measurements in a phantom simulated set-up or an in-vivo patient measurement should be obtained prior to or on the commencement of the course of treatment whenever:

- a new protocol is implemented
- there is a change in supplier of a radioactive material
- a non-standard technique is planned
- there may be uncertainty that the treatment planning system dose calculations are sufficiently accurate.

Useful documents include the IAEA “Lessons learned from Accidental Exposures in Radiotherapy” (2000) and the ICRP document “Prevention of Accidents to Patients Undergoing Radiation Therapy” (2000). A review of incident reports, including near misses, in local training sessions is a key educative element in preventing errors.

If an incident of erroneous administration has occurred, the guidelines outlined in the NSW Health Policy Directive Clinical Procedure Safety must be followed. An apology and explanation must be given to the patient and family in accordance with NSW Health Policy Directive PD2023_034 Open Disclosure. An incident report and Reportable Incident Brief (RIB) must be completed and an appropriate review undertaken, as indicated in the NSW Health Policy Directive PD2020_047 Incident Management.

4.5 Procedures to avoid unintentional irradiation of embryo/foetus

For most oncology patients, the potential effects of treatments on patient fertility and the dangers to pregnancy will be discussed well prior to treatment. However local department procedures must ensure that the risks associated with radiotherapy and pregnancy are fully disclosed and discussed with the patient.

Reasonable steps must be taken to establish whether a patient is pregnant before commencement of a procedure which may result in a radiation dose of 1 mSv or more to an embryo or foetus. Illustrated signs, preferably in several languages, are required to be posted in prominent places in the radiotherapy facility advising patients to inform staff if they are pregnant. Staff have the responsibility to enquire about the possibility of pregnancy in all female patients of childbearing age. It is important to explain to the patient the reasons for needing to know. Pregnancy may be deemed very unlikely or impossible in a woman of childbearing age when the woman has:

- had a hysterectomy
- had a normal menstrual period within the past 10 days and has regular menstrual periods.
- has had tubal litigation more than three months previously and has had other means of contraception for that period
- not had a sexual relationship for more than 9 months
- taken contraceptive measures, such as the contraceptive pill, provided it has been taken regularly on consecutive days.

In all other cases pregnancy should be regarded as possible. If doubt exists as to the pregnancy status of an individual and moderate doses to the abdomen are involved, a

decision must be made to either defer the treatment until after the woman's next menstrual period, to perform a pregnancy test (urinary or serum β-HCG), or to proceed with the treatment. If the β-HCG test is positive or equivocal, the Radiological Medical Practitioner must be consulted. If equivocal the test may be repeated. If the pregnancy status is uncertain and the woman declines pregnancy testing, the procedure should be postponed until the referring doctor has been contacted by the Radiological Medical Practitioner and appropriate counselling has been obtained.

Refer to specific department protocols for

- irradiation of the known not-pregnant woman;
- accidental irradiation of the pregnant woman; and
- deliberate irradiation of the pregnant woman.

4.6 Procedures to avoid unnecessary irradiation of others, particularly children (from prolonged close proximity to a patient with sealed radioactive sources in situ)

If a permanent sealed source implant is in place, the Radiological Medical Practitioner in conjunction with the ROMP will provide the patient with written details of the implant source(s) and activity, and written and verbal instructions regarding radiation protection, with particular reference to contact with children and pregnant women.

Patients should be advised of the period in which radiation safety precautions continue to apply. The patient should be provided with the means of retrieval and storage of dislodged sources, to be returned to the ROMP or the RSO for disposal.

Information should also be supplied to the patient's general practitioner including details of procedures to be followed in the event of unexpected death. The medical responsibility for a decision to allow a LDR brachytherapy patient to leave the facility lies with the Radiological Medical Practitioner. The radiation protection responsibility for such a decision lies with the ROMP and ultimately the RSO, in accordance with the requirements of the relevant regulatory authority.

4.6.1 Procedures to Avoid Secondary Radiation Exposure of a Child under Close Care

Before a radioactive implant is administered, the Radiological Medical Practitioner should query the patient as to whether they are involved with close care of a child. All patients discharged with radioactive sources should be provided with advice relating to the external radiation dose on:

- the length of time for which he or she can hold, or be in close proximity to, a child
- the date or time after which no restrictions will be necessary.

Department specific procedures for patients with sealed radioactive sources in-situ are given in the sections which follow.

4.7 Special procedures for the delivery of radiotherapy

The more complex and non-standard treatment techniques require input into planning and treatment by the Radiation Oncologist, Radiation Therapist and Radiation Oncology Medical Physicist who have each obtained specialised experience in the clinical and dosimetric aspects of these techniques. Some examples of when this is needed are total body irradiation, total body electron therapy and dynamic techniques such as intensity modulated radiotherapy (IMRT), volumetric modulated arc therapy (VMAT), image-guided and 4-D gated radiotherapy.

Special care should be taken when there are complex or unusual treatment plans or when there is a change in procedures such as:

- a non-typical dose
- an unusual target area
- a treatment with the patient in an unusual position
- a complex treatment.

An in-vivo direct measurement and is recommended in such cases listed above.

For the following types of radiotherapy, a ROMP should be present in addition to the person administering the radiation:

- intra-operative photon or electron radiotherapy that may occur in the operating theatre, or in the treatment room following surgical exposure of the area for treatment
- sealed source HDR brachytherapy throughout the surgical and treatment procedures (the ROMP has an integral role during treatment in relation to safety and emergency precautions)
- the insertion of sealed sources for LDR brachytherapy (such as iodine-125 seed prostate implants)
- the application or insertion of sealed radioactive sources for manual brachytherapy (other than non-surgical plaque application). Specific examples are the surgical placement of plaques for orbital retinoblastoma, mould implants to superficial tumours or interstitial implants using radioactive iridium-192
- external beam therapies where a new protocol or technique is being implemented which requires detailed assessment of the accuracy of dosimetry and/or of the reliability of radiation equipment operation, or where the dosimetry needs to be calibrated prior to treatment or measured during treatment.

4.8 Reviews of radiotherapeutic doses delivered

The Radiological Medical Practitioner is responsible for follow-up monitoring and evaluation of treatment outcome and morbidity.

5. DOCUMENTATION

- Dosimetry data used for treatment planning
- Treatment planning procedures
- Local quality assurance protocols for all systems involved in treatment planning and delivery
- Local protocols for irradiation of pregnant patients.

6. AUDIT

The following records should be available for audit:

- Treatment plans and treatment records for all patients treated.
- Records of follow-up monitoring and evaluations of treatment outcomes.

7. REFERENCES

[1] ARPANSA (2019) Code for Radiation Protection in Medical Exposure (RPS C-5), ARPANSA, Yallambie

[2] ARPANSA (2008) Safety guide for Radiation Protection in Radiotherapy (RPS 14.3) ARPANSA, Yallambie

[3] Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) (1997), Recommendations for the Safe Use of External Beams and Sealed Brachytherapy Sources in Radiation Oncology, ACPSEM 20 (3), Supplement.

[4] IAEA Technical Report Series No. 430, Commissioning and Quality Assurance of Computerized Planning Systems for Radiation Treatment of Cancer (2004).

[5] RANZCR (The Royal Australian and New Zealand College of Radiologists) Radiation Oncology Practice Standards Part A: Fundamentals, RANZCR, ASMIRT & ACPSEM 2023

[6] IAEA Safety Reports Series No. 17, Lessons Learned from Accidental Exposures in Radiotherapy (2000).

[7] ICRP Publication No. 86, Prevention of Accidents to Patients Undergoing Radiation Therapy (2000).

[8] NSW Health Policy Directive PD2023_034 - Open Disclosure Policy

[9] NSW Health Policy Directive PD2017_032 - Clinical Procedure Safety

[10] NSW Health Policy Directive PD2020_047 - Incident Management

8. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
01/08/2010	Draft	Area Radiation Safety Officer in conjunction with the Area Radiation Safety Committee
February 2011	0	Approval by Combined Clinical Council
December 2015	1	Periodic Review
October 2016	1	Updates endorsed by Executive Sponsor
March 2020	2	Updates endorsed by Executive Sponsor
16 February 2024	2.1	Minor review: wording changes, hyperlinks updated. Section 4.7 updated. Approved by Executive Sponsor