SESLHD PROCEDURE COVER SHEET

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SUMMARY	Procedures for the maintenance, disposal and reporting of faults of radiation apparatus.

Radiation Safety - Management of Radiation Apparatus

SESLHDPR/550

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 procedures necessary to ensure compliance with this policy in relation to the repair, maintenance, disposal or sale of radiation apparatus.

2. BACKGROUND

Abbreviations

CRE – Consulting Radiation Expert

EPA - Environment Protection Authority

QA – Quality Assurance

RML – Radiation Management Licence

TGA – Therapeutic Goods Administration

3. RESPONSIBILITIES

3.1 The Department Manager

The *Protection from Hardful Radiation Regulation 2013* (NSW) puts certain obligations on the owner of radiation apparatus. These obligations have been devolved from the District Chief Executive to the Department Manager (SESLHDPD/296 - Radiation Safety - Ionising Radiation Safety).

The Department Manager, in collaboration with suppliers, must ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Electrotechnical Commission and the International Organization for Standardization and to any standards adopted by the relevant regulatory authority.

In particular, the Department Manager must ensure compliance with the following procedures relating to the repair, maintenance, disposal or sale of radiation apparatus.

4. PROCEDURE

4.1 Use and Secure Storage of Radiation Apparatus

A person must hold a radiation user licence in order to operate, manipulate or possess for use, any radiation apparatus. They must comply with any conditions to which the licence is subject.

The operator of medical radiological equipment must ensure that no safety interlock devices are bypassed at any time during routine clinical use of the equipment. The Department Manager must ensure that all practicable measures are taken to minimise the

likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment or facilities, from failures of and errors in software, or resulting from human error or the failure of processes.

When not in use, radiation apparatus must be stored securely in such a way as to prevent unauthorised handling. For example, apparatus may be enabled by a physical key; this key should be only be held by or accessible to appropriately licenced individuals.

4.2 Quality Assurance of Radiation Apparatus

The Department Manager must ensure that a comprehensive program of quality assurance for medical exposures is established, performed, maintained and regularly reviewed, with the active participation of radiological medical practitioners, operators, medical physicists and, where relevant, radiopharmaceutical scientists, and in conjunction with other health professionals as appropriate. Principles established by relevant professional bodies and requirements of the relevant regulatory authority must be taken into account.

The Quality Assurance program should include:

a) measurements of the physical parameters of medical radiological equipment conducted:
    i. at the time of acceptance and commissioning of the equipment prior to its clinical use on patients;
    ii. periodically thereafter, according to national protocols and as required by the regulatory authority;
    iii. after any maintenance procedure that could affect protection and safety of patients;
    iv. after any installation of new software or modification of existing software that could affect protection and safety of patients;

b) implementation of corrective actions if measured values of the physical parameters mentioned in a) above are outside established tolerance limits.

c) verification that appropriate physical parameters and clinical protocols are used in radiological procedures.

d) independent verification of calibrations of external beam radiation therapy units, including reference dose verification, non-reference dose verification, and end-to-end dose delivery verification:
    i. at the time of acceptance and commissioning of the equipment prior to its clinical use on patients;
    ii. periodically thereafter, at intervals specified by professional bodies and as required by the regulatory authority.

e) internal verification of calibrations of external beam radiation therapy units after any maintenance procedure or software upgrade that could affect protection and safety of patients.

f) maintaining records of relevant procedures and results, including documentation of work performed for repair, maintenance or modification.

g) periodic checks of the calibration and conditions of operation of dosimetry equipment, reference equipment and monitoring equipment. These must be traceable to relevant national standards.

Furthermore, the Department Manager must ensure that all radiological diagnostic imaging apparatus under their management are periodically certified as compliant with NSW EPA Standard 6 by a Consulting Radiation Expert (CRE) accredited by the NSW EPA. Certification must be carried out:

- Before the apparatus is used; or
- Within a specified time interval of the previous certification which depends on equipment type; or
- Where modifications have been made to the apparatus, including reassembly after relocation; or
- Where the purpose for which the apparatus is used has changed.

4.3 Service, Repair and Maintenance of Radiation Apparatus

In this procedure, the term ‘service’ will be used generically to indicate ‘service’, ‘repair’ or ‘maintenance’ unless a step is specific to a term.

Radiation apparatus must only be repaired by qualified service engineers who possess a current radiation user licence which allows them to use the radiation apparatus they are servicing.

Whenever servicing may have compromised the performance of the equipment or any of its radiation safety features the relevant compliance tests must be repeated and passed successfully before the equipment is used clinically. If the x-ray tube is replaced, the full compliance tests must be performed by a CRE and the EPA must be informed of the change of detail within the time frame allowed by the RML.

Where the CRE has certified the apparatus as compliant, but has specified that minor repairs are necessary to satisfy all the registration requirements, the Department Manager must:

- ensure that these repairs are carried out within the timeframe specified in the CRE’s report; and
- adhere to any restrictions in the use or operation of this apparatus specified by the CRE until the apparatus is fully repaired.

4.4 Records that must be kept relating to radiation apparatus

It is a condition of the RML that the Department Manager must keep copies of all maintenance and inspection reports and summaries of QA tests undertaken on radiation apparatus. The records may be in hardcopy or electronic form.

These records must be kept for at least six years and made available on request to an authorised officer of the EPA.

NSW Public Health Services: Administrative Records (GDA 21) issued by NSW State Records Authority, in section 9.3.1, states "Records relating to the maintenance of technical and quality standards for the service and operation of equipment. This includes operating or service manuals, repair/servicing/maintenance records, purchase and disposal dates for equipment" should be kept for 15 years after the disposal of the equipment. There is also a footnote indicating that if the equipment is involved in pending litigation, that records should be kept until the litigation is finalised.

4.5 The reporting of faults that would compromise patient safety, diagnosis or treatment

The operator of medical radiological equipment, who experiences any fault or error of equipment or system, or unusual operating behaviour must:

a) immediately cease using the equipment or apparatus until the fault, error or unusual operating behaviour is rectified;

b) record the details of the fault, error or unusual operating behaviour;

c) where the fault could compromise patient safety, diagnosis or treatment, report it to:

- the Responsible Person; and
- the radiological medical practitioner.

Any suspected problems with a medical device which has or may present a health hazard must also be reported to the TGA. Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or deficient design.

Details of how to report the problem can be found at the TGA Website.

In addition, the owner must notify the EPA within seven days if the radiation apparatus:

- fails or ceases to satisfy the requirements for registration;
- has an x-ray tube insert replaced; or
- for fixed units, is relocated.

4.6 Disposal of radiation apparatus

The owner may dispose of radiation apparatus only if:

- the radiation apparatus has been rendered permanently inoperable;
- both the District RSO and NSW EPA have been notified of the disposal within the time-frame required by the RML; and
- the Fixed Assets Disposal Advice Form has been appropriately authorised.

4.7 Transfer of radiation apparatus

The owner may sell or otherwise transfer radiation apparatus only if:

- the purchaser or transferee holds a licence to sell/possess radiation apparatus;

- both the District RSO and NSW EPA have been notified of the transfer of ownership within the time-frame required by the RML; and
- the SESLHD Fixed Assets Disposal Advice Form has been appropriately authorised.

5. DOCUMENTATION

- District Radiation Management Licence (held by District RSO)
- Application Form to Vary Radiation Management Licence (held by site RSOs)
- Diagnostic Radiation Apparatus Compliance Certificates
- Fixed Assets Disposal Advice Form (SESLHD District Form F028)
- EPA Disposal, transfer and sale forms

6. AUDIT

The following records should be available for audit:

- Completed RML Variation Forms for additions, transfers and disposals of regulated material
- Maintenance and inspection reports for radiation apparatus
- Compliance certificates for diagnostic radiation apparatus
- Acceptance test reports for radiation apparatus, and
- Summaries of QA tests undertaken on radiation apparatus.

7. REFERENCES

[1] *Protection from Harmful Radiation Regulation 2013* (NSW)

[2] NSW Environment Protection Authority, Standard 6: Compliance requirements for ionising radiation apparatus 2020

[3] NSW State Records Authority, GDA-21- General Retention and Disposal Authority Public health services: administrative records

[4] SESLHDPD/296 - Radiation Safety - Ionising Radiation Safety

8. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
July 2010	Draft	Richard Smart, Area Radiation Safety Officer in conjunction with the Area Radiation Safety Committee
February 2011	0	Approved by Combined Clinical Council
February 2013	1	Fixed Assets Disposal Advice Form updated for SESLHD
December 2015	2	Periodic Review
September 2016	2	Review and updates approved by Executive Sponsor
December 2019	3	Review and updates approved by Executive Sponsor
26 April 2024	4.0	Major review: Updated requirements to reference ARPANSA C1 and C5; Clarified differences in CRE requirements between rad onc and imaging apparatus. Approved by SESLHD Clinical and Quality Council.