

# SESLHD PROCEDURE COVER SHEET



**Health**  
South Eastern Sydney  
Local Health District

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<b>KEY TERMS</b>	Radiation safety; ionising radiation; x-rays; radiology; medical imaging; radiotherapy; equipment management
<b>SUMMARY</b>	Procedures for the maintenance, disposal and reporting of faults of radiation apparatus.

## **COMPLIANCE WITH THIS DOCUMENT IS MANDATORY**

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# SESLHD PROCEDURE

## Radiation Safety - Management of Radiation Apparatus

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### 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 Department Manager must ensure compliance with the following procedures relating to the repair, maintenance, disposal or sale of radiation apparatus. The NSW Radiation Control Regulation 2013 puts certain obligations on the owner of the radiation apparatus. These obligations have been devolved from the General Manager to the Department Manager (SESLHDPD/296).

### 4. PROCEDURE

#### 4.1 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.

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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
- adhere to any restrictions in the use or operation of this apparatus specified by the CRE until the apparatus is fully repaired.

### 4.2 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.

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

Any suspected problems with a medical device which has or may present a health hazard must be reported to the TGA. Typical problems include deficiencies in labelling, instructions or packaging, defective components, performance failures, poor construction or 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
- for fixed units, is relocated.

### 4.4 Disposal of radiation apparatus

The owner may dispose of radiation apparatus only if:

- the radiation apparatus has been rendered permanently inoperable
- the EPA has been notified using the form on the EPA website
- the Fixed Assets Disposal Advice Form has been appropriately authorised.

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### 4.5 Sale of radiation apparatus

The owner may sell radiation apparatus only if:

- the purchaser holds a licence to sell/possess radiation apparatus, or an appropriate licence to use the apparatus
- the EPA has been notified within 21 days using the Application to Vary a Radiation Management Licence form from the EPA website
- the SESLHD Fixed Assets Disposal Advice Form has been appropriately authorised.

### 4.6 Transfer of registration

The owner may transfer the radiation apparatus to another person only if:

- the purchaser holds a licence to sell/possess radiation apparatus, or an appropriate licence to use the apparatus
- the EPA has been notified within 21 days using the Application to Vary a Radiation Management Licence form from the EPA website
- the SESLHD Fixed Assets Disposal Advice Form has been appropriately authorised.

## 5. DOCUMENTATION

- District Radiation Management Licence
- Application Form to Vary Radiation Management Licence
- SESLHD Fixed Assets Disposal Advice Form
- EPA Disposal, transfer and sale forms.

## 6. AUDIT

The following records should be available for audit:

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

## 7. REFERENCES

- [\[1\]](#) NSW Radiation Control Regulation 2013
- [\[2\]](#) SESLHDPR/296 Radiation Safety - Ionising Radiation Safety.

## 8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
July 2010	Draft	Richard Smart, Area Radiation Safety Officer in conjunction with the Area Radiation Safety Committee

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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
March 2020	3	Review and updates approved by Executive Sponsor