SESLHD PROCEDURE COVER SHEET

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Radiation Safety: Quality Assurance in Radiotherapy

SESLHDPR/532

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 the procedures necessary to ensure compliance with this policy in relation to a quality assurance program in radiotherapy which places emphasis on equipment performance, patient safety and patient dose minimisation.

2. BACKGROUND

A quality assurance program is necessary to provide sufficient confidence that requirements relating to safety and protection are satisfied. An effective Quality Assurance program will cover all aspects of radiation delivery including physical and technical aspects of equipment used, the clinical decision process, planning and administration of radiation.

3. RESPONSIBILITIES

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Radiation Protection Series (RPS) C-5 describes the responsibilities of the medical professionals in a radiotherapy department. These responsibilities are adopted by SESLHD, including the “Radiological Medical Practitioner” and the ‘Operator’ which will be either a Radiation Therapist or Radiation Oncology Medical Physicist.

3.1 Radiation Safety Officer

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

3.2 The Supplier

The supplier of radiotherapy equipment shall incorporate current national standards in the design of their equipment or, when national standards are not defined, shall ensure adherence to appropriate international standards. Accompanying documentation shall make reference to which standards have been adopted. Implicit in this is the assurance that the required levels of radiation protection are met, all safety controls and interlocks are in full working order and that there is redundancy within the system in case of failure of one component.

3.3 The Equipment Servicing Agency

Equipment service personnel may be employed by the supplier of the equipment, by the SESLHD, or by a third-party service company. The equipment service personnel will conform to the protection requirements and procedures of the SESLHD. The equipment servicing agency has a responsibility to employ appropriately trained and licensed personnel to service the equipment. The equipment servicing agency must work in close cooperation with the radiation oncology medical physicists (ROMPs) to ensure that the ROMPs are aware at all times of the impact any service may have on the performance of the equipment.

4. PROCEDURE

4.1 Calibration, acceptance and tests of radiotherapy equipment

Australian or international standards applicable to radiotherapy include:

- Australian Standards (AS) 2900.10-2002. Quantities and units – Nuclear reactions and ionizing radiations, 2002.
- AS/NZS 3200.2.1:2014. Medical electrical equipment – Particular requirements for safety – Electron accelerators in the range of 1 MeV to 50 MeV identical to IEC 60601-2-1 – Ed. 3.1 – Medical electrical equipment – Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 MeV to 50 MeV.
- AS/NZS 3200.2.11:2013. Medical electrical equipment – Particular requirements for safety – Gamma beam therapy equipment Identical to IEC 60601-2-11 – Ed. 3.0 – Medical electrical equipment – Part 2: Particular requirements for the safety of gamma beam therapy equipment.
- AS/NZS 3200.2.17:2013. Approval and test specification – Medical electrical equipment – Particular requirements for safety – Remote-controlled automatically-driven gamma-ray afterloading equipment identical to IEC 60601-2-17 – Ed. 3.0 – Medical electrical equipment. Part 2: Particular requirements for the safety of remote-controlled automatically driven gamma ray afterloading equipment.
- AS/NZS 3200.2.29:2008. Medical electrical equipment – Particular requirements for safety – Radiotherapy simulators identical to IEC 60601-2-29 – Ed. 3.0 – Medical electrical equipment – Part 2-29: Particular requirements for the safety of radiotherapy simulators.
- AS/NZS 3200.2.9:1997. Approval and test specification – Medical electrical equipment – Particular requirements for safety – Patient contact dosemeters used in radiotherapy with electrically connected detectors identical to IEC 60601-2-9 – Ed. 2.0 – Medical electrical equipment – Part 2: Particular requirements for the

safety of patient contact dosemeters used in radiotherapy with electrically connected radiation detectors. 1996.

- AS/NZS 3824:1998. Guidelines for radiotherapy treatment rooms design – identical to IEC/ TR3 61859 – Ed. 1.0 – Guidelines for radiotherapy treatment rooms design. 1997.
- AS/NZS 4184.1:1994. Evaluation and routine testing in medical imaging departments – General aspects.
- AS/NZS 4184.3.1:2002. Evaluation and routine testing in medical imaging departments – Acceptance tests – Imaging performance of X-ray equipment for radiographic and radioscopic systems.
- AS/NZS 4358:1996. Medical diagnostic X-ray equipment – Radiation conditions for use in the determination of characteristics.
- AS/NZS 4434.1:2007. Medical electrical equipment – Medical electron accelerators – Functional performance characteristics identical to IEC 60976 – Ed. 2.0 – Medical electrical equipment – Medical electron accelerators – Functional performance characteristics.
- AS/NZS 4434.2:2008. Medical electrical equipment – Medical electron accelerators – Periodic function performance testing identical to IEC/TR 60977 – Ed. 2.0 – Medical electrical equipment – Medical electron accelerators in the range of 1 MeV to 50 MeV – Guidelines for functional performance characteristics.
- AS/NZS 4495:2011. Radiotherapy equipment – Coordinates, movements and scales. Identical to IEC 61217 - Consol. Ed. 2.0 (incl. am1) – Radiotherapy equipment – Coordinates, movements and scales.
- AS/NZS 4537:2016. Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy identical to IEC 60731 – Ed. 3.1 Medical electrical equipment – Dosimeters with ionization chambers as used in radiotherapy.
- AS/NZS 4580:1998. Medical electrical equipment – Digital imaging and communications in medicine (DICOM) – Radiotherapy objects identical to IEC/TR3 61852 – Ed. 1.0 – Medical electrical equipment – Digital imaging and communications in medicine (DICOM) – Radiotherapy objects..
- AS/NZS ISO 31000:2009. Risk management – Principles and guidelines.
- AS/NZS ISO/IEC 27001:2006. Information Technology – Security Techniques.

- International Electrotechnical Commission (IEC) 60601-2-8 - Consol. Ed. 2.1 2015 Medical electrical equipment – Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV.

- IEC 62083 – Ed. 2.0 – Medical electrical equipment – Requirements for the safety of radiotherapy treatment planning systems. 2009.

- IEC/TR 62266 – Ed. 1.0 – Medical electrical equipment – Guidelines for implementation of DICOM in radiotherapy. 2002.

4.1.1 Acceptance testing of radiotherapy equipment

The acquired data and test results for newly installed radiotherapy equipment must be compared to the technical specifications provided by the manufacturer or supplier. Full acceptance testing of new or modified radiotherapy treatment planning or dosimetry equipment shall be completed by a certified radiation oncology medical physicist and is usually performed in cooperation with the installing engineers. The performance of the equipment must comply with Australian standards and/or international standards and in accordance with any requirements of the relevant regulatory authority.

Where non-standard equipment is used, the tests need to take due regard of protocols provided by the supplier and include a risk assessment.

The radiation oncology medical physicist shall:

- ensure that shielding is adequate and safe prior to the commencement of any acceptance tests that involve production of radiation by the equipment being tested;
- ensure that records of all acceptance tests and commissioning data are kept and are readily available for later reference; and
- ensure that the equipment is clinically used only for modes of treatment for which it has been tested and accepted for use, and that all operators are duly informed of the limited conditions of use.

Any modification or additional functionality that is added at a later date to the equipment must undergo the same requirements specified above.

4.1.2 Commissioning and calibration of radiotherapy equipment

Protocols for the dosimetric calibration of radiotherapy equipment shall be in accordance with those adopted by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM). Relevant national and international calibration protocols include the International Atomic Energy Agency (IAEA) TRS-398 (2006), Klevenhagen et al (1996), Aukett et al (2005), American Association of Physicists in Medicine (AAPM) TG61 (2001) and IAEA TECDOC 1274 (2002).

All aspects of dosimetric calibration, shall be performed and recorded by a certified radiation oncology medical physicist. The physicist must confirm that the beam data used and doses calculated by the treatment planning system (TPS) are correct to within the accepted limits of accuracy as outlined in recommended guidelines (IAEA TRS 430, AAPM MPPG 5a, AAPM TG114).

All absolute dose calibrations and adjustments to these calibrations shall be independently checked by another certified physicist, who may be in the same department. Records of measurements are stored securely. Data recorded during the acceptance testing and commissioning shall be used as a reference baseline from which to monitor the performance of the radiotherapy equipment during subsequent quality control performance or operational tests.

All newly installed linear accelerators are also subject to an external audit prior to clinical release to ensure the radiation output is calibrated correctly. It is recommended that this process be carried out by the Australian Clinical Dosimetry Service (ACDS) as a Level 1b audit.

No radiotherapy treatment or planning equipment shall be released for clinical use until a radiation oncology medical physicist is satisfied that the equipment is satisfactorily operating, calibrated and safe to use.

4.1.3 Recalibration

Radiotherapy equipment shall be re-calibrated after initial commissioning and calibration, at least at the frequencies prescribed in the ACPSEM and AAPM quality assurance recommendations (ACPSEM 1997, AAPM TG142). The recalibration procedure shall be performed or overseen by a certified radiation oncology medical physicist who will ensure that the equipment will undergo sufficient recommissioning tests to confirm that the previous standards of operation are still satisfactory in accordance with the calibration recommendations for that equipment (ACPSEM 1997).

In addition to the initial acceptance and commissioning, the same test and measurement procedures shall be followed whenever a major upgrade or overhaul of the equipment is undertaken. ‘Major’ would mean that the calibration or performance specification of the equipment might have changed sufficiently to warrant re-evaluation of the clinical suitability of the equipment or that the associated planning/treatment data needs to be updated. Some examples of changes considered major are as follows:

<u>External beam radiotherapy</u>

Maintenance or replacement of any of the radiation beam generation, shaping and monitoring systems and the mechanical systems require a reassessment of the equipment’s calibration and accuracy of radiation delivery. A limited re-commissioning procedure is necessary when the X-ray tube or linear accelerator waveguide is replaced,

affecting the dosimetry, or when major components are replaced, affecting the mechanical alignment of beam delivery.

Intra-operative radiotherapy

A linear accelerator for intra-operative radiotherapy in the treatment room, or a small mobile electron accelerator or low energy X-ray device in the operating theatre, shall follow the same guidelines as described above.

Remote afterloading brachytherapy

Remote afterloading brachytherapy devices require a modified commissioning procedure after each new replacement radioactive source is loaded. For example, the accuracy of source activity, positional accuracy and source integrity shall be determined prior to use. Any maintenance of the mechanical or electrical controls would necessitate a similar range of essential tests.

Manual brachytherapy – Seeds

Apart from regular quality assurance tests and safe practice housekeeping, individual radioactive sources shall be tested if there is any indication of physical damage or wear, particularly if there is a possibility of radioactive source leakage from its inert, sealed container.

For brachytherapy, source strength may be measured by one of the techniques described in IAEA TECDOC 1274 (2002) or Nath et al (1997).

For sources that do not yet have a national standard, users should develop a constancy check calibrated against the vendor's standard and use this constancy check to verify the source strength. Other options also exist (for example the interpolative free-air standard method), but a clear protocol shall be established before such sources are used clinically.

The measurement technique designed to check the source activity (or air kerma strength) specified by the manufacturer should also consider the specified uncertainty by the manufacturer. Sources of uncertainty by the manufacturer and the local measurement technique will be the result of dosimetric corrections, influence quantities and positional errors.

Manual brachytherapy – Ru-106 Eye Plaques

A clear protocol shall be established before such sources are used clinically.

4.2 Repair and maintenance of the radiotherapy equipment

The preventative maintenance program shall be carried out by the facility's or supplier's engineers, who are specifically trained in servicing the equipment. The radiation oncology medical physicist shall be advised of the details of the work prior to the equipment returning to clinical use. There shall be a clear sign or record book to show which staff group or individual is responsible for the equipment at any time. Following servicing, equipment shall not be used clinically until released by the responsible physicist.

4.3 Radiotherapy Quality Assurance (QA) program

Each radiotherapy department in the LHD shall have their own quality assurance program, the specific details of which will depend on the equipment complexity and quality assurance resources of the radiotherapy department. Refer to local department protocols for specific quality assurance procedures.

Each department must ensure that an up-to-date local procedure is documented and used for all quality assurance activities required on radiotherapy equipment.

All clinical procedures and workflow processes related to prescription, planning, checking and delivery of radiotherapy must be documented. This documentation should be reviewed frequently (at least once per year) and used for training new staff and as a reference point for design of quality assurance of all radiotherapy processes. Modifications to processes should be considered globally not in isolation from the whole treatment workflow. All disciplines should be involved in development and modification of radiotherapy processes relating to clinical process and workflow.

The following is an outline of the minimum quality assurance procedures recommended by ARPANSA RPS C-5.

4.3.1 Linear accelerators

It must be ensured that:

- the equipment complies with the accepted tolerances listed in the ACPSEM QA recommendations (ACPSEM 1997) and the Australian Standard 4434:60601-1 and AAPM TG142 where relevant;
- the equipment is tested and calibrated at regular intervals in accordance with accepted recommendations for linear accelerators: ACPSEM (1997), Klein et al (2009) and AAPM TG142, noting that these documents are guidelines only and may be modified to suit the local requirements.

4.3.2 Kilovoltage X-ray therapy units

The Quality Assurance program for kilovoltage units (up to 400 kVp or maximum 4.5 mm Cu HVL) must ensure that:

- the apparatus complies with accepted tolerances for kilovoltage X ray apparatus listed in the ACPSEM QA recommendations (Hill et al, 2018) for kilovoltage X-ray equipment; and
- the apparatus is tested and calibrated at regular intervals in accordance with the accepted protocol for kilovoltage X ray equipment frequencies listed in the ACPSEM QA recommendations (ACPSEM 1997, Hill et al, 2018)

4.3.3 Brachytherapy Sources

The design and operation of the brachytherapy device must be considered to ensure satisfactory accuracy of treatment. Any computer program used in the dose calculation shall be checked for accuracy after every modification or upgrade. Dempsey et al (2013) outlines the quality assurance recommendations for brachytherapy equipment to be adopted.

Source calibration

The sealed source activity or reference air kerma rate stated on the supplier's consignment details shall be independently checked by an in-house radiation measurement.

Each high dose rate (HDR) source must be independently calibrated before any clinical use of the new source and the results of the check are to be documented. The new source strength shall be incorporated into the brachytherapy treatment planning calculations (manual or computerised) for dose calculations unless the results of the check measurement vary by more than 5% from the certified activity or reference air kerma rate. In this case, the source shall not be used until further independent verification of the source activity has been conducted. A brachytherapy source calibration device shall comply with the tolerances listed in the ACPSEM QA recommendations (Dempsey et al 2013) for Brachytherapy Source Calibrators.

For low dose rate (LDR) sources, it is sufficient to test a subset (minimum 10%) of the sources.

Source sterilisation

Detailed consideration of the safety of methods of sterilisation is needed, to avoid damage to a sealed source that might result in leakage or rupture.

- Caesium-137 and Strontium-90 sources shall not be heat-sterilised. Heat-sterilisation requires purpose designed, temperature-controlled equipment.

- Chemical sterilisation may be used, but attention should be paid to possible deleterious effects of some chemicals on sealed metal encapsulation of radioactive sources and on any attached threads.

Staff responsible for cleaning and sterilising of sealed sources shall be trained appropriately to prevent damage or loss and follow the recommended shielding and sterilisation procedures. Sealed radioactive sources require adequate shielding during sterilisation and from then until immediately before their insertion in the patient. Shield design shall provide protection for the body and head, including the eyes. Where possible, shielding of the fingers and hands from beta radiation shall also be provided. Sources should be manipulated with long forceps, special remote handling devices or other suitable instruments. At times it may be impracticable to provide shielding protection for brachytherapy sources, and in such circumstances, it becomes essential to maintain distance and minimise exposure time.

Brachytherapy contamination checks

Routine checks for integrity of the source, and for surface radioactive contamination of the source or associated equipment, shall be performed with a minimum frequency of:

- high dose rate brachytherapy sources: each time before the source is replaced, or annually when in continuous use;
- plaques: prior to each application.

Contamination checks shall be carried out by a person who is competent in operating the brachytherapy equipment or manipulating the source (as relevant) and in interpreting the contamination test results. Where the results of the contamination testing of afterloading brachytherapy equipment remote control equipment indicate the presence of significant contamination from the source, persons using the equipment will need to:

- cease using it immediately;
- arrange for appropriate shielding to be applied to render the area safe for personnel, as appropriate;
- arrange for the appropriately trained and authorised personnel to review the equipment and identify and correct the problem and/or replace the source, as appropriate;
- arrange thorough decontamination of the equipment before resumption of use; and
- report the incident to the Radiation Safety Officer, the relevant regulatory authority and the vendor of the source.

If the results of the contamination testing of ocular Ru-106 or Sr-90 plaques indicate the presence of significant contamination, the affected plaque will need to be withdrawn from use. If the results of the contamination testing of applicators into which radioactive seeds have been loaded indicate the presence of significant contamination, the applicators will need to be thoroughly decontaminated before resumption of use.

Brachytherapy source containers often have small internal diameters so that it may not be possible to wipe test inside the source container, although a wipe test should be performed wherever possible. When a wipe test is not possible, tests shall be made to detect radiation emitted by any radioactive contamination inside or on the outer surface of the source transfer system or applicator. Significant contamination of remote afterloading brachytherapy equipment is unlikely but is confirmed if the results of the contamination check indicate an activity of more than 200 Bq from the wipe test, or radiation greater than twice normal background from the check with a sensitive radiation detector.

Reporting to the relevant regulatory authority of significant contamination of remote afterloading brachytherapy equipment or sources is necessary so that relevant information can be disseminated to other sites using similar equipment.

Source Security

The recommendations in ARPANSA RPS11 (ARPANSA 2019) are to be followed in regard to brachytherapy source security. This includes the generation of a source security plan for any category 1, 2 or 3 radioactive sources. This plan must be approved by an EPA-accredited radiation security assessor.

Ultrasound QA

The recommendations in Pfeiffer et al (2008) are to be adopted for ultrasound systems used in prostate brachytherapy procedures.

4.3.4 CT/Simulator

The physical data and accuracy of imaging modalities used for anatomical information and for quantitative purposes in treatment planning computer systems shall be checked in accordance with AAPM TG66 and IAEA TRS 430

4.3.5 Treatment planning systems

IAEA TRS 430 (2004) shall be used in conjunction with the ACPSEM (1997) recommendations. Independent treatment planning calculations and /or verification must be performed. The specific details of these checks will depend on the type of treatment and the equipment available. All such procedures shall be documented locally and reviewed periodically to ensure their effectiveness and safety.

4.3.6 Dosimetry equipment

Dosimetry equipment and other equipment used to perform QA on radiotherapy apparatus must itself be subject to quality assurance as specified in ACPSEM 1997 and AAPM TG142 Records of all such QA must be kept securely and permanently as they form an integral component of the QA chain for the radiotherapy apparatus itself.

4.3.7 Image registration software

Image registration software must be subject to quality assurance and control, following recommendations and guidelines outlined by AAPM TG 132 (Brock et al 2017)

4.3.8 Record and Verify Systems

Quality assurance of record and verify systems used in radiotherapy must be subject to quality assurance and control, following recommendations and guidelines outlined by Shakeshaft et al (2014).

4.3.9 Radiotherapy processes

International experience has demonstrated that radiotherapy errors or overdoses can occur due to breakdowns in clinical workflow processes as well as equipment failures or dosimetry calculation errors.

It is essential that the focus of quality assurance in radiotherapy departments is not restricted to just the calibration of the physical radiotherapy equipment used. The whole process from the time of the patient's first contact with the department until their final treatment follow-up, which may occur years after the treatment, needs to be considered in the context of radiation safety.

All clinical procedures and workflow processes shall be assessed by a multidisciplinary team consisting of physicists, radiation therapists and radiation oncologists. This assessment should seek to identify any scope for introduction of treatment errors due to changes in work process or equipment or due to uncommon but potentially foreseeable circumstances.

The practice of keeping a log of incidents and near misses and evaluating these periodically is mandated by SESLHD risk and incident management policy directives. This log shall include a record of occurrences that represent errors that were detected including those before they caused any harm. This will identify those categories of events which either have potential for serious harm or are less serious but frequently occurring. Periodic analysis of these records will enable the procedures in the department to be improved and reduce the possibility of significant errors in future.

Radiation accidents reportable to the EPA NSW as per the NSW Radiation Control Regulation 2013 shall have a report submitted through the IMS+ system. The IMS+ number will be included in the report sent to the SESLHD RSO.

4.3.10 Dosimetry Audits

SESLHD is committed to ensuring the accuracy of the radiotherapy process is maintained. As such, a contract with the Australian Clinical Dosimetry Service (ACDS) is

set up such that linear accelerator systems are audited annually. All newly installed linear accelerators are also audited prior to clinical release to ensure the radiation output is calibrated correctly.

5. DOCUMENTATION

The following documentation must be maintained by the radiotherapy department manager:

- Records of acceptance and commissioning tests to be kept indefinitely either in paper or electronic form.
- Records of all periodic equipment QA to be kept indefinitely either in paper or electronic form.
- Records of Multidisciplinary QA meetings to be kept indefinitely either in paper or electronic form.
- Records of treatment planning system computer software validation following modifications and upgrades.

6. AUDIT

The following audits are to be performed by the facility Radiation Safety Officer:

- Annual review of QA records.

7. REFERENCES

7.1 NSW Health Resources

- NSW Ministry of Health Policy Directive PD2017_032 - Clinical Procedure Safety
- NSW Ministry of Health Policy Directive PD2015_043 - Enterprise-wide Risk Management

7.2 External Resources

- ARPANSA (2007), *Code of Practice for Security of Radioactive Sources* Radiation Protection Series (RPS) Publication No. 11, ARPANSA Yallambie 2007
- ARPANSA Radiation Protection in Planned Exposure Situations; Radiation Protection Series C-1 , ARPANSA, Yallambie 2016
- ARPANSA Code for Radiation Protection in Medical Exposure; Radiation Protection Series C-5 ARPANSA, Yallambie 2019

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8. VERSION AND APPROVAL HISTORY

Date	Version	Version and approval notes
August 2010	Draft	Area Radiation Safety Officer in conjunction with the Area Radiation Safety Committee
February 2011	0	Approved Combined Clinical Council
December 2015	1	Periodic Review
March 2020	2	Periodic Review – Anna Ralston, Simon Downes, Andrew Howie
14 July 2023	3	Minor review: removal of Quality Assurance Committee, addition of IIMS+ details. Approved by Executive Sponsor.