# SESLHD PROCEDURE COVER SHEET

| | |
|---|---|
| **NAME OF DOCUMENT** | Radiation Safety - Calibration and Quality Assurance Procedures for Radiological and Radiation Safety Instruments |
| **TYPE OF DOCUMENT** | Procedure |
| **DOCUMENT NUMBER** | SESLHDPR/553 |
| **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/50 Calibration and Quality Assurance Procedures for Radiological and Radiation Safety Instruments |
| **EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR** | Director People and Culture |
| **AUTHOR** | Brent Rogers, SESLHD Radiation Safety Officer<br>Erin McKay, RSL SESLHD St George Hospital |
| **POSITION RESPONSIBLE FOR THE DOCUMENT** | District Radiation Safety Officer<br>SESLHD-RadiationSafetyOfficer@health.nsw.gov.au |
| **KEY TERMS** | Radiation safety; radiology; medical imaging; nuclear medicine; calibration; quality assurance |
| **SUMMARY** | Procedure for the calibration and quality assurance of equipment used in medical imaging, nuclear medicine and radiation monitoring. |

# Radiation Safety - Calibration and Quality Assurance Procedures for Radiological and Radiation Safety Instruments

SESLHDPR/553

## 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 calibration and quality assurance of equipment used in medical imaging, nuclear medicine and radiation monitoring.

## 2. BACKGROUND

## 3. RESPONSIBILITIES

### 3.1 The Chief Executive:

In accordance with the ARPANSA Medical Code of Practice (RPS-14), the Chief Executive must ensure that a comprehensive equipment Quality Assurance program is established, performed, maintained and regularly reviewed at any site where radiation-producing equipment or radioactive sources are used.

The Chief Executive must also ensure that a Quality Assurance program for all dosimetry and associated measuring instruments is implemented and regularly reviewed to ensure continued accuracy of these devices.

The Chief Executive must also ensure that the results of each Quality Assurance program and their outcomes are clearly documented.

The Chief Executive must, following any repair, maintenance or modification on radiation-producing equipment, or equipment containing radioactive source(s), that could impact radiation safety, ensure that:

a) the operation of the equipment is re-assessed so that the radiation safety of patients, staff and the public is maintained

b) a radiation survey is carried out by a medical physicist.

### 3.2 The Radiation Safety Officer (RSO), Medical Physicist or Chief Radiographer:

The RSO, medical physicist or chief radiographer (for paragraphs 4.1 – 4.3) must undertake or oversee the calibration and quality assurance program, and carry out any radiation surveys that are required.

### 3.3 The Radiographer or Nuclear Medicine Technologist:

The radiographer or nuclear medicine technologist must undertake the calibration and quality assurance program according to the protocols approved by the RSO or medical physicist.

## 4. PROCEDURE

### 4.1 Calibration, acceptance and tests of diagnostic and interventional radiation apparatus

All diagnostic and interventional x-ray equipment used in NSW must be registered with the NSW Environment Protection Authority (EPA). In order to be registered the equipment must pass a series of compliance tests performed by a Consulting Radiation Expert (CRE) who has been accredited by the EPA for the particular class of equipment (mammography, dental, general radiography, etc.). The requirements for compliance and registration are specified in NSW Radiation Guideline 6 requirements and industry best practice for ionising radiation apparatus used in diagnostic imaging.

All new x-ray equipment must be tested for compliance using the test protocols in part 6 of this Guideline. Any deficiencies identified by the CRE must be corrected and retested by the CRE before the equipment can be used clinically. Compliance testing must be repeated at intervals of either two or five years. Equipment which produces relatively high doses, such as CT scanners, has a two year compliance period, while low-dose equipment, such as bone densitometers, has a five year compliance period.

### 4.2 Repair and maintenance of diagnostic and interventional radiation apparatus

Radiation apparatus must only be repaired by qualified service engineers who possess a current radiation licence. Whenever the repair may have compromised the imaging performance of the equipment or any of the radiation safety features the relevant compliance tests must be repeated and passed successfully before the equipment is reused clinically. If the x-ray tube is replaced, the full compliance tests must be performed and the Certificate of Compliance sent to the EPA.

### 4.3 Radiology Quality Assurance

#### 4.3.1 Acceptance Testing

At installation, a series of acceptance tests should be performed to define the acceptable range of parameters that will be monitored in the subsequent constancy tests. The compliance tests necessary for equipment registration will form part of the acceptance tests.

#### 4.3.2 Constancy Testing

Constancy tests designed to assess the subsequent performance of the equipment, image quality and patient dose should be performed at regular intervals. The following table of testing frequencies has been recommended by the ACPSEM (Recommendations for a technical quality control program for diagnostic X-ray equipment, 2008).

| Category of Equipment | Recommended Interval Between Tests |
|---|---|
| Mammographic, CT and fluoroscopic X-ray apparatus (Fixed or mobile). | 6-12 months |
| General radiographic x-ray apparatus | 12 months. (Maximum 24 months) |

| | |
|---|---|
| (including dental OPG and cephalometric) | |
| CR/DR image receptors and other image processing systems | 12 months |
| Dental (intra-oral) and DEXA | 36 months |

The frequency of inspection recommended for the different classes of equipment is seen as a compromise between the potential for injury to individual patients undergoing imaging based procedures, the inherent reliability of different modalities and the cost and inconvenience of testing. The RANZCR, in its Standards of Practice for Diagnostic and Interventional Radiology, Version 9, require the following minimum equipment quality control:

### 4.3.3 BMD Equipment Quality Control (8-2-2)

Practices performing BMD must comply with the quality control requirements of the Accreditation Guidelines for Bone Densitometry, published by the ANZBMS". This requires:

- At time of installation, machine calibration and testing by supplier. Accuracy and precision evaluation
  - In vitro: short-term precision
  - In vivo: short-term precision
- Calibration and quality control according to manufacturer's specifications. The QC phantom shall be scanned at least twice weekly (and preferably daily) using the same scanning parameters. This phantom is not the daily calibration phantom, but is an anthropomorphic (or quasi-anthropomorphic) phantom recommended by (or at least acceptable to) the manufacturer.

### 4.3.4 CT Performance Testing (9-1-1)

The practice shall undertake all quality control requirements as determined by the manufacturer including maintenance and calibration.

### 4.3.5 CT Dose (9-3-4-2)

The practice maintains and regularly reviews CT scanning protocols which are optimised to limit patient radiation exposure.

Where the CT unit being used is capable of displaying DLP or CTDI figures, the practice shall review CT patient dosimetry for specific common scan protocols, and shall document the typical dose length product for the specified protocols.

### 4.3.6 General X-Ray Image Review - Plain Film (10-3-2-1)

The practice shall ensure that X-Ray repeats are monitored and reviewed in adherence to the ALARA Principle.

### 4.3.7 CR/DR Performance Testing (10-3-2-2)

The practice shall maintain a Quality Assurance (QA) program specifically designed to assess the performance of its CR/DR equipment. The practice shall as a minimum follow the manufacturer's recommended QC program.

While the practice shall as a minimum adopt any QA program specifically developed by the manufacturer for the CR/DR equipment, an acceptable QA program must, as a minimum, include:

- Maintaining dose output records (to commence from acceptance testing) and reviewing dose optimisation at least 6 (six) monthly ensuring that any general increase in dosage levels is identified and examined, and where required corrected
- Conducting a repeat analysis and recording findings and corrective and/or preventive action taken.

### 4.3.8 Radiation Safety - Fluoroscopic Examinations (10-4-1)

A log must be maintained of screening times and (where the fluoroscopy equipment is capable of this) dose for all fluoroscopic examinations. Corrective action shall be taken as necessary to minimise patient exposure.

### 4.3.9 Diagnostic Mammography Quality Control for Film Screen Mammography Units (13-2-2)

There must be documented procedures for quality control checks as specified in the ACPSEM Standard for Facility Quality Control Procedures" (Craig AR et al, Recommendations for a mammography quality assurance program, Appendix 1, Aust Phys Eng Sci Med, 2001, 24:107-131).

### 4.3.10 Diagnostic Mammography Annual Equipment Testing (13-2-3)

Mammography equipment must be tested annually in accordance with the ACPSEM Standards for Mammography System Performance and Medical Physics Testing" (Craig AR et al, Recommendations for a mammography quality assurance program, Appendix 2, Aust Phys Eng Sci Med, 2001, 24:107-131).

### 4.3.11 Diagnostic Mammography Annual Equipment Testing - CR/DR Mammography Equipment (13-2-4)

Computed radiography (CR) and full field digital (DR) mammography equipment shall be tested in accordance with the manufacturer's guidelines, and the RANZCR Mammography Quality Assurance Program (CR/DR).

### 4.3.12 Mammography Radiation Dose Limit (13-6-1)

The practice must not exceed the Mammography Radiation Dose Limit requirements of the RANZCR Mammography Quality Assurance Program. The average glandular dose as

determined by the dosimeter must not exceed 2 mGy (200 mrad) per view, using the RMI-156 phantom or another of equivalent constitution.

### 4.4 Calibration, acceptance and tests of nuclear medicine equipment

Nuclear Medicine Quality Assurance programs focus on image quality, radiopharmaceutical quality and patient dose optimisation. The basic elements consist of:

- equipment acceptance testing
- equipment constancy testing
- radiopharmaceutical quality testing
- record keeping
- patient activity surveys
- keeping records of equipment unscheduled downtime and the reason for the failure.

#### 4.4.1 Acceptance Testing of Nuclear Medicine Equipment

At initial installation, the nuclear medicine equipment (e.g. radionuclide dose calibrators, gamma cameras, PET cameras, autogamma counters, laser film imagers) need to undergo acceptance testing to ensure that the equipment performance complies with the manufacturer's specifications and also to establish a baseline against which future equipment performance can be evaluated. The results of the acceptance testing will need to be documented and available for inspection by the relevant regulatory authority.

Any radionuclide sources used in performing accuracy checks of radionuclide dose calibrators will need to have a calibration traceable to a national or international standard.

### 4.5 Repair and maintenance of the nuclear medicine equipment

Nuclear Medicine equipment must only be repaired / maintained by qualified service engineers who possess a current radiation licence covering the use of radioactive substances for quality assurance purposes.

Following calibration or repair (prior to clinical use), equipment performance must be assessed to demonstrate that it is at a level which equals or is better than that expected for routine performance of clinical work. This judgement would be made by comparison of the equipment performance to baseline or recent quality control assessments.

### 4.6 Nuclear medicine Quality Assurance, including radiopharmaceutical QA

Local QA programs should clearly define the:

- types of constancy tests
- frequency of tests
- tolerance of each parameter being monitored
- procedure for staff to follow when tolerance is exceeded.

The results of constancy testing need to be reviewed as a matter of routine and any anomalous results reported immediately to the Responsible Person, usually the department physics staff. Tests designed to assess the performance of the equipment must be conducted, taking into account:

- the likelihood of an equipment failure or a measured parameter falling outside an acceptable tolerance range
- the consequences that follow when such an event occurs.

### 4.6.1 Gamma Cameras

Suggested Gamma Camera tests and frequencies are outlined in the document "Minimum Quality Control Requirements for Nuclear Medicine Equipment," prepared by the Technical Standards Committee of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM).

### 4.6.2 PET Equipment

For PET equipment, the Technical Standards Committee of the Australian and New Zealand Society of Nuclear Medicine (ANZSNM) have produced the document "Requirements for PET Accreditation (Instrumentation & Radiation Safety)" which outlines Minimum performance parameters for the PET scanner in an accredited PET facility measured using NEMA NU2-2001 protocols.

Current required performance parameters are as follows:

| Parameter | Specification |
|---|---|
| resolution at 1 cm radius | <= 6.5 mm |
| Axial resolution at 1 cm radius | <= 6.0 mm |
| Transverse (tangential) resolution at 10 cm radius | <= 8 mm |
| Axial resolution at 10 cm radius | <= 8 mm |
| System sensitivity | >= 4.0 cps/kBq |
| Peak noise equivalent count rate ($NEC_{peak}$) at activity concentrations of 10 kBq/ml | >= 30 kcps |
| Maximum count rate error over the central 80% of axial FOV (after dead time correction) at or below $NEC_{peak}$ | <= 10% |

### 4.6.3 Testing of Dose Calibrators

For dose calibrators, the following tests should be conducted at the frequency indicated below, and to the indicated tolerance:

- background – at least once each work day prior to the first assay of patient dosages or whenever contamination of the dose calibrator is suspected
- constancy – at least once each work day prior to the first assay of patient dosages (±10%)
- linearity – at installation and at least annually thereafter, and after repair or movement (±10%)

- accuracy – at installation and at least annually thereafter, and after repair or movement (±10%)
- geometry independence – at installation and after repair or movement (±10%).

Recommended testing frequencies for dose calibrator quality control procedures are as follows:

| Quality Control Procedure | Testing Frequency |
|---|---|
| Constancy | Daily |
| Linearity | Annually |
| Accuracy | Annually |
| Geometry independence | At calibrator acceptance and then for any change in sample geometry |

Repair, replacement, or arithmetic correction will need to be conducted if the dose calibrator falls outside the indicated tolerances.

Details of procedures that may be used to meet these test requirements are provided in Annex F of ARPANSA's Radiation Protection Series No. 14.2 Safety Guide Radiation Protection in Nuclear Medicine.

### 4.6.4 Testing Radiopharmaceutical Quality

The in vivo behaviour of a radiopharmaceutical is dependent upon its quality, which includes high standards of radionuclidic, radiochemical and chemical purity. The specifications and quality control testing for most of the currently used radiopharmaceuticals are given in the British Pharmacopoeia (BP) or other suitable Pharmacopoeia (eg, USP). There should be written local procedures detailing all aspects of quality control testing that should be considered before the radiopharmaceutical is administered to the patient.

Technetium-99m Generator

A molybdenum-99 breakthrough measurement needs to be performed on all elutions from each technetium-99m generator and the following records kept of all generator elutions:

- dose calibrator setting where the isotope is manually dialled
- reading of long-lived reference source
- time of elution
- volume of eluate
- technetium- 99m activity
- molybdenum-99 activity
- radionuclidic purity.

BP specification for molybdenum-99 impurity in sodium pertechnetate eluate is 0.1% or a limit of 1 MBq of molybdenum-99 per GBq of technetium-99m at the time of administration. If this level is exceeded, then the technetium-99m solution has failed

quality control and is not to be used in the preparation of radiopharmaceuticals for patient use. (Note: The US pharmacopoeia limit of 0.15 MBq Mo-99 per GBq Tc-99m is also commonly used).

Aluminium ion breakthrough should also be checked on any eluate used to prepare products that are adversely affected by the presence of aluminium.

Technetium-99m cold kits

All technetium-99m cold kits should be reconstituted in accordance with the manufacturer's instructions. The (internal) written procedures detailing the method for reconstitution should also state the quality control testing that is to be carried out on each particular product. The procedure should therefore include any appropriate radiochemical purity testing to be performed on the reconstituted kit prior to patient administration.

### 4.7 Use, maintenance and calibration of radiation measuring instruments

Proper radiation survey meters must be used for each radiation survey required by this Plan. A survey meter is considered proper if it:

- has sufficient measurement range to measure ambient dose equivalent rates at least throughout the ranges of 0.5 Sv $hr^{-1}$, or its equivalent, to 1 mSv $hr^{-1}$ (2 mSv $hr^{-1}$ for radiotherapy use) or its equivalent from the radioactive sources used
- continues to indicate, either visibly or audibly, when radiation levels exceed the maximum reading in any measurement range
- indicates the measured quantity with a measurement uncertainty not greater than ± 25% inclusive of uncertainty due to response variation with energy over the range of energies of the radiation to be measured.

Radiation survey meters used as above must have an operational and calibration check performed:

- Prior to initial use
- At intervals not exceeding 12 months
- Following damage or repairs.

## 5. DOCUMENTATION

- SOPs for each Quality Assurance program instituted by a Department.

## 6. AUDIT

The following records should be available for audit:

- Acceptance testing reports for all radiological apparatus
- Regular quality assurance measurements on radiological apparatus
- Records of radiopharmacy quality assurance and control procedures
- Records of repair, modification and testing of radiological apparatus
- Compliance certificates for all diagnostic radiological apparatus

- Calibration of dosimetry and dose measuring instruments
- Logs of screening times for fluoroscopic apparatus.

## 7. REFERENCES

[1] ARPANSA RPS-14 Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)

[2] ARPANSA RPS14.1 Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (2008)

[3] ARPANSA RPS14.2 Safety Guide for Radiation Protection in Nuclear Medicine (2008)

[4] ARPANSA RPS14-3 Safety Guide for Radiation Protection in Radiotherapy (2008)

[5] ANZBMS Accreditation Guidelines for Bone Densitometry (2007)

[6] ANZSNM Minimum Quality Control Requirements for Nuclear Medicine Equipment (2013)

[7] ANZSNM Requirements for PET Accreditation (2013)

[8] RANZCR Standards of Practice for Clinical Radiology, Version 11 (2019)

[9] NSW Radiation Guideline 6 Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging.

[10] ACPSEM Position Paper: Recommendations for a technical quality control program for diagnostic X-ray equipment, Aust Phys Eng Sci Med, 2008, 28:69-75

[11] Craig AR et al, Recommendations for a mammography quality assurance program, Aust Phys Eng Sci Med, 2001, 24:107-131

## 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 |
| February 2011 | 0 | Approved by Combined Clinical Council |
| January 2016 | 1 | Radiation Safety Officer |
| November 2016 | 1 | Review and updates approved by Executive Sponsor |
| March 2020 | 2 | Review and updates approved by Executive Sponsor |