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	April 2024
RISK RATING	Medium
LEVEL OF EVIDENC	National Safety and Quality Health Service Standards: Standard 1 – Clinical Governance Legislative requirements
REVIEW DATE	April 2027
FORMER REFERENCE(S)	SESLHNPD/50 Calibration and Quality Assurance Procedures for Radiological and Radiation Safety Instruments
EXECUTIVE SPONSOR	Executive Director Operations
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FUNCTIONAL GROUP(S)	Radiation Safety
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 and in relation to the calibration and quality assurance of equipment used in medical imaging, nuclear medicine, and radiation monitoring.

2 BACKGROUND

A calibration and 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.

3. RESPONSIBILITIES

3.1 The Chief Executive:

In accordance with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code for Radiation Protection in Medical Exposure: Radiation Protection Series C-5[1], the Chief Executive is responsible for ensuring that comprehensive Quality Assurance (QA) programs are established, performed, maintained, and regularly reviewed at any site that has radiation-producing equipment or where radioactive sources are used.

In accordance with C-5 [1], the Chief Executive is responsible for ensuring that programs of QA include:

1. measurement of physical parameters of medical radiological equipment:
    - i) at time of acceptance and commissioning, prior to the equipment being placed into clinical use for patients.
    - ii) periodically thereafter, as required by the relevant regulatory authority and according to national guidelines.
    - iii) after any maintenance or repair of the equipment that could affect performance or impact patient safety.
    - iv) after any installation of new software or following modification of existing software that could impact equipment performance or patient safety.
2. implementation of corrective actions if measured values of physical parameters are outside locally established tolerance limits.

3. verification that appropriate physical parameters and clinical protocols are used in radiological procedures
4. maintenance of records of QA procedures, results and any corrective actions, including documentation of repair, maintenance and modification work.
5. implementation and periodic checks of the calibration and operation conditions of dosimetry equipment, reference equipment and monitoring equipment.

In relation to calibration, the Chief Executive must ensure that:

1. all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using protocols endorsed by the relevant regulatory authority and professional bodies.
2. calibrations relevant to the intended clinical use are carried out at the time of acceptance/commissioning of the equipment prior to clinical use, after any maintenance procedure that could affect dosimetry, and at intervals approved by the relevant regulatory authority.
3. calibration of all dosimeters used for dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory and is undertaken at intervals approved by the relevant regulatory authority.
4. calibration of all reference equipment is traceable to relevant national standards.

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

The medical physicist or chief radiographer (for paragraphs 4.1- 4.2) must establish the calibration and quality assurance programs, and thereafter either undertake or oversee the programs. At a minimum, a medical physicist must provide documented advice on the programs [1] and approve the protocols to be followed by the staff group delegated to undertake the program.

The medical physicist or chief radiographer must undertake a 2-yearly review of the programs, against the requirements set by the relevant regulatory authority and the guidelines/position papers set by professional bodies. Any updates to the programs must be undertaken with documented advice from a medical physicist.

The RSO, medical physicist or chief radiographer must also carry out any radiation surveys that are required.

3.3 The Radiographer or Nuclear Medicine Technologist:

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

4. PROCEDURE

4.1 Diagnostic and image-guided interventional equipment quality assurance

4.1.1 Acceptance testing

All diagnostic and interventional x-ray equipment used in NSW must be registered with the NSW EPA.

All new x-ray equipment must undergo acceptance testing as specified by NSW EPA Radiation Standard 6: Compliance requirements for ionising radiation apparatus used in diagnostic imaging (2020) Part 1 to 7 [2] and comply with the minimum performance requirements of the Standard relevant to the class of equipment. Acceptance testing must be performed by a Consulting Radiation Expert (CRE) who has been accredited by the EPA for the class of equipment being tested (mammography, dental, general radiography, etc.) and follow the protocols of the Standard.

The site must receive an acceptance test report from the CRE following testing and be provided with confirmation of the equipment's compliance status. Any deficiencies identified must be corrected within the timeframe specified by, and following the recommendation of, the CRE. The report and confirmation of compliance must be held for a period of two years after disposal of the apparatus, as per condition 8.2.2 of a radiation management licence, and be available for inspection by the relevant regulatory authority.

Additional acceptance and commissioning tests are to be conducted locally by a medical physicist to verify the performance of the equipment against manufacturer's specification and establish acceptable ranges and baselines of physical parameters against which future equipment performance can be evaluated.

A physics acceptance/commissioning report should be provided to the senior radiographer of the area and the chief radiographer of the department. The report must include the results of tests performed, identification of any deficiencies or parameters outside acceptable tolerances, and any corrective action, recommendations, or conditions of use for the clinical user.

Record should be held for a period of two years after disposal of the apparatus.

4.1.2 Periodic compliance testing and quality control testing

Compliance testing for all diagnostic and image-guided interventional x-ray equipment must be performed periodically following acceptance, following the testing protocols and the frequency intervals required by NSW EPA Radiation Standard 6 [2]:

Modality	EPA Compliance Test interval
Mammography	Annually
Fluoroscopy (fixed or mobile)	2 yearly
Computed Tomography	2 yearly
Dentistry (including maxillofacial)	5 yearly
General radiography (medical – fixed and mobile) and Bone Mineral Densitometry	5 yearly

Any changes to the frequency requirements of Radiation Standard 6 (detailed above) must be adopted and implemented as per instruction by the EPA.

Compliance testing must be performed by a Consulting Radiation Expert (CRE) who has been accredited by the EPA for the class of equipment to be tested and tested as per the protocols of Radiation Standard 6.

The site must receive a compliance test report from the CRE following testing and be provided with confirmation of the equipment's compliance status. The report and confirmation of compliance must be held for a period of two year after disposal of the apparatus, as per condition 8.2.2 of a radiation management licence, and be available for inspection by the relevant regulatory authority. Any deficiencies identified in the report must be corrected within the timeframe specified by, and following the recommendation of, the CRE.

Local routine quality control (QC) programs are to be instituted and maintained by the site to assess, monitor, and maintain adequate imaging performance, patient dose and radiation safety. At a minimum, programs must at comply with the QC and QA requirements of Radiation Standard 6 [2] and that of the manufacturer (including maintenance and calibration).

Comprehensive programs should additionally adopt the QC recommendations of the Royal Australian and New Zealand College of Radiologists' (RANZCR) Standards of Practice for Diagnostic and Interventional Radiology, Version 11.2, (2020) [6], RANZCR's General X-ray QA and QC Guidelines (2013) [12] and the Australasian College of Physical Scientists and Engineers in Medicine's (ACSPEM) Recommendations for a technical quality control program for diagnostic X-ray equipment, (2008) [7], as appropriate.

Local QC programs must clearly define and document the:

- types of routine quality control tests.
- testing protocols (including identification of tests to be performed following repair/maintenance or modification of components of the equipment).
- frequency of tests.
- tolerance of each parameter being monitored.
- procedure for staff to follow when tolerance is exceeded.

The results of QC testing must be recorded and reviewed as a matter of routine. Records must document:

- measured values of physical parameters tested.
- any deficiencies or parameters outside acceptable tolerances
- if applicable, the corrective action taken to address any deficiencies/out of tolerance results.
- if applicable, any conditions of use for the equipment.

Periodic services, as required by the manufacturer, must also be undertaken as part of periodic testing, and record of service held locally by site for each piece of x-ray equipment.

4.1.2.1 Screening and Diagnostic Mammography

Breast screening units must additionally follow the requirements of Breast Screen Australia's National Accreditation standards.

Diagnostic mammography equipment of sites accredited with RANZCR Mammography Quality Assurance Program (MQAP) must follow and comply with the requirements of the program. This includes routine testing by a ACPSEM Certified Mammography Equipment assessor and local routine quality control testing by the technologist. Testing must be performed in accordance with the frequency and protocols specified by the program.

Documentation and record keeping must follow that required by the RANZCR MQAP program.

4.1.2.2 Bone Mineral Density Equipment (BMD)

Practices performing BMD must additionally comply with the routine quality control requirements of the Accreditation Guidelines for Bone Densitometry, published by the Australian and New Zealand Bone and Mineral Society (ANZBMS) [3]. This includes:

- At time of installation, machine calibration and testing by the 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.

4.1.3 Repair, maintenance or modification work

Radiation apparatus must only be repaired by qualified service engineers who possess a current radiation licence. Record and documentation of any maintenance or repair work must be provided to the site by manufacturer and held locally.

Following replacement of the x-ray tube or imaging detector of any x-ray equipment, the compliance tests specified by EPA NSW Radiation Standard 6 must be performed by an EPA accredited CRE before the equipment is placed back into clinical use. The site must receive a compliance test report from the CRE following testing and be provided with confirmation of the equipment's compliance status. The report and confirmation of compliance must be held for a period of two year after disposal of the apparatus as per condition 8.2.2 of a radiation management licence, and be available for inspection by the relevant regulatory authority. Any deficiencies identified in the report must be corrected within the timeframe specified by, and following the recommendation of, the CRE.

Local quality control testing is to be performed following repair, maintenance or modification (including software installation/changes) that may compromise the equipment performance or any radiation safety features. The tests required should be identified in local quality control program. Testing should verify that measured physical parameters are within local tolerance limits (or, where appropriate, new baselines should be set) prior to the equipment being place back into clinical use. Record and documentation of testing should follow the same requirements as outlined in paragraph 4.1.2 of this procedure.

4.1.4 Calibration of dosimeter reference equipment

Dosimeter reference equipment used for acceptance and routine quality control testing of x-ray equipment must hold a current calibration at time of testing, and calibration must be traceable to an Australian or international primary or secondary standard. Calibration must be performed as per the manufacturer's requirements, or at least every two years.

Dosimetry reference equipment should only be used if:

- calibration is within date.
- operation and functions are working correctly.
- suitable and capable of measuring the radiation type, energy range and dose rate in question.

Calibration certificates must be held locally and available for inspection by the relevant regulatory authority.

Calibration certificates are to be reviewed annually to ensure conditions of operation are suitable for current use.

4.1.5 Establishment and Review of Clinical

Verification of the appropriateness of clinical protocols and physical parameters used for radiological procedures must be conducted at point of commissioning/acceptance of equipment, prior to it being placed into clinical use, with a relevant and appropriately qualified radiologist. Thereafter, routine annual review must be conducted.

Record of current clinical protocols and physical parameters, as well as their periodic review must be documented and held locally.

4.2 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.

4.2.1 Acceptance Testing of Nuclear Medicine Equipment

At initial installation, the nuclear medicine equipment (e.g., radionuclide dose calibrators, gamma cameras, PET cameras, auto-gamma counters, laser film imagers) need to undergo acceptance testing to ensure that the equipment performance complies with the manufacturer's specifications and 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.

4.2.2 Repair and maintenance of 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, prior to clinical use. This judgement would be made by comparison of the equipment performance to baseline or recent quality control assessments. This also applies to any installation of new or modification of current software, that is expected to affect or impact the performance of the equipment.

Service reports must be held locally for the lifetime of the equipment, and available for inspection by the relevant regulatory authority.

4.2.3 Nuclear medicine Quality Control, including radiopharmaceutical QA

Local quality control (QC) programs should clearly define and document 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 recorded and 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, considering:

- 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.

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].

PET Equipment

The Australian and New Zealand Society of Nuclear Medicine (ANZSNM) Technical Standards Committee publication: "Requirements of PET Accreditation (Instrumentation & Radiation Safety). 3rd Edition (2017) V 1.0" [5] sets out the minimum standards that must be met by any centre claiming MBS rebates for PET.

This sets out both minimum performance standards, and the minimum requirements for quality assurance.

A facility performing PET must have:

- A dedicated PET camera with performance that meets the ANZSNM's published specifications.
- A dose calibrator that is designed to measure PET radionuclides.
- Suitable facilities designed to minimise radiation exposure of staff.
- A quality assurance (QA) plan and calibration schedule for all equipment used in the PET imaging procedure with appropriate record-keeping that is available for inspection at any time. This QA plan must be under the active supervision of a Nuclear Medicine Physicist.
- A documented radiation safety program, actively supervised by a designated Radiation Safety Officer.

4.2.4 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 workday prior to the first assay of patient dosages or whenever contamination of the dose calibrator is suspected
- constancy – at least once each workday 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 [11].

Dose calibrators must be calibrated periodically, and the radiation sources used for calibration must be traceable to a national primary standard. It is recommended that department' participate in ANTSO's Australian Nuclear Medicine Traceability Program.

Calibration certificates must be held by the site and available for local audit and inspection by the relevant regulatory authority.

4.2.5 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 (e.g., 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, as well a record of the results of quality control testing performed.

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.

4.2.6 Use, maintenance and calibration of radiation survey meters

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

Records of checks completed, and their results, must be held locally.

Radiation survey meters must hold calibration that is traceable to national primary standard. Calibration certificates must be held by the site and available for local audit and inspection by the relevant regulatory authority.

4.2.7 Establishment and review of clinical protocols used for nuclear medicine procedures.

Verification of the appropriateness of clinical protocols and physical parameters used for nuclear medicine procedures must be conducted at point of commissioning/acceptance of equipment, prior to it being placed into clinical use, with a relevant and appropriately qualified radiologist. Thereafter, routine annual review must be conducted.

Record of current clinical protocols and physical parameters, as well as their periodic review must be documented and held locally.

5. DOCUMENTATION

- Standard Operating Procedures (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
- Radiopharmacy quality assurance and control procedures
- 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 Radiation Protection Series C-5, Code for Radiation Protection in Medical Exposure (2019)

[2] NSW EPA Radiation Standard 6 Compliance requirements for ionising radiation apparatus used in diagnostic imaging: Part 1 to 5 (2020)

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

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

[5] ANZSNM Requirements for PET Accreditation (Instrumentation & Radiation Safety), 3rd Edition (2017) V1.0, ANZSNM Technical Standards Committee

[6] RANZCR Standards of Practice for Clinical Radiology, Version 11.2 (2020)

[7] ACPSEM Position Paper: Recommendations for a technical quality control program for diagnostic X-ray equipment, Aust Phys Eng Sci Med, 2005 28:69-75

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

[9] ACPSEM Position Paper: Recommendation for digital mammography quality assurance program 4.0 (2017)

[10] RANZCR Guidelines for Quality Control Testing for Digital (CR&DR) Mammograph, Version 4.0 (2018)

[11] ARPANSA Radiation Protection Series No. 14.2 Safety Guide Radiation Protection in Nuclear Medicine (2008)

[12] RANZCR General X-ray Quality Assurance and Quality Control Guidelines V1 (2013)

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
January 2016	1	Radiation Safety Officer
November 2016	1	Review and updates approved by Executive Sponsor
December 2019	2	Review and updates approved by Executive Sponsor
26 April 2024	3.0	Major review: to facilitate compliance with ARPANSA documents C1 and C5; acceptance testing requirements for all modalities of diagnostic and therapeutic apparatus updated. Approved by SESLHD Clinical and Quality Council.