Final Draft
Radiation Guideline 6:
Compliance requirements for
ionising radiation apparatus
used in diagnostic imaging

Part 1: Mammography
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Introduction

A mammogram is widely accepted as the most effective tool in the early detection of breast cancer. However, there is a small but significant risk associated with mammography of a patient developing radiation-induced cancer. This makes the technical aspects of the procedure extremely important.

Mammography is one of the most technically difficult radiographic examinations to perform. Specialised apparatus, correct use of that apparatus and rigorous adherence to a quality assurance program are essential to ensuring optimum results.

The success of mammography depends on the production of high-quality images and the delivery of low radiation doses to the patient. Poor-quality mammograms not only lead to a lower rate of detection of breast cancer, but also contribute to unnecessary radiation from repeat examinations.

The complexities of modern mammography apparatus make regular performance monitoring essential for maintaining optimum image quality. It is important that the performance level of each apparatus is established during acceptance testing, and that performance standards are maintained over time by an appropriate quality assurance program. Inadequate performance and quality assurance procedures may cause an unnecessary increase in radiation exposure to the patient and staff and a decrease in the diagnostic value of the examination.

The objectives of this guideline are to:

- ensuring that adequate safety measures are provided to protect patients, occupationally exposed workers and the public from unnecessary radiation exposure
- improving the standard of radiation apparatus in use
- ensuring better monitoring of apparatus performance.

This mammography radiation guideline is for the information of person responsible and licensed users of mammographic apparatus, and persons accredited under section 8 of the Radiation Control Act 1990 as Consulting Radiation Experts (CREs). It is to be used by CREs in the assessment of mammographic apparatus for compliance with conditions of radiation management licence, and should be read in conjunction with the Act and the Radiation Control Regulation 2013. In the event of an amendment to the Act or Regulation, references to the legislation in this document must be deemed to refer to the current legislation. In the event of an inconsistency between the Guideline and the legislation, the requirements of the legislation prevail to the extent of the inconsistency.

This document sets out the minimum requirements for compliance of mammographic diagnostic imaging apparatus, which are stated as ‘must’ statements and are listed in Schedule 1, and promotes industry best practice in radiation safety for the performance of high-quality mammographic examinations.

The guideline was developed by the Radiation Regulation Unit of the EPA in consultation with the Radiation Advisory Council, the Royal Australian and New Zealand College of Radiologists (RANZCR), the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM), and the School of Medical Radiation Technology, Faculty of Health Sciences, University of Sydney.

The EPA acknowledges the assistance of A/Prof Lee Collins, Dr Richard Smart, Dr Philip Pasfield, Mr Paul Cardew, Dr Jennifer Diffey, Dr Ravinder Grewal, Ms Tiffany Chiew, Mr Glen Burt, Dr Donald McLean, Mr Adam Jones and the input received from stakeholders, in preparing this edition.
1. **General requirements and recommendations**

1.1 **Advice to person responsible**

1.1.1 Compliance testing of diagnostic imaging apparatus for the purpose of certification for compliance must be conducted by an EPA-accredited Consulting Radiation Expert (CRE).

1.1.2 Requirements listed in Schedule 1 of this Guideline must be met for compliance of mammography apparatus.

1.1.3 The responsible person must have equipment quality control records available to the inspecting authority and to a CRE on request (details of quality assurance and quality control programs are discussed in sections 2 - 3 of this Guideline).

1.1.4 Specifications for radiation shielding of protective barriers and the design details of rooms used for ionising radiation apparatus should be determined in accordance with Radiation Guideline 7: Radiation shielding design, assessment and verification requirements and documented by an appropriately qualified person before building works start.

1.1.5 The provision of radiation shielding should ensure that the radiation levels behind the shielding comply with the requirements of Radiation Guideline 7.

1.1.6 A protective shield must be provided for the operator’s use.

1.1.7 Where a fixed protective shield is provided it should be not less than 2100 mm in height.

1.1.8 The operator, when behind the protective shield, must have a clear view of the patient and must be able to communicate easily with the patient at all times.

1.1.9 In the case of new installations, the protective shield and all shielded walls and doors must be clearly and durably marked with the lead thickness or lead area density or, for non-lead material, the type and thickness of building material of which they are constructed.

1.1.10 All protective clothing used should comply with the requirements of the EPA Policy on x-ray protective clothing.

1.2 **Advice to Consulting Radiation Expert**

1.2.1 A CRE must ensure that any radiation monitoring device used for compliance testing is:

- suitable for the type of measurement for which it is to be used
- used only when it is fully operational and properly calibrated
- capable of measuring the type of radiation being assessed over the range of energies and dose rates required
- calibrated at least every two years to an Australian or international primary or secondary standard satisfactory to the manufacturers’ requirements.

1.2.2 The following test equipment may be required to carry out compliance testing:

- a radiation meter/detector (including kVp and timer functions)
- tape
• a light meter
• 6 cm total thickness Perspex blocks (e.g. 6 x 1 cm / 3 x 2 cm; ideally 24 x 30 cm² in area)
• image quality phantom (ACR accreditation phantom e.g. RMI 156)
• resolution test tool
• aluminium filters (Grade 1100 or equivalent)
• collimation test tools
• fluorescent screen or Gafchromic film
• lead sheets
• metal ruler
• scales
• a calculator with statistical functions / computer spreadsheet
• a tape measure

1.2.3 Prior to commencing testing the manufacturer’s warm-up procedure should be followed.

1.2.4 All measurements must be in SI units (e.g. Gy for air kerma).
2. **Compliance requirements: mammography**

2.1 **System performance: film-screen**

2.1.1 All tests in Table 1 **must** be carried out at the frequency specified and results **must** comply with the limits referenced in this Guideline or in the *RANZCR Mammography Quality Control Manual (2002)*, hereafter referred to as the RANZCR Manual.

2.1.2 Where reference is made to the RANZCR Manual, the procedure in the *Medical Physicist’s Section* of the RANZCR Manual should be followed.

2.1.3 Data should be recorded using the RANZCR Mammography Quality Assurance Program (MQAP) Film-Screen Equipment Assessor Form.

**Table 1: Tests required for film-screen mammography systems**

<table>
<thead>
<tr>
<th>Test</th>
<th>New installation</th>
<th>2-yearly</th>
<th>After tube replacement</th>
<th>Reference</th>
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<td>Apparatus type</td>
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<td>✓</td>
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<td>Image receptor support</td>
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<td>×</td>
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<tr>
<td>Mammographic Unit Assembly</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>RANZCR Manual</td>
</tr>
<tr>
<td>Compression device</td>
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<td>✓</td>
<td>×</td>
<td>This document, section 2.8</td>
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<td>✓</td>
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<td>RANZCR Manual</td>
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<td>System resolution</td>
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<td>✓</td>
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<td>Image quality</td>
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<td>✓</td>
<td>RANZCR Manual</td>
</tr>
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</table>
## 2.2 System performance: digital (CR and DR)

### 2.2.1 All tests in Table 2 must be carried out at the frequency specified and results must comply with the limits referenced in this Guideline or in the *RANZCR Mammography Quality Assurance Program (MQAP) CR or DR Equipment Assessor Form*, hereafter referred to as the RANZCR Spreadsheet.

### 2.2.2 Data should be recorded using the RANZCR Mammography Quality Assurance Program (MQAP) CR or DR Equipment Assessor Form.
### Table 2: Tests required for digital mammography systems

<table>
<thead>
<tr>
<th>Test</th>
<th>New installation</th>
<th>Annual</th>
<th>After tube replacement</th>
<th>After detector replacement</th>
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<td>Image receptor support (CR only)</td>
<td>✓</td>
<td></td>
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<tr>
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<td>RANZCR Spreadsheet (requirement for correct population of DICOM header is waived for CR)</td>
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<td>Missing tissue at chest wall</td>
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<tr>
<td>kVp accuracy and reproducibility</td>
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<td>Beam Quality (HVL)</td>
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<td>Mean Glandular Dose (MGD)^2</td>
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<td>Monitor and printer QC</td>
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<td>Detector response</td>
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<tr>
<td>Distance calliper accuracy^3</td>
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<td>Artefact evaluation</td>
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<tr>
<td>Detector/image plate homogeneity</td>
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<td>Detector/image plate ghosting</td>
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<td>Uniformity of Image Plate speed (CR only)</td>
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<td>Image plate fogging (CR only)</td>
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## Exposure indication

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### Exposure Indicator calibration and fading (CR only)

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### Dark noise (CR only)

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<th>x</th>
<th>x</th>
<th>RANZCR Spreadsheet</th>
</tr>
</thead>
</table>

---

1. Note that this refers to a DR detector; these tests are not required for new CR plates.
2. MGD **must** be tested following any service which affects patient dose. This may include software upgrades.
3. Distance calliper accuracy should be carried out following a software upgrade on DR systems.
2.3 Radiation warning sign

2.3.1 A radiation warning sign complying with Schedule 6 of the Regulation must be displayed on the outside of the entry doors to any room in which a mammographic apparatus is installed.

2.4 Apparatus type

2.4.1 Only dedicated, purpose-designed mammographic apparatus must be used.

2.5 Radiation leakage

2.5.1 The x-ray tube must be enclosed in a housing in such a manner that the absorbed dose in air from radiation leakage, measured at a distance of 1 m from the focus of that tube in 1 hour averaged over an area not larger than 100 cm$^2$, does not exceed 1.0 mGy at maximum kVp and maximum continuous current.

2.5.2 In addition the radiation leakage in the direction of the patient at 30 cm from the focus must not exceed 0.01 mGy/100 mAs at 30 kVp.

2.6 Image receptor support (film-screen and CR)

2.6.1 The radiation measured at 50 mm below the image receptor or patient support must not exceed 1 μGy/100 mAs at the maximum kVp.

2.7 Markings on x-ray generators and tube assemblies

2.7.1 X-ray generators and tube assemblies must be permanently marked in English and the markings must be clearly visible.

2.7.2 X-ray generators must bear either:
   a) the name or trademark of the manufacturer, and
   b) the type or model number, and
   c) the serial number, or
   d) an EPA-generated number that links to (a), (b) and (c).

2.7.3 X-ray tube assemblies must bear either of the following in a visible position:
   a) the name or trademark of the manufacturer of the x-ray tube housing and insert
   b) the type or model number of the x-ray tube housing and insert
   c) the serial number of the x-ray tube housing and insert, OR
   d) EPA-generated number (s) that links to (a), (b) and (c).

2.7.4 In addition to 2.14.3, x-ray tube assemblies should also bear the following markings on the outer side of the tube housing in a visible position:
   a) the position of the focal spot (s)*
   b) the relative position of the anode and cathode.
2.8 Compression device

2.8.1 Mammographic apparatus must incorporate a compression device.

2.8.2 Breast thickness indicators must be provided which are accurate to within ±5 mm and reproducible to ±2 mm of compressed breast thickness using the manufacturer’s specified compression force and specified paddle.

2.8.3 Compression force indicators must be provided which are accurate to within ±20 N. Prone biopsy tables are exempt from this requirement.

2.8.4 The maximum motorised compression force should not be less than 150 N and must not exceed 200 N.

2.9 Exposure switch

2.9.1 The exposure switch must be of the dead-man type. That is, it must have a circuit closing contact that:
   a) can be maintained only by continuous pressure
   b) makes it impossible to make repeat exposures without releasing the switch.

2.9.2 The exposure switch must be designed so that it is protected against accidental operation.

2.10 Exposure factors

2.10.1 When x-ray tube potential, current and mAs are:
   a) capable of being independently varied, control settings must be provided and clearly indicated on a meter or digital display located at the control panel
   b) not capable of being independently varied, the fixed values must be clearly indicated at the control panel.

2.11 Exposure indication

2.11.1 A visible light must indicate when the x-ray tube is energised. In addition, a signal audible to the operator must indicate either the duration of the exposure or its termination. Both signals must be at the control panel or, for remotely controlled apparatus, at the operator’s position.
3. **Quality assurance**

3.1 **Quality assurance program**

3.1.1 A quality assurance program, such as the RANZCR mammography quality assurance program (MQAP) or the BreastScreen Australia National Accreditation Standards (NAS), **must** be instituted and maintained.

3.1.2 The QA program should ensure that consistent, optimum-quality images are produced so that the exposure to radiation of patients, staff and the general public satisfies the ‘as low as reasonably achievable’ principle.

3.1.3 Routine QC procedures **must** be carried out in accordance with:
   a) *Radiologic Technologist’s Section of RANZCR Mammography Quality Control Manual* (2002) for film, or
   b) *RANZCR Guidelines for Quality Control Testing for Digital (CR & DR) Mammography* for digital mammography, or
   c) *BreastScreen Australia National Accreditation Standards* (NAS)

3.1.4 Equipment should be maintained and serviced according to manufacturer’s recommendations. The service frequency should be at least annually.

3.2 **Review**

3.2.1 A repeat/reject analysis should be performed at quarterly intervals to monitor the effectiveness of the QA program.

3.3 **Records**

3.3.1 A record of maintenance and QA test results **must** be kept for each item of radiation apparatus. Information on any defects found and their repair should be included in the record.

3.3.2 Records **must** be inspected by the CRE and assessed for compliance.

3.4 **Viewing of mammograms**

3.4.1 Mammograms **must** be viewed on a device (light box or monitor) which complies with the standards listed in 3.1.3.
**Schedule 1: Compliance requirements for mammographic radiation apparatus**

The clauses contained in this Schedule are the requirements referred to in Radiation Management Licence Condition 4.1 which the apparatus must meet for compliance.

<table>
<thead>
<tr>
<th>Requirements or Condition</th>
<th>Clause(s)</th>
<th>Requirements or Condition</th>
<th>Clause(s)</th>
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<td>Markings on x-ray generators and tube assemblies</td>
<td>2.7.1, 2.7.2, 2.7.3</td>
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<td>Advice to CRE</td>
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<td>Records</td>
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<td>2.6.1</td>
<td>Viewing of mammograms</td>
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References and further reading


NSW EPA Radiation Guideline 7 *Radiation shielding design, assessment and verification requirements*.

NSW EPA Policy on x-ray protective clothing.
Definitions

In this guideline:

**Absorbed dose** means energy delivered from radiation per unit mass of absorbing material, measured in Gray (Gy) or mGy. One Gray equals one joule per kilogram.

**ACPSEM** means Australasian College of Physical Scientists and Engineers in Medicine.

**Act** means the *Radiation Control Act 1990*.

**Authority** means NSW Environment Protection Authority.

**AEC** means automatic exposure control.

**ACR** means American College of Radiology.

**Barrier** means any wall, door, protective shield etc. between the x-ray source and an adjacent area.

**CR** means computed radiography, also known as photostimulable phosphor luminescence. CR plates can replace film-screen cassettes on existing x-ray units.

**CRE** means consulting radiation expert.

**DR** means digital radiography, where the detector is integrated into the Bucky e.g. a-Si, a-Se, photon counting detector technology.

**EPA** means NSW Environment Protection Authority.

**Filtration** means modification of the spectral distribution of an x-ray beam as it passes through matter by the differential absorption of photons with a range of energy levels.

**Focal spot** means the area of the target from which x-rays are emitted.

**HVL** means half-value layer and refers to the thickness of a specified material that reduces the absorbed dose in air of a given x-ray beam to half its original value.

**Lead equivalent** means the thickness of lead providing the same attenuation of a beam of a specified radiation quality as the material under consideration.

**Mammographic apparatus** means radiation apparatus that emits ionising radiation, used for the purpose of mammography.

**Mean glandular dose** means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast.

**Operator** means a person licensed under section 7 of the Act to use ionising radiation apparatus.

**Person responsible** means as defined in section 6 of the Act.

**Phantom** means a test object that simulates the average composition of various structures.

**Primary beam** means all ionising radiation that emerges through the specified aperture of the protective shielding of the x-ray tube and the collimating device.

**Radiation leakage** means ionising radiation transmitted through the protective shielding of a radiation source other than the primary beam.

**Beam quality** refers to the penetrating ability of a beam of x-rays. It is determined by the energy distribution of the photons in the beam, which in turn depends on the kV waveform and peak voltage across the tube, and on the filtration through which the beam has already been transmitted. The quality of an x-ray beam is described by the HVL of the beam and is measured in terms of mm of aluminium in the diagnostic range.

**RANZCR** means Royal Australian and New Zealand College of Radiologists.
**Regulation** means the Radiation Control Regulation 2013.

**SDNR** means signal difference to noise ratio

**Target** means the area of the anode that is struck by the electrons emitted from the cathode.

**X-ray tube assembly** means the x-ray tube housing with an x-ray tube insert, but not including a beam-limiting (collimating) device.

**X-ray tube housing** means a container in which an x-ray tube is mounted for normal use, providing protection against electric shock and ionising radiation, except for an aperture for the useful beam. It may contain other components.

**X-ray tube insert** means a highly evacuated vessel for the production of x-radiation by the bombardment of a target, usually contained in an anode, with a beam of electrons accelerated by a potential difference.

**X-ray tube potential difference** means the peak value of the potential difference applied to the x-ray tube, expressed as kilovolts peak (kVp).

Unless otherwise defined, all words in this guideline have the same meaning as in the Act and the Regulation.