Environment Protection Authority

# Radiation Standard 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 keeping strictly to a quality assurance program are essential to making sure of best 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 keeping the best image quality. It is important the performance level of each apparatus is set up 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 objects of this standard are to:

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

This mammography radiation standard is for the information of persons responsible and licensed users of mammographic apparatus, and persons accredited under section 8 of the *Protection from Harmful Radiation Act 1990* as consulting radiation experts. It is to be used by consulting radiation experts in the assessment of mammographic apparatus for compliance with conditions of radiation management licences and should be read with the Act and the Protection from Harmful Radiation 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. If there's an inconsistency between the standard and the legislation, the requirements of the legislation prevail.

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 standard was developed by the Radiation Regulation Unit of the NSW Environment Protection Authority (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, Mr Paul Cardew, Dr Jennifer Diffey, Ms Lucy Cartwright, Mr Peter Condon, and Mr Thomas Greig and the input received from stakeholders, in preparing this edition.

# 1. General requirements and recommendations

## 1.1. Advice to person responsible

1.1.1 The conditions of radiation management licences require licensees to make sure that diagnostic imaging apparatus is tested for compliance with the EPA's mandatory requirements. An EPA-accredited consulting radiation expert **must** carry out testing for compliance with these requirements and certify that apparatus is compliant.

1.1.2 For mammography apparatus to comply with the requirements of this standard, it **must** meet the requirements listed in Schedule 1 of this standard.

1.1.3 The responsible person **must** have equipment quality control records available to the inspecting authority and to a consulting radiation expert on request (details of quality assurance and quality control programs are discussed in section 3 of this standard).

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

1.1.5 The provision of radiation shielding should make sure 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 2,100 millimetres (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 In the case of new installations, where no extra shielding is required as a result of self-assessment, the walls and doors do not require 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.

## 1.2. Advice to consulting radiation expert

1.2.1 A consulting radiation expert **must** make sure 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 centimetre (cm) total thickness Perspex blocks (e.g. 6 x 1 cm / 3 x 2 cm; ideally 24 x 30 $cm^2$ in area)
- image quality phantom (ACR Digital Mammography accreditation phantom or ACR small mammography 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 Before starting to test 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 The consulting radiation expert **must** make sure all tests in Table 1 be carried out at the frequency specified and results **must** comply with the limits referenced in this standard or in the *RANZCR Mammography Quality Control Manual (2002),* from here on 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 Film-Screen Equipment Assessor Form.

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

| Test | New installation | Annually | After tube replacement | Reference |
|---|---|---|---|---|
| Radiation warning sign | ✓ | ✓ | × | This document, section 2.3 |
| Apparatus type | ✓ | × | × | This document, section 2.4 |
| Radiation leakage | ✓ | × | ✓ | This document, section 2.5 |
| Image receptor support | ✓ | × | × | This document, section 2.6 |
| Markings on X-ray generators and tube assemblies | ✓ | ✓ | ✓ | This document, section 2.7 |
| Mammographic unit assembly | ✓ | ✓ | ✓ | RANZCR Manual |
| Compression device | ✓ | ✓ | × | This document, section 2.8 |
| Exposure switch | ✓ | ✓ | ✓ | This document, section 2.9 |
| Exposure factors | ✓ | ✓ | ✓ | This document, section 2.10 |
| Exposure indication | ✓ | ✓ | ✓ | This document, section 2.11 |
| Collimation and alignment | ✓ | ✓ | ✓ | RANZCR Manual |
| System resolution | ✓ | ✓ | ✓ | RANZCR Manual |
| Image quality | ✓ | ✓ | ✓ | RANZCR Manual |
| Automatic exposure control | ✓ | ✓ | ✓ | RANZCR Manual |
| kVp performance | ✓ | ✓ | ✓ | RANZCR Manual |

| | | | | |
|---|---|---|---|---|
| Beam Quality (half value layer) | ✓ | ✓ | ✓ | RANZCR Manual |
| Mean Glandular Dose[1] | ✓ | ✓ | ✓ | RANZCR Manual |

[1] MGD **must** be also tested annually and following any service which affects patient dose.

## 2.2. System performance: digital (CR and DR)

2.2.1 The consulting radiation expert **must** make sure all tests in Table 2 be carried out at the frequency specified and results **must** comply with the limits referenced in this standard or in the *RANZCR Mammography Quality Assurance Program (MQAP) CR or DR Equipment Assessor Form,* from here on referred to as the RANZCR spreadsheet.

2.2.2 Data should be recorded using the RANZCR Mammography Quality Assurance Program CR or DR Equipment Assessor Form.

**Table 2: Tests required for digital mammography systems**

| Test | New installation | Annual | After tube replacement | After detector replacement[1] | Reference |
|---|---|---|---|---|---|
| Radiation warning sign | ✓ | ✓ | × | × | This document, Section 2.3 |
| Apparatus type | ✓ | × | × | × | This document, Section 2.4 |
| Radiation leakage | ✓ | × | ✓ | × | This document, Section 2.5 |
| Image receptor support (CR only) | ✓ | × | × | × | This document, Section 2.6 |
| Markings on X-ray generators and tube assemblies | ✓ | ✓ | ✓ | × | This document, Section 2.7 |
| Mammographic unit assembly | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet (requirement for correct population of DICOM header is waived for CR) |
| Compression device | ✓ | ✓ | × | × | This document, Section 2.8 |
| Missing tissue at chest wall | ✓ | × | ✓ | ✓ | RANZCR spreadsheet |
| Collimation assessment | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |
| Signal difference to noise ratio and automatic exposure control evaluation | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |
| Phantom image quality evaluation | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |

| | | | | | |
|---|---|---|---|---|---|
| kVp accuracy and reproducibility | ✓ | ✓ | ✓ | × | RANZCR spreadsheet |
| Beam quality (HVL) | ✓ | ✓ | ✓ | × | RANZCR spreadsheet |
| Mean glandular dose[2] | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |
| Exposure time | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |
| Monitor and printer QC | ✓ | ✓ | × | × | RANZCR spreadsheet |
| Detector response | ✓ | ✓ | × | ✓ | RANZCR spreadsheet |
| System resolution | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |
| Distance calliper accuracy[3] | ✓ | × | × | ✓ | RANZCR spreadsheet |
| Artefact evaluation | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |
| Detector/image plate homogeneity | ✓ | ✓ | ✓ | ✓ | RANZCR spreadsheet |
| Detector/image plate ghosting | ✓ | ✓ | × | ✓ | RANZCR Spreadsheet |
| Uniformity of image plate speed (CR only) | ✓ | ✓ | × | × | RANZCR spreadsheet |
| Image plate fogging (CR only) | ✓ | × | × | × | RANZCR spreadsheet |
| Exposure switch | ✓ | ✓ | ✓ | ✓ | This document, Section 2.9 |
| Exposure factors | ✓ | ✓ | ✓ | ✓ | This document, Section 2.10 |
| Exposure indication | ✓ | ✓ | ✓ | ✓ | This document, Section 2.11 |
| Exposure Indicator calibration and fading (CR only) | ✓ | ✓ | × | × | RANZCR spreadsheet |
| Dark noise (CR only) | ✓ | ✓ | × | × | RANZCR spreadsheet |

[1] Note that this refers to a DR detector; these tests are not required for new CR plates.

[2] MGD **must** also 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 metre (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 Also, 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 2.7.3, 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.
*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. Also, 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 or the BreastScreen Australia National Accreditation Standards, **must** be instituted and maintained.

3.1.2 The quality assurance program should make sure 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 Quality Control 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 quality assurance program.

## 3.3. Viewing of mammograms

3.3.1 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 of the Standard listed in this Schedule are the requirements referred to in Radiation Management Licence Condition 3.1 that a 'person responsible' **must** make sure apparatus meets for compliance with this Standard.

| Requirements or condition | Clause(s) |
|---|---|
| Advice to person responsible | 1.1.1, 1.1.2, 1.1.3, 1.1.6, 1.1.8, 1.1.9 |
| Advice to consulting radiation expert | 1.2.1, 1.2.4 |
| System performance: film-screen | 2.1.1 |
| System performance: digital (computed radiography and direct radiography) | 2.2.1 |
| Radiation warning sign | 2.3.1 |
| Apparatus type | 2.4.1 |
| Radiation leakage | 2.5.1, 2.5.2 |
| Image receptor support (film-screen and computed radiography) | 2.6.1 |
| Markings on X-ray generators and tube assemblies | 2.7.1, 2.7.2, 2.7.3 |
| Compression device | 2.8.1, 2.8.2, 2.8.3, 2.8.4 |
| Exposure switch | 2.9.1, 2.9.2 |
| Exposure factors | 2.10.1 |
| Exposure indication | 2.11.1 |
| Quality assurance program | 3.1.1, 3.1.3 |
| Viewing of mammograms | 3.3.1 |

# References and further reading

Royal Australian and New Zealand College of Radiologists, *Mammography Quality Control Manual* (2002).

Heggie JCP, Barnes P, Cartwright L, Diffey J, Tse J, Herley J, McLean ID, Thomson FJ, Grewal RK, and Collins LT. 2017. *ACPSEM Position Paper: Recommendations for a Digital Mammography Quality Assurance Program V4.0* (2017). Available at: https://www.acpsem.org.au/documents/item/120, accessed 26 February 2018.[1]

RANZCR MQAP Film-Screen Equipment Assessor Form. Available at: https://www.ranzcr.com/college/document-library/mammography-quality-assurance-program-mqap-film-screen-equipment-assessor-form, accessed 26 February 2018.

RANZCR MQAP CR and DR Equipment Assessor Forms. Available at: www.ranzcr.edu.au/quality-a-safety/radiology/practice-quality-activities/mqap, accessed 26 February 2018.[1]

Royal Australian and New Zealand College of Radiologists, *Guidelines for Quality Control Testing for Digital (CR DR) Mammography v3* (2012). Available at: www.ranzcr.edu.au/quality-a-safety/radiology/practice-quality-activities/mqap, accessed 26 February 2018.[1]

[1] Note that these documents are updated periodically. Please ensure that you refer to the most recent version.

# Definitions

In this standard:

**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 *Protection from Harmful Radiation Act 1990*.

**Authority** means NSW Environment Protection Authority.

**ACR** means American College of Radiology.

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

**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 half value layer of the beam and is measured in terms of mm of aluminium in the diagnostic range.

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

**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.

**Half-value layer** 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 that gives the same attenuation in radiation dose rate as the material used instead of lead.

**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.

**New installation** means a completely new build or modifications to barriers in an existing room.

**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.

**RANZCR** means Royal Australian and New Zealand College of Radiologists.

**Regulation** means the Protection from Harmful Radiation Regulation 2013.

**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 parts.

**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 standard have the same meaning as in the Act and the Regulation.