

Radiation Guideline

6

**Registration requirements
& industry best practice
for ionising radiation
apparatus used in
diagnostic imaging**

Part 1

Mammography



ENVIRONMENT PROTECTION AUTHORITY



Department of
Environment and Conservation (NSW)

This is the Guideline defined in clause 3 of the Radiation Control Regulation 2003 as the 'Mammography Radiation Guideline'. This edition supersedes the Guideline published in August 1999.

From 24 September 2003 the Department of Environment and Conservation (DEC) incorporates the Environment Protection Authority (EPA), which is defined in section 4 of the *Radiation Control Act 1990* as the Authority responsible for administering the Act and Regulation. Statutory functions and powers in the *Radiation Control Act 1990* continue to be exercised in the name of the EPA.

For technical information about this Guideline contact the Radiation Control Section of the DEC on (02) 9995 5959.

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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 Mammography Radiation Guideline is for the information of owners and licensed users of mammographic apparatus, and persons accredited under section 9 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 registration, and should be read in conjunction with the Act and the Radiation Control Regulation 2003. In the event of an inconsistency between the Guideline and the legislation, the requirements of the legislation prevail to the extent of the inconsistency.

From 24 September 2003 the Department of Environment and Conservation (NSW) incorporates the Environment Protection Authority (EPA). The EPA is defined in section 4 of the *Radiation Control Act 1990* as the Authority responsible for administering the Act. Therefore, statutory functions and powers in the Act and the Radiation Control Regulation 2003 continue to be exercised in the name of the EPA.

This document sets out the minimum requirements for registration of 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 Mammography Radiation Guideline was developed by the Radiation Control Section of the Department of Environment and Conservation (NSW) in consultation with the Radiation Advisory Council, the Royal Australian College of Radiologists, the Australasian College of Physical Scientists and Engineers in Medicine, and the School of Medical Radiation Technology, Faculty of Health Sciences, University of Sydney.

The Department of Environment and Conservation (NSW) acknowledges the assistance of Mr Lee Collins, Dr Donald McLean and Mr John Robinson, and the input received from stakeholders, in preparing this edition.

SECTION 1—GENERAL REQUIREMENTS

1.1 Advice to owners

- 1.1.1 Compliance testing of diagnostic imaging apparatus for the purpose of certification for registration may only be conducted by an EPA-accredited Consulting Radiation Expert (CRE) using the Royal Australian and New Zealand College of Radiologists *Mammography Quality Control Manual (2002)*, or as in force from time to time.
- 1.1.2 Instruments used for routine dosimetry or equipment performance monitoring should have a current calibration certificate that is traceable to an appropriate national standard.
- 1.1.3 Calibration of instruments should be conducted in accordance with *Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging – Part 6: Test Protocols for Parts 2–5*, a copy of which is available from the Authority.

1.2 Radiation shielding

- 1.2.1 Appropriate radiation shielding should be provided for the doors, walls, floor and ceiling of the room in which the apparatus is installed and for any protective barrier intended for use as a shield for the operators, to ensure that the radiation dose to any person is as low as reasonably achievable.
- 1.2.2 To achieve the requirements of 1.2.1, the provision of radiation shielding should ensure that the radiation levels behind the shielding will not give rise to a dose equivalent greater than:
 - (a) 100 μ Sv per week for occupationally exposed persons
 - (b) 20 μ Sv per week for members of the general public.
- 1.2.3 A protective shield **must** be provided for use by the operator.
- 1.2.4 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.
- 1.2.5 Where a viewing window is used as part of the protective shield, the lead equivalent and the kVp of the x-ray beam at which the lead equivalent was measured **must**, in the case of new installations, be clearly and durably marked on the viewing window.
- 1.2.6 Where a fixed protective shield is provided it should be not less than 2100 mm in height.

1.3 Shielding assessment

- 1.3.1 Specifications for radiation shielding of protective barriers and the design details of rooms used for ionising radiation apparatus should be determined and documented by an appropriately qualified person before building works start.

1.4 Radiation warning sign

- 1.4.1 A radiation warning sign complying with Schedule 5 of the Regulation **must** be displayed on the outside of the entry doors to any room in which a mammographic apparatus is housed.

1.5 Persons present during the examination

- 1.5.1 The operator should ensure that no person, other than the patient, remains in the x-ray room during an exposure unless that person is behind a protective screen or is wearing a protective apron.

- 1.5.2 The only persons who should be present in the room during the x-ray examination are those:

- (a) whose presence during the mammographic procedure is necessary; or
- (b) who are responsible for the care of the patient; or
- (c) who are receiving instruction from the person responsible for conducting the mammographic procedure.

SECTION 2—APPARATUS SPECIFICATIONS AND PERFORMANCE

2.1 Apparatus type

- 2.1.1 Only dedicated, purpose-designed mammographic apparatus should be used.
- 2.1.2 The apparatus should be capable of being set at least as low as 24 kVp and should be adjustable in 1-kVp increments.

2.2 Target and filter material

- 2.2.1 X-ray tubes with tungsten targets and aluminium filtration should not be used for mammographic purposes.
- 2.2.2 X-ray tubes with molybdenum or rhodium targets and filters should be the combination of choice for mammography. Other target and filter element combinations in the atomic number range 41–47 (Nb, Ru, Pd, Ag) may also be used.

2.3 Total filtration

- 2.3.1 The total filtration in the primary beam, measured with the compression device in place, **must** ensure that the first HVL (expressed in mm of aluminium) satisfies the equation:

$$\text{kVp}/100 + 0.03 \leq \text{HVL} \leq \text{kVp}/100 + c$$

where $c = 0.12$ for Mo/Mo; 0.19 for Mo/Rh and 0.22 for Rh/Rh.

2.4 System Resolution

- 2.4.1 System resolution **must** be measured using a high-contrast resolution gauge.
- 2.4.2 The following limits **must** apply in both contact and magnification mode:
 - (a) Bars parallel to anode–cathode axis ≥ 13 line pairs/mm; and
 - (b) Bars perpendicular to anode–cathode axis ≥ 11 line pairs/mm.

2.5 Mean glandular dose

- 2.5.1 The mean glandular dose for a single contact image with grid using a mammographic phantom equivalent to approximately 4.2 cm compressed breast tissue of 50% adipose, 50% glandular, should not exceed 2.0 mGy and **must** not exceed 3.0 mGy.
- 2.5.2 Where a contact non-grid technique is used, the mean glandular dose **must not** exceed 1.0 mGy.
- 2.5.3 The mean glandular dose for each mammographic unit **must** be measured by a CRE at least annually or following any service or modification that may affect patient dose.

2.6 Compression device

- 2.6.1 Mammographic apparatus **must** incorporate a compression device.
- 2.6.2 Compression devices **must not** be curved or mildly contoured, but **must** have an angle of not less than 5° at the chest wall and a radius at the base of not greater than 1.0 cm.
- 2.6.3 Breast thickness indicators **must** be provided which are accurate to a tolerance of ± 5 mm and reproducible to ± 2 mm of compressed breast thickness.
- 2.6.4 The total compression force should not be less than 150 N and should not exceed 200 N.

2.7 Image quality

- 2.7.1 One of the following breast phantoms should be used to evaluate the quality of the mammographic image:
- (a) CIRS-X;
 - (b) RMI-156 or equivalent; or
 - (d) Nuclear Associate 18-220 Mammographic Phantom.
- 2.7.2 The image evaluation for the phantoms identified in 2.7.1 (a) or (b) **must** be equal to or greater than the values set out in Table 1.

TABLE 1 IMAGE EVALUATION

Phantom	Evaluation
CIRS-X	8 of 12 microcalcification groups 5 of 6 simulated tumours
RMI-156 and Nuclear Associate 18-220 Mammographic Phantom	4 of 6 fibres 3 of 5 specks 3 of 5 masses

- 2.7.3 The optical density of the film in the centre of the phantom image should be > 1.4 OD.

2.8 Beam limitation

- 2.8.1 The primary beam:
- (a) may extend to the edge of the image receptor but **must not** extend beyond the image receptor holder, with the exception of the edge adjacent to the patient's chest wall
 - (b) may extend to the edge of the breast support that is designed to be adjacent to the chest wall and **must not** extend beyond this by > 1% of the SID.
- 2.8.2 The illuminance of the light beam collimating device should be ≥ 100 lux at the maximum SID.

2.9 Image receptor support

2.9.1 The radiation measured at 50 mm below the image receptor or patient support **must not** exceed 1 $\mu\text{Gy}/100$ mAs at the maximum kVp.

2.10 Exposure switch

2.10.1 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.

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

2.10.3 The exposure switch **must** be located so that it cannot be operated from outside the shielded area.

2.11 Exposure factors

2.11.1 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.

2.12 Exposure indication

2.12.1 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.

2.13 Exposure control

2.13.1 Where an automatic exposure device is provided, it **must** terminate the exposure after an exposure of no more than 750 mAs.

2.13.2 The coefficient of variation in radiation output, measured through an absorber equivalent to a compressed breast, for a minimum of four exposures at the same settings and with the same absorber in the beam, **must not** exceed ± 0.05 , or the variation in film density **must not** exceed ± 0.3 OD.

2.13.3 A minimum optical density of 1.4 should be achievable over the normal range of compressed breast tissue.

2.13.4 The optical density should be within ± 0.15 of the mean over the range of absorber thicknesses and kVp selections used.

2.13.5 The output reproducibility **must** have a coefficient of variation of ≤ 0.05 , taken over a minimum of four consecutive measurements.

- 2.13.6 Where AEC is not provided the radiation output **must** have a coefficient of linearity of ≤ 0.1 , taken across the range of tube currents for each focal spot size.
- Note:** In relation to 2.13.6, the CRE should refer to *Radiation Guideline 6: Part 6 – Test Protocols for Part 2–5* (2004) Section 5.1, ‘Notes’.

2.14 Accuracy of kilovoltage and timer controls

- 2.14.1 The accuracy of the kVp **must** be within $\pm 5\%$ of the indicated value.
- 2.14.2 The reproducibility of kVp, taken over a minimum of four consecutive measurements, **must** have a coefficient of variation ≤ 0.02 .
- 2.14.3 Where time may be separately controlled, the accuracy of the timer **must** be within $\pm 5\%$ or \pm one pulse of the indicated time, whichever is greater.
- 2.14.4 Where time is separately controlled, the timer reproducibility, taken over a minimum of four consecutive measurements, **must** have a coefficient of variation ≤ 0.05 .

2.15 Radiation leakage

- 2.15.1 Radiation leakage should be measured by using recognised methods such as those described in *Radiation Guideline 6: Part 6 – Test Protocols for Parts 2–5* (2004).
- 2.15.2 The x-ray tube **must** be enclosed in a housing in such a manner that the absorbed dose in air from leakage radiation, measured at a distance of 1 m from the focus of the tube averaged over an area not larger than 100 cm^2 , does not exceed 1.0 mGy in 1 hour.
- 2.15.3 In addition to 2.15.2, 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.

2.16 Markings on x-ray generators and tube assemblies

- 2.16.1 X-ray generators and tube assemblies **must** be permanently marked in English and the markings **must** be clearly visible.
- 2.16.2 X-ray generators **must** bear the following markings:
- the name or trademark of the manufacturer
 - the type or model number
 - the serial number or EPA registration number.
- 2.16.3 X-ray tube assemblies **must** bear the following markings on the outer side of the tube housing in a visible position:
- the name or trademark of the manufacturer of the x-ray tube insert
 - the type or model number of the x-ray tube insert
 - the serial number of the x-ray tube insert or EPA registration number
 - the name or trademark of the manufacturer of the x-ray tube housing
 - the serial number of the x-ray tube housing or EPA registration number

- (f) the nominal value of the inherent filtration and any added filtration of the tube housing at a specific kVp
- (g) the size of nominal focal spot(s) in two dimensions
- (h) the position of the focal spot(s).

Note: For dual focus x-ray tubes, a single indication of mean focal spot position is permissible.

SECTION 3—QUALITY ASSURANCE

3.1 Quality assurance program

- 3.1.1 A quality assurance (QA) program approved by a CRE **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 QA procedures **must** be standardised and documented in a QA manual.

3.2 Ongoing testing

- 3.2.1 The QA program should include checks and test measurements on all parts of the imaging system, as indicated in this Guideline and at appropriate time intervals not exceeding one year.
- 3.2.2 The program should include daily step wedge or equivalent electronic output quality control of x-ray film processors.

3.3 Review

- 3.3.1 A retake (or reject) film analysis should be performed at regular intervals to monitor the effectiveness of the QA program.

3.4 Records

- 3.4.1 A record of maintenance and QA test results should be kept for each item of radiation apparatus. Information on any defects found and their repair should be included in the record.
- 3.4.2 Records should be made available to the Authority on request.

3.5 Viewing of mammograms

- 3.5.1 The minimum brightness in the centre and in each quadrant of the view box should be 3000 cd/m². All brightness levels should be within $\pm 10\%$ of the mean value.
- 3.5.2 The colour of each view box should be consistent throughout a complete set.
- 3.5.3 Means should be available to prevent the viewer from being dazzled by light emitted from the unused portion of the view box.
- 3.5.4 Means for magnifying details in the displayed mammogram should be available. These means should magnify by a factor of two to four times and contain provisions to identify small image details of sizes down to 0.1 mm.
- 3.5.5 An additional spotlight should be available for viewing exceptionally dark areas of the mammographic image.
- 3.5.6 The level of ambient light in the viewing room should not exceed 50 lux.

SCHEDULE 1—REGISTRATION REQUIREMENTS FOR MAMMOGRAPHIC RADIATION APPARATUS

The clauses contained in this Schedule are the requirements referred to in Section 7(5) of the Act that the apparatus **must** meet before the apparatus will be registered.

Requirement	Clause(s)
Radiation shielding	1.2.3, 1.2.4, 1.2.5
Radiation warning sign	1.4.1
Total filtration	2.3.1
Focal spot	2.4.1, 2.4.2
Mean glandular dose	2.5.1, 2.5.2, 2.5.3
Compression device	2.6.1, 2.6.2, 2.6.3
Image quality	2.7.2
Beam limitation	2.8.1
Image receptor support	2.9.1

Requirement	Clause(s)
Exposure switch	2.10.1, 2.10.2, 2.10.3
Exposure factors	2.11.1
Exposure indication	2.12.1
Exposure control	2.13.1, 2.13.2, 2.13.5, 2.13.6
Accuracy of kilovoltage and timer controls	2.14.1, 2.14.2, 2.14.3, 2.14.4
Leakage radiation	2.15.2, 2.15.3
Markings on generators and tube assemblies	2.16.1, 2.16.2, 2.16.3
Quality assurance program	3.1.1, 3.1.3

REFERENCES AND FURTHER READING

Australian Radiation Protection and Nuclear Safety Agency & National Occupational Health & Safety Commission, 2002, *Recommendations for Limiting Exposure to Ionizing Radiation (1995) (Guidance Note [NOHSC:3022(1995)] and National Standard for Limiting Exposure to Ionizing Radiation [NOHSC:1013(1995)]*, Radiation Protection Series Publication No. 1, ARPANSA, Yallambie, Victoria.

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Note: The Australian Radiation Protection and Nuclear Safety Agency is publishing the Radiation Safety Series to replace over time the documents comprising the National Health & Medical Research Council Radiation Health Series.

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.

Act means the *Radiation Control Act 1990*.

Authority means NSW Environment Protection Authority.

Added filtration means the quantity indicating the filtration affected by added filters in the primary beam, but excluding *inherent filtration*.

AEC means automatic exposure control.

Coefficient of linearity = $(X_{\max} - X_{\min}) / (X_{\min} + X_{\max})$.

Coefficient of variation means the standard deviation divided by the mean of a set of numbers.

CRE means consulting radiation expert.

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

Inherent filtration means the filtration affected by the irremovable materials of an x-ray tube assembly (i.e. glass, oil and port seal), through which the radiation beam passes before emerging from the *x-ray tube assembly*. It is expressed in terms of thickness of a reference material that, at a specified potential difference and waveform, gives the same *radiation quality* in terms of *half-value layer*.

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.

Optical density (OD) means the degree of film blackening produced during development, where optical density is the log of the reciprocal of the fraction of light transmitted through the blackened film.

Operator means a person licensed under Section 6 of the Act to use ionising radiation apparatus.

Owner means the owner of the radiation apparatus to which Section 7 of the Act applies.

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.

Radiation 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.

Regulation means the Radiation Control Regulation 2003.

SID means source-to-image receptor distance.

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

Total filtration means the sum of inherent filtration and added filtration between the radiation source and the patient or other defined plane.

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.