health

# Radiation Safety Standard: Mammography X-ray equipment

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Image: © *BreastScreen Victoria*

***Note:** The specification of Radiation Safety Standards under the *Radiation Act 2005* is reviewed periodically to ensure they are up to date. The latest version can be downloaded from: www.health.vic.gov.au/radiation

State Government Victoria

Department of Health

# This Radiation Safety Standard deals with mammography X-ray equipment used for human diagnostic purposes. It does not include digital mammography.

## Required testing frequency: Every 12 months

This document contains the Radiation Safety Standard that have been specified under the *Radiation Act 2005* by the Secretary to the Department of Health in respect of mammography X-ray equipment.

Mammography X-ray equipment is a prescribed radiation source under the *Radiation Act 2005*.

Under the Act the role of an approved tester is to conduct tests on prescribed radiation sources to determine whether the prescribed radiation sources meet the relevant Radiation Safety Standard and issue certificates of compliance if the prescribed radiation sources meet the relevant Radiation Safety Standard.

A certificate of compliance must not be issued if the prescribed radiation source does not comply with any part of the Radiation Safety Standard.

## Terms

### Item

Refers to the compliance standard number.

### Criteria

The Radiation Safety Standard that must be met by the prescribed radiation source when it is tested, in order for a certificate of compliance to be issued and where relevant the radiation safety tests that must be used.

### Australian Standards

A reference in the Radiation Safety Standard to the letters 'AS' followed by a number and/or a number and year is a reference to the Standard so numbered and published by or on behalf of Standards Australia as amended from time to time.

Relevant Australian Standards are listed under Reference Documents on the back page. Copies of Australian Standards can be obtained online from: **www.saiglobal.com\shop**

## Contact


### Radiation Safety Section

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To receive this document in an accessible format contact the Radiation Safety Section, Environmental Health Unit, Health Protection Branch.

| Item | Criteria |
|---|---|
| **1** | **Indicators** |
| 1.1 | **Mains**<br>A mains indicator must be clearly identified. 'ON' and 'OFF' positions must be indicated by a suitable indicator light or other unambiguous means. |
| 1.2 | **Energised X-ray tube**<br>A visible signal, must be displayed at the control panel to indicate when the X-ray tube is energised. |
| 1.3 | **Automatic mode**<br>For X-ray apparatus operating with automatic control systems the preselected mode of operation must be indicated on the control panel. |
| 1.4 | **Audible signal**<br>A signalling device audible at the location from which the equipment is operated must indicate the duration or termination of the exposure. |
| **2** | **Beam collimation and alignment** |
| 2.1 | **Light field / X-ray field alignment**<br>The alignment between any boundary of the light beam and the equivalent boundary of the X-ray beam in the plane of the image receptor must not exceed 1% of the distance between the focus of the X-ray tube and the plane of the image receptor.<br>Note: 1. This test must be performed for all X-ray tube targets, collimators and cassette sizes used clinically. |
| 2.2 | **X-ray field / film/breast-support alignment**<br>The X-ray field must:<br>i. extend to the chest wall edge of the film<br>ii. not extend beyond the edge of the primary beam stop for those edges not adjacent to the patient's chest wall<br>iii. not extend by more than 2% of the SID beyond any edge of the film; and<br>iv. for standard contact views, extend to the non-chest wall edges of the film.<br>Note:<br>1. This test must be performed for all X-ray tube targets, collimators and cassette sizes used clinically.<br>2. For those systems that are unable to meet the requirement for extension of the X-ray field to the non chest wall edges of the film by design, then extension of the X-ray field as per manufacturers specifications is considered acceptable. |
| 2.3 | **Paddle / film alignment**<br>The chest wall edge of the compression paddle must be:<br>i. Aligned just beyond the chest wall edge of the image receptor such that the chest wall compression paddle does not appear in the mammogram.<br>ii. Not extend beyond the chest wall edge of the image receptor by more than 1% of the SID with the paddle at 4.5 cm above the breast support.<br>Note:<br>1. This test must be performed for all X-ray tube targets, collimators and cassette sizes used clinically. |
| **3** | **Exposure switch** |
| 3.1 | **Position of exposure switch**<br>Control of the X-ray unit must be from behind a protective screen or from a distance of not less than 2 metres from the focal spot. |
| 3.2 | **Dead man type switch**<br>Each exposure shall be initiated and maintained by means of a control requiring continuous activation by the operator and the exposure must be able to be interrupted at any time. |
| 3.3 | **Security of exposure switch**<br>It must not be possible to initiate another exposure without releasing the switch. |

| Item | Criteria |
|---|---|
| **4** | **Generator performance** |
| 4.1 | kVp Accuracy<br>The kVp accuracy for kVp settings across the clinical range must not exceed ±5% or 5kVp, whichever is greater of the indicated value. |
| 4.2 | kVp Reproducibility<br>The coefficient of variation (COV) must not be greater than 0.02 for a minimum of four exposures across the clinical range. |
| **5** | **Radiation output** |
| 5.1 | **Dose-rate**<br>For all clinically relevant source to image distances the average rate of absorbed dose to air measured with the paddle in the beam:<br>(i) must be ≥ 7.0 mGy/s at 4.5 cm above the breast support surface for a three second, 28 kVp, Mo/Mo, large focus exposure.<br>(ii) must be ≥ 1.5 mGy/s at the upper surface of the film cassette for a three second, 28 kVp, Mo/Mo, fine focus exposure (applicable only where used). |
| **6** | **Half Value Layer (HVL)** |
| | With the compression device in place, the HVL must be such that:<br>[(kVp/100) + 0.03] ≤ HVL < [(kVp/100 + C)] where:<br>C = 0.12 for Mo/Mo or;<br>= 0.19 for Mo/Rh or;<br>= 0.22 for Rh/Rh<br>= 0.30 mm Al for W/Rh. |
| **7** | **Automatic exposure control performance** |
| 7.1 | **mAs indication**<br>The post exposure mAs indication must be working properly on all mammographic units incorporating automatic exposure control. |
| 7.2 | **Reproducibility**<br>The coefficient of variation (COV) for both absorbed dose and mAs for at least four photo timed exposures of a test object must be better than or equal to 0.05 at clinically relevant kVp and target/filter selection. |
| 7.3 | **Thickness compensation**<br>For photo-timed imaging of 2, 4 and 6 cm phantom thicknesses using a single density setting and clinically relevant kVp and target/filter selections the AEC must be able to maintain optical density to within ± 0.15 of the mean optical density for contact geometry and ± 0.20 of the mean optical density for magnification geometry.<br>Note:<br>1. When a wider range of thicknesses is tested (1 cm to 8 cm) the AEC should be able to maintain the optical density within ± 0.30 of the mean optical density.<br>2. Mean optical density is defined as the mean of optical density measurements made at 4 cm from the chest wall edge on the mid-line of the film for images of 2, 4 and 6cm of Perspex obtained using clinically relevant AEC, kVp and target/filter selections, the 18 by 24 cm film format and a single density setting. |
| 7.4 | **Density control**<br>The difference in film optical density produced by adjacent density control settings across the clinical range must not exceed 0.25. |
| 7.5 | **Back-up timer/security cut-out**<br>Security cut-out mechanisms must be present and terminate the exposure within 50 ms or within 5 mAs.<br>In absence of security cut-out a back-up timer must terminate exposure at ≤ 600 mAs. |

| Item | Criteria |
|---|---|
| **8** | **Compression device** |
| 8.1 | **Compression force**<br>i. For manual compression devices (including manual override) the compression device must not be able to apply a force ≥ 300N.<br>ii. For power driven compression devices, the compression device must be able to apply a force of at least 150N, and it must be unable to apply a force ≥ 200N.<br>iii. For power driven compression, the available operating force must be adjustable down to 70N or less.<br>iv. If the value of applied force is displayed, the indication must be given in units of force and must be accurate to within ±20N (or equivalent).<br>v. The compression force must not decrease significantly during a time interval of one minute or an interval of time that would be typical of clinical compressions.<br>vi. (vi) For mammographic X-ray equipment with a moving anti-scatter grid, the application of the maximum force attainable for the compression device must not impede the motion of the anti-scatter grid. |
| **9** | **System resolution** |
| | The resolution of the mammography system must meet the following criteria:<br>=11 lp/mm for line-pair bars perpendicular to anode-cathode axis and<br>=13 lp/mm for line-pair bars parallel to anode-cathode axis.<br>Note:<br>1. Assess resolution for all large focal spots in contact mode and all small focal spots at the highest magnification used clinically. |
| **10** | **Mean Glandular Dose** |
| | Mean glandular dose for contact imaging (with grid) of a 4.2 cm 50% glandular 50% adipose phantom (ie. ACR accreditation phantom) must be ≤ 2.0 mGy for exposures made using a typical clinical setting Or, for a 5 cm, 50% glandular 50% adipose phantom (ie CIRS 5cm 50/50 phantom) the mean glandular dose for contact imaging with a grid must not exceed 3 mGy per exposure. |

## Reference documents

AS/NZS 3200.1.0:1998 Medical electrical equipment. Part 1.0: General requirements for safety – Parent Standard.

AS/NZS 3200.2.7:1999 Medical electrical equipment. Part 2.7: Particular requirements for safety – High voltage generators of diagnostic X-ray generators

AS/NZS 3200.1.3:1996 Medical electrical equipment. Part 1.3: General requirements for safety – Collateral Standard, Requirements for radiation protection in diagnostic X-ray equipment.

AS/NZS 3200.2.45:1999 Medical electrical equipment – Particular requirements for safety- Mammographic X-ray equipment and mammographic stereotactic devices

ACPSEM Position Paper, Recommendations for a mammography quality assurance program, Australasian Physical & Engineering Sciences in Medicine, Vol 24, no. 3