

Radiation Safety Standard: Plain film radiographic X-ray equipment



This Radiation Safety Standard deals with diagnostic plain film radiographic X-ray equipment (including mobile) used in the medical and chiropractic areas for human diagnostic purposes.

Required testing frequency: Every two years

This document contains the Radiation Safety Standard that have been specified under the *Radiation Act 2005* by the Secretary to the Department of Human Services in respect of plain film radiographic X-ray equipment.

Plain film radiographic 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.

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* 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 the website at:
[www.health.vic.gov.au/
environment/radiation](http://www.health.vic.gov.au/environment/radiation)

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.

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](http://www.saiglobal.com/shop)

Item	Criteria
1	Indicators
1.1	<p>Mains</p> <p>A mains indicator must be clearly identified. 'ON' and 'OFF' positions must be indicated by a suitable indicator light or other unambiguous means.</p>
1.2	<p>X-ray Tube Selection</p> <p>Where more than one X-ray tube can be operated from a single control panel, the active tube must be visually indicated at or near the control panel.</p>
1.3	<p>Energised X-ray Tube</p> <p>A visible signal must be displayed at the control panel to indicate when the X-ray tube is energised.</p>
1.4	<p>Automatic Mode</p> <p>For X-ray apparatus operating with automatic control systems the preselected mode of operation must be indicated on the control panel</p>
1.5	<p>Audible Signal</p> <p>A signalling device audible at the location from which the equipment is operated must indicate the duration or termination of the exposure.</p>
2	Exposure Control
2.1	<p>Position of Exposure Switch for Mobile Equipment.</p> <p>Control of the X-ray unit must be from a distance of not less than 2 metres from the focal spot or X-ray beam.</p>
2.2	<p>Dead Man Type Switch</p> <p>Each exposure must 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.</p>
2.3	<p>Security of Switch</p> <p>It must not be possible to initiate another exposure without releasing the switch.</p>

Item	Criteria																												
3	Beam Quality																												
3.1	<p>Half Value Layer (HVL)</p> <p>The total filtration must be such that the HVL of the primary beam for a given X-ray tube and collimator is not less than the values shown in Table 1.</p> <p>Table 1</p> <table border="1"> <thead> <tr> <th>X-ray Tube Voltage (kVp)</th> <th>Minimum HVL (mm Al)</th> </tr> </thead> <tbody> <tr> <td><50</td> <td>*</td> </tr> <tr> <td>50</td> <td>1.5</td> </tr> <tr> <td>60</td> <td>1.8</td> </tr> <tr> <td>70</td> <td>2.1</td> </tr> <tr> <td>80</td> <td>2.3</td> </tr> <tr> <td>90</td> <td>2.5</td> </tr> <tr> <td>100</td> <td>2.7</td> </tr> <tr> <td>110</td> <td>3.0</td> </tr> <tr> <td>120</td> <td>3.2</td> </tr> <tr> <td>130</td> <td>3.5</td> </tr> <tr> <td>140</td> <td>3.8</td> </tr> <tr> <td>150</td> <td>4.1</td> </tr> <tr> <td>>150</td> <td>*</td> </tr> </tbody> </table> <p>* Calculate by linear extrapolation</p>	X-ray Tube Voltage (kVp)	Minimum HVL (mm Al)	<50	*	50	1.5	60	1.8	70	2.1	80	2.3	90	2.5	100	2.7	110	3.0	120	3.2	130	3.5	140	3.8	150	4.1	>150	*
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150	4.1																												
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4	Timer																												
4.1	<p>Type of Timer</p> <p>The timer must have the following features:</p> <ul style="list-style-type: none"> (i) The timer must be electronic (ii) It must not be possible to make exposures when the timer is set to the zero setting 																												
4.2	<p>Timer Accuracy</p> <p>The exposure timer accuracy for timer settings across a clinical range must be within:</p> <ul style="list-style-type: none"> (i) $\pm 10\%$ of the indicated value for exposure times greater than or equal to 0.1 seconds* (ii) $\pm 20\% \pm 1$ pulse of the indicated value for exposure times less than 0.1 seconds* <p>*Any measuring equipment error must be taken into account in determining whether compliance criteria is satisfied.</p>																												
5	kVp																												
5.1	<p>kVp Accuracy</p> <p>The kVp accuracy for kVp settings across the clinical range must not exceed $\pm 5\%$ or 5kVp, whichever is greater of the indicated value.</p> <p>*Should also allow for measuring equipment error in addition to this.</p>																												
6	Radiation Output																												
6.1	<p>Radiation Output Reproducibility</p> <p>The coefficient of variation of the X-ray output of a series of 5 consecutive exposures taken within a time period of approximately 10 minutes should not be greater than 0.05 for any combination of exposure factors across the clinical range.</p>																												

Item	Criteria
<p>6.2</p>	<p>Radiation Output Linearity</p> <p><i>Note: This test does not apply to condenser discharge equipment.</i></p> <p>(i) Variable mA</p> <p>Where there is a choice of mA settings the linearity of the output of the X-ray unit with nominal X-ray tube current should comply with the following relationship between any pair of current settings taken over a range of clinically used settings for each focal spot size:</p> $\frac{ X_1 - X_2 }{X_1 + X_2} \leq 0.1$ <p>Where X_1 is the average X-ray output expressed in terms of dose to air per mAs at mA setting 1.</p> <p>X_2 is the average X-ray output expressed in terms of dose to air per mAs at mA setting 2.</p> <p>(ii) Variable mAs</p> <p>Where there is a choice of mAs settings the linearity of the output of the X-ray unit should comply with the following relationship between any two mAs settings taken over a range of clinically used settings for each focal spot size:</p> $\frac{ X_1 - X_2 }{X_1 + X_2} \leq 0.1$ <p>Where X_1 is the average X-ray output expressed in terms of dose to air per mAs at mAs setting 1.</p> <p>X_2 is the average X-ray output expressed in terms of dose to air per mAs at mAs setting 2.</p>
<p>7</p>	<p>Automatic Exposure Control Device</p>
<p>7.1</p>	<p>Consistency of Image Receptor Dose</p> <p>(i) Consistency of Optical Density for film as receptor</p> <p>For film as receptor, the AEC device must control exposures such that the optical density of the films produced, varies less than 20% from the average when the patient thickness and kVp are varied over their normal range for which the X-ray machine is used.</p> <p>(ii) Consistency of Image Receptor Dose for digital image receptors</p> <p>For digital image receptors, the AEC must control exposures such that the absorbed dose to the image receptor varies less than 20% from the average when the patient thickness and kVp are varied over their normal range for which the X-ray machine is used.</p>
<p>7.2</p>	<p>Automatic Termination of Exposure</p> <p>A device must be installed which can terminate the exposure after a time no greater than 6 seconds, or after an exposure of no more than 600 mAs, whichever is the lesser. When the exposure has been terminated by the back up timer, it must not be possible to initiate another exposure without first operating a manual reset.</p>

Item	Criteria
7.3	<p>Reproducibility</p> <ul style="list-style-type: none"> Using the centre detector, the X-ray output from 5 consecutive exposures at a clinically relevant kV taken within a time period not exceeding 10 minutes, must be within $\pm 5\%$ of the mean; and the X-ray output from exposures using the lateral detectors must be within $\pm 5\%$ of each other.
8	<p>Focus to skin and focus to image receptor distance</p>
8.1	<p>Minimum Focus to Skin Distance</p> <p>A means must be provided to prevent the use during irradiation of focal spot to skin distances of less than 200 mm.</p>
9	<p>Light beam diaphragm</p>
9.1	<p>Alignment</p> <p>For each focus, the alignment of the area illuminated by the light beam collimator and the X-ray field must be coincident to within $\pm 1\%$ of the distance from the focus to the image receptor.</p>
9.2	<p>Illuminance</p> <p>If a light field indicator is provided it must delineate the edges of the X-ray field and must provide an average illumination of not less than 100 lux in a plane normal to the reference axis at 1 m from the focal spot, or at the largest focal spot to image distance specified in normal use, if this is less than 1 m.</p>
10	<p>Protection against mechanical hazards</p>
10.1	<p>Stability of X-ray Tube Assembly</p> <p>Once positioned, the tube assembly must remain stationary prior to and during exposures.</p>
11	<p>Tube housing leakage</p> <p>The air kerma from leakage radiation from a tube assembly must not exceed 1.0 mGy in 1 hour at a distance of 1 m from the focal spot.</p>
12	<p>Capacitor discharge equipment</p>
12.1	<p>Leakage Radiation With Shutter Open</p> <p>Leakage radiation from the X-ray tube assembly when the exposure device is not activated must not exceed 0.2 mGy in one hour at 50 mm from any accessible surface of the X-ray tube assembly with the collimator fully open and with the maximum voltage on the capacitors.</p>
12.2	<p>Interlocked Shutters</p> <p>Electrically interlocked shutters must be fitted to capacitor discharge apparatus to prevent the emission of radiation before exposure, after exposure and during discharge of the capacitors.</p>

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.

NRL C 5 1994. Code of Safe Practice for the Use of
X-rays in Medical Diagnosis, National Radiation
Laboratory, New Zealand

QLD Radiation Safety Standard HR001:1999

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