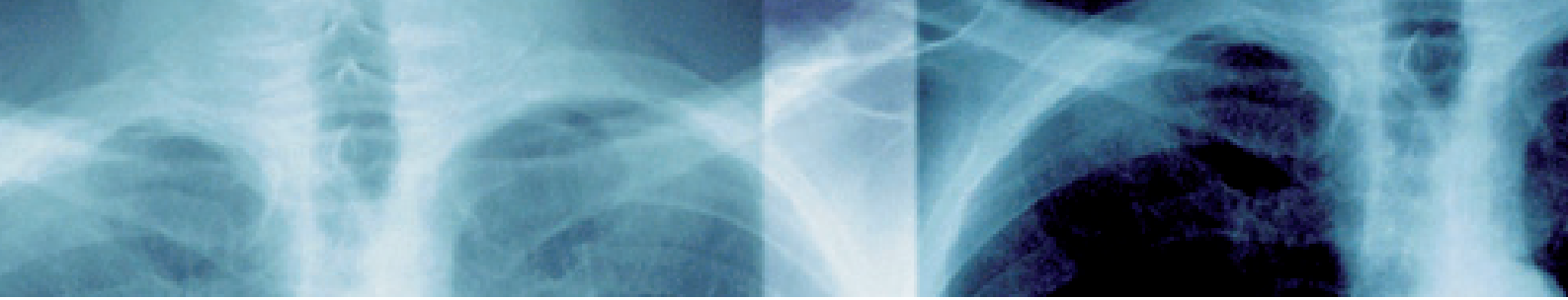


# Radiation Safety Standard: Fluoroscopic X-ray equipment



This Radiation Safety Standard deals with diagnostic fluoroscopic X-ray equipment including **under-table tube, mobile and C-arm image intensifiers** used 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 fluoroscopic X-ray equipment.

Fluoroscopic 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.

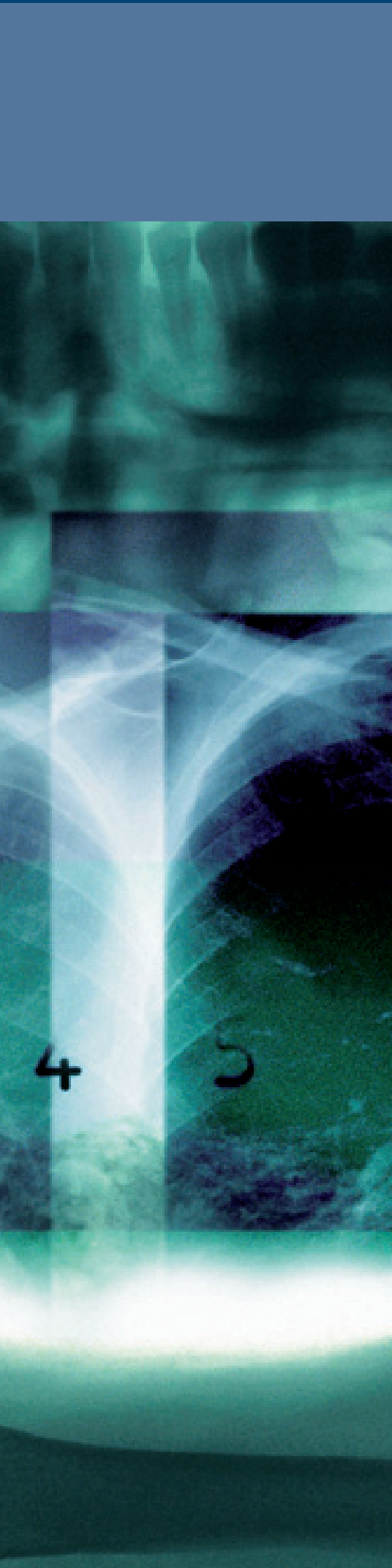
A certificate of compliance must not be issued if the prescribed radiation source does not comply with any part of the Radiation Safety Standard.

**Radiation  
Safety Section**  
GPO Box 4057  
Melbourne VIC 3001

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radiation.safety@  
dhs.vic.gov.au

\* 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	<b>Indicators</b>
1.1	<p><b>Mains</b></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><b>X-ray Tube Selection</b></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><b>Energised X-ray Tube</b></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><b>Automatic Mode</b></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><b>Audible Signal</b></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	<b>Exposure Control</b>
2.1	<p><b>Position of Exposure Switch for Mobile Equipment.</b></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><b>Dead Man Type Switch</b></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><b>Security of Exposure Switch</b></p> <p>It must not be possible to initiate another exposure without releasing the switch.</p>

Item	Criteria																												
<b>3</b>	<b>Beam Quality</b>																												
<b>3.1</b>	<p><b>Half Value Layer (HVL)</b></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 below.</p> <p><b>Table 1</b></p> <table border="1"> <thead> <tr> <th>X-ray Tube Voltage (kVp)</th> <th>Minimum HVL (mm Al)</th> </tr> </thead> <tbody> <tr> <td>&lt;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>&gt;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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<b>4</b>	<b>Timer</b>																												
<b>4.1</b>	<p><b>Type of Timer</b></p> <p>The timer must have the following features:</p> <ul style="list-style-type: none"> <li>(i) The timer must be electronic</li> <li>(ii) It must not be possible to make exposures when the timer is set to the zero setting</li> </ul>																												
<b>4.2</b>	<p><b>Fluoroscopic Timer</b></p> <p>For a fluoroscopic timer, when the duration of irradiation is determined by the operator a means must be provided to terminate the irradiation automatically when a pre-determined integrated loading time, not exceeding 10 minutes has elapsed. After the integrated time had reached a time not exceeding 5 minutes and at least 30 seconds before automatic termination a continuous audible signal must be given to enable resetting of the integrating device.</p>																												
<b>4.3</b>	<p><b>Radiographic Timer Accuracy</b></p> <p>The exposure timer accuracy for timer settings across a clinical range must be within:</p> <ul style="list-style-type: none"> <li>i. <math>\pm 10\%</math> of the indicated value for exposure times greater than or equal to 0.1 seconds</li> <li>ii. <math>\pm 20\% \pm 1</math> pulse of the indicated value for exposure times less 0.1 seconds</li> </ul> <p>Note: Should also allow for measuring equipment error in addition to this.</p>																												
<b>5</b>	<b>Kilovoltage</b>																												
<b>5.1</b>	<p><b>Fluoroscopic Tube kVp Accuracy</b></p> <p>The kVp accuracy for kVp settings across the clinical range must not exceed <math>\pm 5\%</math> or 5kVp, whichever is greater of the indicated value.</p> <p>Note: Should also allow for measuring equipment error in addition to this.</p>																												

Item	Criteria
5.2	<p><b>Radiographic kVp Accuracy</b></p> <p>The kV accuracy for kV settings across the clinical range must not exceed ±5% or 5kVp, whichever is greater of the indicated value.</p> <p>Note: Should also allow for measuring equipment error in addition to this.</p>
6	<p><b>Radiation Output</b></p>
6.1	<p><b>Radiographic Radiation Output Reproducibility</b></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>
6.2	<p><b>Radiographic Radiation Output Linearity</b></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 <math>X_1</math> is the average X-ray output expressed in terms of dose to air per mAs at mA setting 1.</p> <p><math>X_2</math> 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 <math>X_1</math> is the average X-ray output expressed in terms of dose to air per mAs at mAs setting 1.</p> <p><math>X_2</math> is the average X-ray output expressed in terms of dose to air per mAs at mAs setting 2.</p>
7	<p><b>Automatic Exposure Control Device</b></p>
7.1	<p><b>Consistency of Image Receptor Dose</b></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>

Item	Criteria
7.2	<p><b>Automatic Termination of Exposure</b></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 the manual reset.</p>
7.3	<p><b>Indication of AEC Function and Detector Selected</b></p> <p>There must be an indication on the control panel that the automatic exposure control function has been selected and of the actual detectors selected.</p>
7.4	<p><b>Reproducibility</b></p> <ul style="list-style-type: none"> <li>• 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 <math>\pm 5\%</math> of the mean; and</li> <li>• the X-ray output from exposures using the lateral detectors must be within <math>\pm 5\%</math> of each other.</li> </ul>
8	<p><b>Focus to Skin Distance</b></p>
8.1	<p><b>Minimum Focus to Skin Distance (FSD)</b></p> <p>A means must be provided to prevent the use during fluoroscopic irradiation of focal spot to skin distances of less than 200 mm.</p> <p>Note: Mini C-arm apparatus used for extremity surgery and that has a maximum tube current not exceeding 200mA is exempt from this requirement.</p>
9	<p><b>Collimation Accuracy for Fluoroscopy</b></p>
	<ul style="list-style-type: none"> <li>• The fluoroscopic beam area at the image intensifier must be limited automatically by a collimator to the area of the image receptor regardless of changes in the image intensifier field size or the distance between the X-ray tube focus and the image intensifier.</li> <li>• Any changes to the focus to image intensifier distance must be accompanied by an automatic adjustment of collimator to maintain the selected beam area.</li> </ul>
10	<p><b>Film Holding Device for Mobile Image Intensifier with Direct Radiography</b></p>
	<p>The direct radiography mode should be disabled on mobile image intensifiers. Where this is not possible a film holding device must be attached to the front of the image intensifier to support the cassette and align it to the centre of the X-ray beam.</p>
11	<p><b>Collimation Accuracy for Radiography on Mobile Fluoroscopic Apparatus</b></p>
	<p>For equipment where the direct radiography mode is not disabled, the alignment of the area illuminated by the light beam collimator and the X-ray field must be coincident to within <math>\pm 1\%</math> of the distance from the focus to the image receptor.</p>

Item	Criteria																								
12	<b>Radiation Exposure Limits</b>																								
	<p>The absorbed dose rate in air must not exceed the values indicated in Table 2 below measured under the conditions given in Table 3.</p> <p><b>Table 2</b></p> <table border="1" data-bbox="406 555 1216 779"> <thead> <tr> <th>Dose Rate Mode</th> <th>Maximum Absorbed dose rate in air (mGy/min)</th> </tr> </thead> <tbody> <tr> <td>Manual</td> <td>50</td> </tr> <tr> <td>Automatic</td> <td>100</td> </tr> <tr> <td>High level or equivalent (boost)</td> <td>150</td> </tr> </tbody> </table> <p><b>Table 3</b></p> <table border="1" data-bbox="406 846 1216 1355"> <thead> <tr> <th>Condition</th> <th>Measurement distance</th> </tr> </thead> <tbody> <tr> <td>Under-table tube</td> <td>On the table</td> </tr> <tr> <td>X-ray tube permanently under table</td> <td></td> </tr> <tr> <td>Over-table tube</td> <td>300 mm above the table</td> </tr> <tr> <td>Image receptor permanently under the table</td> <td></td> </tr> <tr> <td>C or U arm systems. X-ray tube and image receptor mechanically linked with or without permanent patient support</td> <td>300 mm from image receptor plane but not less than 400 mm from the focal spot</td> </tr> <tr> <td>Other fluoroscopy systems</td> <td>400 mm from focal spot</td> </tr> <tr> <td>No permanent patient support</td> <td></td> </tr> </tbody> </table>	Dose Rate Mode	Maximum Absorbed dose rate in air (mGy/min)	Manual	50	Automatic	100	High level or equivalent (boost)	150	Condition	Measurement distance	Under-table tube	On the table	X-ray tube permanently under table		Over-table tube	300 mm above the table	Image receptor permanently under the table		C or U arm systems. X-ray tube and image receptor mechanically linked with or without permanent patient support	300 mm from image receptor plane but not less than 400 mm from the focal spot	Other fluoroscopy systems	400 mm from focal spot	No permanent patient support	
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13	<b>High Level Boost</b>																								
	<p>Where a high level boost is activated, the control must:</p> <ul style="list-style-type: none"> <li>• Require continuous activation by the operator for its operation</li> <li>• Maintain a continuous audible signal that is readily distinguishable from that used for normal fluoroscopy, to indicate that high level boost is in use</li> <li>• Automatically return to the lower dose rate setting if not used within 5 minutes or if power to apparatus is disconnected.</li> </ul>																								
14	<b>Absorbed Dose Rate in Air at Input Surface of Image Intensifier</b>																								
	<p>The absorbed dose rate in air at the input surface of the image intensifier must not exceed the values indicated in Table 4 below under the measurement conditions listed below:</p> <p><b>Table 4</b></p> <table border="1" data-bbox="406 1933 1034 2123"> <thead> <tr> <th>Field Size (cm)</th> <th>Absorbed dose rate in air (<math>\mu\text{Gy}/\text{min}</math>)</th> </tr> </thead> <tbody> <tr> <td>11 to &lt;14</td> <td>120</td> </tr> <tr> <td>14 to &lt;23</td> <td>80</td> </tr> <tr> <td><math>\geq 23</math></td> <td>60</td> </tr> </tbody> </table>	Field Size (cm)	Absorbed dose rate in air ( $\mu\text{Gy}/\text{min}$ )	11 to <14	120	14 to <23	80	$\geq 23$	60																
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	<p>Measurement conditions:</p> <ul style="list-style-type: none"> <li>The measurement conditions should be such that sufficient copper filtration is added to the X-ray beam to obtain, on automatic brightness/dose rate systems, an X-ray tube voltage between 70kVp and 80kVp</li> <li>For manual systems, the radiation levels should not be exceeded for the normal clinical settings when used with average patients</li> <li>The measurements should be obtained without the grid or alternatively, by applying a traceable grid correction factor for the energy of the radiation beam being used.</li> </ul>																
15	<b>Image Quality</b>																
	<p><b>Table 5: Image Quality</b></p> <table border="1" data-bbox="406 828 1212 1344"> <thead> <tr> <th>Parameter</th> <th>Recommended Limit</th> </tr> </thead> <tbody> <tr> <td>Image Distortion</td> <td>Within <math>\pm 2\%</math> or within the manufacturers specifications, whichever is lesser</td> </tr> <tr> <td>Low Contrast threshold / sensitivity</td> <td>The low contrast resolution must be greater than or equal to 5 % for 10 millimetre diameter detail (using an appropriate test object)</td> </tr> <tr> <td>High Contrast Resolution</td> <td>The high contrast resolution must be greater than or equal to: <table border="1" data-bbox="774 1142 1165 1321"> <thead> <tr> <th>Field Size (mm)</th> <th>Line Pairs/mm</th> </tr> </thead> <tbody> <tr> <td>&lt; 140</td> <td>1.6</td> </tr> <tr> <td>140 to &lt;230</td> <td>1.2</td> </tr> <tr> <td><math>\geq 230</math></td> <td>0.8</td> </tr> </tbody> </table> </td> </tr> </tbody> </table>	Parameter	Recommended Limit	Image Distortion	Within $\pm 2\%$ or within the manufacturers specifications, whichever is lesser	Low Contrast threshold / sensitivity	The low contrast resolution must be greater than or equal to 5 % for 10 millimetre diameter detail (using an appropriate test object)	High Contrast Resolution	The high contrast resolution must be greater than or equal to: <table border="1" data-bbox="774 1142 1165 1321"> <thead> <tr> <th>Field Size (mm)</th> <th>Line Pairs/mm</th> </tr> </thead> <tbody> <tr> <td>&lt; 140</td> <td>1.6</td> </tr> <tr> <td>140 to &lt;230</td> <td>1.2</td> </tr> <tr> <td><math>\geq 230</math></td> <td>0.8</td> </tr> </tbody> </table>	Field Size (mm)	Line Pairs/mm	< 140	1.6	140 to <230	1.2	$\geq 230$	0.8
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16	<b>Tube Housing Leakage</b>																
	The kerma in air from leakage radiation from a tube assembly must not exceed 1.0 mGy in any 1 hour period at a distance of 1 m from the focal spot.																
17	<b>Protection Against Mechanical Hazards</b>																
17.1	<p><b>Stability of X-ray tube assembly</b></p> <p>Once positioned, the tube assembly must remain stationary prior to and during exposures.</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 HR002:1999, Standard for  
radiation apparatus used to carry out radioscopy.

NSW Radiation Guideline 6, Registration requirements and industry  
best practice for ionizing radiation apparatus used in diagnostic  
imaging. Part 2 Fluoroscopy and radiography

ACPSEM Position Paper, Recommendations for a technical  
quality control program for diagnostic X-ray equipment,  
Vol 28, No. 2, 2005.

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