

Radiation Protection Act 2005 – Section 17

**CERTIFICATE OF COMPLIANCE:
STANDARD FOR RADIATION APPARATUS -
X-RAY MEDICAL DIAGNOSTIC
(MOBILE CAPACITOR DISCHARGE)**

SECTION 1: REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION APPARATUS

SECTION 2: PARTS OF STANDARDS AND CODES OF PRACTICE ADOPTED BY THIS STANDARD

This information can also be accessed at
http://www.dhhs.tas.gov.au/peh/radiation_protection

Section 1 – REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION APPARATUS

PART – A

Section 2 of this Standard is to be used by an accredited person when assessing Radiation Apparatus, classified by Radiation Protection Act 2005 licences as “X-ray Mobile Capacitor Discharge”, for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005.

The Radiation Apparatus must be shown to fully comply with the requirements in Section 2 of this Standard.

The requirements in Section 2 are taken from the following:

AS/NZS 3200.1.0 1998 IEC 60601-1	Medical electrical equipment- General requirements for safety – Parent Standard
AS/NZS 3200.1.3:1996 IEC 60601-1-3	Approval and test specification - Medical electrical equipment - General requirements for safety - Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment.
AS/NZS 3200.2.28:1994 IEC 60601-2-28	Approval and test specification - Medical electrical equipment: Particular requirements for safety-X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators.
AS/NZS 3200.2.15:1994 IEC 601-2-15:1988	Approval and test specification - Medical electrical equipment - Particular requirements for safety - Capacitor discharge X-ray generators.
RAR	Regulatory Authority requirements – Department of Health and Human Services

PART – B

The Standards listed in this part are to be used by a person or company licensed to manufacture or sell Radiation Apparatus, classified by Radiation Protection Act 2005 licences as “X-ray Mobile Capacitor discharge”, for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005.

The holder of a licence to manufacture or sell such Radiation Apparatus must be able to show that the Radiation Apparatus fully complies with the following Standards*.

AS/NZS 3200.1.0 1998 IEC 60601-1	Medical electrical equipment- General requirements for safety – Parent Standard
AS/NZS 3200.1.3:1996 IEC 60601-1-3	Approval and test specification - Medical electrical equipment - General requirements for safety - Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment.
AS/NZS 3200.2.28:1994 IEC 60601-2-28	Approval and test specification - Medical electrical equipment: Particular requirements for safety-X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators.
AS/NZS 3200.2.15:1994 IEC 601-2-15:1988	Approval and test specification - Medical electrical equipment - Particular requirements for safety - Capacitor discharge X-ray generators.

* In many cases radiation apparatus will bear the “CE” mark, and comply with the requirements of **MDD 93/42/EEC**. As part of the process of obtaining a CE mark the manufacturer makes an application to a “Certifying Body” to have the equipment assessed. Annex III of the MDD directive states that in making an application for “**EC type examination**” the manufacturer would, in their application, state the “Standards” that they wished to be tested against (article 5).

In order for licensed manufacturers or sellers to issue a certificate of compliance under the Radiation Protection Act 2005, they need only demonstrate that they hold, or have access to, the “*EC Declaration of Conformity*” documents which show that the “make and model” of apparatus they are supplying complies with the Standards listed in Part B above.

Section 2 – PARTS OF STANDARDS AND CODES OF PRACTICE ADOPTED BY THIS STANDARD

ITEM	Requirements
Indicators	<p>AS 3200.1 1998 6.3 a) Note: The colour red shall be used exclusively to indicate that operation must not be started or an immediate action is required to terminate a hazardous state of operation, for example because maximum permitted values have been exceeded;</p>
mains	<p>AS/NZS 3200.1.0 1998 6.3 a) A mains indicator shall be clearly identified. “ON” and “OFF” positions shall be marked according to the symbols in Appendix D, or indicated by a suitable indicator light or other unambiguous means.</p> <p>Note: AS/NZS 3200.1.0:1998 56.8 provides for situations when indicators are not necessarily required. Unless indication is otherwise apparent to the operator from the normal operating position, indicator lights shall be provided to indicate the equipment is energised. Dot matrix and other alphanumeric displays are not considered to be indicator lights.</p> <p>Note Red shall be used exclusively to indicate that operation must not be started or immediate action is required to terminate a hazardous state of operation.</p> <p>AS/NZS 3200.1:1998 Paragraph 6.7 a)</p>
ready to exposure	<p>AS/NZS 3200.2.15:1994 6.7 a) The colour green shall be used at the CONTROL PANEL to indicate the state from which one further action leads to the LOADING STATE (see Item c) of Sub-clause 29.1.103);</p>
energised X-ray tube	<p>AS/NZS 3200.2.15:1994 6.7 a) The colour yellow shall be used at the CONTROL PANEL to indicate the LOADING STATE (see Item d) of Sub-clause 29.1.103).</p>
audible signal	<p>AS/NZS 3200.2.15:1994 29.1.103 d) A signalling device audible at the location from which the equipment is operated shall indicate the termination of the exposure.</p>
Protection against mechanical hazards	
stability and transportability	<p>AS/NZS 3200.2.15:1994 24 Mobile X-ray equipment shall be equipped with wheel locks and brakes or a braking system appropriate to the intended modes of use. Will not move on a 5 degree inclined plane</p>
moves easily	<p>The tube housing should be easy to move and position by an operator.</p> <p>RAR</p>

stays where positioned	Once positioned, the tube housing should not move prior to or during exposures. RAR
Exposure distances focus-skin distance (FSD)	Table 205 AS/NZS 3200.1.3:1996 A minimum focal spot to skin distance of 20 cm
X-ray field	
collimator mandatory	AS/NZS3200.1.3:1996 29.202.1 No X-ray tube shall be utilized unless mounted in an X-ray tube housing to which a beam limiting device has been fitted.
minimum field size	AS/NZS 3200.1.3:1996 29.202.2 An X-RAY TUBE ASSEMBLY shall not have a RADIATION APERTURE larger than is needed to provide the largest X-RAY BEAM required for its specified applications. If necessary, the RADIATION APERTURE shall be restricted to the appropriate size by means of a fixed-size DIAPHRAGM, fitted as close as practicable to the FOCAL SPOT.
type of adjustment	AS/NZS 3200.1.3:1996 29.202.4 a) The beam limiting device shall enable the extent of the X-ray beam to be adjusted within the range of normal use, by manual or automatic means, and having the following characteristics: A minimum selectable size of the X-ray field not exceeding 5 cm in length and width at a distance of 1 m
type of adjustment	AS/NZS 3200.1.3:1996 29.202.4 b) If the adjustment is not stepless then step sizes not exceeding 1 cm
automatic adjustment	AS/NZS 3200.1.3:1996 29.202.4 c) If the adjustment is automatic the operator must be able to reduce the size manually but not increase it beyond the automatically selected size
Exposure controls	
type of timer	Only electronic timers are acceptable RAR
limitation of radiation output by the use of suitable modes of operation	AS/NZS 3200.2.15:1994 29.1.104 a) Means shall be provided to limit the electric energy to be delivered by the use of fixed or preselected combinations of suitable LOADING FACTORS and modes of operation.

preselection of X-ray tube voltage prior to charging	AS/NZS 3200.2.15:1994 29.1.104 a) The preselection of the INITIAL X-RAY TUBE VOLTAGE shall be possible before the charging of the capacitor is initiated.
indication of X-ray tube voltage after “charging”	AS/NZS 3200.2.15:1994 29.101.3 a) The preselected value of the INITIAL X-RAY TUBE VOLTAGE at the charged capacitor shall be indicated on the CONTROL PANEL.
presence of selected X-RAY TUBE VOLTAGE	AS/NZS 3200.2.15:1994 29.101.3 b) A visible indication shall be provided on the CONTROL PANEL to indicate when the storage capacitor is charged to the preselected INITIAL X-RAY TUBE VOLTAGE.
“Shortened” indication of factors	AS/NZS 3200.2.15:1994 50.1.102 a) b) For CAPACITOR DISCHARGE X-RAY GENERATORS operating with one or more fixed combinations of LOADING FACTORS the indication on the CONTROL PANEL may be confined to the value of only one of the significant LOADING FACTORS for each combination, for example the value of X-RAY TUBE VOLTAGE. In this case, the indication of the corresponding values of the other LOADING FACTORS in each combination shall be given in the INSTRUCTIONS FOR USE. In addition, these values shall be listed on a form suitable to be displayed at a prominent location on or near the CONTROL PANEL. For CAPACITOR DISCHARGE X-RAY GENERATORS operating with fixed combinations of semi-permanently preselectable LOADING FACTORS, the indication on the CONTROL PANEL may be confined to a clear reference to the identity of each combination. In this case, provision shall be made — to enable the values of each combination of semi-permanently preselected LOADING FACTORS set at the time of installation to be recorded in the INSTRUCTIONS FOR USE and, in addition, — to enable the values to be listed on a suitable form to be displayed at a prominent location on or near the CONTROL PANEL.
indication of high voltage tube current loading time current time product	AS/NZS 3200.2.15:1994 50.1.101 b) Values of X-RAY TUBE VOLTAGE shall be indicated in kilovolts. If values of X-RAY TUBE CURRENT are indicated, they shall be indicated in milliamperes. If values of LOADING TIME and IRRADIATION TIME are indicated, they shall be indicated decimally in seconds. Values of CURRENT TIME PRODUCT shall be indicated in milliampereseconds.
Exposure switch	
position of exposure switch	AS/NZS 3200.1.3:1996 29.208.1 Control of the X-ray unit shall be from a distance of not less than 2 metres from the focal spot or X-ray beam

no exposure until capacitor charged or discharged to selected value	AS/NZS 3200.2.15:1994 29.1.104 b) It shall not be possible to initiate a LOADING unless the capacitor has been charged or discharged to the preselected INITIAL X-RAY TUBE VOLTAGE.
constant pressure required	AS/NZS 3200.2.15:1994 29.1.104 b) Each LOADING shall be initiated and maintained by means of a control requiring continuous actuation by the OPERATOR.
no repeat exposure without release	AS/NZS 3200.2.15:1994 29.1.104 c) It shall not be possible to initiate any subsequent IRRADIATION without releasing the control by which the previous IRRADIATION was initiated.
dead man type	AS/NZS 3200.2.15:1994 29.1.104 d) Means shall be provided to enable the OPERATOR to interrupt IRRADIATION, or a series of IRRADIATIONS, at any time.
security of switch “safeguard against unintentional exposure”	AS/NZS 3200.2.15:1994 29.1.104 e) Any control by which the LOADING of an X-RAY TUBE can be initiated shall be safeguarded against unintended actuation (see Item b) of Sub-clause 56.11).
Light beam	
thermal protection	AS/NZS 3200.2.28;1994 42.101 Beam limiting devices incorporating a light field indicator shall be provided with one of the following means to reduce the possible temperature rise occurring if the lamp remains energised while the beam limiting device is covered with drapes or other material, reducing the normal heat dissipation a) a thermal cut out b) a time limiting device preventing the lamp remaining on for more than 2 minutes c) a statement in the accompanying documents giving details of a time limiting switch to be connected externally to perform the function described in b)
light beam alignment	AS/NZS 3200.1.3:1996 29.202.9 The lack of alignment between any boundary of the light beam and the equivalent boundary of the X-ray beam in the plane of the image receptor shall not exceed 2% of the distance between the focus of the X-ray tube and the plane of the image receptor
illuminance	AS/NZS 3200 1.3:1996 29.202.7 In X-RAY EQUIPMENT specified for RADIOGRAPHY, a LIGHT FIELD-INDICATOR shall be provided where appropriate, to assist in delineating the position of the X-RAY FIELD on the PATENT SURFACE. If a LIGHT FIELD-INDICATOR is provided, it shall delineate the edges of the X-RAY FIELD and it shall provide an average illumination of not less than 100 lx in a plane normal to the REFERENCE AXIS at 1 m from the FOCAL SPOT, or at the largest FOCAL SPOT TO IMAGE RECEPTOR DISTANCE specified for NORMAL USE, if this is less than 1 m.

contrast	AS/NZS 3200 1.3:1996 29.202.7 At this distance, the contrast at the edge of the LIGHT FIELD shall have a value of not less than 3 in mobile X-RAY EQUIPMENT and not less than 4 in other X-RAY EQUIPMENT.
Capacitor discharge X-ray generator	
selection of exposure factors	AS/NZS 3200.2.15:1994 29.1.104 a) Preselection of the initial X-ray tube voltage shall be possible before the charging of the capacitor
indication of charging	AS/NZS 3200.2.15:1994 29.1.103 f) The process of charging and discharging the capacitor shall be indicated at the control panel
charging completed	AS/NZS 3200.2.15:1994 29.1.104 f) The charging process shall be terminated automatically when the preselected initial X-ray tube voltage has been reached
resetting to a lower kV	AS/NZS 3200.2.15:1994 29.1.104 g) Means shall be provided to discharge the capacitor within the specified range of initial X-ray tube voltages to any value lower than that to which it is initially preselected
discharge of capacitor	AS/NZS 3200.2.15:1994 29.1.107 a) Means to discharge the high voltage storage capacitor to a residual voltage of less than 50 V within 5 s and to maintain that discharged state indefinitely shall be provided. This means shall be independent on the supply mains
adequacy of stored energy	AS/NZS 3200.2.15:1994 29.106 a) In all combinations of exposure factors the residual X-ray tube voltage shall not be less than 50% of its initial value
Tube housing leakage	AS/NZS 3200.1.3:1996 29.204.3 The kerma in air from leakage radiation from a tube assembly shall not exceed 1.0 mGy in any 1-hour period at a distance of 1 m from the focal spot.
Radiation quality	

half value layer	<p>Table 204 of AS/NZS 3200.1.3:1996</p> <p>The total filtration shall be such that the measured half value layers are greater than or equal to the values specified in</p>
	<p>AS/NZS 3200.1.3:1996 29.201.5</p> <p>The total filtration shall be not less than 2.5 mm Al</p>
Output (kerma)	
coefficient of variation for specified tube voltages	<p>AS/NZS 3200.2.15:1994 50.101 AS/NZS 3200.2.15:1994 50.108.</p> <p>The coefficient of variation of measured values of air kerma shall not be greater than 0.1 for any combination of exposure factors</p> <p><i>The COEFFICIENT OF VARIATION of AIR KERMA shall be determined by measurements at 100%, at approximately 70% and at approximately 50% of the NOMINAL X-RAY TUBE VOLTAGE.</i></p> <p>I</p>
measurement of X-RAY TUBE VOLTAGE	<p>AS/NZS 3200.2.15:1994 50.109</p> <p>The X-RAY TUBE VOLTAGE for the determination of the PER CENT AVERAGE ERROR of X-RAY TUBE VOLTAGE shall be at 100%, at approximately 70% and at approximately 50% of the NOMINAL X-RAY TUBE VOLTAGE.</p>
agreement between the indicated and measured values of LOADING FACTORS	<p>AS/NZS 3200.2.15:1994 50.102 AS/NZS 3200.2.15:1994 Table 101</p> <p>Agreement between the indicated and measured values of LOADING FACTORS In CAPACITOR DISCHARGE X-RAY GENERATORS the requirements of this sub-clause on PER CENT AVERAGE ERROR apply to all indicated values of LOADING FACTORS within the SPECIFIED RANGE OF COMPLIANCE, whether fixed, preselected or measured.</p>
information regarding linearity of radiation output	<p>AS/NZS 3200.2.15:1994 6.8.2</p> <p>The INSTRUCTIONS FOR USE shall contain information about the particularities of CAPACITOR DISCHARGE X-RAY GENERATORS compared with the radiation output in transformer X-RAY GENERATORS. Data shall be provided showing the USER the non-linearity of radiation output with LOADING TIME and CURRENT TIME PRODUCT and drawing attention to the fact that the change of RADIATION QUALITY with the LOADING TIME has to be considered when setting the INITIAL X-RAY TUBE VOLTAGE.</p>