Department of Health and Human Services
Population Health

Tasmanian Government

Radiation Protection Act 2005 – Section 17

CERTIFICATE OF COMPLIANCE:

STANDARD FOR RADIATION APPARATUS -

X-RAY MEDICAL DIAGNOSTIC

(FIXED RADIOSCOPY)

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

Radiation Protection Unit
90 Davey Street
HOBART TAS 7001

Phone 03 6222 7256
Fax 03 6222 7257
Email
radiation.protection@dhhs.tas.gov.au

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 Fixed Radioscopy", 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 3200.2.7:1999 IEC 60601-2-7	Approval and test specification - Medical electrical equipment Part 2.7:Particular requirements for safety-High -voltage generators of diagnostic 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 such Radiation Apparatus, classified by Radiation Protection Act 2005 licences as "X-ray Fixed Radioscopy", for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005*.

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 3200.2.7:1999 IEC 60601-2-7	Approval and test specification - Medical electrical equipment Part 2.7:Particular requirements for safety-High -voltage generators of diagnostic X-ray generators
AS/NZS 3200.2.28:1994 IEC 60601-2-28	Approval and test specification- Medical electrical equipment Part 2.28:Particular requirements for safety-X-ray source assemblies for medical diagnosis 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	
mains	**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. **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. **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. **AS/NZS 3200.1:1998 Paragraph 6.7 a)**
ready to exposure	**AS/NZS 3200.2.7:1999 6.7 a)** **AS/NZS 3200.2.7:1999 29.1.102 a)** Visible indication shall be provided on the CONTROL PANEL indicating the state when one further actuation of a control from that CONTROL PANEL will initiate the LOADING of THE X-RAY TUBE in INTERMITTENT MODE. If this state is indicated in INTERMITTENT MODE by means of a single function indicator light, the colour green shall be used; see 6.7 a).
energised X-ray tube	**AS/NZS 3200.2.7:1999 6.7 a)** The colour yellow shall be used at the control panel to indicate the loading state (exposure).
audible signal radiographic mode only	**AS/NZS 3200.2.7:1999 29.1.102 b)** A signalling device audible at the location from which the equipment is operated shall indicate the termination of the exposure.
remote indication	**AS/NZS 3200.2.7:1999 29.1.102 b)** means shall be provided for connections to be made so that exposure can be indicated remotely from the control panel.
Labels and markings: filtration	**AS/NZS 3200.1.3:1996 29.201.6**
Protection against mechanical hazards	
moves easily	The tube housing should be easy to move and position by an operator.

stays where positioned	**RAR** Once positioned, the tube housing should not move prior to or during exposures. "C-arm tomography" equipment is exempt from this requirement
Exposure distances focus-skin distance (FSD)	**AS/NZS 3200.1.3:1996 29.205.1** A means shall be provided to prevent the use during radioscopic irradiation of focal spot to skin distances less than 200 mm during surgery, 400 mm if the X-ray equipment has a patient support permanently between the X-ray tube and the patient or 300 mm for other applications.
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.
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.
correspondence between X-ray and image receptor	**AS/NZS 3200.1.3:1996 29.203.4** for radiography with equipment specified for indirect radioscopy during surgery at a fixed focal spot to image receptor distance, the X-ray field shall not exceed the dimensions of the image receptor.

Exposure controls	
timer	**RAR** Only electronic timer.
safety against excessive radiation	**AS/NZS 3200.2.7:1999 29.1.104** when the duration of irradiation is determined by the operator a means shall be provided to terminate irradiation automatically when a predetermined integrated loading time, not exceeding 10 min, has elapsed. After the integrated time has reached a time not exceeding 5 min and at least 30 s before automatic termination a continuous audible signal shall be given to enable resetting of the integrating device.
Exposure factors	
high voltage indication	AS/NZS 3200.2.7:1999 50.101.1 c) Values of the X-ray tube voltage shall be indicated in kV.
tube current indication	AS/NZS 3200.2.7:1999 50.101.1 c) Values of the X-ray tube current shall be indicated in milliamps.
Shortened Indication	AS/NZS 3200.2.7:1999 50.101.2 a) b) For HIGH-VOLTAGE 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. b) For HIGH-VOLTAGE 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.
Exposure switch	
constant pressure required	**AS/NZS 3200.2.7:1999 29.1.103 b)** Each exposure shall be initiated and maintained by means of a control requiring continuous actuation by the operator.
no repeat exposure without release	**AS/NZS 3200.2.7:1999 29.1.103 c)** It shall not be possible to initiate another exposure without releasing the switch.
dead man type	**AS/NZS 3200.2.7:1999 29.1.103 d)** The exposure shall be able to be interrupted at any time.
security of switch	**AS/NZS 3200.2.7:1999 29.1.103 e)** Any exposure control shall be safeguarded against unintended actuation.

<table>
<tr><td>Exposure limits</td><td></td></tr>
<tr><td>air kerma rates</td><td>AS/NZS 3200.1.3:1996 29.209
air kerma rates shall not exceed
50 mGy/min - manual
100 mGy/min automatic
150 mGy/min high (boost) measured according to Table 211

TABLE 211
TEST CONDITIONS
<table><tr><th>Conditions</th><th>Measurement distance
mm</th></tr><tr><td>UNDER-TABLE X-RAY TUBE
When a patient support is permanently between the X-ray tube assembly and the position of the patient.</td><td>10 from the patient support on the patient side of the support.</td></tr><tr><td>OVER-TABLE X-RAY TUBE
When a patient support is permanently between the position of the patient and the X-ray image receptor.</td><td>300 above the patient support on the X-ray tube side of the support.</td></tr><tr><td>C OR U ARM SYSTEMS
Where the X-ray tube and the image receptor are mechanically linked and where a patient support may or may not be permanently in the radiation beam.</td><td>300 from the image receptor plane but not less than 400 from the focal spot.</td></tr><tr><td>OTHER RADIOSCOPY SYSTEMS
Where no patient support is permanently in the radiation beam.</td><td>400 from the focal spot or the minimum distance, whichever is greater.</td></tr></table></td></tr>
<tr><td>Radiation quality</td><td></td></tr>
<tr><td>half value layer</td><td>Table 204 of AS/NZS 3200.1.3:1996
The total filtration shall be such that the measured half value layers are greater than or equal to the values specified in Table 204.</td></tr>
<tr><td>Output (kerma)</td><td></td></tr>
<tr><td>reproducibility</td><td>AS/NZS 3200.2.7:1999 50.102.1
The coefficient of variation of measured values of air kerma shall not be greater than 0.05 for any combination of exposure factors.</td></tr>
<tr><td>linearity</td><td>AS/NZS 3200.2.7:1999 50.102.2 a)
The quotient of the average of the measured values of air kerma divided by the indicated value of the current time product shall not differ from the quotient of the average of the measured values of air kerma and current time product measured at 0.1 s (or the next highest setting) or the lowest mAs setting by more than 0.2.</td></tr>
<tr><td>radiographic accuracy</td><td>AS/NZS 3200.2.7:1999 50.103.1
The measured kV shall be within 10% of the nominal kV over a range of kV settings.</td></tr>
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