Department of Health and Human Services
Population Health

Radiation Protection Act 2005 – Section 17

CERTIFICATE OF COMPLIANCE:

STANDARD FOR RADIATION APPARATUS -

X-RAY MEDICAL DIAGNOSTIC

(BIOPSY)

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 biopsy", for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005. Equipment of this type is only used for "in-vitro" imaging of incisional, core or excisional biopsies.

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
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.
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 Biopsy", for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005. Equipment of this type is only used for "in-vitro" imaging of incisional, core or excisional biopsies.

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 3200.2.7:1999 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: Particular requirements for safety-X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators.

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* 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	**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
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. ***RAR***
stays where positioned	Once positioned, the tube housing should not move prior to or during exposures. ***RAR***
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. Fixed field sizes are permitted **RAR**

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 b)** If the adjustment is not stepless then step sizes not exceeding 1 cm
Exposure controls	
timer type	Only electronic timers are acceptable **RAR**
exposure factors	**AS/NZS 3200.2.7:1999 50.101.1 a)** Information shall be available to the operator, before during and after exposure about fixed, or semi permanently preselected or otherwise exposure factors or modes of operation so as to allow the operator to preselect appropriate conditions for irradiation
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
abbreviated indication of factors	**AS/NZS 3200.2.7:1999 50.101.2 a)** For operation with one or more fixed combinations of exposure factors the indication at the control panel may be confined to the value of only one of the significant exposure factors
exposure "ready" state	**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 action of a control from that control panel will initiate the exposure

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 **OR** sufficient radiation shielding must be between the operator and the X-ray unit to ensure the occupational dose limit in (regulations) is complied with. **RAR**
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
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/NZS3200.1.3:1996 29.202.7** If a light field indicator is provided it shall delineate the edges of the X-ray field and 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 distance specified in normal use, if this is less than 1 m The contrast at the edge of the light field shall have a value of not less than 4
Radiation quality	
Output (kerma)	
reproducibility	**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
kVp	
accuracy	**AS/NZS 3200.2.7:1999 50.103.1** The measured kV shall be within 10% of the indicated value over a range of kV settings
maintained accuracy	The measured kV shall remain within +/- 5 or +/- 5% of the nominal kV over a range of mAs settings **RAR**
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