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

(COMPUTED TOMOGRAPHY)

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

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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 computed tomography", 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 3200.2.44:2005 IEC 60601-2-44, Ed. 2.1(2002)	Medical electrical equipment - Particular requirements for safety-X-ray equipment for computed tomography

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 computed tomography", 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 3200.2.44:2005 IEC 60601-2-44, Ed. 2.1(2002)	Medical electrical equipment - Particular requirements for safety-X-ray equipment for computed tomography
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 Part 2.28: Particular requirements for safety-X-ray source 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 expose	**AS/NZS 3200.2.44:2005 Paragraph 29.1.101.1 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.
colour of ready indicator	**AS/NZS 3200.2.44:2005 Paragraph 29.1.101.1 a)** If the ready state is indicated by means of a single function indicator light, the colour green shall be used.
colour of exposure indicator	**AS/NZS 3200.2.44:2005 Paragraph 29.1.101.1 b)** The loading state shall be indicated by a yellow indicator light on the control panel of the CT system tube
visual indication	**AS/NZS 3200.2.44:2005 Paragraph 29.1.106.1** The CT conditions of operation to be used during a scan series shall be indicated prior to the initiation of a scan or scan series. On equipment having all or some of these CT conditions of operation at fixed values, this requirement may be met by permanent markings. Indication of the CT conditions of operation shall be visible from any position from which the ready state can be initiated.
beam on status indicator	**AS/NZS 3200.2.44:2005 Paragraph 29.1.106.2** When, and only when, radiation is produced, visible indication shall be provided on the control panel from which X-radiation is actuated and or near the housing of the scanning mechanism. Indicators at or near the housing of the scanning mechanism shall be visible from any point external to the patient opening where insertion of any part of the human body into the primary radiation beam is possible.

shortened Indication	**AS/NZS 3200.2.44:2005 Paragraph 50.102.2** a) for CT scanners operating with one or more fixed combination 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. b) In addition, these values shall be listed in a form suitable to be displayed at a prominent location on or near the control panel for CT scanners 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 the values to be listed in 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 3200.2.44:2005 Paragraph 50.102.1** Values of the X-ray tube voltage shall be indicated in kV Values of the X-ray tube current shall be indicated in milliamps Values of the loading time in seconds Values of the current time product shall be indicated in millamp seconds
indication and position of tomographic section	**AS/NZS 3200.2.44:2005 Paragraph 29.202.101 a) b) c)** a) a preview image shall be provided on which the operator may set up the tomographic sections to be taken. The reference lines indicating these sections shall not differ from the true positions by more than 2mm with the gantry in the vertical position. b) a light field shall be provided for marking the tomographic section. The light field shall be visible under ambient light conditions up to 500 lx. The width of the light field shall not exceed 3 mm, measured in the centre of the gantry opening. The centre of the tomographic section shall be within 2 mm of the centre of the light field. If more than one tomographic section is acquired at a time, the accompanying documents shall describe the position of the light field in reference to the tomographic sections. If additional light fields are provided for reference purposes, their accuracy shall be defined in the accompanying documents. For motions of the patient support beginning at a typical starting position, continuing to a position which is lesser of the maximum selectable scan increment or 30 cm and returning to the starting position, the deviation of the scan increment shall not exceed 1mm. This is for a load of 135 kg spread evenly across the patient support.

Gantry and patient support	**AS/NZS 3200.2.44:2005 Paragraph 22.4.101 a) b) c)** a) General 1) Interruption or failure of powered movements or of the SUPPLY MAINS shall cause any parts in motion to be stopped within the limits given in items b) and c). The maximum value of distance and angle for each stopping condition shall be given in the ACCOMPANYING DOCUMENTS. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS and by interruption of the SUPPLY MAINS to powered movements and measurement of stopping distances. These tests shall be performed with a PATIENT-equivalent mass of 135 kg distributed evenly over the PATIENT SUPPORT.* 2) When a part is provided with one or several devices designed to reduce, in NORMAL USE, the risk of collision with the PATIENT, the operation and limitations of each device shall be described in the INSTRUCTIONS FOR USE. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.* 3) Where there is a possibility that a failure of a powered movement during NORMAL USE of the EQUIPMENT might result in the PATIENT being trapped, controls and switches shall be provided to permit the release of the PATIENT. These means shall be described in the INSTRUCTIONS FOR USE and on a label on the EQUIPMENT when a deliberate action is required. *Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.* b) Tilting of the gantry When the emergency stop control is actuated, the gantry tilt shall stop within an angle of 0,5°. *Compliance is checked by inspection.* c) Linear movements of the PATIENT SUPPORT When the emergency stop control is actuated, the PATIENT SUPPORT shall stop within a distance of 10 mm.
Focus-skin distance (FSD)	**AS/NZS 3200.2.44:2005 Paragraph 29.1.104** A minimum focal spot to skin distance of 15 cm.
Accuracy of radiation output	**AS/NZS 3200.2.44:2005 Paragraph 50.101** The manufacturer shall provide with the accompanying documents information regarding the accuracy of X-ray tube voltage, X-ray tube current and linearity of radiation output
Limitation of radiation output	**AS/NZS 3200.2.44:2005 Paragraph 29.1.101.2 a) b)** a) Means shall be provided to limit the electric energy to be delivered by the use of fixed or pre-selected combinations of suitable LOADING FACTORS and modes of operation. During IRRADIATION, the OPERATOR shall be able to terminate the LOADINGS at any time, but means may be provided to acquire up to one additional rotation of the X-RAY SOURCE. b) Any control by which the LOADING of an X-RAY TUBE can be initiated shall be safeguarded against unintended actuation. Compliance is checked by inspection and by the appropriate functional tests.

Safety measures against excessive radiation	**AS/NZS 3200.2.44:2005 Paragraph 29.1.105 a) b) c) d) e) f)** a) Means shall be provided to terminate the loading automatically by de-energizing the radiation source in the event of timer failure. Such termination shall occur within an interval that limits the total scan time to not more than the lesser of 110% of the preset value or one extra rotation of the xray source assemble through the use of either a back-up timer or devices which monitor the equipment function. A visible indication of termination shall be provided to the operator. b) Means shall be provided to terminate the loading automatically by de-energizing the radiation source in the event of an equipment failure affecting data collection within a specified period. Such a termination shall occur within 1 s of such a failure. A visible indication of termination shall be provided to the operator. c) Means shall be provided so that the operator can terminate the loading at any time during a scan, or series of scans under x ray equipment control, of greater than 0.5 s duration. d) When loading has been terminated by circumstances not noted under a),b) and c) above, resetting of the CT conditions of operation shall be required prior to the initiation of another scan. e) When more than one scan is programmed in the same tomographic plane there shall be a warning on the operator's console that this mode has been selected and the operator shall confirm that this is to occur before continuing another scan series. f) Any data acquired prior to interrupting the loading of a helical scan series should be available for image reconstruction when loading has been interrupted by whatever cause.

Half Value Layer	**AS/NZS 3200.2.44:2005 Paragraph 29.201.5 Table 101**

In addition to the FILTRATION addressed in 29.201.3 and 29.201.4, fixed ADDED FILTERS shall be used such that, for all configurations in NORMAL USE, the first HALF-VALUE LAYERS attained in the X-RAY BEAM incident to the PATIENT shall not be less than the minimum permissible values given in table 101.

Table 101 – HALF-VALUE LAYERS in CT SCANNERS

X-RAY TUBE VOLTAGE (see note 1) kV	Minimum permissible first HALF-VALUE LAYER (see note 2) mm Al
<60	See note 3
60	1,9
70	2,1
80	2,4
90	2,7
100	3,0
110	3,4
120	3,8
130	4,2
140	4,6
>140	see note 3

NOTE 1 HALF-VALUE LAYERS for intermediate voltages are to be obtained by linear interpolation.

NOTE 2 The values correspond to a TOTAL FILTRATION of 2,5 mm Al.

NOTE 3 Linear extrapolation is to be used here.

Compliance with the HALF-VALUE LAYER requirement shall be maintained for all selectable values of ADDITIONAL FILTRATION.

Dose Information provided in the accompanying documents	**AS/NZS 3200 29.1.102.1 a) 1,2,3,4 b) c) d)** **AS/NZS 3200 29.1.103.1** **AS/NZS 3200 29.1.103.2** The following information shall be given in the ACCOMPANYING DOCUMENTS: a) The *CTDI*100 and the corresponding CT CONDITIONS OF OPERATION at the following locations in the dosimetry PHANTOM specified in 29.1.102.2: 1) Along the axis of rotation of the PHANTOM (*CTDI*100(centre)). 2) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM, with the PHANTOM positioned so that the *CTDI*100 is the maximum obtainable at this depth. 3) Along a line parallel to the axis of rotation and 10 mm interior to the surface of the PHANTOM at positions 90°, 180° and 270° from the position in item a) 2) of this subclause. The CT CONDITIONS OF OPERATION shall be the typical values suggested by the MANUFACTURER. The location of the position where the *CTDI*100 is maximum as specified in item a) 2) of this subclause shall be given by the MANUFACTURER with respect to the housing of the scanning mechanism or other readily identifiable part of the CT SCANNER in such a manner as to permit placement of the dosimetry PHANTOM in this orientation. 4) *CTDI*100 (peripheral) is the average of the four values of *CTDI*100 measured around the dosimetry PHANTOM periphery according to 29.1.102.1 a) 2) and 3). b) The *CTDI*100 in the centre location of the dosimetry PHANTOM for each selectable CT CONDITION OF OPERATION that varies either the rate or duration of IRRADIATION or the NOMINAL TOMOGRAPHIC SECTION THICKNESS. This *CTDI*100 shall be presented as a value that is normalized to the *CTDI*100 in the centre location of the dosimetry PHANTOM from item a) of this subclause, with the *CTDI*100 of item a) of this paragraph having a value of 1. As a single CT CONDITION OF OPERATION is changed, all other independent CT CONDITIONS OF OPERATION shall be maintained at the typical values described in item a) of this subclause. These data shall encompass the range of each CT CONDITION OF OPERATION stated by the MANUFACTURER as appropriate. When more than three selections of a CT CONDITION OF OPERATION are available, the normalized *CTDI*100 shall be provided, at least for the minimum, maximum and one mid-range value of the CT CONDITION OF OPERATION. c) The *CTDI*100 at the location coincident with the maximum *CTDI*100 at 10 mm interior to the surface of the dosimetry PHANTOM for each selectable peak X-RAY TUBE VOLTAGE. When more than three selections of the peak X-RAY TUBE VOLTAGE are available, the normalized *CTDI*100 shall be provided, at least for the minimum, maximum and one mid-range value of the peak X-RAY TUBE VOLTAGE. The *CTDI*100 shall be presented as a value that is normalized to the maximum *CTDI*100 located at 10 mm interior to the surface of the dosimetry PHANTOM from item a) above, with the *CTDI*100 of item a) above having a value of 1. d) A statement of the maximum deviation from the values given according to items a), b) and c). Deviation of values shall not exceed these limits. A graphical presentation of the DOSE PROFILE along a line z perpendicular to the TOMOGRAPHIC PLANE measured in the centre location of the head-dosimetry PHANTOM and body-dosimetry PHANTOM shall be given in the ACCOMPANYING DOCUMENTS for each selectable NOMINAL TOMOGRAPHIC SECTION THICKNESS. When more than three NOMINAL TOMOGRAPHIC SECTION THICKNESSES are available, the information shall be provided for at least the minimum, maximum and one mid-range value of NOMINAL TOMOGRAPHIC SECTION THICKNESS. The DOSE PROFILE shall be presented on the same graph and to the same scale as the corresponding SENSITIVITY PROFILE required by 29.1.103.2. A graphical presentation of the SENSITIVITY PROFILE at the location corresponding to the centre

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Dose Information displayed on the control	**AS/NZS 3200.2.44:2005 29.1.103.4** The $CTDI_{100}$ ($CTDI_w$) is defined as $CTDI_w$=1/3 $CTDI_{100}$(centre) +2/3 $CTDI_{100}$(peripheral) If the NOMINAL TOMOGRAPHIC SECTION THICKNESS is not equal to the table increment per rotation, a corrected *CTDI*w value shall be displayed describing the average dose over the total volume scanned for the selected CONDITIONS OF OPERATION. This is required in the following instances: − multi-slice detection arrays; − when the NOMINAL TOMOGRAPHIC SECTION THICKNESS is not equal to the table increment per rotation; or − when the NOMINAL TOMOGRAPHIC SECTION THICKNESS is not equal to the table increment between two consecutive scans. This list is not exclusive. **The value for $CTDI_{vol}$ expressed in milligray (mGy) shall be displayed on the CONTROL PANEL, reflecting the type of examination selected, head or body, and the CT CONDITIONS OF OPERATION.** The volume $CTDI_w$ ($CTDI_{vol}$) describes the average dose over the total volume scanned for the selected CT CONDITIONS OF OPERATION. The $CTDI_{vol}$ is defined as follows: a) for axial scanning $CTDI_{vol} = (NxT/\Delta d)xCTDI_w$ where *N* is the number of TOMOGRAPHIC SECTIONS produced in a single axial scan of the X-RAY SOURCE; *T* is the NOMINAL TOMOGRAPHIC SECTION THICKNESS; Δd is the PATIENT SUPPORT travel in *z*-direction between consecutive scans. b) for helical scanning $CTDI_{vol}=CTDI_{w}/CT\ pitch\ factor$ c) for scanning without pre-programmed movement of the PATIENT SUPPORT $CTDI_{vol} = n \times CTDI_w$ where *n* is equal to the maximum number of pre-programmed rotations.

	When the X-RAY TUBE CURRENT varies within a scan, the pre-programmed LOADING FACTORS that determine the maximum possible $CTDI_{vol}$ shall be used to calculate the $CTDI_{vol}$. If the number of rotations is not pre-programmed, the $CTDI_{vol}$ per second shall be displayed expressed in milligray per second (mGy/s) and the accumulated $CTDI_{vol}$ shall be displayed, expressed in milligray (mGy) during the examination. NOTE 1 The displayed $CTDI_{vol}$ given by the MANUFACTURER may be a representative figure for that model and not the value measured on the particular CT SCANNER NOTE 2 The definition of $CTDI_{vol}$in section c) will likely overestimate the actual dose since the maximum number of pre-programmed rotations is applied, but is used as a conservative estimation of dose to help assure PATIENT protection from skin radiation injury. NOTE 3 The manual movement of the PATIENT SUPPORT is included under c). AS/NZS 3200.2.44:2005 Paragraph 29.1.103.3 AS/NZS 3200.2.44:2005 Paragraph 29.1.103.4 The value of the weighted $CTDI_{100}$ ($CTDI_w$) shall be displayed on the OPERATOR's console, reflecting the type of examination selected, head or body, and the CT CONDITIONS OF OPERATION.