

Radiation Protection Act 2005 – Section 17

**CERTIFICATE OF COMPLIANCE:
STANDARD FOR RADIATION APPARATUS -
X-RAY DENTAL DIAGNOSTIC
(INTRAORAL)**

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 intraoral”, 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 3200.2.201:2000

Approval and test specification- Medical electrical equipment Part 2.201:Particular requirements for safety-Dento-maxillofacial X-ray equipment.

**AS/NZS 3200.1.3:1996
IEC 60601-1-3**

Approval and test specification- Medical electrical equipment Part 1.3: 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 Requirement-
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 intraoral”, 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 3200.2.201:2000

Approval and test specification- Medical electrical equipment Part 2.201:Particular requirements for safety-Dento-maxillofacial X-ray equipment.

AS/NZS 3200.1.3:1996
IEC 60601-1-3

Approval and test specification- Medical electrical equipment Part 1.3: 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.

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.

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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
“Warning”	<p>AS/NZS 3200.2.201:2000 6.101.2 X-ray equipment shall be marked in accordance with the requirements set out in AS/NZS 3200.1.0 and shall carry the following warning on the X-ray equipment control panel to indicate the radiation hazards: <i>“Warning this X-ray equipment may be hazardous to patients and operators unless safe exposure factors and operating instructions are observed”.</i></p>
Markings on the X-ray tube assembly supplier and manufacturer	<p>AS/NZS 3200.2.201:2000 6.103 (a) The name of the supplier and manufacturer</p>
serial numbers	<p>AS/NZS 3200.2.201:2000 6.103 (b) The tube assembly shall be marked with the model and serial number.</p>
type number of tube and insert	<p>AS/NZS 3200.2.201:2000 6.103 (c) The type number of the X-ray tube and X-ray tube assembly. The X-ray tube insert shall be uniquely identified.</p>
focal spot marked	<p>AS/NZS 3200.2.201:2000 6.103 (d) The position and nominal size of the focal spot shall be marked on the tube assembly.</p>
X-ray tube potential and current	<p>AS/NZS 3200.2.201:2000 6.103 (e) Where the X-ray tube potential and current are fixed, their values shall be indicated by permanent labelling</p>
Indication of exposure factors	<p>AS/NZS 3200.2.201:2000 29.101 Where X-ray equipment operates at fixed X-ray tube voltages and currents, the exposure factors shall be indicated in the accompanying documents and on labels attached to the equipment.</p>
Tube Current	<p>AS/NZS 3200.2.201:2000 29.101.1 Adjustment or selection of the X-ray tube current shall be by means of a calibrated control. Where a milli-ammeter is provided, it shall be such that the full scale reading is at least 110 percent of the maximum nominal tube current of the equipment.</p>
Exposure factors	<p>AS/NZS 3200.2.201:2000 29.101.2 X-ray equipment shall be designed to permit the operator to preset exposure factors without the need for energizing the X-ray tube</p>

<p>Supply indicator</p>	<p>AS/NZS 3200.2.201:2000 29.101.3</p> <p>An indicator on the control panel, green in colour, shall be incorporated to indicate when the main switch is in the “ON” position and the control panel is energized.</p> <p>Note: AS/NZS 3200.1.0:1998 56.8 provides for situations when indicators are not necessarily required.</p> <p>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>Beam on indicator and audible indicator</p>	<p>AS/NZS 3200.2.201:2000 29.101.4</p> <p>An amber indicator, clearly visible to the operator, shall indicate when the X-ray tube is energised. The beam on indicator shall be clearly marked.</p> <p>A signal audible to the operator, other than the sound produced fortuitously by switching devices or contactors during the exposure, shall indicate either the duration of the exposure or its termination</p>
<p>Exposure switch</p> <ul style="list-style-type: none"> ▪ “Dead-Man” operation ▪ Continuous pressure required ▪ No repeated exposure without release 	<p>AS/NZS 3200.2.201:2000 29.101.5</p> <p>AS/NZS 3200.2.201:2000 29.101.6</p> <p>The exposure switch for radiography shall be arranged so that the X-ray equipment can be operated from a distance of at least 2000 mm from the X-ray tube and the patient. The switch shall be of the dead-man type.</p>
<p>Remote control</p> <ul style="list-style-type: none"> ▪ “Dead-Man” operation ▪ Continuous pressure required ▪ No repeated exposure without release 	<p>AS/NZS 3200.2.201:2000 29.101.6</p> <p>Where the exposure is initiated by an infra-red or wireless remote handpiece –</p> <ol style="list-style-type: none"> a) the X-ray generator and handpiece shall be encoded so that no other remote control handpiece can initiate exposures; b) the control panel shall have provision for storage of the remote control handpiece; and c) the remote control handpiece shall be permanently labelled with a warning identifying its purpose. <p>All exposure control switch handpieces shall be dead-man so that continuous pressure is necessary to maintain the X-ray exposure and it shall not be possible to make repeat exposures without releasing that switch.</p>
<p>Timer type (Electronic Timer)</p>	<p>AS/NZS 3200.2.201:2000 29.102</p> <p>The exposure timer shall be electronic and the circuit of the apparatus shall be so designed that in the event of any failure, the failure causes the timer to revert to a safe condition and does not lead to the X-ray tube becoming energized or continuing to be energized.</p>

<p>Accuracy of the timer</p>	<p>AS/NZS 3200.2.201:2000 29.102.1 For full and half wave rectified generators, the timer controls shall agree with the measured exposure time to within +/- 10% or one pulse, whichever is greater. The exposure time for these generators shall be determined by counting the total number of pulses, and multiplying by half the mains period (0.01 s for 50 Hz) if full wave rectified, or the mains period (0.02 s for 50 Hz) if half wave rectified. For all other generators, the timer control shall agree with the measured exposure time to within +/- 10% + 1 ms. The exposure time for these generators shall be determined from the time the waveform rises to 75% of the kV peak until the time when it finally drops to below this value. Note: Apparatus which initiates filament heating concurrently with the application of the X-ray tube voltage may exhibit some instability in both the X-ray tube voltage and the air kerma rate until the tube current stabilizes. Short periods (tens of milliseconds) are of little significance but larger periods may affect accuracy of the assessment when using non-invasive test equipment.</p>
<p>Operation of timer</p> <ul style="list-style-type: none"> a) time indicated b) no exposure at zero setting. c) alter setting. d) variations in exposure time due to changes in image receptor speed. e) Indication of image receptor speed/digital radiography. 	<p>AS/NZS 3200.2.201:2000 29.102.2 The timer shall terminate an exposure at a preset time interval or a preset product of current and time. This shall be achieved by selecting the required time on the device or by selecting an icon. The manufacturer/supplier shall clearly document the exposure time for each icon and the film or image receptor speed for which the exposure time is applicable and-</p> <ul style="list-style-type: none"> a) where an icon is used, the exposure time shall be clearly displayed on the timer or the timer handpiece; b) It shall not be possible to make exposures when the exposure device is set to "0" or "off" or an equivalent position; c) It shall be possible to alter the timer setting to a higher or lower values after the initial adjustment without initiating exposure; d) Variations in exposure time caused by changes in image receptor speed settings shall be displayed; and e) Where an image receptor sensitivity control is provided, the exposure setting for the image receptor (e.g. for D, E or F speed film) and/or the setting for electronic (digital) radiography shall be clearly indicated by appropriate labelling of that control or by appropriate display at the user's location. The last value selected shall be the default.
<p>Ready to exposure</p>	<p>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.</p> <p>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).</p>
<p>Accuracy of X-ray tube voltage.</p>	<p>AS/NZS 3200.2.201:2000 29.103 The delivered X-ray tube voltage (kV peak) average shall be within +/-5 kV or +/- 5%, whichever is the greater, of the nominal or indicated value averaged over not less than 0.1 s and commencing 0.1 s from the initiation of the exposure.</p>
<p>kVp maintained accuracy</p>	<p>The measured kV shall remain within +/-5 or +/- 5%, whichever is the smaller, of the indicated value over a range of typical mAs values</p> <p>RAR</p>
<p>Reproducibility of output</p>	<p>AS/NZS 3200.2.201:2000 29.104.1 The coefficient of variation of the measured air kerma for typically used combinations of loading factors shall not exceed 0.05 and compliance with this requirement shall be based on not less than five consecutive measurements taken within 10 min, each with an exposure time of not less than 0.1 s</p>

Output linearity	<p>AS/NZS 3200.2.201:2000 29.104.2</p> <p>At the nominal high voltage setting, the air kerma shall be linear with respect to the current time product (mAs) over its full range. Compliance is obtained if the maximum (X_{max}) and minimum (X_{min}) values of the kerma per mAs are such that-</p> $X_{max} - X_{min} \leq (X_{max} + X_{min})$ <p>For equipment with fixed X-ray tube voltage and current, output linearity with mAs is checked against changes in exposure time. Where the equipment has more than one tube current setting, compliance is checked against changes in tube current setting using an exposure time not less than 0.1 s</p>
Skin dose	<p>The average skin dose at a typical exposure setting shall not be excessive when compared to the skin doses from similar X-ray units at similar settings</p> <p>RAR</p>
Primary limitation of the X-ray beam	<p>AS/NZS 3200.2.201:2000 29.105.1</p> <p>Each X-ray tube shall be mounted in a protective housing or other protective shielding. The X-ray window of such a housing shall have an aperture of such dimension that it will not allow passage of a useful beam larger than the maximum specified. X-ray equipment intended for applications requiring beam sizes smaller than the maximum available useful beam shall incorporate an additional fixed diaphragm to limit the aperture of the X-ray window to the maximum size required.</p>
Radiation leakage of X-ray tube assemblies.	<p>AS/NZS 3200.2.201:2000 29.105.2</p> <p>In the loading state, the air kerma of leakage radiation from X-ray tube assemblies at 1 m from the focal spot, averaged over any area 10 000 mm² of which no principal linear dimension exceeds 200 mm, when operated at the nominal X-ray tube voltage under conditions of loading corresponding to the maximum specified energy input in one hour, shall not exceed the limits stated below, as applicable:</p> <p>a) for X-ray tube assemblies specified for use in X-ray equipment for dental radiography with intra-oral X-ray image receptors at X-ray tube voltages not exceeding 90 kV peak, 0.25 mGy in one hour</p>
Stability of tube head	<p>AS/NZS 3200.2.201:2000 29.105.3</p> <p>The X-ray tube shall remain stationary when placed in position for radiography</p>
Beam quality	<p>AS/NZS 3200.2.201:2000 29.106</p> <p>The total filtration shall be such as to ensure that the measured half-value layers are equal to or greater than those specified in table 29.106.</p>
<p>X-ray tube voltage and field limitations.</p> <p>a) minimum kVp</p> <p>b) field size</p> <p>c) "open ended"</p> <p>d) source skin distance</p>	<p>AS/NZS 3200.2.201:2000 29.107</p> <p>AS/NZS 3200.2.201:2000 29.107.1 a) b) c) d)</p> <p>The minimum X-ray tube voltage and the maximum field dimensions for dental maxillofacial X-ray equipment are given in Table 29.107. Not less than 60 kVp maximum field dimension 60 mm "open ended" circular or rectangular and source to skin distance 200 mm.</p>

Protection by distance

AS/NZS 3200.1.3: 29.208.1

In the following cases, provided that the X-RAY EQUIPMENT is specified exclusively for examinations that do not need the OPERATOR to be close to the PATIENT during NORMAL USE, protection against STRAY RADIATION may be achieved without provision for control from a PROTECTED AREA in accordance with 29.208.2, by enabling the OPERATOR to control radiographic RADIATION from a distance not less than 2 m from the FOCAL SPOT and the X-RAY BEAM:

- mobile X-RAY EQUIPMENT specified exclusively for RADIOGRAPHY;
- X-RAY EQUIPMENT specified for dental RADIOGRAPHY using an intra-oral X-RAY IMAGE RECEPTOR;
- X-RAY EQUIPMENT specified for RADIOSCOPY during surgery, with provision for RADIOGRAPHY.

When protection is effected in this way, statements shall be included in the ACCOMPANYING DOCUMENT, drawing the attention of the USER and the OPERATOR to the need for using PROTECTIVE DEVICES and PROTECTIVE CLOTHING as appropriate to the WORKLOAD involved. Compliance is checked by inspection of the EQUIPMENT and by examination of the ACCOMPANYING DOCUMENTS.