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

(BONE MINERAL DENSITOMETER)

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 bone mineral densitometer", 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
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.
Accreditation Guidelines for Bone Densitometry	Australian and New Zealand Bone and Mineral Society
RAR	Regulatory Authority Requirements – Department of Health and Human Services

Note: Some types of bone mineral density X-ray equipment have low radiation outputs that make it difficult to measure output (kerma) or kVp non-invasively. In these cases measurements made during the last "service" of the equipment (within 6 months), by a licensed service technician, may be used by an accredited person to indicate compliance. These items are marked † in this standard.

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 bone mineral densitometer", 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 3200.2.7:1999 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	**RAR** The tube housing must be easy to move and position by an operator.
Exposure distances focus-skin distance (FSD)	A minimum focal spot to skin distance of 200 mm. Table 205 AS/NZS **3200.1.3:1996**

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.
Exposure controls	
timer type	**RAR** Only electronic timers are acceptable
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	Values of the X-ray tube voltage shall be indicated in kV **AS/NZS 3200.2.7:1999 50.101.1 c)**
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
constant pressure required –	**AS/NZS 3200.2.7:1999 29.1.103 b)** **RAR** Each exposure shall be initiated and maintained by means of a control requiring continuous actuation by the operator. **Note**: for this type of equipment exposure is usually initiated from a "software" switch and the concept of constant pressure does not apply. Operator actuation and monitoring of the scan is acceptable for this requirement.

no repeat exposure without release	**AS/NZS 3200.2.7:1999 29.1.103 c)** **RAR** It shall not be possible to initiate another exposure without releasing the switch. **Note**: for this type of equipment exposure is usually initiated from a "software" switch and the concept of "release" does not apply. Operator actuation and monitoring of the scan is acceptable for this requirement.
dead man type (interruption of scan at any time)	**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
Accuracy of laser light positioning.	**Accreditation Guidelines** To assess the accuracy of the laser light position indicator, two wires meeting at right angles are positioned approximately 1 mm to the right (facing the table) of where the point beam of laser light intercepts the scanning cushion. A PA array spine is carried out to where the wires lie in the field of view. The wires may be imaged on the computer monitor and ideally should lie at the centre of the transverse scan lines and at the starting point of the longitudinal scan motion. A reasonable positioning accuracy is within 5 mm of the start point.
Accuracy of indicated scan time	**Accreditation Guidelines** The timing of a scan is measured from when the X-ray beam light first comes on to when it goes out. The measurement is repeated. The measurements should agree to within 3%.
Radiation quality	
half value layer†	**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 of
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
linearity†	**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
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

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
BMD variation	**RAR (Accreditation Guidelines**) Examines the practice's "control chart", or data used for tracking BMD variation in a standard phantom, for this X-ray unit. The practice must have a suitable method for detecting changes in the measured BMD for the standard phantom. These methods must be constructed from any or all of the following: **Changes in precision:** One method for detecting changes in precision is to examine the cumulative precision value for the densitometer daily QC phantom, as calculated by the densitometry software. Any form of drift, systematic (ie in one direction) or otherwise, will cause this value (usually <0.5% when expressed as CV) to increase. **Warning rule:** A control (phantom) measure exceeds the mean ± 2SD of the baseline phantom measures. This occurrence should prompt additional inspection of control data with the following rules. 2. **Three SD rule:** A control measure, which exceeds the baseline mean ± 3SD indicates the need for instrument evaluation. 3. **Two SD twice rule:** Two consecutive control measures that exceed the mean + 2SD, or mean - 2SD,dictate instrument evaluation. 4. **Range of 4SD rule:** When the difference between two consecutive control measures exceeds 4SD (specifically when one measure exceeds + 2SD and another exceeds - 2SD) the instrument requires evaluation. 5. **Four ± 1SD rule:** When four consecutive measures exceed the same limit (+ 1SD or - 1SD) instrument evaluation a is required. 6. **Mean x 10 rule:** When 10 consecutive control measures fall on the same side of the mean, instrument evaluation is necessary Note: Instrument evaluation must involve repeated (five to ten) control measures.
Action taken to address "drift" or any variation in the "control parameters"	**RAR (Accreditation Guidelines)** Examines the practice's "control chart", or data used for tracking BMD variation in a standard phantom for this X-ray unit. Check that the actions taken by the practice are as follows: **Warning rule:** A control (phantom) measure exceeds the mean ± 2SD of the baseline phantom measures. This occurrence should prompt additional inspection of control data with the following rules. 2. **Three SD rule:** A control measure, which exceeds the baseline mean ± 3SD indicates the need for instrument evaluation. 3. **Two SD twice rule:** Two consecutive control measures that exceed the mean + 2SD, or mean - 2SD,dictate instrument evaluation. 4. **Range of 4SD rule:** When the difference between two consecutive control measures exceeds 4SD (specifically when one measure exceeds + 2SD and another exceeds - 2SD) the instrument requires evaluation. 5. **Four ± 1SD rule:** When four consecutive measures exceed the same limit (+ 1SD or - 1SD) instrument evaluation a is required. 6. **Mean x 10 rule:** When 10 consecutive control measures fall on the same side of the mean, instrument evaluation is necessary. **NOTE: "Instrument evaluation" must mean repeating (five to ten) control measures.** Compliance is demonstrated by examining appropriate documentation e.g. "Scanning guidelines" software etc held by the practice, and sighting the results of the "instrument evaluation" that followed when any control measure exceeded its limits.

Failure following instrument evaluation	**RAR (Accreditation Guidelines)** Repeated failure during instrument evaluation (see above) must automatically lead to the suspension of patient measurement until the instrument is more thoroughly evaluated by a licensed service technician. Compliance is demonstrated by documentation e.g. "Scanning guidelines" held by the practice, or evidence of service reports that have followed such suspension of use.
Independent measurement by Accredited tester. "warning rule"	**RAR** The RPA 2005 accredited person must scan, or observe 10 – 20 scans of the manufacturer's QC phantom carried out by an authorised person Compliance is demonstrated by checking that the measured BMD is within +/- 2SD of baseline phantom measurements **("Warning Rule").**
short term precision	**RAR** From the measurements made above the Coefficient of Variation for BMD in the standard phantom must be < 0.5%.
reproducibility	**Accreditation Guidelines** Examine the daily QA results for array (PA and lateral lumbar spine) and pencil beam modes, to determine whether the repeatability of the areal BMD results for the phantom have fallen within the manufacturer's limits of +/- 1.5 % of the mean BMD.
variation with patient thickness	**RAR** The RPA 2005 accredited person must scan, or observe scans of the manufacturer's QC phantom carried out by an authorised person, in order to test the unit's accuracy with regard to changes in patient soft tissue thickness (for a constant body density). **Method**: several thicknesses of soft tissue equivalent material are placed on top of the spine phantom, and areal BMD measured. Compliance is demonstrated when the differences between these measurements is less than 3%.