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

(MAMMOGRAPHY)

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 mammography", 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 3200.2.28:1994 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.
AS/NZS 3200.2.45:1999 IEC 60601-2-45:1998	Medical electrical equipment Part 2.45: Particular requirements for safety—Mammographic X-ray equipment and mammographic stereotactic devices
ARPANSA Radiation Protection Series 1	Recommendations and National Standard "Recommendations for limiting exposure to ionizing radiation and National standard for limiting occupational exposure to ionizing radiation" (1995)
National Accreditation Standards	Developed by the National Quality Management Committee of BreastScreen Australia. Endorsed by the National Advisory Committee To BreastScreen Australia July 2001. Revisions endorsed by the Australian Screening Advisory Committee November 2004 Revisions recommended by the Digital mammography Accreditation Standards Working Group and the National Quality management Committee endorsed by the Screening Subcommittee April 2008, ***including the 2010 Appendix 1***.
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 mammography", 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 3200.2.28:1994 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.
AS/NZS 3200.2.45:1999 IEC 60601-2-45:1998	Medical electrical equipment Part 2.45: Particular requirements for safety—Mammographic X-ray equipment and mammographic stereotactic devices

* 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 **Indicators**	**Requirements**
Mains	**AS/NZS 3200.1.0 1998 6.3 a)** A mains indicator must be clearly identified. "ON" and "OFF" positions must 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 must be provided to indicate the equipment is energised. Dot matrix and other alphanumeric displays are not considered to be indicator lights. **Note** Red must 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 3200.2.1:1998 6.7 table III**
Energised X-ray tube audible signal exposure signal	**AS/NZS 3200.2.1:1998 6.7 table III** A signalling device audible at the location from which the equipment is operated must indicate the termination of the exposure.
Protection against mechanical hazards	
Mechanical stability	**National Accreditation Standards** Mechanical stability, correct and safe function of system components.
Exposure distances Focus-skin distance (FSD)	**Table 205 AS/NZS 3200.1.3:1996** A minimum focal spot to skin distance of 20 cm.

X-ray field	
Collimator mandatory	**AS/NZS3200.1.3:1996 29.202.1** No X-ray tube must be utilized unless mounted in an X-ray tube housing to which a beam limiting device has been fitted.
Collimation and alignment	**National Accreditation Standards** The X-ray field must: (a) extend to the chest wall edge of the image receptor (b) not extend beyond the edge of the primary beam stop for those edges not adjacent to the patient's chest wall (c) not extend by more than 1% of the source to image distance (SID) beyond any edge of the image receptor and (d) for standard contact views, extend to the non-chest wall edges of the image receptor 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 must not exceed 1% of the distance between the focus of the X-ray tube and the plane of the image receptor (ie. SID). The chest wall edge of the compression paddle must: • be aligned just beyond the chest wall edge of the image receptor such that the chest-wall edge of the compression paddle does not appear in the mammogram • not extend beyond the chest-wall edge of the image receptor by more than 1% of the SID with the paddle at 4.5 cm above the breast support
Patient support/ image receptor	
Transparent compression plate	**AS/NZS 3200.2.45:1999 22.102.4** Transparent compression plate only.
Breast compression facilityl	**National Accreditation Standards** Maximum compression force ≤ 300 Newtons (N) Maximum power-driven compression force in range 150−200 N Force display accurate to within ± 20 N (when present) Compressed breast thickness display accuracy within ± 5 mm (when present)
Attenuation by items in the X-ray beam	**AS/NZS 3200.1.3:1996 29.206.1 Table 206** The ATTENUATION EQUIVALENT of the items listed in table 206, when forming part of an X-RAY EQUIPMENT and located in the path of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR, must not exceed the applicable maximum values given in the table.
Beam limitation for fixed focal spot to image receptor	**AS/NZS 3200.1.3:1996 29.202.4** For fixed focal spot to image receptor distances the X-ray field must be limited by a fixed beam limiting device.

Exposure controls	
Type of timer	Only electronic timers are acceptable. **RAR**
High voltage indication	Values of the X-ray tube voltage must be indicated in kV. **RAR**
Tube current indication	Values of the X-ray tube current must be indicated in milliamps. **RAR**
Abbreviated indication of factors	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. **RAR**
Exposure switch	
Position of exposure switch	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	Each exposure must be initiated and maintained by means of a control requiring continuous actuation by the operator. **RAR**
No repeat exposure without release	It must not be possible to initiate another exposure without releasing the switch. **RAR**
Dead man type	The exposure must be able to be interrupted at any time. **RAR**
Security of switch	Any exposure control must be safeguarded against unintended actuation. **RAR**
Compression device	**AS/NZS 3200.2.45:1999 22.102.1** All mammographic X-ray equipment must be fitted with a breast compression device.
Control of compression movements	**AS/NZS 3200.2.45:1999 22.102.2** All switches controlling movement for the application of compression must be of the type requiring continuous actuation while movement takes place. Hands free actuation must be possible. • Fine adjustment must be possible • Control from both sides of patient • Operator must be able to avoid automatic decompression

Exposure control	
Automatic Exposure Control (AEC)	**National Accreditation Standards** An AEC is essential.
AEC Reporducibility	**National Accreditation Standards** Coefficient of variation for both absorbed dose and milli-ampere seconds (mAs) for four phototimed exposures of a test object must be better than or equal to 0.05.
Mean Optical Density Film Screen	**National Accreditation Standards** Mean optical density must be within ± 0.2 of the nominated optical density baseline for quality control phantom images. For a given imaging geometry, mean optical density is defined as the mean of optical density measurements made at 4 cm from the chest wall edge on the mid-line of the film for images of 2, 4 and 6 cm of perspex (or tissue mimicking material) obtained using clinically relevant AEC, kilovolts peak (kVp) and target/filter selections, the 18 by 24 cm film format and a single density setting.
Compensation film screen	**National Accreditation Standards** For photo-timed imaging of 2, 4 and 6 cm phantom thicknesses using a single density setting and clinically relevant kVp and target/filter selections the AEC must be able to maintain optical density to within ± 0.15 of the mean optical density for contact geometry and ± 0.20 of the mean optical density for magnification geometry (if used).
Compensation & Contrast to Noise Ratio (CNR) Digital radiography	**National Accreditation Standards** The equipment vendor must provide the manufacturer's recommended target pixel values and allowable tolerance for a range of PMMA absorber thicknesses. In some systems, the AEC is designed to maintain an essentially constant MPV over the thickness range, in which case a single target value is appropriate. The MPV should be within ±10% of the baseline value for the respective PMMA thickness. When a 0.2 mm Al foil is used as a contrast test tool the CNR for 2, 4 and 6 cm PMMA may be measured and the provisional requirement is that. The ratio CNR_{2cm} /CNR_{4cm} > 1.1 and ratio CNR_{6cm} /CNR_{4cm} > 0.9 For systems that use hardcopy for reporting the OD should comply with the standards for film screen mammography.
Compensation Computed radiography	**National Accreditation Standards** The absorbed dose to the image plate should be within ±10% of the baseline value for the respective PMMA thickness. Variation of the absorbed dose to the image plate as a function of thickness (2 cm to 6 cm PMMA) should be less than ±20% for both contact and magnification modes (if applicable). For systems that use hardcopy for reporting the OD should comply with the standards for film screen mammography.

Density Control Film screen	**National Accreditation Standards** The difference in film optical density produced by adjacent density control settings should not be less than 0.10 and must not exceed 0.20. Mammography units in use prior to 2010 must not exceed 0.25.
Density Control Digital radiography (if applicable)	**National Accreditation Standards** The density control should be capable of changing the mAs from the value used normally by -25% to +50%.
Density Control Computed radiography	**National Accreditation Standards** The density control should be capable of changing the mAs from the value used normally by -25% to +50%
Security cut-out and backup timer	**National Accreditation Standards** Security cut-out mechanisms should be present and terminate the exposure within 50 ms or within 5 mAs or with an entrance absorbed dose for the American College of Radiology (ACR) accreditation phantom of less than 0.44 mGy. In the absence of security cut-out a back-up timer must terminate exposure at ≤ 600 mAs.
Image uniformity and artefact	
Film screen	**National Accreditation Standards** The optical density produced for photo-timed exposure of a suitable phantom should be within +/- 0.1 and must be within +/- 0.15 of the average optical density for all cassettes of the same size.
Digital radiography Ghost Image Evaluation	**National Accreditation Standards** Maximum deviation of MPV in any ROI ≤ ± 15% of MPV for central ROI Maximum deviation in SNR ≤ ± 15% of mean SNR for central ROI. Maximum deviation in SNR as a function of time is ≤ ± 10%. There must be no evidence of blotches or regions of altered noise appearance, observable grid lines or table top structures, bright or dark pixels Assessed using 40 mm PMMA and 0.1 mm Al foil: ghost image factor < 0.3
Computed radiography Ghost Image Evaluation	**National Accreditation Standards** Maximum deviation of MPV in any ROI ≤ ± 15% of MPV for central ROI Maximum deviation in SNR ≤ ± 15% of mean SNR for central ROI. Maximum deviation in SNR as a function of time is ≤ ± 10%. There must be no evidence of blotches or regions of altered noise appearance, observable grid lines or table top structures, bright or dark pixels Maximum mAs variation ≤ ± 10% between all plates Coefficient of variation (COV) of absorbed dose to QC plate < 0.05 Absorbed dose to individual plate should differ from mean for that size by < ± 5%. Difference in mean absorbed dose to plates of different sizes < ± 20%. Assessed using 40 mm PMMA and 0.1 mm Al foil: ghost image factor < 0.3

Light beam	
thermal protection	**AS/NZS 3200.2.28:1994 42.101** Beam limiting devices incorporating a light field indicator must 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)
illuminance	100 lux at 1 metre. **RAR**
Target	
Focal spot sizes	**National Accreditation Standards** As per manufacturer's specifications prior to November 2004. Note tubes replaced after this time must meet the system resolution requirements of >= 11 line pairs per millimetre (lp/mm) for line pair bars perpendicular to the anode-cathode axis and; >= 13 lp/mm for line pair bars parallel to the anode cathode axis
Filtration	The half value layer (HVL) must satisfy relationship: [(kVp/100) + 0.03] ≤ HVL< [(kVp/100) +C] Where: C = 0.12 mm Al for Mo/Mo = 0.19 mm Al for Mo/Rh = 0.22 mm Al for Rh/Rh = 0.30 mm Al for W/Rh = 0.32 mm Al for W/Al
kVp interlock	**AS/NZS 3200.1.3:1996 29.201.4** FILTRATION in X-RAY SOURCE ASSEMBLIES In respect of FILTRATION, X-RAY SOURCE ASSEMBLIES must comply with the following requirements: — X-ray source assemblies may be provided with means to mount, to dismount, or to select, one or more ADDED FILTERS, without the use of TOOLS. When any such selectable ADDED FILTERS are provided they must comply with the following requirements: a) they must be identifiable when in position for NORMAL USE; b) if the presence of a selectable ADDED FILTER is necessary in order to attain the requirements for TOTAL FILTRATION in X-RAY EQUIPMENT, given in 29.201.5, means must be provided to enable the presence of the appropriate selectable ADDED FILTER to be detected by the control system of an associated HIGH-VOLTAGE GENERATOR; **NOTE - This requirement for an INTERLOCK is of special importance in X-RAY EQUIPMENT for mammography, in respect of which there are no requirements for a minimum QUALITY EQUIVALENT FILTRATION from irremovable materials or for the provision of fixed ADDED FILTERS in the X-RAY TUBE ASSEMBLIES concerned.**

kVp accuracy **kVp reproducibility**	**National Accreditation Standards** Measured kVp must be within +/- 5% of the specified value over the clinically relevant range. **National Accreditation Standards** Coefficient of variation <= 0.02 for a minimum of four exposures.
kVp maintains accuracy with time or mAs	The linearity coefficient must be less than or equal to 10%. **RAR**
Radiation output rate	**National Accreditation Standards** For all clinically relevant SID settings the average rate of absorbed dose to air measured with the paddle in the beam must be: >= 7.0 mGy/s at 4.5 cm above the breast support surface for a three second, 28 kVp, Mo/Mo large focus exposure; and >= 1.5 mGy/s at 4.5 cm above the upper surface of the film cassette for a three second, 28 kVp, Mo/Mo, small focus exposure.
Output Kerma reproducibility (manual setting)	The coefficient of variation of measured values of air kerma must not be greater than 0.05 for any combination of exposure factors **RAR**
Output Kerma linearity (manual setting)	The quotient of the average of the measured values of air kerma divided by the indicated value of the current time product must 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 **RAR**
Mean glandular dose	**National Accreditation Standards** Mean glandular dose for contact imaging (with grid) of a 4.2 cm 50% adipose, 50% glandular breast (ie American College of Radiology accreditation phantom) must be <= 2.0 milligray (mGy) for exposures made using typical clinical settings and for exposures made at 25 kVp using Mo.Mo target filter combination. The 2.0 mGy value must be considered not as a dose limit but as a Diagnostic Reference level (DRL) as defined by ICRP 73.
Tube housing leakage	**National Accreditation Standards** less than 1 mGy/h at 1 m from the focal spot when continuous rated technique factors used. **AS/NZS 3200.1.3:1996 29.204.3** **National Accreditation Standards** less than 0.01 mGy/100 mAs at 30 kVp and at 30 cm from focus.