Department of Health and Human Services
Population Health

Radiation Protection Act 2005 – Section 17

CERTIFICATE OF COMPLIANCE:

STANDARD FOR RADIATION APPARATUS -

X-RAY DIAGNOSTIC

(VETERINARY)

SECTION 1: REQUIREMENTS FOR CERTIFICATES OF COMPLIANCE FOR CLASSES OF RADIATION SOURCES

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 fixed radiography", "X-ray mobile radiography", "X-ray mobile radioscopy" "X-ray mobile capacitor discharge" and "X-ray intraoral", for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005 when these radiation apparatus are to be used for veterinary radiology only.

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 3200.2.28:1994 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 3200.2.15:1994 IEC 601-2-15:1988	Approval and test specification - Medical electrical equipment - Particular requirements for safety - Capacitor discharge X-ray generators.
ARPANSA (RPS 17) July 2009	"Code of Practice for Radiation Protection In Veterinary Medicine (2009)"
RAR	Regulatory Authority Requirements – Department of Health and Human Services

PART – B

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 fixed radiography", "X-ray mobile radiography", "X-ray mobile radioscopy" "X-ray mobile capacitor discharge" and "X-ray intraoral", for the purpose of issuing a certificate of compliance in accordance with 17 (1) (b) of the Radiation Protection Act 2005 when these radiation apparatus are to be used for veterinary radiology only.

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 3200.2.28:1994 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 3200.2.15:1994 IEC 601-2-15:1988	Approval and test specification - Medical electrical equipment - Particular requirements for safety - Capacitor discharge X-ray generators.
ARPANSA (RPS 17) July 2009	"Code of Practice for Radiation Protection In Veterinary Medicine (2009)"

* 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 OF COMPLIANCE.

Requirements Applicable to Diagnostic X-ray Equipment Fixed and Mobile Radiography

ITEM	Requirements
Indicators	
markings	**ARPANSA RPS 17 Schedule B4.2 (b)** all controls, meters, lights and other indicators relevant to the operation of the equipment must be: (i) readily discernible; and (ii) clearly labelled as to function
indication of loading factors	**ARPANSA RPS 17 Schedule B4.2 (f)** for X-ray equipment having (i) adjustable loading factors, the control panel must incorporate indicators that show the loading factors.
	ARPANSA RPS 17 Schedule B4.2 (f) for X-ray equipment having (ii) non-adjustable loading factors, permanent marks or labels must be used to indicate these parameters.
warning signs	**ARPANSA RPS 17 Schedule B4.2 (a)** the X-ray control panel must bear a permanent and conspicuous sign: (i) prohibiting unauthorised use, and (ii) warning that hazardous X-radiation is emitted when the equipment is in operation
irradiation indicator	**ARPANSA RPS 17 Schedule B4.2 (c)** the control panel must have a readily discernible, separate indicator that indicates when X-rays are being produced.
audible signal	**RAR** A signalling device audible at the location from which the equipment is operated shall indicate the termination of the exposure For some X-ray equipment installed and licensed prior to 1 September 2006 (typically manufactured circa 1970) the manufacturer has not provided for an audible signal. These units do not need to comply with this requirement provided an unambiguous visible exposure indicator is present on the X-ray unit.

Beam collimator	
light beam collimator	**ARPANSA RPS 17 Schedule B5.1 (b)** The x-ray unit must have a light beam collimator that:
adjustable	(i) enables adjustment of the size of the X-ray field
field size indicated	(ii) incorporates a means to indicate the size of the X-ray field at the image reception area.
alignment of x-ray field and light beam	(iii) ensures that the respective edges of the X-ray field along either the length or the width of the visually defined field do not exceed 1% of the distance from the source to the centre of the visually defined field when the surface on which it appears is perpendicular to the central axis of the useful X-ray beam;
Indicates the centre of the field	(iv) ensures that the visually defined field (light field) contains crosswires or other acceptable mode of indicating the centre of the X-ray beam (dark cross-wires on an illuminated field are preferred to illuminated cross wires on a dark field.)
Alignment of the x-ray field centre and light beam centre	(v) ensures that the centre of the X-ray beam and indicated centre of the light beam correspond to an accuracy of within 1% of the distance from the source to the point on the illuminated surface at which it appears.
brightness of light beam	(vi) ensures that the brightness of the light field is sufficiently great that the light field is clearly visible in ambient illumination.
contrast for the edge of the light beam.	(vii) clearly shows the outer edges of the light field with a high edge-field contrast ratio.
Light switch	
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)
Protection against mechanical hazards	
mechanical stability	**ARPANSA RPS 17 Schedule B4.2 (d) (i)** the X-ray unit must be arranged so that the X-ray tube is: A. securely fixed; and B. correctly aligned within the X-ray tube housing
stays where positioned	**ARPANSA RPS 17 Schedule B4.2 (d) (ii)** the X-ray source assembly must maintain its required position without drift, oscillation or vibration during operation.

Exposure controls	
irradiation control	**ARPANSA RPS 17 Schedule B4.2 (e)** each X-ray unit must be fitted with an irradiation switch, timer, or other device that:
	(i) initiates and terminates X-ray production
	(ii) requires continuous pressure by the operator to produce X-rays
	(iii) in the case of a foot switch, is constructed so that X-rays cannot be produced by accidental activation of the switch
	(iv) is an electronic type
Output (kerma)	
reproducibility	**ARPANSA RPS 17 Schedule B4.2 (g)** for any selected combination of X-ray tube voltage, current and time, the coefficient of variation of any 5 consecutive irradiations taken at the same distance within a period of 10 minutes must not exceed 0.05
X-ray tube shielding	**ARPANSA RPS 17 Schedule B4.2 (h)** the X-ray tube must be enclosed in a shielded housing so that the leakage radiation from the X-ray tube housing does not exceed 1 mGy in 1 hour at 1 metre from the focal spot at the maximum X-ray tube voltage at which the equipment can be operated.

In addition to the **Requirements Applicable to Diagnostic X-ray Equipment Fixed and Mobile Radiography** the following additional requirements are applicable to **Diagnostic X-ray Equipment –Fluoroscopy.**

ITEM	Requirements
image intensifier	**ARPANSA RPS 17 Schedule B7.1** (a) a properly installed and maintained X-ray image intensification System.
remote monitor	b) a remote television display for group viewing and teaching purposes.
Kerma rates	(c) air kerma rates that: (i) during fluoroscopy do not exceed the values given in Table 2 measured under the conditions given in Table 3; and (ii) at the input surface of an image intensifier do not exceed the relevant value given in Table 4

TABLE 2: AIR KERMA RATES DURING FLUOROSCOPY

Manual	Automatic	High level (boost)[11]
50 mGy/min	100 mGy/min	150 mGy/min

TABLE 3: TEST CONDITIONS

Conditions	Measurement distance
UNDER-TABLE X-RAY TUBE When an animal support is permanently between the X-ray tube assembly and the position of the animal.	10 mm from the animal support on the animal side of the support.
OVER-TABLE X-RAY TUBE When an animal support is permanently between the position of the animal and the X-ray image receptor.	300 mm above the animal support on the X-ray tube side of the support.
FIXED ARM SYSTEMS Where the X-ray tube and the image receptor are mechanically linked and where an animal support may or may not be permanently in the radiation beam.	300 mm from the image receptor plane but not less than 400 mm from the focal spot.
OTHER FLUOROSCOPY SYSTEMS Where no animal support is permanently in the radiation beam.	400 mm from the focal spot or the minimum distance, whichever is greater.

TABLE 4: AIR KERMA RATES AT THE FIELD INPUT SURFACE

Field size (mm)	Air kerma rate (μGy/min)
110 to < 140	120
140 to < 230	80
≥ 230	60

MEASUREMENT CONDITIONS
The measurement conditions are to be such that sufficient copper filtration is added to the X-ray beam to obtain, on automatic brightness/dose rate systems, an X-ray tube voltage between 70 kVp and 80 kVp.

For acceptable manual systems, these air kerma rates are not exceeded for the normal clinical settings when used with average animals.

The measurements are to be obtained without the grid or alternatively, by applying a traceable grid correction factor for the energy of the radiation beam being used.

In addition to the **Requirements Applicable to Diagnostic X-ray Equipment Fixed and Mobile Radiography** the following additional requirements are applicable to **Mobile Capacitor Discharge Equipment.**

ITEM	Requirements
preselection of X-ray tube voltage prior to charging	**AS/NZS 3200.2.15:1994 29.1.104 a)** The preselection of the INITIAL X-RAY TUBE VOLTAGE shall be possible before the charging of the capacitor is initiated.
indication of X-ray tube voltage after "charging"	**AS/NZS 3200.2.15:1994 29.101.3 a)** The preselected value of the INITIAL X-RAY TUBE VOLTAGE at the charged capacitor shall be indicated on the CONTROL PANEL.
presence of selected X-RAY TUBE VOLTAGE	**AS/NZS 3200.2.15:1994 29.101.3 b)** A visible indication shall be provided on the CONTROL PANEL to indicate when the storage capacitor is charged to the preselected INITIAL X-RAY TUBE VOLTAGE.
air kerma rate when exposure switch not activated	**ARPANSA RPS 17 Schedule B 9.1 (i)** when the exposure switch is not activated, ensures that the air kerma rate from any accessible surface of the X-ray tube housing, including the associated diaphragm or light beam collimator, does not exceed 20 µGy.h-1 at 0.05 m even when the collimator is fully open**.**
Capacitor discharge X-ray generator	
selection of exposure factors	**AS/NZS 3200.2.15:1994 29.1.104 a)** Preselection of the initial X-ray tube voltage shall be possible before the charging of the capacitor
indication of charging	**AS/NZS 3200.2.15:1994 29.1.103 f)** The process of charging and discharging the capacitor shall be indicated at the control panel
charging completed	**AS/NZS 3200.2.15:1994 29.1.104 f)** The charging process shall be terminated automatically when the preselected initial X-ray tube voltage has been reached
resetting to a lower kV	**AS/NZS 3200.2.15:1994 29.1.104 g)** Means shall be provided to discharge the capacitor within the specified range of initial X-ray tube voltages to any value lower than that to which it is initially preselected
discharge of capacitor	**ARPANSA RPS 17 Schedule B 9.1 (ii)** (ii) enables the capacitor(s) to be discharged without exceeding these levels.
adequacy of stored energy	**AS/NZS 3200.2.15:1994 29.106 a)** In all combinations of exposure factors the residual X-ray tube voltage shall not be less than 50% of its initial value

Requirements Applicable to Veterinary Dental X-ray Equipment Only

ITEM	Requirements
Indicators	
mains	**ARPANSA RPS 17 Schedule B8.1 (i), (i) and (ii)** have a means of indicating when the main switch is in the "ON" position; and the control panel is energised.
energised X-ray tube	**ARPANSA RPS 17 Schedule B8.1 (j)** Have a clearly visible light to indicate when the X-ray tube is energised.
audible signal	**ARPANSA RPS 17 Schedule B8.1 (k)** Have a signal audible to the operator, other than the sound produced fortuitously by switching devices or contactors during the exposure, to indicate the duration of the exposure or termination of the exposure. **RAR** For some X-ray equipment installed and licensed prior to 1 September 2006 (typically manufactured circa 1970) the manufacturer has not provided for an audible signal. These units do not need to comply with this requirement provided an unambiguous visible exposure indicator is present on the X-ray unit.
Protection against mechanical hazards	
moves easily	**RAR** The tube housing should be easy to move and position by an operator.
stays where positioned	**ARPANSA RPS 17 Schedule B 8.1 (q)** Ensure that the X-ray tube head remains stationary when placed in position for radiography.
X-ray field	
collimator mandatory	**ARPANSA RPS 17 Schedule B 8.1 (b) (i) and (ii)** Be fitted with an open ended beam applicator that limits the maximum dimension of the X-ray field at the open end of the beam applicator to no greater than 60 mm. Ensures that the outline of the open end of the beam applicator coincides with the size and position of the X-ray field and at no point is more than 3 mm outside the corresponding point of the X-ray field.

Exposure controls	
type of timer	**ARPANSA RPS 17 Schedule B8.1 (o)** Be equipped with an electronic timer that terminates an exposure at a preset time interval or product of current and time.
preselection of X-ray exposure factors	**ARPANSA RPS 17 Schedule B8.1 (e)** Be designed to permit the operator to preset exposure factors without the need for energising the X-ray tube to check on the operation of the equipment
"Shortened" indication of factors	**ARPANSA RPS 17 Schedule B8.1 (f)** Where the X-ray equipment operates at fixed potential differences or currents, have the exposure factors indicated on labels attached to the equipment.
Exposure switch	
position of exposure switch	**ARPANSA RPS 17 Schedule B8.1 (m)** Have the exposure switch arranged so that the X-ray equipment can be operated from a distance of at least 2 metres from the X-ray tube and the animal.
constant pressure required dead man type	**ARPANSA RPS 17 Schedule B8.1 (n) (i)** have all exposure switches of the dead-man type, so that continuous pressure is necessary to maintain the X-ray exposure
no repeat exposure without release	**ARPANSA RPS 17 Schedule B8.1 (n) (ii)** it is not possible to make repeat exposures without releasing that switch
Maximum kVp	**ARPANSA RPS 17 Schedule B 8.1 (a)** Where dental X-ray equipment is used for veterinary procedures, it must only be operable at potential differences of up to 90 kVp
Tube head leakage	**ARPANSA RPS 17 Schedule B 8.1 (d)** have sufficient shielding so that the kerma in air from leakage radiation from the tube assembly, including cones, diaphragms and collimator, does not exceed 0.25 mGy in 1 hour at a distance of 1 metre from the focal spot