Test Protocol for medical and veterinary computed tomography X-ray apparatus 2023

Issued February 2023

This protocol provides the mandatory requirements for an accredited tester performing compliance testing of computed tomography X-ray apparatus under the following scenarios:

- when the apparatus is first installed;
- at a frequency as set out in the *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022* published by the Department; (applicable when the apparatus is used on humans only)
- after any major repair or replacement that could affect radiation safety.

It should be read in conjunction with the—

- *Radiation Protection and Control Act 2021* (RPC Act);
- *Radiation Protection and Control Regulations 2022* (RPC Regulations);
- *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022* published by the Department;
- *Code of Compliance for labelling and signage of ionising radiation sources 2022* published by the Department;
- *Code of Compliance for facility design and shielding 2022* published by the Department.

Citation

This protocol may be cited as the *Test Protocol for Medical and Veterinary Computed Tomography X-ray Apparatus 2023.*

Part 1 Interpretation

In this protocol, unless the contrary intention appears—

accredited tester means a person performing compliance testing who is a holder of an accreditation as a third party service provider under section 31 of the RPC Act;

aperture means a gap in the protective material of a *tube housing* through which ionising radiation from an *X-ray tube* within the *tube housing* may pass with little or no attenuation;

apparatus means ionising radiation apparatus;

baseline values, for the purpose of tests specified in this protocol, are the values that must be provided by the manufacturer or be established at the first compliance testing when the equipment is first brought into use;

computed tomography dose index means a measure of dose value as defined in section 2.106 of the *Australian/ New Zealand Standard, Medical Equipment, Part 2.44: Particular requirements for safety—X-ray equipment for computed tomography [AS/NZS 3200.2.44:2005]*;

CT number means the number used to represent the mean X-ray attenuation associated with each elemental area of the CT image. It is normally expressed in Hounsfield units (HU);

EPA means the South Australian Environment Protection Authority;

exposure parameters means *X-ray tube* potential, *X-ray tube* current, and exposure time or a combination thereof;

fixed, in relation to *apparatus*, means any *apparatus* that is neither a *mobile apparatus* nor a *portable apparatus*;

isocentre means the space through which the central ray of the X-ray beam passes through the intersection of the *apparatus* gantry's axis of rotation. In relation to a cylindrical gantry, the isocentre is at the centre of the gantry bore;

mobile, in relation to *apparatus*, means *apparatus* that is designed and constructed so as to be moveable from place to place for use as required but does not include a *portable apparatus*;

PMMA means polymethyl methacrylate;

primary beam means that part of the X-radiation that passes through an *aperture* of an *X-ray tube housing* by a direct path from an *X-ray tube*;

tube housing, in relation to an ionising radiation *apparatus*, means a container in which an *X-ray tube* is mounted for normal use, providing protection against electric shock and against ionising radiation except for an *aperture* for the useful beam;

X-ray tube, in relation to an ionising radiation *apparatus*, means an evacuated envelope in which electrons are accelerated for the purposes of the production of ionising radiation.

Part 2 General requirements

1 – Application of protocol

This protocol applies to *fixed* and *mobile* medical and veterinary X-ray *apparatus* capable of *computed tomography*, including—

(a) diagnostic imaging

(b) radiation therapy planning

(c) diagnostic nuclear medicine imaging

2 – Exemptions applicable to this protocol

There are no exemptions applicable to this protocol.

3 – Complying with this protocol

The accredited tester must—

(a) perform compliance testing in accordance with the test methods specified in Part 3; and

(b) provide in a report—

(i) the details as specified in sections 4 to 7; and

(ii) the parameters used and results obtained for the compliance tests performed under Part 3; and

(c) complete the approved Certificate of Compliance for medical and veterinary computed tomography X-ray apparatus document.

(d) In the event of a critical failure of a test, the accredited tester must immediately inform the owner, or responsible person, of the failure of the test and the owner's obligation to immediately inform the EPA.

4 – Owner details

Record, where known, the contact details of the owner of the apparatus including at least—

(a) the name of the owner; and

(b) the address of the owner; and

(c) the telephone number of the owner.

5 – Apparatus details

Record the details of the apparatus including at least—

(a) the make and model of the apparatus; and

(b) the serial number—

(i) of the generator, where it is practical to do so; and

(ii) the serial number of the *X-ray tube*, where it is practical to do so; and

(iii) the serial number of the *tube housing*, where it is practical to do so; and

(c) the location of the apparatus (eg surgery 1, room 1).

6 – Accredited tester details

Record the details of the accredited tester including at least—

(a) the name of the accredited tester; and

(b) the accreditation number of the accredited tester; and

(c) the date on which the accredited tester performed the compliance tests.

7 – Test instrument details

Record for each test instrument used, at least—

(a) the make and model; and

(b) the serial number; and

(c) the date of the next calibration or the date of the last calibration.

Part 3 Fixed and mobile apparatus

8 – Labelling of apparatus

8.1 Test method

Verify that the apparatus has a label—

(a) that complies with the requirements of *AS 1319–1994 Safety Signs for the Occupational Environment* applying to warning signs; and

(b) bears the words ‘RADIATION PRODUCED WHEN ENERGISED’ or words to that effect; and

(c) bears the radiation symbol as specified in 0; and

(d) is clearly legible at a distance of 2 metres.

8.2 Legislative reference

Clause 4, *Code of Compliance for labelling and signage of ionising radiation sources 2022*.

9 – Radiation area sign

9.1 Test method

(a) Verify that a sign is clearly displayed, at each entrance, walkway or access route to the room or area in which the apparatus is located—other than an entrance to the room from a place or another room which can only be entered from the room.

(b) Verify that the sign—

(i) complies with the requirements of AS 1319–1994 Safety Signs for the Occupational Environment applying to warning signs; and

(ii) if it does bear words, the words are ‘RADIATION AREA’ or ‘X-RAYS’ sign or words of similar effect; and

(iii) has a total surface area of not less than 4,500 square millimetres; and

(iv) bears the radiation symbol as specified in Schedule 1; and

(v) is clearly legible at a distance of 2 metres.

9.2 Legislative reference

Clause 5, *Code of Compliance for labelling and signage of ionising radiation sources 2022.*

10 – Apparatus to be in good working order

10.1 Test method

Verify that there is no abnormality, fault, or condition that is not subject to another section of this protocol that prevents the apparatus from functioning or performing in a manner for which it has been designed.

10.2 Legislative reference

Regulation 80(2), RPC Regulations.

11– Warning device

11.1 Test method

Verify that when the X-ray tube is energised there is a warning device that consists of an illuminated radiation warning sign—

(a) that displays the words ‘Ionising radiation – do not enter’ (or equivalent) and must be positioned directly adjacent to any entry point of the room—other than an entrance to the room from a place or another room which can only be entered from the room; and

(b) that must illuminate immediately upon exposure and continue to illuminate during the exposure.

11.2 Legislative reference

Schedule 2, test 3, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

12 – Exposure termination

12.1 Test method

Verify that the apparatus is fitted with a device that will terminate the exposure after a pre-set—

(a) time interval; or

(b) product of X-ray tube current and exposure time; or

(c) programmed exposure; and

(d) allows the operator to interrupt the radiation exposure at any time.

12.2 Legislative reference

Schedule 2, test 4, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

13 – Indicators of operation

13.1 Test method

Verify that —

(a) the mains indicator is clearly identified and ‘ON’ and ‘OFF’ positions are indicated by light or unambiguous means.

(b) a visible signal is displayed at the control panel and on the gantry to indicate when the X-ray tube is in preparation mode; and

(c) a beam ‘ON’ status signal is displayed to indicate when radiation is produced; and

(d) an audible signal that is audible from the location at which the apparatus is operated and indicates either the duration or termination of the exposure.

13.2 **Legislative reference**

Schedule 2, test 5, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

14 – Mechanical accuracy

14.1 Light localisation

Verify the coincidence between the external axial localisation laser, the internal axial localisation laser (tomographic plane) and the exposure scan plane is to within ±2 mm for apparatus used for diagnostic imaging and within ±1 mm for apparatus used for radiation therapy planning.

(a) Position a strip of Gafchromic film on a foam block along the z axis centred to the coronal and sagittal planes and the external axial laser.

(b) Mark a line on the film aligned with the external axial laser.

(c) Move the couch automatically to the scan plane and mark the position of the internal axial laser.

(d) Measure the difference between the external and the internal lasers

(e) Perform a single axial scan and measure the difference between the internal lasers and the centre of the scan plane as indicated by the blackened line on the film.

Alternative methods are acceptable if they can produce the same result.

Critical failure: if the above requirements are not met for radiation therapy planning.

14.2 Scout (preview) localisation

Verify that the reference lines indicating the start and finish position of the scout image do not differ from the actual slice position by more than 2 mm.

(a) position an appropriate phantom or a thin dense object (short wire) on a foam block, aligned along the X-axis and centred to the coronal and sagittal lasers

(b) perform an AP scout to ensure object is scanned

(c) perform a single axial scan centred on object with the thinnest reconstructed slice thickness available.

(d) count the number of slices between the central reconstructed slice and the slice with the object in view. (eg if there are 30 reconstructed slices, the central slice is 15/16. If the object appears most in focus in slice 16/17, then the difference is 1 slice. Multiplied the number of slices by the reconstructed slice thickness to determine the localisation accuracy in mm.

Alternative methods are acceptable if they can produce the same result.

Critical failure: if the above requirements are not met.

14.3 Coronal and Sagittal plane lights

Verify that the coronal and sagittal plane lights intercept at the x = 0, y = 0 on the corresponding axial image and any difference must not exceed ± 2 mm for apparatus used for diagnostic imaging or ± 1 mm for equipment used for radiation therapy planning. This test may be verified with a suitable phantom, eg CatPhan or a thin dense object (short wire).

(a) align the object with the coronal and sagittal lasers and its length along the z-axis. The isocentre should be through the long axis of the object.

(b) a single axial scan is performed.

(c) Measure the distance between the centre of the object and the centre of the image, as indicated by system's crosshair, using the image system callipers.

Alternative methods are acceptable if they can produce the same result.

Critical failure: if the above requirements are not met

14.4 Legislative reference

Schedule 2, test 6, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

15 – Image quality

15.1 Noise, mean CT number and Uniformity

Verify that the system meets manufacturer's specifications and does not deviate significantly from baseline values that must be established when the equipment is first brought into use or following any maintenance likely to affect these parameters (including tube change).

Measurements of noise, mean CT number (HU) and uniformity must be performed for typical axial or helical head and body scans. For each scan, set up an appropriate water phantom at isocentre and perform scans using exposure parameters as indicated by the manufacturer specifications or that used at baselines. For each scan, place a region of interest (ROI) of approximately 10% and 40% of the diameter of the phantom in the centre of the central slice and note the mean CT number and the standard deviation in HU (noise) respectively. Compare the values with manufacturer specifications or baseline. The measured value of HU must not deviate by more than ±4 HU from the baseline value and the measured noise must not be more than 10% above the baseline value.

To measure the uniformity, draw 5 ROIs one at the centre and four at the edges (3, 6, 9 and 12 o'clock positions) in the image of the water phantom. Calculate the deviation in HU values between each edge and the centre and determine the maximum deviation. The maximum deviation in mean CT number must not vary by more than ±2 HU from the baseline value. Review the image for any significant artefacts or non-uniformity.

Critical failure:

Noise	>15 % of baseline values
Mean CT number (HU)	> ±10 HU of baseline values
Uniformity	> 10 HU for water phantom upto 20 cm diameter or > 20 HU for water phantom above 20 cm diameter

15.2 Spatial (high contrast) resolution

Use a suitable high contrast test phantom (eg line pair patterns or similar) to verify that the spatial resolution for a typical head and body scan is within manufacturer-specified tolerances. If manufacturer specified tolerances are not provided, the measurement must not be greater than 10% below the baseline value. Unless otherwise specified by the manufacturer, spatial resolution is best described by the modulation transfer function curve obtained from the Fourier transform of the point-spread function. Alternative (validated) methods may be used.

15.3 Legislative reference

Schedule 2, test 7, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

16 – Reconstructed slice thickness

16.1 Test method

Configure the apparatus for an axial scan.
For a range of reconstructed slice thicknesses used clinically, verify that the measured slice thickness of the X-ray field acquired for each outer tomographic sections and the representative inner tomographic section is within the value of the manufacturer-specified tolerances or within the limits specified below. This test may be verified using a suitable phantom, eg CatPhan.

Selected slice thickness	Slice thickness limit
<1 millimetre	0.5 millimetres of the selected slice thickness
1 to 2 millimetres	50 percent of the selected slice thickness
greater than 2 millimetres	1.0 millimetres of the selected slice thickness

16.2 Legislative reference

Schedule 2, test 7, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

17 – Computed tomography dose index in air ($CTDI_{air}$)

17.1 Test method

(a) Configure the apparatus for an axial scan.

(b) Set the exposure parameters to values that are compatible with those used by the manufacturer of the apparatus or those used at baseline for such a test.

(c) Set up a 100 mm CTDI chamber free in air (overhanging the patient couch to avoid couch attenuation) with the centre of the detector length at isocentre.

(d) Perform axial scans at the typical head and body conditions of operation at all clinically used kVp settings and at no less than five nominal beam collimations. Determine the value of the computed tomography dose index in air (CTDIair).

(e) Verify that the CTDIair does not exceed the manufacturer-specified tolerance if provided or be within ± 10% of the baseline value established at the first compliance test when equipment is first brought into use.

Critical failure: if deviation is > 20% from manufacturer's specifications or baseline values.

17.2 Legislative reference

Schedule 2, test 8, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

18 – Computed tomography dose index volume in phantom ($CTDI_{vol}$)

18.1 Test method

(a) Configure the apparatus for an axial scan if calculating $CTDI_W$, or helical scan if calculating $CTDI_{vol}$.

(b) Set the exposure parameters to values that are compatible with those used by the manufacturer of the apparatus or those used at baseline for such a test.

(c) Set up a 100-mm CTDI chamber (or equivalent) within the centre location of 16 centimetre PMMA head phantom and a 32-cm PMMA body phantom.

(d) Perform axial or helical scans at the typical head and body conditions of operation at all clinically used kVp settings.

(e) Measure CTDI100, the integrated dose along the Z-axis perpendicular to the tomographic plane, at the central and peripheral locations of the phantom.

(f) Calculate the value of the weighted computed tomography dose index ($CTDI_w$) and the volume computed tomography dose index (CTDIvol) at the isocentre for both head and body protocols using the formula below:

$$CTDI_W = \frac{1}{3}\,(CTDI_{100})centre + \frac{2}{3}(CTDI_{100})peripheral$$

$$CTDIvol = \frac{NT}{d} \times CTDI_W \text{ (for helical scans)}$$

Where N is the number of tomographic slices produced in a single axial scan; T is the nominal collimation thickness; d is the distance travelled by the patient table in the Z-direction (pitch = 1 for axial scan).

(g) Verify that the $CTDI_{vol}$ does not exceed the displayed value by more than ±20%.

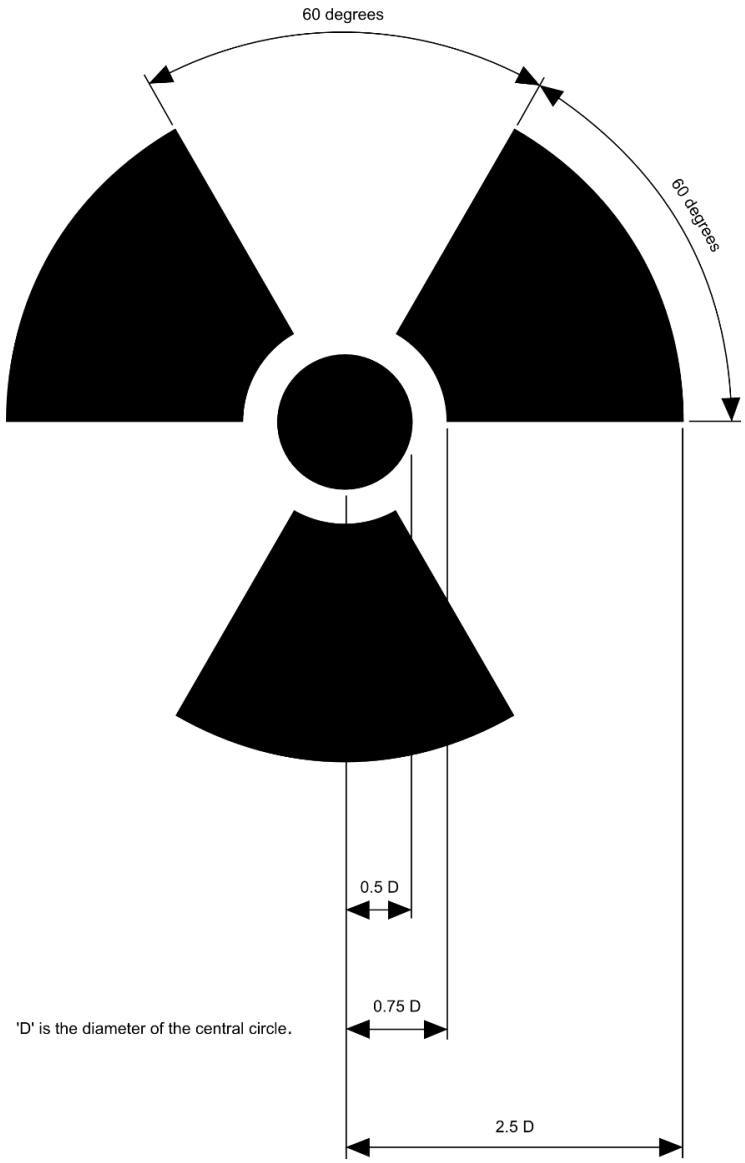
18.2 Legislative reference

Schedule 2, test 8, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

Schedule 1 – Radiation symbol

(a) The radiation symbol consists of the conventional three blade design shown overleaf.

(b) The symbol and background colours must comply with the requirements of *AS 1319–1994 Safety Signs for the Occupational Environment*.



Document history

Publications

This first release of this document replaces *Test Protocol for medical and veterinary computed tomography X-ray apparatus 2016*, which became obsolete on 11 February 2023.

Title	Release	Commencement
Test Protocol for medical and veterinary computed tomography X-ray apparatus 2023	first release	11.2.2023