Test Protocol for medical, veterinary and chiropractic X-ray apparatus used for plain radiography 2023

Issued February 2023

This protocol provides the mandatory requirements for an accredited tester performing compliance testing of plain radiography 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, veterinary and chiropractic X-ray apparatus used for plain radiography 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 30 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;

EPA means the Environment Protection Authority, South Australia;

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

general duty of care means the requirements under section 53 of the Act. Applicable sections are indicated by the symbol;

medical, in relation to *apparatus*, means *apparatus* that is used for medical diagnostic imaging of humans, including chiropractic, and for research purposes;

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*;

plain radiography means the technique for obtaining, recording and processing directly or after transfer, static information contained in an X-ray image at an image receptor where the *X-ray tube* is stationary throughout the exposure;

portable*, in relation to apparatus,* means any *apparatus* that is designed to be carried manually from place to place for use as required;

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*, *mobile*, and *portable* medical, veterinary, and chiropractic X-ray *apparatus* used for *plain radiography*, excluding *apparatus* used for fluoroscopy, tomography, computed tomography, mammography, or soft tissue radiography.

2 – Complying with this protocol

The *accredited tester* must—

(a) perform compliance testing in accordance with the test methods specified in Part 3 to 6; and

(b) provide in a report—

(i) the details as specified in sections 3 to 6; and

(ii) the test parameters used and results obtained for the compliance tests performed under Part 3 to 6; and

(c) complete the approved Certificate of Compliance for medical, veterinary and chiropractic X-ray apparatus used for plain radiography document; and

(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 that test and the owner's obligation to immediately inform the EPA.

3 – Owner details

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

(a) the name of the owner;

(b) the address of the owner; and

(c) and the telephone number of the owner; and

(d) the email of the owner.

4 – 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).

5 – 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.

6 – 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 Construction and installation requirements of fixed, mobile and portable apparatus used for medical, veterinary and chiropractic plain radiography including capacitor discharge apparatus

7 – Application of part

This part of the protocol applies to fixed, mobile, and portable apparatus used for medical, veterinary and chiropractic plain radiography including capacitor discharge apparatus.

8 – Apparatus to be in good working order

8.1 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.

8.2 Legislative reference

Regulation 80(2), RPC Regulations

9 – Labelling of apparatus

9.1 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

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

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

(iii) is clearly legible at a distance of 2 metres; and

(iv) Bears the words ‘caution’ or ‘warning’; and

(v) the symbol and lettering must be black on a yellow background.

9.2 Legislative reference

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

10 – Labelling of generators and tube assemblies

10.1 Test method

Verify that the apparatus has markings on X-ray generators and tube assemblies:

(a) X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available by means of labels on the apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels.

(b) Verify that X-ray generators bear:

(i) the name or trademark of the manufacturer;

(ii) the model name or number; and

(iii) the serial number.

(c) Verify X-ray tube assemblies bear:

(i) the name or trademark of the manufacturer of the X-ray tube housing and insert;

(ii) the type or model number and serial number of the X-ray tube housing and insert;

(iii) the position of the focal spot(s); and

(iv) the relative position of the anode and cathode.

Note: For dual focus X-ray tubes, a single indication of mean focal spot position is permissible.

10.2 Legislative reference

Schedule 5, test 1, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

11 – Radiation area sign

11.1 Test method

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.

Verify that the sign—

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

(b) bears words ‘Caution X-rays in use – authorised entry only’ (or equivalent) must be displayed at each entry point to the room.

(c) bears the radiation symbol as specified in Schedule 1.

11.2 Legislative reference

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

12 – Mains switch

12.1 Test method

Verify that the apparatus has a mains switch—

(a) that controls the supply of mains power to the apparatus; and

(b) is readily accessible; and

(c) has a mains indicator that is clearly identified. ‘ON’ and ‘OFF’ positions must be marked by a suitable indicator light or other unambiguous means.

12.2 Legislative reference

Schedule 5, test 6, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022*.

13 – Exposure parameters

13.1 Test method

Verify that the apparatus is fitted with visual indicators on the control panel that provide an indication of

(a) tube voltage, and

(b) tube current, and

(c) exposure time, or combination of current and time.

These must be displayed by an analogue or digital indicator, even if these factors are under automatic control. Should one factor be permanently fixed, verify its value is indicated on the control panel.

13.2 Legislative reference

Schedule 5, test 7, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022*.

14 – X-ray tube potential

14.1 Test method

(a) Verify that, for a range of set X-ray tube potentials, the measured value of the X-ray tube potential is within ±5 kilovolts peak or ±5 percent, whichever is the greater, of the indicated value.

Critical failure: ≥±10% or ≥±10 kVp whichever is the greater.

(b) The coefficient of variation of at least five consecutive measurements at the same kVp setting must not exceed 0.02.

14.2 Legislative reference

Schedule 5, test 9, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022*.

15 – Half value layer

15.1 Test method

(a) For a range of set X-ray tube potentials, measure the half value layer of the primary beam.

(b) Verify that the measured half value layer, for the selected tube potential, is not less than value specified in Table 1.

Table 1—Minimum half value layers for diagnostic X-ray apparatus

X-ray tube voltage (kVp)	Minimum HVL for X-ray equipment manufactured pre-2015 (mm of Al)	Minimum HVL for X-ray equipment manufactured 2015 onwards (mm of Al)
50	1.5	1.8
60	1.8	2.2
70	2.1	2.5
80	2.3	2.9
90	2.5	3.2
100	2.7	3.6
110	3.0	3.9

X-ray tube voltage (kVp)	Minimum HVL for X-ray equipment manufactured pre-2015 (mm of Al)	Minimum HVL for X-ray equipment manufactured 2015 onwards (mm of Al)
120	3.2	4.3
130	3.5	4.7
140	3.8	5.0
150	4.1	5.4

15.2 Legislative reference

Schedule 5, test 19, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022*.

16 – Exposure switch – closed circuit contact

16.1 Test method

Verify that the exposure switch fitted to the apparatus—

(a) requires continuous pressure in order to maintain radiation exposure; and

(b) after a radiation exposure has terminated, another exposure is not possible without releasing the exposure switch; and

(c) it must be possible to interrupt the exposure at any stage and, in the case of programmed exposures, there is a means of interrupting the programme.

16.2 Legislative reference

Schedule 5, test 8, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

17 – Exposure switch – foot operated

17.1 Test method

In the case of a exposure switch designed to be operated with the foot, the exposure switch must be designed so that it cannot be accidentally operated. This may be achieved by shrouding the
foot switch or by the provision of an isolation switch at the operator's console.

17.2 Legislative reference

Schedule 5, test 8, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

18– Consistency

18.1 Test method

Verify that the apparatus produces a consistent radiation output—

(a) by making at least five measurements of radiation output performed at the same X-ray tube potential, X-ray tube current, and exposure time; and

(b) by calculating the coefficient of variation of at least five measurements; and

(c) by verifying that the calculated coefficient of variation is less than or equal to 0.05.

Critical failure: if the coefficient of variation ≥0.1

18.2 Legislative reference

Schedule 5, test 12, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

19 – Warning device

19.1 Test method

Verify that when the X-ray tube is energised there is a warning device that consists ofan obvious visual and audible indicator when radiation is being emitted.

19.2 Legislative reference

Schedule 5, test 7, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

20 – Leakage from the X-ray tube housing and the beam limiting device

Verify that the air kerma from leakage radiation from a tube assembly does not exceed 1 mGy in 1 hour at a distance of 1 metre from the focal spot, and from the beam limiting device, averaged over an area of not more than 100 cm.

Critical failure: failure to meet above requirements.

20.1 Test method

(a) Cover the end of the beam limiting device with lead of sufficient thickness to ensure that the primary beam contribution to the measurements is negligible.

(b) Verify that leakage radiation from the X-ray tube assembly, at 1 metre from the focus of the X-ray tube, does not exceed 1 mSv in 1 hour, averaged over 10,000 mm^2 of which no principal linear dimension exceeds 200 mm. Measurements should be recorded for all orthogonal aspects about the tube housing.

(c) For purposes of verifying compliance, measures of leakage radiation should be at maximum kVp and normalised to:

(i) a distance of 1 m from the focus by ISL; and

(ii) the manufacturer specified, or a calculation of, maximum continuous tube current for the set kVp; and

(iii) an exposure rate in 1 hour.

20.2 Legislative reference

Schedule 5, test 17, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

Part 4 Special requirements for the construction and installation of fixed, mobile and portable apparatus used for medical plain radiography, mobile apparatus used for veterinary plain radiography, and fixed apparatus used for chiropractic plain radiography

21 – Application of part

This part of the protocol applies to—

(a) fixed, mobile and portable apparatus used for medical plain radiography; and

(b) mobile apparatus used for veterinary plain radiography; and

(c) fixed apparatus used for chiropractic plain radiography.

22 – Exposure switch cord

22.1 Test method

The cord attaching the exposure switch to a mobile apparatus must be not less than 2 metres in length.

22.2 Legislative reference

The general duty of care is applicable

23 – Collimator alignment

23.1 Test method

(a) Verify that the X-ray tube is fitted with a collimator that is—

(b) continuously adjustable; and

(c) has a light beam: and

(d) the centre is indicated; and

(e) the alignment of which, with any boundary of the X-ray beam, does not exceed 1 percent of the distance between the focus of the X-ray tube and the image receptor; and

(f) can be rotated around the centre of the X-ray beam.

Critical failure: misalignment >3% of the SID.

23.2 Legislative reference

Schedule 5, test 16, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

24 – Focus to skin distance

24.1 Test method

In the case of fixed, mobile or portable medical X-ray apparatus—

(a) measure the distance from the X-ray tube focus and the closest point the patent's skin could make contact with the beam limiting device; and

(b) verify that the measured distance is not less than 200 mm.

24.2 Legislative reference

Schedule 5, test 15, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

25 – Stationary tube housing

25.1 Test method

Place the tube housing in positions that would be typically used in radiography for fixed and mobile apparatus

Verify that for each position, the tube housing does not move.

25.2 Legislative reference

Schedule 5, test 4, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

26 – Linearity

26.1 Test method

Verify that the apparatus produces a linear radiation output—

(a) Where there is a choice of mA settings, the linearity of the output of the X-ray unit with nominal X-ray tube current should comply with the following relationship between any pair of current settings taken over a range of clinically used settings for each focal spot size:

$$\frac{X1 - X2}{X1 + X2} \leq 0.1$$

- Where X1 is the X-ray output expressed in terms of dose to air per mA at mA setting 1.
- X2 is the X-ray output expressed in terms of dose to air per mAs at mA setting 2.

(b) Where there is a choice of mAs settings the linearity of the output of the X-ray unit should comply with the following relationship between any two mAs settings taken over a range of clinically used settings for each focal spot:

$$\frac{X1 - X2}{X1 + X2} \leq 0.1$$

- Where X1 is the X-ray output expressed in terms of dose to air per mAs at mAs setting 1.
- X2 is the X-ray output expressed in terms of dose to air per mAs at mAs setting 2.

Critical failure value: ≥ 0.2

26.2 Legislative reference

Schedule 5, test 13, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

27 – Collimator illuminance and manual override

27.1 Test method

Verify that the continuously adjustable collimator fitted to the X-ray tube—

(a) has a light beam with an illuminance which is not less than 100 lux at a distance of 1 metre from the light source; and

(b) in the case where the collimator can be automatically adjusted, a manual override that permits the selection of a smaller area is possible.

Critical failure: <50 lux above ambient.

27.2 Legislative reference

Schedule 5, test 16, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

28 – Multiple X-ray tubes

28.1 Test method

Except in the case of apparatus specifically designed for two tube techniques, verify that if more than one X-ray tube can be operated from a single control panel—

(a) it is not be possible to energise more than one X-ray tube at the same time; and

(b) there is an indication at or near each tube housing and on the control panel showing which X-ray tube is selected.

28.2 Legislative reference

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

29 – Automatic exposure control

29.1 Test method

(a) In the case of an apparatus fitted with an automatic exposure control (AEC) select the AEC and verify that there is a clear indication on the control panel that the AEC has been selected.

(b) Under AEC verify that the AEC limits—

(i) the exposure time to no more than 6 seconds; or

(ii) the product of the X-ray tube current selected and exposure time delivered is no more than 600 milliampere seconds.

Critical failure: if this requirement is not met.

(c) In the case of an exposure that terminates under AEC verify—

(d) there is a visible or audible signal that indicates that termination has occurred; and

(e) manual resetting of the AEC is required before further automatically timed exposures can be made.

(f) Verify that the AEC device controls exposures such that the displayed exposure index (EI) does not vary by more than 20% from the mean EI when kVp and patient thickness are varied over their typical clinical range. Note: If the detector has a non-linear relationship between detector air kerma (DAK) and EI, the EI must be linearised with DAK.

29.2 Legislative reference

Schedule 5, test 14, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

30 – Reproducibility

30.1 Test method

Verify that the apparatus produces a reproducible radiation output—

(1) Using the centre detector, the air kerma from 5 consecutive exposures

(a) at 80 kVp with a patient-equivalent phantom, must be within ±10% of the mean; and

(b) the air kerma from irradiations to the lateral detectors must be within ±10% of each other.

Note: For this test, phantoms constructed of 2 mm of copper or 15 cm of acrylic are suitable substitutes for a patient equivalent phantom.

30.2 Legislative reference

Schedule 5, test 14, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

31 – Radiographic timer accuracy

31.1 Test method

Verify that—

(a) the timer is electronic, and

(b) It must not be possible to make exposures when the timer is set to the zero, and

(c) that measured exposure times across a clinical range—

(i) are within ±10% of the indicated value for exposure times ≥100 ms; or

(ii) within ±20% ±1 pulse of the indicated value for exposure times less ≤100 ms

Critical failure: ≥±20% (for times ≥100 ms) or ≥±30% (for time <100 ms).

Any measuring equipment error must be taken into account in determining whether compliance criteria are satisfied.

The coefficient of variation of at least 5 consecutive measurements at the same timer setting must not exceed 0.05.

31.2 Legislative reference

Schedule 5, test 10 and 11, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022*.

Part 5 Special requirements for the construction and installation of portable apparatus used for veterinary plain radiography

32 – Application of part

This part of the protocol applies to portable apparatus used for veterinary plain radiography including portable capacitor discharge apparatus.

33 – X-ray tube stand

33.1 Test method

Verify that the apparatus is provided with an X-ray tube stand that is designed and constructed so it supports the X-ray tube during radiography.

33.2 Legislative reference

The general duty of care is applicable.

34 – Exposure switch cord

34.1 Test method

The cord attaching the exposure switch to the apparatus must be not less than 2 metres in length.

34.2 Legislative reference

The general duty of care is applicable.

35 – Collimator alignment

35.1 Test method

Verify that the X-ray tube is fitted with a collimator that is—

(a) continuously adjustable; and

(b) has a light beam; and

(c) the centre is indicated; and

(d) the edge of which does not fall outside or inside the edge of the irradiated area by more than 10 mm at a focal spot to image receptor distance of 800 mm.

35.2 Legislative reference

The general duty of care is applicable.

36 – Field size indicator

36.1 Test method

Verify that the collimator is provided with a device or other means that indicates the X-ray field size at various focus to image receptor distances.

36.2 Legislative reference

The general duty of care is applicable.

Part 6 Special requirements for capacitor discharge apparatus used for medical plain radiography

37 – Application of part

This part of the protocol applies to capacitor discharge apparatus used for plain radiography.

38 – Leakage

38.1 Test method

Verify that leakage radiation from the X-ray tube assembly when the exposure device is not activated must not exceed 0.2 mGy in one hour at 50 mm from any accessible surface of the X-ray tube assembly with the collimator fully open and with the maximum voltage on the capacitors.

38.2 Legislative reference

Schedule 5, test 18, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

39 – Interlock shutters

39.1 Test method

Verify that the apparatus is fitted with electrically interlocked shutters to limit emission of radiation before the exposure, after the termination of the exposure and during discharging of the capacitors when patient exposure is not required.

39.2 Legislative reference

Schedule 5, test 18, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

40 – Prevention of exposure during charging

40.1 Test method

Verify that the apparatus is fitted with a device to prevent the initiation of exposure during the charging of the capacitors.

40.2 Legislative reference

Schedule 5, test 18, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

41 – Automatic top-up facility

41.1 Test method

Verify that the apparatus has an automatic top-up facility that operates when the kilovoltage drops below the pre-set value by more than 3%.

41.2 Legislative reference

Schedule 5, test 18, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

42 – Manual discharge

42.1 Test method

Verify that the apparatus has a control switch that allows manual discharge of the capacitors when the apparatus is connected to the mains supply and when patient exposure is not required.

42.2 Legislative reference

Schedule 5, test 18, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

43 – Maximum mAs and minimum kV

43.1 Test method

Verify that the apparatus has a maximum of 30 mAs and the lowest indicated terminating voltage is not less than 45 kV.

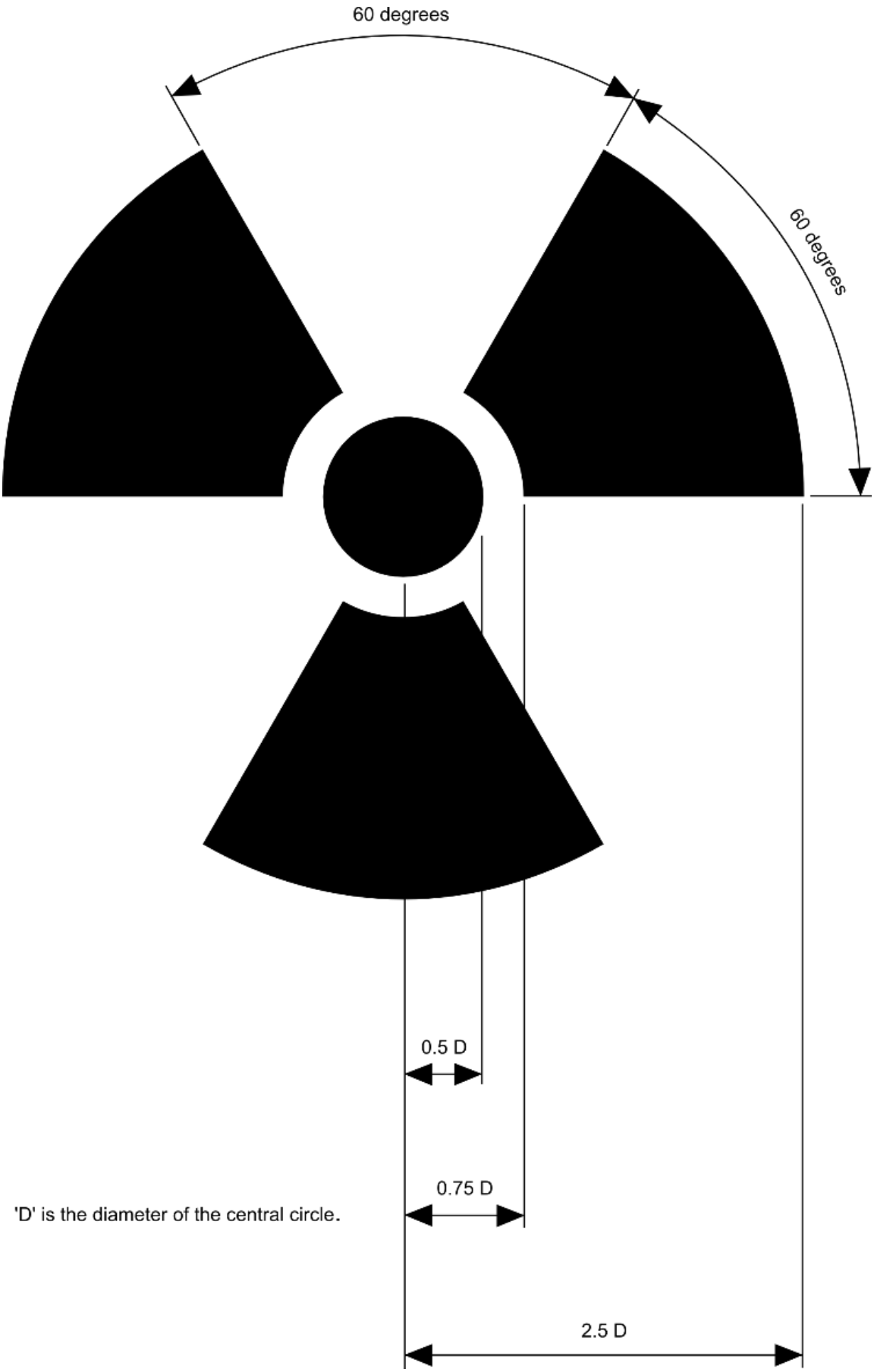
43.2 Legislative reference

Schedule 5, test 18, *Code of Compliance for medical, veterinary and chiropractic X-ray radiation apparatus 2022.*

Schedule 1 – Radiation symbol

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

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



'D' is the diameter of the central circle.

Document history

Publications

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

Title	Release	Commencement
Test Protocol for medical, veterinary and chiropractic X-ray apparatus used for plain radiography 2023	first release	11.2.2023