

Test Protocol for dental panoramic and cephalometric X-ray apparatus 2023

Issued February 2023

This protocol provides the mandatory requirements for an accredited tester performing compliance testing of dental panoramic and cephalometric 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 dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 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 dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022](#) published by the Department;
- [Code of Compliance for labelling and signage of ionising radiation sources 2022](#) published by the Department.

Citation

This protocol may be cited as the *Test Protocol for dental panoramic and cephalometric X-ray apparatus 2023*.

Part 1 Interpretation

Unless the contrary intention appears—

any terms used have the meanings given to them in the RPC Act and in RPC Regulations;

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;

air kerma means kerma in air;

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 to which this code applies;

ARPANSA means Australian Radiation Protection and Nuclear Safety Agency;

Authority means the South Australian Environment Protection Authority;

cephalometric radiography means radiography for the purposes of measurement of the human head;

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

kerma means kinetic energy released per unit mass in material by ionising radiation expressed in the unit of joule per kilogram or gray;

member of the public means a person who is not a worker;

panoramic radiography means radiography of the mandible and the maxilla performed by the controlled rotation of an extra-oral X-ray tube and an extra-oral image receptor around one or more axes in relation to the patient's head;

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

protective barrier means a barrier that includes radiation shielding material that has a lead equivalence of at least 0.15 millimetres or allows no more than 10 percent of the incident radiation to be transmitted through the barrier when the apparatus is operated at an *X-ray tube* potential of 70 kilovolts peak;

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;

worker means a person who is exposed to ionising radiation in the ordinary course of his or her work;

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* dental *X-ray apparatus* capable of *panoramic radiography* and/or *cephalometric radiography*.

2 – Complying with this protocol

The *accredited tester* must—

- (a) perform compliance testing in accordance with the test methods specified—
 - (i) in the case of *apparatus* capable of *panoramic radiography*, in Parts 3, 4 and 6; and
 - (ii) in the case of *apparatus* capable of *cephalometric radiography*, in Parts 3, 5, and 6; and
- (b) provide in a report—
 - (i) the details as specified in sections 3 to 7; and
 - (ii) the test parameters used and results obtained for the compliance tests performed under Parts 3 to 6; and
- (c) complete the approved *Certificate of Compliance for dental panoramic and cephalometric X-ray apparatus 2022*.

3 – Owner details

Record, where known, the 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.

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) of the *X-ray tube*, where it is practical to do so; and
 - (iii) of the *tube housing*, where it is practical to do so.
- (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.

7 – Floor plan

- (a) Make a floor plan of the area in which the *apparatus* is located. Note that it does not need to be to scale. The floor plan must indicate at least—
 - (i) the location of the *apparatus* within the area; and
 - (ii) the location of windows (if installed); and
 - (iii) the location of doors and entrances used to directly access the area; and
 - (iv) the location of the normal operator position; and
 - (v) the approximate dimensions of important features, including the immediate area in which the *apparatus* is located and the distance from the *apparatus* to the normal operating position.
- (b) The floor plan, referred to in subsection (a) must be annotated such that it clearly identifies adjoining areas, including but not limited to—hallways, reception areas, offices, staff rooms, storerooms, adjacent surgeries, external car parks, external walkways, and adjacent businesses.

Part 3 Construction and installation requirements for apparatus in panoramic radiography mode and cephalometric radiography mode

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 Schedule 1; 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

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) if it does bear words, the words are ‘RADIATION AREA’ or ‘X-RAYS’ sign or words of similar effect; and
- (c) has a total surface area of not less than 4,500 square millimetres; and
- (d) bears the radiation symbol as specified in Schedule 1; and
- (e) 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 apparatus 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 safe and manner for which it has been designed.

10.2 Legislative reference

Clause 3, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

11 – Warning device

11.1 Test method

Verify that when the *X-ray tube* is energised there is a warning device that consists of—

- (f) a clearly distinguishable light; and
- (g) an audible signal that is audible from an operator position and indicates either the duration or termination of the exposure.

11.2 Legislative reference

Clause 4, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

12 – Mains switch

12.1 Test method

Verify that the *apparatus*—

- (a) has a mains switch that controls the supply of mains power to the *apparatus* and not to any other device; and
- (b) has a mains indicator light to indicate when the control panel is energised and the mains switch is in the ‘ON’ position.

12.2 Legislative reference

Clause 5, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

13 – Focal spot

13.1 Test method

Verify that the position of the focal spot is clearly indicated on the *tube housing*.

13.2 Legislative reference

Clause 6, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

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

14.1 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 mm² 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.

14.2 Legislative references

Clauses 7 and 8, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

15 – Consistency

15.1 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.

15.2 Legislative reference

Clause 9, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

16– Linearity

16.1 Test method

Verify that the apparatus produces a linear radiation output—

- (a) by making at least five measurements of radiation output made at exposure times not less than 0.1 seconds; and

- (b) by calculating the coefficient of variation of the quotients formed by dividing each radiation output by the associated exposure timer setting; and
- (c) by verifying that the calculated coefficient of variation is less than or equal to 0.1.

16.2 Legislative reference

Clause 10, *Code of Compliance for Dental X-ray Apparatus Used for Plain, Panoramic & Cephalometric radiography and Cone-beam Computed Tomography 2022*.

17 – Half value layer

17.1 Test method

- (a) For a range of *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

Indicated X-ray tube potential (kilovolts peak)	Half value layer (millimetres of Aluminium)
50	1.5
60	1.8
70	2.1
80	2.3
90	2.5
100	2.7
110	3.0
120	3.2
125	3.3
130	3.5

17.2 Legislative reference

Clause 25, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

18 – Mode of use for panoramic radiography and cephalometric radiography

18.1 Test method

Verify that for *apparatus* capable of *panoramic* and *cephalometric radiography*—

- (a) that selectable collimation is interlocked with the mode selected; and
- (b) it is not possible to operate the *apparatus* in more than one mode at a time; and
- (c) the selected mode is observable from a shielded position that complies with section 31.

18.2 Legislative reference

Clause 24, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

19 – Exposure switch

19.1 Test method

Verify that—

- (a) continuous pressure must be maintained on the exposure switch in order to maintain radiation exposure and after exposure termination, another exposure is not possible without releasing the exposure switch; or
- (b) in the case of programmed exposures—
 - (i) there is a means of interrupting the programme; and
 - (ii) is not possible to repeat exposures without resetting; and
- (c) is not operable in parallel with any other exposure switch.

19.2 Legislative reference

Clause 26 *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

20 – Exposure parameters

20.1 Test method

Verify that the selected values of *X-ray tube* potential, tube current, and exposure time, or a combination thereof is clearly indicated on the control panel by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

20.2 Legislative reference

Clause 27, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

Part 4 Special requirements for the construction and installation of apparatus in panoramic radiography mode

21 – Focus to skin distance

21.1 Test method

Verify that the distance between the patient positioning device and the *X-ray tube* focus is not less than 180 millimetres at any time during the exposure.

21.2 Legislative reference

Clause 32 *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

22 – Beam to secondary collimator congruence

22.1 Test method

In the case of an *apparatus* fitted with a secondary collimator, the *primary beam* at the secondary collimator must not fall outside the boundaries of the secondary collimator.

22.2 Legislative reference

Clause 33 *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

23 – Beam to image receptor congruence

23.1 Test method

Verify that the *primary beam* does not fall outside the boundaries of the image receptor.

23.2 Legislative reference

Clause 34 *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

24 – X-ray tube potential

24.1 Test method

Verify that the delivered *X-ray tube* potential—

- (a) is not less than 55 kVp and not greater than 125 kVp; and
- (b) is within ± 5 kilovolts peak or ± 5 percent, whichever is the greater, of the indicated value.

24.2 Legislative reference

Clause 35 *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

Part 5 Special requirements for the construction and installation of apparatus in cephalometric radiography mode

25 – Exposure timer

25.1 Test method

Verify that the *apparatus* is fitted with a timer—

- (a) that terminates the radiation exposure—
 - (i) after a pre-set time interval; or
 - (ii) after a pre-set product of the *X-ray tube* current and exposure time; or
 - (iii) by a programmed exposure; and
- (b) termination causes automatic resetting of timer to zero; and
- (c) is not possible to energise *X-ray tube* if the timer is set to zero; and
- (d) in the case of full and half wave rectified generators, set length of exposure is within ± 10 percent or one pulse, whichever is greater, of the measured exposure time; and
- (e) in all cases within ± 10 percent plus 1 millisecond of the measured exposure time.

25.2 Legislative reference

Clause 36, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

26 – Stationary tube housing

26.1 Test method

- (a) Place the *tube housing* in positions that would be typically used in *cephalometric radiography*.
- (b) Verify that for each position, the *tube housing* does not move.

26.2 Legislative reference

Clause 37, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

27 – Collimator light beam

27.1 Test method

In the case where a collimator, fitted to an *X-ray tube*, has a light beam verify that—

- (a) the illuminance of the light beam is not less than 100 lux at a distance of 1 metre from the light source; and
- (b) the centre of the light beam is indicated; and
- (c) the alignment of the light beam 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.

27.2 Legislative reference

Clause 38, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

28 – Collimator alignment

28.1 Test method

Verify that for all available field sizes no boundary of the X-ray beam exceeds any boundary of the image receptor.

28.2 Legislative reference

Clause 39, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

29 – X-ray tube potential

29.1 Test method

Verify that the delivered *X-ray tube* potential—

- (a) is not less than 60 kVp and not greater than 125 kVp; and
- (b) is within ± 5 kilovolts peak or ± 5 percent, whichever is the greater, of the indicated value.

29.2 Legislative reference

Clause 40, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

Part 6 Shielding requirements for apparatus in panoramic and cephalometric radiography mode

30 – Viewing the patient

30.1 Test method

Verify that the operator has a clear view of the patient that complies with section 31.

30.2 Legislative reference

Clause 28, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

31 – Operator protection

31.1 Test method

Verify that there is no exposure switch capable of initiating X-rays—

- (a) that cannot be located outside the *primary beam* and at least 2 metres from the *X-ray tube* and from the patient; or

- (b) behind a *fixed protective barrier* that complies with section 33.

31.2 Legislative reference

Clause 29, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

32 – Shielding

32.1 Test method

- (a) Identify any location where the *primary beam* is likely to be directed—
 - (i) at an area normally occupied by a person; and
 - (ii) where such an area is less than 5 metres from the *X-ray tube*.
- (b) Verify that there is a *fixed protective barrier* at any location that has been identified as requiring such a barrier, that complies with section 33.

32.2 Legislative reference

Clause 30, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

33 – Protective barrier

33.1 Test method

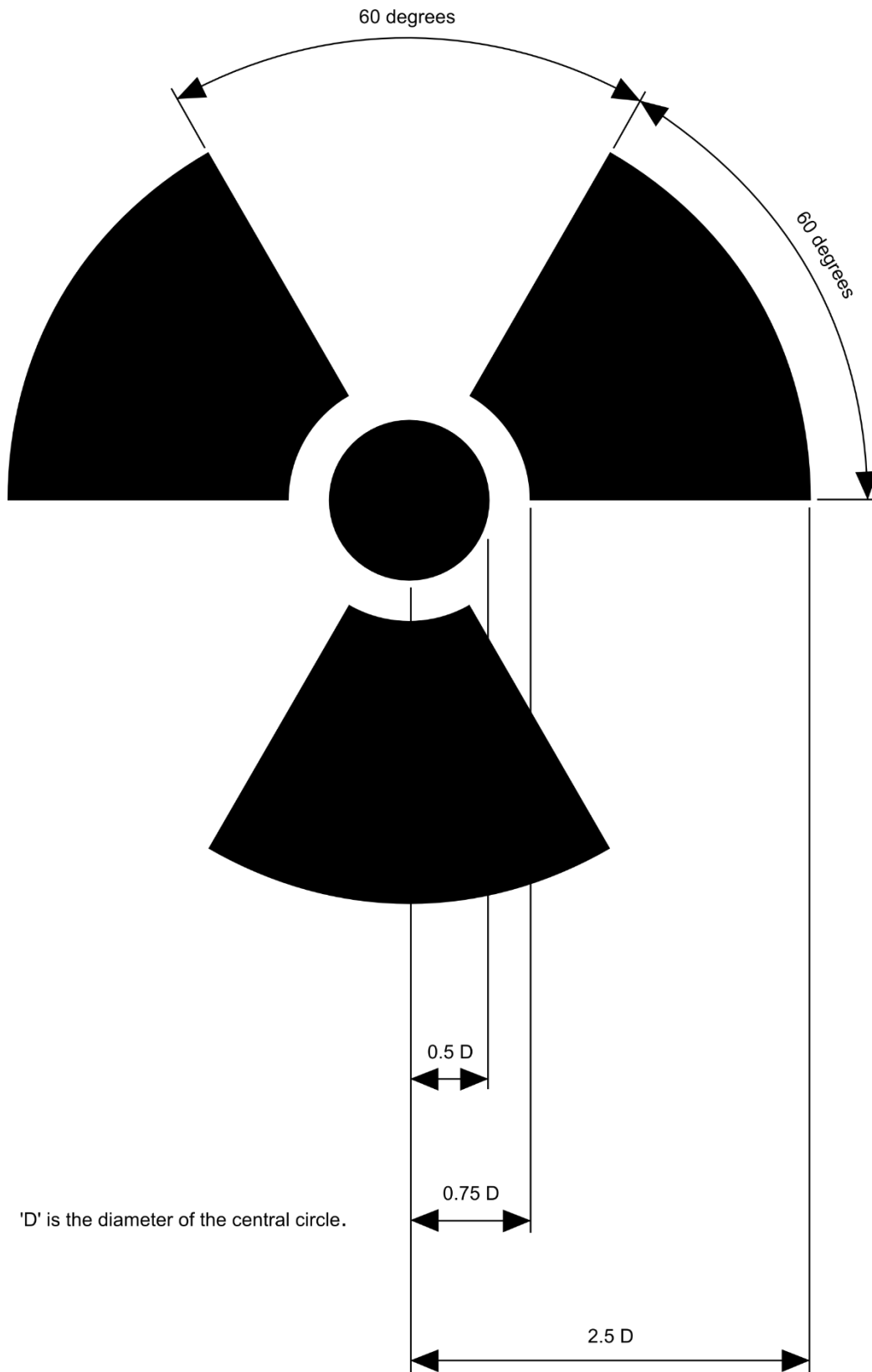
Verify that any *protective barrier* provides radiation shielding to at least the lead equivalence of 0.15 millimetres or allows no more than 10% transmission of an incident radiation beam.

33.2 Legislative reference

Clause 31, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

Schedule 1 – Radiation symbol

- (1) The *radiation symbol* consists of the conventional three blade design shown below.
- (2) 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 dental panoramic and cephalometric X-ray apparatus 2016*, which became obsolete on 11 February 2023.

Title	Release	Commencement
<i>Test Protocol for dental panoramic and cephalometric X-ray apparatus 2023</i>	first release	11.2.2023