Test Protocol for dental cone-beam computed tomography X-ray apparatus 2023

Issued February 2023

This protocol provides the mandatory requirements for an accredited tester performing compliance testing of dental cone-beam 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 Dental X-ray Apparatus Used for Plain, Panoramic & 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;
- *Code of Compliance for facility design and shielding 2022* published by the Department.

Citation

This protocol may be cited as the *Test Protocol for dental cone-beam 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;

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

EPA means the South Australian Environment Protection Authority;

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

fixed protective screen means a *protective screen* that is firmly in position and not readily removable;

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

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*;

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;

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 a *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;

worker means a person who is exposed to ionising radiation in the ordinary course of the person's 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 cone-beam computed tomography, including—

(a) *apparatus* capable of both cone-beam computed tomography and *panoramic radiography*; and

(b) *apparatus* capable of both cone-beam computed tomography and *cephalometric radiography*.

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 Parts 3 and 4; and

(b) provide in a report—

(i) the details as specified in sections 4 to 8; and

(ii) the test parameters used and results obtained for the compliance tests performed under Parts 3 and 4; and

(iii) complete the approved *Certificate of Compliance for Dental Cone-beam Computed Tomography X-ray Apparatus* document; and

(c) in the case of an *apparatus* capable of *panoramic radiography* or *cephalometric radiography*, comply with the requirements of the *Test Protocol for dental panoramic and cephalometric X-ray apparatus 2022* as in force from time to time.

4 – 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.

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.

8 – Floor plan

(1) 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—

(a) the location of the *apparatus* within the area; and

(b) the location of windows (if installed); and

(c) the location of doors and any entrances used to directly access the area; and

(d) the location of the operator's *protective screen* (if applicable); and

(e) the location of the normal operator position; and

(f) 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.

(2) The floor plan, referred to in subsection (1), must be annotated such that it clearly identifies adjoining areas, including but not limited to—hallways, reception areas, offices, staff rooms, store rooms, adjacent surgeries, external car parks, external walk ways, and adjacent businesses.

Part 3 Construction and installation requirements for fixed apparatus

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

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

(c) bears the radiation symbol; and

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

9.2 Legislative reference

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

10 – Radiation area sign

10.1 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 mm^2; and

(iv) bears the radiation symbol; and

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

10.2 Legislative reference

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

11 – Apparatus to be in good working order

11.1 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.

11.2 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*.

12 – Warning device

12.1 Test method

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

(a) a red or amber light that is clearly distinguishable from an operator; and

(b) an audible signal that is audible from that operator position and indicates either the duration or termination of the exposure.

12.2 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*.

13 – Mains switch

13.1 Test method

Verify that the apparatus—

(a) has a mains switch that controls the supply of mains power to the apparatus but does not control the supply of power 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.

13.2 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*.

14 – Focal spot

14.1 Test method

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

14.2 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*.

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

(a) Test method

(b) 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.

(c) Verify that the 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.

(d) 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 inverse square law; 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.

15.1 Legislative reference

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.*

16 – Consistency

16.1 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.

16.2 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.*

17 – Linearity

17.1 Test method

Verify that the apparatus produces a linear radiation output—

(a) by making at least three measurements with the same tube potential and over a range of clinically relevant mA or mAs settings; 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.

17.2 Legislative reference

Clause 10, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

18 – Radiation field size

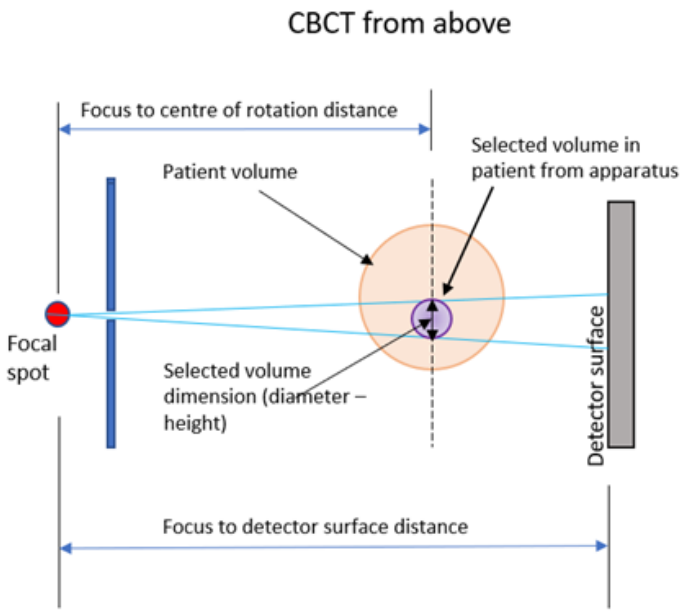
18.1 Test method

Verify that the exposure area at the detector surface is no more than 5% greater than the boundary dimensions of the selected radiation field.

Where the selected radiation field for an apparatus is a cylindrical volume at the centre of rotation (see figure below), the volume dimensions (height and diameter) may be projected from the centre of rotation to the detector surface by the following:

(Focus to detector surface distance/focus to centre of rotation in central beam) x height; and

(Focus to detector surface distance/focus to centre of rotation in central beam) x diameter.



18.2 Legislative reference

Clause 41, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

19 – Exposure parameters

19.1 Test method

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

19.2 Legislative reference

Clause 42, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

20 – Exposure switch

20.1 Test method

Verify that the exposure control switch has a circuit closing contact that can be maintained only by continuous pressure or in case of programmed exposures it is not be possible to make repeat exposures without resetting the exposure parameters and makes it possible to interrupt the exposure at any stage of the program.

20.2 Legislative reference

Clause 43, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

21– Exposure termination

21.1 Test method

Verify that the apparatus is fitted with a device that terminates the radiation exposure after a preset—

(a) time interval; or

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

(c) programmed exposure.

21.2 Legislative reference

Clause 44, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

22 – Half value layer

22.1 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

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

Indicated X-ray tube potential (kilovolts peak)	Half value layer (millimetres of Aluminium)
130	3.5
140	3.8
150	4.1

22.2 Legislative reference

Clause 45, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

23 – Beam to detector congruence

23.1 Test method

Verify that the primary beam does not fall outside the boundaries of the image receptor by greater than 20 mm or 3% of the focus to image receptor distance for rectangular image receptors, provided that the sum of the discrepancies on both axes does not exceed 30 mm or 4% of focal spot to image receptor distance.

23.2 Legislative reference

Clause 46, *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 is greater than 60 kilovolts peak and less than 125 kilovolts peak. And, for a range of set X-ray tube potentials, verify that 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.

24.2 Legislative reference

Clause 47, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

25 – Image quality

25.1 Test method

Verify that—

(a) the mean CT number, noise and uniformity of the water filled phantom (preferably a manufacturer's phantom for the specific apparatus) are within the manufacturer specifications; and

(b) the high contrast and low contrast resolution capability of the scanner, using the appropriate phantoms, are within the manufacturer specifications.

If no manufacturer's specification exists, then the tester should compare against the baseline values established during the acceptance testing or previous compliance measurements. For comparative purposes, the exposure set-up conditions must be clearly stated.

25.2 Legislative reference

Clause 48, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.*

26 – CBCT CTDI (Dose)

26.1 Test method

For a standard image, the Kerma Area Product for the placement of a first upper molar implant for a standard adult patient should not exceed 250 mGy.cm^2. Larger field sizes should be normalised to a 4 cm x 4 cm field.

To verify that the CBCT CTDI value measured in air or in a perspex phantom is within the values quoted by the manufacturer specification. If no manufacturer's specification exists, then the tester should compare against the baseline values established during the acceptance testing or previous compliance measurements. For comparative purposes, the exposure set-up conditions must be clearly stated.

26.2 Legislative reference

Clause 49, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

Part 4 Shielding requirements for fixed apparatus

The shielding verification is required to be performed after installation of the new apparatus and in the instances of major upgrades that alters the output of the machine or when the occupancy of the adjoining areas is changed or when the barrier structures are altered. *The Code of Compliance for facility design and shielding 2022* must be consulted for the shielding requirements for cone-beam computed tomography apparatus.

27 – Operator protection

27.1 Test method

(a) Whenever the X-ray tube is energised, verify that the normal operator's position is located—

(i) in a room, space or enclosure adjacent to but separate from the area in which the *apparatus* is installed; or

(ii) behind a *fixed protective screen* in the same room, space or enclosure in which the *apparatus* is installed.

(b) In the case of an operator's position located in a room, space or enclosure adjacent to but separate from the area in which the apparatus is installed—verify, in accordance with the methodology from one of the approved guidelines specified in Schedule 1, the occupational exposure of a worker will not be greater than an effective dose of 5 millisieverts in a year.

(c) In the case of an operator's position located behind a fixed protective screen in the same room, space or enclosure in which the apparatus is installed verify that—

(i) the screen, where reasonably practicable, is arranged so that the radiation emitted by the apparatus is scattered at least twice before it can enter the area behind the screen; and

(ii) in accordance with the methodology from one of the approved guidelines specified in Schedule 1, the occupational exposure of a worker will not be greater than an effective dose of 5 millisieverts in a year.

27.2 Legislative reference

Clauses 4 and 8, *Code of Compliance for facility design and shielding 2022*.

28 – General shielding

28.1 Test method

(a) Inspect the areas outside the room, space or enclosure in which the apparatus is located, including above ceiling and below floor, and identify the type of occupancy in each area in accordance with the method used. Clearly indicate the type of occupancy for each area identified in the test report and floor plan.

(b) In the case of an area occupied by a radiation worker, verify that in accordance with a methodology from one of the approved guidelines specified in Schedule 1, the occupational exposure of a worker will not be greater than an effective dose of 5 millisieverts in one year.

(c) In the case of an area occupied by a member of the public, verify that in accordance with a methodology from one of the approved guidelines specified in Schedule 1, the exposure to a member of the public will not be greater than 1 mSv in one year.

(d) In the case of an area that is not normally occupied, dose measurements are not required unless it can be reasonably anticipated the occupancy of the area will change, in which case verify compliance in accordance with subsections (b) and (c).

28.2 Legislative reference

Clause 4, *Code of Compliance for facility design and shielding 2022.*

29 – Viewing the patient

29.1 Test method

Verify that the operator is able to clearly view the patient from a position that complies with the requirements of section 27.

29.2 Legislative reference

Clause 7, *Code of Compliance for facility design and shielding 2022*.

30 – Communicating with the patient

30.1 Test method

Verify that the operator is able to communicate with the patient from a position that complies with the requirements of section 27.

30.2 Legislative reference

Clause 7, *Code of Compliance for facility design and shielding 2022*.

Schedule 1

31 – Approved guidelines

- National Council on Radiation Protection and Measurements, *Structural Shielding Design for Medical X-ray Imaging Facilities* (NCRP 147), 2004
- British Institute of Radiology (BIR), *Radiation Shielding for Diagnostic Radiology*, 2012 (BIR 2012).

Document history

Publications

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

Title	Release	Commencement
Test Protocol for dental cone-beam computed tomography X-ray apparatus 2023	first release	11.2.2023