

# Test Protocol for dental 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 dental X-ray apparatus used for plain radiography 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 X-ray apparatus used for plain radiography 2023*.

## Part 1 Interpretation

Unless the contrary intention appears—

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

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

**handheld**, in relation to *apparatus*, means any *portable apparatus* that is designed and constructed so as to be used while held by the operator;

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

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

**mobile**, in relation to apparatus, means any 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 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;

**radiation shield**, in relation to a *handheld apparatus*, means a device that provides protection against backscatter radiation;

**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*, *mobile*, *portable* and *handheld* dental X-ray *apparatus* used for *plain radiography*.

### 2 – Complying with this protocol

The accredited tester must—

- (a) perform compliance testing in accordance with the test methods specified in Part 3 and Part 4; 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 Part 3 and Part 4; and
- (c) complete the approved Certificate of Compliance for dental X-ray apparatus used for plain radiography document.

### 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; 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.

### 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 location where radiation measures are taken for shielding; and
  - (vi) 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 fixed, mobile, portable, and handheld 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 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**

- (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<sup>2</sup>; and
  - (iv) bears the radiation symbol; 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**

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 incorporated into the apparatus that consists of—

- (a) a light clearly distinguishable to the operator; and
- (b) a clearly distinguishable audible signal that is audible at the location from which the equipment is operated 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 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.

### 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 the leakage radiation from X-ray tube assemblies for plain dental radiography, operated at X-ray tube voltages not exceeding 90 kV peak, and at 1 metre from the focus of the X-ray tube, does not exceed 0.25 mSv in 1 hour, averaged over 10,000 mm<sup>2</sup> 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 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*.

## 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 over a range of exposure times from 0.1 second to 1 second; 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 and cephalometric radiography and cone-beam computed tomography 2022*.

## **17 – Stationary tube housing**

### **17.1 Test method**

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

### **17.2 Legislative reference**

Clause 11, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## **18 – Beam limiting device**

### **18.1 Test method**

Verify that the tube housing is fitted with a beam limiting device and that—

- (a) the maximum dimension of the primary beam at the end of the beam limiting device does not exceed 60 millimetres; and
- (b) in the case of a beam limiting device with a closed end, the resulting maximum dimension of the area of exposure, perpendicular to and 10 mm from the end of the beam limiting device, must not exceed the maximum dimension of the beam limiting device by greater than 10%.

### **18.2 Legislative reference**

Clause 12, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## **19 – Focus to skin distance**

### **19.1 Test method**

- (a) Measure the distance between the outer end of the cone or diaphragm of the beam limiting device to the X-ray tube focus.
- (b) Verify that the measured distance is not less than 200 millimetres.

### **19.2 Legislative reference**

Clause 13, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## 20 – Half value layer

### 20.1 Test method

Verify that the half value layer of the primary beam is not less than the value appropriate to the X-ray tube potential set out in the table below.

Indicated X-ray tube potential (kilovolts peak)	Half value layer (millimetres of Aluminium)
60	1.5
70	1.5

### 20.2 Legislative reference

Clause 14, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## 21 – Exposure parameters

### 21.1 Test method

Verify that selected values of X-ray tube potential, X-ray tube current, exposure time, and where parameters are capable of being varied, a combination of tube current and exposure times, are clearly indicated on the control panel. Parameter displays may be by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

### 21.2 Legislative reference

Clause 15, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## 22 – Exposure switch

### 22.1 Test method

Verify that—

- (a) the exposure control switch has a circuit closing contact that can be maintained only by continuous pressure; and
- (b) production of radiation ceases when the exposure switch is released prior to the expiry of the selected exposure time; and
- (c) it is not possible to make repeat exposures without releasing the switch.

### 22.2 Legislative reference

Clause 20, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## 23 – Exposure timer

### 23.1 Test method

For a range of exposure times, verify that—

- (a) the exposure terminates after its pre-set time or after its present product of current and time; and
- (b) the termination of the exposure automatically resets of the timer to its initial setting or zero; and
- (c) it is not possible to energise the X-ray tube if the timer is set to zero.

### 23.2 Legislative reference

Clause 21, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## **24 – Multiple X-ray tubes**

### **24.1 Test method**

Verify that if more than one X-ray tube can be operated from a single control panel—

- (a) it is not 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.

### **24.2 Legislative reference**

Clause 22, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## **25 – X-ray tube potential**

### **25.1 Test method**

Verify that —

- (a) the delivered X-ray tube potential is not less than 60 kilovolts peak and not greater than the 90 kilovolts peak; and
- (b) the measured value of any X-ray tube potential is within  $\pm 5$  kilovolts peak or  $\pm 5$  percent, whichever is the greater, of the indicated value for all available set X-ray tube potentials.

### **25.2 Legislative reference**

Clause 23, *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, mobile, portable, and handheld apparatus**

### **26 – Viewing the patient**

#### **26.1 Test method**

Verify that the apparatus is installed so the operator has a clear view of the patient from a location that complies with section 27.

#### **26.2 Legislative reference**

Clause 16, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

### **27 – Operator position**

#### **27.1 Test method**

Verify that if the apparatus is not designed for hand held use, 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.

#### **27.2 Legislative reference**

Clauses 17 and 51, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

### **28 – Shielding**

#### **28.1 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 meters 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 29.
- (c) In the case of a handheld apparatus —
  - (i) where the apparatus is to be used in a single location, verify that the apparatus complies with the requirements of subsections (a) and (b); and
  - (ii) where the apparatus is to be used in multiple locations, verify that the apparatus complies with subsections (a) and (b) where practical to do so.

## **28.2 Legislative reference**

Clauses 18 and 19, *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

## **29 – Protective barrier**

### **29.1 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.

### **29.2 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*.

## **30 – Radiation shield for a handheld apparatus**

### **30.1 Test method**

In the case of a *handheld apparatus* verify that—

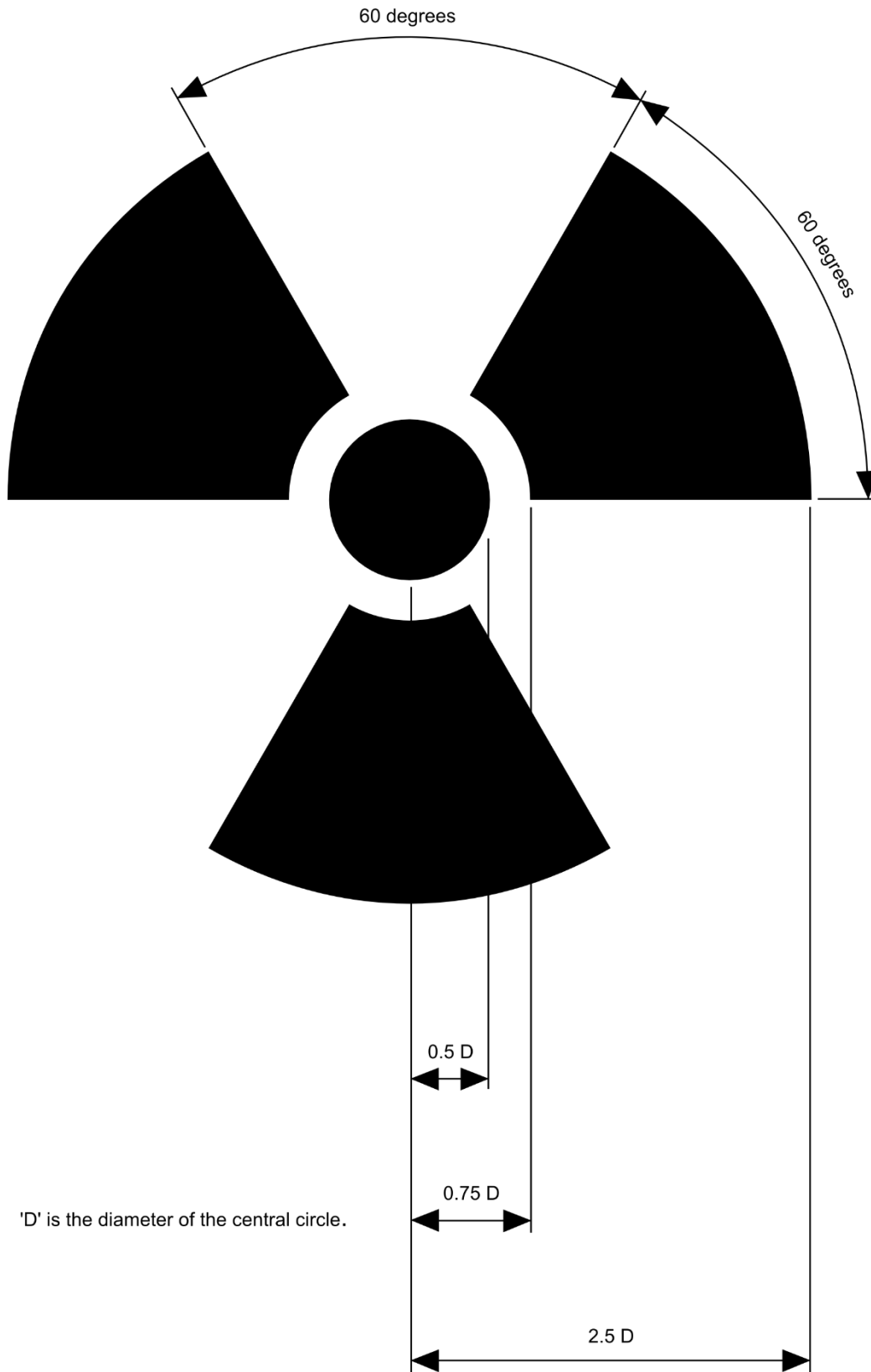
- (a) the apparatus has a radiation shield attached to the beam limiting device or diaphragm; and
- (b) the radiation shield cannot be removed from the beam limiting device or diaphragm.

### **30.2 Legislative reference**

Clause 53, *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 X-ray apparatus used for plain radiography 2016*, which became obsolete on 11 February 2023.

Title	Release	Commencement
<i>Test Protocol for dental X-ray apparatus used for plain radiography 2023</i>	first release	11.2.2023

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