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

Issued February 2023

This code was approved for publication by the Chief Executive of the South Australian Environment Protection Authority on 7 February 2023

This code provides the mandatory requirements for the construction, installation and operation of dental X-ray apparatus used, or designed to be used, for dental and veterinary plain radiography, panoramic radiography and cephalometric radiography. This code also provides the mandatory requirements for the construction and installation of cone-beam computed tomography X-ray apparatus used, or designed to be used, for dental radiography, including apparatus capable of both cone beam computed tomography and panoramic radiography, and apparatus capable of both cone-beam computed tomography and cephalometric radiography.

It should be read in conjunction with the:

- *Radiation Protection and Control Act 2021*
- *Radiation Protection and Control Regulations 2022*
- *Code of Compliance for labelling and signage of ionising radiation apparatus 2022* published by the Department.
- *Code of Compliance for facility design and shielding* 2022 published by the Department
- *Code of Practice for Radiation Protection in Dentistry* (2005), ARPANSA Radiation Protection Series 10, published by the National Health and Medical Research Council.

Citation

This code may be cited as the *Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022*.

Part 1 − Preliminary

1 Interpretation

In this code, unless the contrary intention appears—

Any terms used have the meanings given to them in the Radiation Protection and Control Act 2021 (the Act) and in the Radiation Protection and Control Regulations 2022 (the Regulations).

If a word or phrase is defined in this code, other parts of speech and grammatical forms of the word or phrase have corresponding meanings:

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

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

Department means the administrative unit of the Public Service that is responsible for assisting a Department in the administration of the Act

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, 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

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 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 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

2 Interaction between the regulations and relevant codes

(1) If a provision of this code is inconsistent with the regulations, the regulations prevail to the extent of the inconsistency.

(2) If a provision of a code or other document, published by the ARPANSA, is inconsistent with this code, the provisions of this code prevail to the extent of the inconsistency.

Part 2 – Requirements for all dental apparatus

3 Good working order

The apparatus and all items of equipment necessary for its safe operation must be maintained in good working order.

Dental apparatus used on humans must undergo cyclic compliance testing with a frequency once every five years. The cyclic testing for dental apparatus will be introduced in South Australia from February 2026. Until the commencement of cyclic testing in February 2026, the apparatus must undergo annual servicing as per the manufacturer recommendations. At the conclusion of the annual service the apparatus must comply with the requirements as per the test protocol, published by the Department, relevant to its kind or class of apparatus.

4 Warning device

The apparatus must incorporate a device that provides a warning to the operator whenever the X-ray tube is energised, being a warning that consists of—

(a) a clearly distinguishable light; 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.

5 Mains switch

The apparatus must have 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 a mains indicator light to indicate when the control panel is energised and the mains switch is in the 'ON' position.

6 Focal spot

The position of the focal spot must be clearly indicated on the tube housing.

7 Leakage from the X-ray tube housing

The X-ray tube must be enclosed in a housing in such a manner that the air kerma rate from leakage radiation at a distance of 1 metre from the focus of the X-ray tube, averaged over any area 10,000 mm^2 of which no principal linear dimension exceeds 200 mm, when operated at the nominal X-ray tube potential under conditions of loading corresponding to the maximum specified energy input in 1 hour, must not exceed the limits stated below:

(a) for X-ray tube assemblies specified for use in X-ray equipment for dental radiography with intra-oral X-ray image receptors at X-ray tube voltages not exceeding 90 kV peak, 0.25 mGy in one hour;

(b) for all other X-ray tube assemblies, 1 mGy in one hour.

8 Leakage from the beam limiting device

A device that serves to limit the size of the useful beam must be constructed so that, in combination with the tube housing, it complies with the leakage radiation limits set out in clause 7.

9 Consistency

The apparatus must produce a consistent radiation output so that the coefficient of variation of at least five measurements of the radiation output taken at the same exposure settings is less than or equal to 0.05.

10 Linearity

The apparatus must produce a linear radiation output so that if at least five measurements of radiation output of the machine are made at a range of exposure times from 0.1 second to 1 second, the coefficient of variation of the quotients formed by dividing each radiation output by the associated timer setting is less than or equal to 0.1.

Part 3 − Special requirements for plain dental apparatus

11 Stationary tube housing

The tube housing must remain stationary when placed in position for radiography.

12 Beam size

The tube housing must be fitted with a beam limiting device—

(a) that limits the maximum dimension of the useful beam in a plane at right angles to the central ray of the beam located at the end of that cone or diaphragm to a length not exceeding 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%.

13 Focus to skin distance

A beam limiting device referred to in clause 12 must be constructed so that the minimum distance from the outer end of the cone or diaphragm to the X-ray tube focus is not less than 200 mm.

14 Half value layer

The half value layer of the primary beam must be 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

15 Exposure parameters

If X-ray tube potential, X-ray tube current or exposure time—

(a) are capable of being varied − the values of the selected X-ray tube potential, X-ray tube current, and exposure time or a combination thereof must be clearly indicated on the control panel by means of analogue meters, digital displays or scales, or by calibrated permanent markings; or

(b) are not capable of being varied − the values of the X-ray tube potential, X-ray tube current, and exposure time must be clearly indicated on the tube housing or on the control panel by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

16 Viewing the patient

The apparatus must be installed so that the operator has a clear view of the patient from a position that complies with clause 17.

17 Operator position

The exposure control switch must be arranged so that the operator can remain—

(a) outside the useful X-ray beam and at least 2 metres from the X-ray tube and from the patient; or

(b) behind a fixed protective barrier which complies with clause 19,

while the X-ray tube is energised.

18 Shielding

Whenever the primary beam from such apparatus is likely to be directed at an area normally occupied by a person, being an area less than 5 metres from the X-ray tube, a fixed protective barrier that complies with clause 19, must be provided.

19 Protective barrier

The protective barrier, referred to in clauses 17 and 18 must have a lead equivalent of at least 0.15 millimetres.

20 Exposure switch

The exposure control switch must have a circuit closing contact that can be maintained only by continuous pressure and it must not be possible to make repeat exposures without releasing the switch.

21 Exposure timer

A timer must be provided that will terminate the exposure after a preset time setting or at a preset product of current and time and—

(a) termination of exposure must cause automatic resetting of the timer to its initial setting or zero; and

(b) it must not be possible to energise the X-ray tube if the timer is set to zero.

22 Multiple X-ray tubes

When more than one X-ray tube can be operated from a single control panel, it must not be possible to energise more than one X-ray tube at the same time and there must be an indication at or near each tube housing and on the control panel showing which X-ray tube is selected.

23 X-ray tube potential

The delivered X-ray tube potential—

(a) must be not less than 60 kilovolts peak and not greater than the 90 kilovolts peak; and

(b) must be within ±5 kilovolts peak or ±5 percent, whichever is the greater, of the indicated value for all available set X-ray tube potentials.

Part 4 − Special requirements for panoramic and cephalometric apparatus

24 Mode of use for panoramic radiography mode and cephalometric radiography

The apparatus must, when in a panoramic radiography mode or a cephalometric radiography mode—

(a) have interchangeable and selectable collimation that is interlocked with the mode selected; and

(b) it must not be possible to operate the apparatus in more than one such mode at a time; and

(c) there must be a clear indication, from a shielded position that complies, which mode is selected.

25 Half value layer

The half value layer of the primary beam must be 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)
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

26 Exposure switch

The exposure switch fitted to the apparatus must have a circuit closing contact that—

(a) can be maintained by continuous pressure; or

(b) in the case of programmed exposures −

(i) makes it possible to interrupt the exposure at any stage of the programme, and

(ii) makes it impossible to make repeat exposures without resetting; and

(c) must not be operable in parallel with any other exposure switch.

27 Exposure parameters

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

28 Viewing the patient

The apparatus must be installed so that the operator has a clear view of the patient from a position that complies with clause 29.

29 Operator position

The exposure control switch must be arranged so that the operator can remain—

(a) outside the useful X-ray beam and at least 2 metres from the X-ray tube and from the patient; or

(b) behind a fixed protective barrier which complies with clause 31,

while the X-ray tube is energised.

30 Shielding

Whenever the primary beam from apparatus is likely to be directed at an area normally occupied by a person, being an area less than 5 metres from the X-ray tube, a fixed protective barrier that complies with clause 31 must be provided.

31 Protective barrier

The protective barrier, referred to in clauses 29 and 30, must have a lead equivalent of at least 0.15 millimetres.

Part 5 − Apparatus in panoramic radiography mode

32 Focus to skin distance

In the case of apparatus used for panoramic radiography, the focus to skin distance, determined by the location of the X-ray tube and the patient positioning device, must not be less than 180 millimetres at any time during the exposure.

33 Beam to secondary collimator congruence

For an apparatus fitted with a secondary collimator, the primary beam at the secondary collimator must not fall outside the aperture in the secondary collimator.

34 Beam to image receptor congruence

The primary beam must not fall outside the image receptor.

35 X-ray tube potential for panoramic radiography mode

The delivered X-ray tube potential—

(a) must be not less than 55 kilovolts peak and not greater than the 125 kilovolts peak; and

(b) must be within ±5 kilovolts peak or ±5 percent, whichever is the greater, of the indicated value for all available set X-ray tube potentials.

Part 6 − Apparatus in cephalometric radiography mode

36 Exposure timer

A timer must be provided that will terminate the exposure after a preset time setting or at a preset product of current and time and—

(a) termination of exposure must cause automatic resetting of the timer to its initial setting or zero; and

(b) it must not be possible to energise the X-ray tube if the timer is set to zero; and

(c) the length of the exposure must be—

(d) in the case of full and half wave rectified generators within ±10 percent or one pulse, whichever is the greater, of the measured exposure time; and

(e) in all other cases within ±10 percent plus 1 millisecond of the measured exposure time.

37 Stationary tube

The tube housing must remain stationary when placed in position for radiography.

38 Collimator light beam

If a collimator fitted to an X-ray tube has a light beam—

(a) the illuminance of which must not be less than 100 lux at a distance of 1 metre from the light source; and

(b) the centre of which is must be indicated; and

(c) the alignment of which with any boundary of the X-ray beam must not exceed 1 percent of the distance between the focus of the X-ray tube and the image receptor.

39 Collimator alignment

For all available field sizes no boundary of the X-ray beam can exceed any boundary of the image detector.

40 X-ray tube potential for cephalometric radiography mode

The delivered X-ray tube potential—

(a) must be not less than 60 kilovolts peak and not greater than the 125 kilovolts peak; and

(b) must be within ±5 kilovolts peak or ±5 percent, whichever is the greater, of the indicated value for all available set X-ray tube potentials.

Part 7 − Special requirements for cone-beam computed tomography apparatus

The *Code of Compliance for facility design and shielding 2022* must be applied for the shielding requirements for cone-beam computed tomography apparatus.

41 Radiation field size

The boundary dimensions of the delivered radiation field at the image receptor must be no more than 5 percent greater than the boundary dimensions of the selected radiation field.

42 Exposure parameters

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

43 Exposure switch

The exposure switch fitted to the apparatus must have a circuit closing contact that—

(a) can be maintained only by continuous pressure; or

(b) in the case of programmed exposures −

(i) makes it possible to interrupt the exposure at any stage of the program; and

(ii) makes it impossible to make repeat exposures without resetting; and

(c) must not be operable in parallel with any other exposure switch.

44 Exposure termination

The apparatus must be fitted with a device that will terminate the exposure after a preset—

(a) time interval; or

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

(c) programmed exposure.

45 Half value layer

The half value layer of the primary beam must, for every available X-ray tube potential, be not less than the value of half value layer shown in the table below as being appropriate to the selected X-ray tube potential.

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
130	3.5
140	3.8
150	4.1

46 Beam to detector congruence

The primary beam must not fall outside the image receptor by more than 20 mm or 3% of the focal spot to image receptor distance for rectangular image receptors provided that the sum of the discrepancies on both axes must not exceed 30 mm or 4% of focal spot to image receptor distance.

47 X-ray tube potential

The delivered X-ray tube potential—

(a) must be not less than 60 kilovolts peak and not greater than the 125 kilovolts peak; and

(b) must be within ±5 kilovolts peak or ±5 percent, whichever is the greater, of the indicated value for all available set X-ray tube potentials.

48 Image quality

Image quality checks (mean CT number, noise, uniformity, high spatial resolution, low contrast resolution) should be undertaken during compliance testing and with regular apparatus testing using a phantom (preferably a manufacturer's phantom for the specific apparatus). The results should be within the manufacturer specifications.

49 CBCT CTDI (dose)

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.

If a CTDI is quoted by the manufacturer, it is suggested to measure CTDI for comparison with the specification.

Part 8 − Additional requirements for hand-held apparatus

50 Application of hand-held apparatus

Hand-held apparatus must only be used for the purposes of special need dentistry and forensic odontology where fixed or mobile radiography is unavailable or infeasible.

51 Operator position for hand-held apparatus

Clause 17 does not apply to hand-held apparatus.

52 Personal protective equipment while using hand-held apparatus

In the case of hand-held apparatus where radiation exposure of an operator is likely to exceed 100 microsieverts in a year, personal protective equipment must be considered in the optimisation of protection. Any protective apron to meet optimisation requirements should provide shielding to meet a lead equivalent of at least 0.25 millimetres.

53 Radiation shield for hand-held apparatus

A hand-held apparatus must have a radiation shield attached to the beam limiting device or diaphragm that must not be capable of being removed.

Document history

Publications

Title	Release	Commencement
Code of Compliance for dental X-ray apparatus used for plain, panoramic and cephalometric radiography and cone-beam computed tomography 2022.	Second release	11 February 2023

Amendments

Provision	How changed	Commencement
Introductory text	Include link to regulations	11 February 2023
12(b)	Change requirement from measure of increase exposure to limitation on the spread of the area exposed	11 February 2023
14	Corrected title of heading	11 February 2023
17&18	Corrected cross-reference to Clause 19	11 February 2023
19	Included missing word ‘must’	11 February 2023
26&43	Clarify that it must be impossible to make repeat exposures without resetting the switch	11 February 2023
General information	Updated email address	11 February 2023

Further information

Legislation

Online legislation is freely available.

General information

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