Radiation Protection

Code of Compliance

COC-3

Code of Compliance for Medical, Veterinary, and Chiropractic X-ray Apparatus 2022

This code was approved for publication by the Chief Executive of the Environment Protection Authority of South Australia on the DD MMMM YYYY.

This code provides the mandatory requirements for fixed, mobile, and portable apparatus used or designed to be used for—

- mammography or soft tissue radiography;
- medical or veterinary computed tomography;
- medical or veterinary fluoroscopy;
- medical, veterinary, or chiropractic plain radiography;
- medical X-ray absorptiometry.

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 Environment Protection Authority of South Australia;
- *Code of Compliance for Shielding of Dental CBCT, Medical, Veterinary and Chiropractic X-ray Apparatus 2022* published by the Environment Protection Authority of South Australia;
- *Multijurisdictional Radiation Apparatus Testing Requirements Draft Standard*, 22 September 2022, released for public consultation by Australian Radiation Protection and Nuclear Safety Agency on 9 November 2021.

Citation

This code may be cited as the *Code of Compliance for Medical, Veterinary, and Chiropractic X-ray Apparatus 2022*.

Contents

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;

accredited compliance test means a test or tests performed by a person holding an accreditation granted under section 30 of the Act and acting under the authority conferred under section 31 of the Act;

apparatus means ionising radiation apparatus to which this code applies;

ARPANSA means Australian Radiation Protection and Nuclear Safety Agency;

ARPANSA Standard means *Multijurisdictional Radiation Apparatus Testing Requirements Draft Standard*, 22 September 2022, released for public consultation by ARPANSA on 9 November 2021;

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;

Authority means Environment Protection Authority of South Australia;

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

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 a tube housing by a direct path from an X-ray tube;

tube housing, in relation to an 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 apparatus, means an evacuated glass envelope in which electrons are accelerated for the purposes of the production of ionising radiation.

2—Application of the code

This code applies to fixed, mobile, and portable apparatus used or designed to be used for—

(a) mammography or soft tissue radiography; and

(b) medical or veterinary computed tomography; and

(c) medical or veterinary fluoroscopy; and

(d) medical, veterinary, or chiropractic plain radiography; and

(e) medical X-ray absorptiometry.

3—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—Compliance with the ARPANSA Standard

4—Inclusions and exclusions

Subject to the provisions of clause 3 and the modifications of clause 5, the requirements of the ARPANSA Standard must be complied with, where prescribed in this code as requiring to be complied with.

5—Modifications

The ARPANSA Standard is modified as follows—

(a) a reference to humans in relation to computed tomography, fluoroscopy, and plain radiography in the ARPANSA Standard is a reference to live animals, where the context in this code applies to veterinary apparatus or any apparatus used for research involving live animals;

(b) a reference to an appropriately qualified person, a suitably qualified person, a licensed tester, approved tester, or tester is a reference to a person who is—

(i) a holder of an accreditation accredited under section 30 of the Act; and

(ii) is acting under the authority conferred by that accreditation;

(c) a reference to the regulator, relevant regulatory authority, or relevant radiation regulator is a reference to the Authority;

(d) a reference to installed is a reference to installed or used.

Part 3—Requirements for computed tomography apparatus

6—Special requirements for computed tomography apparatus

Apparatus used or designed to be used for medical or veterinary computed tomography must comply with the requirements of the ARPANSA Standard.

Part 4—Requirements for fluoroscopy apparatus

7—Special requirements for fluoroscopy apparatus

Apparatus used or designed to be used for medical or veterinary fluoroscopy (including apparatus capable of both fluoroscopy and plain radiography) must comply with the requirements of the ARPANSA Standard.

Part 5—Requirements for mammography apparatus

8—Special requirements for mammography or soft tissue radiography apparatus

Apparatus used or designed to be used for mammography or soft tissue radiography must comply with requirements of the ARPANSA Standard.

Part 6—Requirements for plain radiography apparatus

9—Special requirements for fixed apparatus for medical, veterinary, or chiropractic plain radiography

Fixed apparatus used or designed to be used for medical plain radiography, veterinary plain radiography, or by a chiropractor must comply with requirements of the ARPANSA Standard.

10—Special requirements for mobile apparatus for medical plain radiography

Mobile apparatus used or designed to be used for medical plain radiography must comply with requirements of the ARPANSA Standard.

11—Special requirements for mobile apparatus for veterinary plain radiography

(1) In subclauses (3) to (20) ***apparatus*** means mobile apparatus used or designed to be used for veterinary plain radiography.

(2) Apparatus, referred to subclause (1), must undergo an accredited compliance test for the requirements of subclauses (3) to (20) at a frequency not exceeding the time period shown in column 2 of the table of Schedule 2, appropriate to the corresponding apparatus shown in column 1 of the table.

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

(4) The half value layer of the primary beam of the apparatus must, for every available X-ray tube potential, be not less than the value of the half value layer shown in the table set out in Schedule 1 as being appropriate to the selected X-ray tube potential.

(5) 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 exposure time; or
- (c) programmed exposure.

(6) The exposure switch fitted to the apparatus must—

- (a) have a circuit closing contact that—
  - (i) can be maintained only by continuous pressure; and
  - (ii) makes it impossible to make repeat exposures without releasing the switch; and
  - (iii) in the case of programmed exposures—makes it possible to interrupt the exposure at any stage of the programme; and
- (b) if the apparatus is fitted with a foot actuated exposure switch, the switch must have a cover designed to prevent accidental activation.

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

(8) 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 of the apparatus by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

(9) 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.

(10) The apparatus must have a readily accessible mains switch to control the supply of mains power to the apparatus and a mains indicator light to indicate when the control panel is energised and the mains switch is in the "ON" position.

(11) The X-ray tube of the apparatus 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 10000 millimetres squared of which no principal linear dimension exceeds 200 millimetres, must not exceed 1 milligray in 1 hour, when operated at the nominal X-ray tube voltage under conditions of loading corresponding to the maximum specified energy input in 1 hour.

(12) Any beam limiting device of the apparatus used to limit the useful beam to the area of clinical interest must be so constructed that, in combination with the tube housing, it complies with the leakage radiation limits set out in subclause (11).

(13) The position of the focal spot must be clearly indicated on the tube housing of the apparatus.

(14) The delivered X-ray tube potential of the apparatus 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.

(15) The apparatus must produce linear radiation output so that the coefficient of variation of at least five values of the ratio of radiation output to charge, where the radiation output is measured at a fixed X-ray tube potential and the charge is that indicated on the control panel and is varied from measurement to measurement, must be less than or equal to 0.1.

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

(17) The X-ray tube of the apparatus must be fitted with a continuously adjustable collimator that—

- (a) has a light beam—
- (b) the centre of which is indicated; and
- (c) 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
- (d) can be rotated around the centre of the X-ray beam.

(18) The tube housing of the apparatus must be supported in such a way that it remains stationary when placed in position for radiography.

(19) A continuously adjustable collimator fitted to an X-ray tube of the apparatus must—

- (a) have a light beam the illuminance of which is not less than 100 lux at a distance of 1 metre from the light source; and
- (b) where provision is made for the automatic adjustment of the size of the irradiated area—be fitted with a manual override that permits the selection of a smaller area.

(20) If an apparatus is fitted with an automatic exposure control—

- (a) the selection of the control must, when it takes place, be clearly indicated on the control panel; and
- (b) the control must limit—
  - (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 to no more than 600 milliampere seconds; and
- (c) if an exposure has been terminated after the period referred to in subclause (b)—a visible or audible signal must indicate that termination has occurred and manual resetting of the control must then be required before further automatically timed exposures can be made.

12—Special requirements for portable apparatus for medical plain radiography

(1) In subclauses (3) to (21) ***apparatus*** means portable apparatus used or designed to be used for medical plain radiography.

(2) Apparatus, referred to subclause (1), must undergo an accredited compliance test for the requirements of subclauses (3) to (21) at a frequency not exceeding the time period shown in column 2 of the table of Schedule 2, appropriate to the corresponding apparatus shown in column 1 of the table.

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

(4) The half value layer of the primary beam of the apparatus must, for every available X-ray tube potential, be not less than the value of the half value layer shown in the table set out in Schedule 1 as being appropriate to the selected X-ray tube potential.

(5) 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 exposure time; or

(c) programmed exposure.

(6) The exposure switch fitted to the apparatus must—

(a) have a circuit closing contact that—

(i) can be maintained only by continuous pressure; and

(ii) makes it impossible to make repeat exposures without releasing the switch; and

(iii) in the case of programmed exposures—makes it possible to interrupt the exposure at any stage of the programme; and

(b) if the apparatus is fitted with a foot actuated exposure switch, the switch must have a cover designed to prevent accidental activation.

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

(8) 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 of the apparatus by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

(9) 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.

(10) The apparatus must have a readily accessible mains switch to control the supply of mains power to the apparatus and a mains indicator light to indicate when the control panel is energised and the mains switch is in the "ON" position.

(11) The X-ray tube of the apparatus 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 10000 millimetres squared of which no principal linear dimension exceeds 200 millimetres, must not exceed 1 milligray in 1 hour, when operated at the nominal X-ray tube voltage under conditions of loading corresponding to the maximum specified energy input in 1 hour.

(12) Any beam limiting device of the apparatus used to limit the useful beam to the area of clinical interest must be so constructed that, in combination with the tube housing, it complies with the leakage radiation limits set out in subclause (11).

(13) The position of the focal spot must be clearly indicated on the tube housing of the apparatus.

(14) The delivered X-ray tube potential of the apparatus 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.

(15) The apparatus must produce linear radiation output so that the coefficient of variation of at least five values of the ratio of radiation output to charge, where the radiation output is measured at a fixed X-ray tube potential and the charge is that indicated on the control panel and is varied from measurement to measurement, must be less than or equal to 0.1.

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

(17) The X-ray tube of the apparatus must be fitted with a continuously adjustable collimator that—

(a) has a light beam—

(i) the centre of which is indicated; and

(ii) 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

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

(18) If the apparatus is used for medical plain radiography, the focus of the X-ray tube must not be less than 200 millimetres from the patient's skin.

(19) The tube housing of the apparatus must be supported in such a way that it remains stationary when placed in position for radiography.

(20) A continuously adjustable collimator fitted to an X-ray tube of the apparatus must—

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

(b) where provision is made for the automatic adjustment of the size of the irradiated area—be fitted with a manual override that permits the selection of a smaller area.

(21) If an apparatus is fitted with an automatic exposure control—

(a) the selection of the control must, when it takes place, be clearly indicated on the control panel; and

(b) the control must limit—

(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 to no more than 600 milliampere seconds; and

(c) if an exposure has been terminated after the period referred to in subclause (b)—a visible or audible signal must indicate that termination has occurred and manual resetting of the control must then be required before further automatically timed exposures can be made.

13—Special requirements for portable apparatus for veterinary plain radiography

(1) In subclauses (3) to (18) ***apparatus*** means portable apparatus used or designed to be used for veterinary plain radiography.

(2) Apparatus, referred to subclause (1), must undergo an accredited compliance test for the requirements of subclauses (3) to (18) at a frequency not exceeding the time period shown in column 2 of the table of Schedule 2, appropriate to the corresponding apparatus shown in column 1 of the table.

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

(4) The half value layer of the primary beam of the apparatus must, for every available X-ray tube potential, be not less than the value of the half value layer shown in the table set out in Schedule 1 as being appropriate to the selected X-ray tube potential.

(5) 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 exposure time; or

(c) programmed exposure.

(6) The exposure switch fitted to the apparatus must—

(a) have a circuit closing contact that—

(i) can be maintained only by continuous pressure; and

(ii) makes it impossible to make repeat exposures without releasing the switch; and

(iii) in the case of programmed exposures—makes it possible to interrupt the exposure at any stage of the programme; and

(iv) if the apparatus is fitted with a foot actuated exposure switch, the switch must have a cover designed to prevent accidental activation.

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

(8) 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 of the apparatus by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

(9) 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.

(10) The apparatus must have a readily accessible mains switch to control the supply of mains power to the apparatus and a mains indicator light to indicate when the control panel is energised and the mains switch is in the "ON" position.

(11) The X-ray tube of the apparatus 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 10000 millimetres squared of which no principal linear dimension exceeds 200 millimetres, must not exceed 1 milligray in 1 hour, when operated at the nominal X-ray tube voltage under conditions of loading corresponding to the maximum specified energy input in 1 hour.

(12) Any beam limiting device of the apparatus used to limit the useful beam to the area of clinical interest must be so constructed that, in combination with the tube housing, it complies with the leakage radiation limits set out in subclause (11).

(13) The position of the focal spot must be clearly indicated on the tube housing of the apparatus.

(14) The delivered X-ray tube potential of the apparatus 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.

(15) The apparatus must be provided with an X-ray tube stand designed and constructed to support the X-ray tube during radiography.

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

(17) The X-ray tube must be fitted with a continuously adjustable collimator that must have a light beam—

(a) the centre of which must be indicated; and

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

(18) The collimator must be provided with a device or other means to indicate the X-ray field size at various focus to image receptor distances.

Part 7—Requirements for X-ray absorptiometry apparatus

14—Special requirements for X-ray absorptiometry apparatus

(1) In subclauses (3) to (12) ***apparatus*** means X-ray absorptiometry apparatus.

(2) Apparatus, referred to subclause (1), must undergo an accredited compliance test for the requirements of subclauses (3) to (12) at a frequency not exceeding the time period shown in column 2 of the table of Schedule 2, appropriate to the corresponding apparatus shown in column 1 of the table.

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

(4) The apparatus must be fitted with a device that will terminate the exposure after a pre-set —

(a) time interval; or

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

(c) programmed exposure.

(5) The apparatus must be fitted with a device that makes it possible to manually interrupt the exposure, from the control panel, at any time during the exposure.

(6) The exposure switch fitted to the apparatus must not be operable in parallel with any other switch.

(7) The selected scan mode and 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 of the apparatus by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

(8) 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.

(9) The apparatus must have a readily accessible mains switch to control the supply of mains power to the apparatus and a mains indicator light to indicate when the apparatus is energised and the mains switch is in the "ON" position.

(10) The tube housing of the apparatus must be fitted with a beam limiting device.

(11) The position of the focal spot must be clearly indicated on the tube housing of the apparatus.

(12) The focus of the X-ray tube of the apparatus must not be less than 200 millimetres from the patient's skin.

Part 8—Schedules

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

Indicated X-ray tube potential (kilovolts peak)	Half value layer (millimetres of Aluminium)
50	1.2
60	1.3
70	1.5
71	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

Schedule 2—Frequency of accredited compliance test

In the table of this schedule, a reference to the ARPANSA Standard is a reference to Table 4 of the ARPANSA Standard.

Apparatus used or designed to be used for	Time period
medical or veterinary computed tomography	as prescribed in the ARPANSA Standard
medical or veterinary fluoroscopy (including apparatus capable of both fluoroscopy and plain radiography)	as prescribed in the ARPANSA Standard
mammography or soft tissue radiography	as prescribed in the ARPANSA Standard
medical plain radiography, veterinary plain radiography, or by a chiropractor	as prescribed in the ARPANSA Standard
mobile apparatus used or designed to be used for medical plain radiography	as prescribed in the ARPANSA Standard
mobile apparatus used or designed to be used for veterinary plain radiography	2 years
portable apparatus used or designed to be used for medical plain radiography	2 years
X-ray absorptiometry apparatus	5 years

Document history

Publications

Title	Release	Commencement
Code of Compliance for Medical, Veterinary, and Chiropractic X-ray Apparatus 2022	First release	D.M.YYYY

Amendments

Provision	How changed	Commencement
Not applicable	Not applicable	Not applicable