# COC−5
# Code of Compliance for radiation therapy apparatus 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 and installation of apparatus used for radiation therapy, including X-ray apparatus integrated with the radiation therapy unit used for treatment image guidance, where such apparatus is not standalone dental or medical class diagnostic X-ray apparatus. This code does not apply to sealed radioactive sources or particle accelerators used for radiation therapy.

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.

**Citation**

This code may be cited as the *Code of Compliance for radiation therapy apparatus 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

***Department*** means the administrative unit of the Public Service that is responsible for assisting a Minister in the administration of the *Radiation Protection and Control Act 2021*

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

***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 Application of code

This code applies to apparatus regulated under the Act or Regulations.

### 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 – General requirements

### 4 Good working order

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

### 5 Mains switch

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.

### 6 Mode of use

The apparatus must, for medical radiation therapy producing X-rays or electron beams in the energy range 0.5 to 30 MeV or for radiation therapy apparatus in image guidance 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 the operator position, which mode is selected.

### 7 Persons other than patient not to remain in treatment room where apparatus operated or used for radiation therapy above certain voltages

A person other than a patient must not, where apparatus is operated or used for radiation therapy at voltages—

(a) above 50 kilovolts − remain in; or

(b) at or below 50 kilovolts—remain in an unshielded area of the treatment room during the treatment of the patient.

# Part 3 − Requirements for apparatus used for radiation therapy at accelerating voltages up to 0.5 MV

## 8 General requirements

If apparatus is used for treatment at accelerating voltages of up to and including 0.5 Mv, it must comply—

(a) with the provisions of Part 2; and

(b) the requirements of clauses 9 to 19; and

(c) with the provisions of Part 6.

## 9 Leakage from the X-ray tube housing

(1) The X-ray tube must be enclosed in such a housing that, at every specified rating of that tube in that housing, the air kerma rate from the leakage radiation—

(a) in the case of an X-ray tube which is operated at a peak potential of 500 kilovolts or less − at a distance of 1 metre from the focus − does not exceed 10 mGy per hour, nor 300 mGy per hour at any position accessible to the patient at a distance of 50 mm from the surface of that housing or its accessory equipment; and

(b) in the case of an X-ray tube which is operated at a peak potential of 150 kilovolts or less—does not exceed 1 mGy per hour at a distance of 1 metre from the focus.

(2) For the purpose of determining compliance with subclause (1), measurements must be made over an area not exceeding 10,000 $mm^2$ at a distance of 1 metre or 1,000 $mm^2$ at a distance of 50 mm, as the case requires, from the X-ray tube housing.

## 10 Control panel parameters

Control settings, meters or other means must be provided at the control panel of the apparatus to indicate X-ray tube potential and current when these can be varied and for indication of the filtration being used.

## 11 Leakage from permanent diaphragms or cones

Permanent diaphragms or cones fitted to the apparatus must be so constructed that, in combination with the X-ray tube housing, they comply with the requirements for leakage radiation set out in clause 9(1).

## 12 Radiation transmission of additional diaphragms or cones

Additional diaphragms or cones provided with the apparatus must not transmit more than 2% of the primary beam.

## 13 Focal spot

The apparatus must have a clear mark on the exterior of the X-ray tube housing to indicate the position of the focal spot.

## 14 Stationary tube housing

The X-ray tube housing must remain stationary during stationary portal treatment.

## 15 Exposure indicator

The apparatus must have a clearly visible indicator on the control panel that indicates when X-rays are being produced.

## 16 Shutter indicator

Apparatus in which the useful beam is controlled by a shutter must have clearly visible indicators on the control panel that indicate whether the shutter is open or closed.

## 17 Exposure timer

The apparatus must be provided with an automatic timer that terminates an exposure by de-energising the X-ray tube after the preset time has elapsed and that timer must preserve its accumulated response in the event of any failure or interruption in the operation of the apparatus during treatment.

### 18 Monitoring ionisation chamber

Apparatus that can operate at tube potentials exceeding 150 kV must be provided with a transmission monitoring ionisation chamber or equivalent device positioned in the useful beam to provide a continuous check on the constancy of the radiation output, and when that chamber is also employed as an integrating meter, the integrating meter must preserve its accumulated response in the event of any failure or interruption in the operation of the apparatus during treatment.

### 19 Filtration selection

Apparatus must be provided with a means of selecting the filtration to be used at the control panel so that it cannot be operated—

(a) without the filtration selected being placed in the primary beam; and

(b) at unintended combinations of kilovoltage and filtration.

## Part 4 − Requirements for apparatus producing X-rays or electron beams (energy range 0.5−30 MeV) used for radiation therapy

### 20 General requirements

Apparatus that produces either X-rays or an electron beam with energies above 0.5 MeV and less than 30 MeV and is operated or used for medical radiation therapy must comply—

(a) with the provisions of Part 2; and

(b) the requirements of clauses 21 and 22; and

(c) with the provisions of Part 6.

### 21 Leakage radiation

The apparatus must be shielded so that the air kerma rate due to leakage radiation (excluding neutrons)—

(a) at any point outside the maximum useful beam, but inside a plane circular area of radius 2 metres centred around, and perpendicular to, the central axis of the beam at 1 metre from the focal spot—must not exceed 0.2% of the air kerma dose rate on the axis at the same distance; and

(b) at 1 metre from the path of the electrons between their origin and the target or the electron window—must not exceed 0.5% of the air kerma dose rate on the central axis of the beam at 1 metre from the focal spot for areas not included in subclause (a).

### 22 Dose monitoring ionisation chambers

The apparatus must have two independent dose monitoring systems so that any failure or malfunction in one system does not influence the function of the other system and both systems must be capable of independently terminating the irradiation.

## Part 5 − Requirements for X-ray apparatus used for treatment image guidance up to 150 kV

### 23 General requirements

X-ray apparatus, integrated with radiation therapy unit, operating at accelerating voltages up to 150 kilovolts must comply—

(a) with the provisions of Part 2; and

(b) the requirements of clauses 24 to 28; and.

(c) with the provisions of Part 6.

## 24 Control panel parameters

The values of the selected X-ray 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.

## 25 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.

## 26 Exposure switch

The exposure switch fitted to the apparatus must—

(1) have a circuit closing contact requiring continuous pressure; or

(2) in the case of programmed imaging exposures—

(a) makes it possible to interrupt the exposure at any stage of the programme; and

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

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

## 27 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 exposure time; or

(c) programmed exposure.

## 28 Leakage from the tube housing

(1) The X-ray tube must be enclosed in a housing such that, at every specified rating of that tube in that housing, the air kerma rate from leakage radiation—

(a) in the case of an X-ray tube which is operated at a peak potential of 150 kilovolts or less − does not exceed 1 mGy per hour at a distance of 1 metre from the focus; and

(b) in the case of an X-ray tube which is operated at a peak potential of 50 kilovolts or less − does not exceed 1 mGy per hour at any position 50 mm from the surface of that housing or its accessory equipment.

(2) For the purpose of determining compliance with subclause (1), measurements must be made over an area not exceeding 10,000 $mm^2$ at a distance of 1 metre or 1,000 $mm^2$ at a distance of 50 mm, as the case requires, from the X-ray tube housing.

# Part 6 −Installation of radiation therapy apparatus operating above 50 kV

## 29 General requirements

Radiation therapy apparatus that can operate at voltages above 50 kilovolts must be installed so that they comply with the requirements of clauses 30 to 32.

## 30 Operator position

The control panel for the apparatus is located outside the treatment room and in a shielded position.

## 31 Safety interlocks

(1) Safety interlocks must be provided so that when any door to the treatment room is opened—

(a) the production of ionising radiation ceases; or

(b) the air kerma rate within the treatment room is reduced to a maximum of 100 µGy per hour at a distance of 1 metre in any direction from the source of radiation; and

(2) If an interlock, referred to in subclause (1), has caused the apparatus to cease producing useful ionising radiation – useful ionising radiation must not be produced when the door is closed until the apparatus is re-activated from the control panel.

## 32 Warning light

A clearly distinguishable warning light to indicate the production of ionising radiation must be fitted adjacent to any door to the treatment room which is not visible from the control panel.

## Appendix 1

The following guides, issued by radiation regulatory authorities in Australia and other recognised bodies, may assist licence holders to comply with this code.

(a) *Australian/New Zealand Standard 3200.2.8:1994: Medical electrical equipment − Part 2.8: Particular requirements for safety − Therapeutic X-ray generators*

(b) *IEC 60601-2-8 − Medical electrical equipment – Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV*

(c) *ARPANSA Safety Guide – Radiation protection in radiotherapy − Radiation Protection Series 14.3.*

# Document history

**Publications**

| Title | Release | Commencement |
|---|---|---|
| Code of Compliance for radiation therapy apparatus 2022 | Second release | 11 February 2023 |

**Amendments**

| Provision | How changed | Commencement |
|---|---|---|
| Introductory text | Include link to regulations and exclude particle accelerators from application of code | 11 February 2023 |
| 6 | Replace megaelectronvolts with MeV | 11 February 2023 |
| 8 | Replace megavolts with Mv | 11 February 2023 |
| 9 | Replace milligray with mGy | 11 February 2023 |
| 18 | Replace kilovolts with kV | 11 February 2023 |
| 20 | Replace megaelectronvolts with MeV | 11 February 2023 |
| 28 | Replace milligray with mGy | 11 February 2023 |
| 31 | Replace microgray with µGy | 11 February 2023 |
| General information | Update email address | 11 February 2023 |

# Further information

## Legislation

Online legislation is freely available.

## General information

Environment Protection Authority
GPO Box 2607
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Telephone: (08) 8204 2004
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