COC−3
Code of Compliance for medical, veterinary and chiropractic X-ray 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 radiation safety 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 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 medical, veterinary and chiropractic X-ray radiation 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:

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

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 Act

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 envelope in which electrons are accelerated for the purposes of the production of ionising radiation.

2 Application of code

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

(a) mammography or soft tissue radiography

(b) medical or veterinary computed tomography

(c) medical or veterinary fluoroscopy

(d) medical, veterinary or chiropractic plain radiography

(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 − Assessment of compliance with the mandatory provisions of this code

4 Special requirements

(1) All apparatus in Part 1 clause 2 require mandatory assessment and verification of compliance with the requirements of this code. These compliance assessments must be performed by:

(a) a person authorised under section 31 of the Act to assess compliance with relevant aspects; or

(b) a person approved for this purpose by the Department; and

(2) A report certifying compliance with the requirements should be made available to the owner, who must submit the test report and associated certificate of compliance to the department.

(3) When an assessed apparatus is found to be breaching a critical limit as set out in Schedules 3, 4, 5 and 6 the person referred to in subclause (1) above must ensure that the owner is made aware of the critical failure and their obligation to notify the EPA as soon as practicable.

5 Frequency of compliance test

Cyclic testing requires that the apparatus undergoes a complete compliance assessment at regular intervals to ensure the radiation safety and performance of the apparatus continues to comply over time. It applies only to apparatus-specific tests and does not include shielding verification. Cyclic testing must be conducted for all fixed, mobile and portable diagnostic X-ray apparatus when used on humans only. The cyclic compliance testing must be performed at the time of installation, at regular intervals thereafter (as listed in the table below) and after any major repairs that could affect radiation safety (eg tube change, detector change). The cyclic testing will be introduced in South Australia in a staged approach as listed in the following table. Until the commencement of cyclic testing, 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, relevant to its kind or class of apparatus as set out in this code.

Apparatus used or designed to be used for	Frequency of testing	Year of introduction
Medical Computed tomography	2 years	Feb 2024
Medical Fluoroscopy (including apparatus capable of both fluoroscopy and plain radiography)	2 years	Feb 2024
Mammography or soft tissue radiography	1 year	Feb 2025
Medical Plain radiography	2 years	Feb 2025
Medical X-ray absorptiometry	5 years	Feb 2026

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 test requirements of Schedule 2.

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 test requirements of Schedule 3.

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 the test requirements of Schedule 4.

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 the test requirements of Schedule 5.

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 the test requirements of Schedule 5.

11 General requirements for mobile and portable apparatus for veterinary plain radiography and portable apparatus for medical plain radiography

(1) In subclauses (3) to (18) ‘apparatus’ means mobile and portable apparatus used or designed to be used for veterinary plain radiography and portable apparatus used for medical 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 the table in clause (5) 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 program; 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 10,000 mm2 of which no principal linear dimension exceeds 200 mm, must not exceed 1 mGy 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%, 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% 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) The tube housing of the apparatus must be supported in such a way that it remains stationary when placed in position for radiography.

12 Special requirements for mobile apparatus for veterinary plain radiography

(1) 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.

(2) 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 mAs; and

(c) if an exposure has been terminated after the period referred to in subclause (b) above − 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 medical plain radiography

(1) In subclauses (2) to ((20) '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 (20) at a frequency not exceeding the time period shown in the table in clause (5) appropriate to the corresponding apparatus shown in column 1 of the table.

(3) 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.

(4) 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.

(5) 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 program; and

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

(6) 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.

(7) 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.

(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 control panel is energised and the mains switch is in the 'ON' position.

(10) 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 10,000 mm2 of which no principal linear dimension exceeds 200 mm, must not exceed 1 mGy 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.

(11) 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 (10).

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

(13) The delivered X-ray tube potential of the apparatus must be within ±5 kilovolts peak or ±5%, whichever is the greater, of the indicated value for all available set X-ray tube potentials.

(14) 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.

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

(16) 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% 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.

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

(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 mAs; and

(c) if an exposure has been terminated after the period referred to in subclause (b) above − 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.

14 Special requirements for portable apparatus for veterinary plain radiography

(1) In subclauses (2) to (17) ‘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 (2) to (17) at a frequency not exceeding the time period shown in the table in clause (5) appropriate to the corresponding apparatus shown in column 1 of the table.

(3) 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.

(4) 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.

(5) 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 program; and

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

(6) 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.

(7) 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.

(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 control panel is energised and the mains switch is in the ‘ON’ position.

(10) 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 10,000 mm2 of which no principal linear dimension exceeds 200 mm, must not exceed 1 mGy 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.

(11) 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 (10).

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

(13) The delivered X-ray tube potential of the apparatus must be within ±5 kilovolts peak or ±5%, whichever is the greater, of the indicated value for all available set X-ray tube potentials.

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

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

(16) 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 mm at a focal spot image receptor distance of 800 mm.

(17) 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

15 Special requirements for X-ray absorptiometry apparatus

(1) In subclauses (2) to (11) ‘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 (11) at a frequency not exceeding the time period shown in the table in clause (5) appropriate to the corresponding apparatus shown in column 1 of the table.

(3) 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.

(4) 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.

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

(6) 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.

(7) 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.

(8) 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.

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

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

(11) The focus of the X-ray tube of the apparatus must not be less than 200 mm 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 Required tests for computed tomography

This schedule lists the minimum radiation safety requirements for computed tomography (CT) scanners that are intended to be used on humans for:

- diagnostic imaging
- radiation therapy planning
- diagnostic nuclear medicine imaging
- research.

It specifically excludes the following equipment, which will be covered by alternative testing requirements:

- peripheral quantitative CT scanners
- equipment capable of tomosynthesis, eg breast tomosynthesis equipment
- on-board imaging systems of linear accelerators
- cone beam radiation apparatus, including: dental cone beam computed tomography (CBCT) equipment and O-arm fluoroscopy units.

Computed tomography scanners used clinically on humans must comply with all of the following tests.

Test	Requirement
1. Markings on X-ray generators and tube assemblies	1.1 X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available by means of labels on the apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. 1.2 X-ray generator markings must bear: • the name or trademark of the manufacturer; • model name or number; and

Test	Requirement
	• the serial number. 1.3 X-ray tube assemblies must bear: • the name or trademark of the manufacturer of the X-ray tube housing and insert; and • the type or model number and serial number of the X-ray tube housing and insert.
2. Baseline values	**2.1 Baseline values** For the purpose of tests specified in this standard which make reference to baseline values for noise, mean CT number, uniformity, reconstructed slice thickness, high contrast resolution and CT dose index the baseline values must: (a) be established in accordance with IEC 61223-3-5:2019 (or in accordance with IEC 61223-2-6:2006 for systems placed on the market prior to 2019) or be provided by the manufacturer; (b) be established at the first compliance test when equipment is first brought into use; (c) be within the manufacturer's acceptable range; and (d) not be re-established unless the responsible person has provided evidence of a risk assessment conducted by the responsible person in collaboration with, the manufacturer showing that the change in the baseline has been clinically justified. Note: 1. The approved tester must obtain the previously established baseline values, including test parameters, from the Responsible Person prior to the compliance test. 2. The requirements comparing measured values with baseline values do not apply for first compliance test when equipment is first brought into use or when baseline values are re-established. This must be noted in the assessment report. 3. It is not considered justified to change a baseline value if the cause of a deviation from the baseline value is found to be due to a technical fault. 4. Baseline values may be changed following major maintenance, upgrade or repair such as in the case of replacement of the X-ray tube. However, the requirements of Item 2.1 (d) must still be met in these cases. **2.2 Records associated with baseline values** The assessment report must include: (a) The baseline values that were used for the purposes of tests which make reference to baseline values, including all relevant information pertaining to the baseline values used such as the test parameters and equipment used in obtaining the baseline values; and (b) if baseline values have been re-established, the risk assessment as described in section 2.1(d) above.

Test	Requirement
3. Radiation warning signage	3.1 The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words 'caution' or 'warning' • words to the general form of 'X-rays produced when energised'. The symbol and lettering must be black on a yellow background. A radiation warning sign, displaying the words 'Caution X-rays in use – authorised entry only' (or equivalent) must be displayed at each entry point to the room. 3.2 An illuminated radiation warning sign, displaying the words 'Ionising radiation – do not enter' (or equivalent), must be positioned directly adjacent to any entry point of the room. This sign must illuminate immediately upon exposure and continue to illuminate during the exposure.
4. Termination of exposure	**4.1 Termination** Readily identifiable and accessible means must be provided to terminate the exposure at any time during a scan. **4.2 Pre-set time** A device must be incorporated in the X-ray equipment to terminate the exposure after the conclusion of the programmed exposure. For clarity, test 4.2 does not apply to CT fluoroscopy equipment.
5. Indicators of operation	**5.1 Mains indicator** A mains indicator must be clearly identified. 'ON' and 'OFF' positions must be marked with suitable symbols or adjacent indicator light or other unambiguous means. A visible signal must be displayed at the control panel and on the gantry to indicate when the X-ray tube is in preparation mode. **5.2 Beam 'on' status indicator** When and only when radiation is produced, visible and readily identifiable indication of the beam 'ON' status must be provided: (a) on the control panel; and (b) on or near the gantry.
6. Mechanical accuracy	**6.1 Light localisation** Scan plane lights (or laser) must be provided for marking the tomographic section (ie for axial positioning of the patient). The external scan plane lights, if external scan plane lights are available, must coincide with the internal scan plane lights and the scan plane to within: (a) ±2 mm for equipment used for diagnostic imaging, or

Test	Requirement
	(b) ±1 mm for equipment used for radiation therapy planning **Critical failure:** if the above requirements are not met for radiation therapy planning. Note: For clarity, internal scan plane lights are those that are used to identify the tomographic plane. External scan plane lights are those that are used to identify the transaxial plane set at a fixed distance from the tomographic plane. **6.2 Preview image localisation** A preview image must be provided on which the operator may set up the tomographic sections to be taken and the reference lines indicating the start and finish of the preview image must not differ from the true positions by more than 2 mm. **Critical failure:** if the above requirements are not met. **6.3 Coronal and sagittal plane lights** The coronal and sagittal plane lights must intercept at the x = 0, y = 0 on the corresponding axial image and any difference must not exceed: (a) ±2 mm for equipment used for diagnostic imaging, or (b) ±1 mm for equipment used for radiation therapy planning **Critical failure:** if the above requirements are not met.
7. Image quality	**7.1 Noise** The measured value of noise must: (a) be within manufacturer-specified tolerances, where provided, and (b) the measured value of noise must not be more than 10% above the baseline value. **Critical failure:** Measured value of noise is >15% above baseline values **Test parameters** Unless otherwise specified by the manufacturer, measurements of noise must be performed by determining the standard deviation of the CT number for a region of interest placed in the centre of the displayed image of a uniform test device. For the purpose of this test, 'region of interest' means a circular region of interest of approximately 40% of the diameter of the uniform test device. Two CT conditions of operation must be tested, one representing a typical axial head scan and one representing a typical axial body scan. **7.2 Mean CT number** The mean CT number must: (a) be within manufacturer-specified tolerances, where provided, and (b) the mean CT number of the central region of interest must not deviate by more than ±4 Hounsfield units (HU) from the baseline value.

Test	Requirement
	Critical failure: if mean CT number deviates by > ±10 HU from the baseline value for water up to 30-cm diameter **Test parameters** Unless otherwise specified by the manufacturer, mean CT numbers are determined from a region of interest placed in the centre of the displayed image of a uniform test device. For the purpose of this test, 'region of interest' means the circular region of interest of approximately 10% of the diameter of the uniform test device. Two CT conditions of operation must be tested, one representing a typical axial head scan and one representing a typical axial body scan. **7.3 Uniformity** Uniformity must: (a) be within manufacturer-specified tolerances or, (b) if manufacturer-specified tolerances are not provided, the uniformity must not vary by more than ±2 Hounsfield units (HU) from the baseline value. **Critical failure:** deviation of mean CT number from specified value >10 HU for water phantom up to 20 cm diameter, or >20 HU for water phantom above 20-cm diameter. **Test parameters** Unless otherwise specified by the manufacturer, uniformity must be evaluated by calculating the absolute values of the difference between the mean CT number of the region of interest in the central position and those in each of the 3, 6, 9, and 12 o'clock positions in the image of a uniform test device. For the purpose of this test, 'region of interest' means a circular region of interest of approximately 10% of the diameter of the uniform test device. Two CT conditions of operation must be tested with appropriately sized phantoms, one representing a typical axial head scan and one representing a typical axial body scan. **7.4 Reconstructed slice thickness** The reconstructed image slice thickness must: (a) be within manufacturer-specified tolerances, where provided, and (b) must not deviate from the specified nominal values by more than: (i) 1 mm for slice thicknesses >2 mm; (ii) 50% for slice thicknesses 1 mm to 2 mm; (iii) 0.5 mm for slice thicknesses <1 mm. **Critical failure:** The reconstructed image slice thickness does not comply with above requirements. **Test parameters**

Test	Requirement
	The measurements must be performed for all reconstructed slice thicknesses used clinically that are accessible in axial mode. A representative number of tomographic sections must be acquired for each reconstructed slice thickness. The evaluation must be performed for at least both outer tomographic sections and one representative inner tomographic section (in the axial plane). **7.5 Spatial resolution** The spatial resolution must be: (a) within manufacturer-specified tolerances, or (b) if manufacturer specified tolerances are not provided, the measurement of the 50% point and the 10% point of the modulation transfer function curve must be not more than 0.5 line pairs per centimetre or 10% below the baseline value, whichever is the greater. Unless otherwise specified by the manufacturer, spatial resolution is best described by the modulation transfer function curve obtained from the Fourier transform of the point-spread function. Alternative (validated) methods may be used. CT conditions of operation including a typical head and body scan, and a scan having maximum spatial resolution must be tested. **7.6 Low contrast resolution** The low contrast resolution must be within manufacturer-specified tolerances. Note: This test is only required for equipment used for radiation therapy planning
8. Radiation dosimetry	**8.1 CT dose index (CTDI) in air** The dose value must: (a) be within manufacturer-specified tolerances or, (b) if manufacturer-specified tolerances are not provided, all dose values must be within ±10% of the baseline value. **Critical failure:** deviation of CTDI free-in-air from manufacturer's specifications or baseline values >20% **Test parameters** The following dose measurements must be performed for a range of clinical protocols, including: • $CTDI_{free\ air}$ at the typical head and body condition of operation • $CTDI_{free\ air}$ at no less than 5 nominal beam collimations (all other independent conditions of operation must be maintained at the typical body conditions of operation) • $CTDI_{free\ air}$ at all kVp settings clinically used (all other independent conditions of operation must be maintained at the typical body conditions of operation)

Test	Requirement
	8.2 Volume CT dose index and dose length product (a) The volume CT dose index ($CTDI_{vol}$) and the dose length product (DLP) must be available to the operator and recorded with CT images. (b) The displayed value of $CTDI_{vol}$ must be within ±20% of the measured value. **Test parameters** The following dose measurements must be performed for a range of clinical protocols, including: • $CTDI_{vol}$ at the typical head and body condition of operation • $CTDI_{vol}$ at all kVp settings clinically used (all other independent conditions of operation must be maintained at the typical body conditions of operation)

Schedule 3 Required tests for fluoroscopy apparatus

This schedule lists the radiation safety standard for fluoroscopic X-ray equipment that is intended to be used on humans for:

- diagnostic imaging
- interventional, cardiology and orthopaedic procedures
- research.

The standard covers the following types of fluoroscopy apparatus:

- fixed and mobile fluoroscopy units
- mini C-arm
- fluoroscopy units with multiple X-ray tubes
- O-arm fluoroscopy systems used for 2D fluoroscopy and 3D imaging.

Test	Requirement
1. Markings on X-ray generators and tube assemblies	1.1 X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available by means of labels on the apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. 1.2 X-ray generator markings must bear: • the name or trademark of the manufacturer; • model name or number; and • the serial number. 1.3 X-ray tube assemblies must bear: • the name or trademark of the manufacturer of the X-ray tube housing and insert; • the type or model number and serial number of the X-ray tube housing and insert; and

Test	Requirement
	• the position of the focal spot(s). For dual focus X-ray tubes, a single indication of mean focal spot position is permissible.
2. Radiation warning signage	2.1 The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words 'caution' or 'warning' • words to the general form of 'X-rays produced when energised'. The symbol and lettering must be black on a yellow background. A radiation warning sign, displaying the words 'Caution X-rays in use – authorised entry only' (or equivalent) must be displayed at each entry point to the room. For fixed apparatus, an illuminated radiation warning sign, displaying the words 'Ionising radiation – do not enter' (or equivalent), must be positioned directly adjacent to any entry point of the room. This sign must illuminate immediately upon exposure and continue to illuminate during the exposure.
3. Mains indicator	3.1 A mains indicator must be clearly identified. 'ON' and 'OFF' positions must be indicated by a suitable indicator light or other unambiguous means.
4. Energised X-ray tube	4.1 A visible signal must be displayed at the control panel to indicate to the operator when the X-ray tube is energised (in preparation mode). 4.2 There must be an obvious visual and/or audible indicator when radiation is being emitted.
5. Automatic mode (AEC)	5.1 For X-ray apparatus operating with automatic control systems, the preselected mode of operation must be indicated on the control panel.
6. Indicators of operation	6.1 The tube voltage, exposure time, tube current and, where appropriate, current-time product, frame rate and magnification setting must be displayed by a suitable indicator, even if these factors are under automatic control. For permanently fixed exposure factors, the value must be indicated on the control panel.
7. Audible signal − radiographic mode only	7.1 A signalling device audible at the location from which the equipment is operated must indicate the duration or termination of the exposure.
8. Control of multiple X-ray tubes	8.1 Except for apparatus specifically designed for two-tube techniques (eg bi-plane angiography rooms), means must be taken to ensure that it is not possible to energise more than one X-ray tube at any one time. Safety measures must be provided to ensure against accidental activation of the wrong X-ray tube. In the case of two-tube techniques, there must be a clear indication on the control panel that two tubes are energised. 8.2 Where more than one X-ray tube can be operated from a control panel, there must be a clear indication on the control panel to signify which tube is energised. In the case of an under-table tube and associated over-table tubes

Test	Requirement
	used in fluoroscopic apparatus, there should be a visual indicator at or near the fluoroscopy controls to signify which tube is selected.
9. Exposure switch	9.1 The exposure switch must have a circuit closing contact such that continuous pressure must be applied to maintain the exposure and that it must be possible to interrupt the exposure at any time. 9.2 The exposure switch must be designed so that it cannot be accidentally operated. In the case of a foot exposure switch, this may be achieved by shrouding the foot switch or by the provision of an isolation switch at the operator's console. 9.3 It must not be possible to initiate another exposure without first releasing the switch. 9.4 For mobile apparatus, control of the X-ray unit must be possible from a distance of not less than 2 metres from the focal spot or X-ray beam.
10. Protection of the operator at the table side	10.1 For fluoroscopic apparatus with a fixed under-table X-ray tube and adjacent operator controls, an adjustable drape must be provided, and must meet the requirements below: (a) have a lead equivalent of not less than 0.5 mm at 150 kVp (b) have a minimum width of 450 mm (c) be designed to attach to the lower edge of the image receptor carriage (d) consist of overlapping sheets, or equivalent (e) attach to the image receptor carriage in such a way that there is no gap between the drape and the image receptor carriage (f) reach the table-top when the image receptor carriage is in its maximum vertical position (g) be adjustable to protect the operator when the table is in the tilted position. Note: Apparatus used in a sterile environment may not necessarily comply with above requirements. In such instances, alternative means of operator protection, such as a ceiling-suspended shield (at least 0.5 mm lead equivalence) must be provided. 10.2 For a fluoroscopic table also designed for radiography, a shielded bucky slot cover must be provided. Bucky slot should provide the equivalent protection of at least 0.5 mm of lead at 100kVp.
11. Fluoroscopy units with an over-table X-ray tube	11.1 In the case of fluoroscopic apparatus with a fixed over-table X-ray tube: (a) the collimator must contain a light beam device. (b) for equipment where the direct radiography mode is not disabled, the alignment of the area illuminated by the light beam collimator and the X-ray field must be coincident to within ±1% of the distance from the focus to the image receptor. (c) an exposure switch for radiographic exposures must be located at the control panel. (d) additional radiographic exposure switches must not be provided at the table unless shielding is provided for use by the operator.

Test	Requirement
12. Stability of X-ray tube assembly	12.1 The X-ray tube assembly must remain stationary when placed in position and during exposure.
13. Stability of mobile apparatus	13.1 Means must be provided on mobile apparatus to prevent movement once positioned for exposure. 13.2 Mobile fluoroscopic apparatus must be effectively balanced or positively locked to remain stable when the C-arm is in any position.
14. kVp accuracy	14.1 If tube voltage (kVp) is manually selectable, the accuracy of the selected kVp must be within ± 5% or 5kV (whichever is greater) of the indicated (selected) value. For equipment with multiple X-ray tubes, the kVp accuracy must comply for all X-ray tubes across the range of available kVp settings. **Critical failure:** ≥ ±10% or ≥ ±10 kV whichever is the greater.
15. Radiographic timer accuracy	15.1 The exposure timer accuracy for timer settings across a clinical range must be within: • ±10% of the indicated value for exposure times greater than or equal to 100 ms • ±20% ± 1 pulse of the indicated value for exposure times less 100 ms. **Critical failure**: ≥20 % (for times ≥100 ms) or ≥30 % (for times <100 ms).
16. Radiographic radiation output reproducibility	16.1 The coefficient of variation of the X-ray output of a series of 5 consecutive exposures taken within a time period of approximately 10 minutes should not be greater than 0.05 for any combination of exposure factors across the clinical range. **Critical failure:** coefficient of variation ≥0.1
17. Fluoroscopy radiation output reproducibility	17.1 The air kerma from 5 consecutive measurement at 80 kVp must be within ±10% of the mean. **Critical failure:** ≥ ±20%
18. Accuracy of output air kerma product	18.1 Displayed air kerma area product (KAP) must be within ±20% of the measured value. **Critical failure:** ≥ ±35% Note: • Measurement must be taken at a minimum of 5 clinically relevant exposure settings using a patient equivalent phantom or PMMA blocks of suitable size placed on the patient table or couch. At least 5 sets of measurement should be taken. • Automatic exposure control (AEC) may also be used in conjunction with lead or another suitable attenuator covering the image receptor to drive up the kV and mA.

<table>
<tr><th>Test</th><th>Requirement</th></tr>
<tr><td></td><td>

- Direct reading dose area product meter or suitable dosimeter (such as ionisation chamber) may be used to carry out measurement. Field size and backscattering factor must be taken into account where appropriate.

</td></tr>
<tr><td>19. Fluoroscopic timing device</td><td>19.1 A cumulative timing device must be activated by the fluoroscopic control circuit when it is energised and must give an indication of the total screening time.

19.2 After the integrated time has reached pre-set time not exceeding 5 minutes, and at least 30 seconds before automatic termination, a continuous audible signal must be given to enable resetting of the integrating device.</td></tr>
<tr><td>20. Radiation beam quality</td><td>20.1 The permanent filtration must be such that the measured half value layers are greater than or equal to the values specified in the table below.

<table>
<tr><th>X-ray Tube Voltage (kVp)</th><th>Minimum HVL (mm Al) for equipment manufactured prior to 2015</th><th>Minimum HVL (mm Al) for equipment manufactured 2015 onwards</th></tr>
<tr><td>50</td><td>1.5</td><td>1.8</td></tr>
<tr><td>60</td><td>1.8</td><td>2.2</td></tr>
<tr><td>70</td><td>2.1</td><td>2.5</td></tr>
<tr><td>80</td><td>2.3</td><td>2.9</td></tr>
<tr><td>90</td><td>2.5</td><td>3.2</td></tr>
<tr><td>100</td><td>2.7</td><td>3.6</td></tr>
<tr><td>110</td><td>3.0</td><td>3.9</td></tr>
<tr><td>120</td><td>3.2</td><td>4.3</td></tr>
<tr><td>130</td><td>3.5</td><td>4.7</td></tr>
<tr><td>140</td><td>3.8</td><td>5.0</td></tr>
<tr><td>150</td><td>4.1</td><td>5.4</td></tr>
</table>

Critical failure: if the measured HVL does not meet the above requirements.</td></tr>
<tr><td>21. Last-image-hold</td><td>21.1 Apparatus must be capable of retaining the last image on the viewing monitor (‘last-image-hold’).</td></tr>
<tr><td>22. Focus-to-skin distance (FSD)</td><td>22.1 Fluoroscopic apparatus must be designed and constructed such that:

- Fixed apparatus— (i) if the apparatus has a patient support permanently between the X-ray tube and the patient, FSD is not less than 400 mm; and in the case of any other fixed apparatus FSD is not less than 300 mm;
- Mobile apparatus – FSD is not less than 200 mm.

Note: Above requirement is not applicable for mini C-arm apparatus that has a maximum X-ray tube current not exceeding 200 microamperes.</td></tr>
<tr><td>23. Beam alignment and collimation</td><td>23.1 It must not be possible to operate the X-ray tube without the image receptor being properly aligned relative to the primary beam.

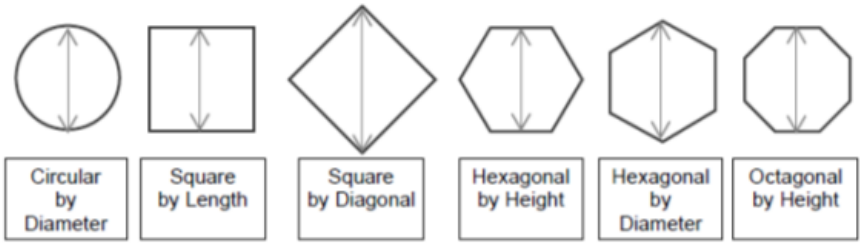
23.2 The primary beam must be centred to the input surface of the image receptor and must appear as the centre of the image on the monitor.

23.3 The primary beam must not fall outside the image receptor (including its associated housing) under any circumstances.</td></tr>
</table>

Test	Requirement
	23.4 It must not be possible to manually override the beam-limiting operation to give a larger field. 23.5 The beam limiting device must limit the area of the primary beam so that the maximum ratio of the radiation field area to the imaged field area is less than or equal to 1.15. 23.6 Beam-limiting devices must allow the collimation of the primary beam to the clinical area of interest. 23.7 The selected nominal field size must not differ from the imaged field size by more than ± 10%. Note that for some flat-panel image receptors, the selected field size refers to the diagonal measurement. **Critical failure:** Radiation area >1.25 × image area **Test method** Exposure factors: • Automatic exposure rate control (AERC) or set low kVp. Method: Note: this example uses a CR cassette. Other means to measure the radiation field area may be substituted. • Set maximum SID. • Ensure collimators are fully open. • Place CR cassette as close as possible to image receptor surface. • Expose cassette under AERC for 1–2 seconds. • Record the radiation field shape and measure the dimensions (see below). Note: A magnification correction is required for the distance between the image receptor and the CR cassette. • Calculate the radiation field area (see below). • Remove the CR cassette and place a test object of known physical dimensions (ideally with markings at known spacings) as close as possible to the image receptor surface. • Expose under AERC for 1–2 seconds. • Record the shape of the imaged field. • Record the dimensions of both the image and the test object on TV monitor. Use the ratio of the nominal test object length and measured test object length from the display image and calculate the imaged field dimensions. Note: A magnification correction is required for the distance between the image receptor and the test object. • Calculate the imaged field area (see below). • Repeat measurements for a selection of nominal field sizes, including the maximum and minimum. • Repeat all the above at minimum SID.

<table>
<tr><th>Test</th><th>Requirement</th></tr>
<tr><td></td><td>

Compare the radiation field area to the imaged field area for all selected field sizes.
Compare the imaged field dimensions to the nominal field dimensions.
Confirm that the radiation field lies within the image receptor (including its associated housing).

Calculating area
The dimension of the radiation field and imaged field should be measured as per the diagrams below:


The radiation and imaged field areas should be calculated for the specific field shape using the formula below:
dimension^2 x shape-specific constant (see table below)
<table>
<tr><th>Field shape</th><th>Constant</th></tr>
<tr><td>Circular (by diameter):</td><td>0.785</td></tr>
<tr><td>Square (by length):</td><td>1.000</td></tr>
<tr><td>Square (by diagonal):</td><td>0.500</td></tr>
<tr><td>Hexagonal (by height):</td><td>0.866</td></tr>
<tr><td>Hexagonal (by diameter):</td><td>0.650</td></tr>
<tr><td>Octagonal (by height):</td><td>0.828</td></tr>
</table>
</td></tr>
<tr><td>24. Exposure limit during fluoroscopy</td><td>
24.1 The incident air kerma rate during fluoroscopy must not exceed the values listed below:
<table>
<tr><th>Mode</th><th>Maximum permissible incident air kerma rate during fluoroscopy (mGy/min)</th><th>Critical failure: maximum air kerma rate during fluoroscopy (mGy/min)</th></tr>
<tr><td>Manual</td><td>50</td><td>≥100</td></tr>
<tr><td>Normal</td><td>100</td><td>≥150</td></tr>
<tr><td>High level (boost)</td><td>150</td><td>≥225</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><th>Test</th><th>Requirement</th></tr>
<tr><td></td><td>Measurements must be made for a combination of X-ray tube potential and current settings which achieves the maximum air kerma rate, and in scatter-free conditions using the detector position as mentioned in the table below:
<table>
<tr><th>Measurement condition</th><th>Detector position</th></tr>
<tr><td>Under table X-ray tube
X-ray tube permanently under the table</td><td>On the table</td></tr>
<tr><td>Over-table X-ray tube Image receptor permanently under the table</td><td>300 mm above the table</td></tr>
<tr><td>C- or U-arm systems
X-ray tube and image receptor mechanically linked, with or without permanent patient support</td><td>300 mm from image receptor plane but not less than 400 mm from the focal spot</td></tr>
<tr><td>C-arm systems specifically for extremity use (FSD ≤ 450 mm)
X-ray tube and image receptor mechanically linked</td><td>At the minimum focus-to-skin distance</td></tr>
<tr><td>Other fluoroscopic systems
No permanent patient support</td><td>400 mm from focal spot</td></tr>
</table></td></tr>
<tr><td>25. Exposure limit during image acquisition</td><td>25.1 The air kerma rate at 300 mm from image receptor plane must not exceed the values specified in the table below during image acquisition.
<table>
<tr><th>Mode</th><th>Maximum air kerma rate</th><th>Critical failure if maximum air kerma rate</th></tr>
<tr><td>DSA</td><td>2.0 mGy/frame</td><td>>2.0 mGy/frame</td></tr>
<tr><td>Cardiac</td><td>0.2 mGy/frame</td><td>>0.2 mGy/frame</td></tr>
</table></td></tr>
<tr><td>26. High level boost during fluoroscopy (excludes DSA)</td><td>Any mode in which the maximum incident air kerma rate can exceed the values applicable to normal mode, is classified as high level (boost) mode.
26.1 Where a high level (boost) mode is activated, the control must:
(a) require continuous activation by the operator for its operation;
(b) maintain a continuous audible signal that is readily distinguishable from that used for normal fluoroscopy, to indicate that the high level control is in use;
(c) be restricted to a maximum of 20 seconds, after which the system returns to normal fluoroscopic mode; and
(d) only be accessed through the automatic mode of operation.
26.2 Where a high level (boost) mode is selected it must automatically return to the lower dose rate setting if not used within 5 minutes or if power to the apparatus is disconnected.</td></tr>
</table>

<table>
<tr><th>Test</th><th>Requirement</th></tr>
<tr><td>27. Entrance air kerma rate at surface of image receptor during fluoroscopy</td><td>27.1 The entrance air kerma rate in air at the input surface of the image receptor (other than high level or boost mode) must not exceed the values indicated in the table below:
<table>
<tr><th>Field size (cm)</th><th>Entrance air kerma rate (µGy/min) AERC</th><th>Critical failure if entrance air kerma (µGy/min) under AERC</th></tr>
<tr><td>11–14</td><td>≤120</td><td>>120</td></tr>
<tr><td>>1 –23</td><td>≤80</td><td>>80</td></tr>
<tr><td>>23</td><td>≤60</td><td>>60</td></tr>
</table>
Measurement conditions:

The measurement conditions should be such that sufficient copper filtration is added to the X-ray beam to obtain, on automatic brightness/dose rate systems, an X-ray tube voltage between 70kVp and 80kVp.
For manual systems, the radiation levels should not be exceeded for the normal clinical settings when used with average patients.
The measurements should be obtained without the grid or alternatively, by applying a traceable grid correction factor for the energy of the radiation beam being used.
</td></tr>
<tr><td>28. Air kerma rate at surface of image receptor during DSA</td><td>28.1 The air kerma rate at the input surface of the image receptor must not exceed the values specified in the table below during DSA.
<table>
<tr><th>Frame rate</th><th>Maximum air kerma rate during DSA</th><th>Critical failure if maximum air kerma rate during DSA</th></tr>
<tr><td>≤10 frames/s</td><td>10 µGy/frame</td><td>>10 µGy/frame</td></tr>
<tr><td>>10 frames/s</td><td>1 µGy/frame</td><td>>1 µGy/frame</td></tr>
</table></td></tr>
<tr><td>29. Air kerma rate at surface of image receptor during cinefluorography</td><td>29.1 The air kerma rate at the input surface of the image receptor must not exceed the values specified in the table below during cinefluorography.
<table>
<tr><td>Frame rate</td><td>Maximum air kerma rate during cinefluorography</td><td>Critical failure if maximum air kerma rate during cinefluorography</td></tr>
<tr><td><17 cm</td><td>0.2 µGy/frame</td><td>>0.2 µGy/frame</td></tr>
<tr><td>≥17 cm</td><td>0.1 µGy/frame</td><td>>0.1 µGy/frame</td></tr>
</table></td></tr>
</table>

<table>
<tr><th>Test</th><th>Requirement</th></tr>
<tr><td>30. High-contrast resolution of the live image</td><td>30.1 The high-contrast resolution of the live image must not be less than the values specified in the table below.
<table>
<tr><th>Apparatus</th><th>Field size(cm)</th><th>Resolution (lp/mm)</th></tr>
<tr><td rowspan="5">Equipment manufactured from 2015 onwards</td><td>8</td><td>1.8</td></tr>
<tr><td>18 to <26</td><td>1.6</td></tr>
<tr><td>26 to <30</td><td>1.4</td></tr>
<tr><td>30 to 36</td><td>1.2</td></tr>
<tr><td>>36</td><td>1.0</td></tr>
<tr><td rowspan="2">Equipment manufactured before 2015</td><td>≤25</td><td>1.2</td></tr>
<tr><td>>25</td><td>1.0</td></tr>
</table>
Critical failure:
<0.8 lp/mm for field sizes > 25 cm
<1.0 lp/mm for field sizes ≤ 25 cm
Note:
• Measurements should be made with clinically relevant AEC exposure settings.
• Source to Image receptor distance (SID) should be minimum.
• High contrast resolution test object (eg line pair phantom) must be placed in the centre of the image receptor.
• The manufacturer’s instructions should be followed while using the test object.
• Exposure should be made at clinically relevant AEC exposure settings
• The number of line pairs visible on the live image on the clinical reference monitor should be evaluated.</td></tr>
<tr><td>31. Low-contrast resolution and low-contrast threshold of the live image</td><td>31.1 Low-contrast resolution of the live image, as displayed on a clinical reference monitor, must not be less than the values indicated in table below.
Low-contrast resolution
<table>
<tr><th>Apparatus type</th><th>Minimum resolution</th></tr>
<tr><td>General</td><td>1.5 mm (6 circles on Westmead phantom)</td></tr>
<tr><td>High dose rate</td><td>1.0 mm (7 circles on Westmead phantom)</td></tr>
</table>
31.2 The low contrast threshold of the live image must not exceed 4% (minimum 10 large circles on Westmead Phantom).
Critical failure: Low contrast threshold >4%
31.3 Any significant distortion must be noted on the compliance inspection report.
Note:</td></tr>
</table>

Test	Requirement
	• Measurements should be made using an appropriate image quality test object (eg Westmead Test Object or equivalent) and following the test object manufacturer's instructions. • The source to image receptor distance (SID) should be set at normal operating distance or at 100 cm. • The test object must be placed directly onto centre of image receptor. • The exposure should be made at clinically relevant AEC exposure settings, and the live image on the clinical reference monitor should be evaluated.
32. Radiation leakage	32.1 The X-ray tube must be enclosed in a housing in such a manner that the air kerma from leakage radiation must not exceed 1.0 mGy in any 1-hour period at a distance of 1 m from the focal spot. **Critical failure:** failure to meet the above requirements. Note: • Collimator must be completely covered with lead of sufficient thickness to ensure that the primary beam contribution to the measurements is negligible. • Automatic Exposure Control (AEC) or set maximum kVp and maximum mA, ensuring that tube rating is not exceeded. • Position the detector at an appropriate distance from focal spot (eg 10–30 cm). Make a series of exposures at positions including cathode, anode and front of tube assembly. • Use inverse square law correction to calculate exposure rates at 1 m from focal spot. • Calculate time averaged leakage using manufacturer recommended continuous mA rating at the kVp used for the measurement or using tube cooling curve data.

Schedule 4 Required tests for mammography apparatus

This Schedule lists the radiation safety standard for mammographic X-ray equipment that is intended to be used on humans for:

- diagnostic imaging
- screening
- research.

It specifically includes the following mammographic X-ray equipment:

- mammography units using digital radiography technology (DR mammography units)
- mammography units using computed radiography technology (CR mammography units)
- tomosynthesis mammography units
- breast biopsy mammography units (includes 'integrated' units where the same detector is used for mammography and biopsy, 'separate image receptor' where a different image receptor is used, and 'stand-alone' biopsy units).

Mammographic X-ray equipment used clinically on humans must satisfy one of the following options:

OPTION 1

Evidence has been provided that the mammographic X-ray equipment meets the following requirement:

Within the last 12 months, there is evidence demonstrating that the radiation apparatus has been assessed by an ACPSEM certified mammography equipment assessor as complying with:

(a) the systems tests, as outlined in the BreastScreen Australia National Accreditation Standards (NAS) accreditation program; or

(b) the system tests, as outlined in the current 'RANZCR *Guidelines for Quality Control Testing for Digital (CR and DR) Mammography'*.

or

OPTION 2

The mammographic X-ray equipment complies with all of the requirements in the table below. The test protocols and methodology as described in the current ACPSEM Radiology Position Paper- "*Recommendations for a Digital Mammography Quality Assurance Program"*- should be used, unless otherwise specified in this document.

Notes: The tests apply to all mammography units, unless otherwise specified.

For the purposes of this option, assume that film-based and computed radiography (CR) technology are not used for biopsy procedures.

Test	Requirement
1. Markings on X-ray generators and tube assemblies	1.1 X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available on labels on the apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. 1.2 X-ray generator markings must bear: • the name or trademark of the manufacturer; and • the model name or number; and • the serial number. 1.3 X-ray tube assemblies must bear: • the name or trademark of the manufacturer of the X-ray tube housing and insert; • the type or model number and serial number of the X-ray tube housing and insert; and • the position of the focal spot.
2. Radiation warning signage	**2.1 Radiation warning signage** The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words 'Caution' or 'Warning' • words to the general form of 'X-rays produced when energised'.

Test	Requirement
	The symbol and lettering must be black on a yellow background. A radiation warning sign, displaying the words 'Caution X-rays in use – authorised entry only' (or equivalent) must be displayed at each entry point to the room.
3. Indicators	**3.1 Mains power indicator** A mains indicator must be clearly identified. 'ON' and 'OFF' positions must be indicated by a suitable indicator light or other unambiguous means. **3.2 Visual indicator** A visible signal must indicate when the X-ray tube is energised. The signal must be displayed at the control panel or, for remotely controlled apparatus, at the operator's position. **3.3 Audible signal** A signalling device audible at the location from which the apparatus is operated must indicate the duration or termination of the exposure. **3.4 Automatic mode** For radiation apparatus operating with automatic exposure control, the preselected mode of operation must be indicated on the control panel. **3.5 Exposure factors** When X-ray tube potential, current and mAs are capable of being independently varied, the values must be indicated on the control panel. If any are not capable of being independently varied, the fixed values must be indicated at the control panel.
4. Exposure switch	**4.1 Position of exposure switch** Control of the X-ray unit must be from behind a protective screen or from a distance of not less than 2 metres from the focal spot. Note: This test does not apply to breast biopsy mammography units. **4.2 Dead man type switch** Each exposure must be initiated and maintained by means of a control requiring continuous activation by the operator and the exposure must be able to be interrupted at any time. **4.3 Security of exposure switch** The exposure switch must: (a) be such that it is not possible to initiate another exposure without releasing the switch; and (b) be designed so that it is protected against accidental operation.
5. X-ray beam collimation and alignment	**5.1 X-ray field/image receptor alignment** The X-ray field must:

Test	Requirement
	(a) fully irradiate the image receptor; and (b) not extend beyond the breast support on the chest wall edge of the image receptor by more than 2 mm. **Critical failure:** if the above requirements are not met **Test parameters** This test must be performed for clinically relevant X-ray tube targets and geometry combinations. Note: This test does not apply to image receptors which are only for biopsy use. **5.2 Compression paddle/image receptor alignment** The chest wall edge of the compression paddle must: (a) be aligned just beyond the chest wall edge of the image receptor such that the chest wall compression paddle does not appear in the image; and (b) not extend beyond the chest wall edge of the image receptor by more than 1% of the source-to-image receptor distance (SID). **Test parameters** This test must be performed for clinically relevant X-ray tube targets, bucky, field sizes and paddle geometry combinations. Note: This test does not apply to image receptors which are only for biopsy use. **5.3 Missing tissue at chest wall** The amount of tissue not imaged between the edge of the breast support and the imaged area must be ≤5 mm in contact mode and ≤ 7mm in Mag mode. **Critical failure:** if the above requirements are not met Note: This test does not apply to image receptors which are only for biopsy use.
6. Generator performance	**6.1 kVp Accuracy** The measured kVp must be within ±5% of the indicated kVp setting over the clinically relevant range in, at most, 2kVp increments. **Critical failure:** if the above requirements are not met **Test parameters** The kVp need only be verified for one target/filter combination. However, the kVp meter must be calibrated for that particular target/filter combination. **6.2 kVp reproducibility** The coefficient of variation for a minimum of 5kVp values at a typical clinical kVp value must not be greater than 0.02. Where: ‘coefficient of variation’ means the standard deviation divided by the mean of a set of numbers. **Critical failure:** if the above requirements are not met.

Test	Requirement
7. Exposure time	**7.1 Exposure time** For all clinically relevant source-image-distance settings, the maximum exposure time when irradiating a 6-cm PMMA phantom must be: (a) less than 3.5 seconds for fine focus; and (b) less than 2 seconds for broad focus. **Test parameters** 1. This test must: • assess both contact and magnification modes; and • use clinically relevant technique factors for the PMMA thickness consistent with SDNR and MGD measurements. 2. Record the mAs and infer the exposure time from tube rating, or measure directly using a manual exposure matched to mAs needed for AEC initiated exposure.
8. Beam quality	**8.1 Half value layer (HVL)** With the compression device in place, the HVL for all X-ray tube target and filter combinations must be such that: [(kVp/100) + 0.03] mm Al ≤ HVL < [(kVp/100 + C)] mm Al where C = 0.12 for Mo/Mo = 0.19 for Mo/Rh = 0.22 for Rh/Rh = 0.23 for Rh/Ag = 0.30 for W/Rh = 0.32 for W/Ag = 0.31 for W/Al (for tomosynthesis mode) = 0.25 for W/Al (for all other modes) **Critical failure:** if the above requirements are not met. Note: This test should include a measure of the HVL required for mean glandular dose calculations.
9. Automatic exposure control (AEC) performance	**9.1 Reproducibility** The coefficient of variation for both absorbed dose and mAs for at least five AEC controlled exposures of a test object must be less than or equal to 0.05 at clinically relevant kVp and target/filter selections. **Test parameters** A 4-cm PMMA phantom, or equivalent must be used for this test. **9.2 Back-up timer and security cut-out** **DR and tomosynthesis mammography units**

Test	Requirement
	A cut-off mechanism must be present and terminate the exposure within 50 ms or within 5 mAs of the exposure being initiated when the current time product (mAs) required to sufficiently expose the detector to form an acceptable image would be greater than 500 mAs. **CR mammography units** The current time product (mAs) must be limited to no more than 500 mAs. **Critical failure:** if the cut-off mechanism does not terminate the exposure < 800mAs. **9.3 Backup timer/security cut-out indication** A visible indication at the control panel must be provided whenever an exposure has been terminated by the backup timer or security cut-out mechanisms. **9.4 Backup timer/security cut-out manual reset** When the exposure has been stopped by the backup timer/security cut-out mechanism it must not be possible to initiate another exposure without first operating a manual reset. **9.5 Density control (DR and CR only)** If density control is available, it must be capable of changing the mAs from the value used normally by −25% to +50%. **9.6 Thickness compensation and SDNR system performance (DR and CR only)** The Signal Difference to Noise Ratio (SDNR) when measured in contact mode and in MAG mode under the conditions specified below for 2, 4 and 6 cm PMMA thicknesses must be: • SDNR for 2-cm PMMA >1.1 × SDNRaccept • SDNR for 4-cm PMMA > SDNRaccept • SDNR for 6 cm PMMA >0.9 × SDNRaccept (does not apply to CR MAG mode) • SDNR for 6-cm PMMA >0.65 × SDNRaccept (CR MAG mode only). **Critical failure:** if the above requirements are not met. Where: 1. SDNRaccept is the minimum acceptable SDNR value for 0.2 mm Al on 4 cm PMMA test object. 2. The SDNRaccept values to be used are those DR and CR manufacture specific values detailed in the current ACPSEM Recommendations for a Digital Mammography Quality Assurance Program* (ACPSEM Program) * Table 2 at time of publication 3. Where an SDNRaccept value is not specified in the ACPSEM Program, an equivalent international body may be used. 4. MPVb and SDb are defined to be the mean pixel value and standard deviation respectively for a ROI located in a uniform part of the PMMA phantom.

Test	Requirement
	5. MPVAl and SDAl are defined to be the mean pixel value and standard deviation respectively for a ROI located in a uniform part of the PMMA phantom with 0.2 mm thickness of Al foil added. **Test parameters** 1. Al test object should be 1 cm x 1 cm. 2. ROIs used in the analysis should be approximately 0.25 cm^2. 3. Both ROIs should be centred on a line parallel to and 6 cm (3 cm for magnification images) from the chest wall to minimise the impact of the heel effect and ideally the image pixel values should be linearised with respect to dose before the SDNR as defined above is calculated. Note: For those DR mammography units with a separate image receptor, and for stand-alone biopsy systems: (a) typical exposure conditions used for biopsy operation should be used (b) a minimum PMMA thickness of 2cm is to be used (c) for those units with a field of view of less than 100 mm^2, the ROIs defining where the SDNR is to be calculated should be placed parallel to the chest wall and centrally in the image along the anode-cathode axis. **9.7 AEC thickness compensation (tomosynthesis mode only)** The AEC must maintain the mAs for 2, 4 and 6-cm PMMA thicknesses within ±10% of the mean mAs value for that thickness of PMMA, when using clinically relevant kVp and target/filter selections. **Test parameters** 1. Mean mAs value is defined as the mean of mAs values used by the AEC for 2, 4 and 6 cm of PMMA thicknesses. 2. The PMMA must completely cover the detector. Note: This test does not apply to breast biopsy mammography units.
10. Compression device	**10.1 Compression force** The radiation apparatus must incorporate a compression device which meets the following requirements. (a) For manual compression devices (including manual override) the compression device must not be able to apply a force ≥300N. (b) For power driven compression devices, the compression device must be able to apply a force of at least 150N, and it must be unable to apply a force ≥200N. (c) For power driven compression, the available operating force must be adjustable down to 70N or less. (d) If the value of applied force is displayed, the indication must be given in units of force and must be accurate to within ±20N (or equivalent). (e) The compression force must not decrease by more than 20 N during a time interval of 30 seconds or an interval of time that would be typical of clinical compressions.

Test	Requirement
	(f) For mammographic X-ray equipment with a moving anti-scatter grid, the application of the maximum force attainable for the compression device must not impede the motion of the anti-scatter grid. **Critical failure:** if the above requirements are not met. Note: This test does not apply to 'stand-alone' biopsy units. **10.2 Compressed breast thickness indicator** The indicated compressed breast thickness must be accurate to ±5 mm and reproducible to ±2 mm across five different readings using the manufacturer's specified compression force and specified paddle.
11. Monitor and print	**11.1 Interpretation* and acquisition monitors** The TG18-QC test pattern image displayed at a scale of 1:1 must be such that: (a) borders are visible (b) lines are straight (c) squares appear square (d) the ramp bars appear continuous without any contour lines (e) there is no smearing or bleeding at black-white transitions (f) all corner patches are visible (g) squares of different shades from black to white are distinct (h) all high contrast resolution patterns and two low contrast patterns are visible in all four corners and in the centre (i) the 5% and 95% pixel value squares are clearly visible (j) the pattern is centred in the active area and no disturbing artefacts are visible, and (k) the number of letters visible in the phrase 'Quality Control' for the dark, mid-grey and light renditions is at least eleven (l) Luminance for interpretation monitor >450 cd/m^2 (m) Luminance for acquisition monitor >250 cd/m^2. * Note: A physical test of the interpretation monitor should be performed if the monitor is attached to the workstation. If the interpretation monitor is remote, it is acceptable to sight a certification that the monitor has been tested to a recognised standard, provided that the certification has been conducted within the last 12 months. **11.2 Printer (if applicable)** Printed TG18-QC test pattern must be such that: (a) all borders are visible (b) lines are straight (c) all corner patches are visible (d) squares of different shades from black to white are distinct

Test	Requirement
	(e) all high contrast resolution patterns are visible in all four corners and the centre (f) the 5% and 95% pixel value squares are clearly visible (g) no disturbing artefacts are visible (h) the number of letters visible in the phrase 'Quality Control' for the dark, mid-grey and light renditions is at least eleven (i) the mid-density (MD) and density difference (DD) must be within ±0.15 OD of their baseline values (j) Base + Fog (B+F) must be within ±0.03 OD of the baseline value, and B+F must also be ≤0.25 OD (k) Dmax must be within ±0.10 OD of the baseline value, and Dmax must also be ≥3.4 OD
12. Image quality	**12.1 Image quality evaluation** <u>DR and CR image receptors:</u> At least the following must be visible in contact mode: (a) 5 fibres, 3.5 speck groups and 4 masses in an image of an ACR accreditation phantom; or (b) 4 fibres, 3 speck groups and 3 masses in an image of an ACR DM phantom. **Critical failure:** if the above requirements are not met. <u>DR image receptors in Digital Breast Tomosynthesis mode:</u> At least the following must be visible in contact mode: (a) 4 fibres, 3 speck groups and 3 masses in an image of an ACR accreditation phantom; or (b) 2 fibres, 1 speck groups and 2 masses in an image of an ACR DM phantom. <u>Biopsy operation: for separate image receptor or stand-alone biopsy systems:</u> At least the following must be visible: (a) 3 fibres, 3 speck groups and 2.5 masses in an image of an ACR 'mini' digital stereotactic phantom; or (b) 3 fibres, 2 speck groups and 1.5 masses in an image of an RMI 156S phantom. **Test parameters** Slice used for scoring should be 37±2 mm (ACR accreditation phantom) or 34±2 mm (ACR DM phantom) above breast support and must not change by more than ±1 mm from previous measurement. Note: 1. It may be necessary to evaluate image quality using a diagnostic image workstation. 2. Image quality requirements outlined in this section for DR and biopsy units must be achieved with a mean glandular dose of ≤2.0 mGy.

<table>
<tr><th>Test</th><th>Requirement</th></tr>
<tr><td>13. System linearity</td><td>
13.1 Image Receptor Linearity (DR only)

The relationship between entrance surface air kerma (ESAK) and mean pixel value (MPV) must be linear, with the square of the correlation coefficient (R-squared value from the RANZCR Equipment Assessor Report Templates) greater than 0.99.

Critical failure: if the above requirement is not met.

Test parameters

1. Use standard test block (4-cm PMMA) at a clinically relevant kVp and target/filter combination (ie those selected under AEC for 4-cm PMMA).

2. Measure the ESAK at 6 cm from chest wall.

3. Measure the MPV and standard deviation in region of interest placed 6 cm from chest wall.

4. Correct MPV for any pixel offset as specified by the manufacturer.

5. The range of mAs values selected should cover the clinically useful range (eg 5 to 300 mAs) so that the MPV increases to a value corresponding to about a factor of three above the value obtained using an AEC initiated exposure. A minimum of seven mAs values should be used.

13.2 Image receptor linearity (CR only)

The relationship between ESAK and exposure indicator listed in the table below must be linear, with the square of the correlation coefficient (R-squared value) greater than 0.99.

Critical failure: if the above requirement is not met.
<table>
<tr><th>Manufacturer</th><th>ESAK and exposure indicator relationship</th></tr>
<tr><td>Fuji, Philips & Konia</td><td>S# versus reciprocal of ESAK</td></tr>
<tr><td>Kodak (Carestream)</td><td>EI versus log (ESAK)</td></tr>
<tr><td>Agfa</td><td>SAL versus SQRT(ESAK) or SAL log versus log(ESAK) or PVI log 16 versus log(ESAK), dependent on software version and plate type</td></tr>
</table>
Where:

1. The ESAK and EI relationship to be used for a particular manufacturer is as detailed in the current ACPSEM Recommendations for a Digital Mammography Quality Assurance Program* (ACPSEM Program). * Appendix 6 at time of publication

2. Where a relationship is not specified in the ACPSEM Program an equivalent international body may be used.

Test parameters

1. Use standard test block (4-cm PMMA) at a clinically relevant kVp and target/filter combination (ie those selected under AEC for 4-cm PMMA).
</td></tr>
</table>

Test	Requirement
	2. Measure the ESAK at 6 cm from chest wall. 3. Measure the EI and standard deviation in region of interest placed 6 cm from chest wall. 4. The range of mAs values selected should cover the clinically useful range (eg 5 to 300 mAs) so that the EI increases to a value corresponding to about a factor of three above the value obtained using an AEC initiated exposure. A minimum of seven mAs values should be used. Note: This test does not apply to breast biopsy mammography units.
14. System resolution	**14.1 System resolution (DR and CR only)** Using a line pair phantom 4 cm above the breast support, or using the MTF tool, the measured system resolution must not be below the baseline resolution value by more than 10%. Note: This requirement applies to both contact and magnification modes. **Critical failure:** if < 5 line pairs per mm **Test parameters** Measurements parallel and perpendicular to the chest wall must be made.
15. Artefact evaluation	**15.1 Artefact evaluation** An image of a 4-cm PMMA phantom using clinically relevant technique factors must not have evidence of any clinically significant artefacts, e.g.: (a) blotches or regions of altered noise appearance; (b) grid lines or breast support structures; (c) bright or dark pixels; (d) dust artefacts mimicking calcifications; (e) stitching or registration artefacts; or (f) any processing artefacts (if applicable). **Test parameters** 1. The assessment should be performed on both the processed and unprocessed image. 2. View the image on the acquisition monitor using zoom and roam to check for possible detector faults. 3. Print the image if interpretation is performed using a hard copy. 4. Artefacts must be assessed for conventional, tomographic and magnification mode and for all clinically relevant target/filter combinations.

Test	Requirement
16. Distance calliper accuracy	**16.1 Distance calliper accuracy** DR and CR image receptors (test only applicable following image receptor system change or significant software upgrades) Distance callipers must agree to within ±2% of the true distance values when allowance has been made for manufacturer's calibration plane. DR image receptors in digital breast tomosynthesis mode Measured dimensions of an object within the reconstructed image plane should be within 2% of the true dimensions. **Critical failure:** if the above requirement is not met. **Test parameters** For DR image receptors in digital breast tomosynthesis mode, the accuracy of the distance calliper must be confirmed in at least three reconstructed slices spread across the full height of the breast. Callipers must be assessed in both contact and magnification modes and in the PACS environment.
17. Image receptor homogeneity	**17.1 Image uniformity** **DR and CR image receptors in 2D mode** The maximum deviation of mean pixel value must be less than ± 10% of the mean pixel value from the central region of interest (ROI). **Critical failure:** if the above requirement is not met. **Digital Breast Tomosynthesis mode** For systems only used in DBT mode, the above 2D mode tests apply. **Test parameters** 1. This test is to be carried out using a 4-cm PMMA phantom. 2. For DR image receptors Use five ROIs each of ~100 mm^2, one central, with the other four at the corners approximately 20 mm from any edge. For biopsy operation, those DR mammography units with a separate image receptor, and for stand-alone biopsy systems, the ROIs in the corners of the image are to be approximately 10 mm from any edge. 3. For CR image receptors Use three ROIs each of ~100 mm^2, one central, with the other two at approximately 20 mm from the edges placed on a line parallel to and approximately 20 mm from chest wall edge. 4. Exclude phantom non-uniformity by rotating block 180° and repeating. Note: This requirement applies to both contact and magnification modes.

Test	Requirement
18. Image receptor ghosting (DR and CR only)	**18.1 Image receptor ghosting (DR and CR only)** The ghost image factor as defined below must be less than 2, when measured under the conditions specified below, and is reliant on having passed the uniformity test above. Ghost Image Factor = |(MPV1 – MPV2)|/SD2 where: MPV1 = mean pixel value in ROI 1 MPV2 = mean pixel value in ROI 2 SD2 = standard deviation of pixel values in ROI 2 Note: This test is not applicable to scanning systems as their design means ghosting is not possible. **Test parameters** Firstly, an exposure must be made using clinical exposure factors under manual control (eg 28kVp, 50 mAs) of a 4-cm thick PMMA block positioned such that half the image receptor is covered. Secondly, a second exposure must be taken at the same clinical settings but with the PMMA block completely covering the image receptor, either as soon as the X-ray system allows (in the case of DR), or as soon as CR plate has been reprocessed (in the case of CR). The ROI 1 and ROI 2 are placed equidistant from the boundary defining where the PMMA and no PMMA regions existed in the initial image, with ROI 2 located in PMMA region.
19. Uniformity of cassette/image plate response	**19.1 Uniformity of cassette/image plate response (CR only)** When imaging a 4-cm thick PMMA block completely covering the CR plate using AEC controlled exposure: (a) the mAs values used for all plates of the same size should be within ±5% of the mean of the mAs values for plates of that size; and (b) for any two different plate sizes, the difference between the mean of the mAs values used for plates of the largest of the two sizes and that used for plates of the smallest of the two sizes must be no more than 20% of the lower value. **Critical failure:** if the above requirements are not met. Note: This test does not apply to breast biopsy mammography units.
20. Exposure indicator calibration and image fading	**20.1 Exposure indicator calibration and image fading (CR only)** The accuracy and fading of the exposure indicator must be within the manufacturer's specifications. Note: This test does not apply to breast biopsy mammography units.
21. Mean glandular dose	**21.1 Mean glandular dose** The calculated mean glandular dose, when assessed using AEC controlled exposure, must be:

Test	Requirement
	(a) ≤2.0 mGy for a 4.2-cm 50% adipose, 50% glandular breast (ie ACR accreditation phantom or ACR DM phantom) for contact and tomosynthesis modes. (b) <1 mGy for 2- cm PMMA (2.3-cm 50% adipose, 50% glandular breast) for contact mode or < 1.2 mGy for tomosynthesis mode. (c) <4.5 mGy for 6- cm PMMA, (6.5-cm 50% adipose, 50% glandular breast) for contact and tomosynthesis modes. **Critical failure:** if the above requirements are not met. Additionally, the displayed mean glandular dose value must be within 25% of the calculated value. Note: integrated units, DR mammography units with a separate image receptor and stand-alone biopsy systems are not required to comply with these requirements when in operation for biopsy purposes.
22. Mechanical stability	**22.1 Stability of X-ray tube and image receptor assembly** Once positioned, the X-ray tube and the image receptor assembly must remain mechanically stable. Additionally, when in biopsy operation, integrated units, DR mammography units with a separate image receptor, and stand-alone biopsy systems, must meet the following requirements: (a) the column rotation, vertical drives, locks and indicators function correctly (b) there are no miscellaneous safety related issues (e.g. jam risk, system stability, loose cabling) (c) the X-ray tube angular locations are positively locked, image receptor and compression plate/biopsy window free of wobble, Vernier drive and needle guide rigid and wobble free, localisation system zeros and biopsy device properly immobilised.
23. X-ray tube housing leakage (Only applicable before first use and following tube change)	**23.1 X-ray tube housing leakage at 1 m** The kerma rate in air at a distance of 1 m from the focal spot of the X-ray tube must not exceed 1 mGy per hour. **23.2 X-ray tube housing leakage at 30 cm** The kerma in air at a distance of 30 cm from the focal spot of the X-ray tube must not exceed 0.01 mGy per 100 mAs at 30kVp.

Test	Requirement
24. Stereotactic accuracy (Only applicable to breast biopsy mammography units)	**24.1 Localisation accuracy** The indicated needle tip coordinates must be within ± 1 mm of the actual pre-set needle position in each direction (horizontal, vertical and depth). **Critical failure:** if the above requirements are not met. **Test parameters** The test may be performed by: (a) using air or a suitable localisation phantom; or (b) following the manufacturer's recommended procedure

Schedule 5 Required tests for plain radiographic apparatus

This appendix lists the radiation safety standard for plain radiographic X-ray equipment that is used for medical diagnostic imaging of humans, including chiropractic, and for research purposes.

This appendix is applicable to fixed, mobile and capacitor discharge X-ray units used for human diagnostic imaging.

Diagnostic X-ray apparatus must comply with all of the following tests.

Test	Requirements
1. Markings on X-ray generators and tube assemblies	1.1 X-ray generators and tube assemblies must be permanently marked in English and the markings must be readily available by means of labels on the apparatus. For infection control reasons, it is acceptable for the labels to be hidden behind a panel, but it must be possible to access these labels. 1.2 X-ray generators must bear: • the name or trademark of the manufacturer; • the model name or number; and • the serial number. 1.3 X-ray tube assemblies must bear: • the name or trademark of the manufacturer of the X-ray tube housing and insert; • the type or model number and serial number of the X-ray tube housing and insert; • the position of the focal spot(s); and • the relative position of the anode and cathode. Note: for dual focus X-ray tubes, a single indication of mean focal spot position is permissible.

Test	Requirements
2. Radiation warning signage	2.1 The radiation apparatus must be marked with a sign or label incorporating the following information: • radiation warning symbol (trefoil) • the words ‘caution’ or ‘warning’ • words to the general form of ‘X-rays produced when energised’. The symbol and lettering must be black on a yellow background. A radiation warning sign, displaying the words ‘Caution X-rays in use – authorised entry only’ (or equivalent) must be displayed at each entry point to the room.
3. Stability of X-ray tube assembly	3.1 The X-ray tube assembly must be supported and remain stationary when placed in position for radiography.
4. Stability of mobile apparatus	4.1 Means must be provided on mobile apparatus to prevent movement once positioned for radiography.
5. Control of multiple X-ray tubes	5.1 Where more than one X-ray tube can be operated from a control panel, there must be a clear indication on the control panel to indicate which tube is selected. 5.2 It must not be possible to energise more than one X-ray tube at the same time, except for two-tube techniques.
6. Mains Indicator	6.1 A mains indicator must be clearly identified. ‘ON’ and ‘OFF’ positions must be marked by a suitable indicator light or other unambiguous means.
7. Indicators of operation	7.1 The tube voltage, tube current and exposure time, or combination of current and time, must be displayed by an analogue or digital indicator, even if these factors are under automatic control. Should one factor be permanently fixed, its value must be indicated on the control panel. 7.2 There must be an obvious visual and audible indicator when radiation is being emitted.
8. Exposure switch	8.1 The exposure switch must have a circuit closing contact such that: • continuous pressure must be applied to maintain the exposure • it must not be possible to make repeat exposures without first releasing the switch • it must be possible to interrupt the exposure at any stage and, in the case of programmed exposures, at any stage of the program. 8.2 In the case of a foot exposure switch, the exposure switch must be designed so that it cannot be accidentally operated. This may be achieved by shrouding the foot switch or by the provision of an isolation switch at the operator’s console. 8.3 For mobile apparatus, control of the X-ray unit must be possible from a distance of not less than 2 metres from the focal spot or X-ray beam.

Test	Requirements
9. Accuracy of kilovoltage controls	9.1 The accuracy of the kVp controls must be within ± 5kV or ± 5% of the indicated value, whichever is greater. **Critical failure:** if the measured value differs from the set value by ≥±10%. 9.2 The coefficient of variation of at least five consecutive measurements at the same kVp setting must not exceed 0.02.
10. Type of timer	10.1 The timer must be electronic 10.2 It must not be possible to make exposures when the timer is set to the zero setting
11. Timer accuracy	11.1 The exposure timer accuracy for timer settings across a clinical range must be within: i. ±10% of the indicated value for exposure times greater than or equal to 0.1 seconds* ii. ±20% ± 1 pulse of the indicated value for exposure times less than 0.1 seconds* *Any measuring equipment error must be taken into account in determining whether compliance criteria are satisfied. **Critical failure:** if the measured value differs from the indicated value by ≥±20% of the indicated value for indicated values ≥100ms or ≥±30% for indicated values <100ms. 11.2 The coefficient of variation of at least 5 consecutive measurements at the same timer setting must not exceed 0.05.
12. Radiation output (air kerma) reproducibility	12.1 The apparatus must produce a consistent radiation output (air kerma), so that the coefficient of variation of at least 5 consecutive measurements, taken at the same control settings, does not exceed 0.05. **Critical failure:** if the coefficient of variation ≥0.1
13. Radiation output (air kerma) linearity	13.1 Variable mA where there is a choice of mA settings, the linearity of the output of the X-ray unit with nominal X-ray tube current should comply with the following relationship between any pair of current settings taken over a range of clinically used settings for each focal spot size: $\frac{X1-X2}{X1+X} \leq 0.1$ • Where X1 is the X-ray output expressed in terms of dose to air per mAs at mA setting 1. • X2 is the X-ray output expressed in terms of dose to air per mAs at mA setting 2. 13.2 Variable mAs where there is a choice of mAs settings the linearity of the output of the X-ray unit should comply with the following relationship between any two mAs settings taken over a range of clinically used settings for each focal spot size: $\frac{X1-X2}{X1+X} \leq 0.1$ Note: Above tests are not applicable for Capacitor discharge units.

Test	Requirements
	• Where X1 is the X-ray output expressed in terms of dose to air per mAs at mAs setting 1. • X2 is the X-ray output expressed in terms of dose to air per mAs at mAs setting 2. **Critical failure:** ≥0.2
14. Automatic exposure control	14.1 There must be a visual indication on the control panel when the automatic exposure control (AEC) is selected. 14.2 Backup timer: when the AEC is utilised, the exposure must terminate after no more than 6 seconds or 600 mAs, whichever occurs first. **Critical failure:** if this requirement is not met. 14.3 In the case of an exposure that terminates under AEC backup timer there must be a visible or audible signal that indicates that termination has occurred; and manual resetting of the AEC must be required before further AEC exposures can be made. 14.4 The AEC device must control exposures such that the displayed exposure index (EI) does not vary by more than 20% from the mean EI when kVp and patient thickness are varied over their typical clinical range. Note: If the detector has a non-linear relationship between detector air kerma (DAK) and EI, the EI must be linearised with DAK. 14.5 Reproducibility • Using the centre detector, the air kerma from 5 consecutive exposures at 80 kVp with a patient-equivalent phantom, must be within ±10% of the mean; and • the air kerma from irradiations to the lateral detectors must be within ±10% of each other. Note: For this test, phantoms constructed of 2 mm of copper or 15 cm of acrylic are suitable substitutes for a patient equivalent phantom.
15. Minimum Focus to skin distance	15.1 The minimum distance between the focal spot and skin must not be less than 200mm, and means must be provided to prevent irradiation using focal spot to skin distances of less than 200 mm.
16. Collimator/light beam alignment	16.1 The X-ray tube must be fitted with a collimator that is continuously adjustable, has a light beam, has the centre of the illuminated area indicated, and can be rotated around the centre of the X-ray beam. 16.2 The area illuminated by the light beam collimator must be effectively coincident with the irradiated area. The total misalignment of any edge of the light field with the respective edge of the irradiated field must not exceed 1% of the source to image distance (SID). **Critical failure:** misalignment >3% of the SID. 16.3 The illuminance of the light beam must be not less than 100 lux above ambient at a distance of 1 metre from the focal spot. **Critical failure:** <50 lux above ambient.

Test	Requirements
17. Tube housing leakage	17.1 The air kerma from leakage radiation from a tube assembly must not exceed 1.0 mGy in 1 hour at a distance of 1 m from the focal spot, averaged over an area of not more than 100 cm2. **Critical failure:** if this requirement is not met.
18. Capacitor discharge apparatus	18.1 Leakage radiation from the X-ray tube assembly when the exposure device is not activated must not exceed 0.2 mGy in 1 hour at 50 mm from any accessible surface of the X-ray tube assembly with the collimator fully open and with the maximum voltage on the capacitors. 18.2 Capacitor discharge apparatus must be fitted with electrically interlocked shutters to limit emission of radiation before the exposure, after the termination of the exposure and during discharging of the capacitors when patient exposure is not required. 18.3 Means must be provided to prevent the initiation of exposure during the charging of the capacitors. 18.4 Capacitor discharge apparatus must be provided with an automatic top-up facility that operates when the kilovoltage drops below the pre-set value by more than 3%. 18.5 A control switch must be provided to allow manual discharge of the capacitors when the apparatus is connected to the mains supply and when patient exposure is not required. 18.6 Capacitor discharge apparatus must be limited to a maximum of 30 mAs. The lowest indicated terminating voltage must not be less than 45kV.

<table>
<tr><th>Test</th><th>Requirements</th></tr>
<tr><td>19. Beam quality filtration</td><td>19.1 The permanent filtration must be such that the measured half value layers are greater than or equal to the values specified in the table below:
<table>
<tr><th>X-ray tube voltage (kVp)</th><th>Minimum HVL for X-ray equipment manufactured pre-2015 (mm of Al)</th><th>Minimum HVL for X-ray equipment manufactured 2015 onwards (mm of Al)</th></tr>
<tr><td>50</td><td>1.5</td><td>1.8</td></tr>
<tr><td>60</td><td>1.8</td><td>2.2</td></tr>
<tr><td>70</td><td>2.1</td><td>2.5</td></tr>
<tr><td>80</td><td>2.3</td><td>2.9</td></tr>
<tr><td>90</td><td>2.5</td><td>3.2</td></tr>
<tr><td>100</td><td>2.7</td><td>3.6</td></tr>
<tr><td>110</td><td>3.0</td><td>3.9</td></tr>
<tr><td>120</td><td>3.2</td><td>4.3</td></tr>
<tr><td>130</td><td>3.5</td><td>4.7</td></tr>
<tr><td>140</td><td>3.8</td><td>5.0</td></tr>
<tr><td>150</td><td>4.1</td><td>5.4</td></tr>
</table>
Critical failure: if equipment does not meet the above requirements.</td></tr>
</table>

Document history

Publications

Title	Release	Commencement
Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022	Second release	11 February 2023

Amendments

Provision	How changed	Commencement
Introductory text	Included link to regulations	11 February 2023
5	Included staged implementation of cyclic testing	11 February 2023
General information	Updated email address	11 February 2023

Further information

Legislation

Online legislation is freely available.

General information

Environment Protection Authority
GPO Box 2607
Adelaide SA 5001

Telephone: (08) 8204 2004
Facsimile: (08) 8124 4670
Freecall: 1800 623 445 (country)
Website: https://www.epa.sa.gov.au
Email: radiationprotection@sa.gov.au