Test Protocol for mammography X-ray apparatus 2023

Issued February 2023

This protocol provides the mandatory requirements for an *accredited tester* performing compliance testing of mammography X-ray *apparatus* under the following scenarios:

- when the apparatus is first installed;
- at a frequency as set out in the Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022 published by the Department; and
- after any major repair or replacement that could affect radiation safety.

It should be read in conjunction with the—

- *Radiation Protection and Control Act 2021* (RPC Act);
- *Radiation Protection and Control Regulations 2022* (RPC Regulations);
- *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022* published by the Department;
- *Code of Compliance for labelling and signage of ionising radiation sources 2022* published by the Department;
- *Code of Compliance for facility design and shielding 2022* published by the Department.

Citation

This protocol may be cited as the *Test Protocol for mammography X-ray apparatus 2023*.

Part 1 Interpretation

In this protocol, unless the contrary intention appears—

accredited tester means a person performing compliance testing who is a holder of an accreditation as a third party service provider under section 31 of the RPC Act;

ACPSEM means Australasian College of Physical Scientists and Engineers in Medicine;

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;

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

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

HVL means half-value layer and refers to the thickness of a specified material that reduces the absorbed dose in air of a given X-ray beam to half its original value;

mammography means imaging of breast tissue;

mean glandular dose means the energy deposited per unit mass of glandular tissue averaged over all the glandular tissue in the breast;

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*;

portable, in relation to *apparatus*, means any *apparatus* that is designed to be carried manually from place to place for use as required;

RANZCR means Royal Australian and New Zealand College of Radiologists;

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.

Part 2 General requirements

1 – Application of protocol

This protocol applies to fixed X-ray apparatus capable of mammography for diagnostic imaging, screening and research. It specifically includes the following mammographic X-ray equipment:

(a) mammography units using digital radiography technology (DR mammography units)

(b) mammography units using computed radiography technology (CR mammography units)

(c) tomosynthesis mammography units

(d) 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)

2 – Exemptions applicable to this of protocol

There are no exemptions applicable to this protocol.

3 – Complying with this protocol

The accredited tester must—

(a) perform compliance testing in accordance with the test methods specified in Part 3; and

(b) provide in a report—

(i) the details as specified in sections 4 to 7; and

(ii) the test parameters used and results obtained for the compliance tests performed as per Part 3; and

(c) complete the approved Certificate of Compliance for mammography X-ray apparatus document.

(d) In the event of a critical failure of a test, the accredited tester must immediately inform the owner, or responsible person, of the failure and the owner’s obligation to immediately notify the EPA.

4 – Owner details

Record, where known, the details of the owner of the apparatus including at least—

(a) the name of the owner; and

(b) the address of the owner; and

(c) the telephone number of the owner.

5 – Apparatus details

Record the details of the apparatus including at least—

(a) the make and model of the apparatus; and

(b) the serial number—

(i) of the generator, where it is practical to do so; and

(ii) the serial number of the *X-ray tube*, where it is practical to do so; and

(iii) the serial number of the *tube housing*, where it is practical to do so; and

(c) the location of the *apparatus* (eg surgery 1, room 1).

6 – Accredited tester details

Record the details of the accredited tester including at least—

(a) the name of the accredited tester; and

(b) the accreditation number of the accredited tester; and

(c) the date on which the accredited tester performed the compliance tests.

7 – Test instrument details

Record for each test instrument used, at least—

(a) the make and model; and

(b) the serial number; and

(c) the date of the next calibration or the date of the last calibration.

Part 3 Construction and installation requirements of mammography apparatus

8 – Labelling of apparatus

8.1 Test method

Verify that the apparatus has a label—

(a) that complies with the requirements of *AS 1319–1994 Safety Signs for the Occupational Environment* applying to warning signs; and

(b) bears the words ‘RADIATION PRODUCED WHEN ENERGISED’ or words to that effect; and

(c) bears the radiation symbol as specified in Schedule 1; and

(d) is clearly legible at a distance of 2 metres.

8.2 Legislative reference

Clause 4, *Code of Compliance for labelling and signage of ionising radiation sources 2022.*

9 – Radiation area sign

9.1 Test method

(1) Verify that a sign is clearly displayed, at each entrance, walkway or access route to the room or area in which the *apparatus* is located—other than an entrance to the room from a place or another room which can only be entered from the room.

(2) Verify that the sign—

(a) complies with the requirements of *AS 1319–1994 Safety Signs for the Occupational Environment* applying to warning signs; and

(b) if it does bear words, the words are ‘RADIATION AREA’ or ‘X-RAYS’ sign or words of similar effect; and

(c) has a total surface area of not less than 4,500 mm^2; and

(d) bears the radiation symbol as specified in Schedule 1; and

(e) is clearly legible at a distance of 2 metres.

9.2 Legislative reference

Clause 5, *Code of Compliance for labelling and signage of ionising radiation sources 2022*.

10 – Apparatus to be in good working order

10.1 Test method

Verify that there is no abnormality, fault, or condition, that is not subject to another section of this protocol, that prevents the apparatus from functioning or performing in a manner for which it has been designed.

10.2 Legislative reference

Regulation 80(2), RPC Regulations.

11– Markings on X-ray generators and tube assemblies

11.1 Test method

Verify that the X-ray generators and tube assemblies are permanently marked in English and the markings are clearly visible. X-ray generators must bear:

(a) the name or trademark of the manufacturer;

(b) the type or model number; and

(c) the serial number.

X-ray tube assemblies must bear the following markings in a visible position:

(a) the name or trademark of the manufacturer of the X-ray tube housing and insert;

(b) the type or model number and serial number of the X-ray tube housing and insert; and

(c) the position of the focal spot.

11.2 Legislative reference

Schedule 4, test 1, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

12 – Warning device

12.1 Test method

Verify that when the X-ray tube is energised there is a warning device that consists of—

(a) a red or amber light that is clearly distinguishable from the operator position; and

(b) an audible signal that is audible from that operator position and indicates either the duration or termination of the exposure.

12.2 Legislative reference

Schedule 4, test 2, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

13 – Mains switch

13.1 Test method

Verify that the apparatus has a mains switch—

(a) that controls the supply of mains power to the apparatus; and

(b) a mains indicator light to indicate when the control panel is energised and the mains switch is in the ‘ON’ position.

13.2 Legislative reference

Schedule 4, test 3, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

14 – Exposure factors

14.1 Test method

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.

14.2 Legislative reference

Schedule 4, test 3, 3.5, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

15 – Exposure switch

15.1 Test method

Verify that—

(a) continuous pressure must be maintained on the exposure switch in order to maintain radiation exposure; and

(b) after a radiation exposure has terminated, another exposure is not possible without releasing the exposure switch; and

(c) the 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; and

(d) in the case of programmed exposures, verify that there is a means of interrupting the programme; and

(e) in the case of a foot operated exposure switch, it is protected from accidental operation by a cover on the switch.

15.2 Legislative reference

Schedule 4, test 4, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

16 – X-ray beam collimation and alignment

16.1 X-ray field/image receptor alignment

Verify that for clinically relevant X-ray tube targets and geometry combinations, the X-ray field will—

(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.

16.2 Compression paddle/image receptor alignment

Verify that for clinically relevant X-ray tube targets, bucky, field sizes and paddle geometry combinations, the chest wall edge of the compression paddle will—

(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).

16.3 Missing tissue at chest wall

Verify that the amount of tissue not imaged between the edge of the breast support and the imaged area is ≤5 mm in contact mode and ≤7mm in magnification (MAG) mode.

16.4 Legislative reference

Schedule 4, test 5, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

17 – Tube voltage (kVp) accuracy and reproducibility

17.1 Test method

Verify that for a given target/filter combination, the measured kVp is within ±5% of the indicated kVp setting over the clinically relevant range in, at most, 2-kVp increments. The coefficient of variation for a minimum of 5 kVp values at a typical clinical kVp value must not be greater than 0.02.

Critical failure: if the above requirements are not met.

17.2 Legislative reference

Schedule 4, test 6, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

18 – Exposure time

18.1 Test method

Verify that for all clinically relevant SID settings, the maximum exposure time when irradiating a 6-cm PMMA phantom is:

(a) less than 3.5 seconds for fine focus; and

(b) less than 2 seconds for broad focus.

Critical failure: if the above requirements are not met.

18.2 Legislative reference

Schedule 4, test 7, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

19 – Beam quality

19.1 Test method

Verify that with the compression device in place, the HVL for all X-ray tube target and filter combinations will be such that:

$$[(\mathrm{kVp}/100) + 0.03]\,\mathrm{mmAl} \leq \mathrm{HVL} < [(\mathrm{kVp}/100 + \mathrm{C})]\,\mathrm{mmAl}$$

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.

19.2 Legislative reference

Schedule 4, test 8, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

20 – Automatic Exposure Control (AEC) Performance

20.1 Reproducibility

Verify that, using a 4-cm PMMA phantom or equivalent, the coefficient of variation for both mean pixel value (MPV) and mAs for at least five AEC controlled exposures of a test object will be less than or equal to 0.05 at clinically relevant kVp and target/filter selections.

20.2 Back-up timer and security cut-out

Verify that for DR and tomosynthesis mammography units, a cut-off mechanism is present and terminates 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.

Verify that for CR mammography units, the current time product (mAs) is limited to no more than 500 mAs.

Critical failure: if the cut-off mechanism does not terminate the exposure <800 mAs.

20.3 Back-up timer/security cut-out indication

Verify that a visible indication at the control panel is provided whenever an exposure has been terminated by the backup timer or security cut-out mechanisms.

20.4 Back-up timer/security cut-out manual reset

Verify that, when the exposure has been stopped by the backup timer/security cut-out mechanism, it will not be possible to initiate another exposure without first operating a manual reset.

20.5 Density control (DR and CR only)

Verify that, if density control is available, it is capable of changing the mAs from the value used normally by −25% to +50%.

20.6 Thickness compensation and SDNR System Performance (DR and CR only)

Verify that 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 is:

- 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)

where:

(a) SDNRaccept is the minimum acceptable SDNR value for 0.2 mm Al on 4 cm PMMA test object.

(b) 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

(c) an SDNRaccept value is not specified in the ACPSEM Program, an equivalent international body may be used.

(d) The SDNR is defined as,

$$\mathrm{SDNR} = \frac{MPV_b - MPV_{Al}}{\sqrt{(SD_b^2 + SD_{Al}^2)/2}}$$

where, 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; 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.

20.7 AEC Thickness compensation (Tomosynthesis mode only)

Verify that, when using clinically relevant kVp and target/filter selections, the AEC will maintain the mAs for 2, 4 and 6-cm PMMA thicknesses to within ±10% of the mean mAs value for that thickness of PMMA.

20.8 Legislative reference

Schedule 4, test 9, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

21 – Compression device

21.1 Test method

Verify that the apparatus incorporates a compression device that meets the following requirements—

(a) For manual compression devices (including manual override) the compression device must not be able to apply a force ≥ 300 N; and

(b) For power driven compression devices, the compression device must be able to apply a force of at least 150 N and it must be unable to apply a force greater than or equal to 200 N; and

(c) For power driven compression, the available operating force must be adjustable down to 70 N or less; and

(d) Breast thickness indicators must be provided which are accurate to within ±5 mm and reproducible to ±2 mm of compressed breast thickness using the manufacturer's specified compression force and specified paddle; and

(e) Compression force indicators must be provided which are accurate to within ±20 N; and

(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.

21.2 Legislative reference

Schedule 4, test 10, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

22 – Monitor and print

22.1 Test method

Verify the performance of the monitor with the use of the TG18 test pattern series prior to conducting any image quality assessments of x-ray images. 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

(k) the number of letters visible in the phrase 'Quality Control' for the dark, mid-grey and light renditions are at least 11

(l) Luminance for interpretation monitor >450 cd/m^2

(m) Luminance for acquisition monitor >250 cd/m^2.

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

(e) all high contrast resolution patterns are visible in all four corners and the centre of the 5% and 95% pixel value squares are clearly visible

(f) no disturbing artefacts are visible

(g) the number of letters visible in the phrase 'Quality Control' for the dark, mid-grey and light renditions is at least eleven

(h) the mid density (MD) and density difference (DD) must be within ±0.15 optical density (OD) of their baseline values

(i) Base + Fog (B+F) must be within ±0.03 OD of the baseline value, and (B+F) must also be ≤0.25 OD

(j) D_{max} must be within ±0.10 OD of the baseline value, and D_{max} must also be ≥3.4 OD

22.2 Legislative reference

Schedule 4, test 11, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

23 – Image quality evaluation

23.1 DR and CR image receptors

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 Digital mammography (DM) phantom.

Critical failure: if the above requirements are not met.

23.2 DR image receptors in Digital Breast Tomosynthesis mode

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 Digital mammography (DM) phantom.

23.3 Biopsy operation: for separate image receptor or stand-alone biopsy systems

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.

23.4 Legislative reference

Schedule 4, test 12, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

24 – Image receptor linearity

24.1 Image receptor linearity (DR only)

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

24.2 Image receptor linearity (CR only)

Verify that the relationship between ESAK and exposure indicator (EI) listed in the table below is linear, with the square of the correlation coefficient (R-squared value) greater than 0.99.
Critical failure: if this requirement is not met.

Manufacturer	ESAK and exposure indicator relationship
Fuji, Philips & Konica	S# versus reciprocal of ESAK
Kodak (Carestream)	EI versus log (ESAK)
Agfa	SAL versus SQRT(ESAK) or SAL log versus log (ESAK) or PVI log 16 versus log (ESAK), dependent on software version and plate type

24.3 Legislative reference

Schedule 4, test 13, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

25 – System resolution (DR and CR only)

25.1 Test method

Verify using a line pair phantom (or MTF tool) that the measured system resolution (both parallel and perpendicular to the chest wall) is not below the baseline value by more than 10%.
Critical failure: if <5 line pairs per mm.

25.2 Legislative reference

Schedule 4, test 14, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

26 – Artefact evaluation

26.1 Test method

Verify that both the processed and unprocessed image of a 4-cm PMMA phantom using clinically relevant technique factors is free of any clinically significant artefacts, eg:

(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).

26.2 Legislative reference

Schedule 4, test 15, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

27 – Distance calliper accuracy

27.1 Test method

Verify that for both DR and CR image receptors in 2D mode (contact and MAG modes) and in the PACS environment, distance callipers agree to within ±2% of the true distance values when allowance has been made for manufacturer's calibration plane.

Critical failure: if this requirement is not met.

27.2 Legislative reference

Schedule 4, test 16, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

28 – Image uniformity

28.1 Test method

Verify that in both contact and MAG modes, the maximum deviation of mean pixel value is less than 10% of the mean pixel value from the central region of interest for DR and CR image receptors in 2D mode.
Critical failure: if this requirement is not met.

28.2 Legislative reference

Schedule 4, test 17, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

29– Image receptor ghosting (DR and CR only)

29.1 Test method

Verify that the Ghost Image Factor, as defined below, is less than 2 and is reliant on having passed the uniformity test above.

$$\text{Ghost Image Factor} = \frac{|(\text{MPV1} - \text{MPV2})|}{\text{SD2}}$$

where: MPV1 = Mean Pixel Value in ROI 1

MPV2 = Mean Pixel Value in ROI 2

SD2 = Standard deviation of pixel values in ROI 2

The Ghost image factor must be measured under the conditions specified below:

(a) Firstly, an exposure must be made using clinical exposure factors under manual control (eg 28 kVp, 50 mAs) of a 4-cm thick PMMA block positioned such that half the image receptor is covered.

(b) 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).

(c) 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.

29.2 Legislative reference

Schedule 4, test 18, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

30 – Uniformity of cassette or Image plate response (CR only)

30.1 Test method

Verify that 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 these requirements are not met.

Note: This test does not apply to breast biopsy mammography units.

30.2 Legislative reference

Schedule 4, test 19, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

31 – Exposure indicator calibration and image fading (CR only)

31.1 Test method

Verify that the accuracy and fading of the exposure indicator is within the manufacturer's specifications.
Note: This test does not apply to breast biopsy mammography units.

31.2 Legislative reference

Schedule 4, test 20, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

32 – Mean glandular dose

32.1 Test method

Verify that the calculated mean glandular dose, when assessed using AEC controlled exposure, is:

(a) ≤2.0 mGy for a 4.2 cm 50% adipose, 50% glandular breast (i.e. ACR accreditation phantom or ACR DM phantom) for contact and tomosynthesis modes;

(b) <1 mGy for 2.0 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 6.0 cm PMMA, (6.5 cm 50% adipose, 50% glandular breast) for contact and tomosynthesis modes.

Critical failure: if the above requirements are not met.
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.

32.2 Legislative reference

Schedule 4, test 21, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

33 – Mechanical stability

Verify that the X-ray tube and the image receptor assembly remains mechanically stable once positioned.

33.1 Legislative reference

Schedule 4, test 22, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

34 – X-ray tube housing leakage (only applicable before first use and following tube change)

34.1 Test method

Verify that the kerma rate in air at a distance of—

(a) 1 m from the focal spot of the X-ray tube must not exceed 1.0 mGy per hour; and

(b) 30 cm from the focal spot of the X-ray tube must not exceed 0.01 mGy per 100 mAs at 30 kVp.

34.2 Legislative reference

Schedule 4, test 23, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022*.

35– Stereotactic accuracy (breast biopsy mammography units only)

35.1 Test method

Verify that the indicated needle tip coordinates are within ±1 mm of the actual pre-set needle position in each direction (horizontal, vertical and depth). The test may be performed by using air or a suitable localisation phantom or following the manufacturer's recommended procedure.

Critical failure: if the above requirements are not met.

35.2 Legislative reference

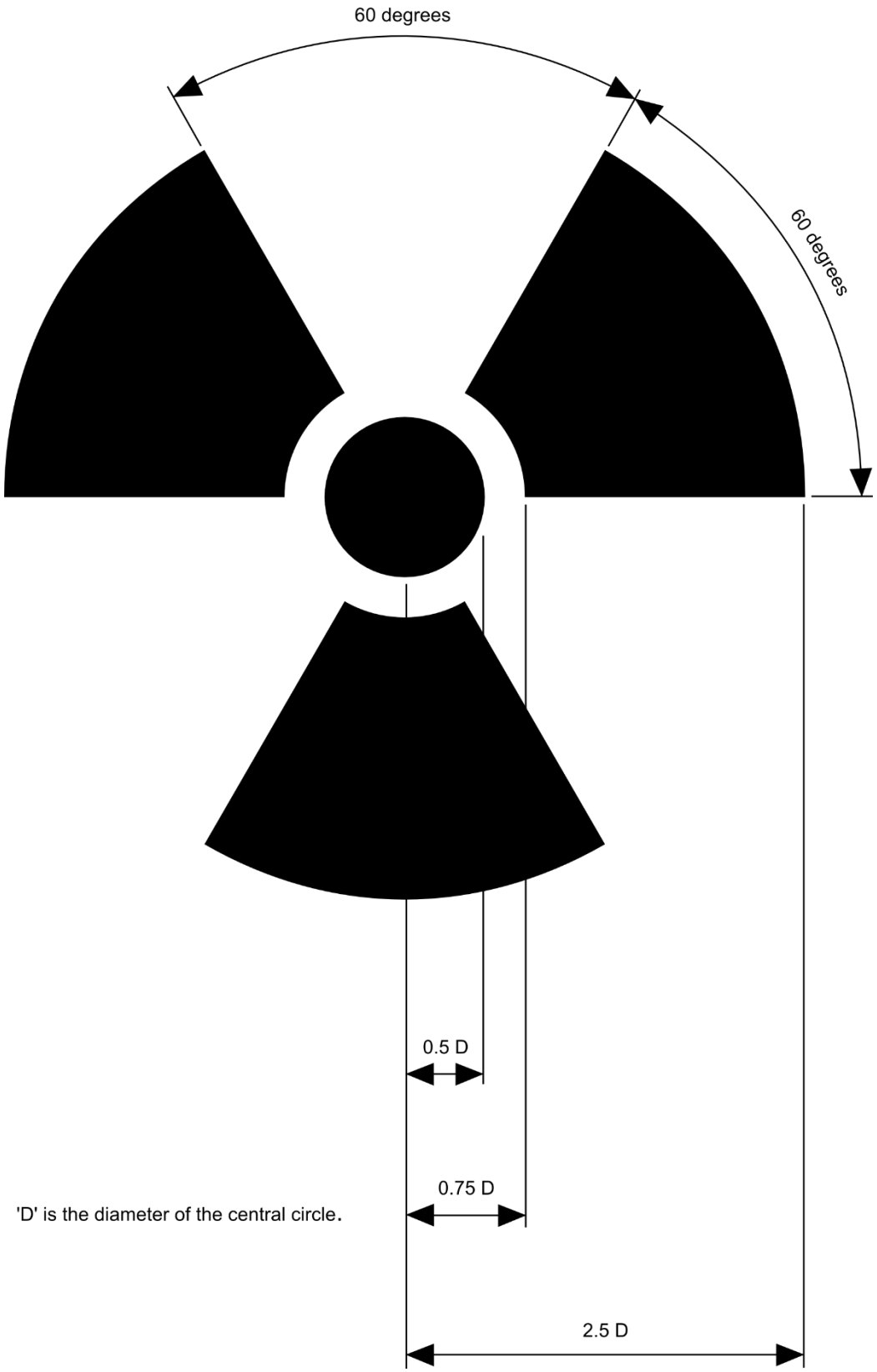
Schedule 4, test 24, *Code of Compliance for medical, veterinary and chiropractic X-ray apparatus 2022.*

Part 4 Schedules

36 – Radiation symbol

(1) The *radiation symbol* consists of the conventional three blade design shown below.

(2) The symbol and background colours must comply with the requirements of *AS 1319–1994 Safety Signs for the Occupational Environment*.



'D' is the diameter of the central circle.

Document history

Publications

This first release of this document replaces *Test Protocol for mammography X-ray apparatus 2016*, which became obsolete on 11 February 2023.

Title	Release	Commencement
Test Protocol for mammography X-ray apparatus 2023	first release	11.2.2023