Environment Protection Authority

Radiation Standard 6

Compliance requirements for ionising radiation apparatus used in diagnostic imaging: Part 4 – Fluoroscopy

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Contents

Introduction 1

1. General requirements and recommendations 2

1.1. Advice to person responsible 2

1.2. Advice to Consulting Radiation Expert 2

2. Compliance requirements: Fluoroscopy 4

2.1. System performance 4

2.2. Radiation warning sign 5

2.3. Fluoroscopic imaging apparatus 5

2.4. Focus-to-skin distance 5

2.5. Markings on X-ray generators and tube assemblies 6

2.6. Accuracy of kilovoltage controls 6

2.7. Filtration 6

2.8. Indicators of operation 7

2.9. Exposure switch 8

2.10. Control of multiple X-ray tubes 8

2.11. Radiation leakage 8

2.12. Control of primary beam during fluoroscopy 8

2.13. Fluoroscopic timing device 9

2.14. Restriction of incident air kerma rate during fluoroscopy 9

2.15. Entrance air kerma rate at surface of image receptor 10

2.16. High-contrast resolution 10

2.17. Low-contrast performance and image distortion 10

2.18. Protection of the fluoroscopist 11

2.19. Provision of an air kerma-area product meter 11

2.20. Fluoroscopy units with an over-table X-ray tube 11

2.21. Provision for radiography on mobile fluoroscopic apparatus 11

2.22. Stability of X-ray tube assembly 12

2.23. Stability of mobile apparatus 12

3. Quality assurance 13

3.1. Quality assurance program 13

3.2. Diagnostic reference levels 13

3.3. Monitors 14

3.4. Records 14

4. Test protocols 15

4.1. Radiation shielding 15

4.2. Kilovoltage accuracy and reproducibility 15

4.3. Half-value layer 15

4.4. Radiation leakage 17
4.5. Collimation 17
4.6. Maximum incident air kerma rate 19
4.7. Entrance air kerma rate at surface of image receptor 19
4.8. High contrast resolution 20
4.9. Low contrast performance and image distortion 21
4.10. Accuracy of air kerma-area product (KAP) meter 21
Schedule 1: Mandatory compliance requirements for fluoroscopic radiation apparatus 23
References and further reading 24
Definitions 25

Introduction

Fluoroscopy is an essential part of medical procedures, both for diagnosis and in research. Diagnostic medical procedures inevitably deliver a radiation dose to the patient. In most cases, the benefits of diagnostic radiology far outweigh any potential risks to the patient from radiation. However, the level of risk is justified only when patients receive a commensurate health benefit and everything reasonable has been done to reduce the dose.

The complexities of modern fluoroscopy apparatus make regular performance monitoring essential for maintaining optimum image quality. It is important that the performance level of each apparatus is established during acceptance testing, and that performance standards are maintained over time by an appropriate quality assurance program. Inadequate performance and quality assurance procedures may cause an unnecessary increase in radiation exposure to the patient and staff and a decrease in the diagnostic value of the examination.

The objects of this standard are to:

- ensuring that adequate safety measures are provided to protect patients, occupationally exposed workers and the public from unnecessary radiation exposure
- improving the standard of radiation apparatus in use
- ensuring better monitoring of apparatus performance
- providing reference dose levels as a guide to patient exposure.

This standard is for the information of the person responsible and licensed users of fluoroscopic apparatus, and persons accredited under section 8 of the *Radiation Control Act 1990* as Consulting Radiation Experts (CREs). It is to be used by CREs to assess apparatus for compliance with the conditions of the radiation management licence and should be read in conjunction with the Act and the Radiation Control Regulation 2013. In the event of an amendment to the Act or Regulation, references to the legislation in this document must be deemed to refer to the current legislation. In the event of an inconsistency between the standard and the legislation, the requirements of the legislation prevail to the extent of the inconsistency.

This document sets out the minimum requirements for diagnostic imaging apparatus, which are stated as '**must**' statements and are listed in Schedule 1 and promotes industry best practice in radiation safety. It applies to all fluoroscopic apparatus, both fixed and mobile.

The standard was developed by the Hazardous Materials Chemicals and Radiation Section of the NSW Environment Protection Authority (EPA) in consultation with the Radiation Advisory Council.

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1. General requirements and recommendations

1.1. Advice to person responsible

1.1.1 Compliance testing of diagnostic imaging apparatus for the purpose of certification for compliance **must** be conducted by an EPA-accredited Consulting Radiation Expert (CRE).

1.1.2 Requirements listed in Schedule 1 of this standard **must** be met for compliance of fluoroscopy apparatus.

1.1.3 The responsible person **must** have equipment quality control records available to the inspecting authority and to a CRE on request (details of quality assurance and quality control program are discussed in sections 2 - 3 of this standard).

1.1.4 Specifications for radiation shielding of protective barriers and the design details of rooms used for ionising radiation apparatus should be determined in accordance with *Radiation Guideline 7: Radiation shielding design, assessment and verification requirements* and documented by an appropriately qualified person before building works start.

1.1.5 The provision of radiation shielding should ensure that the radiation levels behind the shielding comply with the requirements of *Radiation Guideline 7*.

1.1.6 Where the apparatus is a fixed installation, or a mobile apparatus that is used in a dedicated X-ray room, a protective shield **must** be provided for the operator's use.

1.1.7 Where a fixed protective shield is provided it should be not less than 2,100 millimetres (mm) in height.

1.1.8 The operator, when behind the protective shield, **must** have a clear view of the patient and **must** be able to communicate easily with the patient at all times.

1.1.9 In the case of new installations, the protective shield and all shielded walls and doors **must** be clearly and durably marked with the lead thickness or lead area density or, for non-lead material, the lead equivalence and the kVp of the X-ray beam at which the lead equivalence was measured.

1.2. Advice to Consulting Radiation Expert

1.2.1 A CRE **must** ensure that any radiation monitoring device used for compliance testing is:

- suitable for the type of measurement for which it is to be used
- used only when it is fully operational and properly calibrated
- capable of measuring the type of radiation being assessed over the range of energies and dose rates required
- calibrated at least every two years to an Australian or international primary or secondary standard satisfactory to the manufacturers' requirements.

1.2.2 The following test equipment may be required to carry out compliance testing:

- a radiation meter/detector (including kVp and timer functions)
- aluminium filters (Grade 1100 or equivalent)
- tape
- a collimator alignment test grid or lead markers/paper clips
- lead sheets
- a tape measure

- fluorescent screen or Gafchromic film
- a calculator with statistical functions or computer spreadsheet
- 2 mm copper sheet
- 20-centimetre (cm) water or water equivalent phantom
- Westmead Test Object (or equivalent low contrast image quality phantom)
- high contrast resolution test object.

1.2.3 The following information will be required:

- nominal field sizes (including how defined)
- flat-panel detector element size
- image receptor to grid face distance
- grid factor
- Source-to-image receptor distance (SID) range if variable
- leakage technique factors.

1.2.4 Prior to commencing testing the manufacturer's warm-up procedure should be followed.

1.2.5 All measurements **must** be in SI units (i.e. Gy for air kerma).

2. Compliance requirements: Fluoroscopy

Please note that in the case of fluoroscopy apparatus that also has radiography capabilities, the CRE **must** comply with *Radiation standard 6: Part 2 – Radiography and Bone Mineral Densitometry* in addition to this fluoroscopy standard.

2.1. System performance

2.1.1 All tests in **Table 1** that include any clause listed in **Schedule 1 must** be carried out at the frequency specified and results **must** comply with the limits referenced in this standard.

Table 1: Tests required for fluoroscopy systems

Compliance Requirement	Test	Acceptance	2-yearly	After tube replacement	After detector replacement
2.2	Radiation warning sign	✓	✓	×	×
2.3	Fluoroscopic imaging apparatus	✓	✓	×	✓
2.4	Focus-to-skin distance	✓	✓	×	×
2.5	Markings on generators and tube assemblies	✓	✓	✓	×
2.6	Accuracy of kilovoltage controls	✓	✓	✓	×
2.7	Filtration	✓	✓	✓	×
2.8	Indicators of operation	✓	✓	×	×
2.9	Exposure switch	✓	✓	×	×
2.10	Control of multiple X-ray tubes	✓	✓	✓	×
2.11	Radiation leakage	✓	×	✓	×
2.12	Control of the primary beam during fluoroscopy	✓	✓	✓	✓
2.13	Fluoroscopic timing device	✓	✓	×	×
2.14	Restriction of entrance air kerma rate during fluoroscopy	✓	✓	✓	✓
2.15	Entrance air kerma rate at	✓	✓	✓	×

	surface of image receptor				
2.16	High contrast resolution	✓	✓	✓	✓
2.17	Low contrast performance	✓	✓	✓	✓
2.18	Protection of the fluoroscopist	✓	✓	×	×
2.19	Provision of a kerma area product meter	✓	✓	✓	×
2.20	Fluoroscopy units with an over-table X-ray tube	✓	✓	×	×
2.21	Provision for radiography on mobile fluoroscopic apparatus	✓	✓	×	✓
2.22	Stability of X-ray tube assembly	✓	✓	✓	×
2.23	Stability of mobile apparatus	✓	✓	✓	×

2.2. Radiation warning sign

2.2.1 A radiation warning sign complying with Schedule 6 of the Regulation **must** be displayed on the outside of the entry doors to any:

a. room in which a fixed apparatus is installed, or

b. dedicated room in which a mobile or portable apparatus is permanently used.

2.2.2 A radiation warning light **must** be positioned at the entry doors to all X-ray rooms, except in the case of 2.2.1 (b) or where a CRE has determined that not to do so would not pose a risk to the safety of any person.

2.2.3 Where a radiation warning light is provided, the light **must** remain illuminated for the duration of the exposure and must bear the words **'X-RAYS—DO NOT ENTER'** or similar. Immediate illumination **must** be ensured.

2.3. Fluoroscopic imaging apparatus

2.3.1 New apparatus **must** be capable of retaining the last image on the viewing monitor ('last-image-hold').

2.3.2 The apparatus **must** be capable of automatic exposure rate control.

2.3.3 The apparatus should be capable of replaying a continuous cine loop on the viewing monitor.

2.4. Focus-to-skin distance

2.4.1 Fluoroscopic apparatus **must** be designed and constructed such that:

a. the minimum distance between the X-ray tube focus and the patient entrance surface is not less than 300 mm, or

b. in the case of special surgical applications requiring shorter distances, the minimum distance from focus to skin is not less than 200 mm, or

c. in the case of fluoroscopic apparatus specifically designed and labelled for extremity use only, the minimum focus-to-skin distance ensures that the dose limits in section 2.14 are not exceeded.

2.4.2 Where the distance from focus to skin can be varied, the patient should be positioned as close as possible to the image intensifier or image receptor, except where an isocentre is to be maintained.

2.5. Markings on X-ray generators and tube assemblies

2.5.1 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 for the CRE to access these labels.

2.5.2 X-ray generator markings **must** bear either:

a. the name or trademark of the manufacturer, and

b. the type or model number, and

c. the serial number

d. or an EPA-generated number that links to (a), (b) and (c).

2.5.3 X-ray tube assemblies **must** bear either of the following 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 of the X-ray tube housing and insert

c. the serial number of the X-ray tube housing and insert, OR

d. EPA-generated number (s) that links to (a), (b) and (c).

2.5.4 In addition to 2.5.3, X-ray tube assemblies should also bear the position of the focal spot(s) in a visible position. For dual focus X-ray tubes, a single indication of mean focal spot position is permissible.

2.6. Accuracy of kilovoltage controls

2.6.1 If kilovoltage (kVp) is manually selectable, the accuracy of the selected kVp **must** be within ± 5% of the measured value.

2.6.2 If kVp is manually selectable, the coefficient of variation of at least three consecutive measurements at the same kVp setting **must not** exceed 0.02.

2.7. Filtration

2.7.1 The total filtration **must** ensure that the first half-value layer (HVL) of the primary beam for a given X-ray tube and collimator is not less than the values shown in **Table 2 or 3** (as applicable).

2.7.2 Where operator-selectable additional filters are used, determination of the HVL **must** be carried out using minimum filtration.

Table 2: Minimum permissible HVL for X-ray equipment installed pre-2015

X-ray tube voltage (kVp)	Minimum HVL (mm Al)
50	1.5
60	1.8
70	2.1
80	2.3
90	2.5
100	2.7
110	3.0
120	3.2
130	3.5
140	3.8
150	4.1

Table 3: Minimum permissible first HVL for X-ray equipment installed since 2015

X-ray tube voltage (kVp)	Minimum HVL (mm Al)
50	1.8
60	2.2
70	2.5
80	2.9
90	3.2
100	3.6
110	3.9
120	4.3
130	4.7
140	5.0
150	5.4

2.8. Indicators of operation

2.8.1 The tube voltage, exposure time, current and, where appropriate, current-time product, frame rate and magnification setting **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.

2.8.2 There should be a visual indicator on the control panel to indicate to the operator when mains power is supplied to the apparatus.

2.8.3 There **must** be an obvious visual and/or audible indicator when radiation is being emitted.

2.9. Exposure switch

2.9.1 The exposure switch **must** be of the dead-man type. That is, it **must** have a circuit closing contact that:

a. can be maintained only by continuous pressure
b. makes it impossible to make repeat exposures without releasing the switch, except in the case of programmed sequential exposures
c. makes it possible to interrupt the exposure at any stage.

2.9.2 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.

2.9.3 In the case of mobile or portable apparatus, a cable not less than 2 metres (m) in length **must** be provided for the exposure switch, except where the exposure is remotely controlled.

2.10. Control of multiple X-ray tubes

2.10.1 Except for apparatus specifically designed for two-tube techniques (e.g. 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.

2.10.2 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 used in fluoroscopic apparatus, there should be a visual indicator at or near the fluoroscopy controls to signify which tube is selected.

2.11. Radiation leakage

2.11.1 The X-ray tube **must** be enclosed in a housing in such a manner that the air kerma from leakage radiation, measured at a distance of 1 m from the focus of the tube averaged over an area not larger than 100 cm^2, does not exceed 1.0 mGy in 1 hour.

2.11.2 Diaphragms, cones or collimators used to limit the primary beam to the area of clinical interest **must** be constructed so that, in combination with the tube assembly and when fully closed, the leakage radiation does not exceed the limit stated in clause 2.11.1.

2.11.3 Radiation leakage measurements should be conducted in accordance with the method described in this standard.

2.12. Control of primary beam during fluoroscopy

2.12.1 It **must not** be possible to operate the X-ray tube without the image receptor being properly aligned relative to the primary beam.

2.12.2 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.

2.12.3 The primary beam **must not** fall outside the image receptor (including its associated housing) under any circumstances.

2.12.4 It **must not** be possible to manually override the beam-limiting operation to give a larger field.

2.12.5 The beam limiting device should 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 1.15.

2.12.6 Beam-limiting devices **must** allow the collimation of the primary beam to the clinical area of interest.

2.12.7 The selected nominal field size should 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.

2.13. Fluoroscopic timing device

2.13.1 A cumulative timing device **must** be activated by the fluoroscopic control circuit when it is energised and should give an indication of the total screening time until reset.

2.13.2 The timer device **must** give a continuous audible signal at the end of a predetermined time interval not exceeding five minutes.

2.14. Restriction of incident air kerma rate during fluoroscopy

2.14.1 The incident air kerma rate during fluoroscopy **must not** exceed the values in **Table 4**, when measured in scatter-free conditions using the detector position specified in **Table 5**. Measurements should be made at the setting used clinically.

Table 4: Maximum permissible air kerma rates in fluoroscopy

Mode	
Normal	100

Table 5: Conditions for measurement of incident air kerma rate

Condition	Detector position
1. **Under-table X-ray tube** X-ray tube permanently **under** the table	**On** the table
2. **Over-table X-ray tube** Image receptor permanently **under** the table	300 mm **above** the table
3. **C- or U-arm systems** X-ray tube and image receptor mechanically linked, with or without permanent patient support	300 mm from image receptor plane but not less than 400 mm from the focal spot
4. C-arm systems specifically for extremity use (SID ≤ 450 mm) X-ray tube and image receptor mechanically linked	At the minimum focus-to-skin distance
5. **Other fluoroscopic systems** No permanent patient support	400 mm from focal spot

2.14.2 Any mode in which the maximum incident air kerma rate can exceed the values applicable to normal mode in **Table 4** of this standard is classified as high level (boost) mode. Where a high-level 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. only be accessed through the automatic mode of operation.

2.15. Entrance air kerma rate at surface of image receptor

2.15.1 Under Automatic Exposure Rate Control (AERC), the entrance air kerma rate at the input surface of the image receptor (i.e. after any grid) **must** be measured and should comply with the manufacturer's specifications. In the absence of manufacturer's specifications **Table 6** below can be used. Measurements should be made at the setting used clinically.

Table 6: Entrance air kerma rate at the input surface of the image receptor

Field size (cm)	Entrance surface air kerma rate (µGy/min)
11–14	120
>14–23	80
> 23	60

2.16. High-contrast resolution

2.16.1 The high-contrast resolution of the live image, when measured by using an absorber, with AERC and minimum SID, **must not** be less than the values indicated in **Table 7**. Measurements should be made at the setting used clinically.

Table 7: High-contrast resolution

Apparatus	Field size (cm)	Resolution (line pairs/cm)
New	< 18	18
	18 to < 26	16
	26 to < 30	14
	30 to 36	12
	> 36	10
Existing	≤ 25	12
	> 25	10

2.17. Low-contrast performance and image distortion

2.17.1 Using the Image Quality Test Object (Westmead Test Object or equivalent) and 20 cm water equivalent phantom or 2 mm Cu, the low-contrast resolution of the live image **must not** be less than the values indicated in **Table 8**. Measurements should be made at the setting used clinically.

2.17.2 Under the same measurement conditions, the low contrast threshold of the live image **must not** exceed 4% (minimum 10 large circles on Westmead Phantom).

2.17.3 The image should not have significant distortion.

Table 8: Low-contrast resolution

Apparatus type	Minimum resolution
General	1.5 mm (6 circles on Westmead phantom)
High dose rate	1.0 mm (7 circles on Westmead phantom)

2.18. Protection of the fluoroscopist

2.18.1 For fluoroscopic apparatus with a fixed under-table X-ray tube and adjacent operator controls, an adjustable drape **must** be provided, and **must**:

a. have a minimum width of 450 mm
b. be designed to attach to the lower edge of the image receptor carriage
c. consist of overlapping sheets, or equivalent
d. attach to the image receptor carriage in such a way that there is no gap between the drape and the image receptor carriage
e. reach the table top when the image receptor carriage is in its maximum vertical position
f. be adjustable to protect the operator when the table is in the tilted position.

2.18.2 The adjustable drape should have a lead equivalent of not less than 0.5 mm at 150 kVp.

2.18.3 Apparatus used in a sterile environment need not necessarily comply with clause 2.18.1. However, alternative means of operator protection, such as a ceiling-suspended shield, **must** be provided.

2.18.4 For a fluoroscopic table also designed for radiography, a Bucky slot cover **must** be provided.

2.19. Provision of an air kerma-area product meter

2.19.1 An air kerma-area product (KAP) meter **must** be provided on all new purchases of fluoroscopic apparatus and should be provided on all existing high dose rate fluoroscopic apparatus.

2.19.2 Where provided, the KAP meter **must** be functional. Accuracy of displayed KAP **must** be within ±20% of the measured value, ideally it should be within ±10%.

2.19.3 A record of the accumulated KAP should be kept for all patients.

2.19.4 A display of skin dose is recommended for all new purchases of fluoroscopic apparatus.

2.20. Fluoroscopy units with an over-table X-ray tube

2.20.1 In the case of fluoroscopic apparatus with a fixed over-table X-ray tube:

a. the collimator **must** contain a light beam device
b. an exposure switch for radiographic exposures **must** be located at the control panel
c. additional radiographic exposure switches **must** not be provided at the table unless shielding is provided for use by the operator.

2.21. Provision for radiography on mobile fluoroscopic apparatus

2.21.1 All images should be derived from the imaging system and the radiographic mode on mobile fluoroscopic apparatus **must** be disabled.

2.22. Stability of X-ray tube assembly

2.22.1 The X-ray tube assembly must be supported and remain stationary when placed in position for fluoroscopy.

2.23. Stability of mobile apparatus

2.23.1 Means **must** be provided on mobile apparatus to prevent movement away from its stationary position.

2.23.2 Mobile fluoroscopic apparatus **must** be effectively balanced or positively locked to remain stable when the C-arm is in any position.

3. Quality assurance

3.1. Quality assurance program

3.1.1 The quality assurance (QA) program should ensure that consistent, optimum-quality images are produced so that the exposure of patients, staff and the public to radiation satisfies the 'as low as reasonably achievable' principle.

3.1.2 As a minimum requirement, equipment **must** be maintained and serviced according to manufacturer's recommendations. The service frequency **must** be at least annually.

3.2. Diagnostic reference levels

3.2.1 Dosimetric evaluation of fluoroscopic imaging procedures **must** be conducted as part of the QA program.

3.2.2 Practice diagnostic reference levels (DRLs) for routinely performed examinations should be established. **Tables 9 and 10** show the UK national DRLs which can be used for comparison until Australian national DRLs are made available. Dose levels that consistently exceed the national DRLs should be investigated and, where appropriate, the exposure factors for both fluoroscopy and acquisition adjusted to reduce the patient dose.

Table 9: Recommended UK national reference doses for diagnostic examinations on adult patients (HPA-CRCE-034, 2012)

Examination	Fluoroscopy time (min)	Dose-area product (Gy cm2)
Abdomen	–	4.4
Barium (or water soluble) swallow	2.6	21
Barium follow through	2.0	8.4
Barium meal	2.6	12
Barium meal and swallow	2.3	10
Barium (or water soluble) swallow	2.1	7.5
Barium small bowel enema	8.9	23
Barium swallow (video)	3.5	3.4
Chest	–	0.3
Coronary angiography	4.3	31
Coronary graft angiography	13	47
Femoral angiography	5.9	56
Fistulography	6.7	8
Hysterosalpingography	0.7	2
IVU	–	14
Lumbar spine	–	6
MCU	1.6	7
Nephrostography	3.9	9
Proctography	1.3	14

Sialography	1.5	2.8
Sinography	1.7	7
T-tube cholangiography	1.8	5

Table 10: Recommended UK national reference doses for interventional procedures on adult patients (HPA-CRCE-034, 2012)

Examination	Fluoroscopy time (min)	Dose-area product (Gy cm^2)
Biliary intervention	14	43
Facet Joint Injection	1.4	6
Hickman line insertion	1.5	3
Nephrostomy	6.7	13
Oesophageal stent	5	13
Pacemaker (permanent)	6	7
PTCA (single) stent	11.3	40

3.3. Monitors

3.3.1 Monitors are an important part of the imaging chain and should be regularly cleaned, subject to regular servicing and matched in terms of brightness and contrast.

3.4. Records

3.4.1 Records for each radiation apparatus should include any information necessary to allow retrospective dose assessment.

4. Test protocols

4.1. Radiation shielding

See *Radiation Guideline 7: Radiation shielding design assessment and verification requirements*.

Compliance requirement

See section 2.1.

4.2. Kilovoltage accuracy and reproducibility

Only required if the kVp is manually selectable.

Aim

- To determine how the measured kVp compares with the generator setting.
- To determine the variation in average kVp over a number of exposures at the same generator setting.

Exposure factors

- kVp accuracy: Variable kVp, fixed mA.
- kVp reproducibility: Fixed kVp, fixed mA.

Method

- Position kV meter at the distance recommended by the manufacturer.
- Collimate to size of kV meter detector.
- Make a series of exposures across the clinically used kVp range and calculate the difference in selected and measured kVp.
- Make a minimum of three exposures at fixed kVp and mA and calculate average and standard deviation to estimate coefficient of variation.

Compliance requirement

See section 2.6.

Notes

- Protect the image receptor using lead or copper.
- Follow manufacturer recommendations regarding orientation of the kVp meter/detector with respect to the anode-cathode axis of the X-ray tube.

4.3. Half-value layer

Aim

To assess the X-ray beam quality and determine the adequacy of filtration.

Exposure factors

Fixed kVp (i.e.70–100), fixed mA if available. If not, use Automatic Exposure Control Rate (AERC).

Method

- Remove all optional or easily removable filtration.
- Position the appropriate ion chamber or detector at a fixed distance from the focal spot or at the distance specified by the manufacturer. Record actual distance.
- Collimate the beam to the size of the chamber.

If using direct meter reading:

- Make an exposure and record the HVL from the detector.

If using filters and exposure measurements at fixed kVp:

- Make three exposures with no filters added (free in air), then take the average dose rate.
- Tape1 mm of aluminium filter onto the X-ray tube exit port and make an exposure.
- Repeat exposures with additional aluminium filters until dose falls to less than 50% of unfiltered dose.
- Plot exposure against thickness of filter using a semi-log scale.
- Halve the average free in air exposure and determine corresponding thickness of aluminium from graph.

If using filters and exposure measurements with AERC:

- Place five,1 mm aluminium filters between the ion chamber (or detector) and the image receptor i.e. filters are behind the chamber.
- Make three exposures with no filters between the X-ray tube and the chamber then take the average dose rate.
- Take 1 mm of the aluminium filter from behind the chamber, tape it to the X-ray tube exit port and make an exposure.
- Repeat exposures with additional aluminium filters moved from behind the chamber to the X-ray tube exit port, until dose falls to less than 50% of unfiltered dose.
- Plot exposure against thickness of filter using a semi-log scale.
- Halve the average free in air exposure and determine corresponding thickness of aluminium from graph.

Compliance requirement

See section 2.7.

Notes

- kVp should be checked before HVL assessment (where applicable).
- Ensure entire beam is intercepted by filters.
- If kVp selected for HVL assessment is different from those listed in **Table 2 or 3**, use linear interpolation to estimate minimum HVL required for compliance.
- If the measured HVL is compliant with this requirement at a single set tube voltage, it is assumed that it is compliant at all available tube voltages.
- For under-table fluoroscopic X-ray tubes, position the chamber midway between table top and image receptor and place aluminium filters on the table top under the chamber, instead of at the face of the X-ray tube.
- Make an exposure of sufficient time to ensure dose rate stabilises (e.g. 4–5 s).

4.4. Radiation leakage

Aim

To measure any leakage radiation through the X-ray tube assembly and beam limiting device.

Exposure factors

Automatic Exposure Rate Control (AERC) or set maximum kVp and maximum mA, ensuring that tube rating is not exceeded.

Method

- Collimator should be fully closed or covered with ~3 mm of lead.
- Position the leakage chamber at an appropriate distance from focal spot (e.g. 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.

Compliance requirements

See section 2.11.

Notes

- An incorrectly positioned X-ray tube insert or flaws in the lead shielding in a housing may give rise to narrow but intense beams of leakage radiation which fail to ionise the entire chamber and therefore appear not to exceed the specified limit; such beams are highly undesirable, and the cause should be remedied.
- Pinhole leaks or ‘hotspots’ can be detected by the use of a fluorescent screen or non-screen film wrapped around the X-ray tube assembly.

4.5. Collimation

Aim

- To ensure that the primary beam is confined to the image receptor (including its associated housing).
- To ensure that the radiation field area is closely matched to the imaged field area.

Exposure factors

Automatic Exposure Rate Control (AERC) or set low kVp.

Method

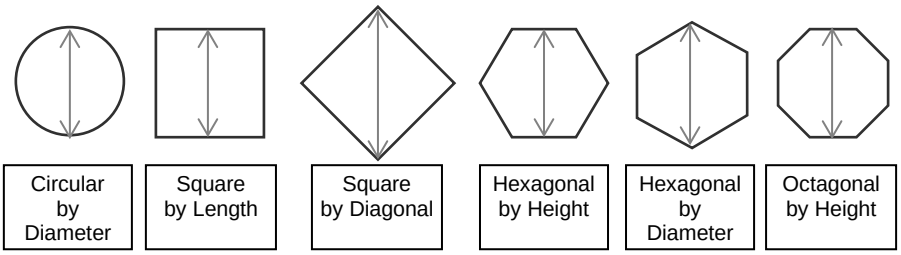
Note: this example uses a CR cassette. Other means to measure the radiation field area may be substituted.

- 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.
- 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 11)

Table 11: Specific field shapes and their constants

Field shape	Constant
Circular (by diameter):	0.785
Square (by length):	1.000
Square (by diagonal):	0.500
Hexagonal (by height):	0.866
Hexagonal (by diameter):	0.650
Octagonal (by height):	0.828

Compliance requirements

See section 2.12.

4.6. Maximum incident air kerma rate

Aim

To measure the maximum incident air kerma rate during fluoroscopy.

Exposure factors

Maximum kVp and maximum mA.

Method

Measurement should be made in scatter-free conditions.

- Set minimum SID.
- Place ion chamber or detector at the position appropriate for that apparatus (see **Table 5**).
- Ensure chamber is central to the X-ray field.
- Cover image receptor with at least 2 mm of lead to protect it; this also ensures that maximum factors are selected under Automatic Exposure Rate Control.
- Irradiate chamber at maximum kVp and mA until dosimeter reading of dose rate stabilises.

Compliance requirement

See section 2.14.

Notes

- Ensure that the image receptor is completely covered with lead to avoid damage. If the lead is smaller than the image receptor, collimate to the size of the lead.
- If the chamber is not placed at the location in **Table 5**, apply an inverse square law correction to the measured dose rate.
- If the measurement is made with backscatter (e.g. an ion chamber placed on top of tissue equivalent material), it is acceptable for the values to be approximately 35% higher than those in **Table 4**.
- Tolerance levels in **Table 4** are taken from AS/NZS 3200.2.7:1999.

4.7. Entrance air kerma rate at surface of image receptor

Aim

To measure the entrance air kerma rate at the input surface of the image receptor during fluoroscopy.

Exposure factors

Automatic Exposure Rate Control (AERC).

Method

- Set SID based on manufacturer’s specifications.

- Remove the grid, if possible. If this is not possible, apply an appropriate grid correction factor to the measurements.
- Place ion chamber or detector without lead backing on the input surface of the image receptor (or as close as possible; see previous bullet point). A detector with lead backing may be placed outside the region controlling the AERC.
- Tape 2 mm Cu to X-ray tube exit port.
- Irradiate chamber until reading of dose rate stabilises.
- Repeat for a range of clinically used settings and field sizes, including those for which the manufacturer has specified a value.

Compliance requirement

See section 2.15.

Notes

If a grid correction factor is not available, use 1.4.

4.8. High contrast resolution

Aim

To assess the ability of the fluoroscopic imaging system to display high contrast information.

Exposure factors

Automatic Exposure Rate Control (AERC).

Method

- Set minimum SID.
- Place high contrast resolution test object (e.g. line pair gauge) directly onto centre of the image receptor surface at 45° to the grid and to the raster lines.
- Collimate to test object.
- Place the absorber material (2 mm Cu) in the beam on the table top or on the test object and make an exposure.
- Score the number of line pairs visible on the live image on the monitor.
- Monitor should be viewed from a distance of four times the screen diameter, in ambient light.
- Repeat for all field sizes.

Compliance requirement

See section 2.16.

Notes

- This is a subjective test that can be affected by room lighting, monitor contrast and brightness settings and orientation of test gauge.
- This test **must** be performed without any time integration or image enhancement.

4.9. Low contrast performance and image distortion

Aim

- To assess the ability of the fluoroscopic imaging system to display low contrast information.
- To assess any image distortion.

Exposure factors

Automatic Exposure Rate Control (AERC).

Method

- Set SID at normal operating distance or 100 cm.
- Place test object directly onto centre of image receptor.
- Place absorber material (20 cm water equivalent phantom or 2 mm Cu) in the beam on the table top or on the test object.
- Collimate to test object.
- Make an exposure and score the phantom on the live image on the monitor.
- Monitors should be viewed from a distance of four times the screen diameter in ambient light.
- Adjust monitor brightness and contrast settings to optimum. This is achieved when both low contrast circles in square backgrounds are seen.
- Record:
  a. distortion – note any ‘S’ or pincushion distortion
  b. contrast threshold – the number of large circles detectable on the live image
  c. contrast detail – the number of hole sizes visible from the contrast detail portion of the test object on the live image (i.e. circles of decreasing size).
- Repeat for all field sizes.

Compliance requirement

See section 2.17.

Notes

- These are subjective tests which can be affected by room lighting, monitor contrast and brightness settings and orientation of test object.
- Many units have an “auto brightness” setting on the monitor. This should be activated, where present.
- This test **must** be performed without any time integration or image enhancement.

4.10. Accuracy of air kerma-area product (KAP) meter

Aim

To ensure accuracy of the KAP meter for patient dosimetry audits.

Exposure factors

- Automatic Exposure Rate Control (AERC).
- Use lead or another suitable attenuator covering the image receptor to drive up the kV and mA.

Method

- Set maximum SID and cover the image receptor with lead or another suitable attenuator.
- Set maximum field size and ensure collimators are fully open.
- Place dosimeter (lead backed) directly onto the image receptor. If an ionisation chamber is used, the chamber should be suspended 20 centimetres away from the image receptor to prevent the measurement of backscatter.
- Screen under AERC for an amount of time suitable to record a displayed KAP value. *Note: the starting KAP may need to be recorded and subtracted from the final KAP*.
- Record the dose on the dosimeter.
- Multiply the dose on the dosimeter by the appropriate radiation field area recorded in test protocol 4.5 to get the measured KAP. *Note: If an ionisation chamber was used at a position different to the surface of the image receptor, an inverse square correction may be applied.*
- Compare the measured KAP with the displayed KAP.
- Repeat measurements for a selection of nominal field sizes, including at least the maximum and minimum field size.

Compliance requirement

See section 2.19.

Schedule 1: Mandatory compliance requirements for fluoroscopic radiation apparatus

The clauses contained in this Schedule are the requirements referred to in condition 4.1 of the radiation management license, which the apparatus **must** meet for compliance.

Requirements or condition	Clause(s)
Advice to responsible person	1.1.1, 1.1.2, 1.1.3, 1.1.6, 1.1.8, 1.1.9
Advice to Consulting Radiation Expert	1.2.1, 1.2.5
System performance	2.1.1
Radiation warning sign	2.2.1, 2.2.2, 2.2.3
Fluoroscopic imaging apparatus	2.3.1, 2.3.2,
Focus to skin distance	2.4.1
Markings on X-ray generators and tube assemblies	2.5.1, 2.5.2, 2.5.3
Accuracy of kilovoltage controls	2.6.1, 2.6.2
Filtration	2.7.1, 2.7.2
Indicators of operation	2.8.1,2.8.3
Exposure switch	2.9.1, 2.9.2, 2.9.3
Control of multiple X-ray tubes	2.10.1, 2.10.2
Leakage radiation	2.11.1, 2.11.2
Control of primary beam during fluoroscopy	2.12.1, 2.12.2, 2.12.3, 2.12.4, 2.12.6
Fluoroscopic timing device	2.13.1, 2.13.2
Restriction of incident air kerma rate dose during fluoroscopy	2.14.1, 2.14.2
Entrance air kerma rate at surface of image receptor	2:15:1
High-contrast resolution	2.16.1
Low-contrast performance and image distortion	2.17.1, 2.17.2
Protection of the fluoroscopist	2.18.1, 2.18.3, 2.18.4
Provision of an air kerma area product meter	2.19.1, 2.19.2
Fluoroscopy units with an over-table X-ray tube	2.20.1
Provision for radiography on mobile fluoroscopic apparatus	2.21.1
Stability of X-ray tube assembly	2.22.1
Stability of mobile apparatus	2.23.1, 2.23.2
Quality assurance program	3.1.2
Diagnostic Reference Levels	3.2.1

References and further reading

AAPM Report No. 125, Functionality and Operation of Fluoroscopic Automatic Brightness Control/Automatic Dose Rate Control Logic in Modern Cardiovascular and Interventional Angiography Systems, 2012, American Association of Physicists in Medicine.

Australian Radiation Protection and Nuclear Safety Agency, *Fundamentals for Protection against Ionising Radiation (2014)*, Radiation Protection Series Publication F-1, ARPANSA February 2014.

Australian Radiation Protection and Nuclear Safety Agency, Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation, ARPANSA RPS 14 (2008).

Australian Radiation Protection and Nuclear Safety Agency, *Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology*, ARPANSA RPS 14.1 (2008).

Australian Radiation Protection and Nuclear Safety Agency, *Code of Practice and Safety Guide for Radiation Protection in Veterinary Medicine,* ARPANSA RPS 17 (2009).

Australian Radiation Protection and Nuclear Safety Agency, *ARPANSA National Diagnostic Reference Level Survey User Guide and Newsletters* (www.arpansa.gov.au/services/ndrl/index.cfm).

European Commission, 2012, Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, Radiation Protection No. 162, European Union, Luxembourg.

Health Protection Agency, 2012, Doses to patients from radiographic and fluoroscopic x-ray imaging procedures in the U.K-2010 Review, HPA-CRCE-034, Chilton.

International Atomic Energy Agency, *Radiation Protection and Safety of Radiation sources: International Basic Safety Standards*, IAEA Safety Standards No. GSR Part 3, 2014, IAEA, Vienna.

International Commission on Radiological Protection, The 2007 *Recommendations of the International Commission on Radiological Protection,* ICRP Publication 103*,* Ann. ICRP 37 (2-4), 2007.

Institute of Physics and Engineering in Medicine, Measurement of the Performance Characteristics of Diagnostic X-Ray Systems used in Medicine, X-ray Image Intensifier Systems, IPEM Report 32 Part II, 1996, U.K. Publication.

National Council on Radiation Protection and Measurements, *Structural Shielding Design and for Medical X-Ray Imaging Facilities,* NCRP Report No. 147, NCRP, Washington DC, USA.

Standards Australia/Standards New Zealand, 1996, Approval and Test Specification – Medical Electrical Equipment Part 1.3: General Requirements for Safety – Collateral Standard: Requirements for Radiation Protection in Diagnostic X-ray Equipment, AS/NZS 3200.1.3,1996.

Standards Australia/Standards New Zealand, 1999, Medical Electrical Equipment Part 2.7, *Particular Requirements for Safety – High voltage generators of diagnostic X-ray generators*, AS/NZS 3200.2.7,1999.

The British Institute of Radiology, *Radiation Shielding for Diagnostic Radiology,* Report of a BIR Working Party, 2012.

Definitions

In this standard:

Absorbed dose means energy delivered from radiation per unit mass of absorbing material, measured in Gray (Gy) or mGy. One Gray equals one joule per kilogram.

Act means the *Radiation Control Act 1990*.

AERC means automatic exposure rate control. This is also known as the Automatic Brightness Control (ABC) for image intensifiers.

Air kerma means *kerma* measured in a mass of air.

Added filtration means quantity indicating the filtration affected by added filters in the useful beam, but excluding inherent filtration.

Authority means NSW Environment Protection Authority.

Barrier means a protective wall of radiation attenuation material(s) used to reduce the dose equivalent on the side beyond the radiation source.

Coefficient of variation means the standard deviation divided by the mean of a set of numbers.

Council means the Radiation Advisory Council.

CRE means consulting radiation expert.

EPA means NSW Environment Protection Authority

Existing apparatus refers to apparatus which is not being tested for the first time.

Filtration means modification of the spectral distribution of an X-ray beam as it passes through matter by the differential absorption of poly-energetic photons.

Fluoroscopic apparatus means radiation apparatus that emits ionising radiation, as defined in the Act, used for the purpose of fluoroscopy or radioscopy. (Standards Australia and the International Electrotechnical Commission have adopted the term ‘radioscopic’, but for the purposes of this document the term ‘fluoroscopic’ is used).

Focal spot means the area of the *target* from which X-rays are emitted.

Half-value layer (HVL) means the thickness of a specified material that reduces the air kerma of a given X-ray beam to half its original value.

High dose rate fluoroscopic apparatus means *fluoroscopic apparatus* in which the product of *air kerma* rate at the patient entrance surface and the total radiation exposure time for a procedure exceeds 80 mGy and includes apparatus used for cardiac catheterisation, angiography and interventional radiology.

Image receptor means an image intensifier or flat panel digital detector.

Inherent filtration means the *filtration* affected by the irremovable materials of an *X-ray tube assembly* (i.e. glass, oil and port seal), through which the radiation beam passes before emerging from the X-ray tube assembly. It is expressed in terms of thickness of a reference material that, at a specified potential difference and waveform, gives the same radiation quality in terms of *half-value layer*.

Kerma (K) means kinetic energy released in a material by ionising radiation and is determined as the quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged ionising particles liberated by uncharged ionising particles in a material of mass dm ($K = dE_{tr}/dm$). The unit of kerma is the gray (Gy), or joule per kilogram.

KAP means air kerma-area product i.e. air kerma multiplied by radiation area. The KAP value may be displayed on the operator's console, or on a separate kerma-area product meter. The units of KAP are typically $Gy.cm^2$, or similar e.g. $mGy.cm^2$, $cGy.cm^2$, $\mu Gy.m^2$. It is important to make a note of the unit when conducting a patient dosimetry audit.

Kerma rate means kerma per unit time and is determined as the quotient of dK by dt, where dK is the increment of kerma in the time interval dt. Variants include incident air kerma rate (does not include backscattered radiation) and entrance surface air kerma rate (includes backscattered radiation).

Lead equivalent means the thickness of lead causing the same attenuation of a beam of a specified radiation quality as the material under consideration.

New installation means a completely new build or modifications to barriers in an existing room.

Operator means a person licensed under section 7 of the Act to use ionising radiation apparatus.

Person responsible means as defined in section 6 of the Act.

Phantom means a test object that simulates the average composition of various structures.

Primary beam means all ionising radiation that emerges through the specified aperture of the protective shielding of the X-ray tube and the collimating device.

Radiation leakage means ionising radiation transmitted through the protective shielding of a radiation source other than the primary beam.

Radiation quality refers to the penetrating ability of a beam of X-rays. It is determined by the energy distribution of the photons in the beam, which in turn depends on the kV waveform and peak voltage across the tube, and on the filtration through which the beam has already been transmitted. The quality of an X-ray beam is described by the HVL of the beam and is measured in terms of mm of aluminium in the diagnostic range.

Regulation means the Radiation Control Regulation 2013.

Scattered radiation means ionising radiation produced from the interaction of electromagnetic ionising radiation with matter. It has a lower energy than, or a different direction from, that of the original incident ionising radiation.

SID means source-to-image receptor distance.

Target means the area of the anode that is struck by the electrons from the cathode.

Total filtration means the sum of inherent filtration and added filtration between the radiation source and the patient or other defined plane.

X-ray tube assembly means the *X-ray tube housing* with an *X-ray tube insert*, but not including a collimating device.

X-ray tube housing 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. It may contain other components.

X-ray tube insert means a highly evacuated vessel for the production of X-radiation by the bombardment of a *target*, usually contained in an anode, with a beam of electrons accelerated by a potential difference.

X-ray tube potential difference means the peak value of the potential difference applied to the X-ray tube, expressed as kilovolts peak (kVp).

Unless otherwise defined, all words in this standard have the same meaning as in the Act and the Regulation.