

**Radiation Guideline**

**6**

**Registration requirements  
& industry best practice  
for ionising radiation  
apparatus used in  
diagnostic imaging**

**Part 2**

**Fluoroscopy &  
radiography**



ENVIRONMENT PROTECTION AUTHORITY



Department of  
Environment and Conservation (NSW)

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From 24 September 2003 the Department of Environment and Conservation (DEC) incorporates the Environment Protection Authority (EPA), which is defined in section 4 of the *Radiation Control Act 1990* as the Authority responsible for administering the Act and Regulation. Statutory functions and powers in the *Radiation Control Act 1990* continue to be exercised in the name of the EPA.

For technical information about this Guideline contact the Radiation Control Section of the DEC on (02) 9995 5959.

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NSW Environment Protection Authority  
59–61 Goulburn Street  
PO Box A290  
Sydney South 1232  
Ph: (02) 9995 5000 (switchboard)  
Ph: 131 555 (information & publications requests)  
Fax: (02) 9995 5999 (general)  
TTY: (02) 9211 4723  
Email: [info@epa.nsw.gov.au](mailto:info@epa.nsw.gov.au)  
Web: [www.environment.nsw.gov.au](http://www.environment.nsw.gov.au)

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## INTRODUCTION

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.

Inadequate performance or quality assurance of radiation apparatus used for diagnostic purposes may cause an unnecessary increase in the radiation dose to patients. The complexities of modern apparatus make regular performance monitoring essential for the maintenance of optimum image quality.

The need to reduce the radiation dose to patients is widely acknowledged. This document aims to contribute to dose reduction by:

- 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.

The Fluoroscopy & Radiography Radiation Guideline is for the information of owners and licensed users of radiographic and fluoroscopic apparatus, and persons accredited under section 9 of the *Radiation Control Act 1990* as consulting radiation experts (CREs). It is to be used by CREs to assess apparatus for registration purposes, and should be read in conjunction with the Act and the Radiation Control Regulation 2003. 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 Guideline and the amended legislation, the requirements of the legislation prevail to the extent of the inconsistency.

From 24 September 2003 the Department of Environment and Conservation (NSW) incorporates the Environment Protection Authority (EPA). The EPA is defined in section 4 of the *Radiation Control Act 1990* as the Authority responsible for administering the Act. Therefore, statutory functions and powers in the Act and the Radiation Control Regulation 2003 continue to be exercised in the name of the EPA.

This document sets out the minimum requirements for registration of 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 and radiographic apparatus, both fixed and mobile.

The Fluoroscopy and Radiography Guideline was developed by the Radiation Control Section of the Department of Environment and Conservation (NSW) in consultation with the Radiation Advisory Council.

The Department of Environment and Conservation (NSW) acknowledges the assistance of Mr Lee Collins, Dr Donald McLean and Mr John Robinson, and the input received from stakeholders, in preparing this edition.

## SECTION 1—GENERAL REQUIREMENTS

### 1.1 Advice to owners

- 1.1.1 Compliance testing of diagnostic imaging apparatus for the purpose of certification for registration may only be conducted by an EPA-accredited Consulting Radiation Expert (CRE) using the *Registration requirements & industry best practice for ionising radiation apparatus used in diagnostic imaging – Part 6: Test Protocols for Parts 2–5*, a copy of which is available from the Authority.
- 1.1.2 Instruments used for routine radiation dosimetry or equipment performance monitoring should have a current calibration certificate that is traceable to an appropriate national standard.
- 1.1.3 Calibration of instruments should be conducted in accordance with the abovementioned *Test Protocols for Parts 2–5*.
- 1.1.4 Variations in line voltage from 240 V may cause equipment to fail the kVp requirements specified in this Guideline. Compliance testing should be carried out at 240 V, which is the optimal line voltage at which diagnostic imaging apparatus should be used. If equipment has failed kVp requirements the owner should have a qualified person monitor the line voltage.

### 1.2 Radiation shielding

- 1.2.1 Appropriate radiation shielding should be provided for the doors, walls, floor and ceiling of the room in which the apparatus is installed and for any protective barrier intended for use as a shield for the operators, to ensure that the radiation dose to any person is as low as reasonably achievable.
- 1.2.2 To achieve the requirements of 1.2.1, the provision of radiation shielding should ensure that the radiation levels behind the shielding will not give rise to a dose equivalent greater than:
  - (a) 100  $\mu$ Sv per week for occupationally exposed persons
  - (b) 20  $\mu$ Sv per week for members of the general public.
- 1.2.3 Where the apparatus is a fixed installation, or a mobile apparatus that is used in a designated x-ray room, a protective shield **must** be provided for the operator's use. The generator or control console **must not** form part of the protective shield, except in the case of dedicated chest-imaging apparatus.
- 1.2.4 Where a fixed protective shield is provided for the operator's use, it **must**, in the case of new installations, be clearly and durably marked with the lead equivalent and the kVp of the x-ray beam at which the lead equivalent was measured.
- 1.2.5 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.

1.2.6 Where a viewing window is used as part of the protective shield, the lead equivalent and the kVp of the x-ray beam at which the lead equivalent was measured **must**, in the case of new installations, be clearly and durably marked on the viewing window.

1.2.7 Where a fixed protective shield is provided it should be not less than 2100 mm in height.

### 1.3 Shielding assessment

1.3.1 Specifications for radiation shielding of protective barriers and the design details of rooms used for ionising radiation apparatus should be determined and documented by an appropriately qualified person before building works start.

### 1.4 Radiation warning sign

1.4.1 A radiation warning sign complying with Schedule 5 of the Regulation **must** be displayed on the outside of the entry doors to any room:

- (a) in which a fixed apparatus is installed, or
- (b) designated as the room in which a mobile or portable apparatus is permanently used.

1.4.2 A radiation warning light **must** be positioned at the entry doors to all rooms, except in the case of 1.4.1 (b) or where a CRE has determined that not to do so would not pose a risk to the safety of any person.

1.4.3 Where a radiation warning light is provided, it **must** light whenever the x-ray tube is placed in the preparation mode before exposure and when fluoroscopy is in progress. 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.

### 1.5 Persons present during the examination

1.5.1 The operator should ensure that no person, other than the patient, remains in the x-ray room during an exposure unless that person is behind a protective screen or is wearing a protective apron.

1.5.2 The only persons who should be present in the room during the x-ray examination are those:

- (a) whose presence during the procedure is necessary, or
- (b) who are responsible for the care of the patient, or
- (c) who are receiving instruction from the person conducting the procedure.

## **1.6 Protective clothing**

- 1.6.1 All protective clothing should comply with the requirements of Appendix A, *Policy on x-ray protective clothing*.

## **1.7 Patient restraint**

- 1.7.1 Mechanical restraining or supporting devices should be used wherever possible.
- 1.7.2 Any person who is required to hold a patient during an x-ray exposure should:
- (a) wear a protective apron and gloves with a shielding value of not less than 0.3 mm lead equivalent at 150 kVp, and
  - (b) not expose any part of the body to the primary x-ray beam, and
  - (c) not be pregnant.
- 1.7.3 The same person should not be called on repeatedly to hold a patient during an x-ray exposure.

## **1.8 Use of portable or mobile apparatus**

- 1.8.1 No person other than the patient should be within 2 m of the primary beam unless shielded as required in clause 1.7.2.

## **1.9 Film/screen systems**

- 1.9.1 Intensifying screens should be used for all examinations where conventional radiographic film is used.
- 1.9.2 A film/screen system speed of less than 200 should be used only for radiography of extremities (American National Standards Institute: ANSI PH2.43-1982).
- 1.9.3 Where a moving grid (bucky) system is fitted, it should be operational.

## SECTION 2—APPARATUS SPECIFICATIONS AND PERFORMANCE

### 2.1 Accuracy of kilovoltage controls

- 2.1.1 The accuracy of the kVp controls **must** be within  $\pm 5\%$  of the measured value.
- 2.1.2 The coefficient of variation of at least five consecutive measurements at the same kVp setting **must not** exceed 0.02.

### 2.2 Accuracy of timer controls

- 2.2.1 The accuracy of the timer controls **must** be within  $\pm 5\%$  or  $\pm$  one pulse of the indicated time, whichever is greater.
- 2.2.2 The coefficient of variation of at least five consecutive measurements at the same timer setting **must not** exceed 0.05.

### 2.3 Exposure consistency and linearity

- 2.3.1 The apparatus **must** produce a consistent radiation output, so that the coefficient of variation of at least five consecutive measurements, taken at the same control settings, does not exceed 0.05.
- 2.3.2 Where the current is selectable (mA can be manually controlled) the apparatus **must** produce a linear radiation output over a continuous range of clinically used settings with respect to the current, so that the coefficient of linearity does not exceed 0.1 for each focal spot size.
- 2.3.3 Where the current is not selectable (mA cannot be manually controlled) the apparatus **must** produce a linear radiation output with respect to the product of the exposure time and the current. The coefficient of linearity **must not** exceed 0.1 for each focal spot size.
- 2.3.4 Capacitor discharge units are exempt from 2.3.2 and 2.3.3.

### 2.4 Filtration

- 2.4.1 The total filtration **must** ensure that the HVL of the primary beam for a given x-ray tube and collimator is not less than the values shown in Table 1.
- 2.4.2 Where apparatus may operate with more than one thickness of filtration, an interlock system **must** be used to prevent exposure if the minimum filtration is not present in the beam, or alternatively the filter **must** be fixed permanently in position.

**TABLE 1 MINIMUM HVL FOR X-RAY TUBE VOLTAGE**

| <b>X-ray tube voltage<br/>(kVp)</b> | <b>Minimum HVL<br/>(mm Al)</b> |
|-------------------------------------|--------------------------------|
| < 50                                | *                              |
| 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                            |
| > 150                               | *                              |

\* Calculate by linear extrapolation

## 2.5 Indicators of operation

- 2.5.1 The tube voltage, current and, where appropriate, 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.
- 2.5.2 There should be a visual indicator on the control panel to indicate to the operator when mains power is supplied to the apparatus.
- 2.5.3 There should be a visual indicator on the control panel, clearly marked as to its function, showing when radiation is being emitted. For radiographic exposures there should be an audible signal either for the duration of each exposure or at the termination of each series of exposures.

## 2.6 Exposure switch

- 2.6.1 The exposure switch **must** be of the dead-man type. That is, it **must** have a circuit closing contact that:
- can be maintained only by continuous pressure
  - makes it impossible to make repeat exposures without releasing the switch, except in the case of programmed sequential exposures
  - makes it possible to interrupt the exposure at any stage of a programmed exposure.

- 2.6.2 The exposure switch **must** be designed so that it cannot be accidentally operated.
- 2.6.3 The radiographic exposure switch **must** be arranged so that it cannot be operated from outside the shielded area. A CRE may exempt an apparatus from this requirement where clinically necessary. The reasoning for doing so **must** be documented in the inspection report.
- 2.6.4 In the case of mobile or portable apparatus, a cable not less than 2 m in length **must** be provided for the exposure switch, except where the exposure is remotely controlled.
- 2.6.5 The operator should not stand in the direction of the primary x-ray beam, and should be at least 2 m from both the x-ray tube and the patient.

## 2.7 Automatic control of exposure

- 2.7.1 Where AEC is provided, the exposure **must** terminate after no more than 6 seconds or after an exposure of no more than 600 mAs, whichever occurs first.
- 2.7.2 The variation in radiation output, measured through a tissue-equivalent absorber, for a minimum of five exposures at the same settings and with the same absorber in the beam, **must not** exceed  $\pm 5\%$ .
- 2.7.3 The minimum response time of an AEC device should not exceed 0.02 seconds.
- 2.7.4 Where fixed fluoroscopic apparatus is capable of radiography, an AEC device should be provided for the radiographic mode.
- 2.7.5 The AEC **must** not operate in the radiographic mode unless the bucky or portable AEC device is selected.
- 2.7.6 The AEC should not activate unless the x-ray tube is centred to the bucky or AEC device.

## 2.8 Control of multiple x-ray tubes

- 2.8.1 Except for apparatus specifically designed for two-tube techniques, 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.
- 2.8.2 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 used in fluoroscopic apparatus, there should be a visual indicator at or near the fluoroscopy controls to signify which tube is selected.

## 2.9 Leakage radiation

- 2.9.1 The x-ray tube **must** be enclosed in a housing in such a manner that the absorbed dose in air from leakage radiation, measured at a distance of 1 m from the focus of the tube averaged over an area not larger than  $100 \text{ cm}^2$ , does not exceed 1.0 mGy in 1 hour.

2.9.2 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 2.9.1.

2.9.3 Radiation leakage measurements should be conducted in accordance with the method described in the *Test Protocols: Part 6*, section 8.1.

## 2.10 Markings on x-ray generators and tube assemblies

2.10.1 X-ray generators and tube assemblies **must** be permanently marked in English and the markings **must** be clearly visible.

2.10.2 X-ray generators **must** bear the following markings:

- (a) the name or trademark of the manufacturer
- (b) the type or model number
- (c) the serial number or the EPA registration number.

2.10.3 X-ray tube assemblies **must** bear the following markings on the outer side of the tube housing:

- (a) the name or trademark of the manufacturer of the x-ray tube insert;
- (b) the type or model number of the x-ray tube insert
- (c) the serial number of the x-ray tube insert or EPA registration number
- (d) the name or trademark of the manufacturer of the x-ray tube housing
- (e) the type or model number of the x-ray tube housing
- (f) the serial number of the x-ray tube housing or EPA registration number
- (g) the nominal value of inherent filtration and any added filtration of the tube housing, expressed in equivalent aluminium thickness at a specified kVp
- (h) the position of the focal spot(s)\*
- (i) the relative position of the anode and cathode.

\*For dual focus x-ray tubes, a single indication of mean focal spot position is permissible.

## 2.11 Control of the primary beam during radiography (including spot film imaging)

2.11.1 An adjustable multileaf collimator **must** be fitted to the x-ray tube assembly. The extent of the diagnostic radiation beam **must** be defined by a light beam unit, except for examinations using a serial changer in association with a fluoroscopic apparatus, or where the x-ray source and field size are fixed in relation to the image receptor.

- 2.11.2 The light beam collimator **must** be attached to the tube housing so that it cannot become detached without the use of tools. It should be capable of rotating around the centre of the x-ray beam, but this rotation **must** not cause the collimator to become loose or detached, or to damage the mounting plate.
- 2.11.3 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 distance from the focus to the image receptor. The coincidence of the light field and irradiated area **must** be determined for each focus.
- 2.11.4 The centre of the illuminated area **must** be indicated.
- 2.11.5 Means **must** be provided to indicate how the selected setting of the beam-limiting device is related to the distance from focal spot to image receptor.
- 2.11.6 The illuminance of the light beam **must** be not less than 100 lux at a distance of 1 metre from the light source.
- 2.11.7 When provision is made for the automatic adjustment of the collimator to the size of the film in use, it **must** be possible to manually override the collimator operation so that a smaller field can be selected.
- 2.11.8 When provision is made for the automatic adjustment of the collimator to the size of the film in use, the x-ray field should be confined to within the image receptor to an accuracy of  $\pm 1\%$  SID.
- 2.11.9 Means should be provided to limit the illuminating period to no greater than 2 minutes, with means of manually initiating further illumination.
- 2.11.10 Light sources should be easily replaced and should not be permanently connected.

## 2.12 Fluoroscopic imaging

- 2.12.1 All fluoroscopic apparatus **must** have an image intensifier or an alternative image acquisition system that provides an equivalent or better resolution at an equivalent or lower dose.
- 2.12.2 Apparatus using a monocular device, mirror optic or direct viewing of the image **must** not be used for fluoroscopic purposes.
- 2.12.3 The apparatus should be capable of retaining the last image on the viewing monitor ('last-image-hold').

## 2.13 Focus to skin distance

- 2.13.1 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.
- 2.13.2 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.

- 2.13.3 In the case of fluoroscopic apparatus specifically designed and labelled for extremity use only, means **must** be provided to restrict the focus-to-skin distance to at least 200 mm.

## 2.14 Control of the primary beam during fluoroscopy

- 2.14.1 It **must** not be possible to operate the x-ray tube without the image receptor being properly aligned relative to the primary beam.
- 2.14.2 The primary beam **must** be centred to the input surface of the image intensifier or image receptor and **must** appear as the centre of the image on the monitor.
- 2.14.3 The primary beam **must** not fall outside the image receptor under any circumstances.
- 2.14.4 The beam-limiting device **must** be of a type designed specifically for fluoroscopic use with the controls situated so that the operator is shielded from stray radiation.
- 2.14.5 The beam-limiting device **must** automatically limit the primary beam to the x-ray image receptor area (within  $\pm 1\%$  SID), which it **must** set to the selected field of the image intensifier or image receptor in the fluoroscopic mode. This limitation of area is to apply at all focal-image receptor distances selected within the normal operating range of movement.
- Note:** this requirement is not applicable when beam-limiting devices attached to x-ray tubes are not used for fluoroscopic purposes, even when used as second tubes in association with fluoroscopic tables.
- 2.14.6 For fluoroscopic image receptor areas of circular shape, the beam **must** be limited to a square of a size equal to the effective selected input diameter. Circular beam-limiting devices should be provided.
- 2.14.7 Beam-limiting devices **must** allow the limitation of the primary beam to the area of interest. Such devices may consist of two pairs of radio-opaque lamellae offset by  $90^\circ$ , or an adjustable iris diaphragm. A pair of semi-radio-opaque lamellae may be incorporated to reduce the level of primary radiation surrounding the area of interest. All adjustable lamellae **must** be remotely controlled and rotatable through an angle of not less than  $45^\circ$ .
- 2.14.8 It **must not** be possible to manually override the beam-limiting operation to give a larger field.
- 2.14.9 The field size viewed on the TV monitor should not differ from the selected field size by more than  $\pm 10\%$ .

## 2.15 Fluoroscopic timing device

- 2.15.1 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.
- 2.15.2 The timer device **must** give a continuous audible signal at the end of a predetermined time interval not exceeding 10 minutes and should terminate the irradiation when this time interval is exceeded. A characteristic continuous and audible signal **must** be given for at least 30 seconds before the end of the time interval to enable the device to be reset if necessary.

## 2.16 Restriction of absorbed dose rate in air during fluoroscopy

2.16.1 The absorbed dose rate in air during fluoroscopy **must not** exceed the values given in Table 2, when measured under the conditions listed in Table 3.

**TABLE 2 ABSORBED DOSE RATE IN AIR DURING FLUOROSCOPY**

| Mode               | Maximum absorbed dose rate in air (mGy/min) |
|--------------------|---|
| Manual             | 50  |
| Automatic          | 100   |
| High level (boost) | 150   |

**TABLE 3 CONDITIONS FOR MEASUREMENT OF ABSORBED DOSE RATE IN AIR**

| Condition   | Detector position   |
|---|---|
| 1. UNDER-TABLE X-RAY TUBE<br><i>X-ray tube permanently <b>under</b> the table</i>   | <b>On</b> the table   |
| 2. OVER-TABLE X-RAY TUBE<br><i>Image receptor permanently <b>under</b> the table</i>  | 300 mm <b>above</b> the table   |
| 3. C- OR U-ARM SYSTEMS<br><i>X-ray tube and image receptor mechanically linked, with or without permanent patient support</i> | 300 mm from image receptor plane but not less than 400 mm from the focal spot |
| 4. OTHER FLUOROSCOPIC SYSTEMS<br><i>No permanent patient support</i>  | 400 mm from focal spot  |

2.16.2 Any mode in which the maximum absorbed dose rate in air at skin entrance can exceed the values applicable to manual (50 mGy/min) or automatic (100 mGy/min) systems in Table 2 of this Guideline is classified as high level (boost). Where a high level boost 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) automatically return to the lower dose rate setting if not used within 5 minutes or if power to the apparatus is disconnected

- (d) be restricted to a maximum of 20 seconds, after which the system **must** return to normal fluoroscopic mode
- (e) high level (boost) mode **must** only be accessed through the automatic mode of operation.

2.16.3 The following typical skin entry doses, using the standard patient equivalent phantom (20 cm water), should be used as guidance levels:

II field size > 17 cm: 17 mGy/min

II field size ≤ 17 cm: 25 mGy/min

## 2.17 Absorbed dose rate in air at surface of image receptor

2.17.1 For systems with ABC, the absorbed dose rate in air at the input surface of the image receptor with the grid removed, should not exceed the values in Table 4. Alternatively, measurements may be obtained by applying a traceable grid correction factor for the energy of the radiation beam being used.

2.17.2 For manually controlled systems, the absorbed dose rates in air in Table 4 should not be exceeded for normal clinical settings when used for the imaging of average patients.

**TABLE 4 ABSORBED DOSE IN AIR AT THE IMAGE RECEPTOR**

| Field size (cm) | Absorbed dose rate in air (µGy/min) |
|-----------------|-------------------------------------|
| 11–14           | 120                                 |
| >14–23          | 80                                  |
| > 23            | 60                                  |

## 2.18 High-contrast resolution

2.18.1 The high-contrast resolution of the live image, when measured by using a 20 cm water equivalent absorber, with ABC (where available) or at 70 kVp, and minimum SID, **must not** be less than the values indicated in Table 5.

**TABLE 5 HIGH-CONTRAST RESOLUTION**

| Apparatus | Field size (cm) | Resolution (line pairs/cm) |
|-----------|-----------------|----------------------------|
| New       | 11 to < 18      | 18                         |
|           | 18 to < 26      | 16                         |
|           | 26 to < 30      | 14                         |
|           | 30 to 36        | 12                         |
|           | > 36            | 10                         |
| Existing  | ≤ 25            | 12                         |
|           | > 25            | 10                         |

## 2.19 Low-contrast resolution

- 2.19.1 Using the Westmead Test Object (or equivalent) and 20 cm water equivalent phantom, the low-contrast resolution of the live image **must not** be less than the values indicated in Table 6.
- 2.19.2 Under the same measurement conditions, the low contrast threshold of the live image **must not** exceed 4%.

**TABLE 6 LOW-CONTRAST RESOLUTION**

| Apparatus type | Minimum resolution |
|----------------|--------------------|
| General        | 6 circles (1.5 mm) |
| High dose rate | 7 circles (1.0 mm) |

## 2.20 Protection of the fluoroscopist

- 2.20.1 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.
- 2.20.2 The adjustable drape should have a lead equivalent of not less than 0.5 mm at 150 kVp.
- 2.20.3 Apparatus used in a sterile environment need not necessarily comply with clause 2.20.1. However, alternative means of operator protection, such as a ceiling-suspended shield, **must** be provided.
- 2.20.4 For a fluoroscopic table also designed for radiography, a bucky slot cover **must** be provided.

## 2.21 Provision of a dose area product meter

- 2.21.1 A dose area product meter should be provided on all high dose rate fluoroscopic apparatus.
- 2.21.2 A record of the accumulated dose should be kept for all patients.

## 2.22 Attenuation equivalent of ancillary devices

- 2.22.1 The attenuation equivalent at 100 kVp for each of the items listed in Table 7 should not exceed the corresponding limits.
- 2.22.2 The fluorescent screen and the associated mechanical support panel and anti-scatter grid of a film changer are excluded from this requirement. Radiation detectors are also excluded.

**TABLE 7 MAXIMUM ATTENUATION EQUIVALENTS**

| Item  | Attenuation equivalent (mm Al) |
|---|--------------------------------|
| Front panel of cassette holder (total of all)         | 1.2                            |
| Front panel of film changer (total of all)            | 1.2                            |
| Stationary patient support                            | 1.2                            |
| Moveable patient support (including stationary layer) | 1.7                            |
| Cradle  | 2.3                            |

## 2.23 Fluoroscopy units with an over-table x-ray tube

- 2.23.1 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.

## 2.24 Provision for radiography on mobile fluoroscopic apparatus

- 2.24.1 All images should be derived from the imaging system and the radiographic mode on mobile fluoroscopic apparatus should be disabled. Where this is not possible and radiographs are to be taken, a cassette-holder that aligns the cassette to the centre of the primary beam **must** be available.
- 2.24.2 The radiographic cassette-holder referred to in clause 2.24.1 **must** be capable of being firmly secured to the image intensifier or image receptor housing. It **must** allow the apparatus to be used for fluoroscopy while the cassette holder is attached to the image intensifier or image receptor housing, without interfering with the fluoroscopic image. The cassette holder **must** allow the attachment of a grid and **must** be capable of securely holding the grid and cassette when oriented in any position.
- 2.24.3 During radiography the primary beam **must not** exceed the dimensions of the cassette selected. If the primary beam is circular, its diameter **must not** exceed the smallest dimension of the cassette.

## 2.25 Stability of x-ray tube assembly

- 2.25.1 The x-ray tube assembly **must** be supported and remain stationary when placed in position for fluoroscopy or radiography, except in tomography and other procedures in which it is a requirement that the x-ray tube assembly move in a predetermined manner.

## 2.26 Stability of mobile apparatus

- 2.26.1 Means **must** be provided on mobile apparatus to prevent movement away from its stationary position.
- 2.26.2 Mobile fluoroscopic apparatus **must** be effectively balanced or positively locked to remain stable when the C-arm is in any position.

## 2.27 Capacitor discharge apparatus

- 2.27.1 For capacitor discharge apparatus, in addition to the requirements of 2.9.1, the absorbed dose in air from leakage radiation through the dark shutter when the exposure switch or timer is not activated **must** not exceed 20  $\mu\text{Gy}$  in any 1 hour. This is to be measured at 50 mm from any accessible surface of the x-ray tube assembly or associated diaphragm or collimator with the collimator fully open.
- 2.27.2 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.
- 2.27.3 Means **must** be provided to prevent the initiation of exposure during the charging of the capacitors.
- 2.27.4 Capacitor discharge apparatus **must** be provided with an automatic top-up facility that operates when the kilovoltage drops below the preset value by more than 3%.
- 2.27.5 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.
- 2.27.6 Capacitor discharge apparatus **must** be limited to a maximum of 30 mAs. The lowest indicated terminating voltage **must not** be less than 45 kV.
- 2.27.7 Capacitor discharge apparatus should not be used for radiography of the skull, bones of the thorax, spine, pelvis or abdomen.

## SECTION 3—QUALITY ASSURANCE

### 3.1 Quality assurance program

- 3.1.1 A quality assurance (QA) program approved by a CRE **must** be instituted and maintained.
- 3.1.2 The 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.
- 3.1.3 QA procedures **must** be standardised and documented in a QA manual.

### 3.2 Ongoing testing

- 3.2.1 The QA program should include checks and test measurements on all parts of the imaging system, as indicated in this Guideline, at appropriate time intervals not exceeding one year.
- 3.2.2 The program should include daily step wedge or equivalent electronic output quality control of x-ray film processors.

### 3.3 Dose guidance levels

- 3.3.1 Dosimetric evaluation of diagnostic procedures should be conducted as part of the QA program.
- 3.3.2 The entrance dose at the skin surface should not exceed the values listed in Tables 8 and 9. Doses in excess of the guidance levels are acceptable only if based on sound clinical judgement.

**TABLE 8 DOSE GUIDANCE LEVELS FOR RADIOGRAPHIC EXPOSURES FOR A STANDARD SIZE PATIENT (70 KG)**

| Examination                                | Entrance surface dose per radiograph* (mGy) |            |
|--|---|------------|
|  | Projection                                  | Dose (mGy) |
| Lumbar spine                               | AP  | 10         |
|  | Lat   | 30         |
|  | LSJ   | 40         |
| Thoracic spine                             | AP  | 7          |
|  | Lat   | 20         |
| Chest                                      | PA  | 0.4        |
|  | Lat   | 1.5        |
| Pelvis                                     | AP  | 10         |
| Abdomen, IV urography and cholecystography | AP  | 10         |
| Skull                                      | AP  | 5          |
|  | PA  | 5          |
|  | Lat   | 3          |

\* In air with backscatter. Values are for conventional film–screen combinations in the relative speed range of 200. For higher film–screen combinations (400–600), the values should be reduced by a factor of 2–3.

PA: Postero–anterior projection

AP: Antero–posterior projection

Lat: Lateral projection

LSJ: Lumbo–sacral joint projection

**TABLE 9 DOSE GUIDANCE LEVELS FOR FLUOROSCOPIC EXAMINATIONS**

| Mode of operation               | Surface entrance dose rate* |
|---------------------------------|-----------------------------|
| Normal<br>If field size > 17 cm | 17 mGy/min                  |
| Normal<br>If field size ≤ 17 cm | 25 mGy/min                  |
| High Level                      | 100 mGy/min                 |

\* In air with backscatter

## 3.4 Film processing

- 3.4.1 Good processing procedures and quality control should be adhered to in order to ensure correct and consistent film processing and good-quality radiographs and to avoid the necessity for repeated x-ray examinations.
- 3.4.2 Chemicals used for developing and processing x-ray film should be in accordance with good radiographic practice.
- 3.4.3 Unexposed film should be stored in dry conditions at temperatures between 10°C and 21°C. The film should be suitably protected from secondary radiation.
- 3.4.4 Adequate chemistry replenishment should be provided in accordance with the workload of the facility.

## 3.5 Image viewing

- 3.5.1 Viewing conditions should meet the following requirements to ensure proper assessment of image quality and accurate reporting:
  - (a) the minimum luminance in the centre and in each quadrant of the illuminator should be >1000 nit (candela/m<sup>2</sup>). All brightness levels should be within ± 10% of the mean value
  - (b) the colour of the illuminator should be white or blue and should be consistent throughout a complete set of illuminators
  - (c) means should be available to restrict the illuminated area of the radiograph to avoid dazzling the viewer
  - (d) means for magnifying details in the displayed radiograph should be available. These means should magnify by a factor of two to four times and contain provisions to identify small image details of sizes down to 0.1 mm
  - (e) an additional spotlight should be available for viewing exceptionally dark areas of the radiographic image
  - (f) there should be a low level of ambient light in the viewing room.

## 3.6 Records

- 3.6.1 A record of maintenance and QA test results should be kept for each item of radiation apparatus. Information on any defects found and their repair should be included. For ABC (or video gain) systems, this record should include details of the manufacturer's set level and the measured level of air kerma at the input surface.
- 3.6.2 Records for each radiation apparatus should include any information necessary to allow retrospective dose assessment.
- 3.6.3 All QA records, including faults, modifications and maintenance, should be made available to the Authority on request.

## SCHEDULE 1—REGISTRATION REQUIREMENTS – RADIOGRAPHIC AND FLUOROSCOPIC RADIATION APPARATUS

The clauses contained in this Schedule are the requirements referred to in Section 7(5) of the Act, which the apparatus **must** meet before it is registered.

| Requirements or Condition                  | Clause(s)                  | Requirements or Condition                                  | Clause(s)              |
|--|----------------------------|--|------------------------|
| Radiation shielding                        | 1.2.3, 1.2.4, 1.2.5, 1.2.6 | Focus-to-skin distance                                     | 2.13.1, 2.13.3         |
| Radiation warning sign                     | 1.4.1, 1.4.2, 1.4.3        | Control of primary beam during fluoroscopy                 | 2.14.1–2.14.8          |
| Accuracy of kilovoltage controls           | 2.1.1, 2.1.2               | Fluoroscopic timing device                                 | 2.15.1, 2.15.2         |
| Accuracy of timer controls                 | 2.2.1, 2.2.2               | Absorbed dose rate in air during fluoroscopy               | 2.16.1, 2.16.2         |
| Exposure consistency and linearity         | 2.3.1, 2.3.2, 2.3.3        | High-contrast resolution                                   | 2.18.1                 |
| Filtration                                 | 2.4.1, 2.4.2               | Low-contrast resolution                                    | 2.19.1, 2.19.2         |
| Indicators of operation                    | 2.5.1                      | Protection of the fluoroscopist                            | 2.20.1, 2.20.3, 2.20.4 |
| Exposure switch                            | 2.6.1, 2.6.2, 2.6.3, 2.6.4 | Fluoroscopy units with an over-table x-ray tube            | 2.23.1                 |
| Exposure controls                          | 2.7.1, 2.7.2, 2.7.5        | Provision for radiography on mobile fluoroscopic apparatus | 2.24.1, 2.14.2, 2.24.3 |
| Control of multiple x-ray tubes            | 2.8.1, 2.8.2               | Stability of x-ray tube assembly                           | 2.25.1                 |
| Leakage radiation                          | 2.9.1, 2.9.2               | Stability of mobile apparatus                              | 2.26.1, 2.26.2         |
| Markings on x-ray generators etc.          | 2.10.1, 2.10.2, 2.10.3     | Capacitor discharge apparatus                              | 2.27.1–2.27.6          |
| Control of primary beam during radiography | 2.11.1–2.11.7              | Quality assurance program                                  | 3.1.1, 3.1.3           |
| Fluoroscopic imaging                       | 2.12.1, 2.12.2             |  |                        |

## **APPENDIX A—POLICY ON X-RAY PROTECTIVE CLOTHING**

### **A1 Conditions for use**

#### **A1.1 General**

- A1.1.1 All staff in a radiographic room during x-ray exposures not standing behind protective screens must wear protective clothing. In general, this means protective aprons of not less than 0.3 mm lead equivalence.
- A1.1.2 Protective gloves should also be worn if it is essential for the hands to be placed in the direct beam at any time, although there may be cases where this is impractical.
- A1.1.3 Aprons and gloves must have radiation attenuation of not less than 0.3 mm lead equivalence at 150 kVp.
- A1.1.4 Aprons must cover the full width of the front of the body from the throat to within 10 cm of the knees, as well as the sides of the body. Wrap-around types of aprons must cover from the shoulder blades to below the buttocks. Fastenings must be provided to keep aprons closed.
- A1.1.5 All staff working in a room where fluoroscopy or cineangiography is being performed must wear a lead apron.
- A1.1.6 If the operator's eyes or thyroid are likely to be exposed when working in the immediate vicinity of the patient, then it is advisable to wear additional protection for these organs.
- A1.1.7 Where appropriate, protection for the patient should also be provided in the form of a lead apron or gonad shield.
- A1.1.8 Personal dosimeters must be worn under the lead apron. A dosimeter must not be worn outside the apron unless it is additional to one worn underneath, and this fact is appropriately reported to the body issuing the dosimeter.
- A1.1.9 The Chief Radiographer must be consulted before the purchase of x-ray protective clothing.
- A1.1.10 The manufacturer's recommendations regarding the handling and storage of protective clothing must be strictly observed. Lead aprons must be stored either flat or on hangers to prevent the development of cracks in the protective material.
- A1.1.11 Inspection and testing of protective clothing must be performed as described in section A2 of this appendix.

### **A2 Inspection and testing requirements**

#### **A2.1 Identification**

- A2.1.1 Each item of protective clothing must be identified with a number that is indelibly marked on the outside of the article.
- A2.1.2 A register must be kept that includes the identification number, usual location, date of purchase, lead equivalence, style, testing dates and results.

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for ionising radiation apparatus used in diagnostic imaging

## A2.2 Visual inspection

- A2.2.1 Each user must visually inspect each article of x-ray protective clothing at the time of each use and be confident of its integrity. Clothing must not be used if the surface appears cracked or damaged. (Note that most aprons have a non-shielding protective cover that may appear undamaged even if the shielding material underneath is faulty.)
- A2.2.2 If there is a suspicion that protective clothing is faulty, it must be tested by a licensed radiographer or other appropriate person.

## A2.3 Shielding integrity testing procedures

- A2.3.1 All new protective clothing must be tested for shielding integrity before use.
- A2.3.2 Protective clothing must be tested regularly at regular intervals of no more than 12 months, or more frequently if indicated.
- A2.3.3 A licensed radiographer or other appropriate person must carry out testing.
- A2.3.4 Testing may be performed using fluoroscopy at approximately 60 kVp (ideally with a floating-top table), which gives good radiographic contrast. Faults or inhomogeneities in shielding should be easily observed. (Note that the lead equivalence cannot be measured or verified by this method.)
- A2.3.5 If faults are found, a radiograph should be taken, and the article must be immediately removed from use and returned to the Chief Radiographer.
- A2.3.6 The date, article identification and outcome of each test must be recorded in the register.

For further information, consult the following British Standards:

- BS 2606: X-ray Protective Gloves for Medical Diagnostic Purposes up to 150 kV (peak)
- BS 3783: X-ray Lead-rubber Protective Aprons for Personal Use.

### **Radiation Advisory Council (October 1992)**

## REFERENCES AND FURTHER READING

American National Standards Institute, 1982, *Method for the Sensitometry of Medical X-ray Screen-film-processing Systems* (ANSI PH2.43-1982), New York. ANSI PH2.43-1982

Australian Radiation Protection and Nuclear Safety Agency & National Occupational Health & Safety Commission, 2002, *Recommendations for Limiting Exposure to Ionizing Radiation (1995) (Guidance Note [NOHSC:3022(1995)]) and National Standard for Limiting Exposure to Ionizing Radiation [NOHSC:1013(1995)]*, Radiation Protection Series Publication No. 1, ARPANSA, Yallambie, Victoria.

International Atomic Energy Agency, 1996, *International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources*, IAEA Safety Series No 115, IAEA, Vienna.

International Commission on Radiological Protection, 1991, *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Ann. ICRP 21 (1/3), Pergamon Press, Oxford.

National Council on Radiation Protection and Measurements, 1976, *Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies up to 10 MeV, Recommendations of the National Council on Radiation Protection and Measurements*, NCRP Report No. 49, 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.

**Note:** The Australian Radiation Protection and Nuclear Safety Agency is publishing the Radiation Safety Series to replace over time the documents comprising the National Health & Medical Research Council Radiation Health Series.

## DEFINITIONS

In this Guideline:

**ABC** means automatic brightness control.

**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*.

**AEC** means automatic exposure device.

**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.

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

**Coefficient of linearity** =  $(X_{\max} - X_{\min}) / (X_{\min} + X_{\max})$

**Council** means the Radiation Advisory Council.

**CRE** means consulting radiation expert.

**EPA** means NSW Environment Protection Authority

**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. (It should be noted that 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 absorbed dose in air 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.

**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 relaxed 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.

**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  $dt$ .

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

**Optical density (OD)** means the degree of film blackening produced during development, where optical density is the log of the reciprocal of the fraction of light transmitted through the blackened film.

**Operator** means a person licensed under Section 6 of the Act to use ionising radiation apparatus.

**Owner** means the owner of the radiation apparatus to which Section 7 of the Act applies.

**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.

**Radiographic apparatus** means ionising radiation apparatus, which emits ionising radiation, used for the purpose of radiography.

**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 2003.

**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 Guideline have the same meaning as in the Act and the Regulation.