

Environment Protection Authority

Radiation Standard 6

Compliance requirements for ionising radiation apparatus used in diagnostic imaging: Part 2 - Radiography (Medical) and Bone Mineral Densitometry

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Introduction

Radiography 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.

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 Radiography (Medical) and Bone Mineral Densitometry Radiation standard, hereafter referred to as the Radiography standard is for the information of owners (person responsible) and licensed users of radiographic 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 conditions of 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 amended legislation, the requirements of the legislation prevail to the extent of the inconsistency.

This document sets out the minimum requirements for compliance of diagnostic imaging apparatus, which are stated as '**must**' statements and promote industry best practice in radiation safety. These requirements are listed in Schedule 1 and 2 and apply to both fixed and mobile medical radiography and bone mineral densitometry apparatus respectively.

The Radiography 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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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 and 2 of this standard are to be met for compliance of medical radiography and bone mineral densitometry apparatus respectively.
- 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 section 3 and 4 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 X-ray apparatus is a fixed installation or a mobile that is used in a dedicated X-ray room, a protective shield must be provided for the operator's use. A protective shield must also be provided in case of any BMD apparatus if beam geometry and patient workload dictate the need for operator protection.
- 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 type and thickness of building material of which they are constructed.

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 dosimeter (including kVp and timer functions)
- aluminium filters (Grade 1100 or equivalent)
- tape
- a collimator alignment test grid or lead markers/paper clips
- · a light meter

- lead sheets
- a tape measure
- radiographic cassettes or film/fluorescent screen
- a calculator with statistical functions / computer spreadsheet
- 1 mm copper sheet
- 5, 10, 15, 20-centimetre (cm) water or PMMA phantom.
- 1.2.3 The following information will be required to carry out compliance testing.
- An acquisition protocol to be used for testing of digital image receptors so as to acquire and access images that have minimal clinical image processing.
- Leakage technique factors for assessment of tube leakage radiation.
- 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 (e.g. Gy for air kerma).

2. Compliance requirements: Medical radiography

Please note that in the case of radiographic apparatus that also has fluoroscopic capabilities the apparatus **must** comply with *Radiation Standard 6: Part 4 - Fluoroscopy* in addition to this radiography standard.

2.1. System performance

2.1.1 All tests listed 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 medical radiography systems

Compliance Requirement	Test	Acceptance	5-Yearly	After tube replacement	After detector replacement
2.2	Radiation warning sign	✓	✓	×	×
2.3	Accuracy of kilovoltage controls	✓	✓	✓	×
2.4	Accuracy of timer controls	✓	✓	✓	×
2.5	Exposure consistency and linearity	✓	✓	✓	×
2.6	Filtration	✓	✓	✓	×
2.7	Indicators of operation	✓	✓	×	×
2.8	Exposure switch	✓	✓	×	×
2.9	Automatic exposure control	✓	✓	×	✓
2.10	Digital image receptors	✓	✓	×	✓
2.11	Control of multiple X-ray tubes	✓	✓	✓	×
2.12	Leakage radiation	✓	×	✓	×
2.13	Markings on X-ray generators & tube assemblies	✓	✓	✓	×
2.14	Control of the primary beam during radiography	✓	✓	✓	×
2.15	Provision of an air kerma area product meter	✓	✓	✓	×

2.16	Stability of X-ray tube assembly	✓	✓	✓	×
2.17	Stability of mobile apparatus	✓	✓	✓	×
2.18	Capacitor discharge 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 radiography 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 radiography rooms, except in the case of 2.2.1 (b) or where a CRE has determined that it would not pose a risk to the safety of any person if there were no warning light.
- 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. Accuracy of kilovoltage controls

- 2.3.1 The accuracy of the kVp controls **must** be within ± 5% of the indicated value.
- 2.3.2 The coefficient of variation of at least three consecutive measurements at the same kVp setting **must not** exceed 0.02.

2.4. Accuracy of timer controls

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

2.5. Exposure consistency and linearity

- 2.5.1 The apparatus **must** produce a consistent radiation output, so that the coefficient of variation of at least three consecutive measurements, taken at the same control settings, does not exceed 0.05.
- 2.5.2 Where the current is selectable (mA can be manually controlled) the apparatus **must** produce a linear radiation output over a range of clinically used mA settings so that the coefficient of linearity does not exceed 0.1 for each focal spot size.
- 2.5.3 Where the current is not selectable (mA cannot be manually controlled) the apparatus **must** produce a linear radiation output over a range of clinically used mAs settings so that the coefficient of linearity does not exceed 0.1 for each focal spot size.
- 2.5.4 Capacitor discharge units are exempt from 2.5.2 and 2.5.3.

2.6. Filtration

2.6.1 The total filtration **must** ensure that the first 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).

- 2.6.2 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.
- 2.6.3 Where removable or 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

2.7. Indicators of operation

- 2.7.1 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.
- 2.7.2 There should be a visual indicator on the control panel to indicate to the operator when mains power is supplied to the apparatus.
- 2.7.3 There **must** be an obvious visual and/or audible indicator when radiation is being emitted.

2.8. Exposure switch

- 2.8.1 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 of a programmed exposure.
- 2.8.2 The exposure switch **must** be designed so that it cannot be accidentally operated.
- 2.8.3 The 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.
- 2.8.4 In the case of mobile or portable apparatus, a cable not less than 2m in length **must** be provided for the exposure switch, except where the exposure is remotely controlled.

2.9. Automatic exposure control

- 2.9.1 There **must** be a visual indication when the automatic exposure control (AEC) is selected.
- 2.9.2 When the AEC is utilised, the exposure **must** terminate after no more than six seconds or 600 mAs, whichever occurs first.
- 2.9.3 The coefficient of variation in post exposure mAs, measured air kerma and displayed air kerma area product (if available), for a minimum of three exposures using the same exposure parameters and with the same absorber in the beam, **must not** exceed 0.05 for each AEC sensor.
- 2.9.4 In the case of 2.9.3, the percentage difference in post exposure mAs and measured air kerma between the lateral AEC sensors **must not** exceed 10%.
- 2.9.5 The AEC device should control exposures such that the displayed exposure index (EI) does not vary by more than 20% from the mean EI when kVp and patient thickness are varied over their typical clinical range (see Appendix 1 for systems with a non-linear relationship between EI and detector air kerma).

2.10. Digital detectors

- 2.10.1 An acquisition protocol **must** be available on a digital radiography system to acquire and access images that have minimal clinical image processing (flat-field images). This means removing any high frequency image processing, edge enhancement, noise reduction etc.
- 2.10.2 The Signal Transfer Property (STP) of the system i.e. the relationship between the detector air Kerma (DAK) and mean pixel value (MPV) **must** be verified as simple (e.g. linear, logarithmic or power). Systems with an unknown or a complex relationship **must not** be accepted.
- 2.10.3 The maximum difference in MPV's between five regions of interest placed centrally and in the centre of the four quadrants of a uniform image **must** be within ±10% of the mean MPV. If the STP relationship is not linear, the pixel values **must** be linearised to DAK_{MPV} (see Appendix 1).
- 2.10.4 When viewed using a narrow window width, the image acquired in 2.10.3 **must** be free from any significant artefacts that have the potential to impact clinical diagnosis (such as variations in signal and/or noise, blurring, pixel line defects, stitching etc).
- 2.10.5 The El **must** be repeatable, so that the coefficient of variation of at least three consecutive measurements, taken using the same exposure settings, does not exceed 0.1. If the

relationship between DAK and EI is not linear, the EI should be repeatable. EI values will need to firstly be linearised to DAK_{EI} (see Appendix 1).

2.11. Control of multiple X-ray tubes

2.11.1 Where more than one X-ray tube can be operated from a control panel, there **must** be a clear indication on the control panel to signify which tube is energised.

2.12. Radiation leakage

- 2.12.1 The X-ray tube **must** be enclosed in 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 cm², does not exceed 1.0 mGy in 1 hour.
- 2.12.2 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 2.12.1.

2.13. Markings on X-ray generators and tube assemblies

- 2.13.1 X-ray generators and tube assemblies **must** be permanently marked in English and the markings **must** be clearly visible.
- 2.13.2 X-ray generators **must** bear either:
 - a. the name or trademark of the manufacturer
 - b. the type or model number
 - c. the serial number, OR
 - d. an EPA-generated number that links to (a), (b) and (c).
- 2.13.3 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).
- 2.13.4 In addition to 2.13.3, X-ray tube assemblies should also bear the following markings on the outer side of the tube housing in a visible position:
 - a. the position of the focal spot (s)*
 - b. the relative position of the anode and cathode.

2.14. Control of the primary beam during radiography

- 2.14.1 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.
- 2.14.2 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.
- 2.14.3 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 source to image distance (SID). The centre of the illuminated area **must** be indicated.

^{*}For dual focus X-ray tubes, a single indication of mean focal spot position is permissible.

- 2.14.4 Where tube locking devices are available, the alignment of the crosswire of the light field with the centre of the imaged area **must** be within 1% of the SID. Additionally, where the centre of the detector housing is marked, the alignment of the crosswire of the light field with the detector housing markings **must** be within 1 cm at an SID of 100 cm.
- 2.14.5 When provision is made for the automatic adjustment of the collimator to the size of the detector in use:
 - a. it **must** be possible to manually override the collimator operation so that a smaller field can be selected.
 - b. the X-ray field **must not** exceed the size of the detector at the detector plane by > 1% of the SID.
- 2.14.6 The illuminance of the light beam **must** be not less than 100 lux at a distance of one metre from the focal spot.
- 2.14.7 Means should be provided to limit the illuminating period to no greater than two minutes, with means of manually initiating further illumination.
- 2.14.8 Light sources should be easily replaced and should not be permanently connected.

2.15. Provision of an air kerma area product meter

- 2.15.1 An air kerma area product (KAP) meter should be provided on all radiography systems.
- 2.15.2 Where provided, the air kerma area product meter **must** be functional. Accuracy of displayed KAP **must** be within ±20% of the measured value and should be within ± 10%.

2.16. Stability of X-ray tube assembly

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

2.17. Stability of mobile apparatus

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

2.18. Capacitor discharge apparatus

- 2.18.1 For capacitor discharge apparatus, in addition to the requirements of 2.12.1, 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 µGy in any one hour at 50 mm from any accessible surface of the X-ray tube assembly or associated diaphragm or collimator with the collimator fully open.
- 2.18.2 Capacitor discharge apparatus **must** be fitted with electrically interlocked shutters to limit emission of radiation before the exposure, after the termination of the exposure and during discharging of the capacitors when patient exposure is not required.
- 2.18.3 Means **must** be provided to prevent the initiation of exposure during the charging of the capacitors.
- 2.18.4 Capacitor discharge apparatus **must** be provided with an automatic top-up facility that operates when the kilovoltage drops below the pre-set value by more than 3%.
- 2.18.5 A control switch **must** be provided to allow manual discharge of the capacitors when the apparatus is connected to the mains supply and when patient exposure is not required.

- 2.18.6 Capacitor discharge apparatus **must** be limited to a maximum of 30 mAs. The lowest indicated terminating voltage **must not** be less than 45 kV.
- 2.18.7 Capacitor discharge apparatus should not be used for radiography of the skull, bones of the thorax, spine, pelvis or abdomen.

3. Quality assurance requirements: Medical radiography

3.1. Quality assurance program

- 3.1.1 A quality assurance (QA) program **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. RANZCR standards of practice and the RANZCR General X-ray QA and QC Guideline should be followed.
- 3.1.4 Equipment should be maintained and serviced according to manufacturer's recommendations. The service frequency should be at least annually.

3.2. Routine equipment testing

- 3.2.1 The QA program should include checks and test measurements on all parts of the imaging system, as indicated in this standard, at appropriate time intervals not exceeding one year.
- 3.2.2 For film screen systems the program should include daily step wedge or equivalent electronic output quality control of X-ray film processors.
- 3.2.3 For X-ray systems with digital detectors, the ongoing site quality control program should include checks and test measurements listed in **Table 4** below, at appropriate time intervals not exceeding six months.
- 3.2.4 In addition, other digital detector tests including detector calibration, dark noise evaluation, cleaning of CR plates etc. should be routinely carried out as per manufacturer recommendations.

Table 4: Ongoing tests, recommended protocols and action limits

Test	Recommended protocol and action limits
Imaging System Mechanical and Safety Evaluation (Visual Checks)	Section 5.1 RANZCR Guideline
X-ray to Light Field and Detector Alignment	Section 5.2 RANZCR Guideline
AEC consistency (where applicable)	Section 5.5 RANZCR Guideline
Consistency of Exposure Index	Section 5.3 RANZCR Guideline
Image Uniformity and Artefact Evaluation	Section 5.4 RANZCR Guideline

3.3. Image quality

- 3.3.1 The QA program should include periodic reviews of clinical images to ensure that radiographers are using proper collimation, markers, correct positioning and exposure techniques to obtain clinical images. Based on the image quality reviews, corrective and/or preventive action should be taken.
- 3.3.2 Radiologists should be involved in the clinical image quality assessment. An example of image quality assessment criteria for chest X-ray is given in Section 6.1 of the RANZCR General X-ray QA and QC Guideline.

3.4. Diagnostic reference levels and exposure index

- 3.4.1 Dosimetric evaluation of diagnostic procedures should be conducted as part of the QA program.
- 3.4.2 Practice diagnostic reference levels (DRLs) for common X-ray examinations should be established. **Table 5** shows the UK national DRLs and 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 adjusted to reduce the patient dose.

Table 5: Diagnostic reference levels per radiograph for a Standard-sized patient (70 kg) - UK 2010 review

Examination	Entrance Surface Dose (ESD*) in mGy	Dose Area Product (DAP) in Gycm²
Chest PA	0.15	0.1
Chest AP	0.2	0.15
Chest Lat	0.54	-
Cervical spine AP	-	0.15
Cervical spine Lat	-	0.15
Thoracic Spine AP	3.5	1.0
Thoracic Spine Lat	7.0	1.5
Lumbar Spine AP	5.7	1.5
Lumbar Spine Lat	10.0	2.5
Abdominal AP	4.4	2.5
Pelvis AP	3.9	2.2

^{*}ESD is absorbed dose in air including backscatter at the point of incidence of the beam axis with the patient entrance surface.

- 3.4.3 For imaging systems with digital detectors, the target range for the EI as recommended by the manufacturer for various diagnostic procedures should be displayed near the acquisition monitor. Any consistent change in the EI should be investigated.
- 3.4.4 New and upgraded digital radiography systems should display the deviation index as per IEC standard 62494-1 to provide radiographers the necessary feedback related to the level of exposure used to create the image. Radiographers should use this feedback to obtain diagnostic images at the lowest possible dose.

3.5. Wet film processing

- 3.5.1 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.
- 3.5.2 Chemicals used for developing and processing X-ray film should be in accordance with manufacturer's recommendations.
- 3.5.3 Unexposed film **must** be stored as per manufacturer's recommendations for temperature and humidity. The film **must** be suitably protected from secondary radiation.
- 3.5.4 Adequate chemistry replenishment should be provided in accordance with the workload of the facility.

3.6. Digital image printing

3.6.1 Where digital images are printed for review or reporting by clinicians, a periodic check of printing quality should be done at appropriate intervals, not exceeding six months. The manufacturer-recommended protocol or section 4.2 of the RANZCR General X-ray QA and QC Guideline should be followed for printer QC.

3.7. Image viewing

- 3.7.1 Viewing conditions should meet the following requirements to ensure proper assessment of image quality and accurate reporting from films (including printed digital images):
 - a. the minimum luminance in the centre and in each quadrant of the illuminator should be >1000 candela/m². All brightness levels within an individual box should be within \pm 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 and 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.
- 3.7.2 For soft copy reporting, the primary monitors should comply with the current RANZCR Standards of Practice.
- 3.7.3 Monitor QC should be performed at an appropriate interval not exceeding six months. Where an auto-QC program is not installed on the primary monitor, the AAPM TG 18-QC test pattern of appropriate image resolution should be available for routine QC. Details of this test pattern and the procedure for monitor QC are discussed in Section 4.1 of the RANZCR General X-ray QA and QC Guideline.

4. Compliance requirements: Bone mineral densitometry

4.1. Radiation warning sign

4.1.1 A radiation warning sign complying with Schedule 6 of the Regulation **must** be displayed on the outside of the entry doors to any room in which a bone mineral density apparatus is installed.

4.2. Markings on X-ray generators and tube assemblies

- 4.2.1 X-ray generators and tube assemblies **must** be permanently marked in English and the markings **must** be clearly visible.
- 4.2.2 X-ray generators **must** bear either:
 - a. the name or trademark of the manufacturer,
 - b. the type or model number.
 - c. the serial number, OR
 - d. an EPA-generated number that links to (a), (b) and (c).
- 4.2.3 X-ray tube assemblies **must** bear either of the following markings in a visible position:
 - a. the name or trademark of the manufacturer of the X-ray tube housing,
 - b. the type or model number of the X-ray tube housing,
 - c. the serial number of the X-ray tube housing, OR
 - d. an EPA-generated number that links to (a), (b) and (c).

4.3. Quality assurance program

- 4.3.1 A quality assurance (QA) program **must** be instituted and maintained.
- 4.3.2 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.
- 4.3.3 QA procedures **must** be standardised and documented in a QA manual.
- 4.3.4 The manufacturer's recommended QC program should be followed. This program should include daily calibration of BMD before clinical use. CRE **must** examine the daily calibration results to determine whether the repeatability of BMD results is within the manufacturer's limits.
- 4.3.5 The practice should have a control chart or data used for tracking BMD variations and an action plan to address variations.
- 4.3.6 Equipment should be maintained and serviced according to manufacturer's recommendations. The service frequency should be at least annually.

5. Test protocols

5.1. Kilovoltage accuracy and reproducibility

Aim

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

Exposure factors

- kVp accuracy: Variable kVp, fixed mA and fixed time (e.g. 200 mA, 0.1s) or fixed mAs.
- kVp reproducibility: Fixed kVp, fixed mA and fixed time or fixed mAs.

Method

- Position the dosimeter at the distance recommended by the manufacturer.
- Collimate to the size of the dosimeter.
- Make a series of exposures across the clinically used kVp range and calculate the difference between the set and measured kVp.
- Make a minimum of three exposures at fixed kVp, mA and time (e.g. 70 kVp, 200 mA, 0.1s) and calculate the coefficient of variation from the quotient of the standard deviation (σ) and mean (\bar{x})

Coefficient of variation
$$=\frac{\sigma}{\bar{x}}$$

Compliance requirement

See section 2.3.

Notes

- Do not use times below 0.1 seconds.
- Follow manufacturer recommendations regarding orientation of the dosimeter with respect to the anode-cathode axis of the X-ray tube.

5.2. Exposure timer accuracy and reproducibility

Aim

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

Exposure factors

- Exposure timer accuracy: Fixed kVp, fixed mA, (e.g. 70 kVp, 200 mA) variable time.
- Exposure time reproducibility: Fixed kVp, fixed mA and fixed time.

Method

- Position the dosimeter at the distance recommended by the manufacturer.
- Collimate to the size of the dosimeter.
- Make a series of exposures commencing at the clinically used shortest exposure time, then
 across the range of commonly used timer settings up to 0.5 seconds and calculate the
 difference in selected and measured time.
- Make a minimum of three exposures at fixed kVp, fixed mA and time (i.e. 70 kVp 200 mA, 0.1 s or similar) and the calculate the coefficient of variation.

Compliance requirement

See section 2.4.

Notes

This test is not required for apparatus where mAs is selected as a single component.

5.3. Radiation output reproducibility

Aim

To determine the variation in radiation output over a number of exposures at the same generator setting.

Exposure factors

70 kVp, 20 mAs or similar.

Method

- Position the dosimeter at a fixed distance (75-100 cm) from the focal spot or at the distance specified by the manufacturer. Record the distance used.
- Place a lead sheet under the dosimeter to minimise backscatter (if applicable; note that some dosimeters are lead-backed).
- Collimate the beam to the size of the dosimeter.
- Make a minimum of three exposures and calculate the coefficient of variation.

Compliance requirement

See section 2.5.1.

Notes

If a unit fails output reproducibility other measurements may be meaningless.

5.4. Radiation output linearity with mA or mAs

Aim

To determine the linearity of the radiation output over a range of mA or mAs settings.

Exposure factors

70 kVp or similar, variable mA, 0.1 s or variable mAs.

Method

- Position the appropriate dosimeter at a fixed distance (75-100 cm) from the focal spot or at the distance specified by the manufacturer. Record the distance used.
- Place a lead sheet under the dosimeter to minimise backscatter (if applicable; note that some dosimeters are lead-backed).
- Collimate the beam to the size of the dosimeter. Make a series of exposures at as many mA or mAs settings as practicable, covering the clinically used range.
- Calculate μGy/mAs (X) by dividing output by the nominal mAs.
- Determine X_{max} and X_{min}
- Calculate the coefficient of linearity:

$$\label{eq:coefficient} \text{Coefficient of linearity=} \frac{X_{max} \text{-} X_{min}}{X_{min} \text{-} X_{max}}$$

The coefficient of linearity must not exceed 0.1.

Compliance requirement

See sections 2.5.2 and 2.5.3.

Notes

- kVp should be measured at each mA setting to assess kVp compensation.
- Linearity should be measured for both/all focal spot(s) sizes as μGy/mAs may vary.

5.5. 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 mAs (e.g 20 mAs).

Method

- Remove all optional or easily removable filtration.
- Position the dosimeter at a fixed distance (75-100 cm) from focal spot or at the distance specified by the manufacturer. Record the actual distance used.
- Place a lead sheet under the dosimeter to minimise backscatter (if applicable; note that some dosimeters are lead-backed).
- Collimate the X-ray beam to the size of the dosimeter.

If using direct meter reading

Make an exposure and record the HVL from the dosimeter.

If using filters and air kerma measurements

- Make three exposures with no filters added (free in air), then calculate the mean air kerma.
- Position a 1 mm thick aluminium filter between the X-ray tube and dosimeter, make an exposure and record the air kerma.
- Repeat the exposures with additional aluminium filters until the measured air kerma falls to less than 50% of the unfiltered air kerma value.

- Plot air kerma against filter thickness using a semi-log scale.
- From the plot, determine the thickness of aluminium corresponding to half of the mean unfiltered air kerma.

Compliance requirement

See section 2.6.1.

Notes

- kVp should be checked before HVL assessment.
- Ensure the entire X-ray beam is intercepted by the filters.
- If the kVp selected for the HVL assessment is different from those listed in **Table 2**, use linear interpolation to estimate the 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.

5.6. Dead-man exposure switch

Aim

To ensure that the exposure is terminated by removing pressure from the exposure switch.

Exposure factors

Low kV, mA, long exposure time (e.g. 0.5 seconds).

Method

- Position the dosimeter in the primary beam at 50 cm or similar from focus.
- Initiate an exposure and release the switch before the exposure terminates.
- Radiation emission **must** cease when the switch is released.
- The dosimeter will indicate the time taken for the exposure to terminate.

Compliance requirement

See section 2.8.

5.7. Backup/Guard timer

Aim

To ensure that the guard timer and/or backup timer are functioning, and the backup time or post exposure mAs do not exceed the specified tolerances.

Exposure factors

Low kVp (e.g. 40-50 kVp).

Method

- Cover the selected AEC sensor with the lead.
- Place the dosimeter in the beam.

 Make an exposure and record the displayed post exposure mAs and the measured exposure time.

Compliance requirement

See section 2.9.2.

Notes

- Use a low mA setting to test time cut off.
- Use a high mA setting to test for mAs cut-off.
- Some systems will activate the guard timer and an error message will be displayed indicating that the dose rate was insufficient to produce a clinical image.

5.8. Automatic Exposure Control reproducibility

Aim

- To assess the variation in radiation output and exposure time for a number of exposures of the same object under AEC.
- To assess the percentage difference in sensitivity of lateral AEC sensors.

Exposure factors

80 kVp, 200 mA or similar.

Method

- Place 1mm of copper or another appropriate absorber at the tube head.
- Place the dosimeter in the beam. If a lead backed dosimeter is used, ensure that the dosimeter is not situated directly in front of the selected AEC sensor.
- Set the SID and focal spot size to typical clinical conditions.
- Select the central AEC sensor and expose.
- Record the measured air kerma, post exposure mAs and displayed air kerma area product (KAP), if available.
- · Repeat twice.
- Repeat for all other AEC sensors.
- Calculate the coefficient of variation for all recorded parameters for each AEC sensor.
- Calculate the percentage difference in either the post exposure mAs and measured air kerma
 of the lateral AEC sensors (Y_{left} and Y_{right}).

Percentage difference (%)=
$$\frac{\left|Y_{left} - Y_{right}\right|}{Y_{mean}} \times 100$$

Compliance requirements

See section 2.9.3 and 2.9.4.

Notes

- For CR, the dosimeter can be placed inside the Bucky next to the CR cassette.
- For DR, the dosimeter should be placed on the detector housing at the periphery of the beam to ensure it does not cover any of the AEC sensors. Ideally the grid should be removed

- At acceptance, any combinations of AEC sensors used clinically should be assessed.
- An estimation of the AEC detector air kerma (DAK) can be made by applying a distance correction and grid factor (if a grid is present) to the air Kerma measurement.
- Use identical technique factors when assessing difference in sensitivity of lateral sensors.
- If there are a total of five AEC chambers, the lateral sensors can be grouped into a left and right pair.

5.9. Automatic Exposure Control: kVp and thickness compensation

Aim

To ensure that the AEC device controls exposure such that the exposure index (EI) is within 20% of the mean EI when both kVp and patient thickness are varied.

Exposure factors

Variable kVp, AEC exposure.

Method

- Place an appropriate absorber at the patient position (10 or 15 cm water or PMMA phantom is recommended).
- Undertake an exposure at a clinically utilised kVp using the central AEC sensor and record the El. Repeat the measurements by varying the kVp across the clinical tube potential range (e.g. 60, 70, 80 etc.).
- Repeat the measurements at 70 kVp by varying the attenuator thickness to mimic the range of attenuations found clinically (e.g. 5 cm, 10 cm, 15 cm & 20 cm of PMMA).
- Determine the mean EI across the kVp range and the mean EI across the range of attenuator thicknesses.
- Determine if the variation in each EI measurement is within 20% of the respective mean EI.

Compliance requirements

See section 2.9.5.

Notes

- Collimation must be fixed during the test as the EI may change with variations in collimation.
- The grid should be present in the beam.
- The relationship between the EI and DAK is not always linear. For non-linear systems, the relationship between the EI and DAK can be obtained simultaneously with the system STP in section 2.10.2. The inverse of this relationship can then be used to linearise the EI measurements to DAK_{EI} which will enable them to be used quantitatively (see Appendix 1). In this case, each DAK_{EI} value should be within 20% of the mean DAK_{EI}.

5.10. Digital image receptors: Signal transfer properties

Aim

To establish the relationship between DAK and mean pixel value (MPV) on digital detectors.

Exposure factors

70 kVp, various mAs.

Method

- Set the X-ray tube above the table top or floor and place the dosimeter in the centre of the X-ray beam at a minimum distance of 130 cm from the tube focus.
- Collimate the X-ray beam to the size of the dosimeter.
- Place an absorber (1 mm copper) at the collimator.
- Make a trial exposure and establish the mAs setting required to result in an air kerma of approximately 10 μGy. Measure the air kerma at a range of mAs settings (typically 1, 4, 10 and 20 μGy).
- Remove the dosimeter and position the detector at the same distance from the focus. The detector should ideally be placed onto a lead apron to minimise backscatter.
- Remove the copper or absorber used and open the collimator to fully cover the detector. Put the absorber back on the collimator.
- Select the acquisition protocol that produces images with minimal clinical processing (flat-field images).
- Expose the entire detector using the mAs pre-set estimated above to give a DAK of ~1 μGy.
 Draw a region of interest (ROI) of approximate size 2 cm x 2 cm in the centre of the image and record the MPV.
- Repeat the above procedure using the mAs presents required to give a range of DAK's of \sim 4, 10 & 20 μ Gy.
- Plot the relationship between DAK and MPV and obtain the detector's STP.

Compliance requirements

See section 2.10.2.

Notes

- Some detectors are integrated into a Bucky/housing that may incorporate a fixed grid. The air kerma measurements will overestimate the DAK on these systems. However, this will not affect the methodology used to ascertain the STP of the detectors.
- ROI analysis can often be completed within the software on the acquisition workstation. However, detectors from certain vendors will require the images to be viewed and analysed on a reporting workstation.
- The exposure index may also be recorded following each exposure. This will enable the relationship between the DAK and EI to be established.

5.11. Digital image receptors: Uniformity and artefacts

Aim

- To quantify the uniformity of the recorded signal from a uniformly exposed digital detector.
- To visually inspect a uniform image for the presence of artefacts.

Method

- View the image obtained in Test 5.10 taken with a DAK of \sim 4 μ Gy on an appropriate reporting workstation.
- Visually inspect the image using 1:1 magnification and a narrow window width to identify any artefacts.

- Draw five ROI's of an approximate size of 2 cm x 2 cm, one in the centre of the image and one
 in the centre of each quadrant. Record the MPV in each ROI.
- Calculate the mean of the MPV's across the five ROI's.
- Calculate the percentage difference between each of the 5 ROI MPV's from the calculated mean MPV.

Compliance requirements

See section 2.10.3 and 2.10.4.

Notes

- If the detectors STP established in test protocol 5.10 is not linear, use the inverse of the STP equation to linearise pixel values to DAK_{MPV} (see Appendix 1).
- ROI analysis can often be completed within the software on the acquisition workstation.
 However, detectors from certain vendors will require the images to be viewed and analysed on a reporting workstation.

To identify any areas of blurring, line defects or stitching artefacts, an image of a fine wire mesh can be obtained using a low kVp (50 kV, 2.5mAs, no copper in the beam) and viewed on a reporting monitor.

5.12. Digital image receptors: Exposure index

Aim

To ensure that the detector EI is repeatable.

Method

- Repeat the 4 μGy exposure in test protocol 5.10 three times and record the EI each time.
- Calculate the coefficient of variation in the EI measurements.

Compliance requirements

See section 2.10.5.

Notes

- For systems with a non-linear EI relationship with DAK, the displayed EI's will need to be linearised to DAK_{EI} prior to being used quantitatively.
- To determine the accuracy of the displayed EI, it is recommended that the manufacturer methodology (where available) is adopted.

5.13. Leakage radiation

Aim

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

Exposure factors

Maximum clinical kVp, with appropriate mAs (time should not exceed one second). Ensure tube rating is not exceeded.

Method

- The collimator should be fully closed or covered with ~ 3 mm of lead.
- Position the dosimeter at 1m from focal spot. Make a series of exposures to measure leakage
 at various positions, including the cathode, the anode and the front of tube assembly.
 Distances other than 1m may be used providing an inverse square law correction is applied.
- Calculate the time averaged leakage using the manufacturer recommended continuous mA rating at the kVp used for the measurement or alternatively, use tube cooling curve data.

Compliance requirements

See section 2.12.1 and 2.12.2.

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.

5.14. Collimation

Aim

- To ensure coincidence of the radiation field with the light field.
- To ensure the alignment of the centre of the light field with the centre of the imaged field.
- To ensure the alignment of the centre of the light field with the image receptor housing markings (when the centre of the image receptor is marked on the receptor housing).
- The X-ray field **must** not exceed the size of the image receptor at the image receptor plane by > 1% of the source to image distance (SID) (when there is provision for automatic adjustment of the collimator).

Exposure factors

60 kVp, 5 mAs or similar.

Method

- Align the X-ray tube to the centre of the detector and set the SID to 100 cm from the focus to the detector plane. The tube detents should be used for positioning when available.
- If the centre of the detector is marked on the housing, calculate the misalignment of the crosswire of the light field with the detector housing markings.
- Place the beam alignment test tool on the detector housing with its central axis aligned with the crosswire of the light field.
- Adjust the light field to alignment markers on test tool or collimate to approximately two-thirds of the detector size and use metal markers to delineate the four edges of the light field.
- Mark either the cathode or anode end of the tube for orientation purposes.
- Expose and process the image.
- Calculate the misalignment between the radiation field and light field for all edges.

- Measure the distance from the centre of the image of the test object to each of the four edges
 of the image. Calculate the misalignment between the centre of the light field and the centre of
 the imaged field.
- If the automatic adjustment of the collimator to the size of the detector is available, confirm that the light field does not exceed the detector at the detector plane by > 1% of the SID.

Compliance requirements

See section 2.14.3, 2.14.4 and 2.14.5.

Notes

- At acceptance and following the replacement of an X-ray tube, the above procedure should be completed using all available focal spot sizes.
- Apply an appropriate correction for magnification if a test tool or alignment markers are placed on the detector housing.
- X-ray assembly and collimator should be visually inspected to assess the perpendicularity before starting alignment test.
- If the alignment of the radiation field and light field is within tolerance, the light field can be used for the purposes of assessing compliance with clause 2.14.5 b.

5.15. Accuracy of air kerma area product meter

Aim

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

Exposure factors

Variable kVp (e.g. 60, 80 or 100), 10 mAs or similar.

Method

- Position the X-ray tube over a table and collimate to ~ 10x10 cm at a distance of 100 cm from the focus of X-ray tube.
- Place the dosimeter at the centre of the X-ray beam.
- Expose using 60 kVp and 10 mAs and record the measured air kerma and displayed KAP.
- Remove the dosimeter and position a CR cassette or portable digital detector at the centre of the X-ray beam without changing distance or collimation.
- Expose using a low level of radiation (direct exposure of digital detectors should be avoided).
- Process the image and measure the irradiated area.
- Multiply the measured air kerma by the measured irradiated area to calculate KAP.
- At acceptance, the above procedure should be repeated at another clinically utilised kVp and using a different collimated area.

Compliance requirements

See section 2.15.2.

Notes

• Be aware of the different KAP units and apply any necessary corrections when comparing the measured and displayed KAP.

- If the X-ray and light field alignment is already established, the exposed area may be inferred using the light field.
- Some systems will not display a KAP unless a digital image receptor has been directly exposed. If this is the case, lead should be used to cover the image receptor when measuring the air kerma using a lead backed dosimeter.

Schedule 1: Compliance requirements for medical radiography apparatus

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

Requirements or Condition	Clause(s)
Advice to person responsible	1.1.1, 1.1.3, 1.1.6, 1.1.8, 1.1.9,
Advice to CRE	1.2.1, 1.2.5
System Performance	2.1.1
Radiation warning sign	2.2.1, 2.2.2, 2.2.3
Accuracy of kilovoltage controls	2.3.1, 2.3.2
Accuracy of timer controls	2.4.1, 2.4.2
Exposure consistency and linearity	2.5.1, 2.5.2, 2.5.3
Filtration	2.6.1, 2.6.2, 2.6.3
Indicators of operation	2.7.1, 2.7.3
Exposure switch	2.8.1, 2.8.2, 2.8.3, 2.8.4
Automatic exposure control	2.9.1, 2.9.2, 2.9.3, 2.9.4,
Digital detectors	2.10.1, 2.10.2 2.10.3, 2.10.4, 2.10.5,
Control of multiple X-ray tubes	2.11.1
Leakage radiation	2.12.1, 2.12.2
Markings on X-ray generators etc.	2.13.1, 2.13.2, 2.13.3
Control of primary beam during radiography	2.14.1, 2.14.2, 2.14.3, 2.14.4, 2.14.5, 2.14.6,
Provision of an air kerma area product meter	2.15.2
Stability of X-ray tube assembly	2.16.1
Stability of mobile apparatus	2.17.1
Capacitor discharge apparatus	2.18.1, 2.18.2, 2.18.3, 2.18.4, 2.18.5, 2.18.6
Quality assurance program	3.1.1, 3.1.3
Wet film processing	3.5.3

Schedule 2: Compliance requirements for bone mineral densitometry apparatus

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

Requirements or Condition	Clause(s)
Advice to person responsible	1.1.1, 1.1.3, 1.1.6, 1.1.8, 1.1.9, 1.1.10
Advice to CRE	1.2.1, 1.2.5,
Radiation warning sign	4.1.1
Markings	4.2.1, 4.2.2, 4.2.3
Quality assurance program	4.3.1, 4.3.3, 4.3.4

Appendix 1

(a) Digital detectors: Signal Transfer Property

In order to obtain meaningful quantitative measurements, a digital detector system **must** have a linearisable relationship between detector air kerma (DAK) and mean pixel value (MPV). This relationship defines the signal transfer property (STP) of the detector. A simple STP relationship (linear, logarithmic or power) should be obtained as specified in compliance test 2.10.2. The equations for these STP relationships and their respective inverses are shown below, where a, b and c are constants, and DAK_{MPV} is the MPV linearised with DAK.

Linear:
$$MPV = a + bDAK \rightarrow DAK_{MPV} = \left(\frac{MPV - a}{b}\right)$$
 [A1.1]

Logarithmic:
$$MPV = a \ln(DAK) + b \rightarrow DAK_{MPV} = exp\left(\frac{MPV - b}{a}\right)$$
 [A1.2]

Power:
$$MPV = aDAK^b + c \rightarrow DAK_{MPV} = \left(\frac{(MPV - c)}{a}\right)^{\frac{1}{b}}$$
 [A1.3]

The inverse STP equations above can be used to obtain the linearised DAK_{MPV} values required for compliance tests 2.10.2 and 2.10.3.

(b) Digital Image Receptors - Exposure Index

Compliance test 2.10.5 requires the repeatability of the exposure index (EI) to be assessed by calculating the coefficient of variation in the EI from a series of exposures. If the detector has a non-linear relationship between DAK and EI, the EI **must** be linearised with DAK.

The EI can simply be interchanged for the MPV in the appropriate equation (A1.1, A1.2 or A1.3) to obtain a linearised EI (DAK_{EI}). The EI measurements can be completed simultaneously using the exposures taken during compliance test 2.10.2.

(c) Automatic Exposure Control - Exposure Index

Compliance test 2.9.6 requires that the EI is recorded and used to check the consistency of the automatic exposure control (AEC) function when varying both tube potential and water/PMMA thickness placed at the patient position. The EI values for all exposures should not vary by more than 20% from the mean EI. This quantitative analysis requires a linear relationship between DAK and EI.

If the detector has a non-linear relationship between DAK and EI, the EI **must** be linearised with DAK. The relationship between DAK and EI established in compliance test 2.10.5 can be used to infer DAK_{EI} from the measured EI values when operating under AEC with the absorber placed at the patient position.

References and further reading

American Association of Physicists in Medicine (AAPM) Task Group 18: Assessment of Display Performance for Medical Imaging systems (deckard.mc.duke.edu/~samei/tg18).

Australian and New Zealand Bone and Mineral Society: *ANZBMS Accreditation Guideline for Bone Densitometry, March 2003.*

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: *ARPANSA National Diagnostic Reference Level Survey User Guide and Newsletters* (www.arpansa.gov.au/services/ndrl/index.cfm).

European Commission Report (2012): Radiation protection No. 162 – Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, European Union Publication.

IEC 62494-1: International Electrotechnical Commission Report (2008): *Medical electrical equipment – Exposure index of digital x-ray imaging systems – Part 1: Definitions and requirements for general radiography.*

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: Digital Imaging Systems*, IPEM Report 32 Part VII, 2010, 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.

The British Institute of Radiology: *Radiation Shielding For Diagnostic Radiology*, Report of a BIR Working Party, 2012, U.K. Publication.

The Royal Australian and New Zealand College of Radiologists: *RANZCR General QA and QC Guideline*, November 2013, Sydney, Australia.

The Royal Australian and New Zealand College of Radiologists: Standards of Practice for Diagnostic and Interventional Radiology, Version 10.1 – 2016.

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.

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.

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.

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

Council means the Radiation Advisory Council.

CRE means Consulting Radiation Expert.

Detector air kerma (DAK) is the kerma measured in a mass of air at the position of the radiographic detector.

Deviation Index is a parameter which quantifies the deviation of an actual exposure index from the appropriate exposure index (called target exposure index) as defined in IEC 62494-1. D = $10.\log \{EI/EI_T\}$ where D is the deviation index, EI is the actual exposure index and EI_T is the target exposure index.

EPA means NSW Environment Protection Authority.

Exposure Index is a number which is a measure of the detector response to radiation in the relevant region of an image acquired with a digital X-ray imaging system.

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.

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.

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 <u>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</u>

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.cm², or similar e.g. mGy.cm², cGy.cm², μGy.m². It is important to make a note of the units 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.

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 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.

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 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.

Target Exposure Index means the expected value of exposure index when the detector is appropriately exposed.

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 (kVpkVp).

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