

Radiation Guideline

6

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

Part 5

**Computed
tomography &
bone mineral
densitometry**



ENVIRONMENT PROTECTION AUTHORITY



Department of
Environment and Conservation (NSW)

This is the Guideline defined in clause 3 of the Radiation Control Regulation 2003 as the 'Computed Tomography and Bone Mineral Densitometry Guideline'. This edition supersedes the Guideline published in August 1999.

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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INTRODUCTION

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

The objects of this Guideline are to:

- provide adequate safety measures to protect patients, occupationally exposed persons and the public from unnecessary radiation exposure
- improve and maintain the standard of radiation apparatus
- ensure better monitoring of apparatus performance
- provide reference dose levels as a guide to patient exposure.

The Computed Tomography and Bone Mineral Densitometry Radiation Guideline is for the information of owners and licensed users of ionising radiation 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 in the assessment of apparatus for registration purposes and should be read in conjunction with the Act and the Radiation Control Regulation 2003. In the event of 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 to be implemented during the medical use of CT scanners and bone mineral densitometers.

The 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 *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*.

1.2 Radiation shielding for CT apparatus

- 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 μ Sv per week for occupationally exposed persons
 - (b) 20 μ Sv per week for members of the general public.
- 1.2.3 A protective shield **must** be provided for use by the operator. The generator or control console **must not** form part of the fixed protective shield.
- 1.2.4 Where a fixed protective shield is provided for use by the operator 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.

1.3 Radiation shielding for densitometers

- 1.3.1 Where beam geometry and patient workload dictate the need for operator protection, a protective shield should be provided.
- 1.3.2 To achieve the requirements of 1.3.1, radiation shielding should be provided such that the radiation levels behind the shielding will not give rise to a dose equivalent greater than:
- (a) 100 μ Sv per week for occupationally exposed persons
 - (b) 20 μ Sv per week for members of the general public.
- 1.3.3 Where a protective shield is provided for use by the operator it **must**, for new installations, be clearly and durably marked with the lead equivalence and the kVp of the x-ray beam at which the lead equivalence was measured.
- 1.3.4 The operator, when behind the protective shield, **must** have a clear view of the patient at all times and **must** be able to communicate easily with the patient undergoing the examination.
- 1.3.5 Where a lead glass or lead acrylic viewing window forms part of the protective shield the lead equivalence of the window and the kVp of the x-ray beam at which the lead equivalence was measured **must**, for new installations, be clearly and durably marked on the window.

1.4 Shielding assessment

- 1.4.1 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.

1.5 Radiation warning sign

- 1.5.1 A radiation warning sign complying with Schedule 5 of the Regulation **must** be displayed on the outside of the entry doors to any room housing a CT or bone mineral densitometer apparatus.
- 1.5.2 A radiation warning light **must** be positioned at the entry doors to all rooms housing CT apparatus, except where a CRE has determined that not to do so would not pose a risk to the safety of any person.
- 1.5.3 Where a radiation warning light is provided, it should illuminate whenever the x-ray tube is placed in the preparation mode before exposure or 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 should be ensured.

1.6 Persons present during CT examination

- 1.6.1 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.

- 1.6.2 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.

1.7 Protective clothing

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

1.8 Markings on x-ray generators and tube assemblies

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

- 1.8.2 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 EPA registration number.

- 1.8.3 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.

Note: Tube details can be confirmed from service records if they are not easily accessible or visible.

SECTION 2—QUALITY ASSURANCE

2.1 Quality assurance program

- 2.1.1 A quality assurance (QA) program approved by a CRE **must** be instituted and maintained.
- 2.1.2 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.
- 2.1.3 QA procedures **must** be standardised and documented in a QA manual.
- 2.1.4 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.

2.2 CT baseline values

- 2.2.1 Baseline values for noise, mean CT number, uniformity, slice thickness, high-contrast resolution and CT dose index should be established at the start of operation and following any maintenance likely to affect these parameters.
- 2.2.2 Values for parameters in clause 2.2.1 should be defined using the appropriate image quality phantoms for all field sizes.
- 2.2.3 CT apparatus should be tested in accordance with the Australian / New Zealand Standard AS/NZS 4184.2.6:1995.
- 2.2.4 Deviations from baseline values should not exceed those given in Table 1.

TABLE 1 ACCEPTABLE DEVIATIONS FROM CT BASELINE LEVELS

Parameter	Deviation
Noise	± 10% or 0.2 HU* (whichever is greater)
Mean CT number	± 4 HU
Uniformity	± 2 HU
Slice thickness	± 1.0 mm for thicknesses > 2.0 mm or ± 50% for thicknesses ≤ 2.0 mm
Dose index	± 20%
High-contrast resolution	± 15% modulation
Couch positioning	± 2.0 mm

* HU = Hounsfield unit

2.3 Diagnostic reference levels

- 2.3.1 Dosimetric evaluation of CT procedures should be conducted as part of the QA program.
- 2.3.2 Dose levels that consistently exceed those in Table 2 should be investigated and justified.

TABLE 2 SOME DIAGNOSTIC GUIDANCE LEVELS FOR CT PROCEDURES¹

Examination	CT Dose Index_w (mGy)*	Dose Length Product (mGy cm)
Routine Head	60	1050
Routine Chest	30	650
Routine Abdomen	35	780
Routine Pelvis	35	570

¹EC, Report EUR 16262, *European Guidelines on Quality Criteria for Computed Tomography*, 1999.

* Part 6 – Test Protocols, Section 11.3 contains details of dose measurement and definitions

2.4 Records

- 2.4.1 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 **must** be included.
- 2.4.2 Records should include necessary information to allow retrospective dose assessment.
- 2.4.3 All QA records, including faults, modifications and maintenance, **must** be made available to the Authority on request.

SCHEDULE 1—REGISTRATION REQUIREMENTS FOR COMPUTED TOMOGRAPHY AND BONE MINERAL DENSITOMETRY APPARATUS

The clauses contained in this Schedule are the requirements referred to in section 7(5) of the Act that the apparatus **must** meet before the apparatus will be registered.

Requirement	Clause(s)
Radiation shielding CT	1.2.3, 1.2.4, 1.2.5, 1.2.6
Radiation shielding densitometers	1.3.3, 1.3.4, 1.3.5
Radiation warning sign	1.5.1, 1.5.2, 1.5.3
Markings of generator and tube assemblies	1.8.1, 1.8.2, 1.8.3
Quality assurance program	2.1.1, 2.1.3
Records	2.4.1, 2.4.3

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 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, below.

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.

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 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, the following British Standards should be consulted:

- 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

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.

European Commission, 1999, *European Guideline on Quality Criteria for Computed Tomography*, Report EUR 16262 EN.

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.

Standards Australia/Standards New Zealand, 1995, *Australian/New Zealand Standard: Evaluation and Routine Testing in Medical Imaging Departments, Part 2.6: Constancy tests—X-ray Equipment for Computed Tomography*, AS/NZS 4184.2.6:1995.

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:

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*.

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

Apparatus means computed tomography scanner, bone mineral densitometer or both.

Authority means the NSW Environment Protection Authority.

CRE means consulting radiation expert.

CT means computed tomography.

CT dose index means integral of the dose profile along a line perpendicular to the tomographic plane from $-7T$ to $+7T$ (where T is the nominal slice thickness), divided by the product of the nominal slice thickness and the number of tomograms (N) produced in a single scan.

CT number means the number used to represent the mean x-ray attenuation associated with each elemental area of the CT image. It is normally expressed in Hounsfield units.

Densitometer means a bone mineral densitometer emitting x-radiation for the purposes of determining bone mineral density.

Dose profile means a representation of the dose as a function of the position along a line perpendicular to the tomographic plane.

EPA means the Environment Protection Authority.

High contrast resolution means the ability to resolve different objects in the displayed image, when the difference in attenuation between the objects and the background is large compared to noise. Also known as spatial resolution.

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.

Mean CT number means the mean value of the CT numbers of all pixels within a certain defined region of interest.

Noise means the variation of CT numbers from a mean value in a defined area in the image of a uniform substance.

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

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

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

Pencil beam means the x-ray beam collimated so as to produce a point source of radiation for bone densitometry.

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.

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 different direction from, that of the original incident ionising radiation.

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.