

A decorative graphic on the right side of the page consisting of a pattern of orange hexagons. The pattern is arranged in a way that it appears to be peeling away from the white background, following a diagonal line that runs from the top right towards the bottom left. The hexagons are of varying shades of orange and are arranged in a somewhat irregular, honeycomb-like structure.

Final Draft

Radiation Guideline 6: Compliance requirements for ionising radiation apparatus used in diagnostic imaging

Part 5: Computed Tomography

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Introduction

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

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

The objectives 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 optimising patient exposure.

This guideline for computed tomography is for the information of the person responsible and licensed users of ionising radiation 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 in the assessment of apparatus for compliance with conditions of the radiation management licence and should be read in conjunction with the Act and the Radiation Control Regulation 2013. In the event of 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.

This document sets out the minimum requirements for satisfactory compliance 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.

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

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1. General requirements and recommendations

1.1 Advice to person responsible

- 1.1.1 Compliance testing of diagnostic imaging apparatus for the purpose of certification **must** be conducted by an EPA-accredited Consulting Radiation Expert (CRE).
- 1.1.2 Requirements listed in Schedule 1 of this guideline **must** be met for compliance of CT scanners.
- 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 are discussed in section 3 of this guideline).
- 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 A protective shield **must** be provided for the operator's use.
- 1.1.6 Where a fixed protective shield is provided it should be not less than 2100 mm in height.
- 1.1.7 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.
- 1.1.8 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.
- 1.1.9 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.
- 1.1.10 All protective clothing used **must** comply with the requirements of the EPA *Policy on x-ray protective clothing*.

1.2 Advice to Consulting Radiation Expert

- 1.2.1 A CRE **must** ensure that any radiation monitoring device used for compliance testing is:
- suitable for the type of measurement for which it is to be used
 - used only when it is fully operational and properly calibrated
 - capable of measuring the type of radiation being assessed over the range of energies and dose rates required
 - calibrated at least every two years to an Australian or international primary or secondary standard satisfactory to the manufacturers' requirements.
- 1.2.2 The following test equipment may be required to carry out compliance testing:
- a radiation meter/detector

- a pencil ionisation chamber
- a CT phantom specific to the manufacturer/model of the CT scanner
- a head and/or body phantom suitable for the measurement of the CT Dose Index (CTDI)

1.2.3 Manufacturer-specific acquisition protocols will be required for the testing of CT image quality and for the measurement of CT dose index.

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: Computed tomography

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 guideline.

Table 1: Tests required for computed tomography

Compliance Requirement	Test	Acceptance	2-yearly	After tube replacement	After detector replacement
2.2	Radiation warning sign	✓	✓	✗	✗
2.3	Markings on x-ray generators and CT gantry	✓	✓	✓	✗
2.4	Termination of exposure	✓	✓	✗	✗
2.5	Indicators of operation	✓	✓	✗	✗
2.6	Mechanical accuracy	✓	✓	✓	✗
2.7	X-ray beam quality	✓	✓	✓	✗
2.8	Image quality	✓	✓	✓	✓
2.9	Radiation dosimetry	✓	✓	✓	✓

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 room housing CT apparatus.
- 2.2.2 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.
- 2.2.3 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 the beam is being produced. 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 Markings on x-ray generators and CT gantry

- 2.3.1 X-ray generator and gantry **must** be permanently marked in English and the markings must be clearly visible.
- 2.3.2 X-ray generators **must** bear either:
- the name or trademark of the manufacturer, and
 - the type or model number, and
 - the serial number, or
 - an EPA-generated number that links to (a), (b) and (c).
- 2.3.3 Gantry **must** bear either of the following markings in a visible position:
- the name or trademark of the manufacturer of the x-ray tube housing and insert, and
 - the type or model number of the x-ray tube housing and insert, and
 - the serial number of the x-ray tube housing and insert, or
 - EPA-generated number (s) that links to (a), (b) and (c).

2.4 Termination of exposure

- 2.4.1 Means **must** be provided so that the operator can terminate the exposure at any time during a scan.

2.5 Indicators of Operation

- 2.5.1 Beam on indicator

A visible signal **must** be displayed at the control panel and on the gantry to indicate when the X-ray tube is energised.

- 2.5.2 Audible signal

Provision should be made for an audible signal at the location from which the equipment is operated to indicate the duration or termination of the exposure.

2.6 Mechanical accuracy

- 2.6.1 Light localisation accuracy

The error of the scan localisation lights and the scan plane **must** not exceed ± 2 mm.

- 2.6.2 Scout localisation accuracy

The error in the correspondence of localisation image parameters with the actual slice position **must** not exceed ± 2 mm with the gantry in the vertical position.

- 2.6.3 Coronal and sagittal plane lights

The coronal and sagittal plane lights **must** intercept at the $x = 0, y = 0$ on the corresponding axial image. The error **must** not exceed ± 2 mm.

2.6.4 Axial scan incrementation accuracy

When the scanner is used in axial mode, the incrementation accuracy between successive axial slices **must** not exceed ± 1 mm.

2.6.5 Couch positioning accuracy

The couch positioning accuracy **must** not deviate by more than ± 2 mm.

2.7 X-ray beam quality

2.7.1 The first half value layer in the x-ray beam incident to the patient **must** be verified by direct measurement or inspection of service documents and **must** be greater than or equal to:

- a) 3.2 mm of aluminium at 120 kVp; or
- b) 3.5 mm of aluminium at 130 kVp; or
- c) 3.8 mm of aluminium at 140 kVp.

2.8 Image quality

2.8.1 Baseline values

Baseline values for noise, mean CT number, uniformity, reconstructed slice thickness and high contrast resolution **must** be established when the equipment is first brought into use or following any maintenance likely to affect these parameters (including tube change).

Note:

1. These figures can be provided by the supplier.
2. If these figures have not yet been determined the tests must be carried out at the first compliance test to establish them in accordance with the manufacturer-recommended protocols. As such, the requirements specified in section 2.8.4 do not apply for that initial test. This **must** be noted in the assessment report.
3. When establishing baseline values, the same test procedures, test conditions and test device **must** be used for future tests. All selectable values of scan parameters, the area of the test device to be imaged and the position of the test device during irradiation **must** be recorded in the assessment report.

2.8.2 Tests in 2.8.1 should be performed in accordance with the manufacturer-recommended protocols.

2.8.3 Values for parameters in clause 2.8.1 **must** comply with manufacturer's specifications.

2.8.4 Values of reconstructed slice thickness **must** be within the following limits: ± 1.0 mm for thicknesses > 2.0 mm or $\pm 50\%$ for thicknesses ≤ 2.0 mm.

2.8.5 Deviations from baseline values **must** not exceed those given in Table 2.

Table 2: 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
High-contrast resolution	± 15% modulation

* HU = Hounsfield unit

2.9 Radiation dosimetry

2.9.1 Baseline values

Baseline values of CT dose index in air for all clinical kV settings and typical slice thicknesses **must** be established when the equipment is first brought into use or following any maintenance likely to affect these parameters (including tube change).

2.9.2 Subsequent CT dose index in air **must** be measured using the same parameters and must be within ±10% of the baseline values.

2.9.3 The weighted CT dose index (CTDI_w) should be measured using Perspex phantoms.

2.9.4 Measured values of CTDI_w should be within 20 per cent of the manufacturer's specifications.

2.9.5 The volume CTDI (CTDI_{vol}) and the Dose Length Product (DLP) **must** be available to the operator and recorded with the CT images.

3 Quality assurance and recommendations for best practice

3.1 Quality assurance program

- 3.1.1 A quality assurance (QA) program approved by a CRE **must** be instituted and maintained. Where no QA program is in place, a CRE should make appropriate recommendations.
- 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.
- 3.1.4 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.
- 3.1.5 The QA program **must** include a weekly measurement in a water phantom of the CT number in water and the image noise.
- 3.1.6 The CT number of water **must** be 0.0 ± 4 HU.
- 3.1.7 Equipment should be maintained and serviced according to manufacturer's recommendations. The service frequency should be at least annually.

3.2 Diagnostic reference levels

- 3.2.1 A dosimetric evaluation of routine CT procedures **must** be conducted as part of the QA program at least every two years. This should include both paediatric and adult procedures.
- 3.2.2 Average patient values for CTDI_{vol} in mGy and DLP in mGy.cm should be assessed against the current Australian National Diagnostic Reference Levels for MDCT as published by the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) on their website.
- 3.2.3 Dose levels that consistently exceed the national DRLs should be investigated and, appropriate action taken.
- 3.2.4 The results of the dosimetric comparison and any subsequent actions taken **must** be recorded and be available to the Authority and to a CRE on request.

3.3 Inspection and testing of x-ray protective clothing

- 3.3.1 The QA program **must** include regular testing of x-ray protective clothing as required in the EPA *Policy on X-ray Protective Clothing*.

3.4 Records

- 3.4.1 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.

3.4.2 All QA records, including faults, modifications and maintenance, **must** be made available to the Authority on request.

3.5 Test protocols

3.5.1 Test protocols are currently being developed

Schedule 1: Compliance requirements

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.

Requirement	Clause(s)
Advice to person responsible	1.1.1, 1.1.2, 1.1.3, 1.1.5, 1.1.7, 1.1.8, 1.1.9,1.1.10
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
Markings of x-ray generators and tube assemblies	2.3.1, 2.3.2, 2.3.3
Termination of exposure	2.4.1
Indicators	2.5.1
Mechanical accuracy	2.6.1, 2.6.2, 2.6.3, 2.6.4, 2.6.5
X-ray beam quality	2.7.1
Image quality	2.8.1, 2.8.3, 2.8.4, 2.8.5
Radiation dosimetry	2.9.1, 2.9.2, 2.9.5
Quality assurance program	3.1.1, 3.1.3, 3.1.5, 3.1.6
Diagnostic reference levels	3.2.1, 3.2.4
Testing of X-ray protective clothing	3.3.1
Records	3.4.1, 3.4.2

References and further reading

Australian Radiation Protection and Nuclear Safety Agency *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (2008)*, Radiation Protection Series Publication No. 14.

Australian Radiation Protection and Nuclear Safety Agency *Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology (2008)*, Radiation Protection Series Publication No. 14.1.

Standards Australia/Standards New Zealand, 1996, *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/Amdt 1:1996.

Australian National Adult Diagnostic Reference Levels for MDCT
www.arpana.gov.au/services/NDRL/adult.cfm, accessed 25 November 2015.

Institute of Physics and Engineering in Medicine, *Measurement of the Performance Characteristics of Diagnostic X-ray Systems used in Medicine. Report No. 32, second edition, Part III: Computed Tomography X-ray Scanners (2003)*, IPEM York.

American Association of Physicists in Medicine, *Specification and Acceptance Testing of Computed Tomography Scanners, Rep. 39*, AAPM, New York (1993).

American Association of Physicists in Medicine, *The Measurement, Reporting and Management of Radiation Dose in CT, Rep. 96*, AAPM, New York (2008).

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. **Authority** means the NSW Environment Protection Authority.

Barrier means any wall, door, protective shield etc. between the CT scanner and an adjacent area.

CRE means Consulting Radiation Expert.

CT means computed tomography.

CT dose index means the integral of the dose profile along a line perpendicular to the tomographic plane. It should be measured using a 10 cm chamber and expressed as $CTDI_{100}$ which means that the limits of integration are from -5 cm to +5 cm. The measured air kerma should be multiplied by the length of the chamber (100 mm) and divided by the product of the nominal slice thickness and the number of tomograms ($n.T$) produced in a single scan.

CTDI_w, weighted CTDI means the value obtained by summing one-third of the CTDI at the centre of a standard head or body phantom and two-thirds of the CTDI at the periphery of the phantom, expressed in mGy.

CTDI_{vol} means the $CTDI_w$ divided by the scan pitch and represents the average absorbed dose in the scan volume, expressed in mGy.

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.

DLP, Dose Length Product means the product of the $CTDI_{vol}$ and the scan length, expressed in mGy.cm.

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

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

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.

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 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.

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 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.