Draft Radiation Guideline 6
Compliance requirements and industry best practice for ionising radiation apparatus used in diagnostic imaging

Part 5
Computed Tomography
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Definitions
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 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 optimising patient exposure.

This guideline for computed tomography is for the information of owners (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 testing 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 Radiation Regulation Unit of the Environment Protection Authority (NSW) in consultation with the Radiation Advisory Council.

The Environment Protection Authority (NSW) acknowledges the assistance of A/Prof Lee Collins, Dr Richard Smart, Dr Philip Pasfield, Mr Paul Cardew, Dr Jennifer Diffey, Dr Ravinder Grewal, Mr Glen Burt and Ms Tiffany Chiew, Mr Adam Jones and the input received from stakeholders, in preparing this edition.
Draft Radiation Guideline 6 – Computed Tomography

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 and quality control program are discussed in section 3 of this guideline).

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

1.2.4 All measurements should be in SI units (i.e. Gy for absorbed dose). All radiation output measurements should be recorded as absorbed dose in air (1R = 8.73 mGy in air).

1.2.5 A Certificate of Compliance must be completed and provided to the owner within a time not exceeding 21 days from the date of compliance testing, regardless of whether the apparatus has passed or failed.

1.2.6 The CRE conducting the compliance test must issue the owner a signed report (including readings and calculations) detailing non-compliance with any mandatory requirements and recommendations.

1.2.7 The report must include details of the test protocols (if significantly different from those outlined in this guideline) and test equipment used (including the date equipment was last calibrated).
1.2.8 The report should note any mandatory requirements that are not applicable to the apparatus.

1.2.9 The report may include recommendations relating to matters outside mandatory requirements listed in Schedule 1 of this guideline (for example, recommended best practice).

1.2.10 Where an apparatus fails to comply with a mandatory requirement but may be safely used while the fault is corrected, a CRE may, at their discretion, certify the equipment as compliant. In exercising this discretion a CRE should specify a deadline (not exceeding three months) for the apparatus to be brought to full compliance and may impose restrictions on the use of the apparatus until it is repaired.

1.3 Advice to operators

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

1.3.2 The only persons who should be present in the room during the CT 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.

1.3.3 Mechanical immobilisation or supporting devices should be used wherever possible.

1.3.4 All protective clothing used must comply with the requirements of the EPA Policy on x-ray protective clothing.

2 Compliance requirements and recommendations for best practice: Computed tomography

2.1 Radiation shielding

2.1.1 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.

2.1.2 To achieve the requirements of Guideline 7, 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 μSv per week for occupationally exposed persons

(b) 20 μSv per week for members of the general public.
2.1.3 A protective shield **must** be provided for the operator's use. The generator or console **must** not form part of the fixed protective shield.

2.1.4 In the case of new installations, all barriers **must** be clearly and durably marked with the lead equivalent and the kVp of the x-ray beam at which the lead equivalent was measured.

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

2.1.6 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.

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

### 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 tube assemblies

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:
   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).

2.3.3 Gantry **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).
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**

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 **must** 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 scan localisation lights and 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 Values for parameters in clause 2.8.1 should be defined using the appropriate image quality phantoms for all field sizes.

2.8.3 Tests in 2.8 should be performed in accordance with the manufacturer-recommended protocols.

2.8.4 Deviations from baseline values must not exceed those given in Table 1.

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<th>Deviation</th>
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<td>Noise</td>
<td>± 10% or 0.2 HU* (whichever is greater)</td>
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<tr>
<td>Mean CT number</td>
<td>± 4 HU</td>
</tr>
<tr>
<td>Uniformity</td>
<td>± 2 HU</td>
</tr>
<tr>
<td>Reconstructed slice thickness</td>
<td>± 1.0 mm for thicknesses &gt; 2.0 mm or ± 50% for thicknesses ≤ 2.0 mm</td>
</tr>
<tr>
<td>High-contrast resolution</td>
<td>± 15% modulation</td>
</tr>
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</table>

* 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 (CTDIw)** should be measured using Perspex phantoms.

2.9.4 Measured values of CTDIw should be within 20 per cent of the manufacturer’s specifications.

2.9.5 **The volume CTDI (CTDIvol)** 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.

3.2 **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 CTDIvol 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 Records

3.3.1 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.

3.3.2 All QA records, including faults, modifications and maintenance, must be made available to the Authority on request.
Schedule 1 – Compliance requirements: Computed tomography

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.

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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.

**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<sub>100</sub> 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<sub>w</sub>, 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<sub>vol</sub>** means the CTDI<sub>w</sub> 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<sub>vol</sub> 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<sub>r</sub> by dm, where dE<sub>r</sub> 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<sub>r</sub>/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 7 of the Act to use ionising radiation apparatus.

Person responsible means a person licensed to which Section 6.1 of the Act applies.

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

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

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.