Test Protocol for Medical and Veterinary Computed Tomography X-ray Apparatus 2016

Published by the Environment Protection Authority of South Australia on 5 February 2016.

This protocol provides the mandatory requirements for an accredited tester compliance testing medical and veterinary X-ray apparatus capable of computed tomography.

It should be read in conjunction with the Radiation Protection and Control Act 1982 (the Act) and the Radiation Protection and Control (Ionising Radiation) Regulations 2015 (the regulations).

Citation

This protocol may be cited as the Test Protocol for Medical and Veterinary Computed Tomography X-ray Apparatus 2016.

Part 1—Interpretation

In this protocol, unless the contrary intention appears—

accredited tester means a person performing compliance testing who is a holder of an accreditation as a third party service provider under section 33B of the Act;

aperture means a gap in the protective material of a tube housing through which ionising radiation from an X-ray tube within the tube housing may pass with little or no attenuation;

apparatus means ionising radiation apparatus;

computed tomography dose index means a measure of dose value as defined in section 2.106 of the Australian / New Zealand Standard, Medical Equipment, Part 2.44: Particular requirements for safety—X-ray equipment for computed tomography [AS/NZS 3200.2.44:2005];

EPA means the Environment Protection Authority, South Australia;

exposure parameters means X-ray tube potential, X-ray tube current, and exposure time or a combination thereof;

fixed, in relation to apparatus, means any apparatus that is neither a mobile apparatus nor a portable apparatus;

general objective means the requirements under section 23 of the Act. Applicable sections are indicated by the symbol †;

ioscentre means the space through which the central ray of the X-ray beam passes through the intersection of the apparatus gantry’s axis of rotation. In relation to a cylindrical gantry, the isocentre is at the centre of the gantry bore;

mobile, in relation to apparatus, means apparatus that is designed and constructed so as to be moveable from place to place for use as required but does not include a portable apparatus;
**portable, in relation to apparatus**, means any **apparatus** that is designed to be carried manually from place to place for use as required;

**PMMA** means polymethyl methacrylate;

**primary beam** means that part of the X-radiation that passes through an **aperture** of an **X-ray tube housing** by a direct path from an **X-ray tube**;

**tube housing**, in relation to an ionising radiation **apparatus**, 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;

**X-ray tube**, in relation to an ionising radiation **apparatus**, means an evacuated glass envelope in which electrons are accelerated for the purposes of the production of ionising radiation.

### Part 2—General requirements

1—Application of protocol

This protocol applies to **fixed** and **mobile** medical and veterinary X-ray **apparatus** capable of **computed tomography**.

2—Exemptions applicable to this protocol

There are no exemptions applicable to this protocol.

3—Complying with this protocol

The **accredited tester** must—

(a) perform compliance testing in accordance with the test methods specified in Part 3; and

(b) provide in a report—

(i) the details as specified in sections 4 to 7; and

(ii) the parameters used and results obtained for the compliance tests performed under Part 3, including but not limited to—

1) the value of the **computed tomography dose index** in air, as specified by the manufacturer of the **apparatus** or approved by the **EPA** (refer section 15); and

2) the value of the **computed tomography dose index** with a phantom, as specified by the manufacturer of the **apparatus** or approved by the **EPA** (refer section 16); and

(c) complete the approved **Certificate of Compliance for Medical and Veterinary Computed Tomography X-ray Apparatus** document.

4—Owner details

Record, where known, the contact details of the owner of the **apparatus** including at least—

(a) the name of the owner; and

(b) the address of the owner; and

(c) the telephone number of the owner.

5—Apparatus details

Record the details of the **apparatus** including at least—

(a) the make and model of the **apparatus**; and

(b) the serial number—

(i) of the generator, where it is practical to do so; and
(ii) the serial number of the X-ray tube, where it is practical to do so; and
(iii) the serial number of the tube housing, where it is practical to do so; and
(c) the location of the apparatus (e.g. surgery 1, room 1).

6—Accredited tester details

Record the details of the accredited tester including at least—
(a) the name of the accredited tester; and
(b) the accreditation number of the accredited tester; and
(c) the date on which the accredited tester performed the compliance tests.

7—Test instrument details

Record for each test instrument used, at least—
(a) the make and model; and
(b) the serial number; and
(c) the date of the next calibration or the date of the last calibration.

Part 3—Fixed and mobile apparatus

8—Apparatus to be in good working order

8.1 Test method

Verify that there is no abnormality, fault, or condition, that is not subject to another section of this protocol, that prevents the apparatus from functioning or performing in a manner for which it has been designed.

8.2 Legislative reference

Regulation 8(2) of the regulations is applicable.

9—Labelling of apparatus

9.1 Test method

Verify that the apparatus has a label—
(a) that complies with the requirements of AS 1319–1994 Safety Signs for the Occupational Environment applying to warning signs; and
(b) bears the words “RADIATION PRODUCED WHEN ENERGISED” or words to that effect; and
(c) bears the radiation symbol as specified in Schedule 1; and
(d) is clearly legible at a distance of 2 metres.

9.2 Legislative reference

Regulation 63 of the regulations is applicable.

10—Radiation area sign

10.1 Test method

(1) Verify that a sign is clearly displayed, at each entrance, walkway or access route to the room or area in which the apparatus is located—other than an entrance to the room from a place or another room which can only be entered from the room.

(2) Verify that the sign—

(a) complies with the requirements of AS 1319–1994 Safety Signs for the Occupational Environment applying to warning signs; and
(b) if it does bear words, the words are "RADIATION AREA" or "X-RAYS" sign or words of similar effect; and
(c) has a total surface area of not less than 4500 square millimetres; and
(d) bears the radiation symbol as specified in Schedule 1; and
(e) is clearly legible at a distance of 2 metres.

10.2 Legislative reference
Regulation 64 of the regulations is applicable.

11—Exposure parameters†

11.1 Test method
Verify that the values of the selected exposure parameters are clearly indicated on the control panel by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

11.2 Legislative reference
The general objective is applicable.

12—Warning device†

12.1 Test method
Verify that when the X-ray tube is energised there is a warning device that consists of—
(a) a red or amber light that is clearly distinguishable from the operator position; and
(b) an audible signal that is audible from that operator position and indicates either the duration or termination of the exposure.

12.2 Legislative reference
The general objective is applicable.

13—Exposure termination†

13.1 Test method
Verify that the apparatus is fitted with a device that will terminate the exposure after a preset—
(a) time interval; or
(b) product of X-ray tube current and exposure time; or
(c) programmed exposure; and
(d) allows the operator to interrupt the radiation exposure at any time.

13.2 Legislative reference
The general objective is applicable.

14—Slice thickness†

14.1 Test method
(1) Configure the apparatus for an axial scan.
(2) For a range of set slice thicknesses, verify the measured slice thickness of the X-ray field at the isocentre, is within the value of the slice thickness limits specified in Table 1.

<table>
<thead>
<tr>
<th>Selected slice thickness</th>
<th>Slice thickness limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>less than or equal to 2 millimetres</td>
<td>±50 percent of the selected slice thickness</td>
</tr>
<tr>
<td>greater than 2 millimetres</td>
<td>±1.0 millimetres of the selected slice thickness</td>
</tr>
</tbody>
</table>
14.2 Legislative reference
The general objective is applicable.

15—Computed tomography dose index in air†

15.1 Test method
(1) Configure the apparatus for an axial scan at a suitable slice thickness (e.g. 10 millimetres).
(2) Set the exposure parameters to values that are compatible with those used by the manufacturer of the apparatus for such a test.
(3) Using a 100 millimetre ionisation pencil probe (or equivalent) determine the value of the normalised computed tomography dose index (i.e. $n_{\text{CTDIair}}$) at the isocentre.
(4) Verify that the $n_{\text{CTDIair}}$ does not exceed the manufacturer's specifications by more than 20%.

15.2 Legislative reference
The general objective is applicable.

16—Computed tomography dose index with a phantom†

16.1 Test method
(1) Configure the apparatus for an axial scan at a suitable slice thickness (e.g. 10 millimetres).
(2) Set the exposure parameters to values that are compatible with those used by the manufacturer of the apparatus for such a test.
(3) Using a 100 millimetre ionisation pencil probe (or equivalent) and a 16 centimetre PMMA head phantom or a 32 centimetre PMMA body phantom, determine the value of the normalised computed tomography dose index (i.e. $n_{\text{CTDIw}}$) at the isocentre.
(4) Verify that the $n_{\text{CTDIw}}$, does not exceed the manufacturer's specifications by more than 20%.

16.2 Legislative reference
The general objective is applicable.

17—Mean CT number, uniformity, and image noise†

17.1 Test method
(1) Configure the apparatus for an axial scan.
(2) Using a water phantom, measure the mean and standard deviations of the CT number of the phantom image in regions of interest representing water.
(3) Verify that the mean CT number, uniformity, and the image noise are within the limits specified in Table 2.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean CT number</td>
<td>$0 \pm 4$ hounsfield units</td>
</tr>
<tr>
<td>Uniformity</td>
<td>$\pm 2$ hounsfield units</td>
</tr>
<tr>
<td>Image noise</td>
<td>$\pm 10$ percent or $0.2$ hounsfield units (whichever is larger)</td>
</tr>
</tbody>
</table>

17.2 Legislative reference
The general objective is applicable.

18—High contrast spatial resolution†

18.1 Test method
Using a suitable high contrast test phantom (e.g. line pair patterns or similar) verify that the high contrast spatial resolution is within the value specified by the manufacturer of the phantom.
18.2 Legislative reference

The general objective is applicable.

19—Low contrast resolution†

19.1 Test method

Using a suitable low contrast test phantom (e.g. representative objects of water, fat, soft tissue, bone, and air or similar) verify that the low contrast resolution is within the value specified by the manufacturer of the phantom.

19.2 Legislative reference

The general objective is applicable.
Schedule 1—Radiation symbol

(1) The radiation symbol consists of the conventional three blade design shown below.

(2) The symbol and background colours must comply with the requirements of AS 1319–1994 Safety Signs for the Occupational Environment.

'D' is the diameter of the central circle.