Test Protocol for Dental Cone-beam Computed Tomography X-ray Apparatus 2016

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This protocol provides the mandatory requirements for an accredited tester compliance testing dental cone-beam computed tomography X-ray apparatus including apparatus capable of both cone-beam computed tomography and panoramic radiography and apparatus capable of both cone-beam computed tomography and cephalometric radiography.

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 Dental Cone-beam 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;

cephalometric radiography means radiography for the purposes of measurement of the human head;

EPA means the Environment Protection Authority, South Australia;

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

fixed protective screen means a protective screen that is firmly in position and not readily removable;

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

member of the public means a person who is not a radiation worker;

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;

panoramic radiography means radiography of the mandible and the maxilla performed by the controlled rotation of an extra-oral X-ray tube and an extra-oral image receptor around one or more axes in relation to the patient’s head;
portable, in relation to apparatus, means any apparatus that is designed to be carried manually from place to place for use as required;

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

protective screen means a barrier that includes radiation shielding material that has a shielding capacity that conforms to the dose limits of Schedule 2;

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;

radiation worker means a person who by reason of his or her profession, trade or occupation—
(a) uses any source of ionising radiation; or
(b) is directly involved in any activity or operation in which any source of ionising radiation is used and who may be exposed to ionising radiation from that source as a result of being directly involved in such activity or operation; or
(c) is a designated employee; or
(d) is directly involved in the transport of a radioactive substance and is likely in the course of that profession, trade or occupation to receive an annual effective dose in excess of 1 millisievert;

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 dental X-ray apparatus capable of cone-beam computed tomography, including—
(a) apparatus capable of both cone-beam computed tomography and panoramic radiography; and
(b) apparatus capable of both cone-beam computed tomography and cephalometric radiography.

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 Part 4; and
(b) provide in a report—
(i) the details as specified in sections 4 to 8; and
(ii) the test parameters used and results obtained for the compliance tests performed under Part 3 and Part 4; and
(iii) complete the approved Certificate of Compliance for Dental Cone-beam Computed Tomography X-ray Apparatus document; and
(c) in the case of an apparatus capable of panoramic radiography or cephalometric radiography, comply with the requirements of the Test Protocol for Dental Panoramic and Cephalometric X-ray Apparatus 2016 document, as in force from time to time.
4—Owner details

Record, where known, the 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.

8—Floor Plan

(1) Make a floor plan of the area in which the apparatus is located. Note that it does not need to be to scale. The floor plan must indicate at least—
   (a) the location of the apparatus within the area; and
   (b) the location of windows (if installed); and
   (c) the location of doors and any entrances used to directly access the area; and
   (d) the location of the operator’s protective screen (if applicable); and
   (e) the location of the normal operator position; and
   (f) the approximate dimensions of important features, including the immediate area in which the apparatus is located and the distance from the apparatus to the normal operating position.

(2) The floor plan, referred to in subsection (1), must be annotated such that it clearly identifies adjoining areas, including but not limited to—hallways, reception areas, offices, staff rooms, store rooms, adjacent surgeries, external car parks, external walk ways, and adjacent businesses.
Part 3—Construction and installation requirements for fixed apparatus

9—Apparatus to be in good working order

9.1 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.

9.2 Legislative reference
Regulation 8(2) of the regulations is applicable.

10—Labelling of apparatus

10.1 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 3; and
(d) is clearly legible at a distance of 2 metres.

10.2 Legislative reference
Regulation 63 of the regulations is applicable.

11—Radiation area sign

11.1 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 3; and
(e) is clearly legible at a distance of 2 metres.

11.2 Legislative reference
Regulation 64 of the regulations is applicable.

12—Radiation field size†

12.1 Test method
Verify that for all selectable collimation settings, the boundary dimensions of the delivered radiation field at the image receptor is no more than 1.5 percent greater than the boundary dimensions of the selected radiation field.

12.2 Legislative reference
The general objective is applicable.
13—Beam to detector congruence†

13.1 Test method
Verify that the primary beam does not fall outside the boundaries of the image receptor.

13.2 Legislative reference
The general objective is applicable.

14—Exposure parameters†

14.1 Test method
Verify that the values of the selected X-ray tube potential, X-ray tube current, and exposure time or a combination thereof are clearly indicated on the control panel by means of analogue meters, digital displays or scales, or by calibrated permanent markings.

14.2 Legislative reference
The general objective is applicable.

15—Warning device†

15.1 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 an operator position that complies with the requirements of section 22; and
(b) an audible signal that is audible from that operator position and indicates either the duration or termination of the exposure.

15.2 Legislative reference
The general objective is applicable.

16—Exposure termination†

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

16.2 Legislative reference
The general objective is applicable.

17—Half value layer†

17.1 Test method
(1) For a range of set X-ray tube potentials, measure the half value layer of the primary beam.
(2) Verify that the measured half value layer, for the selected tube potential, is not less than value specified in Table 1.

<table>
<thead>
<tr>
<th>Indicated X-ray tube potential (kilovolts peak)</th>
<th>Half value layer (millimetres of Aluminium)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
<td>0.3</td>
</tr>
<tr>
<td>40</td>
<td>0.4</td>
</tr>
<tr>
<td>Indicated X-ray tube potential (kilovolts peak)</td>
<td>Half value layer (millimetres of Aluminium)</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>49</td>
<td>0.5</td>
</tr>
<tr>
<td>50</td>
<td>1.2</td>
</tr>
<tr>
<td>60</td>
<td>1.3</td>
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<tr>
<td>70</td>
<td>1.5</td>
</tr>
<tr>
<td>71</td>
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<tr>
<td>80</td>
<td>2.3</td>
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<td>2.5</td>
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<td>100</td>
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<tr>
<td>120</td>
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<tr>
<td>130</td>
<td>3.5</td>
</tr>
<tr>
<td>140</td>
<td>3.8</td>
</tr>
<tr>
<td>150</td>
<td>4.1</td>
</tr>
</tbody>
</table>

17.2 Legislative reference†

The general objective is applicable.

18—X-ray tube potential†

18.1 Test method

Verify that, for a range of set X-ray tube potentials, the measured value of the X-ray tube potential is within ±5 kilovolts peak or ±5 percent, whichever is the greater, of the indicated value.

18.2 Legislative reference

The general objective is applicable.

19—Consistency†

19.1 Test method

Verify that the apparatus produces a consistent radiation output—

(a) by making at least five measurements of radiation output performed at the same X-ray tube potential, X-ray tube current, and exposure time; and
(b) by calculating the coefficient of variation of at least five measurements; and
(c) by verifying that the calculated coefficient of variation is less than or equal to 0.05.

19.2 Legislative reference

The general objective is applicable.

20—Leakage from the X-ray tube housing and the beam limiting device†

20.1 Test method

(1) Cover the end of the beam limiting device with lead of sufficient thickness to ensure that the primary beam contribution to the measurements is negligible.

(2) Subject to subsection (3), verify that the leakage radiation, at a distance of 1 metre from the focus of the X-ray tube and from the beam limiting device, measured at sufficient points around the tube housing and the beam limiting device to provide appropriate coverage, does not exceed 1 millisievert in 1 hour at every rating specified by the manufacturer for that X-ray tube and tube housing combination.

(3) For purposes of verifying compliance, leakage radiation may be measured using test parameters, being—

(a) the maximum rated (i.e. available) X-ray tube potential; and
(b) the maximum available X-ray tube current, with due consideration to the manufacturers cooling requirements of the X-ray tube and tube housing combination; or
(c) a set X-ray tube current that is less than maximum available X-ray tube current, as long as the measured leakage radiation is scaled to a value corresponding to one that has been measured at the maximum available X-ray tube current; or
(d) the maximum continuous tube current specified by the manufacturer of the apparatus or derived from manufacturers data, as long as the measured leakage radiation is appropriately scaled to a value corresponding to one that has been measured at the maximum available X-ray tube current; and
(e) an exposure time of less than one hour, as long as the measured leakage radiation is scaled to a value corresponding to one that has been measured in 1 hour; and
(f) at a distance of other than 1 metre, as long as the measured leakage radiation is corrected for distance using the inverse square law for radiation intensity.

20.2 Legislative reference
The general objective is applicable.

Part 4—Shielding requirements for fixed apparatus

21—Room, space or enclosure to be fit for purpose†

21.1 Test method
Verify that the room, space or enclosure in which the apparatus is installed is of sufficient size to—
(a) allow the operator to position the X-ray tube; and
(b) allow the operator to position the patient correctly; and
(c) allow the appropriate focus to skin distance to be used; and
(d) allow other persons to be in the area as required; and
(e) ensure the installation complies with the general objective.

21.2 Legislative reference
The general objective is applicable.

22—Operator protection†

22.1 Test method
(1) Whenever the X-ray tube is energised, verify that the normal operator’s position is located—
   (a) in a room, space or enclosure adjacent to but separate from the area in which the apparatus is installed; or
   (b) behind a fixed protective screen in the same room, space or enclosure in which the apparatus is installed.
(2) In the case of an operator’s position located in a room, space or enclosure adjacent to but separate from the area in which the apparatus is installed—verify, in accordance with the methodology specified in Schedule 1, that 50 millimetres from any wall, door, window, floor or ceiling the dose does not exceed the radiation worker limit specified in Schedule 2.
(3) In the case of an operator’s position located behind an fixed protective screen in the same room, space or enclosure in which the apparatus is installed verify that—
   (a) the screen, where reasonably practicable, is arranged so that the radiation emitted by the apparatus is scattered at least twice before it can enter the area behind the screen; and
   (b) in accordance with methodology specified in Schedule 1 verify that—
(i) 50 millimetres from behind the screen the dose does not exceed the radiation worker limit specified in Schedule 2; and
(ii) from the operator position at the control panel, no part of the operator can be exposed to radiation that exceeds the radiation worker limit specified in Schedule 2.

22.2 Legislative reference
The general objective is applicable.

23—General shielding†

23.1 Test method
(1) Inspect the areas outside the room, space or enclosure in which the apparatus is located and identify the type of occupancy in accordance with areas that are—
   (a) continuously occupied by a radiation worker, other than the operator referred to in section 22, or occupied by a member of the public for a short time only; or
   (b) occupied by a member of the public for other than a short period of time; or
   (c) not normally occupied, and
   in the report clearly indicate the type of occupancy for each area identified.
(2) In the case of an area continuously occupied by a radiation worker or an area (i.e. a corridor, walkway, lift, stairway, car park, toilet or other area) occupied by a member of the public for a short time—verify, in accordance with the methodology specified in Schedule 1, 50 millimetres from any wall, door, window, floor or ceiling outside the area in which the apparatus is located, the dose does not exceed the radiation worker limit specified in Schedule 2.
(3) In the case of an area occupied by a member of the public for other than a short period of time—verify, in accordance with the methodology specified in Schedule 1, 50 millimetres from any wall, door, window, floor or ceiling outside such an area, the dose does not exceed the member of the public limit specified in Schedule 2.
(4) In the case of an area that is not normally occupied, dose measurements are not required unless it can be reasonably anticipated the occupancy of the area will change, in which case verify compliance in accordance with subsections (2) and (3).

23.2 Legislative reference
The general objective is applicable.

24—Viewing the patient†

24.1 Test method
Verify that the operator is able to clearly view the patient from a position that complies with the requirements of section 22.

24.2 Legislative reference
The general objective is applicable.

25—Communicating with the patient†

25.1 Test method
Verify that the operator is able to communicate with the patient from a position that complies with the requirements of section 22.

25.2 Legislative reference
The general objective is applicable.
26—Dimensions of the protective screen†

26.1 Test method
Verify that the protective screen, referred to in section 22, has a minimum height of 2 metres and a minimum width of 1 metre.

26.2 Legislative reference
The general objective is applicable.
Part 5—Schedules

Schedule 1—Shielding measurement methodology

27—Test method

Except in the case where there is clear evidence, in an area continuously occupied by a radiation worker or an area occupied by a member of the public, that no person can be exposed to radiation that exceeds the dose limits of Schedule 2, verifying compliance with the dose limits must be performed in accordance with the requirements of this schedule or using an alternative method approved, in writing, by the EPA.

28—Configuration

(1) Place a phantom in the primary beam that is suitable for simulating radiation scatter from a patient’s head.

(2) Configure the apparatus to operate at—

(a) an X-ray tube current and exposure time (or the product of the X-ray tube current and exposure time) that is at least sufficient to produce a measurable dose above background radiation; and

(b) configure other test parameters as specified in Schedule 2.

29—Measuring dose

(1) Measure the dose, at appropriate points, 50 millimetres from any wall, door, window, floor or ceiling outside a room, space or enclosure in which the apparatus is located.

(2) As desired, correct each dose, referred to in subsection (1)—

(a) for background radiation; and

(b) for measurement tolerances and uncertainties.

30—Dose calculation

(1) Determine the specified mAs in accordance with Schedule 2.

(2) Determine the product of the X-ray tube current and exposure time referred to in section 28(2)(a). This is the set mAs.

(3) If required convert each dose, referred to in section 29, to units of nanogray. This is the measured dose in nanogray.

(4) Calculate the dose in nanosieverts using the formulae below—

\[
\text{dose in nanosieverts} = \left( \frac{\text{specified mAs}}{\text{set mAs}} \right) \times \text{measured dose in nanogray}.
\]

(5) Compare each dose in nanosieverts calculated in subsection (4) with the appropriate limit specified in Schedule 2.
**Schedule 2—Protocol Dose limits**

<table>
<thead>
<tr>
<th>Apparatus type</th>
<th>Radiation worker limit</th>
<th>Member of the public limit</th>
<th>Limit parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental cone-beam computed tomography</td>
<td>500 nanosieverts</td>
<td>250 nanosieverts</td>
<td>Tube potential: maximum <strong>specified mAs</strong>; maximum Collimator: maximum Scan time: maximum</td>
</tr>
</tbody>
</table>

The *specified mAs* is the product of the set *X-ray tube current* and exposure time at its maximum value.
Schedule 3—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.