



Environment Protection Authority

# Radiation Standard 6

Compliance requirements for ionising radiation apparatus used in diagnostic imaging: Part 3 – Dentistry (including maxillofacial)



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# Introduction

Dental radiography procedures are an essential part of dentistry. Although the effective dose from such procedures is low, the frequency of examinations is high enough to warrant monitoring of the doses delivered. Poor performance of radiation apparatus and inadequate quality assurance procedures may cause an unnecessary increase in patient dose.

The need to reduce the radiation dose to patients is widely acknowledged. This document aims to contribute to dose reduction by:

- ensuring that adequate safety measures are provided to protect patients, occupationally exposed workers and the public from unnecessary radiation exposure
- improving the standard of radiation apparatus in use
- ensuring better monitoring of apparatus performance.

This guideline for dental radiography is for the information of the person responsible and licensed users of dental radiography 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 to assess apparatus for compliance with the 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 an 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 legislation, the requirements of the legislation prevail to the extent of the inconsistency.

This document sets out the minimum requirements for diagnostic imaging apparatus, which are stated as '**must**' statements and are listed in Schedule 1 and promotes industry best practice in radiation safety. It applies to all dental apparatus, both fixed and mobile.

The guideline was developed by the Hazardous Materials Chemicals and Radiation Section of the NSW Environment Protection Authority (EPA) 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 for compliance **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 dental radiography apparatus.
- 1.1.3 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.
- 1.1.4 The provision of radiation shielding should ensure that the radiation levels behind the shielding comply with the requirements of *Radiation Guideline 7*.
- 1.1.5 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.
- 1.1.6 The operator, when behind the protective shield, **must** have a clear view of the patient for medical diagnostic radiology procedures, and **must** be able to communicate easily with the patient at all times.
- 1.1.7 Where a fixed protective shield is provided it should be not less than 2,100 millimetres (mm) in height.
- 1.1.8 When using portable or mobile apparatus, the operator should ensure that no person other than the patient is within 2 metres of the primary beam unless shielded.

## 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 (including kVp and timer functions)
- aluminium filters (Grade 1100 or equivalent)
- tape
- a light meter
- lead sheets
- a tape measure

- radiographic cassettes and film/fluorescent screen
  - a calculator with statistical functions or preconfigured spreadsheet.
- 1.2.3 Prior to commencing testing the manufacturer's warm-up procedure should be followed.
- 1.2.4 All measurements **must** be in SI units (e.g. Gy for air kerma).

# 2. Compliance requirements: dentistry

## 2.1. System performance

2.1.1 All tests 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 dentistry (including maxillofacial) systems**

Compliance requirement	Test	Acceptance	5-yearly	After tube replacement
2.2	Radiation warning sign	✓	✓	✗
2.3	Location of exposure switch	✓	✓	✗
2.4	Exposure indication	✓	✓	✗
2.5	Control of operation	✓	✓	✗
2.6	Remote control	✓	✓	✗
2.7	Indicators of exposure	✓	✓	✗
2.8	Beam limiting devices	✓	✓	✓
2.9	Filtration	✓	✓	✓
2.10	Operating kilovoltage	✓	✓	✓
2.11	Accuracy of kilovoltage controls	✓	✓	✓
2.12	Accuracy of intra-oral and cephalometric apparatus timer controls	✓	✓	✓
2.13	Exposure consistency and linearity	✓	✓	✓
2.14	Absorbed dose in air at the patient's skin surface	✓	✓	✓
2.15	Radiation leakage	✓	✗	✓
2.16	Stability of X-ray tube assembly	✓	✓	✓
2.17	Control of multiple X-ray tubes	✓	✓	✗
2.18	Markings on X-ray generators and/or tube assemblies	✓	✓	✓

## 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 to any room that is designated exclusively for the use of dental or maxillofacial apparatus. Where there is no requirement for a radiation warning sign on the outside of the room, there **must** be a radiation warning sign conspicuously displayed in the immediate vicinity of the apparatus.



## 2.3. Location of exposure control switch

- 2.3.1 The exposure control switch **must** be arranged so that while the X-ray tube is energised, the operator can remain:
- outside the useful X-ray beam and at least 2m from the X-ray tube and from the patient, or
  - behind a protective barrier.

## 2.4. Exposure indication

- 2.4.1 The apparatus **must** incorporate a device that provides a warning to the operator whenever the tube is energised; that warning **must** consist of:
- a light, clearly marked as to its function.
  - an audible signal, other than sounds produced fortuitously by switching devices or contactors, to indicate either the duration of the exposure or its termination.
- 2.4.2 Both audible and visible signals **must** be at the control panel or, for remotely controlled apparatus, where these devices could not otherwise be seen or heard, at the position of the operator.

## 2.5. Control of operation

- 2.5.1 An electronic timer **must** be provided that will terminate the exposure after a pre-set time setting or at a pre-set product of current and time or programmed exposure.
- 2.5.2 Termination of the exposure **must** cause automatic resetting of the timer to its initial setting or zero.
- 2.5.3 It **must not** be possible to energise the X-ray tube if the timer is set to zero.
- 2.5.4 It **must** be possible to alter the timer setting to a higher or lower value without initiating an exposure.
- 2.5.5 The exposure control switch, including that for remote-control handpieces, **must** be of the dead-man type, such that continuous pressure is necessary to maintain the X-ray exposure, and it **must not** be possible to make repeat exposures without releasing the switch.

## 2.6. Remote control

- 2.6.1 Where the exposure is initiated by a remote-control handpiece, this handpiece **must**:
- be encoded to the X-ray control unit so that no other remote-control handpiece can initiate exposure
  - be permanently labelled with a warning identifying the purpose of the control.

## 2.7. Indicators of exposure

- 2.7.1 Analogue meters, digital displays or scales or permanent markings **must** indicate either:
- the selected voltage (kVp) and current (mA) and the exposure time, or
  - the selected kVp and the product of tube current and exposure time (mAs).
- 2.7.2 Apparatus that provides for object-programmed control (exposure selection by an icon) **must** indicate the selected exposure time in seconds on the control panel or on the exposure control switch. This may be achieved, for example, by having a table of calibrated times corresponding to each icon permanently fixed on or adjacent to the control panel.

- 2.7.3 When object-programmed control exposure times can be modified by a further control that can be adjusted to account for variations in the speed of the film or digital receptor used, that control **must**:
- be clearly labelled to indicate its purpose
  - clearly indicate on or adjacent to it (eg by way of an exposure chart) the setting to be used for normal diagnostic intra-oral techniques.
- 2.7.4 There **must** be an obvious visual and/or audible indicator when radiation is being emitted.

## 2.8. Beam-limiting devices

- 2.8.1 For dental radiography using intra-oral image receptors, a beam-limiting device or cone **must**:
- limit the focus-to-skin distance to not less than 200 mm
  - be of the open-ended type
  - limit the maximum dimension of the useful beam at the open end of the cone to not more than 60 mm.
- 2.8.2 For beam-limiting devices for panoramic tomography:
- for film and CR systems the dimensions of the primary beam **must not** exceed the slot in the secondary collimator immediately adjacent to the image receptor and the vertical dimension of the primary beam should not exceed the height of the image receptor
  - for a DR system where there is no slot in the secondary collimator adjacent to the image receptor, the primary beam **must** fall within the dimensions of the image receptor.
- 2.8.3 For beam-limiting devices for cephalometric radiography:
- a beam-limiting device **must** be provided to restrict the radiation field to the image receptor area. The dimensions of this field, where practicable, should be smaller than the maximum selectable field size, e.g. 180 mm × 240 mm and **must not** exceed 240 mm × 300 mm
  - for a DR system where there is no slot in the secondary collimator adjacent to the image receptor, the primary beam **must not** exceed the receptor dimensions by more than 10mm or 10% (whichever is the greater)
  - there **must** be means to ensure correct alignment of the image receptor and the primary beam.
- 2.8.4 For beam-limiting devices for cone beam CT:
- a beam-limiting device **must** be provided to restrict the radiation field to the image receptor housing
  - the primary beam **must not** exceed the receptor dimensions by more than 20 mm for circular image receptors
  - the primary beam **must not** exceed the receptor dimensions by more than 20 mm or 3% of the focal spot to image receptor distance for rectangular image receptors provided that the sum of the discrepancies on both axes **must not** exceed 30 mm or 4% of focal spot to image receptor distance
  - there **must** be means to ensure correct alignment of the image receptor and the primary beam.

## 2.9. Filtration

- 2.9.1 The total filtration **must** ensure that the half-value layer (HVL) of the primary beam for a given X-ray tube and collimator is not less than the values shown in **Table 2**.

**Table 2: Minimum HVL for X-ray tube voltage**

Type of apparatus	X-ray tube voltage (kVp)	Minimum HVL (mm Al)
Apparatus using intra-oral image receptors	60	1.5
	70	1.5
	80	2.3
	90	2.5
Other dental apparatus	50	1.5
	60	1.8
	70	2.1
	80	2.3
	90	2.5
	100	2.7
	110	3.0
	120	3.2
	125	3.3

Note: HVL for intermediate voltages should be obtained by linear interpolation.

## 2.10. Operating kilovoltage

2.10.1 The nominal kVp of dento-maxillofacial apparatus **must** satisfy the requirements of **Table 3**.

**Table 3: Range of X-ray tube voltage**

Apparatus	Nominal tube voltage (kVp)
Apparatus designed for use with intra-oral image receptors	60–70
Panoramic tomography	≥60
Cephalometric	≥60
CBCT	≥60

## 2.11. Accuracy of kilovoltage controls

2.11.1 Selected kVp **must** be accurate to within  $\pm 5$  kVp of the indicated value.

2.11.2 The coefficient of variation of at least three consecutive measurements at the same kVp setting **must not** exceed 0.02.

## 2.12. Accuracy of intra oral and cephalometric apparatus timer controls

2.12.1 The exposure controls **must** ensure that the measured exposure time across the clinical range is within  $\pm 10\%$  or  $\pm$  one pulse of the indicated time, whichever is greater.

2.12.2 The exposure time **must** be determined from the time the kV waveform first rises to 75% of the kVp or 50% of the radiation output until it falls below this value.

2.12.3 The coefficient of variation of at least three consecutive measurements at the same timer setting **must not** exceed 0.05.

## 2.13. Exposure consistency and linearity

- 2.13.1 The apparatus **must** produce a consistent radiation output so that the coefficient of variation of at least three consecutive measurements, taken at the same control settings, does not exceed 0.05.
- 2.14.1 Where the current is selectable (mA can be manually controlled) the apparatus **must** produce a linear radiation output over a continuous range of clinically used settings with respect to the current, so that the coefficient of linearity does not exceed 0.1 for each focal spot size.
- 2.15.1 Where the current is not variable (mA cannot be manually controlled) the apparatus **must** produce a linear radiation output with respect to the product of the exposure time and the current. The coefficient of linearity **must not** exceed 0.1 for each focal spot size.

## 2.14. Incident Air Kerma and Air Kerma Area Product (KAP)

- 2.14.1 The incident air Kerma at 10 mm from the end of the collimator for any intra-oral radiograph **must not** exceed 4 mGy on any exposure setting.
- 2.14.2 The exposure factors for a typical adult mandibular molar radiograph should be appropriately adjusted to meet the optimal doses for the type of image receptor used, **Table 4** shows the typical adult mandibular molar mean incident air Kerma at the patient's skin surface (IAK) from the 2010 UK dose survey for a range of intra-oral detectors. These can be used for comparison until Australian data is made available.

**Table 4: Mean IAK at patient's skin surface for a range of intra-oral detectors – UK 2010 review**

Examination	Mean IAK in mGy
C Film	2.8
D Film	2.0
E Film	1.5
E/F Film	1.2
F Film	1.4
Digital (CR/DDR)*	1.15
Unknown	1.3

\* CR: Computed Radiography; DDR: Direct Digital Radiography

- 2.14.3 For Cone Beam Computed Tomography (CBCT) apparatus the Kerma Area Product for a standard image for the placement of a first upper molar implant for a standard adult patient should not exceed 250 mGy.cm<sup>2</sup>. Field sizes larger than this should be normalised to a 4 cm x 4 cm field.
- 2.14.4 For a panoramic examination the Kerma Area Product for any examination should not exceed 100 mGy.cm<sup>2</sup>.
- 2.14.5 For a cephalometric examination the incident air kerma should not exceed 3 mGy for an AP/PA skull and 1.5 mGy for a lateral skull.

## 2.15. Radiation leakage

- 2.15.1 The X-ray tube **must** be enclosed in a housing in such a manner that the air kerma from radiation leakage measured at a distance of 1 metre (m) from the focus of that tube in one hour, averaged over an area not larger than 100 cm<sup>2</sup>, does not exceed:
- 0.25 mGy for apparatus used with intra-oral image receptors

- b. 1 mGy for other apparatus.
- 2.15.2 Beam-limiting devices referred to in clause 2.6 used to limit the primary beam to the area of clinical interest **must** be constructed so that, in combination with the tube assembly, they comply with the leakage limits set out in clause 2.12.1.

## 2.16. Stability of X-ray tube assembly

- 2.16.1 The X-ray tube assembly **must** remain stationary when placed in position for radiography, except for panoramic tomography and cone beam CT.
- 2.16.2 For handheld units, the design **must** be such that motion artefacts are not apparent on any image.

## 2.17. Control of multiple X-ray tubes

- 2.17.1 Where it is possible to control more than one X-ray tube with a single control unit, it **must not** be possible to energise more than one X-ray tube at any one time. Safety procedures **must** be provided to ensure against accidental activation of the wrong X-ray tube.
- 2.17.2 Where more than one X-ray tube can be operated from a control panel, there **must** be a clear indication on the control panel to signify which tube is energised.

## 2.18. Markings on X-ray generators and/or tube assemblies

- 2.18.1 X-ray generators and tube assemblies **must** be permanently marked in English and the markings **must** be readily available on labels on the apparatus.
- 2.18.2 X-ray generator markings **must** include:
- 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).
- 2.18.3 X-ray tube assemblies **must** bear either of the following in a visible position:
- a. the name or trademark of the manufacturer of the X-ray tube housing and insert
  - b. the type or model number of the X-ray tube housing and insert
  - c. the serial number of the X-ray tube housing and insert, OR
  - d. EPA-generated number (s) that links to (a), (b) and (c).
- 2.18.4 In addition to 2.14.3, X-ray tube assemblies should also bear the following markings on the outer side of the tube housing in a visible position:
- a. the position of the focal spot.
  - b. the relative position of the anode and cathode.

# 3. Quality assurance

## 3.1. Quality assurance program

- 3.1.1 A quality assurance program **must** be instituted and maintained.
- 3.1.2 The program should ensure that consistent, optimum-quality images are produced so that the exposure of operator, staff and the general public to radiation satisfies the 'as low as reasonably achievable' principle.
- 3.1.3 Quality Assurance (QA) procedures should be standardised and documented in a QA manual.
- 3.1.4 The person responsible should ensure that a logbook is maintained in which all details of test results apparatus faults and repairs are recorded. This logbook should be made available to the Authority on request.
- 3.1.5 Equipment should be maintained and serviced according to manufacturer's recommendations. The service frequency should be at least annually.

## 3.2. Maintenance

- 3.2.1 Regular maintenance of dento-maxillofacial apparatus should be carried out in accordance with the manufacturer's instructions.

## 3.3. Film processing quality control

- 3.3.1 The person responsible should ensure that a test film is exposed and processed at regular intervals, not exceeding one week, before the processing of clinical X-ray film.
- 3.3.2 The test film procedure should follow the protocol described in ARPANSA RPS 10, *Code of Practice & Safety Guide for Radiation Protection in Dentistry*.
- 3.3.3 All tests results **must** be recorded.

## 3.4. CR and Digital Receptor Quality Control

- 3.4.1 Equipment using digital detectors such as CCD sensors require periodic calibration. The manufacturer's recommendation for such calibrations and routine testing should be followed.
- 3.4.2 PSPs (Photostimulable Phosphor Plates) are subject to artefacts caused by scratches, bending or contamination of the surface. These require regular care and testing to ensure such damage does not lead to artefacts on the images rendering them unacceptable for diagnostic purpose.
- 3.4.3 All tests results **must** be recorded.

## 3.5. Additional requirements for CBCT

- 3.5.1 Reject analysis of radiological examinations should be carried out as images are acquired.
- 3.5.2 Image quality checks should be undertaken at least monthly with a phantom (preferably a manufacturer's phantom for the specific apparatus).
- 3.5.2 All tests results **must** be recorded.

# 4. Test protocols

## 4.1. Kilovoltage accuracy and reproducibility

### Aim

- To determine how the measured kVp compares with the generator setting.
- To determine the variation in average kVp over a number of exposures at the same generator setting.

### Exposure factors

- kVp accuracy: Variable kVp, fixed mA and fixed time (e.g. 8 mA, 0.1s) or fixed mAs.
- kVp reproducibility: Fixed kVp, fixed mA and fixed time or fixed mAs.

### Method

- Position detector in centre of beam at a distance to ensure proper coverage.
- Make a series of exposures across the clinically used kVp range and calculate the difference in selected and measured kVp.
- Make a minimum of three exposures at fixed kVp, mA and time (e.g. 70 kVp, 8 mA, 0.1s) and calculate average and standard deviation to estimate coefficient of variation.

### Compliance requirement

See section 2.11.

### Notes

- If an apparatus fails kVp reproducibility other measurements may be meaningless.
- Where exposure times are less than 0.1s, use the largest exposure time available.
- Follow manufacturer recommendations regarding orientation of the kVp meter/detector with respect to the anode-cathode axis of the X-ray tube.
- For panoramic and CBCT apparatus, where possible use stationary mode for testing.
- Where practical protect digital detectors using appropriate shielding material.

## 4.2. Exposure timer accuracy and reproducibility

### Aim

- To determine how the exposure time compares with the selected time.
- To determine the variation in exposure time over a number of exposures at the same generator setting.

### Exposure factors

- Exposure timer accuracy: Fixed kVp, fixed mA, (e.g. 70 kVp, 8 mA) variable time.
- Exposure time reproducibility: Fixed kVp, Fixed mA and fixed time.

### Method

- Position detector in centre of beam at a distance to ensure proper coverage.

- Make a series of exposures commencing at the clinically used shortest exposure time, then across the range of the timer at commonly used settings up to the maximum used and calculate the difference in selected and measured time.
- Make a minimum of three exposures at fixed kVp, fixed mA and time (i.e. 70 kVp 8 mA 0.1s or similar) and calculate average and standard deviation to estimate coefficient of variation.

### **Compliance requirement**

See section 2.12.

### **Notes**

- This test is not required for apparatus where mAs is selected as a single component.
- This test is not required for panoramic and CBCT apparatus.
- Where practical, protect digital detectors using appropriate shielding material.

## **4.3. Radiation output reproducibility**

### **Aim**

To determine the variation in radiation output over a number of exposures at the same generator setting.

### **Exposure factors**

- Intra-oral apparatus 70 kVp, 8mA 0.1s or similar.
- Cephalometric, panoramic and CBCT apparatus, use typical clinical setting.

### **Method**

- Position detector in centre of beam at a distance to ensure proper coverage.
- Place lead sheet under chamber to absorb backscatter.
- Make a minimum of three exposures and calculate the coefficient of variation.

### **Compliance requirement**

See section 2.13.

### **Notes**

- If an apparatus fails output reproducibility other measurements may be meaningless.
- For older apparatus with mechanical switching, turn controls away from set positions between exposures and return to original settings.
- For panoramic and CBCT apparatus an alternate measurement of dose rate can be used in conjunction with an abbreviated exposure (2 – 4 s) to limit loading of the X-ray tube and protection of any digital detector.

## **4.4. Radiation output linearity with mA or mAs**

### **Aim**

To determine the linearity of the radiation output over a range of mA or mAs settings.



## Exposure factors

- 70 kVp or similar, variable mA, 0.1 s or variable mAs.
- Cephalometric, panoramic and CBCT apparatus, use typical clinical setting.

## Method

- Position detector in centre of beam at a distance to ensure proper coverage.
- Place lead sheet under chamber to absorb backscatter.
- Make a series of exposures at as many mA or mAs settings as practicable, covering the clinically used range.
- Calculate  $\mu\text{Gy/mAs}$  ( $X$ ) by dividing output by the nominal mAs.
- Determine  $X_{\text{max}}$  and  $X_{\text{min}}$
- Calculate linearity coefficient:

$$\text{linearity coefficient} = \frac{X_{\text{max}} - X_{\text{min}}}{X_{\text{min}} + X_{\text{max}}}$$

- Linearity coefficient **must not** exceed 0.1.

## Compliance requirement

See sections 2.13.

## Notes

For panoramic and CBCT apparatus an alternate measurement of dose rate can be used in conjunction with an abbreviated exposure (2–4 s) to limit loading of the X-ray tube and protection of any digital detector.

## 4.5. Half-value layer

### Aim

To assess the X-ray beam quality and determine the adequacy of filtration.

### Exposure factors

- Fixed kVp (i.e. 70), 8mA 0.1s.
- Cephalometric, panoramic and CBCT apparatus, use typical clinical setting.

### Method

- Position detector in centre of beam at a distance to ensure proper coverage.
- Place the lead sheet under the chamber to absorb backscatter.
- Collimate the beam to the size of the chamber.

### If using direct meter reading

Make an exposure and record the HVL from the dose meter.

### If using filters and exposure measurements

- Make three exposures with no filters added (free in air), then take the average.
- Tape a 1 mm aluminium filter onto the face of the collimating device and make an exposure.
- Repeat exposures with increasing steps of between 0.2 and 0.5 mm aluminium.

- Plot exposure against thickness of filter using a semi-log scale.
- Halve the average free in air exposure and determine corresponding thickness of aluminium from graph.

### Compliance requirement

See section 2.9.

### Notes

- kVp should be checked before HVL assessment.
- Ensure entire beam is intercepted by filters.
- If the measured HVL is compliant with this requirement at a single set tube voltage, it is assumed that it is compliant at all available tube voltages.
- For panoramic and CBCT apparatus an alternate measurement of dose rate can be used in conjunction with an abbreviated exposure (2–4 s) to limit loading of the X-ray tube and protection of any digital detector.

## 4.6. Dead-man exposure switch

### Aim

To ensure that the exposure is terminated by removing pressure from the exposure switch.

### Exposure factors

Low kV, mA, long exposure time.

### Method

- Position detector in centre of beam at a distance to ensure proper coverage.
- Initiate exposure and release switch before exposure is terminated.
- Radiation emission **must** cease when switch is released.
- Measuring instrument will indicate time when exposure is terminated.

### Note

Given the extremely short exposure times on intra-oral dental apparatus calibrated for use with DR receptors, this may not be a practical test to undertake.

## 4.7. Leakage radiation

### Aim

To measure any leakage radiation through the X-ray tube assembly and beam limiting device.

### Exposure factors

Maximum clinical kVp, with appropriate mAs (time should not exceed 0.5 second). Ensure tube rating is not exceeded.

### Method

- Collimator should be covered with ~ 3 mm of lead.

- Position the leakage chamber at 1m from focal spot. Make a series of exposures to measure leakage at positions, including cathode, anode and front of tube assembly. Distances other than 1m may be used and an inverse square law correction is applied.
- Calculate time averaged leakage using manufacturer recommended continuous mA rating at the kVp used for the measurement or using tube cooling curve data.

### Compliance requirements

See section 2.15

### Notes

- An incorrectly positioned X-ray tube insert or flaws in the lead shielding in a housing may give rise to narrow but intense beams of leakage radiation which fail to ionise the entire chamber and therefore appear not to exceed the specified limit; such beams are highly undesirable, and the cause should be remedied.
- Pinhole leaks or 'hotspots' can be detected by the use of a fluorescent screen or non-screen film wrapped around the X-ray tube assembly.

## 4.8. Collimation

### Aim

To ensure coincidence of the radiation field with the light field.

### Exposure factors

- Intra-oral apparatus longest conventional exposure.
- Cephalometric apparatus use typical AP/PA skull exposure.
- Panoramic and CBCT apparatus, use typical clinical setting.

### Method

Intra-oral apparatus:

- Use alignment object such as 7-centimetre (cm) wire cross and position on a detector such as one or more films/CR plates, gafchromic film, or Fluorescent screen with collimator centred on cross.
- Mark cathode, anode or other identifiable part on the tube for orientation.
- Expose and process the image to verify collimation.

### Compliance requirements

See section 2.8.

## 4.9. Skin Dose (Intra-oral apparatus only)

### Aim

To ensure skin doses are within acceptable limits.

### Exposure factors

- Determine factors for standard patient bitewing exposure.
- Determine factors for maximum patient bitewing exposure.

## **Method**

- Setup detector 1 cm below end of intra-oral cone.
- Expose and record dose for both settings.

## **Compliance requirements**

See section 2.14.

# Schedule 1: Mandatory compliance requirements for dental radiation apparatus

The clauses contained in this Schedule are the requirements referred to in condition 4.1 of the radiation management licence which the apparatus **must** meet before compliance.

Requirement	Clause(s)
Advice to Person Responsible	1.1.1, 1.1.2 1.1.5, 1.1.6
Advice to CRE	1.2.1, 1.2.4
System Performance	2.1.1
Radiation warning sign	2.2.1
Location of exposure control switch	2.3.1
Exposure indication	2.4.1, 2.4.2
Control of operation	2.5.1, 2.5.2, 2.5.3, 2.5.4, 2.5.5
Remote control	2.6.1
Indicators of exposure	2.7.1, 2.7.2, 2.7.3, 2.7.4
Beam-limiting devices	2.8.1, 2.8.2, 2.8.3, 2.8.4
Filtration	2.9.1
Operating kilovoltage	2.10.1
Accuracy of kilovoltage	2.11.1, 2.11.2
Accuracy of timer controls	2.12.1, 2.12.2, 2.12.3
Exposure consistency and linearity	2.13.1, 2.13.2, 2.13.3
Incident air kerma and air kerma area product	2.14.1
Radiation leakage	2.15.1, 2.15.2
Stability of X-ray tube assembly	2.16.1, 2.16.2
Control of multiple X-ray tubes	2.17.1, 2.17.2
Markings on X-ray generators etc.	2.18.1, 2.18.2, 2.18.3
QA	3.1.1
Film Processing	3.3.3
CR & DR receptor quality control	3.4.3
Additional requirements for CBCT	3.5.3

# References and further reading

NSW EPA, *Radiation Guideline 7: Radiation Shielding design assessment and verification requirements*

Australian Radiation Protection and Nuclear Safety Agency, *Code of Practice and Safety Guide for Radiation Protection in Dentistry*, 2005, (RPS10)

European Commission, *Radiation Protection Number 162: Criteria for Acceptability of Medical Radiological Equipment Used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy*, 2012

European Commission, *Radiation Protection Number 172: Cone Beam CT for Dental and Maxillofacial Radiology – Evidence Based Guidelines*, 2012

Health Protection Agency (UK), *HPA-CRCE-010 Guidance of the Safe Use of Dental Cone Beam CT (Computed Tomography) Equipment* – Report prepared by HPA working party on Cone Beam CT equipment, 2010

# 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.

**Added filtration** means quantity indicating the filtration affected by added filters in the useful beam, but excluding inherent filtration.

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

**CRE** means consulting radiation expert.

**Coefficient of variation** means the quotient of the standard deviation and the mean.

**Coefficient of linearity** =  $(X_{\max} - X_{\min}) / (X_{\min} + X_{\max})$ .

**CBCT (Cone Beam Computed Tomography)** means the process of acquiring a 3D image of a patient's anatomy, dental, maxillofacial or ENT, by use of a divergent beam X-ray source and an image receptor which acquires a series of images from exposures taken around the patients head.

**Dento-maxillofacial apparatus** means radiation apparatus, which emits ionising radiation, used for the purpose of radiographic imaging of the teeth and maxillofacial region. This includes apparatus with extra-oral X-ray sources designed for use with intra-oral image receptors, dental panoramic tomography and cephalometric radiography.

**Filtration** means modification of the spectral distribution of an X-ray beam as it passes through matter, by the differential absorption of poly-energetic photons.

**Focal spot** means the area of the *target* from which X-rays are emitted.

**Half-value layer (HVL)** means the thickness of a specified material that reduces the absorbed dose in air of a given X-ray beam to half its original value.

**Image receptor** is the device or medium used to record the image from an X-ray procedure. This may be, but is not limited to, an X-ray film, a digital receptor incorporating a wired or wireless sensor (DR), or a photostimulable plate (PSP).

**Inherent filtration** means the *filtration* affected by the irremovable materials of an *X-ray tube assembly* (glass, oil and port seal), through which the radiation beam passes before emerging from the X-ray tube assembly. It is expressed in thickness of a reference material that, at a specified potential difference and waveform, gives the same radiation quality in terms of the *half-value layer*.

**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  $dm$  (i.e.  $K = dE_{tr}/dm$ ). 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 units of KAP are typically  $Gy.cm^2$ , or similar e.g.  $mGy.cm^2$ ,  $cGy.cm^2$ ,  $\mu Gy.m^2$ .

**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).

**Operator** means a person licensed under section 7 of the Act to use ionising radiation.

**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.

**Radiation leakage** means ionising radiation transmitted through the protective shielding of a radiation source other than the primary beam.

**Radiation quality** refers to the penetrating ability of a beam of X-rays. It is determined by the energy distribution of the photons in the beam, which in turn depends on the kV waveform and peak voltage across the tube, and on the filtration through which the beam has already been transmitted. The quality of an X-ray beam is described by the HVL of the beam and is measured in terms of mm of aluminium in the diagnostic range.

**Regulation** means the Radiation Control Regulation.

**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.

**Target** means the area of the anode that is struck by the electrons from the cathode.

**Total filtration** means the sum of *inherent filtration* and *added filtration* between the radiation source and the patient or other defined plane.

**X-ray tube assembly** means the *X-ray tube housing* with an *X-ray tube insert*, but not including a collimating device.

**X-ray tube housing** means a container in which an X-ray tube is mounted for normal use, providing protection against electric shock and ionising radiation except for an aperture for the useful beam. It can contain other components.

**X-ray tube insert** means a highly evacuated vessel for the production of X-radiation by the bombardment of a target, usually contained in an anode, with a beam of electrons accelerated by a potential difference.

**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.