Recommendations for the Design of X-ray Facilities and the Quality Assurance of Dental Cone Beam CT (Computed Tomography) Systems

A report of the HPA Working Party on Dental Cone Beam CT

J R Holroyd and A Walker*

***NORTH WESTERN MEDICAL PHYSICS, THE CHRISTIE NHS FOUNDATION TRUST, MANCHESTER, M20 4BX**

ABSTRACT

This report provides guidance on two important areas of radiation protection related to dental cone beam CT equipment. Guidance is provided for Radiation Protection Advisers (RPAs) involved in the design of X-ray facilities and for RPAs, medical physicists and others involved in the acceptance/commissioning testing or routine performance evaluation of dental cone beam CT equipment. Current guidance for conventional X-ray equipment in these areas is not appropriate, and this report details the recommendations of the HPA Working Party established to develop guidance on all aspects of radiation safety matters related to dental cone beam CT equipment.

An achievable dose of 250 mGy cm^2 is proposed as a starting point for the optimisation of patient dose, although it is recognised that the large differences between equipment models require that local diagnostic reference levels should be set after consultation between the user and their Medical Physics Expert (MPE).

It is recommended that new equipment should be purchased that is capable of restricting doses to below the achievable dose, as well as provided with the means to carry out the appropriate quality assurance checks proposed in this report. Employers are strongly encouraged to seek the advice of their MPE prior to purchasing a cone beam CT machine, to ensure the selected equipment best meets their requirements and is capable of restricting patient doses as far as reasonably practicable.

Centre for Radiation, Chemical and Environmental Hazards
Radiation Protection Division
Chilton, Didcot, Oxfordshire OX11 0RQ

Approval: February 2010
Publication: March 2010
£15.00
ISBN 978-0-85951-664-8

CONTENTS

1 INTRODUCTION

In 2008, the Health Protection Agency (HPA) established a UK Working Party (WP) to consider the many radiation protection issues associated with dental cone beam CT (CBCT). The HPA has since issued initial guidance aimed at those who use and install this type of equipment to make them aware of the most important issues and help them to meet their legal obligations and follow best practices (Holroyd and Gulson, 2009).

Dental CBCT is a significant new technology in dentistry which is typically associated with higher radiation doses delivered to patients (and potentially to staff within the practice) than conventional dental X-ray equipment. Due to this potential for higher doses and the complexity of the imaging systems, existing guidance for conventional dental X-ray equipment covering the design of radiography rooms and quality assurance procedures should not be considered applicable for CBCT.

This report considers two areas where detailed advice is most urgently needed: the initial design of CBCT facilities to ensure adequate radiation protection and the quality assurance of CBCT equipment to ensure continued satisfactory performance. The advice is primarily aimed at Radiation Protection Advisers (RPAs) involved in providing design advice for the installation of dental CBCT units in dental practices or hospital departments, and Medical Physics Experts (MPEs) involved in the testing of dental CBCT units and advising users on establishing their local quality assurance procedures. It will also be of interest to equipment manufacturers, suppliers and users.

2 DESIGN OF DENTAL CBCT FACILITIES

Dentists and Radiology Departments considering the installation of CBCT facilities should contact their RPA at the earliest opportunity to discuss requirements. It should be noted that due to the significantly higher radiation doses associated with CBCT equipment, it cannot be assumed that the protection afforded in existing facilities (designed for intra oral, panoramic or cephalometric dental X-ray sets) will be adequate.

Each CBCT facility must be designed to meet the key requirements of the Ionising Radiations Regulations 1999 (IRR99) (i.e. to ensure that doses to employees and other persons are restricted as far as reasonably practicable). Design criteria to ensure that radiation doses to persons outside the facility are adequately restricted are discussed further below. This includes consideration of CBCT output, levels of scattered radiation, size of facility, distances to barriers and workload.

2.1 Dose rates from dental CBCT equipment

The primary beam can be considered to be fully attenuated by the image detector and housing assembly and therefore the only significant contribution to occupational exposure is from scattered radiation. Scattered radiation dose levels vary significantly between units. A survey of manufacturer's data by the HPA in 2008 indicates that maximum values of secondary radiation in the horizontal plane, at a distance of one metre from the centre of the equipment, vary between 2.3 to 40 μGy per scan with kV settings varying from 80 to 120.

If the make of scanner is unknown, it is suggested that the upper limits of these ranges are assumed, i.e. 40 μGy per scan and 120 kV.

The above data is for a horizontal plane. Information on scattered radiation levels above and below scanners is not yet readily available. It is assumed that the above represents the worst case situation although this might not be the case for CBCT models involving a vertical scanning plane, which might give rise to higher scattered radiation levels in areas above and below the scanning room.

Scatter data, including measurements out of the horizontal plane, will be available via the SEDENTEXCT project (2010) in the near future. Most manufacturers will provide scatter dose data on request.

2.2 Minimum distances to barriers

Dental CBCT units are quite compact and are likely to be fitted into relatively small areas; they have a similar footprint to dental panoramic units, typically 110 cm x 150 cm. Most need to be fixed to a supporting wall and could be close to at least one other wall. It is suggested that a minimum distance of 0.5 m from the patient to any wall be assumed if the actual room layout is not known.

2.3 Workload

The calculations below have been based on a typical medium workload of 20 scans per week for a CBCT installed in private practice and 50 scans per week for a unit installed in a hospital department. These are thought to be maximum likely values taking into account the current uses of dental CBCT. However, the clinical use of dental CBCT is still developing and workload should be kept under review. It is important to consider the likelihood of an increased workload at the design stage so that the installation is to some extent "future proofed".

2.4 Sample calculations

Calculations have been performed assuming the above workload, the worst case scenario of 40 μGy per scan, 120 kV setting and barrier to patient distances of 0.5 m and 1 m. Lead equivalence values are calculated using the calculation protocol

provided in the BIR/IPEM working party report entitled “Radiation Shielding for Diagnostic X-rays” (BIR, 2000) using the high energy coefficients given in table 4.6 in that publication. Barrier shielding requirements have been calculated to ensure that the instantaneous dose rate (IDR) outside the room is less than 7.5 µSv per hour and the time averaged dose rate over 2000 hours (TADR2000) is sufficiently low to ensure that no person outside the room should receive an annual effective dose greater than 0.3 mSv per year (Appendix 11 in IPEM, 2002).

Dose constraint	IDR < 7.5 $\mu Sv h^{-1}$		TADR2000 < 0.15 $\mu Sv h^{-1}$ (assuming 100% occupancy)			
Workload	1 scan per minute		20 scans per week		50 scans per week	
Distance of barrier from patient, m	0.5	1	0.5	1	0.5	1
Dose rate at barrier, $\mu Sv h^{-1}$	9600	2400	83	21	208	52
Barrier transmission $x10^{-4}$	7.8	31	18	72	7.2	29
mm Pb equivalence at 120 kV	2.3	1.6	1.9	1.3	2.3	1.7
mm concrete (density 2350 kgm^3) at 120 kV	160	120	135	100	160	125

Table 1 Shielding requirements for rooms containing dental CBCT equipment.

This indicates that Code 5 lead shielding (2.24 mm) may be needed to achieve the above dose rate constraints. The figures in table 1, however, relate to the worst case scenario and should be treated as guidance only. Due to the significant differences in maximum operating potential and levels of scattered radiation, many installations may be satisfactorily shielded with lower lead equivalences, possibly as low as Code 2 lead (0.9 mm) for the low dose, low kV units.

It is also likely that doors will need some additional shielding, although as they will normally be further away from the unit, the required lead equivalence will be lower. In addition, floor and ceiling protection needs to be considered and it is possible that ground floor windows will also require additional shielding. Each installation should, therefore, be assessed on a case by case basis with the input of a Radiation Protection Adviser.

2.5 Operator protection

IRR99 requires operator doses to be kept as low as reasonably practicable; less than 1 mSv per year should be easily achievable. For conventional dental radiography an operator position of 1.5 m from the X-ray equipment ensures that the operator’s annual effective dose is unlikely to exceed 1 mSv. For dental CBCT, if distance alone was used as a means of restricting exposure and assuming 20 scans per week and the maximum scatter dose rate, an operator would need to be at least 6.5 m from the patient. This is not practical and would, if the room allowed such a distance, mean that the operator was too far away to observe the patient and supervise the exposure

adequately. For CBCT X-ray sets, with low scatter dose rates, this distance would be significantly reduced.

In this worst case scenario, all people (other than the patient) should, therefore, either always be excluded from the room during radiography or provided with a shielded area inside the room. The operator must take up a position such that the operator can clearly see the patient and the room entrance(s) and can interrupt the scan using the emergency stop or mains isolator if required. If the operator's position is inside the room, the protective screen should have a lead equivalence typically greater than 1.3 mm dependent on position and workload, with a large viewing window with the same lead equivalence. Alternatively, the operator may be positioned outside the room entrance, viewing the patient through an adequately shielded window.

2.6 Exposure control

Some units require authorisation of the exposure by computer software prior to exposure. Ideally, this should be achieved via a dedicated computer located close to the X-ray unit rather than operated over a network to avoid the possibility of authorisation of exposure without the operator being present at the CBCT control.

It is normal for the mains power supply be left on to CBCT equipment throughout the working day as lengthy warm up procedures are required. If another X-ray set is located in the same room, particular care will need to be taken to minimise the risk of accidentally initiating a CBCT exposure during use of the other set, e.g. by providing a labelled exposure switch in a separate location or by placing the exposure switch in a lockable box.

If the exposure switch is located outside of the radiography room, the exposure switch should be key controlled or placed in a lockable box to prevent unauthorised use.

2.7 Warning lights

Where practicable, it is recommended that standard two stage X-ray room warning lights and signs be installed as recommended in sections 3.23 to 3.25 of the Medical and Dental Guidance Notes (IPEM, 2002). A single warning light could be considered sufficient if adequately explained by warning signs but only if it is possible that the equipment can be switched off, or have the exposure control disabled between periods of use (e.g. using a key switch) when the unit is not in use.

2.8 Additional IRR99 considerations

For completeness, guidance on compliance with other procedural controls required by IRR99 is given below.

2.8.1 Designated areas

It is recommended that RPAs advise that the whole room is designated as a controlled area. This is because the generally much higher levels of scattered radiation within the room, and hence higher potential for exposure of staff, compared to conventional dental X-ray equipment mean that it is necessary to follow special procedures to restrict exposure.

The controlled area should be considered to exist throughout the time that the equipment is ready to emit radiation. For machines that can be switched on and off during the working day, or have their controls disabled between periods of use, the controlled area need only be considered to exist when the power is switched on, or the initiation of exposures enabled.

Dental CBCT equipment should be installed in a room used solely for radiography, so that persons not involved in radiography will not have a need to enter the controlled area. If the room is utilised for other uses (e.g. reading images from phosphor plates), changes to working practices (e.g. moving the phosphor plate reader to a different room) should be recommended.

As with other forms of dental radiography, it should not normally be necessary to designate a supervised area outside a room that has been properly designed and constructed following consultation with a suitable RPA.

2.8.2 Personal Monitoring

The need for personal monitoring should be considered in the prior risk assessment. If the operating position is such that an exposure cannot be initiated unless the operator is standing behind an adequately shielded door or barrier, occasional monitoring is suggested (e.g. when new for a short period to establish that operator doses are low and then on an annual basis if considered necessary). Where the room design allows operation of the unit without being behind an adequately shielded door or barrier, routine continuous monitoring is recommended.

It is not expected that any person other than the operator would need to regularly enter a controlled area; however, if regular access was required, personal monitoring should be considered for these persons.

3 QUALITY ASSURANCE REQUIREMENTS

A quality assurance (QA) programme is necessary to ensure that equipment continues to perform satisfactorily and adequately restrict patient doses. This section outlines the recommended elements of a QA programme.

3.1 Duties of suppliers of X-ray equipment

Equipment suppliers have a duty to pass on *'adequate information about proper use, testing and maintenance'* (IRR99) of X-ray equipment to the purchaser. As part of the requirement to pass on information about proper testing, it is expected that the supplier should provide the dental practice with information regarding the nature, frequency and acceptable results of the required tests.

To enable users to carry out routine quality assurance as easily as possible the WP recommends that suppliers provide all necessary test equipment and procedures, including dedicated QA software, as part of the equipment sale.

3.2 Duties of users of X-ray equipment

Users are required to establish a QA programme which must include adequate testing of equipment before it is first put into clinical use (usually called acceptance or commissioning testing) and routine testing of the equipment performance at regular intervals, including measurements of patient doses, to ensure the equipment provides on-going adequate performance and restriction of exposure.

The content of the QA programme should be derived from the information provided by the equipment supplier and any available reference texts. The current authoritative guidance on the requirements of performance testing for many types of medical X-ray equipment is found in IPEM Report 91 (IPEM, 2005). Report 91 provides guidance as to what constitutes adequate testing by way of the nature and frequency of tests. However, Report 91 does not specifically consider dental CBCT.

Report 91 considers panoramic and cephalometric X-ray equipment, therefore, dental CBCT machines which provide these modes of operation should have these functions assessed against the existing test standards and should meet the requirements expected of a dedicated panoramic or cephalometric machine.

3.3 Development of performance testing requirements for dental CBCT

There is currently no standardised guidance available as to what adequate testing should be. The only source of information currently available considering testing is that provided by the equipment supplier. However, the testing recommended by

equipment suppliers has been found to vary significantly. Some equipment is provided with dedicated test procedures and test equipment, whereas other equipment is provided without any information with respect to appropriate testing.

Due to the lack of available information for performance testing of dental CBCT, the HPA WP has developed a testing regime. It was agreed that the content of the QA testing for dental CBCT would need to be significantly different from established test methods for conventional dental X-ray equipment and require detailed quantitative testing of the imaging system.

The draft testing regime was made available for a limited consultation to the Institute of Physics and Engineering in Medicine (IPEM) Radiation Protection and Diagnostic Radiology Special Interest Groups, medical physicists, equipment suppliers and some users of dental CBCT. This report provides the agreed testing standards prepared by the WP following the consultation process. The WP recommends that the testing standards are adopted immediately in the UK (see Appendix A). Manufacturers are encouraged to provide performance specification with their equipment covering the range of tests presented in this report, with appropriate test equipment and software where appropriate.

3.4 Recommended frequency of testing

The WP recommends that equipment should be subject to routine monthly QA by the dental practice. These are simple tests that are designed to indicate any significant changes in the performance of the equipment.

The WP also recommends that a full radiation safety test is carried out annually for dental CBCT equipment; unlike conventional dental X-ray equipment which only needs to be subjected to a full radiation safety test at least once every three years. This is a separate test in addition to the electrical and mechanical checks that are carried out by equipment suppliers as part of a servicing agreement. It is unlikely that the supplier or service engineer would carry out this type of testing, which would normally be carried out by the practice's RPA or MPE.

Additional tests are also recommended that need only be performed during the initial acceptance/commissioning testing of the equipment or after significant maintenance or modification of the equipment (e.g. replacement of the X-ray tube or detector).

3.5 Presentation of test standards

The tests recommended in this report are split into three sections relating to when the tests should be performed. Appendix A1 details the frequent tests that should be carried out in-house in the dental practice. Appendix A2 lists those tests that should be included in an annual test and appendix A3 details additional tests for acceptance/commissioning testing that should be carried out in addition to the tests in appendix A2.

All the recommended tests provided in Appendix A have suggested remedial and suspension criteria. If equipment is assessed to exceed remedial levels then the equipment should be corrected as soon as practicable. If suspension levels are exceeded then the equipment should be taken out of use until corrective action is carried out.

Dental practices should discuss with their RPA or MPE how best to carry out these tests, how to record and interpret the results and what corrective action to take should any remedial or suspension levels be exceeded.

The initial commissioning testing should establish baseline values for the equipment which can be used for comparison purposes during future testing to ensure consistent performance of the equipment. It is important that subsequent tests are carried out using identical exposure parameters to ensure appropriate comparisons can be made (e.g. identical operating potential, tube current, exposure time, field of view, resolution, etc.) as any changes in these parameters can significantly alter the measurement.

Two different priority levels are suggested for the tests in Appendices A2 and A3. Where tests have a priority of 1, it is recommended that the test should always be carried out. Tests that have a priority of 2 should be carried out at the discretion of the person testing the equipment. For example, some of these tests may be considered only necessary for certain equipment models.

Appendix A4 provides details of suggested test methods and additional resources for further information on the requirements of the tests. The individual tests are referenced to specific tests in IPEM Report 91 where the test uses a similar method. Appendix A is intended to provide a similar format to IPEM Report 91 to provide a consistent style for those involved in the testing of diagnostic X-ray equipment. It is expected that the next revision of IPEM Report 91 will include specific tests for dental CBCT based on those tests contained in this report.

3.6 Software requirements

Many of the tests recommended in this document require the analysis of reconstructed images, however, software packages provided with some models of equipment do not provide the necessary functions to carry out these tests. For the tests recommended to be carried out annually, the tester should export the images from the reconstruction PC and perform the analysis using an alternative software package. Examples of such software packages are:

- Osiris®, available from: http://www.dim.hcuge.ch/osiris/01_Osiris_Presentation_EN.htm,
- ImageJ®, available from: http://rsbweb.nih.gov/ij/,
- IQWorks®, available from: http://wiki.iqworks.org/.

The following are considered the minimum software capabilities for the quality assurance of dental CBCT, and equipment manufacturers are encouraged to provide these functions within their software packages:

a. The ability to draw a circular or rectangular region of interest (ROI) of arbitrary size and report the average image density value and standard deviation over the ROI.
b. The ability to draw a straight line of arbitrary length between any two points in the imaged volume and the software reports the true length of the line.
c. The ability to draw a straight line of arbitrary length between any two points in the imaged volume and the software reports a graph of image density values versus position along the line.
d. The ability to navigate through an image in all three planes and select individual image slices.

Dedicated software routines to automate the quality assurance tests and enable the dental practice to carry out routine quality assurance as easily as possible would be the preferred approach and the WP recommends that manufacturers provide suitable software configured to work with suitable test equipment.

The WP would also recommend that those considering purchasing dental CBCT equipment, request that the supplier provide appropriate quality assurance software and test equipment.

4 DIAGNOSTIC REFERENCE LEVELS

Users of dental X-ray equipment are required to establish local Diagnostic Reference Levels (DRLs) for their X-ray equipment (IR(ME)R, 2000). For intra-oral equipment, national DRLs exist to assist users in establishing their local reference levels (Department of Health, 2007). National DRLs are levels which have been formally adopted by the Department of Health. Many of the current national DRLs were set based on the National Reference Doses (NRDs) proposed by the HPA for many common radiographic procedures (Hart, 2002; Napier, 1999). A NRD is defined as the rounded third quartile value of the patient dose distribution observed for a specific radiographic procedure during a wide scale survey.

At present there are no national DRLs or NRDs established for Dental CBCT. The WP recommends that reference levels for CBCT are set using the dose quantity, Dose Area Product (DAP). DAP is readily measureable and is used to set reference levels for a wide variety of medical and dental radiographic procedures. Dose area product can be measured by either using a dedicated DAP meter or by making measurements of dose and X-ray field size at a common position in the X-ray field. DRLs should be set for both adult and child radiography and for common radiographic techniques. The WP agreed that the adult protocol should be that used for the placement of an upper first molar implant in a standard adult patient and the child measurement should be made using the clinical protocol used to image a single

impacted maxillary canine in a 12 year old male. Both these procedures essentially involve the imaging of a single tooth and it is the view of the WP that these protocols represent typical uses of CBCT equipment, therefore, the equipment should be provided with suitable collimation to enable these images to be obtained. It is recognised that equipment that can only produce image volumes significantly larger than that needed for a single implant are commonly available, however, the use of such machines should be limited to situations where the larger image volume is necessary for the procedure being carried out. In these cases, then MPE may consider alternative views for setting local DRLs depending on the local uses of the equipment.

Given the wide range of DAP measurements recorded for different CBCT models, it was not considered appropriate to derive a NRD based on the third quartile DAP measurement of a dose survey as this would be of little benefit for dose optimisation. Instead an achievable dose is presented in this report, which is based on the third quartile DAP value of a dose survey, where the X-ray field size has been normalised to an appropriate size to adequately image the two views proposed above.

The WP recommends that the image volume necessary to obtain an adequate diagnostic image for the placement of a single implant is a 4 cm diameter x 4 cm height cylindrical volume.

To derive the achievable dose, the measured DAP values were normalised to an area of 16 cm^2, corresponding to a 4 cm x 4 cm field of view at the isocentre of the equipment, to give an adjusted DAP measurement representative of the DAP the equipment could achieve with an appropriate collimation to image a 4 cm x 4 cm volume.

The consequence of using this achievable dose will be that equipment that can only produce image volumes significantly larger than a 4 cm x 4 cm cylindrical volume may significantly exceed the achievable dose value. In these cases, setting a local DRL above the achievable dose may be appropriate but it should trigger an investigation into whether the continued use of the equipment can be justified, and if so, whether any further measures to optimise patient dose can be identified, such as the reduction of exposure factors or determining whether a more appropriate, smaller collimator could be fitted.

Based on data collected by the HPA (33 CBCT units) and provided by hospital medical physics departments (8 CBCT units) an achievable dose of 250 mGy cm^2 is proposed for the adult procedure. All the DAP measurements are presented in figure 1. Due to the lack of available patient dose data for child examinations it is suggested that the adult value can be initially used as to a guide to dose optimisation for child radiography until further data is collected. The user and their MPE should establish the user's local DRLs with regard to this value; however, it may be appropriate to set a higher level based on the user's equipment type and their use of the equipment. Additionally, the local DRL for children would be expected to be set at a lower dose than the adult value. Advice provided to users considering the purchase of a CBCT machine should recommend that equipment is selected which is capable of restricting patient exposure to below the achievable dose.

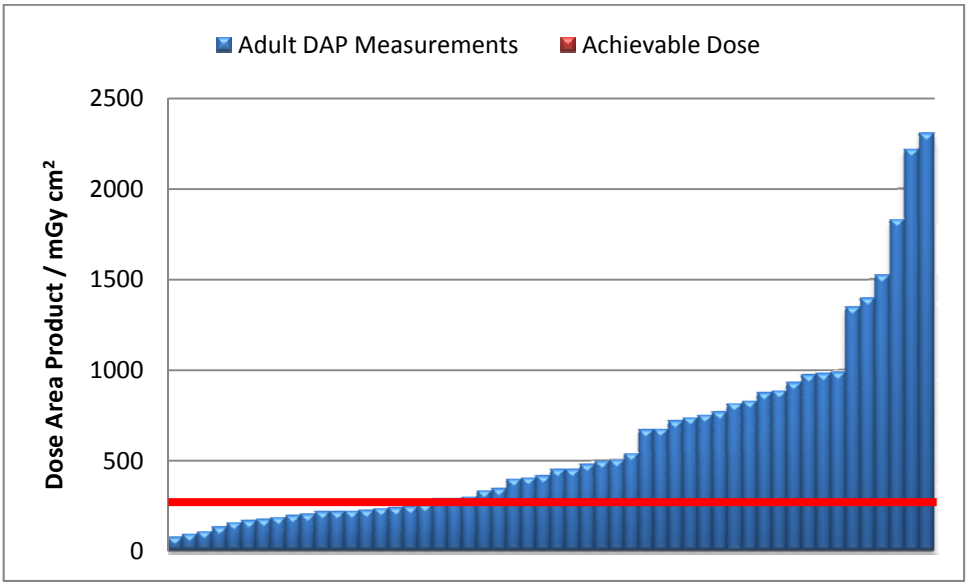

Figure 1 Summary of DAP measurements, in ascending DAP value. The horizontal bar represents the achievable dose, which is equal to the third quartile dose value of the adjusted DAP measurements (which was found to be equal to the 33rd percentile value of the actual DAP measurements)

In order to review this achievable dose the HPA asks that details of measurement results are provided to DXPS.Admin@hpa.org.uk using the results template provided in appendix B. An electronic version of the template can be obtained by sending a request to the same e-mail address. Separate adult and child achievable doses will be proposed once sufficient patient dose data has been collected. It is hoped that equipment models with smaller fields of view become the equipment of choice, and in the future it will be possible to recommend NRDs to reflect equipment and practices in the UK.

5 SUMMARY OF KEY RECOMMENDATIONS

- Existing guidance for conventional dental X-ray equipment covering the design of radiography rooms and quality assurance procedures should not be considered applicable for CBCT (Section 1).
- Users of dental CBCT equipment should consult their RPA and MPE prior to installing a dental CBCT unit (Section 2).
- The shielding requirements for each dental CBCT installation should be assessed on a case by case basis by the RPA (Section 2.4).
- All persons others than the patient should be excluded from the room during CBCT radiography; or provided with a shielded area within the room (Section 2.5).
- Unauthorised or accidental operation of the CBCT exposure control should be prevented (Section 2.6).
- Room warning lights should always be used and standard two stage X-ray room warning lights are preferred (Section 2.7).
- The whole of a radiography room should be designated a controlled area whenever the equipment is in a state of readiness to emit radiation (Section 2.8.1).
- Equipment suppliers should provide all necessary test equipment and procedures to enable QA checks to be performed by the user, as part of the equipment sale (Section 3.1).
- Users of dental CBCT must establish a QA programme which should include an initial acceptance/commissioning test, routine monthly QA checks and an annual full radiation safety test covering the tests included in Appendix A (Section 3.2, 3.4, Appendix A).
- An achievable dose of 250 mGy cm^2 is proposed as a starting point of dose optimisation and should be considered when users set their local DRLs (Section 4).
- New equipment should be selected that is capable of restricting patient exposure to below the achievable dose and provide appropriate fields of view for the dentist's intended uses (Section 4).
- Existing equipment that exceeds the achievable dose should be investigated to determine if it is possible to reduce the patient exposure (Section 4).

6 REFERENCES

British Institute of Radiology 2000 Radiation Shielding for Diagnostic X-rays, Report of a joint BIR/IPEM working party

Department of Health 2007 Guidance on the establishment and use of diagnostic reference levels (DRLs)

European Commission 1999 Radiation Protection 109. Guidance on Diagnostic Reference Levels (DRLs) for Medical Exposures. Luxembourg, Office for Official Publications of the European Communities. Available from:

ec.europa.eu/energy/nuclear/radiation_protection/doc/publication/109_en.pdf

European Commission 2004 Radiation Protection 136. European Guidelines on Radiation Protection in Dental Radiology. Luxembourg, Office for Official Publications of the European Communities, Available at:

ec.europa.eu/energy/nuclear/radioprotection/publication/doc/136_en.pdf [accessed 11 January 2010]

IEC (International Electrotechnical Commission) 2008 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment. IEC publication 60601-1-3.

Hart D, Hillier MC, Wall BF 2002 Doses to Patients from Medical X-ray Examinations in the UK - 2000 Review. NRPB-W14.

Holroyd JR, Gulson AD 2009 The radiation protection implications of the use of cone-beam computed tomography (CBCT) in dentistry – what you need to know. HPA: Chilton. Available at: www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1245914954194?p=1194947303775 [accessed 11 January 2010]

IPEM (Institute of Physics and Engineering and Medicine) 2002 Medical and Dental Guidance Notes. IPEM: York.

IPEM (Institute of Physics and Engineering and Medicine) 2005 Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Equipment, IPEM Report 91. IPEM: York.

KCARE 2005 DDR Commissioning and Annual QA Protocol Draft 8.0. KCARE: London. Available at:

www.kcare.co.uk/content.php?page=DDR(Physics)protocol_8.0.doc&folder=Education [accessed 11 January 2010]

Lofthag-Hansen S, Thilander-Klang A, Ekestubbe A, Helmrot E, Gröndahl K 2008 Calculating effective dose on a cone beam computed tomography device: 3D Accuitomo and 3D Accuitomo FPD. *Dentomaxillofac Radiol.* **37**:72–79.

Napier I 1999 Reference doses for dental radiography. *Br Dental J.* **186**:392–396.

RCR (Royal College of Radiologists) 2002 Clinical Radiology and Electronic Records. RCR Report BFCR(02)3 (Royal College of Radiologists, London)

SEDENTEXCT Project. [online] Available at: www.sedentexct.eu [Accessed 11 January 2010]

The Ionising Radiation (Medical Exposure) Regulations 2000. SI 2000/1059, London: HMSO.

The Ionising Radiations Regulation 1999. SI 1999/3232, London: HMSO.

7 ACKNOWLEDGEMENTS

The authors wish to thank the other members of the HPA working party who contributed to this document:

Jackie Brown, British Society of Dental and Maxillofacial Radiology
Andrew Dawood, Dental Surgeon
Cliff Double, Care Quality Commission
Nick Drage, University Dental Hospital, Cardiff
Crawford Gray, Dental Surgeon
Andrew Gulson, HPA
Phil Hollaway, Royal Surrey County Hospital
Keith Horner, University of Manchester
Daniel McAlonan, British Dental Association
Sally MacLachlan, HPA
Mike Nettleton, Health and Safety Executive
Paul Shrimpton, HPA
Kathlyn Slack, HPA

We would also like to express our thanks to the individuals and organisations that provided invaluable comments and expertise including:

IPEM Radiation Protection and Diagnostic Radiology Special Interest Groups
CT Users Group

Finally, we would like to thank all those who shared their experiences and measurement results from performance testing dental CBCT equipment.

APPENDIX A

Dental CBCT Performance Testing Requirements

A1 REGULAR TESTS

Ref	IPEM91 Ref	Description	Level	Frequency	Priority	Remedial Level	Suspension Level
DCB01	CT01	Image noise	A	Monthly	1	Baseline +/- 10%	Baseline +/- 25%
DCB02	CT02	Image density values	A	Monthly	1	Baseline +/- 10%	Baseline +/- 25%
DCB03	CT08	Image uniformity	A	Monthly	1	Baseline +/- 10%	
DCB04	IDD06	Image display monitor condition	A	Monthly	1	see Explanatory paragraph	
DCB05	IDD08	Image display monitor distance calibration	A	3 Monthly	1	+/- 5 mm	
DCB06	IDD09	Image display monitor resolution	A	3 Monthly	1	see Explanatory paragraph	

A2 ANNUAL TESTS

Ref	IPEM91 Ref	Description	Level	Frequency	Priority	Remedial Level	Suspension Level
DCB07	DDR11	Reconstructed Image measurement	B	12 Monthly	1	+/- 0.5 mm	
DCB08	CT06	Image noise	B	12 Monthly	1	Does not meet manufacturer's spec or Baseline or Inter-slice variation mean +/-10%	Baseline +/- 25%
DCB09	CT07	Image density values	B	12 Monthly	1	Does not meet manufacturer's spec or Baseline +/- 10%	Baseline +/- 25%
DCB10	CT08	Image uniformity	B	12 Monthly	1	Does not meet manufacturer's spec or Baseline +/- 10%	
DCB11	CT09	High contrast spatial resolution	B	12 Monthly	1	Does not meet manufacturer's spec or Baseline +/- 20%	
DCB12	CT10	CTDI - free in air	B	12 Monthly	2	Does not meet manufacturer's spec or Baseline +/- 15%	Baseline +/- 40%
DCB13	CT11	CTDI for single slice or rotation ($CTDI_w$)	B	12 Monthly	2	Does not meet manufacturer's spec or Baseline +/- 15%	
DCB14	---	Radiation field size	B	12 Monthly	1	> 10 mm or 10% of expected field size (whichever is smaller)	> size of the solid detector housing
DCB15	RAD09	Radiation output repeatability	B	12 Monthly	1	Mean +/- 10%	Mean +/- 20%
DCB16	RAD10	Radiation output reproducibility	B	12 Monthly	1	Baseline +/- 10%	Baseline +/- 20%
DCB17	RAD12	Operating potential	B	12 Monthly	2	+/- 5% of intended or +/- 5kV or < 60 kV	+/- 10% of intended or +/- 10kV
DCB18	---	Dental cone beam CT: DAP	B	12 Monthly	1	Does not meet manufacturer's spec or > Reference level	> 2 x Reference level

A3 COMMISSIONING TESTS

Description	Level	Frequency	Priority	Remedial Level	Suspension Level
X-ray tube leakage			2	see Explanatory notes	
Total filtration			1	< 2.5 mmAl total or less than manufacturer's lower limit if appropriate	
Slice thickness			2	+/- 20% or +/- 1mm (whichever is greater)	
High contrast material			1	see Explanatory paragraph	

A4 EXPLANATORY PARAGRAPHS

DCB01 (CT01)	Image noise

Suggested method: System manufacturer's quality control phantom, water or PMMA phantom.

References: IPEM (2005)

Comments: Measure standard deviation for a central ROI (or alternative ROI location if specified by the manufacturer) for the phantom. The size of the ROI should be 40% of the phantom diameter, to improve the statistical accuracy of the measurement. Ensure that the same size ROI is used every time the test is performed and that it is placed in the same position on the image.

Measurements are made in a transaxial slice at the centre of the phantom.

The test should be performed at the frequency recommended by the manufacturer, if this is greater than that in the preceding table.

DCB02 (CT02)	Image density values

Suggested method: System manufacturer's quality control phantom, water or PMMA phantom.

References: IPEM (2005)

Comments: Measure image density values for water or water equivalent material and a high density material (or in the absence of a suitable phantom use air). Perform measurements at an appropriate scan field of view for the size of the phantom, which should be fixed for all subsequent measurements. Measurements should be made in a transaxial slice.

DCB03 (CT08)	Image uniformity

Suggested method: System manufacturer's quality control phantom, water or PMMA phantom.

References: IPEM (2005)

Comments: Measure image density values for a ROI at the centre and around the periphery of the image (unless alternative ROI locations are specified by the manufacturer).

The remedial level is based on the difference between image density values at the centre and periphery.

Measurements should be made in a transaxial slice.

Before performing any measurements on the scanner, visually assess the image with a narrow window for obvious artefacts such as rings. Then review on a wider window to assess clinical relevance.

DCB04 (IDD06)	Image display monitor condition

Suggested method: Visual inspection of test pattern image such as SMPTE or TG18-QC and appropriate cleaning materials.

References: IPEM (2005)

Comments: Image display monitors should be clean, and the perceived contrast of the test pattern should be consistent between monitors connected to the same workstation (RCR, 2002). Ensure that the 5% and 95% details superimposed on the 0% and 100% squares, respectively, are visible.

DCB05 (IDD08)	Image display monitor distance calibration

Suggested method: Measure fixed distance and angle on a regular test pattern image.

References: IPEM (2005)

Comments: This test is intended for those applications where measurements of distance and angle are performed using the image display monitor and diagnostic workstation (RCR, 2002).

DCB06 (IDD09)	Image display monitor resolution

Suggested method: Visual inspection of test pattern image such as SMPTE or TG18-QC.

References: IPEM (2005)

Comments: Review both the low contrast and high contrast resolution patterns. Check resolution at centre and periphery is consistent and similar to baseline image.

DCB07 (DDR11)	Reconstructed image measurement

Suggested method: System manufacturer's quality control phantom containing at least two high contrast objects of known separation.

References: IPEM (2005); KCARE (2005)

Comments: Measure the distance between two points of known distance on the image. The QA phantom should allow measurements to be made in all three planes. Where possible the measurement should be for a distance of at least 5 cm.

DCB08 (CT06)	Image noise

Suggested method: System manufacturer's quality control phantom, water or PMMA phantom.

References: IPEM (2005)

Comments: As DCB01. Additional measurements should be made for a number of transaxial slices. At commissioning, measurements should also be made in all three planes.

DCB09 (CT07)	Image density values

Suggested method: System manufacturer's quality control phantom or CT Number phantom.

References: IPEM (2005)

Comments: As DCB02. Use a wider range of materials, such as aluminium, Teflon, PMMA, air, water, etc.

DCB10 (CT08)	Image uniformity

Suggested method: System manufacturer's quality control phantom, water or PMMA phantom.

References: IPEM (2005)

Comments: As DCB03. Additional measurements should be made in all three planes and for a number of slices.

DCB11 (CT09)	High contrast spatial resolution

Suggested method: Phantom containing a high contrast edge, pin, bead or bar test insert.

References: IPEM (2005)

Comments: Measurement should be made near the centre of the image. At commissioning, an additional measurement should be made at the periphery of the image.

DCB12 (CT10)	CTDI – free in air

Suggested method: Dosemeter and pencil ion chamber on-axis in air.

References: IPEM (2005)

Comments: Only necessary to measure when included in the manufacturer's equipment specification.

DCB13 (CT11)	$CTDI_{vol}$ for single slice or rotation

Suggested method: Pencil ionisation chamber in appropriate head CT dosimetry phantom.

References: IPEM (2005)

Comments: Only necessary to measure when included in the manufacturer's equipment specification.

DCB14	Radiation field size

Suggested method: Film or suitable CR or DR detector.

References: -----

Comments: Place film across detector; mark on film the bounds of the detector and perform a normal scan. The size of the resultant developed film image should be no greater than the bounds of the detector and must be no greater than the size of the solid detector housing. Scans should be performed at a range of available field sizes, but should always include the maximum field size.

DCB15 (RAD09)	Radiation output repeatability

Suggested method: Radiation dosemeter.

References: IPEM (2005)

Comments: Carry out at least 3 measurements at a typical clinical setting.

DCB16 (RAD10)	Radiation output reproducibility

Suggested method: Radiation dosemeter.

References: IPEM (2005)

Comments: In addition to DCB15, carry out measurements at low kV, low mA and high kV, high mA settings, covering the range of settings that may be clinically used.

DCB17 (RAD12)	Operating potential

Suggested method: Digital kV meter.

References: IPEM (2005)

Comments: Standard dental kV meter may not be suitable for equipment provided with high filtration (e.g. an additional copper filter). A standard medical kV meter should be appropriate.

DCB18	Dental cone beam CT: DAP

Suggested method: Suitable dosemeter to measure dose together with a beam area measurement or a suitable DAP meter.

References: European Commission (1999, 2004); Lofthag-Hansen et al (2007)

Comments: DAP measurements should be made for adult and child procedures.

The adult measurement should be made using the clinical protocol for the placement of an upper first molar implant in a standard male patient.

The child measurement should be made using the clinical protocol to image a single impacted maxillary canine of a 12-year old male.

Care should be taken on units where the beam size changes during the scan. A suitable DAP meter would be necessary for DAP measurements on these units.

If a dosemeter is to be used, it should be securely fixed to the centre of the image detector.

	X-ray tube leakage

Suggested method: Suitable leakage detector.

References: IEC (2008), NRPB (2001)

Comments: At every rating specified by the manufacturer, the air kerma from leakage radiation at a distance from the focal spot of 1 m, averaged over an area not exceeding 100 cm^2, does not exceed 1 mGy in one hour.

	Total filtration

Suggested method: Suitable HVL meter or aluminium filters.

References: IEC (2008)

Comments: Measure equivalent aluminium HVL and determine the total beam filtration.

(CT13)	Image slice thickness

Suggested method: Test phantom with inclined plates.

References: IPEM (2005)

Comments: none.

	High contrast object

Suggested method: System manufacturer's quality control phantom or high contrast material phantom (e.g. lead).

References: -----

Comments: Visual inspection of the reconstructed image should show the high contrast object clearly defined and undistorted. The presence of artefacts created by the object should be minimal and not significantly detrimental to the whole image.

APPENDIX B

Measurement Results Template

Dental Cone Beam CT Results Collection Form

Contact details

Name:
Organisation: **Tel:**
Address: **Email:**

Items in BOLD are required fields

Description		Units	Result(s)	Comments
Manufacturer				
Model				
Identifier				
Date of Test				
Operating potential		kV		
Tube current		mA		
Exposure time		s		
Voxel size		mm^3		
Field of view		diameter x height (cm)		
Image noise	Mean	Image Density		
	Std Dev	Image Density		
CT number uniformity	Centre	Image Density		
	North	Image Density		
	South	Image Density		
	East	Image Density		
	West	Image Density		
CT number Values	Teflon	Image Density		
	Air	Image Density		
	Acrylic	Image Density		
	LDPE	Image Density		
	Water	Image Density		
HC spatial resolution		Line Pairs / cm		
CTDI - in air	Centre	mGy		
CTDI - in PMMA	Centre	mGy		
	North	mGy		
	South	mGy		
	East	mGy		
	West	mGy		
CTDIw		mGy		
Dose @ detector - Adult		**mGy**		
Dose @ detector - Child		**mGy**		
Beam size @ detector - Adult		width x height (cm)		
Beam size @ detector - Child		width x height (cm)		
Dose area product - Adult*		**mGy cm^2**		
Dose area product - Child*		**mGy cm^2**		

Notes

a) kV, mA, time and voxel should be those used to obtain the results, rather that the range of settings
b) North = position closest to the x-ray tubehead prior to initiating an exposure
c) CTDI: If not CTDI100, please provide details of CTDI method in comments
d) Image density = the reported values for a ROI and may be a CT number, greyscale, etc.
***** The adult measurement should be made using the clinical protocol for the placement of an upper first molar implant in a standard male patient and the child measurement should be made using the clinical protocol to image a single impacted maxillary canine

If measurements carried out at range of settings e.g. FOV, please state. Once complete this form should be e-mailed to DXPS.Admin@hpa.org.uk