

Guidance on the Safe Use of Dental Cone Beam CT (Computed Tomography) Equipment

**Prepared by the HPA Working Party
on Dental Cone Beam CT Equipment**

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This report from the HPA Centre for Radiation, Chemical and Environmental Hazards reflects understanding and evaluation of the current scientific evidence as presented and referenced in this document.

PREFACE

Dental cone beam computed tomography (CBCT) is a relatively new application in dental imaging that is being rapidly taken up by specialist dental surgeons. The previous guidance on the safe use of dental x-ray equipment does not address CBCT and as described in this document, the radiation protection measures needed for dental CBCT extend beyond those set down in previous guidance.

Radiation doses to patients and potential doses to employees and other persons arising from the use of dental CBCT, although lower than from medical CT equipment, can be significantly higher than from conventional dental x-radiography equipment. This means that additional safeguards for patients, dental practice staff and other persons need to be considered. Typical radiation doses from various types of x-ray examinations of the head are shown in the table below.

TABLE 1 Typical patient doses from x-ray examinations of the head

Examination	Effective dose (μSv)¹	Dose as a multiple of the dose from a typical panoramic exam
Panoramic	24	1
Small FOV* CBCT	48 – 652	2 - 27
Large FOV* CBCT	68 – 1073	3 - 45
CT scan (dental programme)	534 – 2100	22 - 88

* FOV = Field of view

To put the numbers into context, the annual radiation dose to a member of the UK population is on average around 2,700 microsieverts. The dose from a conventional panoramic radiograph (24 microsieverts) is equivalent to that which would be received from a few days' exposure to natural background radiation, and carries an additional lifetime risk of cancer of one in a few million. The dose and attendant risk from a dental CBCT scan is, from the table, a few times to a few tens of times that from a panoramic radiograph.

Furthermore, it is far more likely that patients will be referred from one practice to another for a CBCT examination than has been the case with conventional dental examinations, involving more complex administrative procedures to meet legal requirements.

The aim of this publication is provide definitive guidance to enable all persons involved with dental CBCT equipment to work with it safely and in accordance with UK radiation protection legislation.

THE HPA WORKING PARTY ON DENTAL CBCT

Terms of reference

As a result of its experience providing radiation safety advice to dentists and carrying out the performance testing of dental x-ray equipment, HPA Centre for Radiation, Chemical and Environmental Hazards (CRCE) recognised the need to address the radiation protection implications arising from the increasing use of dental CBCT, and made this an objective of the corporate business plan for 2008-2009. The HPA working party (WP) was subsequently established in September 2008, with two main goals.

- Determine recommended standards for testing dental CBCT and prepare standards for publication
- Improve understanding of the radiation protection implications associated with the use of CBCT in dental practice

The WP issued interim guidance addressing the issues where advice was most urgently needed, on the HPA website in July 2009¹. The first of the main objectives was realised with the publication of HPA-RPD-065, also on the HPA website, in March 2010². This, in addition to setting out the WP's recommended Quality Assurance (QA) protocols, testing methods and criteria for dental CBCT, provided guidance on the recommended design features of dental CBCT facilities.

WP members also contributed to the NHS Purchasing and Supply Agency's comparative evaluation report CEP10048, Dental Cone Beam Computed Tomography (CBCT) Systems, also published in March 2010³.

Publication of this document marks the culmination of the WP's work. It is anticipated that the guidance contained herein will be adopted as a standard of best practice for the use of dental CBCT equipment within the UK, and will serve as the basis for any future guidance on radiation protection in dentistry with regard to dental CBCT equipment.

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Summary of essential actions when acquiring a dental CBCT system

The table below provides a guide to the most significant actions that must be addressed to comply with the Ionising Radiations Regulations 1999 (IRR99)⁴ and the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER)⁵, when planning to obtain a new dental CBCT system. However, it is essential to refer to the various sections of the guidance in order to fully understand how to comply with the relevant requirements.

The legal person at the practice (see section 1.2) is responsible for making sure that all the following are carried out.

“Done” (✓)	Action/Task	Relevant Section of this guidance
<input type="checkbox"/>	Unless at premises where x-ray equipment has previously been used by the practice, notify HSE at least 28 days in advance.	2.1
<input type="checkbox"/>	When buying CBCT equipment check that it is capable of ensuring the dose to the patient is as low as reasonably practicable and below “achievable dose levels” (or any future reference dose levels). Seek help from the MPE/RPA.	2.2, 2.3, 4.1.6, 4.2
<input type="checkbox"/>	Consult the RPA about the design of the CBCT facility, including required structural protection and safety and warning devices.	2.4, 2.5
<input type="checkbox"/>	Revise the radiation risk assessment and local rules, taking advice from the RPA.	2.6, 2.8 to 2.15 inclusive
<input type="checkbox"/>	Ensure all staff radiation protection training is updated for use of the CBCT.	2.17
<input type="checkbox"/>	Get evidence from the installer that a suitable critical examination has been carried out.	2.7
<input type="checkbox"/>	Have the CBCT “adequately tested” before first use and then annually by the MPE/RPA.	2.16, 2.7
<input type="checkbox"/>	Set up an in-house QA programme.	2.16, 4.3
<input type="checkbox"/>	Adopt appropriate referral criteria for CBCT and inform all referrers.	3.2, 3.3
<input type="checkbox"/>	Review entitlement of referrers, practitioners and operators for the CBCT imaging and document in legal person’s procedures.	3.1
<input type="checkbox"/>	Review all legal person’s IRMER procedures to ensure that they adequately cover the CBCT work, paying particular attention to patient identification, justification and arrangements for the clinical evaluation of images.	3.4 to 3.8 inclusive
<input type="checkbox"/>	Document guideline exposure settings for average sized patients undergoing standard CBCT examinations, paying particular attention to the optimisation of patient dose (IRMER protocols).	4.1
<input type="checkbox"/>	Ensure all practitioners, operators (including those carrying out the clinical evaluation) and referrers have adequate training.	3.9
<input type="checkbox"/>	Carry out patient dose audits with the help of the MPE.	4.1.7

CONTENTS

Preface	iii
The HPA Working Party on Dental CBCT	iv
Terms of reference	iv
Membership of working party	iv
Acknowledgements	v
Summary of essential actions when acquiring a dental CBCT system	vi
1 Introduction	1
1.1 Application of guidance	1
1.2 Legal person	1
2 Requirements of IRR99 for Dental CBCT	2
2.1 Notification to the Health and Safety Executive	2
2.2 Radiation Protection Adviser (RPA)	2
2.3 Equipment selection	3
2.4 Design of facilities	3
2.5 Safety and warning systems	4
2.6 Restriction of exposure	5
2.6.1 Design features	5
2.6.2 Procedural controls	5
2.7 Critical examination	6
2.8 Prior risk assessment	6
2.8.1 Potential for radiation exposure from routine work	7
2.8.2 Potential for radiation exposure from reasonably foreseeable accidents	7
2.9 Personal protective equipment (PPE)	7
2.10 Designation of areas	8
2.11 Classified persons	9
2.12 Personal dosimetry	9
2.12.1 Pregnant employees	9
2.13 Dose investigation level	9
2.14 Local rules	9
2.15 Monitoring of designated areas	10
2.16 QA programme for equipment	11
2.16.1 Adequate testing	11
2.16.2 Achievable dose	12
2.16.3 Routine annual testing and tests after repairs or modifications	12
2.16.4 Monthly QA checks	13
2.16.5 Maintenance and examination of engineering controls	13
2.17 Information, instruction and training	13
2.17.1 Dental practices	13
2.17.2 Manufacturers and suppliers, etc	14
2.18 Co-operation between employers	14
2.19 Patient doses much greater than intended	15
2.20 Requirements of IRR99 – summary of key aspects	16
3 IRMER Requirements for Dental CBCT – Administrative Aspects	17
3.1 Introduction	17
3.2 Referrals	19
3.3 Referral criteria	20
3.4 Justification	21

3.5	Patient identification	22
3.6	Patient pregnancy	22
3.7	Documentation of the exposure	22
	3.7.1 Records to be kept for each dental CBCT examination	22
	3.7.2 Patient doses much greater than intended	23
3.8	Clinical evaluation	23
3.9	Training	24
3.10	Administrative requirements of IRMER – summary of key aspects	26
4	IRMER Requirements for Dental CBCT – Practical Aspects	27
	4.1 Optimisation of patient dose – operation of dental CBCT equipment	27
	4.1.1 Written protocols	27
	4.1.2 Patient positioning	27
	4.1.3 Use of thyroid shields and lead aprons	28
	4.1.4 Exposure settings	28
	4.1.5 Image detector	29
	4.1.6 Image reconstruction	29
	4.1.7 Patient dose audit	29
	4.2 Requirements for display screen equipment	30
	4.3 QA of dental CBCT image quality	31
	4.4 Practical requirements of IRMER – summary of key aspects	34
5	References	35
APPENDIX A	Dental CBCT Performance Testing Requirements	37
	A1 Regular Tests	38
	A2 Annual Tests	39
	A3 Commissioning Tests	40
	A4 Explanatory paragraphs	41
	A5 Measurement Results Template	47
APPENDIX B	Core Curriculum In Cone Beam Computed Tomography (CBCT) for Dentists and Dental Care Professionals	48
	B1 Introduction	48
	B2 Theoretical Instruction in the use of CBCT Equipment	49
	B3 Practical Instruction	52
	B4 Time Required	52
	B5 Tuition	53
	B6 References	53
APPENDIX C	Example Service-Level Agreement	54
APPENDIX D	Example Imaging Referral Form	55
APPENDIX E	EADMF Basic Principles for Use of Dental CBCT – Sections Relevant to Referral/Justification	56

1 INTRODUCTION

This publication provides advice to dentists and others supplying, using, or working with dental CBCT equipment, regarding the practical application of the Ionising Radiations Regulations 1999 (IRR99), the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) and its subsequent amendments^{6,7}. It supplements that already provided in the Guidance Notes for Dental Practitioners on the Safe Use of X-Ray Equipment⁸ (the Dental GNs) published by the National Radiological Protection Board (NRPB), or the Medical and Dental Guidance Notes⁹ (MDGNs) published by the Institute of Physics and Engineering in Medicine (IPEM).

The guidance provided in this report is set out primarily under the title of each piece of legislation. However, the order in which each topic is addressed also approximates the order in which issues should normally be considered by anyone planning to obtain a dental CBCT system for the first time.

1.1 Application of guidance

This guidance is aimed primarily at dental practices and other users of dental CBCT such as hospital departments. However, for simplicity, the terms “dentist” and “dental practice” are used throughout to represent all users of dental CBCT and the various establishments in which dental CBCT is used, respectively. In practice, all users will include those with legal responsibility for CBCT equipment, prescribers of dental CBCT scans, those who refer patients for CBCT scans, operators of CBCT equipment and those who perform maintenance on CBCT equipment.

1.2 Legal person

Responsibilities under IRR99 relate to an “employer” and a “radiation employer” whilst IRMER uses only the term “employer” but with a definition based on the concept of responsibility rather than employment law. What matters is that there is a clearly defined person, or body corporate, that takes legal responsibility for implementing the requirements of both sets of legislation. Throughout this guidance, that person or body corporate is referred to as the *legal person* unless the context demands otherwise.

2 REQUIREMENTS OF IRR99 FOR DENTAL CBCT

2.1 Notification to the Health and Safety Executive

The Health and Safety Executive (HSE) must be notified when it is intended to use ionising radiation for the first time, or a “material change” is going to be made to an existing use. With respect to the latter, provided that the legal person has already informed the HSE of the use of x-ray equipment at the premises involved, the addition of dental CBCT does not constitute a ‘material change’ and further notification is not required. However, if the premises are new or the practice has changed its name the HSE must be informed.

If required, notification of work with ionising radiation should be made to HSE, in writing, at least 28 days in advance of its commencement. This can be done by email to irrnot@hse.gsi.gov.uk. For further information on notifications see <http://www.hse.gov.uk/radiation/ionising/notification.htm>. It should be noted that HSE has the power to require legal persons to provide further information regarding any notification.

2.2 Radiation Protection Adviser (RPA)

According to Regulation 13(1), legal persons must consult one or more suitable RPAs as necessary for advice regarding compliance with IRR99. Consultation with an RPA for advice on any of the matters set out in schedule 5 of IRR99 (indicated in bold type in the list below) is specifically required under Regulation 13(1). As dental CBCT is a relatively new use of ionising radiation, it is important that the advice of a suitable RPA is obtained at the appropriate time, particularly on the following matters.

- Equipment selection.
- **Prior assessment of installation plans.**
- Review of risk assessment, local rules and contingency plans.
- **Designation of areas and subsequent requirements.**
- Personal dosimetry.
- QA programme, including **adequate testing** and routine testing.
- Periodic testing of engineering controls, design features, safety and warning devices etc

A suitable RPA would be an individual, or RPA body, able to demonstrate compliance with HSE’s current criteria of competence and having specific knowledge and adequate experience of radiation protection as applied to diagnostic radiology in the medical/dental sector.

2.3 Equipment selection

Legal persons are required by Regulation 32(1) to consider the restriction of patient doses when purchasing equipment. As with other types of x-ray imaging equipment, dental CBCT equipment should be capable of providing images of adequate diagnostic quality while restricting patient exposures so far as reasonably practicable. Detailed guidance on this is provided in the section on Optimisation (see section 4.1).

In addition, new dental CBCT equipment should be supplied with the following features:

- The safety and warning features (or the capability to incorporate them into its operation), described in section 2.5.
- Imaging software that meets the specification set out in section 4.1.6 to allow the manipulation and clinical evaluation of patient images.
- Display screen equipment meeting the specification set out in section 4.2.
- Additional software tools and any test objects necessary to allow the adequate testing and monthly in-house QA checks (see section 2.16) to be performed.
- CE marking in accordance with the Medical Devices Directive¹⁰.

A Medical Physics Expert (MPE) or RPA should be able to offer useful advice on the suitability or otherwise of different equipment for its intended clinical use. Further guidance may be obtained from the NHS Purchasing and Supply Agency Evaluation Report³ on dental CBCT systems.

2.4 Design of facilities

It is important that those planning to purchase dental CBCT equipment and suppliers planning to install it realise that the advice on adequate shielding provided in the Dental GNs and MDGNs is not adequate for dental CBCT. The radiation protection aspects of the planned installation must be considered by the legal person on a case-by-case basis, in consultation with a suitable RPA. Guidance developed by the WP on the design of dental CBCT facilities has already been published by the HPA².

A summary of the key issues is given below.

- When assessing a planned installation, the dose constraint to be used should continue to be the public dose constraint for a new source of ionising radiation of 0.3 mSv per year.
- The average weekly workload used for calculation purposes should be the maximum foreseeable in the long term, and should not normally be assumed to be less than 20 exposures per week in a dental practice setting, or 50 per week in a hospital department.
- Consideration should be given to ensuring that the instantaneous and time-averaged dose rates outside the room do not exceed 7.5 microsieverts per hour, especially in areas that are accessible to people untrained in radiation protection.
- Dental CBCT equipment should be installed in a dedicated room used solely for radiography.

- The position and construction of the walls, doors, windows, floor and ceiling and the use and occupancy of areas above and below the room, must all be considered, regardless of their distance from the dental CBCT equipment.
- Where high workloads are involved (above 50 scans per week on average), or the dental CBCT unit is installed close to a wall, the lead equivalence of walls required to protect people in adjacent areas might be as much as 2.3 mm.
- In particular, dental CBCT scanners where the patient lies down and the tubehead rotates in a vertical plane will give rise to much higher scattered radiation levels in areas above and below the scanning room. The shielding of floors and ceilings may then be critical, especially in buildings where timber is used in construction.
- Information regarding the maximum likely scattered radiation dose per scan, and the operating potential, should be provided by the supplier or manufacturer of the equipment to enable the shielding requirements to be assessed.
- The operator must be provided with a means of observing the patient throughout the exposure, from his or her normal position. This should be either outside the room or inside, from behind a shielded barrier (see section 2.6.2). Alternatively, the use of a CCTV camera and screen could be considered. The determination of the shielding requirements for any window provided for this purpose should be included at the planning stage.

2.5 Safety and warning systems

Compared to conventional dental x-ray equipment, dental CBCT equipment produces generally higher scattered doses during exposures, and unlike conventional equipment, often requires the mains power to be on throughout the working day. Due to the higher potential for the exposure of staff and other persons represented by dental CBCT, the supervision of entry points by the operator is not considered a satisfactory means of restricting access to the room. The following safety and warning features are recommended for dental CBCT, and should be applied in preference to any administrative controls on access.

- Two-stage warning lights should be provided outside each entrance to the radiography room, regardless of the operator's position. The warning lights should operate automatically, one to indicate when the unit is in a state of readiness to emit x-rays (usually whenever the power is switched on), and the second to indicate when x-rays are being generated. The significance of both lights should be made clear, either by means of a supplementary notice or legends on the light box panels. The lights and/or notice should incorporate the trefoil symbol and clearly indicate when a controlled area exists (see section 2.10). They must also comply with the Health and Safety (Safety Signs and Signals) Regulations 1996¹¹.
- The operator should not normally have to enter the room to initiate exposures, or to disconnect the equipment from its power supply in the event of an incident. Where dental CBCT equipment requires that the exposure is initiated from a computer keyboard and does not employ a dead-man switch, a suitable emergency off/stop switch or mains isolator should be provided in a position that the operator can easily reach without having to enter the room.

- Sufficient safeguards must be provided to ensure dental CBCT equipment cannot be operated by persons not authorised to do so. It is usual for the scanner and the controlling computer to need to be put into a ready mode before it is possible to initiate an exposure, and this is considered satisfactory as long as the computer is kept in a password protected, locked state when not in use (see section 2.14).

Note that the electrical safety aspects of the planned installation must comply with the relevant requirements, as specified in the MHRA's Medical Electrical Installation Guidance Notes (commonly referred to as MEIGaN)¹².

2.6 Restriction of exposure

2.6.1 Design features

The legal person has a fundamental duty under Regulation 8(1) 'to restrict so far as is reasonably practicable the extent to which his employees and other persons are exposed to ionising radiation.' Regulation 8(2) further lays down a hierarchy of control measures to achieve this, with priority given to the use of design features and engineering controls, supported by safety features and warning devices. Only after these have been applied should consideration be given to the use of systems of work to restrict exposure.

A dental CBCT facility that is designed, constructed and equipped according to the guidance in sections 2.4 and 2.5 will fulfil the requirements of IRR99 Regulations 8(1) and 8(2) regarding the physical control measures to achieve the adequate restriction of exposure to the operator and other persons.

2.6.2 Procedural controls

For conventional dental radiography an operator position of 1.5 m away from and behind the x-ray tubehead would normally be sufficient to ensure that annual effective doses are unlikely to exceed 1 mSvⁱ. For dental CBCT equipment, however, the generally higher levels of scattered radiation produced during examinations could lead to operators receiving annual effective doses in excess of the statutory dose limit for employees of 20 mSv unless further precautions were taken. This being the case, the operator and all other persons (apart from the patient) should either be positioned outside the room or behind a shielded area inside the room during CBCT examinations.

Special consideration should be given where it is essential for a person to remain inside the room to provide reassurance or other form of support for the patient, to ensure that adequate radiation protection is provided for that person. This would normally involve the supporter wearing a lead apron with a lead equivalence of at least 0.25 mm (see section 2.14).

ⁱ This is the dose limit set in IRR99 for members of the public (excluding patients) and employees not considered to be working with ionising radiation, such as reception staff and others with no involvement in the practical aspects of radiography.

2.7 Critical examination

The installer is responsible for ensuring that a critical examination is carried out for each and every dental CBCT installation, as for any other application of ionising radiation. A critical examination will also be necessary following any relocation of existing equipment. The scope and conduct of the examination must be subject to consultation with an RPA, but should ensure that all aspects of the radiation safety of the equipment that might be affected by the installation are properly covered, including the radiation safety of the patient. It is recommended that this should include an examination of the presence and correct operation of the following safety and warning features of the equipment and the environment in which it is installed:

- Equipment warning lights indicating “mains on” and “x-rays”.
- Equipment audible warning of x-ray emission.
- Warning lights and signs outside all entrances to the room.
- Presence and operation of mains isolation switches and / or emergency stops.
- Adequacy of the exposure control, including security against unauthorised use.
- Adequacy of the shielding provided for the operator and other persons, including suitable measurements of radiation levels in adjacent areas (see section 2.15).
- Adequacy of the general layout of the room with respect to radiation protection.
- Patient safety features such as filtration and tubehead leakage.

This list is not exhaustive. HSE provides guidance on critical examinations and related matters in Guidance Note PM77¹³.

It would be of great benefit to users if the adequate testing (‘acceptance testing’) that is required by Regulation 32 (see section 2.16) to be carried out before the equipment is put into clinical use, could be carried out on behalf of the user, at the same time as the critical examination. It is recommended that dental practices and their RPAs address this issue at an early stage of the discussions with the installer.

It will also be appropriate to carry out further tests following any major repairs or modifications etc that might have consequences for the radiation safety of existing equipment. The QA programme for equipment (see section 2.16) should make adequate provision for tests made under these circumstances, and the scope of the tests should be decided in consultation with an RPA.

2.8 Prior risk assessment

The legal person, in consultation with an RPA, must ensure that a suitable and sufficient risk assessment has been carried out before any new activity involving work with ionising radiation commences (Regulation 7). The aims of the risk assessment are to:

- Evaluate the nature and magnitude of risks to employees and other persons (other than patients), during both accident situations and routine work.
- Identify the means necessary to ensure that doses to employees and other persons are restricted, so far as reasonably practicable, as required by Regulation 8(1).

- Identify all hazards with the potential to cause a radiation accident.
- Prevent any such accidents occurring, and limit the consequences of any that do occur.

Paragraph 44 of the Approved Code of Practice to IRR99 (the ACoP) specifies the matters that (where relevant) must be considered when undertaking a risk assessment, and paragraph 45 of the ACoP specifies the subjects that (where relevant) must be included in the decisions arising from the risk assessment. Before installing dental CBCT equipment for the first time, it is important that any existing risk assessment for conventional dental radiography is reviewed thoroughly against paragraphs 44 and 45 of the ACoP, in consultation with a suitable RPA, and the outcome documented.

2.8.1 Potential for radiation exposure from routine work

Providing that the guidance in sections 2.4 to 2.6 is followed, effective doses to operators and other persons arising from routine work should be less than 1 mSv per year.

2.8.2 Potential for radiation exposure from reasonably foreseeable accidents

Accidents that should be considered to be reasonably foreseeable for dental CBCT equipment include the following.

- Failure of x-ray emission to terminate at the end of an exposure.
- Damage to the equipment affecting the shielding of the x-ray tubehead.
- Initiation of an exposure while a person remains inside the room.
- Inappropriate use of the equipment (eg, taking radiographs of persons to check the correct functioning).

This list is not exhaustive. In common with other forms of dental x-ray diagnostic equipment, it is not considered reasonably foreseeable that accidents could give rise to effective doses exceeding 6 mSv, or equivalent doses exceeding 3/10 of the relevant dose limit.

The findings of the risk assessment with regard to reasonably foreseeable accidents should be incorporated into the contingency plans (see section 2.14).

2.9 Personal protective equipment (PPE)

If the approach recommended in this guidance is followed and employees stand outside the room or behind a protective shield during exposures, the use of PPE should not normally be necessary as effective doses to employees would then be expected to be very low, certainly less than 1 mSv per year. Where lead aprons are used (for instance, by persons supporting or reassuring patients), these must be stored appropriately when not in use. Lead aprons should be hung on rails of sufficiently large diameter to avoid creasing, and should never be folded. Each apron should be visually

examined at frequent intervals. Thorough examinations for cracks in the protective material should be made annually and the results recorded. Any apron showing damage should be replaced.

2.10 Designation of areas

For conventional dental x-ray equipment with normal radiographic workloads, the Dental GNs⁸ suggest that it is normally satisfactory to designate a controlled area which extends in the direction of the primary beam until this is intercepted by shielding (for intra oral equipment), and up to 1.5 m away from the patient and x-ray tubehead in all other directions. In addition, for conventional dental x-ray equipment, usual practice is that a controlled area is considered to exist for the short time necessary for radiography, with the power supply being switched off immediately afterwards. In effect, however, this is a relaxation of the requirements in IRR99 for the demarcation of a controlled area, based on the fact that the work is of short duration.

For dental CBCT equipment, this relaxation cannot be justified and the requirements of IRR99 for the designation of a controlled area then apply in full. The following approach to the designation of controlled areas is recommended for dental CBCT.

- The controlled area should normally be considered to extend throughout the entire room. This is because of the high levels of scattered radiation within the room during exposures, requiring special procedures to be followed to restrict the exposure of the operator and other persons.
- This approach should apply during the installation, maintenance or testing of the equipment by service engineers or physicists, as well as during routine clinical use.
- The controlled area should be considered to exist whenever the equipment is switched on and the exposure controls enabled (meaning that no exposure disabling features such as key switches or passwords for the controlling software are in use).
- In most cases, this will mean that the controlled area will exist throughout the working day as unlike conventional dental x-ray equipment, where the mains power should be switched off when the equipment is not in use, the mains power to dental CBCT equipment must normally be left switched on. This is due to the need for the equipment to perform extensive self-calibration routines each time it is switched off and on again.
- For equipment that can be switched on and off, or have its exposure controls disabled between periods of use, the user would have the option of designating a controlled area only when the equipment was in use.
- Throughout the time that the controlled area exists, access to it must be restricted to persons who are either classified or work in accordance with written arrangements, laid down in suitable local rules (see section 2.14).
- Staff must be made aware of the meaning of the warning lights and notices at the room entrances, and obey the prohibitions on entry when these apply (see section 2.17).

It should not normally be necessary to designate any other areas as either controlled or supervised, outside a room that has been properly designed and constructed in accordance with the guidance laid down in sections 2.4 and 2.5.

2.11 Classified persons

Decisions regarding the designation of persons as classified and the provision of personal dosimetry should be made during the process of the prior risk assessment. However, it should not normally be necessary for any persons working with dental CBCT in accordance with this guidance to be classified, as annual effective doses and doses likely to be received during reasonably foreseeable accidents, should be well below 6 mSv, or 3/10 of any relevant dose limit.

2.12 Personal dosimetry

Personal dosimetry is appropriate for the operators (including service engineers and physicists testing the equipment) and any dental practice staff who regularly enter the room, to ensure that the written arrangements covering access to the room are effective in restricting exposures. Due to the anticipated low annual doses if proper procedures are followed, dosimetry could, if preferred, be provided for an initial trial period. On the advice of the RPA, continuous monitoring may not be considered necessary if the trial period can establish that doses are adequately restricted. Any significant changes to workload, equipment or techniques should trigger a review of the risk assessment, including whether a further fixed period or continuous personal monitoring is required.

2.12.1 Pregnant employees

As the dose received by any employee is expected to be significantly lower than 1 mSv per year, the dose to the foetus should also be lower than this level and therefore no special protection measures are necessary. However, the legal person may opt to provide personal dosimetry for female employees for reassurance purposes, should they wish.

2.13 Dose investigation level

Doses to employees arising from the use of a dental CBCT scanner in a facility designed in accordance with this guidance should be well below 1 mSv per year, and this would be an appropriate value for the dose investigation level.

2.14 Local rules

Local rules should be drawn up. Where there are existing local rules these must be reviewed and revised as necessary to reflect the differences between dental CBCT and

other forms of dental radiography, and incorporate the findings of the risk assessment (see section 2.8). The local rules must include the following.

- The description of the extent of the controlled area, and the exact conditions under which it exists (see section 2.10).
- The means of restricting access to the controlled area.
- The name of the radiation protection supervisor (RPS).
- The means of preventing operation of the equipment by unauthorised persons (see section 2.5).
- The 'key working instructions' setting out the safety precautions that staff must follow to restrict exposures to themselves and other persons.
- Written arrangements governing access to the controlled area (especially where persons have to support the patient during exposures).
- The dose investigation level (see section 2.13).
- The need to address personal dosimetry.
- Contingency plans to be followed in the event of accidents.

The standard contingency plans for conventional dental x-ray equipment, that is to switch off the equipment's power supply without approaching the tubehead, inform the RPS and prohibit further use pending investigation, will also suffice for dental CBCT.

2.15 Monitoring of designated areas

Regulation 19 requires levels of ionising radiation to be adequately monitored to ensure that any controlled and supervised areas remain correctly designated over time. In view of the higher radiation risks that dental CBCT systems represent compared to conventional dental equipment, the following approach is recommended.

- The legal person should make suitable contractual arrangements with the installer for adequate monitoring to be made around the installation at the time of the critical examination. Details of the type and scope of measurements should be formally agreed between the practice and installer, following consultation with the practice's RPA, and/or the installer's RPA as appropriate. Alternatively, the practice's RPA might make the measurements if in a position to do so. The practice's RPA should normally already have been consulted regarding the design and construction of the room, and the measurements made should provide confirmation that the shielding is in fact adequate.
- Further measurements should be made at regular intervals, perhaps during the annual routine tests. Measurements should be made at least once every three years. Further measurements should also be considered if changes in the working arrangements suggest that the RPA's original prior assessment of installation plans may no longer be valid, for instance if the radiographic workload increases or if any changes to the equipment or the layout or structure of the room are subsequently made.

Measurements may be made with an ion chamber or other suitable instrument, capable of measuring the dose per exposure cycle transmitted through the room boundaries to the operator's position and other occupied areas. Some dental CBCT equipment generates a pulsed x-ray output and care should be taken to select instruments capable of measuring pulsed radiation fields, if relevant. The likely annual dose may then be calculated on the basis of the assumed (or actual) workload. An alternative approach might be to fix suitable "environmental" dosimeters on the outside walls of the room for extended periods, and log the number of exposures made during the period of monitoring. All measurements should be made with a suitable phantom in the position of the patient's head to act as a scattering medium, using the largest field of view and highest exposure factors, to give the worst case.

The room boundaries should provide shielding sufficient to ensure that annual doses arising from the operation of the dental CBCT equipment are unlikely to exceed 0.3 mSv, and that the instantaneous dose rate in any areas outside the room that are accessible to people untrained in radiation protection is less than 7.5 microsieverts per hour during an examination.

A record of the results of the monitoring should be retained by the practice for at least two years after the date that they were made.

2.16 QA programme for equipment

Legal persons are required by Regulation 32(3) to establish a QA programme, in consultation with a suitable RPA, to ensure that equipment remains capable of the adequate restriction of patient dose. (Note that IRMER also contains extensive QA requirements, details of which are set out in sections 3 and 4.)

The QA programme under IRR99 must include the following:

- Adequate testing before the first clinical use (commonly known as 'acceptance testing').
- Routine retesting (including in-house checks) at appropriate intervals and following any major maintenance.
- Representative measurements of patient dose.
- Remedial and suspension levels for action.
- Preventative maintenance and inspections in accordance with the supplier's recommendations.

2.16.1 Adequate testing

Details of the tests and performance standards recommended by the WP have been published² and are provided as Appendix A to this guidance. The tests carried out immediately after installation should be sufficient to enable the results to be compared to the manufacturer's specification and the remedial and suspension levels recommended by the WP, or any subsequent update. In particular, measurements of representative

patient doses should be made for comparison with the achievable doseⁱⁱ (or any future national reference doses published by HPA), and to provide a baseline against which the results of future routine tests can be compared.

2.16.2 Achievable dose

The achievable dose is intended to help persons responsible for purchasing new dental CBCT models to select those that are most capable of adequately restricting patient doses during dental examinations. It is recognised that users of some existing equipment, especially models with large fixed fields of view will not be able to reduce doses below the achievable dose and still obtain image data of sufficient quality for clinical purposes. It is not suggested that such equipment would need to be immediately replaced. Instead, the WP recommends that RPAs and MPEs should apply the achievable dose to existing equipment realistically, advising users how best to optimise radiation exposures of patients until such time as the equipment can be upgraded or replaced with equipment that can comply with the achievable dose. Where the patient dose is particularly high, the RPA/MPE may recommend that the equipment is only used for specific examinations for which it might be better suited; for example large field of view (FOV) equipment for imaging areas of interest extending outside the dento-alveolar regionⁱⁱⁱ such as severe trauma of the facial bones where cross-sectional imaging is required.

2.16.3 Routine annual testing and tests after repairs or modifications

Diagnostic x-ray equipment should be subject to routine testing at suitable intervals. While it is sufficient to carry out routine tests once every three years for conventional dental equipment, dental CBCT units should be subject to an annual routine test. Additional tests should be carried out following any significant repairs or modifications that may have affected the equipment's performance. If the modifications may have affected the radiation safety of the equipment, a critical examination may also be required (see section 2.7). The results of all tests should be compared to the baseline results obtained after installation to ensure no deterioration in image quality performance or significant increase in patient dose has occurred. Until such time as national reference levels for dental CBCT are established, the WP recommends that a change in patient dose of more than 20% from the local diagnostic reference level (LDRL) set with the help of the RPA/MPE (see section 4.17), is used as a remedial level.

ⁱⁱ When imaging the dental anatomy new CBCT equipment should be capable of delivering patient doses below the achievable dose recommended by the HPA WP, or any national reference dose that is subsequently published by the HPA in its five-yearly reviews of the national patient dose database. The achievable dose is a dose-area product (DAP) value of 250 mGy cm² for the clinical protocol that would normally be used for the placement of an upper first molar implant in a standard male patient. This examination should be used as the basis for any future national reference dose. The WP also recommends that a separate reference level for paediatric examinations is set as soon as possible, based on the DAP for the clinical protocol that would normally be used to image a single impacted maxillary canine of a 12-year old male. See HPA-RPD-065.

ⁱⁱⁱ For the purpose of this guidance the dento-alveolar region is defined as the teeth and their supporting bone, including the mandible and maxilla up to the floor of the nose.

2.16.4 Monthly QA checks

In addition to the annual routine testing, the WP recommends² that monthly checks on the image quality performance of the equipment, including the display screen, should be carried out by the user, compared to the manufacturer's performance specification and baseline values, and the results recorded. Where remedial levels are exceeded, action should be taken to improve performance. If a suspension level is exceeded, the equipment should be immediately withdrawn from clinical use until the fault has been rectified or the equipment replaced. Where a specialised QA test object is necessary for these checks to be carried out, this should be supplied with the equipment as standard.

2.16.5 Maintenance and examination of engineering controls

The legal person's quality assurance programme should include the preventative maintenance and inspection carried out by the supplier (or a qualified service agent), which would normally include any safety and warning features and engineering controls supplied with the equipment. Adequate maintenance and examination of engineering controls is also a requirement of Regulation 10 of IRR99.

In addition, the legal person should establish a programme of in-house inspections of the following features of the equipment.

- Equipment warning lights indicating "mains on" and "x-rays".
- Equipment audible warning of "x-rays".
- Warning lights and signs outside all entrances.
- Emergency stops and / or mains switches.
- Adequacy of the exposure control, including security against unauthorised use.

Observing whether or not these features are operating correctly should be a matter of habit for all operators, so that any problems are brought to the immediate attention of the RPS or legal person and any necessary action taken. However, it is advisable for routine functional checks to be made, and the results recorded, at intervals not exceeding once every six months.

2.17 Information, instruction and training

2.17.1 Dental practices

Staff should have their training updated following the introduction of dental CBCT. In particular, equipment operators should have a good understanding of the requirements of any revised local rules and the importance of compliance, while staff not directly involved in radiography should be provided with information sufficient to ensure their continued safety; for instance, the significance of the room warning lights and signs and the restrictions on access to the room when these are illuminated.

The appointed RPS must be aware of the differences in the magnitude of the radiation hazard presented by the dental CBCT unit in question, compared to conventional dental x-ray sets, and the reasons underlying the different working arrangements set out in the local rules for use of the equipment. Formal training in radiation safety, including the requirements of IRR99 specific to dental CBCT, may be appropriate for RPSs who are

otherwise adequately trained for their role. It is important to realise that update training courses provided for the purposes of IRMER will not necessarily be adequate for the purposes of IRR99, and care should be taken in selecting the most appropriate course for RPSs.

2.17.2 Manufacturers and suppliers, etc

Employers whose staff install, test, maintain or repair dental CBCT equipment will need to provide training for their staff similar to that outlined above for equipment operators.

Manufacturers and suppliers also have a duty to pass adequate information to the user to enable them to comply with IRR99 in respect of the proper use, testing and maintenance of the equipment.

This information should include the following aspects:

- General information for prospective purchasers regarding the safe siting, shielding, installation and operation of the equipment.
- A strong recommendation that the client should consult a suitable RPA.
- A performance specification adequate to enable comparison with the results of acceptance tests, annual routine tests and the user's in-house quality assurance checks, including expected patient doses for standard viewing conditions (see Appendix A).
- A schedule for the recommended maintenance and inspection of the equipment.
- Practical training in the safe use of the equipment and the associated software.

See also section 3.9 regarding the information and training to be provided by manufacturers and suppliers in relation to IRMER, as recommended in the WP Core Curriculum for dental CBCT¹⁴, which is summarised in Appendix B.

2.18 Co-operation between employers

Where employees undertake work with ionising radiation on another employer's premises, IRR99 requires that the different employers co-operate through the exchange of information and in other ways, to ensure that all employees are adequately protected and that responsibility for the requirements of IRR99 is clearly allocated and agreed between them. This is relevant to the maintenance, repair or testing of dental CBCT equipment in the following ways.

- Service engineers must inform the dental practice of any maintenance, repair or testing work on x-ray equipment that may have affected its radiation safety, before it is handed back. Suitable checks should be carried out before the equipment re-enters clinical use.
- The dental practice's RPS will not usually have been suitably trained to supervise the work of a service engineer, and the practice's local rules are unlikely to include suitable arrangements for the engineer's work. Consideration should therefore be given to formally handing over responsibility for the area from the practice to the engineer for the duration of the visit. This should be documented and the paperwork signed by both parties.

If a practice owning a dental CBCT unit were to allow visiting staff from another practice to operate it by arrangement, it would again be necessary for the two employers involved to co-operate to agree the allocation of responsibility between them for compliance with IRR99. The requirements of IRMER (see sections 3 and 4) would also need special consideration. In such cases it is recommended that the RPA and MPE are consulted.

2.19 Patient doses much greater than intended

For dental CBCT examinations, patient doses that would need to be notified to HSE as “much greater than intended” as a result of equipment failure (Regulation 32(6)), are those that are 10 times greater than intended¹⁵. The parameter best suited to be an indicator of effective dose in any investigation is dose-area product. It is suggested that the same guideline multiplying factor should be considered appropriate for notifications made in pursuance of IRMER Regulation 4(5), in cases of patient doses being much greater than intended as a result of human factors (see section 3.7.2). HSE provides guidance on ‘doses much greater than intended’ in Guidance Note PM77¹³.

In the event that a patient is suspected of receiving a dose much greater than intended, the legal person should be notified immediately and the RPA/MPE contacted for advice and assistance. A note should be made of all relevant circumstances of the exposure to assist with estimating the dose actually received by the patient. It would be helpful to be able to provide reassurance to the patient that the effects of any excessive exposure on their health are likely to be negligible, at an early stage.

2.20 Requirements of IRR99 – summary of key aspects

Topic	Brief description of requirement	Relevant section of this guidance
Notification to HSE	Work with ionising radiation must be notified if it is: <ul style="list-style-type: none"> Being done for the first time, or Being done at new premises. Change of dental practice name is also notifiable 	2.1
Appointment and consultation of an RPA	A suitable RPA must be appointed, and consulted for advice on IRR99 as required.	2.2
Selection of new dental CBCT equipment	New equipment must be: <ul style="list-style-type: none"> Capable of restricting patient doses to ALARP Supplied with suitable software and display screens for clinical imaging Supplied with test objects and imaging tools for QA purposes 	2.3 4.16, 4.2 2.16, Appendix A
Prior assessment of installation plans	Particular attention to be paid to: <ul style="list-style-type: none"> Shielding of the room in which dental CBCT equipment to be installed The need for warning lights outside the room Position of operator and controls normally outside room 	2.4 2.5 2.6.2
Critical examination	Arrangements made with installer and RPA should include: <ul style="list-style-type: none"> Confirmation that environment suitable for installation of dental CBCT Radiation measurements to confirm adequacy of shielding Installer to undertake adequate testing on behalf of user (especially for General Dental Practices) 	2.7 2.15 2.16
Radiation Risk Assessment	Risk assessment to be reviewed with RPA, and to pay special attention to: <ul style="list-style-type: none"> Adequacy of room shielding Protection for the operator Adequacy of safety and warning features Designation of controlled areas Administrative controls Provision of personal dosimetry 	2.8 2.4 to 2.6 inclusive 2.10 2.6.2 2.12
Designation of controlled areas for dental CBCT	Controlled areas for dental CBCT <ul style="list-style-type: none"> Will extend throughout the room Will normally exist throughout the working day 	2.10
Additional requirements for controlled areas for dental CBCT	<ul style="list-style-type: none"> Suitable warning lights and signs required at all entrances Access restrictions more stringent than for conventional dental x-ray equipment – room may have to be reserved solely for dental CBCT Personal dosimetry recommended for operators and others regularly entering controlled area 	2.5 2.10 2.12
Local rules and RPSs	<ul style="list-style-type: none"> Local rules must be drafted or reviewed with RPA Description of conditions under which controlled area exists requires careful consideration Written arrangements necessary for staff and if patients require support. Contingency plans should cover all reasonably foreseeable accidents. 	2.14
Training	<ul style="list-style-type: none"> Radiation safety training should be updated for all employees after installation a dental CBCT unit Manufacturers and suppliers should provide adequate information regarding the safe use, testing and maintenance of dental CBCT systems they supply 	2.17.1 2.17.2
Monitoring of designated areas	<ul style="list-style-type: none"> Radiation measurements must be made at installation and must be repeated at intervals to confirm correct designation Measurements should be made at least every three years or when conditions change. 	2.15
QA for dental CBCT equipment	<ul style="list-style-type: none"> Recommended that adequate testing be done by arrangement with installer at time of critical examination Routine tests required on an annual basis Monthly QA checks to be done by user 	2.16 and Appendix A
High patient doses as a result of equipment faults	<ul style="list-style-type: none"> Notifiable to HSE if more than ten times intended value 	2.19

3 IRMER REQUIREMENTS FOR DENTAL CBCT – ADMINISTRATIVE ASPECTS

3.1 Introduction

The use of dental CBCT equipment must comply with the Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) and subsequent amendments. These regulations concern patient protection and the guidance on IRMER in the Dental GNs applies equally to dental CBCT use as to conventional dental x-ray imaging. Measures to comply with IRMER should already be in place for intra-oral, panoramic and cephalometric radiography in dental practices; this section recaps and expands on this advice specifically for the use of dental CBCT equipment.

For all types of dental exposures, the legal person must set up a documented framework to ensure the safe and efficient use of the dental x-ray equipment. This will include:

- Training duty-holders under the regulations (practitioners, referrers and operators).
- Entitlement of duty holders to practice within a defined scope.
- Arrangement for the justification and authorisation of each medical exposure.
- The subsequent clinical evaluation of the outcome of each medical exposure.
- The selection of equipment and techniques to keep patient dose as low as reasonably practicable, with written protocols for each x-ray set for common projections.
- Written procedures covering a range of matters such as patient identification, setting and use of diagnostic reference levels, clinical audit and evaluation.
- Extra requirements if research or medico-legal exposures are undertaken.
- Availability of a MPE to advise on patient dose issues as appropriate.

Please note that this is not an exhaustive list and reference should be made to the original Dental GNs.

In general dental practice it is common for the dentist to be referrer, practitioner and operator for intra-oral x-ray exposures, with each surgery having an x-ray unit. Consequently, the required framework is relatively straightforward and simple. However, a practice with a dental CBCT unit is likely to have several dentists within the practice making use of this one unit, with a limited number of staff trained and competent to operate the equipment. In addition, it is likely that referrals will be accepted from other dental practices in order to make full use of the resource. As such, robust management systems need to be in place to ensure that the equipment is used correctly, without incident and in line with IRMER.

There is often confusion regarding the different roles of the different duty holders under IRMER. Table 2 outlines the main roles involved in dental radiography with dental CBCT and the corresponding IRMER title and principal duties.

TABLE 2 IRMER roles and duties for persons involved with dental CBCT

	What do you do?	Your IRMER roles	Your IRMER duties
1	I refer my patients to have a dental CBCT examination at another dental practice/hospital. A written report is sent back to me. I may need to look at the images during diagnosis and treatment.	Referrer	When you request a dental CBCT you must supply sufficient clinical information to allow the receiving clinician (IRMER Practitioner) to justify the examination. To do this, you should be familiar with selection criteria for dental CBCT investigations. Practical training in use of the imaging software will be required.
2	I refer my patients to have a dental CBCT examination at another dental practice/hospital. I report on the images myself.	Referrer Operator	As 1, plus: As an “operator”, in terms of interpreting images, you must be adequately trained in this task. For most dentists in this position, you will almost certainly require additional training in dental CBCT interpretation including use of the software. This might be provided by the equipment supplier (see section 3.9)
3	I am a dentist working in a practice as an associate. The practice has a dental CBCT facility. I decide that CBCT images are required for my patients and interpret them but do not operate the dental CBCT unit.	Referrer Practitioner Operator	As 2, plus: As IRMER practitioner you must decide that the examination is justified and authorise it as such by a written or electronic signature (see section 3.4). You will need additional training in dental CBCT to be able to do this (see section 3.9).
4	I am a dentist working in a practice as an associate. The practice has a dental CBCT facility. I decide that CBCT images are required for my patients, operate the CBCT unit and interpret the images	Referrer Practitioner Operator	As 3, plus: As an “operator”, in terms of conducting the CBCT examinations, you must be adequately trained in the technique of operating dental CBCT equipment. Your undergraduate degree does not automatically provide this. An <i>applications specialist</i> from the dental CBCT manufacturer may best deliver much of this aspect of machine-specific training (see section 3.9).

TABLE 2 (cont'd) IRMER roles and duties for persons involved with dental CBCT

	What do you do?	Your IRMER roles	Your IRMER duties
5	I am not a dentist. I am the owner and director of several dental practices, one of which has a dental CBCT facility.	Legal person	As the “legal person” you must ensure that the management framework is in place to ensure the safe and effective use of the equipment, and compliance with the responsibilities of the Employer under IRMER.
6	I am a dentist who owns a practice with a dental CBCT facility and all of the dentists, including myself, use it for their patients	Legal person Referrer Practitioner Operator	As 4 and 5.
7	I am a Dental Nurse. I already have a qualification in Dental Radiography and routinely take dental radiographs in our practice. A dental CBCT machine has just been purchased and it is planned that I will operate this as well.	Operator	As an “operator”, in terms of conducting the dental CBCT examinations, you must be adequately trained in the technique of operating dental CBCT equipment. Your qualification in dental radiography does not automatically provide this. An <i>applications specialist</i> from the dental CBCT manufacturer may best deliver much of this aspect of machine-specific training (see section 3.9).
8	I am a specialist dental radiologist. I provide a reporting service for a dental practice with a dental CBCT machine.	Operator	As an “operator”, in terms of interpreting images, you must be adequately trained in this task. Dental radiologists should already have received sufficient training in interpretation of cross-sectional images to be able to do this.
9	I am a clinical radiologist (medical specialist). I provide a reporting service for a dental practice with a dental CBCT machine.	Operator	As an “operator”, in terms of interpreting images, you must be adequately trained in this task. Clinical radiologists will have training in interpretation of cross-sectional images, but may lack relevant dental knowledge. Consideration should be given to obtaining some additional training in dento-alveolar pathology.

3.2 Referrals

Requests for dental CBCT exposures should only be accepted from referrers who have been entitled to refer as detailed in the practice’s IRMER procedures. The legal person at the practice where the dental CBCT device is installed (the ‘CBCT practice’) should make a local decision on which dental surgeons it is felt appropriate to accept referrals from, and this decision must be documented.

It should be noted that under IRMER only registered healthcare professionals may act as referrers (registration can be confirmed on the GDC website, www.gdc-uk.org). Only those referrers who can provide evidence that they are competent to provide adequate clinical information to facilitate the justification process for dental CBCT examinations should be so entitled under the CBCT practice's IRMER procedures. Evidence of appropriate training could help in this decision; eg attendance at a training course covering the core curricula published by the WP¹⁴.

The WP recommends that a service level agreement (SLA) is established in writing between referrers and the CBCT practice, so that the necessary arrangements under IRMER (eg, the entitlement of persons to refer patients to the CBCT practice for dental CBCT examinations) are properly put in place and documented. The SLA must be kept up to date and the WP recommends that routine reviews are made on an annual basis to ensure this. An example SLA is provided in Appendix C.

Full clinical information, along with information to allow patient identification, must be included in each referral. If essential information is missing, the referral should be returned or more details sought. A standard referral form providing the following information could facilitate this process.

- Patient unique identifier information.
- The clinical context for requesting the dental CBCT examination.
- Relevant results of history, clinical examination and other imaging.
- The question which the referrer would like the dental CBCT examination to answer.
- A clear indication of the area(s) for which dental CBCT imaging is requested.

A suggested example is given in Appendix D.

3.3 Referral criteria

IRMER requires that referrers have access to suitable referral criteria to provide guidance on when it is appropriate to refer patients for dental CBCT examinations. Criteria for dental radiography have been available for some years^{16, 17} but these do not consider the use of dental CBCT. As CBCT is still a new technique in dentistry, the research evidence required to develop high grade, robust, referral criteria for dental CBCT is quite limited. Furthermore, research evidence may be valid for the specific dental CBCT unit on which the research was performed, but not applicable to all. The European Academy of Dental and Maxillofacial Radiology (EADMFR) has produced Consensus Guidelines including a list of Basic Principles for dental CBCT use¹⁸ and further guidance is under development by the Faculty of General Dental Practice (UK) of the Royal College of Surgeons¹⁹ and also by the European Union funded SEDENTEXCT project. Chapter 4 of the SEDENTEXCT Provisional Guidelines²⁰ provides a summary of the current evidence base for the use of dental CBCT along with recommendations which may be used as referral criteria for dental CBCT for the time being, until a revised version of this document becomes available in early 2011. The seven Basic Principles relevant to referral, are summarised in Appendix E. The legal person at the CBCT practice must ensure that all referrers are aware of suitable referral criteria, and these could be provided by the CBCT practice as part of the SLA.

3.4 Justification

As with any x-ray exposure, dental CBCT entails a risk to the patient. The first stage in eliminating unnecessary exposure is to ensure that any dental CBCT examination undertaken is 'justified'. Before a dental CBCT examination can take place, it must be justified by an IRMER practitioner and authorised by a written or electronic record. As stated in the Dental GNs, in dental practice only a dentist will normally be considered to be adequately trained to act as practitioner. This role should normally be undertaken by a dentist (or dentists) at the CBCT practice.

In deciding whether an individual exposure is justified the practitioner must give appropriate weight to:

- the availability and findings of previous radiographs.
- the specific objectives of the exposure in relation to the history and examination of the patient.
- the total potential diagnostic benefit to the individual.
- the radiation risk associated with the radiographic examination.
- the efficacy, benefits and risk of available alternative techniques having the same objective but involving no, or less, exposure to ionising radiation.

The practitioner within the CBCT practice must take into account the clinical information supplied by the referrer. Only dental CBCT examinations that will provide extra information to aid the patient's management or prognosis, and which cannot be gained from lower dose conventional imaging techniques, should be authorised. For further details, refer to the EADMFR "Basic Principles"¹⁸ and SEDENTEXCT Provisional Guidelines²⁰. If no net benefit is expected for the patient or a decision cannot be made from the information supplied by the referrer, then the referring dentist should be contacted and clarification obtained. The CBCT practice must not undertake a dental CBCT examination unless the dentist acting as IRMER practitioner is able to justify the exposure.

The legal person should establish the method of authorisation. It will depend on local circumstances and may include a signature in the patient's clinical notes or the addition of an electronic signature. If the referrer and practitioner are the same dentist within the CBCT practice, then this process is relatively straightforward but a signature clearly "authorising as justified" is still required. Anyone carrying out the exposure would be in breach of IRMER if they performed the examination without it having been so authorised. The use of a standard form for all patients, whether from within or from outside the practice carrying out the dental CBCT examination, could help standardise the information recorded and provide a means of recording the justification. Whatever the method, any subsequent audit should be able to identify who authorised any particular exposure as justified. It is not necessary to detail the reasoning behind the decision.

If the exposures are being done for medico-legal reasons or if there will be no direct health benefit to the patient (eg the exposure is being done purely for research purposes), IRMER requires that the need for and usefulness of such examinations is critically examined when assessing whether they are justified. It is also recommended

that the patient's informed consent is obtained in writing before such an examination takes place.

3.5 Patient identification

It is obviously important to ensure that the correct examination is done on the correct patient. If the patient is passed from a referrer to a practitioner to the operator carrying out the exposure, there is always the possibility of a mistake being made at each transfer. This is more likely if an operator is dealing with several patients at the same time, if the examination is delayed or if they are carrying out exposures for outside referrers.

A system must be in place to ensure that, at each transfer, the patient identity is confirmed. This should include the positive confirmation by the patient (or escort if there are communication difficulties) of at least three pieces of information eg name, address and date of birth; to be checked against the information provided by the referrer. There should be a record kept of the operator who makes the final identity check prior to exposure. The legal person must ensure that a written procedure outlining the identification process is in place.

3.6 Patient pregnancy

IRMER requires that the legal person establishes a procedure to ensure that, where relevant, each female patient is asked whether she is pregnant prior to the exposure taking place. It is usually deemed relevant if the patient is of child bearing age and the examination involves the irradiation of the patient's abdomen. By way of comparison, within general radiology departments, it is not usual to ask the pregnancy question for CT examinations of the head. The dose associated with dental CBCT is lower than conventional CT and so it is the opinion of the WP that routinely asking the pregnancy question prior to dental CBCT examinations is not required. The CBCT practice's policy on this matter should be documented within the legal person's IRMER procedures.

3.7 Documentation of the exposure

This section considers the administrative aspects of undertaking dental CBCT exposures.

3.7.1 Records to be kept for each dental CBCT examination

It is important that the identity of the referrer, practitioner and operator(s) is recorded for each examination, and that sufficient information is recorded from the dental CBCT equipment so that an estimate of patient dose can be made subsequently if required, especially if the examination deviates from the standard operating protocol for any reason. This information should be available within the record of the examination in the patient's notes. Again, the use of a standard form, which can then be included within the

patient's notes, will facilitate this. It will usually be sufficient to record the view undertaken and which patient size setting was selected to allow a rough estimate of dose from the standard protocols. The dose area product reading should be noted if it is provided as a readout on the unit post-exposure. Some systems may allow exposure and technique factors to be stored electronically alongside the image data in a secure electronic patient image and data archive. It is recommended^{iv} that the exposure and technique factors, and the image data, are retained for at least eleven years, except for children where the retention period should be eleven years or up to the age of 25, whichever is longer.

3.7.2 Patient doses much greater than intended

Regulation 4(5) of IRMER requires that patient doses much greater than intended as a result of human factors, are notified to the relevant national enforcing authority for IRMER. The same factor as applies under IRR99 Regulation 32(6), eg 10 times the intended dose, should also be used to determine if an incident is notifiable under IRMER. See section 2.19 for further details.

The enforcing authorities for IRMER are as follows.

In England, the Care Quality Commission (CQC) – telephone 020 7448 9039

In Wales, the Healthcare Inspectorate Wales (HIW) – telephone 029 2092 8917

In Scotland, the Scottish Executive (SE) – telephone 0131 244 2779

In Northern Ireland, the Regulation and Quality Improvement Authority (RQIA) – telephone 028 9051 7500

3.8 Clinical evaluation

A clinical evaluation must be carried out of each image and a written record kept of the findings. Images must be viewed on a suitable monitor using suitable software, as set out in sections 4.1.6 and 4.2. Regions outside the area of interest that appear on the image must also be evaluated. This may require the services of a dental and maxillofacial radiologist or a clinical radiologist. If this arrangement has been made this also needs to be recorded.

For images acquired for the practice's own patients a record should be made within the patient's notes as for all other x-ray imaging and treatment.

^{iv} See the Consumer Protection Act 1987. Ideally, for medico-legal purposes, dental records (including CBCT scans) should be retained indefinitely. Personal representatives can take legal action in respect of a deceased patient (although in dentistry this is very rare). Records for deceased patients should therefore be retained for the same period. For further details see http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Patientconfidentialityandcaldicottguardians/FAQ/DH_065886

For patients from outside the practice a written report may be provided to the referring clinician. Alternatively, the images may be returned without a report and, in these circumstances, there should be an arrangement for the referrer to carry out and record the clinical evaluation on behalf of the CBCT practice. In doing this, the referring dentist becomes an operator (reporting) under IRMER, and should be adequately trained to carry out relevant image interpretation, as specified in the curriculum. The SLA (or standard referral form) should set out clearly who is to evaluate the image. Exposures should not be authorised if it is not clear to the practitioner who is to write the report. Any referrer carrying out the clinical evaluation would need to be entitled as an operator for the purpose of clinical evaluation and this decision documented in the IRMER procedures of the legal person at the CBCT practice. The WP recommends that the arrangements for clinical evaluation are agreed between the referring practice and the CBCT practice as part of the SLA.

Planning subsequent treatment arising from the dental CBCT examination is itself evidence of an evaluation (as it is in other clinical areas such as planning radiotherapy treatment). It should, however, be clear from the records which images were used and who undertook the planning.

If the intention is to provide the referrer with the images alone with no clinical evaluation report or surgical planning advice, then consideration also needs to be given by the legal person of the CBCT practice to ensuring that appropriate software is available to the referrer and that staff at the referring practice who will use this software are adequately trained to do so, to understand and interpret the image dataset and to plan any treatment.

A written procedure detailing the arrangements for clinical evaluation must be in place and should cover all the above aspects.

3.9 Training

Under IRMER both practitioners and operators must be adequately trained to carry out their duties. They must undertake regular continuing professional development (CPD) to ensure that they are up to date in their radiological and radiation protection practice. Clearly the introduction of a new technique such as dental CBCT will require additional training. At the time of publication the only training available for users of dental CBCT equipment is the applications training provided by the equipment suppliers. It is hoped that radiography and dental departments within the university system will set up courses on dental CBCT in the near future, following the Core Curriculum in Cone Beam Computed Tomography (CBCT) for Dentists and Dental Care Professionals¹⁴ produced by the WP, which is summarised in Appendix B.

The minimum training requirements recommended in the Core Curriculum are summarised below.

TABLE 3 Recommended minimum training requirement for each IRMER dutyholder

		Dutyholder:			
		Referrer	Practitioner	Operator (imaging)	Operator (reporting)
Initial training	Theoretical	3 hours	3 hours	3 hours	3 hours
	Radiological interpretation	See curriculum	2 hours*	See curriculum	2 hours*
	Practical§	†	6 hours	6 hours	6 hours
Refresher training (as part of Verifiable CPD)		1 hour	1 hour	1 hour	1 hour

*Further supervised reporting of cases is recommended for Practitioners and Operators (Reporting) for CBCT images extending beyond the dento-alveolar region.

§This could be provided by an applications specialist, eg from the equipment manufacturer.

†Referrers who also look at and use CBCT images (eg, as a guide during surgery) but are not Operators (reporting) will require some practical training in use of the imaging software.

It should be noted that:

- The Core Curriculum is limited to CBCT examinations of the dento-alveolar region. Examinations extending into other anatomical regions (eg, the airways and base of the skull) are considered outside the experience and expertise of dentists, in terms of radiology.
- As well as specifying the adequate training standard for practitioners and operators involved with dental CBCT, the Core Curriculum also specifies a training requirement for referrers. This includes practical training in use of the imaging software unless there will be no need to look at CBCT images.
- The initial training requirement for dental CBCT is additional to that already required as part of the Continuing Education and Training in radiology and radiation protection.
- Practices owning a dental CBCT unit, or wishing to refer patients for dental CBCT examinations, should arrange training for their staff to meet the Core Curriculum, as soon as possible.

It is the responsibility of the legal person at the CBCT practice to maintain up to date records of all relevant training for both IRMER practitioners and operators entitled by him. Only individuals for whom there is evidence of adequate training should be entitled to act in these roles. If dentists at other sites are entitled to act as operators for the purpose of clinical evaluation (eg: reporting), then the legal person at the CBCT practice should be permitted to gain access to their training records.

3.10 Administrative requirements of IRMER – summary of key aspects

Topic	Brief description of requirement	Relevant section of this guidance
Entitlement of persons	<p>Legal person must ensure suitable persons are identified and entitled to act in these roles, including persons at other practices if appropriate:</p> <ul style="list-style-type: none"> • Practitioner • Referrer (including persons at other practices if appropriate)* • Operator (for taking the exposure) • Operator (for reporting on images, which may include persons at other practices)* <p>*This may be best achieved by means of a Service Level Agreement</p>	<p>3.1</p> <p>Appendix C</p>
IRMER procedures	<p>Legal person must ensure IRMER procedures are drafted or revised for dental CBCT as necessary:</p> <ul style="list-style-type: none"> • Referral criteria • Justification and authorisation • Patient identification • Pregnancy enquiry • Documenting the exposure • Clinical evaluation 	<p>3.2, 3.3</p> <p>3.4</p> <p>3.5</p> <p>3.6</p> <p>3.7</p> <p>3.8</p>
Training	<p>Legal person must ensure IRMER dutyholders are adequately trained</p> <ul style="list-style-type: none"> • BSDMFR Core Curriculum specifies requirements, including for referrers 	<p>3.9</p> <p>Appendix B</p>
Patient doses much greater than intended due to human factors	<ul style="list-style-type: none"> • Notifiable to the relevant enforcing authority for IRMER if more than ten times the intended dose 	<p>3.7.2</p>

4 IRMER REQUIREMENTS FOR DENTAL CBCT – PRACTICAL ASPECTS

4.1 Optimisation of patient dose – operation of dental CBCT equipment

Once a dental CBCT scan has been authorised it is important that the exposure is fully optimised; ie, keeping the radiation dose as low as reasonably practicable (ALARP), but ensuring the images are still of diagnostic quality. The main principles of optimisation are contained within the Dental GNs.

The operator undertaking the exposure has the key responsibility of ensuring the equipment is used in such a way as to keep the dose to the patient as low as reasonably practicable. This involves selection of the most appropriate exposure protocol and making adjustments as required to take into account the size of the patient. Particular consideration should be given to these points when examining children; child-specific settings should always be used when available.

4.1.1 Written protocols

There should be a written protocol (sometimes known as a standard operating protocol) for each standard dental CBCT examination undertaken. This should include details of patient positioning, the use of laser beam light beam markers, centring points, the use of immobilisation devices, as well as the guideline exposure parameters (mAs and kV) and volume size. Written protocols should be reviewed on a nominal annual basis, or when the imaging performance or any other important characteristics of the scanner change significantly.

4.1.2 Patient positioning

Accurate patient positioning using the light beam markers is important so that the correct area of interest is captured in the volume. A scout view (if available) before the full exposure is recommended to ensure the correct part of the jaw (or jaws) is being imaged. The number of scout views should be kept to a minimum.

Immobilisation devices such as head rests chin cups and head straps must be used to prevent patient movement that could lead to artefacts. Some single jaw scans may be as long as 40 seconds and even small amounts of movement can render the images diagnostically unacceptable. Patients should be instructed to remain still throughout the exposure. It is also useful to ask the patient to close their eyes during the exposure to prevent the patient inadvertently turning their head during the exposure cycle. If there has been minimal patient movement but the scan is still diagnostically acceptable it should not be repeated. It may be possible with some dental CBCT equipment to reconstruct a portion of a 360 degree scan to minimise or exclude any movement artefact without significant loss of image quality.

4.1.3 Use of thyroid shields and lead aprons

It has been shown that the wearing of a thyroid shield during maxillofacial CBCT examinations can reduce the absorbed dose to the thyroid and the cervical spine and the effective dose to the patient²¹. As the thyroid gland should not normally be in the primary x-ray beam during dental CBCT examinations conducted using suitable equipment, the WP does not consider it necessary to recommend the routine use of thyroid shields. However, this should be considered on a case by case basis together with the RPA/MPE, taking into account the particular dental CBCT equipment used and the examinations it will be used for. Where thyroid shielding is used it must be positioned so that it does not interfere with the primary beam since this could lead to significant artefacts rendering the image diagnostically unacceptable.

In common with conventional forms of dental radiography, there is no need (on radiation protection grounds) for the routine use of lead aprons for patients undergoing dental CBCT examinations^{8,9}.

4.1.4 Exposure settings

The following features may be under operator control and can be adjusted to optimise the dose:

- Volume size
- Exposure factors (kV, mAs) and voxel size
- Angle of rotation

These are discussed in turn.

4.1.4.1 Volume size

If the machine offers a choice of volume sizes, the smallest volume size needed to answer the clinical question should be used. Larger volumes are generally associated with higher radiation doses to the patient, and increased scatter which will degrade image quality. If the dental CBCT unit has a fixed large volume size and the region of interest is small, then the justification of the examination should be reviewed before proceeding.

4.1.4.2 Exposure factors and voxel size

Optimal exposure factors should be selected (kV and mAs) to satisfy the diagnostic requirements of the examination. Spatial resolution is related to the exposure factors selected and can be measured in terms of the maximum number of line pairs per millimetre that can be distinguished by eye in a displayed image. For instance, a longer exposure time or higher mA will produce images with a higher spatial resolution, but with a higher dose to the patient. Until evidence-based guidelines become available in the future, the manufacturer's recommended exposure factors should be used, taking into account the advice of an RPA or MPE.

The size of the reconstruction voxel can often be selected by the operator. This is closely linked to the spatial resolution. If choosing a larger voxel size results in a

reduced patient dose (due to lower exposure factors being used) then this should be considered as long as the lower resolution is compatible with the aims of the radiographic examination.

4.1.4.3 Angle of rotation

Some machines offer a quick scan where the rotation arc is reduced, for example to 180 degrees. This feature reduces the number of projections taken and therefore reduces the dose. If the required diagnostic information can be obtained using this scan protocol then it should be selected. However, care should be taken as the use of a 180 degree protocol may lead to increased artefact where metal posts or other radiodense restorations are present.

4.1.5 Image detector

Dental CBCT units use either a flat panel detector or image intensifier linked to a charged coupled device as the imaging detector. Whichever detector is used, it should be fully optimised in terms of dose reduction before use²⁰. Until evidence-based guidelines are available, the manufacturer's recommended exposure factors should be used, taking into account the advice of an RPA/MPE

4.1.6 Image reconstruction

Dental CBCT images should be reconstructed using software meeting the following basic requirements.

- The cross sectional images should be able to be aligned at any desired plane to allow visualisation of the jaw in that plane (eg, in line of implant insertion).
- The measurement tool should be able to be aligned at any angulation to allow accurate measurement at any angle.
- It would be desirable to have facilities for zoom, changes of contrast and brightness (usually referred to as 'windowing' and levelling'), magnification and edge enhancement within the software.
- It would be useful to have the ability to rotate and examine the item being viewed from all angles.
- The format should maintain dimensionally stable images.
- It should be possible to export images together with appropriate viewing software to a portable storage device such as a CD.

Dental CBCT images should be viewed on a suitable monitor. The requirements for display monitors are outlined in section 4.2.

4.1.7 Patient dose audit

Under IRMER, Diagnostic Reference Levels (DRLs) must be set as an aid to optimisation. At present national DRLs (NDRLs) are not available for dental CBCT examinations although the WP has recommended an achievable dose for new equipment, based on dose area product (DAP) data². (For further information regarding

this achievable dose and how it should be applied to existing equipment, refer to section 2.16 on QA of equipment.) Nevertheless, Local DRLs (LDRLs) should be set for commonly performed examinations with help from the Medical Physics Expert (MPE). For dental CBCT, this should include an examination of the placement of an upper first molar implant in a standard adult male patient. This will allow LDRLs to be compared to the achievable dose as recommended by the WP. Similarly, where dental CBCT examinations of children take place, separate LDRLs should be set, again with the help of the MPE, for the examination to image a single impacted maxillary canine of a 12-year old male. LDRLs should be set, based on mean doses to average size patients and expressed in terms of DAP (mGy cm^2).

An audit of patient dose measurements should be completed at least once every three years in conjunction with the MPE. This will require patient dose data such as kV, mAs, field size and any DAP readout (where available) to be recorded for a representative sample of patients. The data should be assessed in conjunction with the MPE and the doses compared to the relevant NDRLs (when available) and used to set LDRLs.

It should be noted that where a dental CBCT system with a fixed large field of view is used for examinations that only require a small field of view, LDRLs are likely to be significantly higher than the achievable dose².

Patient dose audit data should also be compared to LDRLs set at the previous dose audit. This will indicate if local practice has changed. If the mean doses are measured to be more than 20% from the LDRL, an investigation should take place in conjunction with the MPE and dose and image quality should be reviewed to ensure they are optimised. It is recommended that patient dose data also be provided to HPA CRCE for inclusion in the National Patient Dose Database. Details of the information required, together with a proforma for supplying the information, is given in HPA-RPD-065². (The MPE may be able to undertake this for the practice.) Further guidance on the establishment and use of DRLs is given in IPEM Report 88²².

4.2 Requirements for display screen equipment

Dental CBCT images should always be viewed and interpreted on a suitable display device under specific lighting conditions to obtain the maximum image quality in order to optimise the diagnostic benefit from the exposure. Display screens used to interpret images should be supported by regular checks as part of the overall QA programme (see section 2.16). The Royal College of Radiologists' (RCR's) minimum and recommended specifications for diagnostic display devices for clinical image interpretation²³ are summarised in Table 4. This guidance applies to all display screens used for interpreting conventional computed tomography images and also applies to viewing dental CBCT images. This should be considered at the planning stage of a new dental CBCT facility (see section 2.3) and suppliers asked to confirm their display screens comply with current RCR standards and are CE marked as required by the Medical Devices Directive¹⁰.

The performance of display screens used for dental CBCT examinations should be regularly checked as part of the local quality control programme. The programme should

follow the recommended standards for the installation and routine performance testing of Dental CBCT Systems². Display screens will deteriorate over time and may need replacing in the lifetime of the CBCT unit. Display screens can be checked, and if necessary adjusted, using a suitable test pattern such as a Society of Motion Picture and Television Engineers (SMPTE) test pattern that may be supplied with the dental CBCT software or the TG-18 QC test pattern. The TG-18QC test patterns are available from the American Association of Physicists in Medicine (AAPM) website in DICOM and 16 bit TIF format²⁴, along with guidance on their use.

TABLE 4 Summary of the minimum and ideal specifications for the display device

	Minimum	Recommended
Screen resolution	≥ 1280 x1024 (~1.3 megapixels)	≥1500 x 2000
Screen size (viewable diagonal)	≥ 42 cm (~17")	≥ 50 cm (~20")
Maximum luminance	> 170 cd/m ²	≥ 500 cd/m ²
Luminance contrast ratio	≥ 250:1	≥ 500:1
Greyscale bit depth	8-bit greyscale (24-bit colour)	≥ 10-bit greyscale

The ambient room lighting is also important and this should be equivalent to the display screen luminance to maximise the inherent contrast arising from the screen²⁵ and to avoid distracting reflections. The RCR has produced guidance on both diagnostic display devices and on ergonomics of the work place. Users are advised to check the RCR website to obtain the most up to date guidance.

It is acceptable to review (but not interpret) dental CBCT images on display screens that do not meet the above standards, for instance during training sessions.

4.3 QA of dental CBCT image quality

A three-point scale for the subjective quality rating is normally recommended for the assessment of dental radiographs⁸. As metallic restorations in the teeth will inevitably cause artefacts in dental CBCT images, the WP recommends the use of a two point scale where the images are rated either 'diagnostically acceptable' or 'unacceptable' in accordance with Table 5. When viewing the images, a suitable grey scale (window level and window width) should be chosen to allow optimum visualisation of the bone and the teeth. A SMPTE or TG-18QC test pattern could be used to configure the display screen if required.

The radiation dose from dental CBCT investigations is generally higher than from conventional dental radiography. In addition, the digital capture of images is more reliable than that using conventional film. For these reasons the performance targets should be set higher. Table 5 shows the suggested minimum targets for image quality for dental CBCT investigations.

TABLE 5 Subjective image quality ratings and minimum targets for dental CBCT

Quality rating	Basis	Target
Diagnostically acceptable	No errors or minimal errors in either patient preparation, exposure, positioning or image reconstruction and of sufficient image quality to answer the clinical question	Not less than 95%
Diagnostically unacceptable	Errors in either patient preparation, exposure, positioning or image reconstruction which render the image diagnostically unacceptable	Not greater than 5%

The quality assurance programme should include an image quality analysis to allow comparison of the image quality against these targets. Image quality should be monitored at regular intervals and may either be carried out prospectively (as the images are being produced) or retrospectively (as an audit). If the latter is undertaken the intervals between audits should not exceed six months. As well as grading each image as either 'acceptable' or 'unacceptable' it is important that the underlying cause of each unacceptable image is identified and recorded. This allows the operator to instigate appropriate corrective action. Common errors that are seen with dental CBCT are shown in Table 6. An example of a record that can be used in either a prospective or retrospective manner to analyse image quality is shown in Table 7.

TABLE 6 Common errors in dental CBCT imaging

Category of error	Cause	Effect
Patient preparation	Failure of radiographic stent to be seated properly when scanning to assess the alveolus prior to implant placement using a 'guided' surgery technique	Radiographic markers are not accurately related to the alveolus leading to errors in planning
Exposure	Exposure factors used too low	Image may be noisy, pale and lack contrast
Positioning	Inadequate immobilisation used leading to movement of the patient	Blurred image
	Patient incorrectly positioned within the machine	Region of interest not included in scan volume
Image reconstruction	Inappropriate positioning/thickness of 'panoramic curve' *	Failure to detect and fully visualise the complete area under investigation
	Inappropriate adjustments to brightness/contrast/thresholds*	Failure to identify relevant anatomy and disease, particularly small low density structures

* In most cases these particular problems are reversible and the scan would not need repeating. It is important to be able to recognise these errors so the investigation is not repeated unnecessarily.

4.4 Practical requirements of IRMER – summary of key aspects

Topic	Brief description of requirement	Relevant section of this guidance
Optimisation of patient dose	<ul style="list-style-type: none"> • Legal person must ensure written protocols are in place for all standard dental CBCT examinations • Manufacturer's recommended exposure settings to be used (taking into account MPE advice) unless evidence-based guidance available • Images must be reconstructed using suitable software • Images must be viewed on suitable display screens under suitable conditions 	<p>4.1.1 to 4.1.3, inclusive</p> <p>4.1.4</p> <p>4.1.6</p> <p>4.2</p>
Patient dose audit	<ul style="list-style-type: none"> • Local DRLs must be established with the MPE, for specified standard views, and compared to the Achievable Dose (AD) • LDRLs may be higher than the AD for some equipment • Local DRLs also to be compared to last derived figure, every 3 years 	<p>4.1.7, 2.16.2,</p> <p>Appendix A</p>
QA of dental CBCT image quality	<ul style="list-style-type: none"> • A two-point rating system to be used for dental CBCT images • Analysis of reject images to be undertaken. 	4.3

5 REFERENCES

- ¹ The Radiation Protection Implications of the Use of Cone Beam Computed Tomography (CBCT) in Dentistry – What You Need To Know. J R Holroyd, A D Gulson. Health Protection Agency, July 2009 (available on HPA website).
- ² 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, A Walker. HPA-RPD-065. Health Protection Agency, March 2010.
- ³ NHS Purchasing and Supply Agency, Centre for Evidence-Based Purchasing Evaluation Report CEP10048, Dental Cone Beam Computed Tomography (CBCT) Systems, March 2010.
- ⁴ The Ionising Radiations Regulations 1999 Statutory Instrument 1999 No 3232.
- ⁵ The Ionising Radiation (Medical Exposure) Regulations 2000 Statutory Instrument 2000 No. 1059.
- ⁶ The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 Statutory Instrument 2006 No. 2523.
- ⁷ The Ionising Radiation (Medical Exposure) (Amendment) Regulations (Northern Ireland) 2010 Statutory Rules of Northern Ireland 2010 No. 29
- ⁸ Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment, Department of Health, June 2001
- ⁹ Medical and Dental Guidance Notes – A good practice guide on all aspects of ionising radiation protection in the clinical environment, IPEM et al, 2002.
- ¹⁰ Council Directive 93/42/EEC of 14 June 1993, concerning medical devices (and subsequent amendments) See <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF>
- ¹¹ The Health and Safety (Safety Signs and Signals) Regulations 1996 (SI 1996/341). (See http://www.opsi.gov.uk/si/si1996/uksi_19960341_en_1.htm)
- ¹² Medical Electrical Installation Guidance Notes 'MEIGaN' Version 2, September 2007. (See <http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Technicalinformation/Electricalsafetyinmedicaldevices/MEIGaN-MedicalElectricalInstallationGuidance/CON071429>)
- ¹³ Equipment Used in Connection with Medical Exposure. Health and Safety Executive, Guidance Note PM77 3rd Edition, March 2006. (See <http://www.hse.gov.uk/pubns/guidance/pm77.pdf>)
- ¹⁴ Core Curriculum in Cone Beam Computed Tomography (CBCT) for Dentists and Dental Care Professionals. Health Protection Agency and the British Society of Dental and Maxillo-Facial Radiology, December 2009.
- ¹⁵ Cliff Double, Care Quality Commission. Personal communication.
- ¹⁶ Faculty of General Dental Practitioners (UK). Selection Criteria for Dental Radiography. Faculty of General Dental Practitioners (UK) Royal College of Surgeons of England, London, 1998 (1st edition) and 2004 (2nd edition).

¹⁷ European Commission. Radiation Protection 136. European guidelines on radiation protection in dental radiology. The safe use of radiographs in dental practice. Luxembourg: Office for Official Publications of the European Communities, 2004. See http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/136_en.pdf

¹⁸ Horner K, Islam M, Flygare L, Tsiklakis T, Whaites E. Basic Principles for Use of Dental Cone Beam CT: Consensus Guidelines of the European Academy of Dental and Maxillofacial Radiology. *Dentomaxillofac Radiol* 2009; 38: 187-195.

¹⁹ FGDP (UK). Selection Criteria for Dental Radiography, 3rd edition, 2010. Faculty of General Dental Practice (UK), London (in preparation)

²⁰ SEDENTEXCT Guideline Development Panel. Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology. Provisional guidelines (v 1.1) May 2009). www.sedentexct.eu

²¹ [Dose reduction in maxillofacial imaging using low dose Cone Beam CT](#). Tsiklakis K, Donta C, Gavala S, Karayianni K, Kamenopoulou V, Hourdakakis CJ. *Eur J Radiol*. 2005 Dec;56(3):413-7.

²² Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-ray Examinations. IPEM Report 88. Institute of Physics and Engineering in Medicine, York.

²³ The Royal College of Radiologists. IT guidance: Picture archiving and communication systems (PACS) and guidelines on diagnostic display devices Ref No: BFCR(08)7. See http://www.rcr.ac.uk/docs/radiology/pdf/IT_guidance_PACSApr08.pdf

²⁴ See http://deckard.mc.duke.edu/~samei/tg18#_DOWNLOAD_THE_TG18

²⁵ The Royal College of Radiologists. IT guidance: Ergonomics Ref No: BFCR(08)3 http://www.rcr.ac.uk/docs/radiology/pdf/ITguidance_Ergonomics.pdf

APPENDIX A

Dental CBCT Performance Testing Requirements

Extracted from HPA-RPD-065

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*

* At the present time national reference levels for dental CBCT have not been established. In the interim, the WP recommends that a remedial level is set at a change in DAP of more than 20% from the LDRL (see sections 2.16.2 and 4.1.7).

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 +/- 1 mm (whichever is greater)	
High contrast material			1	see Explanatory paragraph	

A4 EXPLANATORY PARAGRAPHS

DCB01 (CT01)	Image noise
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Suggested method: System manufacturer's quality control phantom, water or PMMA phantom.

References: IPEM (2005)

Comments: Measure standard deviation for a central region of interest (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
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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
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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
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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
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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
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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.

Appendix 1 – testing standards (excerpt from HPA-RPD-065)

DCB12 (CT10)	CTDI – free in air
--------------	--------------------

Suggested method: Dosimeter 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 dosimeter.
 References: IPEM (2005)
 Comments: Carry out at least 3 measurements at a typical clinical setting.
 Appendix 1 – testing standards (excerpt from HPA-RPD-065)

DCB16 (RAD10)	Radiation output reproducibility
------------------	----------------------------------

Suggested method: Radiation dosimeter.
 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 dosimeter 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 dosimeter 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 cm², 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.

A5 MEASUREMENT RESULTS TEMPLATE

Dental Cone Beam CT Results Collection Form

Contact details	
Name:	Tel:
Organisation:	Email:
Address:	

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 cm²		
Dose area product - Child*		mGy cm²		

Notes

- kV, mA, time and voxel should be those used to obtain the results, rather than the range of
 - North = position closest to the x-ray tubehead prior to initiating an exposure
 - CTDI: If not CTDI100, please provide details of CTDI method in comments
 - 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

APPENDIX B

Core Curriculum in Cone Beam Computed Tomography (CBCT) for Dentists and Dental Care Professionals

Extracted from the Core Curriculum developed by the HPA Working Party in association with the British Society of Dental and Maxillofacial Radiology (BSDMFR), Version 10 December 2009

This is an abridged form of the Core Curriculum. Readers are strongly recommended to refer to the full version of the Curriculum which is available for download from the BSDMFR website (see <http://www.liv.ac.uk/~ppnixon>), and Section 3.9 of this guidance.

B1 INTRODUCTION

Regulation 11 paragraph 1 of the Ionising Radiation (Medical Exposure) Regulations 2000 states that no IRMER *practitioner* or *operator* shall carry out a medical (or dental) x-ray exposure or any practical aspect without having been adequately trained. The requirements for adequate theoretical training are set out in Schedule 2 of these Regulations. The Schedule states that *practitioners* and *operators* shall have completed training, including theoretical knowledge and practical experience in; radiation production, radiation protection and statutory obligations relating to ionising radiations, as are relevant to their functions as *practitioner* or *operator*, and diagnostic radiology as relevant to their specific area of practice. Whilst IRMER makes no explicit requirement for the training of *referrers*, the legal person will need to be confident that anyone acting as a *referrer* for CBCT is capable of making appropriate referrals and of providing adequate clinical information. Evidence of formal training would help this decision.

The advent of CBCT has introduced a new field of dental and maxillofacial radiological practice which has only recently been introduced into the dental undergraduate curriculum (as defined by the BSDMFR core curriculum for Dental Radiology¹) and is beyond the remit of current IRMER radiation update courses. It is also not covered in Dental Radiography courses for dental nurses, hygienists, therapists or other dental care professionals (DCPs), nor examined for in the National Examining Board for Dental Nurses (NEBDN) Certificate in Dental Radiography.

The aim of the curriculum is to specify the material that should be covered in order to ensure individuals are adequately trained in a specific area of radiological practice, ie; the use of Cone Beam Computed Tomography (CBCT) in dental and maxillofacial imaging and to meet the requirement for adequate training in the use of dental and maxillofacial CBCT as required by IRMER 2000/2006.

B2 THEORETICAL INSTRUCTION IN THE USE OF CBCT EQUIPMENT

B2.1 Radiation protection and radiological principles relevant to CBCT

General principles of radiation protection and radiography would normally be covered during undergraduate training and updated during regular Radiation Protection updating courses, as required by the General Dental Council (GDC) for registered dental professionals. These form the background to, and underpin, CBCT training.

It is recommended that items on this list should specifically be covered in CBCT training:

<i>Radiation Physics in relation to CBCT equipment:</i>	Referrer	IRMER Practitioner	Operator (imaging)	Operator (reporting)
• Biological effects of radiation at doses relevant to CBCT	x	x	x	x
• Risks/benefits of radiation at doses relevant to CBCT	x	x	x	x
• Dosimetry- absorbed dose, equivalent dose, effective dose and their units		x	x	x
• Factors affecting radiation dose including variables on CBCT units such as exposure factors (kV, mA exposure time, pulsed/constant beam), field size, voxel size, region of interest		x	x	x
• CBCT Image quality versus radiation dose		x	x	x
• Dose optimisation for CBCT examinations		x	x	x
• Comparative doses for CBCT and other dental examinations	x	x	x	x
<i>Radiation Protection in relation to CBCT examinations:</i>	Referrer	IRMER Practitioner	Operator (imaging)	Operator (reporting)
• Use of radiation protection devices during CBCT				
• For the patient		x	x	
• For personal & staff protection		x	x	
• Definition and procedures for untoward incidents involving overexposure to ionising radiation during CBCT examinations		x	x	x
• Pregnancy and potential pregnancy	x	x	x	x
• Medical research and health screening	x	x	x	x
• Infants and children	x	x	x	x
• Justification of the individual exposure and application of appropriate selection criteria	x	x	x	x
• Patient identification and consent	x	x	x	x
• Use of existing appropriate radiological information	x	x	x	x
• Alternative techniques	x	x	x	x
• Clinical evaluation of outcome and duties in relation to the reporting of CBCT images	x	x	x	x
• Medico-legal issues relevant to CBCT	x	x	x	x
• Local Rules and Working Procedures specific to CBCT		x	x	x
• Routine inspection and testing of equipment		x	x	x

<i>Apparatus and equipment:</i>	Referrer	IRMER Practitioner	Operator (imaging)	Operator (reporting)
• Applied potential (kV), tube current (mA) and exposure setting (mAs) - how change affects x-ray quality and quantity and CBCT image quality		x	x	x
• Selection of other image parameters that may influence patient dose		x	x	x
• Relationship of image quality to patient dose		x	x	x
<i>CBCT image acquisition and processing:</i>	Referrer	IRMER Practitioner	Operator (imaging)	Operator (reporting)
• Principles of CBCT image production	x	x	x	x
• Imaging detectors for CBCT		x	x	x
• Care of imaging receptors		x	x	
• CBCT image faults and Quality Assurance		x	x	x
• Data storage and retrieval, and data protection	x	x	x	x
• Information exchange	x	x	x	x
<i>Principles of CBCT imaging:</i>	Referrer	IRMER Practitioner	Operator (imaging)	Operator (reporting)
• Importance of image quality	x	x	x	x
• Optimisation of viewing conditions	x	x	x	x
• Use and limitation of CBCT as a diagnostic aid	x	x	x	x
• Viewing, manipulation and diagnostic pitfalls in 3D imaging	x	x	x	x
• Knowledge of multiplanar reconstruction and applications	x	x	x	x

B2.2 Radiological interpretation in the dento-alveolar region

Radiological anatomy and an understanding of the image should form part of the updating for any healthcare professional who takes on a role in interpreting and evaluating the CBCT image dataset. Thus *referrers*, *IRMER practitioners* and *operators* (including those who undertake clinical evaluation and report the images) should be familiar with the anatomy of the dento-alveolar region as seen on CBCT images, in order to properly target and evaluate the quality of the examination.

Those making a radiological diagnosis from CBCT images act in an ***operator (reporting)*** role - this curriculum is intended to guide the further training of those dentists, doctors and radiologists undertaking this radiological reporting of CBCT images of the dento-alveolar region. It builds on knowledge gained during their undergraduate training, on anatomy and disorders affecting this region.

Note that this curriculum does not include radiological interpretation in areas such as base of skull, temporal bones, neck and spine. If your scans incorporate these regions the European and SEDENTEXCT Guidelines recommend that these are reported by a radiologist unless the reporting operator has appropriate experience^{2,3}.

<i>Principles and practice of interpretation of dento-alveolar 3D CBCT images:</i>	Referrer	IR(ME)R Practitioner	Operator (imaging)	Operator (reporting)
• Principles of radiological differential diagnosis		X		X
• Reporting on cross sectional imaging of the dento-alveolar region - methods and conventions		X		X
• Recommendation that reporting of larger volume images covering structures beyond the immediate dento-alveolar region is undertaken by a trained maxillofacial or head and neck radiologist.	X	X		X
<i>An update on radiological anatomy of teeth and jaws relevant to CBCT:</i>				
• An update on fundamentals of radiological anatomy	X	X	X	X
• Teeth, periodontium and jaws, including TMJ	X	X	X	X
• Facial bones and sinuses	X	X	X	X
• Soft tissue structures and air spaces	X	X	X	X
• Normal development of teeth and jaws	X	X	X	X
<i>An update on dental and maxillofacial pathology that may include:</i>	Referrer	IRMER Practitioner	Operator (imaging)	Operator (reporting)
• Definition of fundamental terms	X	X	X	X
• Methods of describing radiological lesions		X		X
• Understanding the appearances on CBCT imaging of;				
o Developmental abnormalities		X		X
o Disorders of teeth and periodontium		X		X
o Infective disorders, caries and periapical infection within the dento-alveolar region		X		X
<i>Radiological interpretation may also cover:</i>	Referrer	IRMER Practitioner	Operator (imaging)	Operator (reporting)
• <i>Localised and spreading infection in the jaws</i>		X		X
• <i>Cysts of jaws</i>		X		X
• <i>Tumours and tumour-like lesions of the jaws</i>		X		X
• <i>Fibro-osseous lesions</i>		X		X
• <i>Metabolic disorders of significance in dental practice</i>		X		X
• <i>Trauma including fractures - teeth & facial bones</i>		X		X
• <i>Disorders of the maxillary sinuses on dento-alveolar scans</i>		X		X
• <i>Disorders of the temporomandibular joints</i>		X		X

B3 PRACTICAL INSTRUCTION

Operators should obtain practical experience in the safe use of CBCT equipment and optimise the exposure by making best use of dose reduction features. An *applications specialist* from the CBCT manufacturer may best deliver much of this aspect of machine-specific training. Practical instruction will help develop accurate radiography.

IRMER practitioners should ensure they are aware of patient doses arising from the imaging techniques which are available.

B3.1 Techniques

Operators should know the fundamentals of CBCT radiological techniques relevant to dental and maxillofacial imaging and be able to:

- Advise the patient regarding the practical aspects of the procedure
- Position the patient and equipment accurately
- Select and use the most appropriate imaging programmes and correct exposure factors
- Store and transmit the image data appropriately and in keeping with current legislation
- Manipulate the 3D image data to allow suitable clinical interpretation of the image

B3.2 Quality assurance for CBCT imaging systems

- Quality assurance and quality control relevant to CBCT
- The use of a two-point quality scale with a reject rate target of less than 5%

Quality Rating	Target
Diagnostically acceptable	Not less than 95%
Diagnostically unacceptable	Not greater than 5%

B3.3 Understand care of patients

- Children
- Special care patients
- Infection control
- Communication of risks to patients

B4 TIME REQUIRED

This course could be covered using lectures, practical radiography workshops and/or seminars. In addition, other teaching styles may also be used such as computer-aided learning, supervised case reporting, and mentoring. The main objective of the course is that the dental personnel should be competent to undertake CBCT radiography, and radiology of the dento-alveolar structures, to a level and standard required for general practice.

Both theoretical training and practical instruction are required in order that duty-holders are 'adequately trained'. The working party recommends that this be undertaken commensurate with the purchase of the CBCT device.

B4.1 Theoretical training

Radiological physics, protection, and principles of CBCT imaging

It is suggested that a minimum of 3 hours is sufficient to cover the theoretical knowledge of radiation protection and imaging for the *referrer, IRMER practitioner and operator*, as outlined in this document.

Radiological interpretation of the dento-alveolar region

A further minimum of 2 hours should be allocated to coverage of interpretation, anatomy and pathology of the teeth and their supporting structures for the *IRMER practitioner* and *operator (reporting)*. Further supervised reporting of cases is recommended.

IRMER updating and refresher courses

It is suggested that at least a further 1 hour of CBCT-related training is required to cover the radiological updating for the *referrer*, *IRMER practitioner* and *operator* as part of their 5 year re-accreditation cycle with the GDC, once initial CBCT training has been completed.

B4.2 Practical Instruction

It is suggested that staff undertake a minimum of 6 hours in practical training in the use of the specific CBCT machine and in its software. This would be ideally delivered by a trained applications specialist.

B5 TUITION

Training of personnel to undertake CBCT radiography should draw on the combined expertise of:

- A dental & maxillofacial radiologist +/- specialist dental radiographer
- An applications specialist from the manufacturer of the equipment and
- A Medical Physics Expert

B6 REFERENCES

¹ Core Curriculum in Dental Radiography and Radiology for Undergraduate Dental Students. British Society of Dental & Maxillofacial Radiology (BSDMFR) 2008.

² Horner K, Islam M, Flygare L, Tsiklakis T, Whaites E. Basic Principles for Use of Dental Cone Beam CT: Consensus Guidelines of the European Academy of Dental and Maxillofacial Radiology. *Dentomaxillofac Radiol* 2009; 38: 187-195.

³ SEDENTEXCT Guideline Development Panel. Radiation Protection: Cone Beam CT for Dental and Maxillofacial Radiology. Provisional guidelines (v 1.1) May 2009). www.sedentexct.eu

APPENDIX C

Example Service-Level Agreement

Service-Level Agreement for the Referral of Patients to the XYZ Dental Practice for Dental Cone Beam CT Examinations					
Address of CBCT practice:		Address of referring practice:			
Tel:		Tel:			
Email:		Email:			
Name of legal person*:		Name of legal person*:			
Referral criteria for dental CBCT:					
The document specified below will be used by both parties as the basis for the referral of patients and the justification/authorisation of dental CBCT examinations:					
Name of document: <i>[Example: SEDENTEXCT Provisional Guidelines V1.1 May 2009, Chapter 4]</i>					
Entitlement of Persons					
Enter below details of all persons at referring practice who will refer patients for dental CBCT examinations and/or report on dental CBCT images. Evidence of training meeting the requirements of the HPA/BSDFMR Core Curriculum in Dental CBCT must be provided.					
For completion by referring practice:			For completion by CBCT practice:		
Name(s):	GDC/GMC Reg No.	IRMER Roles (tick)		Training OK?	Registration OK?
		Referrer	Operator (reporting)		
Signatures of agreement:					
We the undersigned agree: (1) to use the referral criteria stated above; (2) that evidence of adequate training has been provided for each of the persons named above appropriate to their IRMER roles; (3) that adequate information will accompany each referred patient to allow the justification process to proceed, as set out in the attached Standard Referral Form.					
For the CBCT practice:		For the Referring practice:			
Name of legal person*:		Name of legal person*:			
Signature:		Signature:			
Date:		Date:			
* The "legal person" is the person/body corporate that takes legal responsibility for implementing the Ionising Radiations Regulation 1999 and the Ionising Radiation (Medical Exposure) Regulations 2000 within the practice.					

APPENDIX D

Example Imaging Referral Form

Dental Cone Beam CT Imaging Referral Form for The XYZ Dental Practice		
Patient details		
Name:	Date of birth:	
Address:		
Patient contact telephone numbers: H: W: M:		
Referrer details		
Name:		
Address:		
Signature:		
Date of referral:		
Referrer contact telephone number:		
The clinical context for requesting a dental CBCT examination		
Relevant results of history, clinical examination and other imaging		
What information do you want the dental CBCT examination to provide?		
Define the anatomical area that the scan(s) should cover		
Justification		
Name of IRMER practitioner:		
Signature:		
Date:		
Details of scan authorised:		
Scan information:		
Name of Operator:		
Signature:		
Date of scan:		
Exposure factors used:		
Clinical evaluation (Reporting)*		
Name of Operator (Reporting):		
Signature:		
Date:		
Outcome:		
<p><i>* If, under the Service Level Agreement dental CBCT images will be reported on by the referring practice, this fact should be recorded here. The referring practice will then be responsible for ensuring the clinical evaluation takes place and is properly recorded.</i></p>		
ON COMPLETION, RETAIN THIS FORM AND RETURN A COPY TO THE REFERRING PRACTICE		

APPENDIX E

EADMFR Basic Principles for Use of Dental CBCT – Sections Relevant to Referral/Justification

The following text is extracted from the Basic Principles for Use of Dental Cone Beam CT: Consensus Guidelines of the European Academy of Dental and Maxillofacial Radiology (EADMFR)

This is an abridged form of the Basic Principles, which together with the Provisional Guidelines, are intended to provide **interim guidance** on referral criteria relevant to dental CBCT examinations. For more detailed information on this subject readers are strongly recommended to refer to the full version of the Provisional Guidelines which are available for free download from the homepage of the SEDENTEXCT website (see <http://www.sedentexct.eu/>).

Summary of SEDENTEXCT Basic Principles relevant to Referral/Justification

- 1 Dental CBCT examinations must not be carried out unless a history and clinical examination have been performed
 - 2 Dental CBCT examinations must be justified for each patient to demonstrate that the benefits outweigh the risks
 - 3 Dental CBCT examinations should potentially add new information to aid the patient's management
 - 4 Dental CBCT should not be repeated 'routinely' on a patient without a new risk/benefit assessment having been performed
 - 5 When accepting referrals from other dentists for CBCT examinations, the referring dentist must supply sufficient clinical information (results of a history and examination) to allow the CBCT Practitioner [*IRMER practitioner*] to perform the Justification process
 - 6 Dental CBCT should only be used when the question for which imaging is required cannot be answered adequately by lower dose conventional (traditional) radiography
 - 7 Where it is likely that evaluation of soft tissues will be required as part of the patient's radiological assessment, the appropriate imaging should be conventional medical CT or MR, rather than dental CBCT
-

In view of the rapidly developing nature of this imaging modality, readers are further advised to consult their RPA or MPE regarding the latest available guidance when drafting guidelines on referral criteria for CBCT examinations, as part of their IRMER procedures (see sections 3.2 to 3.4). Note that the third edition of the FGDP (UK) Selection Criteria for Dental Radiology is expected to be available in late 2010, and the Provisional Guidelines will be updated by April 2011.