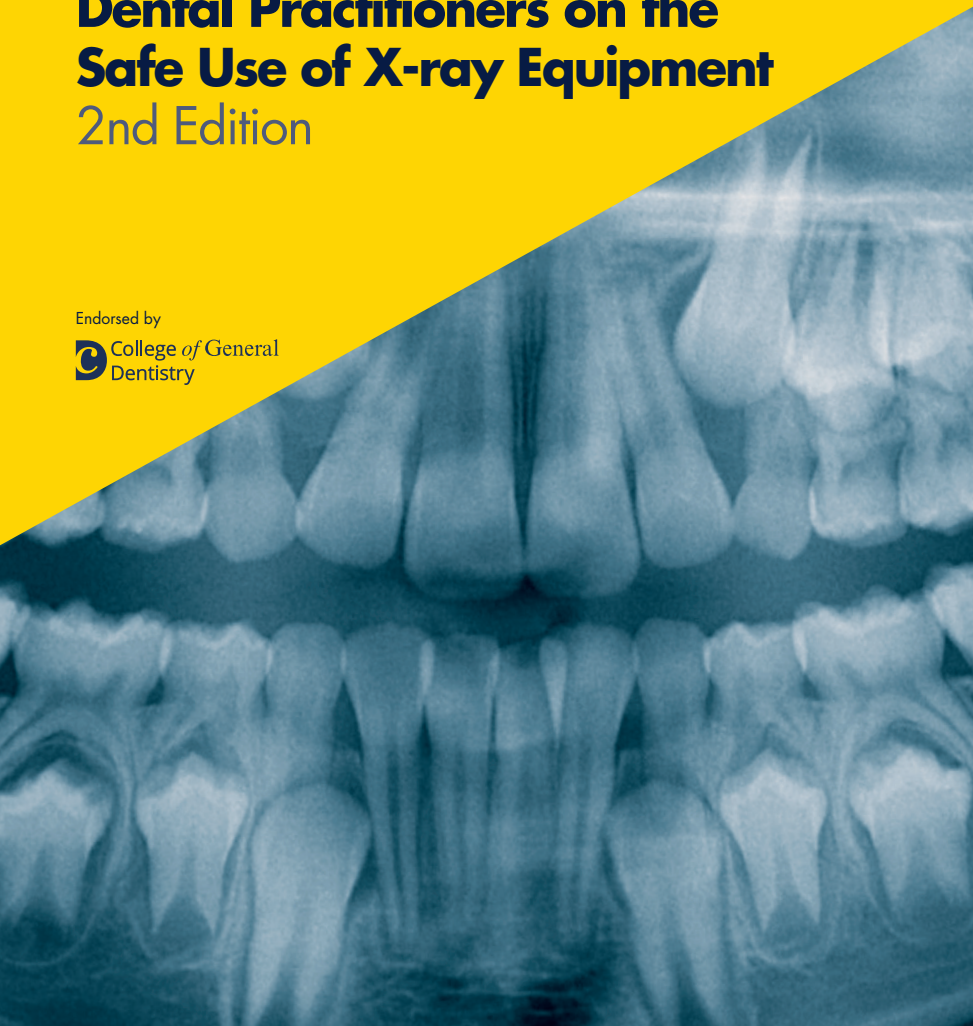


Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment

2nd Edition

Endorsed by



Public Health
England



FGDP
(UK)

FACULTY OF GENERAL DENTAL PRACTICE

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Foreword

Dental radiography is a long-established aspect of modern dentistry, with the first instance of its use dating from 1896, just a year after Wilhelm Röntgen's discovery of X-rays.

Across the UK, more dental radiographs are taken each year than any other form of X-ray diagnostic image, and the various forms of dental X-ray imaging now available to the profession have become indispensable tools in the efficient diagnosis of disease and the effective planning of treatment. However, against the undoubted benefits arising from dental radiography it is important to balance the risks arising from exposures of ionising radiation to the patient, members of the dental team and other persons who may be affected. In the absence of any controls, the potential doses to individuals from dental X-ray equipment could be substantial, and it is only through careful adherence to principles of good practice such as set out in these guidelines that doses can be restricted, so far as reasonably practicable, as required by UK radiation protection legislation.

This is the second edition of the *Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment*, the original version of which was published in 2001. Since that time, developments in dental X-ray equipment, imaging technology, professional best practice guidelines, and UK radiation protection legislation have all contributed to the case for reviewing and updating the original document. Furthermore, the regulatory bodies have at times expressed concern over the low levels of compliance with radiation protection legislation observed at some dental practices. This second edition provides well-founded, expert and up to date guidance that is detailed and comprehensive while remaining clear, intelligible and logically ordered. From a basis of considering the best means of complying with the two main items of UK legislation, the guidance deals with the administrative and practical issues that must be addressed within dental practice, as if it were being established at a new premises, and in an appropriate chronological order. The guidance addresses the following key issues: equipment selection, design and layout of dental surgeries and X-ray rooms, risk assessment and risk management, operational procedures, optimisation of doses to both staff and patients, quality assurance, and staff training.

The working party that generated this guidance included representatives from all the UK regulatory bodies as well as experts from various professional and advisory bodies and consultant dental radiologists, but just as importantly, general dental practices. The Chief Dental Officers congratulate the working party and FGDP(UK) on having successfully delivered this publication. Adherence to the guidance should materially contribute to and support high standards of radiation protection throughout the UK dental profession and the Chief Dental Officers therefore expect all dental care professionals to implement it within their own practices.

Colette Bridgman CDO Wales

Michael Donaldson Acting CDO Northern Ireland

Tom Ferris CDO Scotland

Sara Hurley CDO England

Foreword

The core function of the Faculty of General Dental Practice (UK) is to raise the standards of care delivered to patients through education of the dental profession and the provision of evidence-based guidance. We have long been developing our own standards, but are delighted to work with Public Health England (PHE) to produce a second edition of the *Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment*.

Dental X-ray imaging is an important diagnostic tool supporting dental health care professionals in assessment and delivery of an accurate diagnosis. The rapid development of digital technology has greatly enhanced our ability to acquire high quality images with greater diagnostic yield, whilst at the same time potentially lowering radiation exposure. Digital imaging is increasingly being used as a patient information tool to allow patients to be more involved in shared decision making, which is key to the provision of informed and valid consent.

The quality of X-ray images has improved dramatically over the years, but is still highly dependent on the correct selection, use and maintenance of X-ray equipment. There are risks involved in every exposure and it is incumbent on the dental team to ensure that they have adequate training, knowledge and understanding of these risks. To minimise the risks, X-ray equipment must be used safely, and appropriate guidance should be followed, such as FGDP(UK)'s Selection Criteria in Dental Radiography.

The previous guidance from 2001 has been an important reference text in setting standards for safe use of X-ray equipment within dental practice, and this updated edition will undoubtedly continue to be a key reference document for the primary care dental team. I am grateful to the various contributors who have spent considerable time and effort ensuring that this document is informative, accessible and highly relevant to all members of the dental team, and in particular to PHE for inviting the Faculty to collaborate, and to Dr Keith Horner who represented FGDP(UK) on the working group.

Ian Mills Dean of the Faculty of General Dental Practice (UK)
and Trustee, the College of General Dentistry

Preface

The aim of this publication is to provide definitive guidance to assist all persons involved with dental radiography or dental cone-beam CT (CBCT) imaging to work safely, to achieve adequate restriction of exposure to persons undergoing X-ray examinations, and to comply with UK radiation protection legislation.

This publication updates and replaces the first edition of the *Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment* (the Dental GNs) published by the National Radiological Protection Board in 2001 and the guidance on dental CBCT systems published by the Health Protection Agency in 2010. The recent changes in legislation have relatively few implications for the use of hand-held dental X-ray equipment and the guidance published by Public Health England in 2016¹ remains largely valid, with the exception of chapter 4 which is superseded by these Guidance Notes.

A summary of the most significant differences between this second edition of the Dental Guidance Notes and the first edition, which was published in 2001, is given below, along with the section of the guidance in which it is covered:

- Previous guidance on dental CBCT and hand-held dental X-ray equipment has been updated and incorporated into this document – various sections
- All dental practices must now register their ‘work with a radiation generator’ with the Health and Safety Executive (HSE), or the HSENI in Northern Ireland, and update this registration if subsequent ‘material changes’ occur – section 2.2
- Updated guidance is provided on the extent, duration and demarcation (using warning signs and/or warning lights) of controlled areas during dental radiography or dental CBCT imaging – section 2.11
- New guidance is provided on the legal requirement to assess doses to persons who need to enter controlled areas – section 2.14
- Guidance is provided on the new requirement to formally investigate the circumstances when contingency plans are activated, and on the need to rehearse contingency plans – section 2.17
- New guidance is provided on the legal requirement to monitor radiation levels at the boundaries of controlled areas – section 2.19

- New guidance is given on the requirement for employers to co-operate when employees work with dental X-ray equipment on another employer's premises, including arrangements for the formal handover of responsibility – section 2.22
- Updated recommendations are provided on the training required for referrers, practitioners and operators with respect to dental CBCT – section 3.10
- Detailed practical guidance is provided on how to achieve the optimisation of patient dose – section 4
- Updated guidance is provided on the content of acceptance tests and routine tests for all dental X-ray equipment and the recommended intervals between routine tests – section 5.2
- New guidance is provided on the quality assurance of digital imaging systems and viewing screens – section 5.3
- Revised guidance is provided on image quality rating and analysis – section 5.4
- New guidance is provided on what should be expected of service engineers who undertake the testing of dental X-ray equipment – section 6.1
- New guidance is provided on the disposal or selling-on of X-ray equipment – section 6.2
- New guidance is provided on the retention times for various records required to be kept under both IRR17 and IRMER17 – section 6.3
- Templates are provided in the appendices for the radiation risk assessment required by IRR17 and the employer's procedures required by IRMER17 (including the procedures for explaining the benefits and risks of exposure, dose constraints and guidance for carers and comforters and investigation and notification of significant and clinically significant accidental or unintended exposures)

Those working in the hospital sector are advised to refer to the latest version of the Medical and Dental Guidance Notes published by the Institute of Physics and Engineering in Medicine (IPEM).²

To ensure the continuing relevance of this guidance, it will be reviewed and, if necessary, updated no later than five years after the date of publication.

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Available at <https://www.gov.uk/government/publications/hand-held-dental-x-ray-equipment-guidance-on-safe-use>.
- 2 Institute of Physics and Engineering in Medicine. Medical and Dental Guidance Notes. A good practice guide on all aspects of ionising radiation protection in the clinical environment. York, UK: Institute of Physics and Engineering in Medicine; 2002.

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Dental Guidance Notes

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Summary of essential actions when commencing work with dental X-ray equipment for the first time

The table on the next two pages provides a guide to the most significant actions that must be addressed to ensure compliance with the Ionising Radiations Regulations 2017 (IRR17) and the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER17), when planning to use dental X-ray equipment for the first time (e.g. when setting up a new dental practice)*.

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 “employer” (see section 1.2) is responsible for making sure that all the following steps are carried out.

*Note that dental practices in Northern Ireland are subject to the Ionising Radiations (Northern Ireland) Regulations 2017 (IRRN17) and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018 (IRMERN18)

Summary of essential actions when commencing work with dental X-ray equipment for the first time

"Done" (✓)	Action/task	Relevant sections of this guidance
<input type="checkbox"/>	Register 'work with a radiation generator' with the appropriate enforcing authority before use of the X-ray equipment commences** . This online registration includes questions about whether you have appointed an RPA and completed your legal obligations such as carrying out a risk assessment and providing local rules. Although the questions are straightforward, an RPA may be able to assist (but is not allowed to complete the registration for the employer). There is a fee for registration (£25 in 2020).	2.2 and Appendix A
<input type="checkbox"/>	Appoint a suitable radiation protection adviser (RPA) to advise on IRR17 and a medical physics expert (MPE) to advise on IRMER17.	2.3
<input type="checkbox"/>	Consult MPE about the selection of suitable dental X-ray equipment and ancillary equipment – including dental CBCT or hand-held units.	3.7
<input type="checkbox"/>	Consult RPA about the layout and construction of the dental radiography facilities, including required structural protection and safety and warning devices. Forward RPA's report to the builder and/or installer.	2.4, 2.5, 2.6
<input type="checkbox"/>	Confirm with the installer that a critical examination will be carried out in consultation with an RPA and a report issued. Make arrangements for acceptance testing with the MPE.	2.9 5.2
<input type="checkbox"/>	Draft a radiation risk assessment in consultation with the RPA and implement the control measures identified.	2.10
<input type="checkbox"/>	Draft local rules (including contingency plans) in consultation with the RPA and issue the agreed local rules to relevant staff. **If the airborne radon level exceeds a certain threshold at the premises this must be notified to HSE (see section 2.2.1)	2.16, 2.17

Table continued on next page

Table continued

"Done" (✓)	Action/task	Relevant sections of this guidance
<input type="checkbox"/>	Draft the employer's procedures in consultation with the MPE as relevant to the proposed work and issue them to staff:	3.5
<input type="checkbox"/>	Appoint one or more persons to act as radiation protection supervisors (RPSs) and arrange for them to be trained in the requirements of IRR17.	2.18
<input type="checkbox"/>	Entitle suitable staff to act as referrers, practitioners and operators in accordance with IRMER17 and the GDC Scope of Practice document and ensure that they are adequately trained, competent and indemnified for their roles and included in the employer's procedures.	3.2, 3.3, 3.4
<input type="checkbox"/>	Ensure staff are adequately trained in radiation safety, including the significant findings of the risk assessment and the requirements of the local rules.	2.21
<input type="checkbox"/>	Establish a quality assurance programme for the employer's procedures and local rules including: <ul style="list-style-type: none"> • Document issue, review and control • Staff training and refresher training 	5.1
<input type="checkbox"/>	Establish a quality assurance programme for the dental X-ray equipment and ancillary equipment in conjunction with the MPE and RPA, including: <ul style="list-style-type: none"> • Adequate testing • Representative measurements of patient dose and comparison with local DRLs • Routine surveillance • Quality assurance checks on image processing and viewing facilities • Maintenance and fault logs 	5.2, 5.3
<input type="checkbox"/>	Establish a quality assurance programme for image quality in conjunction with the MPE	5.4

1 INTRODUCTION

This publication provides advice to dentists and others supplying, using, or working with all forms of dental X-ray equipment outside the hospital sector, regarding the practical application of the relevant radiation protection legislation. This is the Ionising Radiations Regulations 2017 (IRR17) together with its Approved Code of Practice (ACoP) and guidance,¹ and the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER17)² together with its subsequent amendments,³ and supporting guidance issued by the Department of Health and Social Care (DHSC).⁴

Attention is drawn to the special legal status of the ACoP supporting IRR17; if legal action is taken against an employer for a breach of the regulations and the employer has not followed the relevant provisions of the ACoP, the onus will be on the employer to demonstrate that compliance with IRR17 was achieved in some other way. The DHSC guidance accompanying IRMER17 has no equivalent legal status. Where a section of the guidance refers to an explicit legal requirement (or an aspect of the ACoP to IRR17) the word “must” is used. Otherwise, the word “should” is used to refer to recommended actions that derive from published guidance, or which represent established best practice.

Throughout this guidance, references to IRR17 and IRMER17 should also be taken as referring to the very similar legislation applying in Northern Ireland (namely the Ionising Radiations Regulations (Northern Ireland) Regulations 2017⁵ and the Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2018.⁶ It should be noted that the UK regulations do not apply in the Isle of Man, which has its own, very similar legislation, or the Channel Islands.

These Dental Guidance Notes are structured under the title of each piece of legislation, with the order in which each topic is then addressed approximating the order in which issues should normally be considered by a person planning to undertake dental radiography for the first time (e.g. when setting up a new dental practice).

To assist the reader, the guidance contains checklists of the essential actions that must be completed to fulfil the requirements of IRR17 and IRMER17.

1.1 Application of guidance

This guidance is aimed primarily at general dental practices and other users of dental X-ray equipment outside the hospital sector. However, for simplicity, the terms “dentist” and “dental practice” are used throughout to represent all users of dental X-ray equipment, including those in community dental services, corporate dental bodies and armed forces etc. In practice, the term “all users” is used to refer to anyone with legal responsibilities arising from their involvement with dental radiography, including those who refer patients for dental radiography or dental CBCT imaging, operators of X-ray equipment and/or imaging equipment or software and those who perform maintenance or testing of dental X-ray equipment.

1.2 The terms “employer” and “employee”

Responsibilities under both IRR17 and IRMER17 relate to an “employer,” however, in IRMER17 the term “employer” is used with a definition based on the concept of responsibility for health and safety matters rather than employment law. The employer, as a duty holder under IRMER17, is responsible for providing a framework of written procedures, written protocols and QA programmes within which the various duty-holders undertake their functions. For the purposes of compliance with IRMER17 it is recommended⁷ that the employer’s procedures should identify which individual(s), company or body corporate has been designated as the employer within the organisation.

Much of the requirements of IRR17 and IRMER17, and the guidance presented in this document, is addressed at “employees”. However, where any individual who is identified as the “employer” is also required to work under the employer’s procedures or local rules, they must also be considered to be an “employee” for the purposes of complying with the legislation. This will certainly be the case if the individual acts as either an IRMER practitioner, referrer or operator (from IRMER17), or a radiation protection supervisor (from IRR17).

1.3 References

- 1 The Health and Safety Executive. Working with ionising radiation. The Ionising Radiations Regulations 2017, Approved Code of Practice and guidance. (Series code: L121 second edition). Norwich, UK: HSE Books; 2018.
Available at <https://www.hse.gov.uk/pubns/books/l121.htm>
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2 REQUIREMENTS OF IRR17

2.1 Scope of IRR17

The IRR17 is made under the provisions of the Health and Safety at Work etc. Act 1974,¹ and as such provide a legislative framework for the protection of persons who are exposed to ionising radiation during the course of their work activities, and other persons, such as members of the public, who may be incidentally exposed. It should be noted that IRR17 does not apply to persons undergoing any kind of medical exposures, including dental X-ray examinations; these types of exposure are regulated under IRMER17 (see sections 3 and 4).

2.2 Registration with the Health and Safety Executive

Prior to commencing work with dental X-ray equipment for the first time, the employer must register their 'work with a radiation generator' with the Health and Safety Executive (HSE).

There is no distinction between the use of dental X-ray equipment for diagnostic, non-medical imaging or research exposures in terms of registering with HSE. However, see section 3.12 for guidance on non-medical imaging and section 3.13 for guidance on the approvals process and the requirements of IRMER17 relating to research exposures.

Employers at existing dental practices that have yet to register under IRR17 should do so as soon as possible, as it is an offence to work with X-ray generators without doing so.

Registrations in England, Scotland and Wales all require an application to be submitted to HSE via a dedicated website at <https://services.hse.gov.uk/bssd/>. In Northern Ireland, the application for a registration must be submitted to the Health and Safety Executive for Northern Ireland (HSENI) using their website at <https://www.secure.hseni.gov.uk/Forms/IonisingRadiationNotification.aspx>.

The registration process requires the employer to provide basic information, such as the business name, address and number of premises, and make declarations that certain specific requirements of IRR17 have been met. Several of these will require the employer to appoint and consult a suitable radiation protection adviser (RPA) in order to fulfil them (see section 2.3). Registration applications attract a fee which must be paid for the process to be completed (except in Northern Ireland where there is no fee).

Appendix A summarises the questions that an employer applying for a registration must answer, and provides a guide as to the suggested responses.

If the employer is asked to answer questions regarding 'expected dose' received by staff or whether the Radiation (Emergency Preparedness and Public Information) Regulations 2019 (REPPiR 19,² or REPPiR(NI)2019³ in Northern Ireland) apply, this indicates they have mistakenly selected a category of work requiring a 'consent' which is not appropriate for routine work with dental X-ray equipment. In this case, the employer should consult their radiation protection adviser (RPA; see section 2.3) or refer to the guidance on HSE's (or HSENI's) website.

Once the registration has been accepted by HSE, the 'certificate of registration' and 'summary details of registration' should be downloaded and retained by the practice.

Any subsequent change in the details submitted to HSE when the registration was first made will require the employer to amend the relevant details; however, only a "material change" will involve payment of another fee. If the practice commences dental radiography at care homes using mobile X-ray equipment, this would be a material change; however, simply purchasing a new type of dental X-ray set that the practice has not previously used would not constitute a material change.

If the name or address of the practice changes, this will require the original registration to be cancelled and a new registration application to be made.

2.2.1 Notifying HSE about radon

Any employer who owns premises where employees work in an atmosphere where the annual average radon gas activity concentration has been assessed to be above 300 becquerels per cubic metre of air should also make a notification to HSE using the same process as above. Notifications are free of charge. In this situation, the employer must also consult a suitable radiation protection adviser (see section 2.3) regarding any protection measures that may be necessary.

All employers are advised to use the interactive map on Public Health England's UKRadon website at <https://www.ukradon.org/> to determine if their premises are in areas that may be affected by radon.

For further information on notifications and registrations, see the guidance on HSE's website at <http://www.hse.gov.uk/radiation/ionising/notification.htm>.

2.3 Radiation protection adviser (RPA)

Employers must consult one or more suitable RPAs as necessary for advice regarding compliance with IRR17, and this should cover the following matters (as relevant to dental radiography).

- **Prior assessment of installation plans**
- **Acceptance into service of engineering controls, design features, safety and warning devices in relation to new or modified radiation sources**
- Drafting and review of risk assessment, local rules and contingency plans
- **Designation of controlled and supervised areas and subsequent requirements**
- Working arrangements for pregnant employees

- **Calibration of radiation monitoring equipment and checks on its condition**
- Personal protective equipment
- Designation of classified persons and personal dosimetry
- Training programmes
- Prevention, investigation and analysis of accidents
- Quality assurance
- **Periodic testing of engineering controls, design features, safety and warning devices and regular checking of systems of work**

Consultation with an RPA for advice on any of the matters indicated in **bold** is specifically required under regulation 14(1). It is important that RPA advice is obtained at the appropriate time, particularly when planning new or modified installations of dental X-ray equipment, so that any recommendations can be put in place.

A suitable RPA is an individual, or an RPA body, able to demonstrate compliance with HSE's current criteria of core competence and having specific knowledge and adequate experience of radiation protection as applied to diagnostic radiology in the dental sector. A list of individual RPAs holding current certificates awarded by the assessing body RPA2000 can be found at <http://www.rpa2000.org.uk/list-of-certificate-holders/>, and a list of RPA bodies that have been formally recognised by HSE can be found on its website at <http://www.hse.gov.uk/radiation/rpnews/bodieshse.htm>.

The RPA must be appointed in writing by the employer and the appointment must specify the scope of advice that the RPA will be expected to provide. The RPA should be appointed on an ongoing basis so that any necessary advice can be provided promptly. Any advice addressing the matters listed above (or any other substantive requirement of IRR17) should be provided in writing.

The employer's attention is also drawn to the equivalent requirement to appoint a medical physics expert (MPE) for advice on compliance with IRMER17 (see section 3.7).

2.4 Restriction of exposure to employees and members of the public

2.4.1 Optimisation (the 'ALARP' principle)

Regulation 9(1) of IRR17 requires that:

'Every employer must, in relation to any work with ionising radiation that it undertakes, take all necessary steps to restrict so far as is reasonably practicable the extent to which its employees and other persons are exposed to ionising radiation.'

The phrase 'as low as reasonably practicable' (or 'ALARP') is usually used to refer to this principle as it has a precedent in the British legal system. Adherence to these guidance notes should ensure that occupational radiation exposure arising from dental radiography will be ALARP.

2.4.2 The hierarchy of controls

Regulation 9(2) specifies a hierarchy in terms of the control measures the employer should use to achieve ALARP. Priority must, so far as reasonably practicable, be given to the use of design features and engineering controls, (such as a well-considered layout of the X-ray room with shielding provided where necessary to protect persons

in adjacent areas) supported by safety features and warning devices (such as warning lights, audible signals and warning notices where appropriate). Only after these measures have been applied should consideration be given to the use of systems of work and, lastly, personal protective equipment, to further restrict exposure. A dental radiography facility that is designed and constructed according to the guidance in sections 2.5 and 2.6 will fulfil the requirements of IRR17 regulations 9(1) and 9(2) regarding the use of physical control measures to achieve the adequate restriction of exposure to employees and other persons.

Employers must then identify the key working procedures that are necessary to further restrict exposures and ensure that these are adhered to by all employees. For further guidance, refer to section 2.7 (see also sections 2.10, 2.16, 2.17 and 2.18 relating to radiation risk assessment, local rules, contingency plans and radiation protection supervisors, respectively).

Personal protective equipment (PPE) should only be used for radiation protection purposes (e.g., protective aprons or thyroid shields) when unavoidable, when there are no alternative measures that can be applied to restrict exposures. The appropriate use of PPE for the radiation protection of employees is covered in section 2.8.

2.4.3 Dose limits

Schedule 3 of IRR17 sets out statutory dose limits for occupational exposures, which must not be exceeded under any circumstances. These are presented for information in Table 2.1. The overriding requirement, however, is that all doses must be as low as reasonably practicable (ALARP) as described in section 2.4.1. For dental radiography, annual effective doses to all employees and other persons at a well-managed dental practice should be well below 1 mSv.

TABLE 2.1 **Statutory dose limits set out in schedule 3 of IRR17**

Region of body	Dose limit (mSv per year):		
	Employees and trainees aged 18 and over	Trainees aged under 18	Other persons*
Whole body	20	6	1
Lens of the eye	20	15	15
Skin, hands, forearms, feet and ankles	500	150	50

*"Other persons" refers to 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 radiography

2.4.3.1 Restriction of exposure to pregnant employees

The employer must ensure that the equivalent dose to the foetus is as low as is reasonably practicable and is unlikely to exceed 1 mSv during the declared term of pregnancy. The radiation risk assessment (see section 2.10) should identify whether or not this level of dose could be exceeded, and if it could, what additional controls will

be necessary to comply with this dose restriction. It would then be important to ensure that all employees understand that additional dose limits apply during pregnancy and are encouraged to tell their employer as soon as they know that they are pregnant.

Where the risk assessment indicates that no additional controls are required to comply with this dose restriction, no further action need be taken and there is no need for employees to inform their employer of their pregnancy. This is likely to be the case for the great majority of dental practices.

2.4.3.2 Estimation of doses to members of the public

Regulations 12(3) and 12(4) of IRR17 require the employer to estimate the highest likely annual effective dose to a representative member of the public arising from their work with ionising radiation, to ensure that the relevant dose limits are not exceeded. The employer should identify the group of people who are most likely to receive the highest exposures, and make an estimation of the potential annual dose to this group. The RPA should be involved in the estimation of doses to members of the public and the findings should be documented in the radiation risk assessment (see section 2.10).

2.5 Design of dental radiography facilities

The radiation protection aspects of a planned new installation of dental X-ray equipment (including the planned use of hand-held units), must be considered by the employer on a case-by-case basis, in consultation with a suitable RPA. This should ensure that the appropriate engineering controls and design features are in place from the outset and will also allow for any building work to take these features into account and avoid additional costs and delays from having to make changes at a later stage.

An RPA must also be consulted where existing X-ray equipment is moved or significantly modified, or where the room construction, layout or working arrangements change. It is not appropriate to rely solely on the advice of the company providing or installing the X-ray equipment, although they will be well-placed to offer initial suggestions on surgery layout and to provide technical information to be passed on to the RPA.

PHE has published data⁴ on representative levels of scattered and transmitted doses produced during intra-oral and panoramic radiography, which can be used in conjunction with a suitable calculation method⁵ to assess the level of protection afforded by commonly used building materials. Data on scattered radiation levels produced by cephalometric and dental CBCT equipment should be available from the manufacturer (see section 2.9.1).

To enable the RPA to make a realistic assessment, the employer should provide information on the type, make and model of X-ray equipment, an estimate of the radiographic workload for each X-ray set and an accurate plan of the rooms to be used for dental radiography and their surroundings, including any areas above and below the X-ray room.

2.5.1 Dose constraints

Dose constraints should be considered at the planning stage for new installations. If used, a dose constraint of 0.3 mSv (effective dose) per year for both employees and members of the public is suggested.

2.5.2 Design considerations

A summary of the key issues is given below.

- The radiographic workloads to be used for calculation purposes should be the maximum foreseeable in the long term
- Dental X-ray equipment should be installed in a room or area from which all persons whose presence is unnecessary can be readily excluded while X-rays are being produced
- This room or area should not be used for other work or as a passageway whilst radiography is in progress
- Either the room should be large enough to allow the operator to stand at a safe distance from the X-ray set and well away from the direction of any intra oral primary X-ray beams, or a protected area should be provided for the operator inside the room (this does not apply to hand-held X-ray equipment)
- The shielding requirements for the walls, doors and other boundaries of the room should be determined on a case by case basis, taking into account the use and occupancy of areas adjacent to the room regardless of their distance from the X-ray tubehead and patient – this is particularly important for dental CBCT equipment where the radiation output per examination may be significantly higher than for other types of dental X-ray equipment
- For dental CBCT equipment it may also be necessary to consider the shielding of floors and ceilings if the adjacent areas are frequently occupied
- The exposure switch and mains on/off switch (or emergency stop) should be clearly labelled and installed at, or as close as possible to, the operator's position; it should not be necessary for the operator to pass through the intra oral X-ray beam, or approach the X-ray tubehead to reach the on/off switch in the event of an accident
- The equipment should be selected, installed and used in such a way that any potential inadvertent or unauthorised use can be prevented (e.g., by means of a key switch on the control panel, ensuring that 'wireless' exposure switches are kept under the constant care of the operator, use of a PIN or password to lock the exposure controls or installing the exposure switch inside a wall-mounted lockable box)
- The operator must be provided with a means of observing the patient throughout the exposure, from his or her normal position – options may include a suitably positioned mirror, a shielded viewing panel or a camera and TV screen if the operator stands outside a shielded door or behind a shielded barrier

Note that the electrical safety aspects of the planned installation must comply with the relevant requirements as specified in the IET Wiring Regulations (BS 7671: 2018, Requirements for Electrical Installations).⁶

2.6 Safety and warning systems

2.6.1 Dental X-ray equipment exposure controls

The exposure should terminate automatically when a predetermined condition, such as the pre-set time, has been attained. Systems employing automatic exposure

control (AEC), for example on some panoramic, cephalometric or dental CBCT units should incorporate a suitable guard timer circuit to prevent excessive exposure in the event of failure of the AEC. AEC systems should provide a post-exposure indication of the dose delivered, or factors allowing the dose to be calculated (e.g., mAs or dose area product).

Exposure switches on dental X-ray equipment should be arranged so that an exposure occurs only while continuous pressure is maintained on the switch and terminates immediately if pressure is released. It should be ensured that pressure on the switch has to be released completely before the next exposure can be made. Exposure switches relying on wireless communication with the control panel to initiate the exposure should incorporate all the safety features of conventional exposure switches, with regard to exposure control and release.

With some dental CBCT models, the exposure sequence is initiated by a mouse click on an icon in the operating software or a momentary press of an exposure button. In such cases, there must be a suitably labelled 'emergency stop' or mains on/off switch provided at the operator's position that will immediately terminate the emission of X-rays when used. The operator must remain at the controls throughout the exposure and be ready to terminate the exposure if necessary, using the emergency stop; this includes during any exposures made for QA testing or warming-up purposes.

Panoramic, cephalometric or dental CBCT X-ray equipment that is computer-controlled often requires the X-ray set's operating software to be used to set up the exposure parameters before an exposure can be initiated. Practices should make use of this feature, where available, to protect the X-ray equipment from unauthorised or accidental use between exposures or when the equipment is left unattended for a short time, by employing a password, known only to the operators of the equipment, to lock the keyboard. When adopted, this should be stated as a requirement of the practice's local rules (see section 2.1.6).

Panoramic, cephalometric or dental CBCT equipment should be designed to abort the exposure automatically on sensing a failure or interruption of the rotational or scanning movement of the tubehead and/or image receptor, thereby avoiding an unnecessary and high localised skin dose to the patient. Additionally, the immediate release of the exposure switch (or use of the 'emergency stop') should also abort the exposure. When an exposure is interrupted, the unit should be unable to restart from the interrupted position.

IRMER17 requires employers to select equipment that is capable of ensuring that doses to patients are ALARP, which has some overlap with the requirements of IRR17. See section 4.1 for further details.

2.6.2 Dental X-ray equipment warning devices

All dental X-ray equipment should be provided with automatic warning devices which (1) indicate when the tube is ready to emit radiation and (2) has a clearly distinguishable signal when X-rays are being emitted. These should allow the operator, and other persons in the vicinity who need to know, to see what the status of the X-ray equipment is.

The first requirement will be satisfied by provision of a suitably labelled light (or

indication on a computer screen or control panel) that is illuminated or displayed automatically whenever the equipment's power supply is switched on, as illustrated in Figure 2.1. This should be visible to anyone in the immediate vicinity of the control panel or X-ray tubehead, for instance when the operator is positioning the X-ray tube and patient (or QA test object) and selecting the exposure parameters in preparation for an exposure, but it does not need to be visible at any other positions.



Figure 2.1: Examples of X-ray equipment warning devices with a suitable 'power on' indication (circled in red)

The second requirement will be satisfied by provision of a separate suitably labelled warning light (or indication on a computer screen or control panel) that illuminates or displays automatically during the emission of X-rays and which should be visible to the operator or other persons in the vicinity of the control panel or X-ray tubehead, as illustrated in Figure 2.2. This 'X-rays' warning light must be supplemented by an auditory signal that can be easily heard by the operator and anyone else in the vicinity, including at all entrances to the X-ray room.

An 'X-rays' warning light should also be visible from the operator's usual position during the exposure and this may be either the light on the control panel, X-ray unit or tubehead, or a light incorporated into the exposure hand-switch. Should this not be practicable, however, it is sufficient if the operator is able to hear the auditory signal during the exposure.

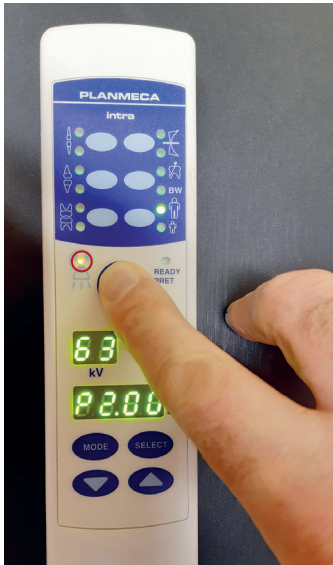


Figure 2.2 Examples of X-ray equipment warning devices with a suitable 'X-rays' indication (circled in red)

2.6.3 Dental X-ray room warning signs and lights

When a controlled area extends to any entrance to the X-ray room, access through that entrance must be effectively restricted (see section 2.11). The appropriate means of achieving this should be identified by means of the radiation risk assessment (see section 2.10) and may involve using safety and warning features, procedural controls (see section 2.7) or a combination of both, with due regard to the hierarchy of controls set out in IRR17. Unless the radiation risk assessment identifies that it is not reasonably practicable to do so, warning signs should be provided in visible positions at each accessible entrance to the controlled area, including any entrance at which the operator may stand to initiate exposures.

These signs may take the form of notices or lights. Warning notices should include the ionising radiation trefoil symbol and wording such as 'controlled area: X-rays: no unauthorised entry' and must comply with the Health and Safety (Safety Signs and Signals) Regulations 1996⁷ and accompanying guidance.⁸ An example of a suitable warning notice is shown in Figure 2.3.

However, warning notices must be removed or covered when the X-ray equipment is not in a state of readiness to emit X-rays so that it is always clear to other persons when the controlled area and attendant restrictions on access are in force. The employer should ensure that all X-ray equipment operators are aware of this requirement.

Instead of warning notices, single-stage warning lights may be fitted outside the entrances to automatically indicate when the controlled area exists. If warning lights are fitted, these must be suitably marked as described, and as shown in Figure 2.4;

alternatively, each light must be accompanied by a notice explaining the significance of the lights and the action to be taken when they are illuminated, as shown in Figure 2.5. These warning lights should be connected to the X-ray set's control system by a qualified electrician in such a way that they illuminate automatically while the X-ray set is in a state of readiness to emit X-rays. This should be easily achievable when the power supply to the X-ray set can be switched off when it is not in use, but might not be possible for equipment that is switched on throughout the working day and where a password is used to disable the exposure controls when the equipment is not being used.



Figure 2.3 Example of a warning notice that should be placed outside the entrances to the controlled area



Figure 2.4 Example of a single-stage warning light that illuminates automatically when the X-ray set is in a state of readiness to emit X-rays, incorporating suitable wording

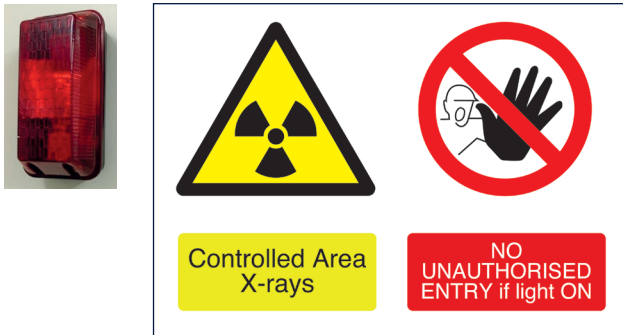


Figure 2.5 Example of a single-stage unlabelled warning light that illuminates automatically when the X-ray set is in a state of readiness to emit X-rays, with a suitably worded accompanying notice

Where there are multiple entrances to the controlled area, it may be more practical to employ procedural controls, such as locking the doors (see section 2.7).

2.6.3.1 Hand-held X-ray equipment

As hand-held equipment is not mains powered it will not be possible to employ automatically operating room warning lights. In this case, it will be necessary to rely solely on warning signs and supporting procedural controls to restrict access to the controlled area while the equipment is being used (see section 2.7).

2.7 Procedural controls

Once the appropriate engineering controls have been identified, the procedural controls required to further restrict exposure in a given situation must be identified in the radiation risk assessment that is specific to the dental practice, in consultation with an RPA. These should include the following:

- The means of restricting access to the controlled areas during radiography
- Instructions regarding switching off the power, or use of passwords for software-controlled systems, when X-ray equipment is not in use
- Where it is necessary for staff to enter controlled areas, written arrangements that will restrict exposure to levels below which employees would need to be designated as classified persons
- Where relevant, the proper use and care of personal dosimeters
- Where relevant, the situations under which personal protective equipment (PPE) should be worn by staff
- Where relevant, the working procedures required to adequately restrict the exposure of operators of hand-held equipment, such as maintaining the X-ray beam in the horizontal plane⁹
- Any measures necessary to restrict the exposure of pregnant employees
- Any other key working instructions necessary to ensure staff and other persons

are adequately protected from exposure to X-rays (such as avoiding directing intra oral X-ray beams towards the operator or other areas, if required)

- Actions that must be taken in the event of a radiation accident

The above list is not exhaustive. The above procedural controls must be included, where relevant, in the dental practice's local rules (section 2.16) and contingency plans (section 2.17).

Procedural controls are also required to restrict the exposure of patients, carers and comforters. However, these exposures are subject to IRMER17 rather than IRR17 and are detailed in section 3.

2.8 Personal protective equipment (PPE) for employees

Where it is necessary for another person to remain in close proximity to the patient to provide reassurance or other form of support whilst radiography is taking place, this should normally be undertaken by the patient's parent, guardian or other accompanying adult. Exposures received by people who are not employees, while they provide support to a patient undergoing dental X-ray examinations, are regulated by IRMER17. See section 3.11 for guidance on carers and comforters.

Employees should not normally be required to remain in close proximity to patients during dental X-ray examinations, except in the following circumstances:

- Care home staff who volunteer to assist residents during dental X-ray examinations (whether at the care home or the dental practice), where assistance from a friend or relative is not available
- Prison staff who accompany inmates to a dental practice for dental X-ray examinations and who are required to stay in close contact with the inmate during the exposure
- Where a hand-held dental X-ray set is being used

In these or very similar cases where it is necessary for an employee to stay close to the patient, the risk assessment must identify what measures are required to ensure that adequate radiation protection is provided for that employee. This may involve the employee wearing a protective apron (or other form of PPE) with a lead equivalence of at least 0.25 mm.

Whether or not a protective apron is required, the local rules must specify any additional precautions employees should follow when supporting patients (see section 2.16).

The employer must ensure that, where supplied, protective aprons are stored appropriately when not in use, e.g. by hanging on rails of sufficiently large diameter to avoid creasing and that they are never stored folded. Each apron should be visually examined for cracks in the protective material and the results recorded at least annually. Any apron showing signs of damage should be replaced.

Other forms of PPE, such as thyroid collars and lead shielded spectacles, are not necessary for employees involved in dental radiography, as the doses received from X-rays scattered from the patient will be very low if appropriate working methods are used.

2.9 Critical examination

The installer is responsible for ensuring that a critical examination is carried out for each and every installation of dental X-ray equipment, that the safety features and warning devices operate correctly, and that there is adequate protection for employees and other persons from exposure to ionising radiation. Paragraph 614 of the non-statutory guidance to IRR17 makes it clear that, in this context, 'other persons' includes patients. The examination should be carried out as soon as possible after installation, and the equipment should not be used (other than for the purposes of the examination) until written confirmation has been received from the installer that it provides adequate protection.

A critical examination will also be necessary following any relocation or significant modification or repair of existing equipment (such as replacement of the X-ray tube). The scope and conduct of the examination must be subject to consultation with an RPA and 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.

A critical examination should include the following aspects of the equipment and the environment in which it is installed:

For all equipment:

- Presence and operation of warning lights indicating "mains supply on" and "X-rays are being emitted"
- Presence and operation of "X-rays" audible warning
- Safety features such as beam filtration, collimation and tubehead shielding
- Adequacy of the exposure control, including appropriate location and security against unauthorised use
- Presence, operation and clear labelling of mains on/off switches and/or emergency stops
- Adequacy of the general layout of the room with respect to radiation protection, including:
 - The proposed operator's position
 - The likely direction of any intra oral X-ray beams
 - The siting of the exposure controls and mains on/off switches
 - Protection afforded to persons other than the operator
 - The adequacy of the means of restricting access to the controlled area including, where fitted, any warning lights and signs at room entrances

Suitable measurements of scattered radiation levels at the operator's position and in adjacent occupied areas may be required, in addition to the above, based on the advice of the RPA.

Hand-held and mobile dental X-ray equipment is not 'installed', and therefore not subject to the formal requirement for a critical examination. However, the radiation protection afforded to the operator by the tubehead shielding and other design features is crucially important with hand-held equipment, and these features must be examined prior to use commencing:

- Tube head shielding, designed to protect the operator from leakage radiation and backscattered radiation when used in a hand-held manner, that meets the

standard proposed in the PHE guidance⁹

- The additional safety and warning features described in the PHE guidance

The above lists are not exhaustive.

The critical examination report should incorporate an overall conclusion as to whether or not the equipment's safety features are operating correctly and the installation provides sufficient protection for the operator and other persons from exposure to X-rays. Any deficiencies should be clearly identified so the dental practice's employer can consult an RPA regarding the remedial measures to be taken before the equipment enters clinical use.

For details of the recommended content of acceptance testing required by IRR17 and the subsequent report refer to section 5.2 of this guidance.

Dental practices should agree with the installer who will conduct the critical examination and provide the necessary report, and whose RPA will be consulted regarding this. Likewise, it should be agreed who will conduct the acceptance testing and provide the report, and which MPE will be involved. These matters should be confirmed in writing at the planning stage.

2.9.1 Information to be provided by the supplier

Manufacturers and suppliers also have a duty to pass adequate information to the user to enable them to comply with IRR17 in respect of the proper use, testing and maintenance of the equipment.

This information should include the following aspects:

- A full technical description including features important for the radiation protection of the operator (e.g., the meaning of warning labels and controls, warning lights and audible signals) and the patient (e.g., the available exposure settings and how to use them to control image quality and patient dose)
- A schedule for the recommended maintenance and inspection of the equipment
- For dental CBCT, the documentation should include a performance specification to enable comparison with the results of acceptance tests, routine tests, including expected patient doses for standard examinations (see section 3.5.9), and the user's in-house quality assurance checks

The above information should be provided in the operator's and service manuals or other documentation that is provided as standard with the equipment at the point of supply. The UK Medical Devices Regulations¹⁰ also require that the 'instructions for use' contain details of the 'nature, type, intensity and distribution' of the radiation emitted.

For technically complex or novel equipment, it is recommended that the equipment supplier provides hands-on training in the use of the equipment, or at least advises the user of the need for training and where this can be obtained. This is particularly important for hand-held equipment (see section 2.7) and dental CBCT equipment (see section 3.10).

2.10 Radiation risk assessment

The employer, in consultation with an RPA, must ensure that a suitable and sufficient radiation risk assessment has been carried out and recorded before any new activ-

ity involving work with ionising radiation commences, or when any factors relevant to radiation safety change. 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 reasonably foreseeable 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, and hence
- Identify any improvements or changes required in terms of the design features and engineering controls, safety and warning features and procedural controls
- Identify if there is any need to use personal protective equipment
- Identify all hazards with the potential to cause a radiation accident (i.e., an accident requiring immediate action to be taken to avoid or restrict significant exposures)
- Identify the steps that must be taken to prevent any such accidents occurring, and limit the consequences of any that do occur

Paragraph 70 of the Approved Code of Practice to IRR17 (the ACoP) specifies the matters that (where relevant) must be considered when undertaking a risk assessment, and paragraph 71 specifies the subjects that (where relevant) must be included in the decisions arising from the risk assessment.

A proforma radiation risk assessment for dental radiography that conforms to paragraphs 70 and 71 of the ACoP is provided in Appendix B. This must be carefully adapted to describe exactly how the work with dental X-ray equipment is carried out at the practice to ensure that the significant findings of the risk assessment are accurate and any areas for improvement can be readily identified.

The findings of the radiation risk assessment should be used to identify what additional safety and warning features are required, if any, and to determine the main working instructions which are intended to restrict exposures, and other key aspects of the local rules such as the dose investigation level (see section 2.15). They should also identify the actions that should be specified in the contingency plans as being necessary to prevent, or limit, exposures in the event of a radiation accident (see section 2.17).

For portable (or hand-held) X-ray equipment, the risk assessment should address the safety and security of the equipment when it is not in use, and if used at other premises, during transport. Where portable (or hand-held) X-ray equipment is used at multiple premises, such as care homes, it will be necessary to review the arrangements for radiation protection whenever a visit is made to premises for the first time, to ensure that the work can be conducted safely and in accordance with IRR17. A dynamic risk assessment approach is recommended for this situation, whereby those aspects of the main radiation risk assessment that are likely to change with each premises visited can be assessed on a case-by-case basis. In order for this to work smoothly, it may be necessary to discuss arrangements for radiation protection with the premises prior to the visit taking place.

A copy of the radiation risk assessment should be retained by the employer and reviewed at three-yearly intervals or when changes occur which may have radiation safety implications.

Note also the guidance in section 2.22 dealing with co-operation between employers, which is particularly relevant to work carried out on another employer's premises, when service engineers visit to undertake maintenance or testing of dental X-ray equipment, or when employees (such as prison guards or care home workers) are required to remain close to the patient during the exposure.

2.11 Controlled areas

2.11.1 Criteria for designating controlled areas

Two criteria are used to determine whether it is necessary to designate an area in which work with ionising radiation takes place as a controlled area.

- The first consideration is whether it is necessary for persons to follow special working procedures (once all reasonably practicable design features and engineering controls have been applied) to avoid, or restrict, significant exposures
- The second consideration is whether the annual dose to someone working in the area could exceed the dose thresholds given in regulation 17(1)(b) of IRR17 which is highly unlikely in dental radiography

A controlled area must be designated if either of the above criteria apply to the work.

2.11.2 Requirements for controlled areas

IRR17 specifies the following requirements for controlled areas:

- The local rules must describe the extent of the controlled areas and when they are considered to exist
- Access to controlled areas must be restricted to classified persons or other persons who enter in accordance with written arrangements (this does not apply to the patient who is undergoing the X-ray examination)
- Where reasonably practicable, controlled areas should be physically demarcated
- Controlled areas must be furnished with warning signs in suitable positions indicating the area's designation and the nature of the radiation source (e.g., X-rays)
- The radiological conditions in and around the area must be monitored to ensure the area remains correctly designated (see section 2.19)

2.11.3 Controlled areas in dental radiography

Decisions regarding the designation of areas must be made as part of the radiation risk assessment process and involve consultation with an RPA. Nevertheless, it is appropriate to provide general advice regarding what would constitute a sensible outcome for dental radiography in the majority of situations. In general, operators and other persons are required to follow 'special procedures' to restrict significant exposure and as such it will be necessary to designate a controlled area in accordance with regulation 17 of IRR17.

2.11.3.1 Extent of the controlled area

Where practicable, the whole room should be designated as the controlled area while the equipment is in a state of readiness to emit X-rays. This makes use of the

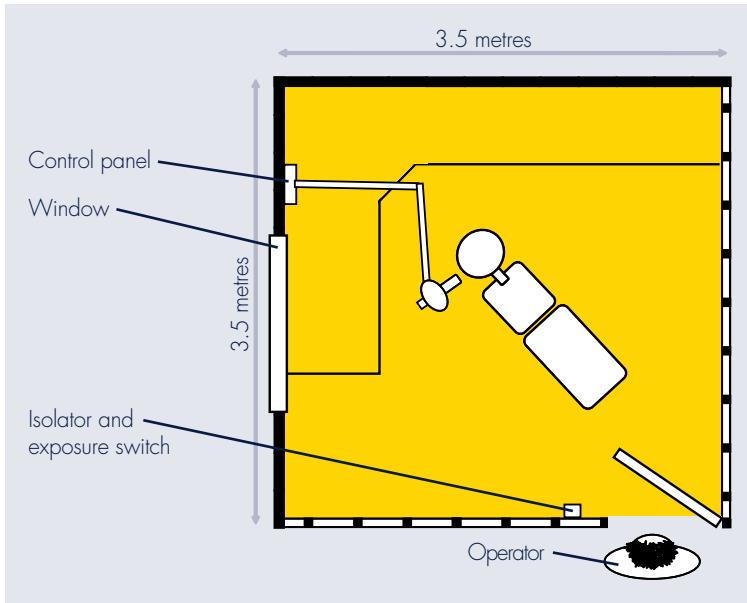


Figure 2.6 Example of the controlled area [indicated in yellow] being the whole room (option 'A') when the X-ray equipment is in a state of readiness to emit X-rays

room boundaries to physically demarcate the area and assists with the restriction of access by permitting entry to be controlled at the doorways. Throughout the rest of the guidance this is referred to as **option A**.

For dental CBCT equipment, this is the only recommended option due to the higher levels of scattered radiation that are generally produced by dental CBCT equipment compared to other modalities. If the operator remains inside the CBCT room to initiate an exposure, then a protected area should be provided.

Where option A is not practicable, the controlled area may be designated as:

- Within 1.5 metres of the X-ray tube and the patient, in any direction, while the equipment is in a state of readiness to emit X-rays, and
- In the case of intra oral equipment, within the primary X-ray beam until it has been sufficiently attenuated by distance or shielding (the primary beam from other types of dental X-ray equipment is entirely absorbed by the image receptor)

Throughout the rest of the guidance this is referred to as **option B**.

Option B has the disadvantage that the controlled area boundary is not physically demarcated and the restriction of access relies solely on the operator exercising effective supervision.

These two approaches are illustrated in Figures 2.6 and 2.7. (In both figures

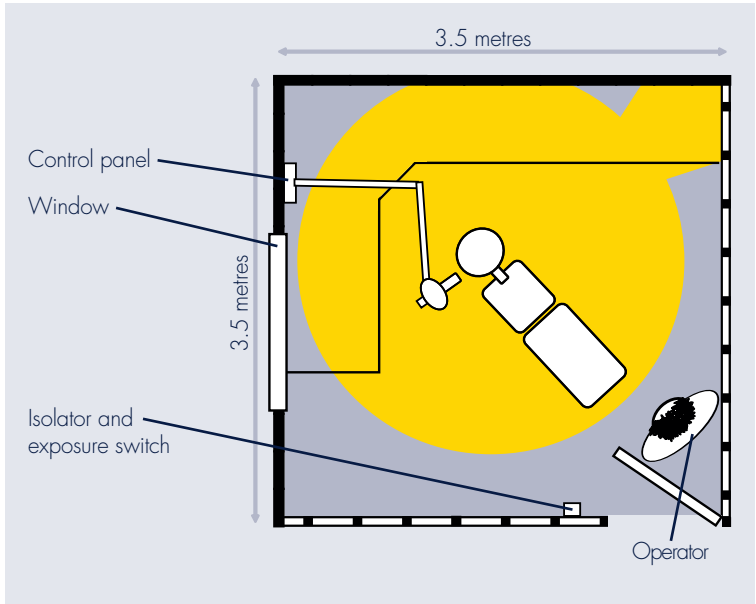


Figure 2.7 Example of the controlled area (indicated in yellow) being the main X-ray beam and 1.5 metres from the tubehead and patient in all other directions (option 'B') when the X-ray equipment is in a state of readiness to emit X-rays

the walls indicated by solid lines are brick or concrete construction, and the walls indicated by black and white lines are unshielded partition construction.)

Note that the range of possible beam directions includes the 180 degree arc behind the patient's head. In both cases, it will be necessary to establish, in consultation with the RPA, whether the top right-hand section of partition wall will require shielding, and whether precautions need to be taken to protect persons who may be outside the window during exposures.

2.11.3.2 Duration of the controlled area

If the power supply to the X-ray set is switched off after a set of exposures have been taken or at the end of a working session, this permits the surgery to then be de-designated as a controlled area, thereby reducing the amount of time when access to the controlled area has to be restricted.

Computer-controlled X-ray equipment may require the exposure settings to be selected and confirmed using the operating software before an exposure can be initiated. If unauthorised use of the software can be prevented effectively by means of a password, this will be an acceptable alternative to switching off the power and will avoid the need for the controlled area to be designated throughout the time that power is switched on.

2.11.3.3 Restriction of access to controlled areas

Dental practice employees will frequently need to enter a controlled area to prepare the patient and X-ray equipment for radiography and to remove the image receptor afterwards. In some cases, particularly where hand-held dental X-ray equipment is used, it will be necessary for the operator to remain in the controlled area during the exposure.

Whatever the reason, employees must only enter a controlled area in accordance with suitable written arrangements. These written arrangements must ensure that, as long as they are adhered to, there should be no possibility of doses exceeding those above which classification would be required (see section 2.13). The employer must demonstrate that this is the case, either by issuing personal dosimeters or other suitable measurements (see section 2.14). Written arrangements should be included in the local rules (see section 2.16). If the area is no longer controlled (such as after a series of radiographs when initiation of exposures has been prevented by locking the keyboard of the controlling computer, or at the end of the work period when the equipment is switched off) then access does not have to be restricted.

2.11.4 Warning notices and lights for controlled areas

For details of the required wording and appearance of 'controlled area' warning notices and lights, refer to section 2.6.3.

2.12 Supervised areas

An area must be designated as supervised when the risk assessment identifies that it is necessary to keep the conditions in the area under review to determine whether it should be designated as a controlled area (i.e., if it is likely that conditions will change), or that annual doses to someone working in the area could exceed the dose thresholds given in regulation 17(3)(b).

For the purposes of dental radiography, it should never be necessary to designate any supervised areas.

2.13 Classified persons

The employer must designate any of its employees who are likely to receive an effective dose greater than 6 mSv in a calendar year, or an equivalent dose to the lens of the eye greater than 15 mSv per year, or greater than 150 mSv per year to the skin or extremities.

It will not normally be necessary for dental practice staff working with dental X-ray equipment in accordance with this guidance to be classified, as annual effective doses during routine work and doses likely to be received during reasonably foreseeable accidents should be well below any of these figures.

2.14 Personal dose monitoring

Doses to operators and any other non-classified persons who enter controlled areas must be assessed, using personal dosimetry or other suitable measurements, to confirm that the written arrangements are effective in adequately restricting their exposure.

Whichever method is used must allow the individual annual doses to these persons to be either directly measured, estimated or calculated so that they can be compared to the dose investigation level set by the employer (see section 2.15). There are several ways in which this may be achieved, as follows:

- Issuing all staff who enter controlled areas with a personal dosimeter provided by an approved dosimetry service (ADS) which reports the assessed doses to the employer
- Issuing staff with direct-reading electronic personal dosimeters that are suitable for use with X-rays and keeping a log of the doses locally
- Estimating the annual doses based on measurements made at the operator's position as part of the arrangements for area monitoring (see section 2.19)

Decisions regarding the most appropriate method of assessing personal doses should be made as part of the risk assessment process in consultation with a suitable RPA.

Thermo-luminescent dosimeters ('TLDs'), or other dosimeters advised by the RPA, can usually be worn for periods of up to three months before being sent back to the ADS for the doses to be assessed. Due to the anticipated low annual doses received by staff if proper procedures are followed, personal dosimeters may be provided initially for a trial period of six months. On the advice of the RPA, continuous monitoring may not be considered necessary if the trial period can establish that annual doses will be adequately restricted.

Direct-reading electronic personal dosimeters allow doses to be read and recorded on an ongoing basis, however, not all types are suitable for X-rays. It will also be necessary to subtract the dose due to natural background radiation, and the advice of the RPA must be obtained on these matters. Direct-reading dosimeters may also be issued for a trial period after which the RPA will advise on the need, or otherwise, for ongoing monitoring.

The results of measurements of dose or dose rate made at the operator's positions in pursuance of the requirement to carry out area monitoring (see section 2.19) may be used as the basis for calculating personal doses, with the assistance of the RPA.

Whatever method is used to assess doses to staff who enter controlled areas, any significant changes to radiographic workload, X-ray equipment, radiographic techniques or layout of the surgery should trigger a review of the risk assessment, including whether a further fixed period of personal monitoring is required. The advice of the RPA should be sought in these cases.

A record of the total annual doses received by non-classified staff who enter controlled areas should be retained by the employer for at least two years after the end of the calendar year to which they relate.

2.14.1 Dosimetry for pregnant employees

As the dose received by any employee from dental radiography is expected to be significantly lower than 1 mSv per year, the dose to the foetus over the term of pregnancy should also be lower than this level and therefore no special protection measures will usually be necessary. However, the employer may, having consulted their RPA, opt to provide personal dosimetry for employees who have declared that

they are pregnant, should they wish to confirm that doses are low.

2.15 Dose investigation level

Employers are required to set a dose investigation level during the risk assessment process. This is a level of cumulative effective dose in a calendar year, which, if exceeded, should trigger an investigation into the circumstances of the exposure with the aim of determining if doses are being adequately restricted. IRR17 states that the dose investigation level must not exceed 1.5 mSv and where appropriate should be set at a lower level.

Doses to employees arising from routine dental radiography that is conducted in X-ray rooms designed and laid out in accordance with this guidance, and following the working procedures set out in this guidance, should be well below 1 mSv per year. This is therefore an appropriate value for the dose investigation level. Whatever dose investigation level is chosen, it must be documented in the risk assessment and in the local rules.

2.16 Local rules

Local rules are mandatory for any work that takes place in a controlled area. The local rules must be drafted following consultation with the RPA, set down in writing and brought to the attention of all employees and other persons who may be affected by them (see section 2.21). The current version of the local rules should also be readily accessible by the staff to whom they relate. This may be achieved by saving the document in an accessible electronic form, placing a printed copy in a central 'radiation protection file' or displaying copies in the practice.

The key purpose of the local rules is to communicate the main working instructions intended to restrict any exposures arising from work in the controlled area; however, the guidance accompanying IRR17 states that local rules should always contain the following information (as relevant to dental radiography):

- The dose investigation level (see section 2.15)
- A summary of the contingency plans, and the reasonably foreseeable accidents to which they relate
- The name(s) of the radiation protection supervisors (RPSs)
- Identification of the controlled areas, and descriptions of the conditions under which they exist
- 'Key working instructions' setting out the procedures that employees must follow to restrict exposures to themselves and other persons
- Written arrangements governing access to the controlled area

Where employees need to remain in the controlled area during the X-ray exposure, the required protection measures to include in the written arrangements should be identified in the risk assessment. Generally, these will involve the following:

- Staying well clear of the main intra oral X-ray beam directions
- Avoiding holding the X-ray tubehead or collimator of intra oral X-ray equipment
- Avoiding placing the hands (or any other part of the body) in the X-ray beam from extra oral equipment
- Maintaining as much distance from the X-ray tube and patient as possible to

- reduce exposure to scattered X-rays
- In the case of hand-held X-ray equipment, maintaining the X-ray beam in the horizontal plane to maximise the protection afforded by the tubehead shielding and the backscatter shield
- Wearing PPE and a personal dosimeter if necessary

It should be noted that, where supervision or support is provided by parents or other individuals who are not employees, their exposure is regulated by IRMER17 (see section 3.11).

The following might also be useful additions to the local rules:

- The means of restricting access to the controlled area
- The means of preventing operation of the equipment by unauthorised persons
- Arrangements for personal dosimetry
- Arrangements for pregnant staff
- A general requirement to adhere to the guideline exposure settings for X-ray equipment and to keep doses to patients ALARP (which will also reduce doses to operators and other persons)
- Procedures for initiating investigations
- Contact details for the RPA

Local rules address the requirements of IRR17 and so should not contain detailed instructions on matters that are regulated under IRMER17, such as the guideline exposure settings for X-ray equipment (see section 3.6.3) or procedures for carers and comforters (see section 3.11). The employer may choose to have a separate set of local rules for each room or X-ray set, or a single document that covers all dental radiography in the practice. In the latter case, any matters that apply to specific rooms or equipment must be clearly spelt out.

It is important that the local rules, once drafted and issued for the first time, are regularly reviewed (in consultation with the RPA), updated and reissued to staff. An annual review interval is recommended. Reviews should also take place following any changes to equipment or working practices so that they remain relevant. This can be most readily achieved by including the local rules in a system of document control and supporting QA as set out more fully in section 5.1. As part of this, the local rules should always include a version number and issue date so that out of date copies can be easily recognised and withdrawn from circulation. A record should be kept that staff have read and understood the local rules, and this should be updated as new versions are issued.

2.17 Contingency plans

The radiation risk assessment (see section 2.10) should identify any reasonably foreseeable radiation accidents that require immediate action to prevent them from occurring or, if they do occur, to limit the consequences. For dental X-ray equipment, reasonably foreseeable accidents would normally include the following, depending on the types of equipment used (this is not an exhaustive list):

- Failure of the timer to terminate the exposure after the pre-set time has elapsed
- Failure of the rotational or scanning motion of panoramic, cephalometric or

- dental CBCT equipment, combined with a failure to terminate the exposure
- Loss of shielding or damage to an X-ray tube
- Failure of a system of work, such that the intra-oral main beam is directed at the operator or another person (either directly or through an unshielded door)
- Failure of a system of work, such that a person remains in the room during a panoramic, cephalometric or CBCT exposure
- Loss or theft of a hand-held unit

For each identified accident scenario, the risk assessment should also assess the likelihood of its occurrence, the magnitude of any exposures to persons that may result from it, and the actions necessary to deal with them effectively while restricting doses. The findings of the risk assessment concerning reasonably foreseeable accidents should be incorporated into the contingency plans (see section 2.17).

In the majority of accidents that could affect dental X-ray equipment, relatively simple measures, such as in the following list, may be all that are required to prevent radiation accidents occurring, and to deal effectively with those that do occur:

- Immediately releasing the exposure switch (and if necessary, switching off the power or pressing the 'emergency stop') in cases of failure of the timer, or failure of the rotational or scanning motion of panoramic, cephalometric or dental CBCT equipment – appropriate siting of the mains switch or emergency stop is important in this regard
- In the case of timer failure with hand-held X-ray equipment, the operator should immediately direct the X-ray beam away from the patient, and then switch off the power at the control panel, or quickly remove the battery in order to avoid potential exposures to the operator's hands and body (it is important that the design of the unit would allow the operator to do this)
- Paying proper attention to the security of hand-held X-ray equipment, whether in use, in transit for use at other premises or being kept on the premises outside of working hours, would limit the likelihood of loss or theft and any potential exposures of persons that may follow
- If staff are properly trained and vigilant, any signs of potential loss of shielding or damage to an X-ray tube that might lead to accidental exposures should be noticed and reported promptly so that the situation can be investigated and the equipment removed from use if necessary
- The proper training of staff should significantly reduce the likelihood of failure of a system of work, and support prompt reporting of any incidents that do occur

Should any contingency plan need to be enacted, the employer must investigate the circumstances of the incident, in consultation with the RPA, to identify the underlying causes and to determine if any action is required to prevent a reoccurrence of the incident. A record of this investigation should be made and kept for at least two years. If any person receives a radiation exposure as a result of the incident, this should be noted on any relevant dose record. If it is suspected that the exposure exceeds a statutory dose limit, then the HSE must be informed forthwith. The RPA must be consulted before making such a notification, and regarding the further requirements of IRR17 that would follow.

It is a legal requirement that, where appropriate, contingency plans are rehearsed at suitable intervals to test their effectiveness and to ensure all relevant staff are aware of the plans and the actions that should be taken. The rehearsal should as far as possible include both the practical and administrative aspects of the contingency plans. For dental radiography, an annual interval would be appropriate, or following any significant changes to the contingency plans.

Attention is also drawn to the arrangements for notifying the equipment manufacturer and the appropriate national competent authority, of any adverse incidents involving medical devices. This applies to dental X-ray equipment and more information is provided in section 3.5.10.

2.18 Radiation protection supervisor

Whenever a controlled area is designated, the employer must appoint one or more suitable persons as radiation protection supervisors (RPSs). These appointments should be confirmed in writing. The key function of the RPS is to supervise the work with ionising radiation with the aim of ensuring that employees adhere to the requirements of the local rules.

Ideally, a person appointed as an RPS will be an employee who works at the practice and is closely involved in dental radiography. Unless the practice is particularly large, one or two RPSs will generally be sufficient to adequately supervise the work and provide continuity of cover. The RPA should be consulted regarding who, within the dental practice, would be suitable candidates for the role.

It is common for the employer to delegate to the RPS numerous additional tasks related to radiation protection, such as the administration of personal dosimetry, arranging for the testing and maintenance of X-ray equipment, record keeping and liaison with the RPA. However, legal responsibility for compliance with IRR17 (and IRMER17 for that matter) rests squarely with the employer and cannot be delegated to any other person, including the RPS.

The following points regarding RPS appointments should be noted:

- The RPS should understand the requirements of IRR17 as relevant to dental radiography, the precautions to be taken and the extent to which they will restrict exposures
- The RPS should have sufficient authority to enable them to effectively supervise the radiation protection aspects of dental radiography
- The RPS should know what action to take in an emergency
- The employer must ensure the RPS is adequately trained for their role (and this training is refreshed at suitable intervals) and given sufficient time and resources to carry out their functions effectively
- The employer should confirm in writing what is expected of persons appointed as RPSs

Training for RPSs (including refresher training) should include the following, as relevant to dental radiography, and enable them to supervise the work safely and maintain the precautions that will restrict exposure to staff and other persons within the practice:

- Radiation protection principles and procedures
- The requirements of IRR17
- The arrangements in the local rules and contingency plans

The training may be provided by attending a formal course or by means of a presentation delivered by a suitable person, such as the RPA. A period of no longer than five years is a suitable interval for refresher training for RPSs involved with dental radiography. It should be noted that update training courses for dentists and dental care professionals provided for the purposes of IRMER17 will only be adequate for the purposes of RPS training if they also cover the subjects listed in this section.

2.19 Monitoring of designated areas

Levels of ionising radiation must be adequately monitored to ensure that any controlled areas remain correctly designated over time.

Dental radiography involves X-ray exposures of short duration with usually no more than a few tens of exposures per working day in each room where X-ray equipment is installed. Additionally, levels of scattered and transmitted radiation at the boundaries of controlled areas designated in accordance with the guidance in section 2.11 are generally low. The following approaches are recommended:

- Where it is practicable and suitable equipment is available, levels of scattered and transmitted radiation per exposure may be directly measured at the operator's position and other occupied areas outside the controlled area, under conditions representative of clinical use, with a phantom in place of the patient's head. These measurements should be undertaken by a person trained and competent in the use of the monitoring equipment.
- Doses from scattered and transmitted radiation may be measured at the operator's position and other occupied areas, using dosimeters which are left in situ for an extended period of time (e.g., three months)
- Levels of scattered and transmitted radiation in occupied areas outside the controlled area may be calculated based on measurements of radiation dose at the image receptor position (or the end of the cone for intra oral equipment) using empirically-derived methods^{4,5}

Decisions regarding the most appropriate method to be used must be made in consultation with a suitable RPA and documented in the risk assessment. Where monitoring equipment or dosimeters other than those approved by HSE are used, these must first be tested by a qualified person to confirm that they are suitable.

Measurements, by whatever method is decided, should be made as soon as possible after installation of the equipment and at routine three-yearly intervals thereafter. Records of the measurements must be kept, and these should include the location of the measurement, the exposure parameters used, the radiation monitoring method used, the numerical results (using suitable units of measurement), the significance of the results, the name of the person making the record and the date. The records should be retained for at least three years.

The results of the monitoring and their significance should be reviewed in consultation with the RPA and any recommendations acted upon by the employer.

Changes to the X-ray equipment, room layout or construction, radiographic workload or working practices could affect the existing designation of areas. In such cases, the RPA should be consulted regarding the need for further measurements to check that areas remain correctly designated.

2.20 Maintenance and examination of engineering controls

The employer's quality assurance programme for equipment should include, as a minimum, the maintenance and inspection schedule recommended by the manufacturer to ensure the equipment operates properly and safely at all times. This would normally include maintenance and examination of any safety and warning features and engineering controls supplied with the equipment and can often be carried out by the supplier (or a qualified service agent). Any safety and warning features etc., fitted after installation of the equipment should be subject to similar inspections and maintenance as required.

In addition, the employer should establish a programme of in-house inspections of the following features of the equipment:

- Visual inspection of the X-ray tubehead (including a check for signs of leakage of oil, and the presence and condition of any backscatter shield for hand-held equipment)
- Stability of any intra oral arm counterbalance
- Smoothness of rotational or scanning motion with panoramic, cephalometric or dental CBCT equipment (faults may result in artefacts on radiographs and increased patient doses)
- Operation of equipment warning lights indicating "mains on" and "X-rays"
- Operation of equipment audible warning of X-rays
- Operation of warning lights and legibility of signs outside room entrances
- Operation of mains on/off switches and/or emergency stops
- Adequacy of the exposure control, including security against unauthorised use
- Condition of cabling and connections including power leads and plugs

All operators should be in the habit of checking daily that these features are in good condition and functioning correctly. Problems should be brought directly to the attention of the RPS or employer and any necessary action taken. The results of these checks should be formally recorded at intervals not exceeding once every six months.

It should be noted that IRR17 also requires the employer to have in place a comprehensive QA programme for X-ray equipment and ancillary equipment (see sections 5.2 and 5.3).

2.21 Information, instruction and training

2.21.1 Employees who operate dental X-ray equipment

Employers must ensure that all of their staff who undertake X-ray exposures receive training that includes the following:

- Risks to health arising from exposure to dental X-rays
- The significant findings of the risk assessment and precautions that need to be taken, in particular the specific requirements of the local rules and contingency plans at their place of work

- The requirements of IRR17 relevant to dental radiography and the importance of complying with them (this is especially relevant to RPSs; see section 2.18 for further details)

Employers will need to ensure their staff receive formal training of the appropriate standard. This may be provided by attending a course, completing an online training module or by attending a presentation delivered in-house by a suitable person, such as the RPA. Most courses intended to provide dentists and dental care professionals (DCPs) with the update training required by IRMER17 (see section 3.9) will also be adequate for this purpose, providing the bullet points in this section are adequately covered. However, this may not be the case for RPSs who have additional training needs, as discussed in section 2.18.

Training in the requirements of the employer's local rules is best provided by a staff briefing on the premises.

2.21.2 Staff not directly involved in radiography

Dental staff whose duties are limited to assisting with the identification of patients or processing films or phosphor plates, or non-clinical staff such as receptionists and cleaners should be provided with information sufficient to enable them to work safely. This should include, for instance:

- Awareness that X-rays are used, the benefits and risks, and the need to avoid any personal exposure
- Training in the requirements of the local rules, especially:
 - The significance of any room warning notices and lights and the restrictions on access to rooms during radiography
 - The name and contact details of the RPS (in case of emergency)

Training of this nature may be provided as an in-house staff briefing.

2.21.3 Other persons

Employees of child-bearing potential involved with radiography must be informed of the theoretical risk to the foetus arising from exposure to ionising radiation, the additional dose limits that apply during pregnancy and the conclusions of the risk assessment regarding the need, or otherwise, to inform their employer if they become aware that they are pregnant. See section 2.14.1 for further details.

The exposure of parents or guardians supporting a child or a patient with additional needs is not subject to IRR17; see section 3.11 for details of the employer's duties under IRMER17 with regard to carers and comforters.

2.21.4 Records of training

The employer must maintain an up to date record of all radiation safety training undertaken by employees, including formal training and in-house briefings. The records should include the title of the course or the subject covered, the training provider, the names of those attending and the date it took place.

2.22 Co-operation between employers

Where employees undertake work with ionising radiation on another employer's premises, the different employers must 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 IRR17 is clearly allocated and agreed between them.

2.22.1 Outside workers

When employees from other organisations (such as the RPA, MPE or service engineers) visit dental practices to undertake the inspection, maintenance, repair or testing of dental X-ray equipment, it is recommended that the dental practice formally hands over responsibility for the area where the work with X-rays will take place from the practice to the visiting employee for the duration of the work, and back to the practice on completion. This handover should be documented, the paperwork signed and a copy retained by both parties. The aims of this are as follows:

- To avoid the obligations that would otherwise fall on the dental practice, to make entries in the radiation passbooks of visiting employees who are classified persons, which they are unlikely to be adequately trained to do
- To ensure both parties understand that the local rules drafted by the visiting employee's employer will apply, and that the same employer will take responsibility for compliance with IRR17 during the work – this is because the dental practice's RPS will not have been suitably trained to supervise the work of the visiting employee, and the practice's local rules will not include suitable arrangements for the visiting employee's work
- As part of the above process, the visiting employee should make the practice aware of the extent and duration of the controlled areas (if any) that they intend to designate during the work, and agree how these will be demarcated and how access will be restricted – if warning notices are used by the visiting employee, these should be similar to those shown in Figure 2.3
- To ensure the dental practice is made aware of any maintenance, repair or testing work on X-ray equipment that may have affected its radiation safety, before it is handed back
- To ensure suitable checks are carried out on the X-ray equipment by the visiting employee before it re-enters clinical use

Employers whose employees are likely to operate dental X-ray equipment on other employers' premises must consult their RPA to ensure their risk assessment, local rules and contingency plans adequately cover this work and that suitable arrangements for the handover process are put in place. Appendix C provides a template handover form that may be used to document this process. Alternatively, the Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (commonly known as 'AXREM'), in association with the Society of Radiological Protection, has produced a handover form that is widely used within the hospital sector, which is available from the AXREM website at: <https://www.axrem.org.uk/wp-content/uploads/2018/08/RADIATION-CONTROLLED-AREA-AND-EQUIPMENT-HANDOVER-FORM.pdf>.

It is important that the dental practice representative signing the handover form is someone who can appreciate the significance of the process and who is in a position to ensure dental practice staff avoid the areas in which the visiting employee will be working.

If there are good reasons why the above handover process cannot take place, both employers will need to consult their RPAs regarding suitable alternative arrangements that will meet the additional requirements of IRR17 that will then apply.

2.22.2 Work experience or training at other practices

If an employer allows visiting staff employed by another employer to undertake dental radiography using their X-ray equipment by arrangement (for example as part of a person's training in dental radiography), it would be necessary for the two employers involved to co-operate to agree the allocation of responsibility between them for compliance with IRR17. This should include the following:

- Confirmation that the training already received by the trainee is sufficient for the intended work, and what further training or instruction might be necessary
- Agreement of the tasks that the trainee will undertake, the level of supervision required for each of them and who will provide supervision
- Review and updating of the host practice's risk assessment and local rules to ensure that they are consistent with what is intended

In this case, the requirements of IRMER17 (see sections 3 and 4) would also need special consideration, and both employers should consult their RPAs and MPES.

2.22.3 Employees supporting patients during radiography

It should not normally be necessary for dental practice staff to support patients during radiography. However, there may be occasions where it is appropriate for another employer's employees to remain in the controlled area with patients during radiographs. For example, prison guards supervising inmates during visits to dental practices, care home staff assisting or supporting residents during radiography being undertaken at the care home using mobile X-ray equipment, or similar occasions.

Under these circumstances, it would be necessary for the two employers involved to co-operate to agree the allocation of responsibility between them for compliance with IRR17. This should normally include the following:

- Reviewing and updating of the dental practice's risk assessment and local rules in consultation with the RPA to identify any precautions that may need to be taken to restrict the exposure of the employee (e.g., use of PPE, positioning of the patient, employee and the X-ray set, the need for personal dosimetry – see section 2.14)
- Providing the other employer and the employee concerned with a copy of the risk assessment and local rules
- Informing the other employer and the employee concerned of the magnitude of the radiation dose that will result from the exposure and its significance (which are likely to be trivial)

Table 2.2 Requirements of IRR17 – summary of key aspects

Topic	Brief description of requirement	Relevant sections of this guidance
Registration with HSE	Work with a 'radiation generator' must be registered if it is: <ul style="list-style-type: none"> • Being done for the first time, or • Being done at new premises (that are not covered by an existing registration made by the same employer) • Change of dental practice name or ownership is also notifiable 	2.2 and Appendix A
Appointment and consultation of an RPA	A suitable RPA must be appointed and consulted for advice on IRR17 as required	2.3
Prior assessment of installation plans	Consult RPA about the layout and construction of the dental radiography facilities. Particular attention to be paid to: <ul style="list-style-type: none"> • Shielding of the room in which X-ray equipment is to be installed • Position of operator and controls including mains on/off switch • The need for safety and warning systems for the room • Considering the means by which access will be restricted Forward RPA's report to the builder and/or installer	2.4, 2.5, 2.6
Critical examination	Confirm with the installer that a critical examination will be carried out in consultation with an RPA and a report issued Check that the supplier/manufacturer has provided information on the safe use, testing and maintenance of the equipment	2.9

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Table continued

Topic	Brief description of requirement	Relevant sections of this guidance
Radiation risk Assessment	Risk assessment to be drafted/ reviewed with RPA, using the list specified in paragraphs 70 and 71 of the ACoP	2.10 and Appendix B
Designation of controlled areas	Designate appropriate controlled areas for the dental X-ray equipment and ensure these are suitably demarcated with warning lights or signs when they are in force, and that access is effectively restricted	2.11
Additional requirements for controlled areas	Depending on findings of risk assessment (and in accordance with RPA's advice): <ul style="list-style-type: none"> • Arrange for doses to employees who enter controlled areas to be assessed • Arrange for monitoring of radiation levels in and around controlled areas 	2.14 2.19
Local rules	Local rules must be drafted or reviewed with RPA <ul style="list-style-type: none"> • The duration and extent of controlled areas must be accurately described • Written arrangements necessary for employees who enter controlled areas must be included • Contingency plans should cover all reasonably foreseeable accidents or incidents 	2.16 2.17
Radiation protection supervisors	RPSs should be: <ul style="list-style-type: none"> • Suitable persons able to effectively supervise the work • Trained in the requirements of IRR17 • Appointed in writing 	2.18

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Table continued

Topic	Brief description of requirement	Relevant sections of this guidance
Training	Radiation safety training should be provided for all employees involved in radiography and others who may be incidentally exposed <ul style="list-style-type: none"> • Details should be recorded • Training should be refreshed at least every 5 years, or when details of the work change 	2.21
Co-operation between employers	Employers at the dental practices must co-operate with other employers, by the exchange of information and in other ways, when: <ul style="list-style-type: none"> • ‘Outside workers’ (e.g., the RPA, MPE or service engineers) visit and work in controlled areas designated by the dental practice • Visitors to the practice work in controlled areas they themselves designate (e.g., the responsibility for controlled area designation is handed over) • Employees work at other dental practices as part of their training (eg, in dental radiography) • Employees of another employer need to remain in the controlled area during exposures (e.g., prison officers escorting inmates) 	2.22 Appendix C

2.23 References

- 1 Health and Safety at Work etc. Act 1974. London, UK. Her Majesty’s Stationery Office, 1974. Available at <http://www.legislation.gov.uk/ukpga/1974/37/contents>
- 2 The Radiation (Emergency Preparedness and Public Information) Regulations 2019. London, UK: Department for Business, Energy and Industrial Strategy. Available at <http://www.legislation.gov.uk/uksi/2019/703/contents/made>
- 3 The Radiation (Emergency Preparedness and Public Information) Regulations (Northern Ireland) 2019. Belfast, UK: Department for the Economy. Available at <http://www.legislation.gov.uk/nisr/2019/185/contents/made>

- 4 J R Holroyd. Measurement of scattered and transmitted X-rays from intra-oral and panoramic dental X-ray equipment. *J Radiol Prot.* 2018 May; 38:793-806.
Available at <https://doi.org/10.1088/1361-6498/aabce3>
- 5 B R Archer, J I Thornaby, S C Bushong. Diagnostic X-ray shielding based on an empirical model of photon attenuation. *Health Phys.* 1983; 44:507-517
- 6 British Standards Institute. BS 7671: 2018, Requirements for Electrical Installations IET Wiring Regulations, 18th Edition. London, UK. British Standards Institute; 2018
- 7 Health and Safety (Safety Signs and Signals) Regulations 1996. London, UK: Department for the Environment. Available at <http://www.legislation.gov.uk/uksi/1996/341/contents/made>
- 8 Health and Safety Executive. Safety signs and signals. The Health and Safety (Safety Signs and Signals) Regulations 1996. Guidance on Regulations. L64 (Third edition) Published 2015. Norwich, UK. HSE Books; 2015.
Available at <https://www.hse.gov.uk/pubns/books/l64.htm>
- 9 Public Health England. Guidance on the Safe Use of Hand-Held Dental X-ray Equipment (PHE-CRCE-023). Chilton, UK: Public Health England; 2016.
Available at <https://www.gov.uk/government/publications/hand-held-dental-x-ray-equipment-guidance-on-safe-use>
- 10 Medical Devices (Amendment etc) (EU Exit) Regulations 2019. Department of Health and Social Care. Available at <http://www.legislation.gov.uk/ukdsi/2019/9780111179260/contents/BS/EN60601-2-28:2010>

3 REQUIREMENTS OF IRMER17 – ADMINISTRATIVE ASPECTS

3.1 Scope of IRMER17

The use of dental X-ray equipment for the exposure of human subjects must comply with the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER17) and subsequent amendments. With regard to ionising radiation exposures within dentistry these regulations apply to:

- Patients having X-rays for diagnostic or treatment planning purposes
- The exposure of carers and comforters (see section 3.1.1)
- Individuals who have X-rays taken using dental X-ray equipment for non-medical reasons (see section 3.1.2)
- Patients or other persons who volunteer to take part in research programmes involving X-rays (see section 3.1.3)

The great majority of dental X-ray examinations in the UK are taken for diagnostic or treatment planning purposes, and accordingly this is the main focus of these guidelines.

3.2 Roles and functions defined under IRMER17

3.2.1 Referrer

In IRMER17, a referrer means a registered medical practitioner, dental practitioner or other registered healthcare professional (e.g. a hygienist or therapist) who is entitled in accordance with the employer's procedures to refer individuals to an IRMER practitioner for medical (or non-medical) exposure. The referrer is responsible for ensuring that sufficient clinical information is provided to enable the IRMER practitioner to decide whether the exposure can be justified. A history and clinical examination of the patient is essential prior to any referral for radiographs being made.

3.2.1.1 The referral process

In a dental practice, the referrer and IRMER practitioner will often be the same person, in which case the formal exchange of clinical information is unnecessary. However, a referral should nevertheless be considered to have occurred in such cases. Where the referrer and IRMER practitioner are not the same person (e.g. a patient is referred to another practice or hospital, or to another IRMER practitioner at the same practice), the referrer must supply the required information in writing (either paper or electronic

forms are acceptable). It is recommended that this includes any previous relevant radiographs (where possible) and at least the following:

- Unique identification of the patient
- Clinical information (including any previous medical imaging) to enable the IRMER practitioner to decide if the requested exposure can be justified
- Unique identification of the referrer
- Date of referral

The referrer should provide this information in a complete and legible form to enable the IRMER practitioner to carry out the justification.

The employer must establish local referral guidelines for radiographic examinations and ensure that these are available to all referrers even when the practitioner and referrer are the same person. When establishing such guidelines, the employer may wish to make use of, or refer directly to, the latest appropriate evidence-based guidelines published by expert groups and professional bodies (see sections 3.6.1 and 3.6.2).

3.2.2 Practitioner

In IRMER17, a 'practitioner' means a registered healthcare professional, (e.g., a medical practitioner, a dental practitioner or dental hygienist or therapist) who is entitled in accordance with the employer's procedures to take responsibility for an individual medical exposure. In this guidance the term 'IRMER practitioner' has been used to distinguish persons who are acting in this capacity, from others whose job title or description may include the word 'practitioner', but who have no involvement with exposures of the type that are subject to IRMER17. The primary function of the IRMER practitioner is to undertake the justification of individual exposures. All IRMER practitioners must be adequately trained to undertake this function.

Dentists, as well as hygienists and therapists who qualified after 2013, and who are registered with the GDC are all adequately trained to justify intra oral, panoramic and cephalometric radiographs. However, dentists are likely to require additional training to enable them to justify dental CBCT imaging, and hygienists and therapists should not normally be expected to justify cephalometric radiography or dental CBCT imaging (see sections 3.3.6 and 3.10).

3.2.2.1 The justification process

Before an exposure can take place, an IRMER practitioner must decide whether the benefit to the patient from the diagnostic information obtained will outweigh the detriment arising from the exposure. This process is termed 'justification.' The exposure would normally be expected to provide information to aid or change the patient's management or prognosis in order to be justified.

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

- The availability and findings of previous radiographs (or dental CBCT images)
- The specific objectives of the exposure in relation to the history and examination of the patient
- The age of the individual (bearing in mind the increased radiosensitivity of children compared to adults)

- 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 IRMER practitioner must also take into account the clinical information supplied by the referrer and should also consider any relevant published referral criteria guidelines. If the information provided by the referrer is incomplete or inadequate, the IRMER practitioner should not justify and authorise the exposure until the full information has been provided.

Particular attention is needed for the justification of dental X-ray examinations in children, especially for dental CBCT, because of the greater radio-sensitivity of younger age groups compared to the general population. The availability of 'low dose protocols', developed with the advice of a medical physics expert, may help to shift the risk/benefit considerations in favour of dental CBCT for appropriate clinical uses.

Special attention is also needed for the justification of dental CBCT examinations where patients are referred from one practice to another, to ensure that the referral is appropriate and consistent with evidence-based referral guidelines (see section 3.6.2), and to ensure that the clinical evaluation will be conducted by an appropriately trained person (see section 3.5.6).

There can be no possible justification for the routine radiography of 'new' patients without a thorough clinical examination. A history and clinical examination are the only acceptable means for determining if dental disease is suspected, and to help decide which are the most appropriate, and necessary, radiographic views.

3.2.2.2 The authorisation process

The IRMER practitioner should then make a written record of the justification decision, known as 'authorisation'. The employer 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 (e.g., the initials of the IRMER practitioner who is securely signed into the record). Whatever the method, the process should be detailed in the employer's procedures with any subsequent audit able to identify who made the clinical examination and who authorised any particular exposure as justified. It is not necessary to record the reasoning behind the justification decision. If the IRMER practitioner were to reject an exposure request, then the reasoning should be recorded and the referrer informed.

3.2.2.3 Special circumstances regarding authorisation

It is recognised that, in some specific circumstances, it may not be feasible for a dentist to carry out authorisation in advance of an exposure. Should this situation arise, the IRMER practitioner justifying the exposure should be present in the room while the X-ray is carried out, and authorisation of the exposure must occur as soon as possible within the same episode of care.

Circumstances where this may occur are during treatments (e.g. surgery) where it is not in the best interests of the patient for the dentist to leave them to document authorisation in the patient's dental record.

At all other times authorisation must be carried out in advance of the dental exposure.

A suggested template for a procedure for the justification and authorisation of dental exposures, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.2.3 Operator

In IRMER17 an operator is any person who is trained and entitled, in accordance with the employers' procedures, to carry out all or part of the practical aspects associated with a radiographic examination. Practical aspects include for example:

- Patient identification
- Positioning the image receptor, the patient and the X-ray tube head
- Setting the exposure parameters
- Pressing the exposure button to initiate the exposure
- Processing phosphor plates or films
- Clinical evaluation (interpretation and reporting) of radiographs or dental CBCT images
- Exposing test objects (or other practical activities) as part of the QA/QC programme for equipment

In fact, any single exposure could involve a number of different operators performing the various functions. Because of this range of functions carried out by operators and the differing levels of training these require, it is essential that the functions and responsibilities of individual operators are clearly defined by the employer. In dental practices, it is common for an individual dentist to act as referrer, IRMER practitioner and operator. However, many dental nurses, hygienists, therapists or other dental care professionals will also perform some or all of the functions of an operator. IRMER17 requires operators who carry out clinical evaluation to undergo detailed training, and accordingly, these operators are referred to as 'operators (reporting)' in this guidance, where it is important to distinguish them from operators who undertake other tasks.

All operators must be adequately trained to undertake their functions (see section 3.9 for details). Non-clinical staff (e.g. practice managers and receptionists) should not normally be asked to undertake the majority of operator's duties. Some of the more straightforward operator's duties (such as the processing of phosphor plates) may be undertaken by non-clinical staff, but the staff must have been appropriately trained and entitled by the employer for all of the tasks that they perform and their training must be recorded.

3.3 Scope of practice for dentists and dental care professionals

The General Dental Council's (GDC's) Scope of Practice (2013) document¹ provides guidance on the skills and abilities that each registrant group (dentists and the different dental care professionals) should have. It lists the procedures that the registrant can undertake once they are adequately trained, competent and indemnified. The GDC makes clear that this does not provide a list of tasks that someone can automatically do. The document highlights that a registrant's scope of practice is likely to change over the course of a career, both because of technological changes

in dentistry, and because of further training and development. The document also describes additional skills that a registrant might develop after registration to increase their scope of practice. It is emphasised that a registrant should only carry out a task or type of treatment or make decisions about a patient's care if they are sure that they have the necessary skills and are appropriately trained, competent and indemnified.

A summary of the procedures allowed for each registrant group by the GDC Scope of Practice document is given below. All these are subject to the individual being adequately trained (in accordance with IRMER17), competent and indemnified. It should be noted that there is nothing within IRMER17 to prevent an individual from acquiring the training and skills necessary to undertake any of the procedures; however, in some cases it would be necessary for the individual to requalify and re-register with the GDC in another registrant group. It should also be noted that the terminology used in the Scope of Practice document does not match that used in IRMER17 (or indeed that commonly used in dentistry); however, the following has been confirmed with the GDC and should be taken as the definitive interpretation.

3.3.1 Dentists

Dentists can carry out all roles in radiography and radiology. It is important, however, to emphasise that additional training will always be needed for new tasks for which there is inadequate or no previous training (e.g., the introduction of dental cone beam CT).

3.3.2 Dental hygienists and dental therapists

If appropriately trained, competent and indemnified to do so, dental hygienists and dental therapists can refer a patient for X-ray examination, take responsibility for an X-ray examination under IRMER17 (e.g., by selecting the appropriate radiographic examination) and perform operator roles including the taking and interpretation of conventional dental radiographs, within their scope.

It should be noted that the scope of practice of dental hygienists and dental therapists was extended in 2013 to encompass the "prescription" of radiographs (i.e., the referrer and IRMER practitioner roles as defined under IRMER17). While those qualified after that date might be expected to have received adequate training, those qualified before that date will not necessarily have acquired the necessary skills and abilities to fulfil the referrer and IRMER practitioner roles, or indeed the operator role of clinical evaluation. The employer should take special care to ensure that the skills and abilities of these groups of dental professionals are adequate and kept up-to-date for all the roles they perform, irrespective of their dates of qualification.

3.3.3 Dental nurses

Dental nurses should have the skills and abilities to perform certain operator roles as part of their training, such as assisting a dentist in preparing to take a radiograph, pressing the exposure button under supervision, processing a film radiograph or a CR plate. They have the possibility of acquiring the additional operator skills of preparing and taking radiographs by further training. Dental nurses do not refer patients for X-ray examinations, take responsibility for an X-ray examination (i.e., act as IRMER practitioner) or clinically evaluate radiographs.

3.3.4 Clinical dental technicians

Clinical dental technicians can “take and process radiographs” (and other images related to providing removable dental appliances). They have the possibility of acquiring additional skills in referring patients for X-ray examinations and taking responsibility for an X-ray examination under IRMER17 (e.g., by selecting the appropriate radiographic examination) by additional training. However, they do not perform the operator role of clinically evaluating dental radiographs.

3.3.5 Orthodontic therapists and dental technicians

Orthodontic therapists and dental technicians do not have the skills and abilities to perform the roles of referrer or IRMER practitioner, or to take or clinically evaluate radiographs, and do not have the scope to undertake additional training to do so.

3.3.6 General comments on scope of practice

For all dental professional groups, the types of X-ray imaging for which they may be entitled by their employer to act as referrer, IRMER practitioner or operator should only be those relevant to the scope of their clinical practice. For example, the scope of practice of a dental hygienist or dental therapist might be expected to include intra oral and possibly panoramic radiography, but never cephalometric radiography or dental cone-beam CT, and they should not, therefore, be expected to act as IRMER practitioner or operator (reporting) for these examinations.

Referrer and IRMER practitioner roles for dental cone-beam CT, along with the operator (reporting) role for dental cone-beam CT images, should only ever be within the scope of practice of dentists (after additional training to acquire the necessary skills and competence) because cross-sectional imaging is unlikely to have any relevance to other dental professional groups. Suitably qualified dental nurses, hygienists and therapists may, however, be entitled to act as operator (imaging) for any form of dental X-ray equipment, subject to them having the necessary theoretical and practical training.

A further summary of the above is presented in Table 3.1 overleaf, illustrating how the specific roles defined in IRMER17 match up with the GDC Scope of Practice guidance for each registrant group.

Notes to table 3.1 (see page 43)

- 1 Dentists are permitted to undertake any of the roles described in IRMER17, although further training is likely to be required before working with dental CBCT equipment for the first time, or before referring patients for dental CBCT examinations or clinically evaluating CBCT images
- 2 Dental hygienists and dental therapists can only clinically evaluate images where this is within their own scope of practice or experience (this is unlikely to include cephalometric or dental CBCT images)
- 3 Clinical dental technicians may take and process radiographs related to providing removable complete dental appliances, but may only act as referrer or IRMER practitioner on development of additional skills and having undergone additional training
- 4 Dental nurses who have not yet completed their radiography training may only initiate exposures under the direct supervision of another appropriately trained and properly entitled operator
- 5 Suitable training in radiation protection must have been completed within the initial qualification and continuing education and training cycle (to comply with the training requirement under IRR17)

TABLE 3.1 Illustrating which of the roles described in IRMER17 are associated with each registrant group

Registrant groups described in the GDC 'Scope of Practice' document	Roles described in IRMER17 associated with each registrant group									
	IRMER practitioner	Referrer	Operator roles			Operator roles				
			Patient identification	Preparing the X-ray set, patient and image receptor	Initiating exposures, ie 'pressing the button'	Processing films/ phosphor plates	Clinical evaluation	QA test exposures		
Dentist ¹	✓	✓	✓	✓	✓	✓	✓	✓		✓
Dental hygienist	✓	✓	✓	✓	✓	✓	✓ ²	✓		✓
Dental therapist	✓	✓	✓	✓	✓	✓	✓ ²	✓		✓
Clinical dental technician	✓ ³	✓ ³	✓	✓ ³	✓ ³	✓ ³	X ³	✓ ⁵		✓ ⁵
Dental nurse (with additional training)	X	X	✓	✓	✓	✓	X	✓		✓
Dental nurse (without additional training)	X	X	✓	X	✓ ⁴	✓	X	✓ ⁵		✓ ⁵
Orthodontic therapist	X	X	X	X	X	X	X	X		X
Dental technician	X	X	X	X	X	X	X	X		X

3.4 IRMER17 duty-holders in dental radiography and dental CBCT imaging

In general dental practice it is common for the dentist to be referrer, IRMER practitioner and operator for dental X-ray exposures, in which case the governance system required to comply with the administrative aspects of IRMER17 is relatively straightforward.

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, competent and entitled 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, more detailed and robust systems need to be in place to ensure that the equipment is used correctly, without incident and in line with IRMER17.

In addition, there is often confusion regarding the different roles of the different duty holders under IRMER17 in cases where referrals are made between practices, particularly so in the case of dental CBCT where the images may be interpreted and reported on at either the referring practice or the practice that undertakes the examination. Table 3.2 outlines the main roles involved in dental radiography, including dental CBCT imaging, and the corresponding IRMER roles and principal duties.

TABLE 3.2 IRMER17 roles and duties for persons involved with dental radiography and/or dental CBCT imaging

What do you do?	Your IRMER17 roles	Your IRMER17 duties
1 I am not a dentist. I am the owner and director of several dental practices	Employer	As the employer you have legal responsibility under IRMER17 for providing the framework, involving written procedures, protocols, QA programmes and training, to ensure safe clinical practice when using ionising radiation (for the employer's responsibilities under IRR17 – see section 2)
2 I am a dentist who owns a practice. All of the dentists, including myself, undertake radiography for their patients	Employer Referrer IRMER Practitioner Operator	As 1 and 6

Table continued on next page

Table continued

What do you do?	Your IRMER17 roles	Your IRMER17 duties
<p>3 I refer my patients to have a dental X-ray 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.</p>	Referrer	<p>When you request a dental X-ray examination 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 relevant to the examination you are requesting. To refer patients to another practice for CBCT examinations you will need to be entitled as a referrer by the employer at the CBCT practice and agree the referral guidelines to be used with the CBCT practice. To clinically evaluate CBCT images you will need additional training, including practical training in use of the imaging software. These matters should be established and agreed in writing by means of a service-level agreement (SLA) (see section 3.6.1).</p>
<p>4 I refer my patients to have a dental X-ray examination at another dental practice/hospital. I report on the images myself.</p>	Referrer Operator (reporting)	<p>As 3, plus: As an “operator”, in terms of interpreting images, you must be adequately trained in this task, and entitled as an operator by the employer at the practice to which you are referring patients. Most dentists will require additional training to be able to report on dental CBCT images, including use of the imaging software (see section 3.10).</p>

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What do you do?	Your IRMER17 roles	Your IRMER17 duties
<p>5 I am a dentist working in a practice as an associate. I decide that X-rays are required for my patients and I interpret the images but do not operate the dental X-ray equipment myself.</p>	<p>Referrer IRMER Practitioner Operator (reporting)</p>	<p>As 4, plus: As an IRMER practitioner, you must decide that the examination is justified and authorise it as such by a written or electronic signature (see section 3.2.2). You will need additional training to be able to justify and clinically evaluate for dental CBCT examinations (see section 3.10), and be entitled as an IRMER practitioner and operator.</p>
<p>6 I am a dentist working in a practice as an associate. I decide that X-rays are required for my patients, operate the X-ray equipment (including dental CBCT) and interpret the images.</p>	<p>Referrer IRMER Practitioner Operator</p>	<p>As 5, plus: As an “operator”, in terms of conducting the X-ray examinations, you must be entitled as such by the employer and adequately trained, including in the use of the equipment. Your undergraduate degree does not automatically provide this for dental CBCT. An <i>applications specialist</i> from the dental CBCT manufacturer may best deliver much of this practical aspect of machine-specific training (see section 3.10).</p>
<p>7 I am a dental nurse/dental therapist/dental hygienist. 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.</p>	<p>Operator</p>	<p>As an “operator”, in terms of conducting the X-ray examinations, you must be entitled as such by your employer and adequately trained, including in use of the equipment. Your qualification in dental radiography does not automatically provide this for dental CBCT. An <i>applications specialist</i> from the dental CBCT manufacturer may best deliver much of this aspect of machine-specific training (see section 3.10).</p>

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Table continued

What do you do?	Your IRMER17 roles	Your IRMER17 duties
<p>8 I am a specialist dental radiologist. I provide a reporting service for a dental practice with a dental CBCT machine.</p>	Operator	As an “operator”, in terms of interpreting images, you must be entitled as such by the employer at the CBCT practice and 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.
<p>9 I am a clinical radiologist (medical specialist). I provide a reporting service for a dental practice with a dental CBCT machine.</p>	Operator	As an “operator”, in terms of interpreting images, you must be entitled as such by the employer at the CBCT practice and 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.

3.5 Employer’s procedures

For all types of dental exposures, the employer must set up a documented compliance and assurance system to ensure the safe and efficient use of the dental X-ray equipment. This will include the employer’s written procedures as specified in IRMER17, and as detailed in sections 3.5.1 to 3.5.11, 3.11, 3.12 and 3.13*. In order to ensure that these procedures are understood and complied with, the employer should issue these procedures to all persons who are required to work in accordance with them and to keep a record of who they have been issued to, the date of issue, and that they have been signed to say they have been read. As with the local rules required under IRR17 (see section 2.16), the employer’s procedures may be saved and distributed to staff in either printed or electronic formats.

*Note that there is no need for a procedure covering the provision of written instructions and information to patients undergoing treatment or diagnosis with radioactive substances as these are not used in dentistry

3.5.1 Identification of the individuals entitled to act as referrer, IRMER practitioner or operator

The employer must clearly define, in writing, who is entitled to act as a referrer (see section 3.2.1), IRMER practitioner (see section 3.2.2) and operator (see section 3.2.3). As operators have a broad range of duties, the scope of duties that an individual operator has been entitled by the employer to perform should also be clearly defined. This is known as a scope of practice. The employer must also ensure that all those entitled as referrer, IRMER practitioner or operator are suitably trained and competent for their role and range of duties (see section 3.3). A suggested template for this procedure, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.2 Identification of individuals to be exposed

Dental radiography generally takes place immediately after the clinical examination, meaning that the operator can be confident that the correct patient is receiving the correct radiographic examination. If the operator carrying out the exposure is not the same person as the referrer, and the exposure is carried out at a different time to the clinical assessment, the patient should be positively identified prior to the exposure taking place. IRMER17 requires an employer's procedure which describes how and when this identification process should take place. A suggested template for this procedure, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.3 Pregnancy enquiry

IRMER17 prohibits the carrying out of a medical exposure of an individual of child-bearing potential without an enquiry as to whether that individual could, or might be, pregnant, if relevant. 'Child-bearing age' should be regarded as being in the range of 12 to 55 years of age.

IRMER17 requires an employer's procedure to be in place, although such an enquiry will not normally be relevant in dental radiography because the primary X-ray beam will not irradiate the pelvic area during any properly conducted form of dental radiography or dental CBCT imaging. A suggested template for this procedure, which should be drafted in consultation with the MPE, is provided in Appendix D. See also section 4.41 regarding the use of patient contact shielding.

3.5.4 Information on benefits and risks of exposure

Wherever practicable, the patient or the patient's representative should be provided with adequate information relating to the benefits of having the exposure and risks associated with the radiation dose. This information must be provided prior to the exposure taking place.

In order to communicate the risk to the patient, it may be helpful to put it into perspective by comparing the radiation dose from the exposure to the radiation dose received from something to which the patient can relate (e.g., the dose from cosmic rays resulting from a plane flight or the dose from background radiation over a specific length of time).

Professional bodies have produced leaflets/posters that may support staff fulfilling this requirement.^{2,3}

Examples are provided in Figure 3.1.

Your X-Ray and You

- Things you might like to know

Your Well-Being

- Dental X-rays are undertaken to investigate suspected problems with your teeth and gums and to plan treatments.
- Your dentist or dental care professional can explain how the information gained will help to improve your diagnosis or treatment.
- These X-rays allow for faster and more effective interventions and can save you discomfort and pain.
- Our overriding concern is to ensure that when you have an X-ray, the benefits from making the right diagnosis or providing the correct treatment outweigh the very low risk involved with the X-ray itself. We make sure that this is the case before you have an X-ray.

Our Standards

- Our X-ray equipment is well maintained and regularly checked by appropriately qualified staff.
- This ensures that the amount of radiation we use is kept as low as possible to get the pictures we need. If there are any technical problems during the X-ray, we will tell you.

About X-Rays and Radiation

- X-ray machines use radiation to generate the “pictures” we need for your diagnosis and treatment.
- We are all exposed to natural background radiation every day of our lives. This comes from our environment, the air we breathe, the food we eat and even from outer space (cosmic rays).

Putting it in Perspective

- Each dental X-ray gives us a very small additional amount of radiation on top of this natural background.
- The examination you will be having today carries a very low risk.

Scottish Medical Physics Network (MPNET)
Scottish Clinical Imaging Network (SCIN)



Did you know?

Over 5000 dental radiographs are taken in Scotland every working day.

Age

The risks from X-rays are much lower for older people and a little higher for children. Extra care is taken with young patients.

Pregnancy

Because the risk to a developing baby from a dental X-ray is negligible, we will not ask any intrusive questions about pregnancy.

Consent

Please feel free to ask your dentist or dental care professional if you have any further questions or concerns. *You can refuse to have the X-ray if you do not feel you have sufficient information.*

Figure 3.1a: Poster produced by the Scottish Dental Clinical Effectiveness Programme (SDCEP) that may be used to provide information on the benefits and risks of exposure
Reproduced from SDCEP/NHS Scotland

Dental X-rays

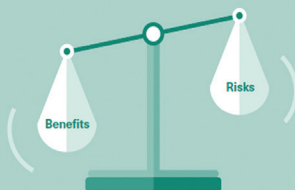
Your health

- Dental X-rays help with making a diagnosis, planning treatment or monitoring the health of your teeth.
- They involve the use of ionising radiation (X-rays) to produce detailed images of teeth, gums and jaws.



Radiation

- Everyone receives ionising radiation every day from radioactivity in the air, food we eat and even from space.
- The amount of radiation used for dental X-rays is similar to your everyday exposure over a few days, so the risks associated with them are very low for both adults and children.
- The main benefit of the X-ray is making the correct diagnosis or plan, or ensuring your teeth are healthy, so you can get the treatment that's right for you. The X-ray will have been approved by a specialist (usually your dentist) who has agreed that the benefit is far greater than the small risk from X-rays.



Our staff and equipment

- Staff are trained to take the best possible images using the lowest amount of radiation.
- Equipment is regularly checked to make sure the test is safe and effective.



Your test

- You may have your X-ray taken during your dental examination or you may need to go to an X-ray room, depending on the type of exam required to get the appropriate information.
- You will normally be informed of the outcome of the X-ray before you leave. If not, our staff will tell you when and how you will be told the outcome of your X-ray.



If you have any questions, please ask

Produced by the **Clinical Imaging Board**, a collaboration between the Institute of Physics and Engineering in Medicine, The Royal College of Radiologists and the Society and College of Radiographers.



Figure 3. 1b: Poster produced by the Clinical Imaging Board that may be used to provide information on the benefits and risks of exposure

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If such a leaflet or poster is used, a written procedure is still required, and the operator must check that the patient has read the leaflet/poster and answer any questions that they may have.

A suggested template for this procedure, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.5 Dose constraints and guidance for carers and comforters

Dose constraints and guidance for carers and comforters who support patients during exposures must be established in consultation with the MPE. Carers and comforters are those who are knowingly and willingly exposed to ionising radiation whilst supporting an individual undergoing an exposure. The guidance should include those situations when carers and comforters should be present during an exposure and how exposures can be minimised, for example where the carer and comforter should stand and what other radiation protection measures should be followed. For further guidance on the subject of carers and comforters refer to section 3.11.

If the practice does not under any circumstances permit carers and comforters to assist patients, then the employer's procedure should state this, and no further detailed procedure will be required.

A suggested template for this procedure, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.6 Clinical evaluation

A clinical evaluation of the outcome of each exposure must be carried out and recorded by suitably trained and competent operators. (Note that the term 'clinical evaluation' includes both the interpretation of the image and documentation of the findings, and should not be confused with image quality rating, which is a separate process and is covered in section 5.4.). The clinical evaluation must cover the whole image, including any regions outside the area of interest, using appropriate viewing facilities (see section 4.2). The clinical evaluation report does not need to be a full radiology report but should show that each image has been clinically evaluated and enough information recorded that it can be subject to a later audit. For example, the clinical evaluation record could include:

- The charting of caries
- Findings relevant to the patient's management, treatment or prognosis
- In the case of a pre-extraction radiograph, it may be sufficient to record either "root form simple" or "hooked roots"

The clinical evaluation should, where possible, be made on the same day as the exposure, and be recorded (reported on) as soon as possible thereafter.

Planning subsequent treatment arising from the exposure is itself evidence of a clinical evaluation. It should, however, be clear from the records which images were used and who undertook the planning. If more than one person reports on the radiograph (this is likely if the radiograph or CBCT image extends outside the den-to-alveolar region) then each reporter must record an evaluation.

If no clinical evaluation takes place, then this indicates that the radiograph was not justified, and the exposure should not have taken place.

For images acquired for the practice's own patients a record should be made within the patient's notes.

For patients referred from other practices a written clinical evaluation 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 practice carrying out the exposure. In doing this, the referring dentist becomes an *operator (reporting)* under IRMER17, and should be adequately trained to carry out relevant image interpretation. This should not be a problem for conventional dental radiography. However, for dental CBCT it will be necessary for the imaging practice to establish that the referring dentist (or whoever the referring dentist has named as the person to undertake the clinical evaluation) has received adequate training as specified in section 3.10 of this guidance. The SLA (or standard referral form) should, therefore, set out clearly who is to evaluate the image and whether their training is adequate. Exposures should not be justified or authorised if it is not clear to the IRMER practitioner who is to write the clinical evaluation report.

Any referrer carrying out the clinical evaluation of dental CBCT images would need to be entitled as an operator for the purpose of clinical evaluation and this decision may be documented as part of the SLA.

If the intention is to provide the referrer with the images alone with no clinical evaluation report or surgical planning advice, the employer at the CBCT practice should ensure that appropriate software is available to the referrer. The CBCT practice employer should also ensure that staff at the referring practice who will use this software are adequately trained to understand and interpret the image dataset and to plan any treatment.

An employer's procedure detailing the arrangements for clinical evaluation must be in place and should cover all the relevant aspects described above.

A suggested template for this procedure, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.7 Assessment of patient dose

The assessment of individual patient dose as part of each radiographic examination is not considered necessary in dental radiography. It will be sufficient to make measurements of representative patient doses for standard examinations as part of the routine quality assurance testing of dental X-ray equipment (see section 5.2). However, where it is clinically necessary for the operator to depart from the guideline exposure settings (see section 3.6.3), the exposure settings used should be recorded to enable an estimate of patient dose to be made, if necessary.

A suggested template for a procedure for the assessment of patient dose, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.8 The setting, use and review of diagnostic reference levels

IRMER17 requires that employers establish diagnostic reference levels (DRLs), having due regard to European and national DRLs where available, and make these available to operators.

A DRL is an aid to the optimisation of patient dose and is defined in IRMER17 as

a level of patient dose in diagnostic radiology for typical examinations of groups of standard-sized individuals or standard phantoms for broadly defined types of equipment. The employer must set DRLs for local use in consultation with its MPE for each type of dental X-ray set in use at the practice, and where relevant, separate DRLs should be set for adult and child patients. It is sufficient to set local DRLs only for those examinations for which there exists a relevant national DRL. Local DRLs should be set at values no higher than the relevant national DRLs.

National DRLs are published by PHE based on national patient dose surveys and are updated every few years. The current values are available on the gov.uk website at <https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls>. These include national DRLs for intra oral, panoramic, cephalometric and dental CBCT examinations for both adult and child patients.

Local DRLs should be set at a level which represents the upper boundary of patient doses that can be considered to be optimised, taking into account the X-ray sets and imaging equipment in use at the practice, and as such should not normally be exceeded without good reason. PHE has published a study of the national patient dose data from dental radiography that was used to set the national DRL values in 2019,⁴ which will be useful in selecting appropriate values for local DRLs.

Patient doses should be reviewed regularly against the local DRLs with assistance from the MPE. This should include the representative patient doses measured at the acceptance test and each routine test (e.g., at least every three years), and whenever any significant changes which may affect patient doses occur, such as the installation of new X-ray equipment or the modification of existing X-ray equipment and changes in the types of image receptors and image processing facilities.

Where there is evidence that patient doses consistently exceed the local DRLs, a thorough review of radiographic practices must be made in consultation with the MPE to improve the current techniques or justify their continued use. Equipment that is incapable of producing images of adequate diagnostic quality at doses above twice the national DRL should be immediately removed from use.⁵

Attainment of patient doses at or below the local DRL does not necessarily indicate that patient doses are fully optimised; the operator must select suitable exposure settings and other factors for each individual X-ray examination in order to achieve optimisation of patient dose as outlined in section 4.

A suggested template for a procedure for the use and review of DRLs, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.9 Reducing the probability and magnitude of accidental or unintended exposures

The protection programme required under IRMER17 involves adequate training, employer's procedures and X-ray equipment and ensures that the probability and magnitude of accidental or unintended exposure is reduced as far as practicable. A procedure which documents the arrangements is needed, however, this could simply refer to the practice's radiation protection programme or radiation protection file. A suggested template for this procedure, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.10 Significant, and clinically significant, accidental or unintended exposures

The employer must have a comprehensive system in place for the analysis, recording and reporting of accidental or unintended exposures. IRMER17 differentiates between 'significant accidental or unintended exposures' (SAUE) and 'clinically significant accidental or unintended exposures' (CSAUE) depending on the level of associated risk to the exposed person. Radiation incidents arising from either equipment or procedural failures are subject to the requirements for SAUE or CSAUE under IRMER17 as outlined below.

3.5.10.1 SAUE

The enforcing authorities for IRMER17 have published joint guidance on notification thresholds and notification requirements for SAUE. It can be found at <https://www.cqc.org.uk/guidance-providers/ionising-radiation/saue-criteria-making-notification>. This guidance only applies once equipment has entered clinical use. Any accidental or unintended exposures of dental practice staff or other persons, or any equipment related faults arising prior to that stage should be investigated under the requirements of IRR17 (see section 2.17) and, if necessary, reported to HSE.

An 'accidental exposure' occurs when an individual receives an exposure in error, when no exposure of any kind was intended; and an 'unintended exposure' occurs when, although the exposure of an individual was intended, the exposure they received was significantly greater or different to that intended. Any accidental or unintended exposure that is deemed to be 'significant' must be notified to the relevant enforcing authority. The UK enforcing authorities apply this in different ways and so it is important to refer to the current guidance. For instance, a particular enforcing authority may require notification if the effective dose to the exposed person exceeds a specified threshold. Alternatively, another enforcing authority may require any accidental or unintended exposure to be notified, regardless of the size of the effective dose.

Regardless of whether notification is required, in the event of any accidental or unintended exposure, the system that the employer has in place must involve the following steps:

- The employer should be notified of the circumstances of the exposure and a preliminary investigation undertaken in consultation with the MPE
- If the preliminary investigation shows beyond reasonable doubt that a SAUE has occurred, the relevant enforcing authority must be notified as soon as possible, and in any event, within two weeks of the incident occurring
- A detailed investigation of the circumstances of the exposure must then take place, in consultation with the MPE (and RPA if appropriate), and a record of the investigation and its findings kept
- If the incident is confirmed as being a SAUE, a detailed report of the investigation must be provided to the relevant enforcing authority within twelve weeks of the incident occurring
- It is recommended that the employer retains a copy of any report which is prepared in connection with either a preliminary SAUE investigation or a detailed SAUE investigation for at least five years

3.5.10.2 CSAUE

Guidance on what is considered to be a ‘clinically significant’ accidental or unintended exposure has been published by the RCR⁶. To be considered clinically significant, an exposure must either involve an additional lifetime radiation-induced cancer risk of more than 1:1000 (or in the case of foetal exposures, an additional risk of childhood cancer of more than 1:1000), or an unjustified exposure of a specific organ or tissue in excess of the dose thresholds specified in the RCR guidance. The thresholds for radiation-induced cancer risk and tissue doses mean that it is highly unlikely that any accidental or unintended exposure arising from dental X-ray equipment will ever be classed as ‘clinically significant.’ It should be noted, however, that in rare circumstances an accidental or unintended exposure may be classed as a CSAUE on psychological grounds if it affects the individual’s quality of life to an extent that requires intervention or treatment. Should a CSAUE nevertheless occur, the employer must ensure that the referrer, the IRMER practitioner and the exposed individual or their representative, are informed of the outcome of the analysis of the exposure.

For incidents involving equipment failures, regardless of whether anyone received an accidental or unintended exposure, the equipment manufacturer and, in England, the Medicines and Healthcare Products Regulatory Agency (MHRA), should be informed, using the YellowCard online facility (see <https://www.gov.uk/report-problem-medicine-medical-device>). The reporting requirements differ in Wales, Scotland and Northern Ireland, however, guidance is available from the link.

It is recommended that the employer retains a copy of any report prepared in connection with a CSAUE investigation for at least 30 years.

A suggested template for a procedure dealing with SAUE and CSAUE incidents, which should be drafted in consultation with the MPE, is provided in Appendix D.

3.5.11 Quality assurance of employer’s procedures

Each employer’s procedure or protocol should be dated and given an issue number. The employer’s quality assurance programme should include the provision and maintenance of an issue log to record the title, issue number and date of each procedure and a record of each occasion on which they are reviewed or updated. This should happen whenever there has been a change in practice, equipment or service delivery. Routine reviews should also be undertaken by the employer, in consultation with the MPE, at intervals not exceeding three years. See section 5 and Appendix D for further details.

3.6 Employer’s duties under IRMER17

As well as producing and ensuring that the employer’s procedures set out in section 3.5 are adhered to, the employer must also document the protocols and guidelines detailed in this section. These should be issued to all persons who are required to work in accordance with them and a record kept of who they have been issued to, and the date of issue. These documents should be subject to the quality assurance programme detailed in section 5.1.

3.6.1 Referral guidelines

The employer must establish and document local guidelines for referral criteria for radiographic examinations and ensure that these are available to all referrers even when

the IRMER practitioner and referrer are the same person. When establishing such criteria, the employer may wish to make use of, or refer directly to, the latest appropriate evidence-based guidelines published by expert groups and professional bodies, for example FGDP(UK)'s *Selection Criteria for Dental Radiography*.⁷ A suggested template for a procedure that documents the referral process and includes examples of references to suitable referral guidelines is provided in Appendix D. Where referrals for any type of dental radiograph or dental CBCT imaging are made between dental practices, both practices must agree which set of referral guidelines they will work with.

Requests for radiographic examinations from other dental practices should only be accepted from referrers who have been entitled to refer as detailed in the practice's employer's procedures. The employer at the practice receiving the referred patient should make a local decision on which individuals it is appropriate to accept referrals from, and this decision must be documented and these referrers entitled in the procedures accordingly.

It should be noted that under IRMER17, 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 present evidence that they are competent to provide adequate clinical information to facilitate the justification process for the particular type of radiographic examination requested should be so entitled under the receiving practice's employer's procedures. (See also section 3.3.6 which summarises the GDC's Scope of Practice guidance.) With regard to dental CBCT, evidence of appropriate training in CBCT will support this decision (see section 3.10).

A service level agreement (SLA) should be established in writing between referrers and the receiving practice, so that the necessary arrangements under IRMER17 (e.g., the entitlement of persons to refer patients to the receiving practice for the radiographic examination requested, and agreement regarding who will carry out the clinical evaluation) are properly put in place and documented. The SLA must be kept up to date and it is recommended that routine reviews are made on an annual basis to ensure this. An example SLA is provided in Appendix E.

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 as a minimum could facilitate this process.

- Patient unique identifier information (for example; name, date of birth, current address)
- The clinical context for requesting the radiographic examination
- Results of medical history, clinical examination and relevant other imaging
- The question the referrer would like the radiographic examination to answer
- A clear indication of the area(s) required for inclusion in the imaging

A suggested example of an imaging referral form is given in Appendix F.

Requests for dental CBCT exposures should only be accepted from referrers who can provide evidence that they are competent to provide adequate clinical information to facilitate the justification process. It must also be agreed who will undertake the clinical evaluation of dental CBCT images (e.g., suitably trained individuals at either the referring practice or the practice undertaking the imaging). Evidence of

appropriate training should be considered by the CBCT practice in this decision, e.g., attendance at a training course covering the relevant sections of the syllabus detailed in section 3.10. The entitlement of referrers and operators (for clinical evaluation) should be established between the referring practice and the CBCT practice in writing, by means of a SLA as described above.

3.6.2 Referral guidelines for dental CBCT

Although dental CBCT has been available for several years, the research evidence required to develop high grade, robust, referral guidelines for dental CBCT remains limited. Furthermore, research evidence may be valid for one specific dental CBCT unit on which the research was performed, but not applicable to all due to the wide variation in equipment and image quality.

Nevertheless, there are several documents which can be used to provide referral guidelines for dental CBCT. The European Academy of Dental and Maxillofacial Radiology (EADMFR) produced Consensus Guidelines including a list of Basic Principles for dental CBCT use, seven of which are relevant to referrals for dental CBCT.⁸ The European Commission published evidence-based guidelines on the use of dental CBCT in 2012,⁹ and the Faculty of General Dental Practice (UK) (FGDP[UK]) published the third edition of their *Selection Criteria for Dental Radiography* guidelines in 2013 which include aspects of the use of CBCT.⁷ Both the FGDP[UK] guidelines and the European guidelines are suitable for use as referral guidelines for dental CBCT.

In terms of specialist practice, referral guidelines for dental CBCT have been developed for orthodontics,¹⁰ implant dentistry¹¹ and endodontics.¹² An extensive list of potentially useful publications, including referral guidelines for dental CBCT, is contained within a review from 2015.¹³

These referral criteria are united in taking a general stance that conventional radiography should be the first choice of imaging method. This is based on the lower doses and lower economic costs of conventional imaging which may provide adequate information for diagnosis and treatment planning. In almost all clinical situations, therefore, CBCT should be reserved for cases in which conventional radiography has failed to provide sufficient information. Exceptionally, as part of implant planning, there could be selected cases (with adequate historical conventional imaging) for which CBCT could be chosen as the first imaging examination.

Some diagnostic tasks require greater image detail than others, notably some aspects of endodontic practice. These may include imaging of fine root canals, root resorption and root fracture detection. However, “high resolution” settings on CBCT equipment mean higher radiation doses and that these should not be used routinely for every situation. Most guidelines specify that localised (small field of view) CBCT should be used when high resolution settings are required as a means of limiting the radiation dose.

Some CBCT scanners have been manufactured with both dental and ENT (ear, nose and throat) uses in mind. It is feasible, therefore, that dental practices with this type of equipment may be approached to undertake scans of the paranasal sinuses or the middle ear. This is beyond the normal practice of dentistry and the employer at the CBCT practice should ensure that a clinical radiologist or dental and maxillofacial radiologist is involved in the justification process and that suitable referral guidelines are available. The MPE should also be consulted regarding the drafting

of appropriate guideline exposure protocols.

The evidence for efficacy of any imaging modality changes over time and it would be inappropriate for this document to present detailed referral guidelines. The employer should ensure that referrers and IRMER practitioners always have access to up-to-date referral guidelines. The research evidence has, however, led to some general recommendations about clinical situations in which CBCT should *not* be used routinely:

- **Dental caries diagnosis:** Although CBCT may demonstrate dental caries in scans taken for other reasons, false positive diagnoses are seen, particularly when there are metal objects (e.g. restorations) in teeth but also from the enamel itself
- **General periodontal bone assessment:** Localised CBCT may have a role in imaging complex periodontal defects and “perio-endo” lesions, particularly when regenerative surgery is planned, but there is no evidence of any value for everyday periodontal practice
- **Detection of root fractures in teeth containing metal posts:** The metal posts produce artefacts that both obscure the root and cause false positive diagnoses
- **Routine review of dental implants:** Routine review of dental implants should be done using conventional radiography. CBCT may produce artefacts around the implant that mimic a failure of osseointegration. However, there may be some situations in which CBCT may be useful (e.g. suspected misplacement of an implant)
- **Routine pre-surgical imaging of impacted lower third molars:** There is substantial randomised-controlled trial evidence¹⁴ that CBCT has no impact on patient outcome after lower third molar surgery. Its use should be limited to carefully selected cases with a high risk of iatrogenic damage to the inferior dental nerve
- **Routine imaging as part of orthodontic treatment:** There is no evidence of improved patient outcome from using CBCT. Localised CBCT may have diagnostic value for specific situations when conventional radiography has failed to provide sufficient information for management (e.g. detection of root resorption in relation to unerupted extracted teeth)
- **As part of a general ‘screening’ procedure:** Screening for unsuspected abnormalities using CBCT scans has no evidence to support it

3.6.3 Guideline exposure protocols

Written protocols must be available for all standard radiographic procedures. A protocol is required for each X-ray machine and this should include the exposure settings to be used for each type of radiograph routinely taken. The detail required will depend on the settings on the machine that can be changed by the operator but will include some of the following: operating potential (kV), tube current (mA), exposure time, density/coefficient/sensitivity setting, film or digital image receptor settings, patient size and the anatomical view and/or field size or collimation options. If non-medical radiographs or research exposures are taken, these should be included in the protocol. The operator undertaking an exposure should adhere to the standard settings as laid out in the dental practice’s written protocols, unless there are sound clinical reasons to depart from them.

The MPE should be able to advise on guideline exposure protocols, taking into

account (where available) the manufacturer's recommended exposure settings, the results of adequate testing and/or routine QA testing, and information on diagnostic performance from clinical use. Suggested template protocols are provided in Appendix G.

3.7 Medical physics expert (MPE)

IRMER17 requires employers to ensure that a suitable MPE is appointed and involved, as appropriate, for every type of exposure subject to the regulations. An MPE is defined in IRMER17 as an individual or group of individuals having the knowledge, training and experience to act or give advice on matters relating to physics applied to exposures of the type subject to the regulations, and whose competence is formally recognised by the Secretary of State. The list of registered MPEs can be found on the RPA2000 website (see <http://www.rpa2000.org.uk/mpe-recognition-scheme/>).

For dental radiography, the MPE must be involved as appropriate for the following matters:

Consultation on optimisation of patient doses

Giving advice on:

- Dosimetry and QA in relation to exposures
- Measurement methods for the evaluation of the dose delivered to patients
- Dental X-ray equipment and ancillary equipment (e.g., digital image receptors, phosphor plate or film processors, computer screens used for interpreting radiographs etc.)

Contributing to:

- Preparation of technical specifications for equipment and installation design
- Acceptance testing of dental X-ray equipment
- The definition and performance of QA programmes for dental X-ray and ancillary equipment
- Optimisation of doses to patients and others (such as carers and comforters)
- Application and use of diagnostic reference levels
- Analysis of events involving suspected or actual accidental or unintended exposures
- Selection of equipment to perform radiation protection measurements
- Training of IRMER practitioners and other staff in radiation protection
- Advising the employer regarding compliance with IRMER17

It is clear that several of the above topics are also subject to the requirements of IRR17 and IRMER17 requires that the MPE liaises with an RPA as and when this is appropriate.

3.8 Records to be kept for each dental X-ray examination

The identity of the IRMER practitioner who justifies and authorises the exposure must be recorded (see section 3.2.2). In cases where patients are referred between practices (e.g., for dental CBCT examinations) the name(s) of the referrer(s) and operator(s) who will report on the images should also be recorded (see section 3.6.1).

Where X-ray examinations are conducted in accordance with a guideline exposure protocol, the exposure factors do not need to be recorded. Where there is a deviation from these standard settings, the exposure settings used should be recorded, along with the reason for the deviation and the total number of exposures carried out at these settings so that, if necessary, an estimation of the dose to the patient can be made at a later date.

3.9 Adequate training for conventional (non-CBCT) radiography

IRMER17 states that the employer must take steps to ensure that any IRMER practitioner or operator who carries out a medical or dental X-ray exposure, or any practical aspect of that exposure, is adequately trained for the role that they play. IRMER17 further specifies that adequate training consists of theoretical knowledge and practical experience in: radiation production, radiation protection and statutory obligations relating to ionising radiations as are relevant to their functions as IRMER practitioner or operator; as set out in Table 1 of Schedule 3 of IRMER17, and such of the subjects detailed in Table 2 of schedule 3 as are relevant. For general dental practice, only the 'General' and 'Diagnostic radiology' sections under the 'All Modalities' heading in Table 2 are relevant.

Furthermore, the employer must take steps to ensure that IRMER practitioners and operators undertake continuing education and training after qualification.

It should be noted that in addition to the requirements of IRMER17, the training of dentists and DCPs should comply with the professional recommendations of the GDC and the core curricula in dental radiography and radiology for the dental team devised by the British Society of Dental and Maxillofacial Radiology (BSDMFR).¹⁵ The GDC recommendations¹⁶ state that dentists and DCPs who carry out radiography should undertake at least five hours of verifiable CPD (continuing professional development) in radiography and radiation protection, in each five-year CPD cycle (with the exception of dental technicians, who may do five hours of CPD in materials and equipment, instead of radiography and radiation protection).

The 'radiation protection' content of verifiable CPD courses should cover the subjects detailed in Table 3.3.

TABLE 3.3 Recommended ‘radiation protection’ content of verifiable CPD courses for IRMER practitioners and operators who undertake dental radiography

Subject	Training recommended for each duty-holder	
	IRMER practitioner	Operator
The principles of radiation physics	✓	✓
Risks of ionising radiation	✓	✓
Radiation doses in dental radiography	✓	✓
Factors affecting doses in dental radiography	✓	✓
The principles of radiation protection	✓	✓
Statutory requirements	✓	✓
Selection criteria	✓	X
Quality assurance	✓	✓

3.10 Adequate training for dental CBCT

Dental CBCT is currently not sufficiently taught in undergraduate dental programmes to allow the newly qualified dentist to be considered adequately trained to refer, justify, perform or interpret dental CBCT examinations. Dental CBCT is similarly largely absent from the professional qualifications of other dental care professionals at the time of publication. Further training is therefore required for all dental practice staff, including those intending to refer patients for dental CBCT examinations. (Although IRMER17 does not require any specific training for referrers, it is strongly recommended that training should be undertaken to ensure that the referrals they make are appropriate and in accordance with current referral guidelines for dental CBCT.)

It is recommended that radiography and dental departments within the university system set up courses on dental CBCT, following the guidance presented in sections 3.10.1 to 3.10.4.

The following presents a summary of a recommended ‘adequate training’ standard for dental practice staff referring for, performing and reporting on dental CBCT examinations. This draws on the ‘Basic Principles for Use of Dental Cone Beam CT’ of the EADMFR (2009)¹⁷ and the principles of the EADMFR Working Group recommendations ‘Basic training requirements for the use of dental CBCT by dentists: a position paper prepared by the European Academy of Dentomaxillofacial Radiology’ 2014.¹⁸

Two levels of training are required to meet the needs of two broad groups of users. Firstly, an initial period of training (‘Level 1’, or ‘Core training’) which would be required for all IRMER duty holders, followed by further periods of more advanced further training (‘Level 2’ training) tailored to those staff undertaking the roles of IRMER practitioner, operator (imaging) or operator (reporting). These are outlined below with a more detailed summary provided in Appendix H.

3.10.1 Level 1 (Core) training in dental CBCT

This is intended for dentists, dental nurses with the certificate in dental radiography (CDR), dental hygienists and dental therapists who are already adequately trained to take 2D radiographs.

It would be limited to CBCT imaging of the dento-alveolar region.

A period of 12 hours is recommended, part of which could be provided by up to five hours of verifiable CPD in radiography and radiation protection (which is highly recommended for those who undertake dental radiography under the GDC's "enhanced CPD" scheme).¹⁹

3.10.2 Level 2 (Further) training for operators performing dental CBCT imaging

This is intended for dentists, dental nurses with the CDR, dental hygienists and dental therapists who act as operators undertaking dental CBCT examinations.

The training covers the practical aspects of dental CBCT equipment and should be provided by the manufacturer or agent installing the CBCT unit. The training should be specific to the unit.

An initial period of 6 hours training is recommended. This should allow the operator to become familiar with the equipment and to begin imaging patients safely and confidently. A second 6-hour period should be undertaken after a short period (e.g. one month) of initial usage, in order to provide further detailed training on patient positioning, dose and image optimisation, further machine options, to answer queries and address any problems.

3.10.3 Level 2 (Further) training in dental CBCT justification and image interpretation

Further training in interpretation is designed to extend the knowledge of those dentists undertaking the justification and interpretation of CBCT imaging in the dento-alveolar region. It would not be appropriate for this training to be available to dental nurses, hygienists or therapists as the roles of IRMER practitioner and operator (reporting) are not relevant to their clinical practice, in so far as dental CBCT is concerned.

Further training in CBCT image interpretation must follow on from the successful completion of a Level 1 ('core training') course.

The training should be undertaken as a combination of didactic teaching, hands-on training in the use of imaging software and case-based interpretation exercises over an initial period of at least 6 hours, ideally with a further 6 hours for self-study and small group-study, including case-based discussions, interpretation exercises and mentoring to follow.

3.10.4 Refresher training in dental CBCT

The employer must take steps to ensure that IRMER practitioners and operators undertake continuing education and training after qualification. For those involved with dental CBCT, it is suggested that as a minimum, about one of the recommended five hours of verifiable CPD in radiology and radiation protection should be specific to dental CBCT.

3.11 Exposures of carers and comforters

IRMER17 defines “carers and comforters” as individuals, who are not employees, and who knowingly and willingly incur an exposure to ionising radiation by helping in the support and comfort of individuals undergoing an exposure. Whenever a patient requires a relative or guardian to remain with them (e.g., inside the controlled area) to provide support or other assistance during a dental exposure, the relative or guardian is considered to be a carer or comforter and any exposure they receive as a consequence of the patient’s exposure is subject to IRMER17.

The employer must, in consultation with the MPE, carry out a risk assessment to determine the potential dose to the carer or comforter, establish a dose constraint for the carer or comforters, identify any steps necessary to restrict exposure of the carer or comforter and ensure that, if these steps are taken, the dose constraint is not exceeded.

Every exposure of a carer or comforter must be justified by an IRMER practitioner and authorised as such in writing, taking into account the findings of the risk assessment. This must be considered separately to the justification and authorisation of the patient’s exposure. For further details, see section 3.5.5 and Appendix D.

If an employee, such as a prison guard or a care home worker, provides support or assistance, that employee is not a carer or comforter and their exposure is regulated under IRR17 (see section 2.22). Dental practice staff are strongly discouraged from remaining in the controlled area to provide support or assistance to patients undergoing radiography.

3.12 Exposures taken for non-medical imaging purposes

These might include dental radiographs where the benefit to the individual being examined may be financial rather than medical in nature, or may be to a third party.

Where these types of exposures are carried out, the employer’s procedures must set out exactly how these types of exposures will be justified.

3.12.1 Procedures for non-medical imaging exposures

As there is no direct health benefit to the person being examined, the procedure for non-medical exposures should require special attention to be paid to the justification of the exposure. The procedure should make it clear that only a medical/dental practitioner may request the exposure, and that the patient’s written consent should be obtained before the exposure takes place.

If the practice does not under any circumstances undertake non-medical imaging, then the procedure need only consist of a statement of this fact and no further details will be required. A suggested template for this procedure is provided in Appendix D.

3.13 Research exposures

IRMER17 requires that nobody should carry out an exposure in the course of a research programme unless that programme has been approved by a research ethics committee (REC), even if the exposures are part of normal clinical care. It is uncommon for general dental practices to be involved in research exposures, however, should this arise, the guidance in this section should be carefully followed.

The Health Research Authority’s (HRA’s) online decision tool should be used to judge whether or not a project should be considered to be research, regardless of

whether or not the work will be conducted on NHS premises. Further information on research exposures is available on the Integrated Research Application System (IRAS) website (<https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx>). It is also essential that the employer consults their RPA and MPE regarding research exposures.

3.13.1 Procedures for medical research programmes, including dose constraints

When developing a research protocol involving the use of X-ray examinations of patients, the principal investigator (PI) should consult both an RPA and MPE to ensure compliance with IRR17 and IRMER17 requirements. When making the REC application, authorisations by a “clinical radiation expert” (CRE)* and an MPE are required prior to submission. The research sponsor should work with the MPE and CRE to ensure that an appropriate risk statement is used in the Participant Information Sheet. It is most likely that dentists working in primary care locations would be supporting research sponsored by another organisation (e.g. a university) and that the ethical application would be dealt with by the PI. Nonetheless, IRMER17 imposes duties on employers and those acting as referrers, IRMER practitioners and operators to protect persons undergoing medical exposures as part of research. The employer at the premises where the X-ray examinations will take place should ensure that all ethical processes required under IRMER17 have been followed and that ethical approval has been obtained before commencing the research.

For each research project, the employer’s procedures must provide that:

- a** The individuals concerned participate voluntarily in the research
- b** The individuals concerned are informed in advance about the risks of the exposure and that a statement about this is included in the Participant Information Sheet
- c** Dose constraints are established for individuals for whom no direct clinical benefit is expected from the exposure and these are adhered to
- d** Individual target levels of doses are planned by the IRMER practitioner, either alone or with the input of the referrer, for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a diagnostic or therapeutic benefit

Over and above the normal requirements for IRMER practitioners and operators to have successfully completed theoretical and practical training and experience, special attention needs to be given to management and radiation protection of the individual being exposed as part of research.

If the practice does not under any circumstances undertake research exposures, then the procedure need only consist of a statement of this fact and no further details will be required. A suggested template for this procedure is provided in Appendix D.

*A clinical radiation expert is a registered doctor or dentist with clinical expertise relevant to the planned exposures

Table 3.4 Administrative requirements of IRMER17 – summary of key aspects

Topic	Brief description of requirement	Relevant section of this guidance
Medical physics expert	Appoint a suitable medical physics expert (MPE) to advise on IRMER17	3.7
Employer's procedures	<p>Draft the employer's procedures in consultation with the MPE as relevant to the proposed work and issue them to staff:</p> <ul style="list-style-type: none"> • Entitlement (see below) • Identification of the individual to be exposed • Pregnancy enquiries • Information for the patient on the benefits and risks of exposure • Carers and comforters • Clinical evaluation • Assessment of patient dose • DRLs • Non-medical imaging exposures • Research exposures • Reducing the probability and magnitude of accidental or unintended exposures • Analysis and information provided on clinically significant accidental or unintended exposures • QA programmes for written procedures/protocols and QA programme for equipment (see below) 	3.2.1, 3.2.2, 3.5, 3.11, 3.12, 3.13, 5.1, 5.2 and Appendix D
Entitlement of duty holders	Entitle suitable staff to act as referrers, practitioners and operators in accordance with GDC Scope of Practice document and ensure that they are adequately trained, competent and entitled for their roles	3.2, 3.3, 3.4, 3.9, 3.10
Quality assurance of written procedures	<p>Establish a quality assurance programme for the employer's procedures including:</p> <ul style="list-style-type: none"> • Document issue, review and control • Staff training and refresher training 	5.1
Quality assurance of equipment	Establish a quality assurance programme for the dental X-ray equipment and ancillary equipment affecting radiation dose in conjunction with the MPE and RPA, including:	5.2, 5.3

Table continued on next page

Table continued

Topic	Brief description of requirement	Relevant section of this guidance
	<ul style="list-style-type: none"> • Adequate testing • Representative measurements of patient dose and comparison with local DRLs • Routine surveillance • Quality assurance checks on image processing and viewing facilities • Maintenance and fault logs 	
Quality assurance of images	Establish a quality assurance programme for image quality in conjunction with the MPE	5.4

3.14 References

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4 REQUIREMENTS OF IRMER17 – OPTIMISATION OF PATIENT DOSE

4.1 Selection of X-ray equipment

Regulation 12 of IRMER17 places the responsibility for ensuring patient doses are ALARP through the appropriate selection of equipment and methods on the IRMER practitioner (who justifies the exposure) and the operator (who undertakes the exposure). In the context of general dental practice, where only one X-ray set and choice of image receptor may be available to the operator, the following guidance on 'selection' may be most usefully applied to decisions made at the purchasing stage.

Employers should, therefore, ensure that all staff involved with the selection of X-ray equipment and image receptors to be purchased and used at their practice are aware of the desirable features with regard to the optimisation of patient doses. In this context, 'optimisation' means keeping the patient dose ALARP while producing images of adequate diagnostic quality. The employer should ensure that the equipment is designed, constructed and installed in compliance with recognised British, European or international standards. It should be appropriately marked to be in compliance with the UK medical devices regulations¹ and capable of producing clinically acceptable images using patient doses that are below any relevant national diagnostic reference levels (see section 3.5.9). Under IRMER 14 3(c), The MPE must also be consulted for advice on the preparation of technical specifications for equipment; this is especially important for dental CBCT or hand-held equipment.

4.1.1 Requirements for all dental X-ray equipment

All dental X-ray equipment should be capable of passing the relevant performance tests specified in Appendix I. In addition, X-ray equipment should meet the following requirements:

4.1.1.1 X-ray source assembly

- For fixed intra-oral units, the X-ray source assembly (comprising an X-ray tube, an X-ray tube housing and a beam-limiting device) should be constructed so that, at every rating specified by the manufacturer for that X-ray source assembly, the air kerma from the leakage radiation at a distance from the focal spot of 1 metre averaged over an area not exceeding 100 cm² does not exceed 0.25 mGy in one hour²

- For hand-held dental X-ray equipment the X-ray source assembly should be constructed so that the annual effective dose to the operator is unlikely to exceed 0.25 mSv during normal use, and the annual equivalent dose to the skin of the operator's hands is unlikely to exceed 10 mSv, under all reasonably foreseeable circumstances³
- For all other dental X-ray equipment (including panoramic, cephalometric and dental CBCT units), at every rating specified by the manufacturer for that X-ray source assembly, the air kerma from the leakage radiation at a distance from the focal spot of 1 metre averaged over an area not exceeding 100 cm² does not exceed 1 mGy in one hour⁴
- The position of the focal spot should be indicated, either by a marking on the X-ray tube head or in the accompanying documents^{2,4}

4.1.1.2 Beam filtration

- The value of the inherent filtration and any added filtration should be marked clearly on the tube housing in millimetres of aluminium (mm Al) equivalent
- Every added filter should also be clearly marked with its filtration in mm Al equivalent
- The total filtration of the beam (made up of the inherent filtration and any added filtration) should be equivalent to not less than 1.5 mm Al for nominal X-ray tube voltages up to and including 70 kV, and not less than 2.5 mm Al (of which 1.5 mm Al should be permanent) for nominal X-ray tube voltages above 70 kV
- Where materials other than aluminium have been used as filters, the X-ray tube should be clearly marked with the chemical symbol and thickness in millimetres of the filter or marked with the equivalent filtration in millimetres of aluminium

4.1.1.3 Display and recording of parameters relevant to patient dose

- Equipment installed on or after 6 February 2018 must have a device, or other feature, capable of informing the IRMER practitioner of relevant parameters for assessing the patient dose (such as exposure time, operating potential, tube current, field size or collimation options etc.)
- Dental CBCT equipment installed on or after 6 February 2018 must have the capacity to transfer information relating to these parameters to the record of a person's exposure (for instance, within or accompanying the DICOM image file)

4.1.2 Requirements for intra oral X-ray equipment

In addition to the requirements in 4.1.1, intra oral X-ray equipment should also meet the following requirements:

- The operating potential of new equipment should be in the range 60 to 70 kV
- Rectangular collimation should be provided as standard
- The spacer cone should provide a minimum focus-to-skin distance of at least 200 mm
- There should be a sufficient range of exposure time and/or tube current settings available to enable even the fastest digital imaging systems to be exposed correctly and consistently

4.1.3 Requirements for panoramic X-ray equipment

In addition to the requirements in 4.1.1, panoramic X-ray equipment should also meet the following requirements:

- The operating potential of new equipment should be in the range 60 to 90 kV
- New equipment should be provided with automatic selection of field limitation to use when it is not necessary to take a full panoramic view (e.g., sectional images of wisdom teeth or paediatric settings)
- The beam height at the image receptor or secondary collimator should be no more than required to expose the area of interest and the beam height and width should be no greater than the height and width of the image receptor in use
- The start and end of X-ray emission should be correctly synchronised with the image capture process so that the X-ray beam is contained within the active area of the image receptor
- Light beam and physical alignment aids should be available to assist with patient positioning
- There should be a sufficient range of exposure time, operating potential and/or tube current settings available to take into account patients of different sizes and the range of speeds of imaging systems available

4.1.4 Requirements for cephalometric X-ray equipment

In addition to the requirements in 4.1.1, cephalometric X-ray equipment should also meet the following requirements:

- The operating potential of new equipment should be in the range 60 to 90 kV
- To minimise magnification effects, the focus-to-image receptor distance should be greater than 1 m and ideally within the range 1.5 to 1.8 m
- New equipment should be provided with automatic selection of beam limitation for use when only a partial view is required
- The beam height at the image receptor or secondary collimator should be no more than required to expose the area of interest and the beam height and width should be no greater than the height of the image receptor in use
- The start and end of X-ray emission should be correctly synchronised with the image capture process so that the X-ray beam is contained within the active area of the image receptor
- The patient should be positioned by means of a cephalostat
- There should be a sufficient range of time, operating potential and/or tube current settings available to take into account patients of different sizes and the range of speeds of imaging systems available

4.1.5 Requirements for dental CBCT X-ray equipment

In addition to the requirements in 4.1.1, dental CBCT X-ray equipment should also meet the following requirements:

- The operating potential of new equipment should be in the range 60 to 120 kV
- New equipment should be provided with a range of field of view (FOV) options that are matched to the full range of diagnostic tasks the equipment could be used for; the collimation should be adjusted automatically depending on the

FOV selected (although the manual fine adjustment of collimation based on a scout view is acceptable)

- Light beam and physical alignment aids should be available to assist with patient positioning
- There should be a sufficient range of time, operating potential and/or tube current settings available to take into account patients of different sizes

Detailed guidance on how to correctly use dental X-ray equipment to successfully optimise patient doses is provided in section 4.3 of this guidance.

4.2 Selection of image processing and viewing facilities

Whether a digital or film-based imaging system is used, the fastest available system compatible with satisfactory diagnostic results should be selected. See section 4.3 for specific guidance on this.

In order to extract full diagnostic information from the image and avoid unnecessary repeat examinations it is also essential to have dedicated, suitable, and well-maintained image processing and viewing facilities. Where there is more than one viewing station, the viewing conditions should be consistent across the practice. See section 5.3 for details of the QA programme for image processing and viewing facilities.

4.2.1 Display screen equipment and viewing conditions

It is important that digital images are always viewed and interpreted on a suitable display device under ideal lighting conditions to extract the maximum diagnostic benefit from the exposure. Display screens used to interpret images should be supported by regular checks as part of the overall QA programme, and the brightness and contrast adjusted if necessary using a suitable test pattern (see section 5.3). Display screens that cannot meet the basic QA tests described in Appendix I are unlikely to be suitable for diagnostic purposes.

The ambient room lighting should be free from glare and distracting reflections and set to a level to maximise the inherent contrast arising from the screen; this is likely to be a lower level than usual for a working dental surgery or office.

The MPE should be consulted as necessary on the selection of suitable display screen equipment and appropriate viewing conditions.

For information, the Royal College of Radiologists (RCR) publishes guidance on diagnostic display devices and on ergonomics of the work place, including viewing conditions. This is reviewed and updated regularly and the reader is advised to check the RCR website (see <https://www.rcr.ac.uk/clinical-radiology/publications-and-standards>) to obtain the most up to date guidance; however, it should be noted that the guidance is intended primarily for the hospital sector.

4.2.2 Film-based imaging systems and viewing conditions

A specially designed light-box should be installed in an area where the ambient lighting can be adjusted to appropriate levels and glare and distracting reflections can be eliminated. Suitable film masking should be used to optimise the viewing conditions by cutting out stray light. For viewing dense areas of a radiograph, the

incorporation of a high intensity light source in the light box is recommended. The provision of magnification by a factor of two is also recommended.

4.3 Operation of dental X-ray equipment

Once a dental exposure has been justified and authorised, the aim must be to produce a diagnostic image while keeping the dose to the patient ALARP.

This is a key requirement of IRMER17 which, in a dental practice setting, largely relies on the knowledge and experience of the operator, supported by a number of administrative requirements of IRMER17. These include the adequate training of operators (see sections 3.9 and 3.10), involvement of the MPE in preparing technical specifications for equipment (see sections 3.7 and 4.1), the establishment and use of guideline exposure protocols (see section 3.6.3), the establishment and use of local DRLs (see section 3.5.8) and the quality assurance of equipment (see sections 5.2 and 5.3), image quality (see section 5.4) and employer's procedures (see section 5.1).

The operator's practical skills and knowledge that are most important in the successful optimisation of patient dose are as follows:

- Selection of the most appropriate radiographic technique – the lowest dose technique that is capable of answering the clinical question should be used
- Selection of the most appropriate dental X-ray equipment and image receptor
- Selection of the most appropriate exposure protocol, making adjustments as required to take into account the size of the patient and the image quality required to answer the clinical question, ensuring that whenever possible the patient dose does not exceed the relevant local diagnostic reference level (see section 3.5.8)

The features of dental X-ray equipment that most strongly influence patient dose and which are, or may be, under the control of the operator are described below for each type of X-ray set along with how they should be used to optimise doses. Details of the design features of X-ray equipment that are important for the optimisation of patient dose are discussed in section 4.1.

4.3.1 Intra oral X-ray equipment (including hand-held)

4.3.1.1 Collimation, positioning aids and techniques

Use of rectangular collimation has been shown to reduce the effective dose to the patient by about 50% compared to circular collimation.⁵ Rectangular collimation should, therefore, always be used for periapical, bitewing and occlusal radiography, unless there are sound clinical reasons for not doing so (such as patients with additional needs who have difficulty keeping still and where the use of rectangular collimation would lead to a high number of repeat exposures). In such cases, the circumstances under which the use of circular collimation is considered justified should be documented in the guideline exposure protocol (see section 3.6.3), following consultation with the MPE.

Where X-ray equipment is supplied with a circular collimator, a rectangular collimator adaptor should be obtained and used whenever practicable. The adaptor should be tested to check that it contains sufficient shielding to modify the X-ray

beam profile and that it is fitted correctly on the spacer cone with no stray leakage of the X-ray beam. The size of the collimator should be appropriate to the size of image receptor being used; for example, the X-ray beam size at the end of the spacer cone should be no greater than 40 mm by 50 mm for a size 2 image receptor, and preferably less than 35 mm by 45 mm.

Beam aiming devices and image receptor holders should be used for periapical and bitewing radiography wherever clinically possible to ensure ideal positioning of the X-ray set in relation to the image receptor; this is essential for rectangular collimation. This will improve image quality and reduce the number of reject images requiring retakes. Circumstances where it may not be clinically possible to make use of beam aiming devices and image receptor holders (and also, therefore, rectangular collimation) may include patients with additional needs who have difficulty keeping still, and patients who are under sedation or general anaesthesia.

For periapical radiography, the paralleling technique should always be used in preference to the bisecting angle technique, unless there are clear clinical reasons for not doing so. Use of the paralleling technique is associated with improved image quality, better reproducibility and a lower patient dose compared to the bisecting angle technique.⁶ Where use of the bisecting angle technique is unavoidable (for instance when patients are under general anaesthetic), appropriate holders should be used where practicable. Use of the bisecting angle technique may involve the thyroid gland being exposed to the main X-ray beam for some projections, such as for the maxillary incisors and maxillary canines; this should be avoided whenever clinically possible. In cases where it is unavoidable that the main X-ray beam will be directed at the thyroid gland or very close to it, the MPE should be consulted regarding the use of a suitable thyroid shield (see section 4.4.2).

4.3.1.2 Operating potential (kV)

Where it is possible to select the operating potential, use of a higher setting is associated with lower patient dose. This benefit should be balanced against the possible detriment of a slight reduction in image contrast. Where X-ray sets operating at 60 kV are used with film-based imaging, care should be taken to ensure that the patient dose does not exceed the national DRL.

X-ray sets generating a constant potential ('DC' or 'gridded') waveform produce an X-ray beam with a higher mean energy than an 'AC' unit at the same operating potential, producing a lower patient dose. The majority of modern X-ray sets on the UK market at the time of publication have DC waveforms, older X-ray equipment is more likely to be of the 'AC' type.

4.3.1.3 Focus to skin distance (FSD)

A spacer cone that produces a focus-to-skin distance of 30 cm is associated with significantly lower patient doses compared to a shorter cone producing an FSD of 20 cm (all other factors being unchanged). Use of a longer cone will also improve image quality, as the X-ray beam is less divergent when it intercepts the patient. Where an X-ray set is supplied with interchangeable cones, the longer cone should be used. However, care must be taken to select the correct exposure settings at the control panel for the length of cone used.

The end of the spacer cone should always be placed as close as possible to the patient's skin, but without touching, in order to reduce the size of the incident X-ray beam and consequently the dose to the patient.

4.3.1.4 Selection of appropriate exposure settings

Most modern intra oral X-ray sets have control panels displaying an array of icons representing the exposure settings available for different anatomical views and patient sizes. The timers of these X-ray sets should be programmed to match the range of available exposure times to the speed of the imaging system in use, in accordance with the advice of the MPE.

The operator is responsible for ensuring that the equipment is operated correctly and in accordance with the guideline exposure settings. The operator will also have to use their judgement in cases when it may be necessary to depart from the guideline settings (for example, due to an unusually large or small patient).

4.3.1.5 Compatibility with digital image receptors

Older X-ray sets, particularly those with AC waveforms, may not have exposure timers with the very small exposure times that are often required to take full advantage of the dose reduction potential of DR or CR digital imaging systems compared to film. This is particularly relevant when dental practices upgrade their imaging facilities from film to digital. Due to the automatic image correction algorithms in image processing software, any unnecessarily high exposure of digital sensors or phosphor plates, and consequently patients, might not be apparent to the operator. The MPE should, therefore, be consulted regarding the suitability of existing X-ray equipment prior to its use with any new digital imaging systems.

4.3.2 Hand-held X-ray equipment

Dental X-ray equipment designed to be held in the hands should comply with the design standard specified in chapter 3 of the *Guidance on the Safe Use of Hand-Held Dental X-ray Equipment*.³ The above guidance for intra-oral X-ray equipment is equally applicable to hand-held equipment, however, operators will require additional practical training before commencing clinical use. This additional training should cover the different approach to patient positioning that is necessary for hand-held equipment in order to restrict the X-ray beam to the horizontal plane, and the effective use of rectangular collimation, bespoke beam aiming devices and image receptor holders.

4.3.3 Panoramic and cephalometric X-ray equipment

4.3.3.1 Collimation

An appropriate X-ray field size should be selected to image only the area of clinical interest as this may significantly reduce the patient dose (for example, by selecting a sectional view instead of a full panoramic view). Exposure of the thyroid gland to the main X-ray beam should also be avoided. Panoramic and cephalometric equipment is generally provided with a range of collimation options that allow for this.

The appropriate patient size setting should always be selected as this will adjust the X-ray field size and, in the case of panoramic equipment, match the size of the 'focal trough' to the patient.

4.3.3.2 Manual selection of exposure settings

Modern panoramic and cephalometric X-ray sets have control panels displaying an array of icons representing the pre-set exposure settings available for different anatomical views and patient sizes, which generally include the operating potential, tube current (mA), exposure time and collimation, some or all of which may be adjustable or programmable by the operator. Reprogramming the default settings should only be carried out in accordance with the advice of the MPE.

The operator is responsible for ensuring that the equipment is operated correctly and in accordance with the guideline exposure settings. The operator will also have to use their judgement in cases when it may be necessary to depart from the guideline settings (for example, due to an unusually large or small patient).

4.3.3.3 Automatic exposure control (AEC) and displayed dose

AEC systems, which are provided on a small number of units, automatically select the exposure settings according to the size of each patient which is determined by the degree of attenuation of the X-ray beam during the exposure cycle. However, the patient doses resulting from use of the AEC should be checked against the relevant national DRLs and adjusted if necessary, in accordance with the advice of the MPE, to ensure these are not routinely exceeded.

Many panoramic and cephalometric units provide a display of the patient dose based on the exposure settings selected in units of dose area product. The accuracy of the displayed dose is known to vary between units and should be checked by the MPE if the practice intends to use it for dose control purposes.

4.3.3.4 Patient positioning

Accurate patient positioning using the light beam markers is important so that the correct area of interest is captured, and the patient is properly aligned with the focal trough.

Immobilisation devices, such as head rests, chin cups and head straps or ear rods, must be used to prevent patient movement that could lead to artefacts. Patients should be instructed to remain still throughout the exposure.

For panoramic radiography, it is also useful to ask the patient to close their eyes to prevent them inadvertently turning their head during the exposure cycle. Just before the exposure is made, the patient should be asked to swallow, place their tongue against the roof of their mouth and then to keep very still until the machine stops moving.

4.3.4 Dental CBCT X-ray equipment

It is stressed that dental CBCT images must not be taken purely to reconstruct a panoramic or cephalometric image as the patient dose associated with a dental CBCT image is higher than from a conventional panoramic radiograph, and much higher than from a cephalometric radiograph.

4.3.4.1 Volume size

If the dental CBCT unit 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 unit has a fixed large volume size and the region of interest is small, the justification of the examination should be reviewed carefully to decide whether to proceed.

4.3.4.2 Exposure factors and voxel size

Where the manufacturer sets pre-programmed exposure factors, it is often possible to significantly reduce the default exposure factors (kV, mA, time or mAs) without apparent loss of accuracy of linear distance measurements. Image quality is likely to be affected, although it may still be possible to reduce the default exposure factors without compromising diagnostic quality.⁷⁻¹¹ Optimal exposure factors should, therefore, be selected to satisfy the diagnostic requirements of each examination, in consultation with the MPE.

The size and age of the patient should also be considered when selecting the exposure factors. Head size in particular is a useful indicator of exposure needs.¹²

High resolution images generally involve higher doses to the patient than low resolution images, all other factors being equal. Where compatible with the diagnostic aims of the examination, a larger voxel size, lower mA, lower exposure time, lower mAs or a combination of these would reduce patient dose.

There are currently few evidence-based guidelines on which to base imaging protocols for different imaging tasks, and so clinical judgement has to be used when selecting the appropriate voxel size. For example, if fine detail is required for examining the root canal during endodontics, then a smaller voxel size (leading to higher resolution but also higher patient dose) may be appropriate. For implant planning where bone morphology is being assessed, it may be possible to select a larger voxel size (and lower exposure factors and lower patient dose) without decreasing the diagnostic yield.

4.3.4.3 Angle of rotation

Some units offer both a full and partial rotation scan where the arc of rotation can be reduced, for example from 360 degrees to 270 or 180 degrees. This reduces the number of basis projections taken and hence the dose, in proportion to the reduction in rotation angle (e.g., a reduction in dose of 50% for a reduction in rotation angle from 360 to 180 degrees). These reduced dose scan protocols can often be used with little or no loss of diagnostic information, in which case they should be selected routinely. Care should be taken, however, where metal posts or other dense restoration materials are present as reduced angle protocols may lead to increased image artefacts in these cases.

4.3.4.4 AEC systems and displayed dose

A small number of dental CBCT units are equipped with AEC systems. Where the AEC sets the exposure parameters based on a scout view, the additional patient dose resulting from this is generally low and may potentially lead to a reduced overall dose due to the unit selecting appropriate factors.

As for panoramic and cephalometric equipment, patient doses resulting from use of AEC systems on dental CBCT units should be checked against the relevant

national DRLs to ensure these are not exceeded. The accuracy of the displayed dose should be checked if the practice intends to use it for dose control purposes. The MPE should be asked to assist with these matters.

4.3.4.5 Patient positioning and immobilisation

Accurate patient positioning using the light beam markers is important so that the correct area of interest is captured in the volume, especially when a small field of view is to be used. Where available, a scout view should be taken before the full exposure 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 and not to swallow throughout the exposure. It is also useful to ask the patient to close their eyes to prevent them inadvertently turning their head during the exposure cycle. Children are much more likely to move during CBCT examinations¹³⁻¹⁵ and past experience of patient co-operation should be used when deciding whether a CBCT scan is feasible or not.

If there has been minimal patient movement but the scan is still diagnostically acceptable then 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, and where possible, this should be done in preference to repeating the exposure.

4.3.5 Image receptors

4.3.5.1 Intra oral radiography

There are two types of digital imaging systems available; solid state detectors (SSDs), also referred to as direct digital radiography (DR) and photostimulable phosphor plates (PSPs), otherwise known as computed digital radiography (CR). Both systems offer a dose reduction compared with chemical film-based imaging, although some PSPs have effective speeds comparable to speed group D film, and should, therefore, be avoided.

DR systems generally require a slightly lower dose than CR. However, CR systems have a greater latitude than film and DR systems such that both overexposure and underexposure can result in near-perfect images. Care is required to avoid unnecessarily high exposures with both types of digital imaging, as this may not be apparent in the radiographic image.

Where chemical film-based imaging continues to be used, speed group F film should be selected as this is approximately 20% faster than speed group E film. Speed group D film is associated with high patient doses and should no longer be used.

Self-developing film should only be used where it is impracticable to use digital imaging or conventional film with rapid processing facilities (e.g., during surgery or general anaesthesia, or in a domiciliary care setting). Where the use of self-developing film is essential, care should be taken to ensure it is of the fastest available

speed (with the advice of the MPE). Staff must also be properly trained in its use to ensure consistently good quality images are produced and the practice's QA programme should specifically check that this is the case.

4.3.5.2 Extra oral radiography

Both DR and CR digital systems may be employed for panoramic and cephalometric radiography. For panoramic radiography the dose saving afforded by a digital system can vary greatly and the MPE should be involved at the equipment procurement stage to provide advice. For cephalometric systems, the use of a digital system that scans a narrow X-ray beam across the patient generally provides a significant dose reduction compared to a system employing either a large digital image receptor or a film cassette and intensifying screen.

Where film continues to be used for extra-oral radiography, the fastest available film and intensifying screen combination, consistent with satisfactory diagnostic results, should be used. The effective speed of the film-screen system should be at least 400. The light sensitivity of the film must be correctly matched to the colour of the light emitted by the intensifying screen during radiography (for instance, if the screen emits light in the green part of the spectrum then green light-sensitive film must be used).

4.3.5.3 Dental CBCT imaging

Dental CBCT equipment employs DR image receptors almost exclusively, although there are a small number of image intensifier-based systems available at the time of publication. For dental CBCT equipment, factors other than the detector technology tend to have the greatest influence on patient dose and image quality, as referred to in sections 4.3.4.

4.4 Use of patient contact shielding

4.4.1 Protective aprons

There is no justification for the routine use of protective aprons for patients undergoing any form of dental radiography or dental CBCT imaging as the main X-ray beam should never be directed towards the abdomen. Doses to the patient or the foetus from scattered X-rays and leakage will then be negligible as will the associated risk. See also section 3.5.3

4.4.2 Thyroid shields

For intra-oral, panoramic and cephalometric radiography, the use of appropriate equipment, exposure factors, technique (e.g., paralleling technique as opposed to bisecting angle technique for intra oral radiography), collimation or field limitation techniques all have an equal or greater influence on the dose to the thyroid than provision of a thyroid shield. As these factors also reduce both the effective dose to the patient and the exposure of the operator, these measures should be advocated in preference to the use of a thyroid shield.¹⁶

Thyroid shields should, nevertheless, be used in any situation when the thyroid gland may unavoidably be in the primary X-ray beam, based on advice from the MPE. This may occur in some circumstances such as the following:

- Dental CBCT, panoramic or cephalometric examinations where the field

of view extends well below the mandible – in these cases the advice of the MPE should be sought, taking into account the specific examination and model of X-ray unit

- Upper standard (or anterior) occlusals and maxillary central incisor views taken with the bisecting angle technique, where the intra oral X-ray beam may irradiate the thyroid gland
- Certain patient groups requiring unusual positioning techniques which may place the thyroid in the primary beam

For all extra-oral imaging the operator should ensure, as far as possible, that the thyroid shield is outside the primary X-ray beam, to avoid the adverse effects of scattered X-rays on the diagnostic quality of the image.

For CBCT systems using an AEC and where the MPE has advised it is appropriate for the patient to wear a thyroid shield, the thyroid shield should not be worn for the scout view, as its presence might lead to an inappropriately high exposure being used for the scan. It should be positioned after the scout view has been taken.

Table 4.1 Requirements of IRMER17 – Optimisation of patient dose – summary of key aspects

Topic	Brief description of requirement	Relevant section of this guidance
Selection of dental dental X-ray equipment	Consult MPE when drawing up technical specifications for new X-ray equipment to ensure that it is capable of restricting patient doses to ALARP.	4.1
	Dental CBCT equipment must be supplied with suitable software and display screens for clinical imaging, and supplied with test objects, software and imaging tools for QA purposes.	5.2.5
Selection of new ancillary equipment	Consult MPE when drawing up technical specifications for new ancillary equipment to ensure that it is capable of restricting patient doses to ALARP.	4.1
	<ul style="list-style-type: none"> • Display screens should meet the recommended standard • Specially-designed light-boxes should be used to view film radiographs • Attention should be paid to the adequacy of the viewing conditions for all dental radiographs or dental CBCT images 	4.2

Table continued on next page

Table continued

Topic	Brief description of requirement	Relevant section of this guidance
Operation of X-ray equipment	Operators to select the most appropriate X-ray equipment, radiographic technique and appropriate protocol (including collimation and field of view where relevant) in order to keep patient dose ALARP; for <ul style="list-style-type: none"> • Intra oral X-ray equipment • Hand-held dental X-ray equipment • Panoramic and cephalometric equipment • Dental CBCT equipment • Image receptors 	4.3.1 4.3.2 4.3.3 4.3.4 4.3.5
Use of patient contact shielding	Protective aprons and thyroid shields are not recommended for routine use on patients.	4.4

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5 QUALITY ASSURANCE IN DENTAL RADIOLOGY

The purpose of quality assurance (QA) in dental radiology is to ensure consistently adequate diagnostic information, whilst radiation doses to patients (and other persons) are kept ALARP, taking into account the relevant requirements of IRMER17 and IRR17.

The QA programme should be comprehensive, based on evidence-based guidance where possible, and convenient to operate and maintain. It should contribute to the overall efficiency of operations by being well structured. Formal records will need to be maintained and checked; this is an essential feature of QA.

A basic principle of quality assurance is that, within the overall QA programme, all necessary procedures are set down in writing. In particular, the following are recommended:

- Implementation of the overall QA programme should be the responsibility of a named person (usually the practice owner or a senior partner)
- The various tasks required by the QA programme should only be undertaken by suitably trained staff
- The frequency of operations should be defined
- The content of the essential supporting records should be defined, as should the frequency for the formal auditing of such records and the required retention times

The overall QA programme should cover the following important subject areas:

- QA of the employer's procedures required by IRMER17 (distinguished from any other form of procedure by using italics: "*employer's procedures*")
- QA of X-ray equipment and patient dose
- QA of image processing and display equipment
- QA of image quality

These are discussed in sections 5.1, 5.2, 5.3 and 5.4 respectively. An overall procedure should also be drafted, in consultation with the MPE, to ensure that the QA programmes in respect of written procedures, written protocols and equipment are followed. A suggested example is provided in Appendix D.

5.1 QA programme of employer's procedures

5.1.1 Radiation protection file

The provision of a radiation risk assessment, local rules, contingency plans and *employer's procedures* are legal requirements as described in sections 2.10, 2.16, 2.17 and 3.5. It is suggested that master copies of all the procedures, operational records and other documents (such as the radiation risk assessment) that are essential to the safe use of X-ray equipment, are held together in a specified location that is known to all staff who have responsibilities for completing, maintaining, reviewing or working in accordance with them.

This radiation protection file may be held in either hard copy (printed) version or stored electronically. It should be kept up to date, in good order and be readily accessible by all staff who need access to it during day-to-day work or practice inspections.

In addition to the *employer's procedures* required by IRMER17, operational procedures should be provided for all activities that indirectly affect radiation safety and diagnostic quality, i.e. those not directly linked to the use of the X-ray equipment. An example would be procedures for the correct preparation and subsequent use of processing chemicals.

The QA programme should include the maintenance of a procedures log to record the existence of the local rules, *employer's procedures* and operational procedures, together with a record of each occasion on which they are reviewed or modified, and their issue to relevant staff. It is recommended that such reviews are undertaken whenever the circumstances at the dental practice change, or otherwise at routine intervals not exceeding three years. All such procedures should be marked on each page with a version number or date to enable effective document control within the practice.

5.1.2 QA procedures for training

IRMER practitioners and operators (and those who refer patients for dental CBCT examinations) must have received adequate training as set out in sections 2.21, 3.9 and 3.10, to meet the requirements of IRR17 and IRMER17*. The practice's QA programme should incorporate a register of all staff involved with any aspect of dental radiology and include the following information:

- Name
- Responsibilities defined under IRR17 and/or IRMER17 (e.g., RPS, IRMER practitioner, referrer, and which operator duties they perform)
- Date and nature of training received
- Recommended date for a review of training needs (this should be set so as to identify training needs before the recommended dates for refresher training have elapsed)

*It should be noted that IRMER17 does not mandate any training for referrers. Apart from dental CBCT, the training needs of persons entitled to act as referrers would be covered by the professional qualifications of each registrant group that is permitted to refer under the GDC Scope of Practice document.

This register should incorporate details of the formal training provided for staff under both IRR17 and IRMER17, and any informal in-house training, briefings or instruction that is provided for employees (for instance, covering the requirements of the local rules or *employer's procedures*).

5.2 QA programme for X-ray equipment

The employer is required by IRMER17 to establish a QA programme, in consultation with the MPE, to ensure that equipment remains capable of the adequate restriction of patient dose.

The QA programme must include the following:

- An inventory of all dental X-ray equipment and ancillary equipment which would influence the dose to the patient
- Adequate testing before the first clinical use (commonly known as 'acceptance testing')
- Routine retesting at appropriate intervals and following any major maintenance
- In-house checks where appropriate (see sections 5.2.4 and 5.2.5)
- Representative measurements of patient dose
- Remedial and suspension levels for action

It should be noted that IRR17 also requires the employer to have a QA programme for the maintenance and examination of engineering controls; guidance on this is set out in section 2.20.

5.2.1 Equipment inventory

The inventory must include details of each X-ray set and imaging equipment (such as a phosphor plate reader, desk-top film processor, direct digital sensors, film cassettes, light-boxes for viewing films or computer screens used for viewing digital clinical images). It must include the following details for each item of equipment:

- The manufacturer
- Model name or number
- Serial number or other unique identifier
- Year of manufacture
- Year of installation

5.2.2 Adequate testing

IRMER17 requires the employer to undertake adequate testing ('acceptance testing') before X-ray equipment is put into clinical use. The purpose of this is to confirm that the equipment is operating correctly and is capable of the adequate restriction of patient dose. Installers often provide acceptance testing on behalf of the user at the same time as the critical examination (required under IRR17), and employers should confirm with the installer that both the critical examination and acceptance test will be carried out, and a report of the results provided, before clinical use commences. If this is not the case, the employer should consult its MPE regarding alternative arrangements (see sections 2.9, 3.7 and 6.1).

5.2.3 Routine testing and tests after repairs or modifications

Routine tests should normally be carried out at intervals not exceeding three years, except in the following circumstances where annual testing is recommended, subject to the advice of the practice's MPE:

- Patient doses consistently exceed the relevant NDRL despite previous recommendations to reduce the dose
- Image quality analysis indicates a persistent failure to meet the targets specified in section 5.4.1 (or other targets set in consultation with the practice's MPE where appropriate)
- For dental CBCT equipment, where no suitable QA test object (see Appendix I2) is available
- For hand-held dental X-ray equipment, in all cases

Annual testing should be maintained until the MPE advises that acceptable performance has been restored or achieved.

Testing should also be carried out following any repairs or modification of the equipment that could significantly affect image quality or patient doses. Examples include:

- Relocation of X-ray equipment (including re-installation in the same location, e.g. following surgery refurbishment)
- Replacement of the X-ray tubehead or other important feature which will affect radiation dose
- Upgrading of existing equipment to include additional modalities, e.g. of panoramic equipment to introduce cephalometric or dental CBCT capability (even if this involves purely a software upgrade)

If in doubt, the MPE should be consulted regarding the need for, and scope of, any testing following repairs or modification. The potential need for a critical examination should also be considered by the person installing, repairing or upgrading the equipment, who should consult their RPA on this matter (see section 2.9).

Appendix I details the recommended content of acceptance tests, routine tests and tests after repair or modification and the relevant action levels and suspension levels.

5.2.4 In-house QA checks on X-ray equipment

Both IRR17 and IRMER17 require employers to maintain routine surveillance of those features of X-ray equipment that could affect the radiation safety of staff or patients. Operators should, as a matter of habit, check the correct functioning of the following during their work:

- Safety and warning systems (lights, audible warnings, etc.)
- Exposure switch
- Intra oral arm counterbalance
- Smooth and unimpeded rotational or scanning motion of panoramic, cephalometric and dental CBCT equipment
- The overall general condition of the tube head and any other relevant physical attributes of the X-ray equipment

It should also be noted that deficiencies in the operation of X-ray equipment may first be apparent in clinical images.

A record of the above checks should be completed at least once every six months to confirm that this routine surveillance has been maintained.

5.2.5 In-house QA checks on dental CBCT X-ray equipment

In addition to the checks advised in section 5.2.4, dental CBCT systems should be subject to regular imaging performance checks using the manufacturer’s QA test object. The results should be compared to the manufacturer’s performance specification or, where relevant, the action levels and suspension levels set out in Appendix I. In addition, any test images generated using QA test objects should be visually checked for any non-uniformities and artefacts that might detract from diagnostic performance.

These checks should be carried out, and a record of the results kept, at the frequency recommended by the manufacturer, or otherwise, as specified in Appendix I. Where any remedial or suspension levels are exceeded, the employer should seek advice from the MPE. Should any suspension levels be exceeded, the equipment should be immediately withdrawn from use until the matter has been resolved. A record should be kept of any remedial action taken.

5.3 QA programme for image processing and viewing facilities

Digital sensors and phosphor plates are reusable, and as a result are subject to wear and tear during normal use, and may suffer damage from mishandling, which could affect image quality. Their condition and performance should therefore be checked at suitable intervals as summarised in Table 5.1, and the results recorded. Before these tests are carried out, the display screen used for viewing images and the viewing conditions should be checked and adjusted if necessary.

Provided that the sensors and phosphor plates are handled carefully during routine use, cleaning should only be required infrequently. When cleaning is necessary it should be in accordance with the manufacturer’s instructions.

TABLE 5.1 Recommended schedule of QA tests for digital image receptors

Test	Frequency	Fail criteria
1 Visual inspection	Three-monthly, or whenever damage is suspected	Damage to wires, casings or phosphor
2 Image uniformity	Three-monthly, or whenever damage is suspected	Evidence of significant deterioration compared to baseline image. Any artefact that may affect clinical image quality
3 Subjective check of image quality	Three-monthly, or whenever damage is suspected	Evidence of significant deterioration compared to baseline image

5.3.1 Intra oral image receptors

5.3.1.1 Visual inspection

The image receptor should be removed from any protective packet, inspected for damage (including any cables for sensors), and cleaned if required. Phosphor plates should be erased prior to being exposed during the uniformity or image quality checks, and before returning to clinical use.

5.3.1.2 Image uniformity

Each image receptor should then be exposed to a low dose (the child mandibular incisor setting may be used) with nothing between the image receptor and the X-ray tube. For consistency, the same X-ray set and exposure settings should always be used (note that too low a dose may produce a noisy image with a granular or textured appearance). The image should then be viewed on a suitable display screen. The image should show a uniform density over the exposed portion of the plate or sensor with no artefacts or signs of damage. The image should be assessed in accordance with the guidance below and the findings recorded.

Phosphor plates are prone to damage in a number of ways which may be apparent in the image, including the following:

- Cracking of the phosphor due to being over flexed, or repeated flexing
- Delamination of the phosphor from its mounting substrate (usually around the periphery of the plate) which may be due to ingress of liquid (e.g., during cleaning and disinfection, or from the patient's mouth)
- Scratches and other damage caused by bite marks, mishandling (e.g., abrasion with a surface when not in its protective cover) and through normal use such as when it passes through the reader

Figure 5.1 shows a clinical image, taken with a phosphor plate, with clearly visible scratch marks, delamination on the left and right-hand sides and small, bright features due to either specks of debris on the plate or a deep loss of phosphor material. The image is not considered diagnostically acceptable.



Figure 5.1 Clinical image showing signs of damage to a phosphor plate image receptor
Image courtesy of Professor Keith Horner

Phosphor plates should be replaced when damage is observed (particularly towards the central region) that could significantly affect diagnostic performance. It may be useful to generate a baseline image when the plate is new, against which images produced during routine tests may be compared.

Other issues that may be observed are finger marks or smudges and dust on the plate (seen as light or dark spots) or on the optics within the reader (often observed as a straight line passing across the image) indicating that cleaning of the phosphor plate or of the reader's optics are required. The latter may require the services of an engineer, or the cleaning procedure may be described in the user manual, which should be referred to.

In the case of digital sensors, non-uniformities in the form of squares or rectangles may indicate an issue with the sensor and remedial action should be taken. Dead pixels and lines may also be observed as bright features. Dead pixels can be tolerated in small numbers. Where there are a significant number of dead pixels, or a close grouping of dead pixels, remedial action will be required.

5.3.1.3 Check of image quality

A subjective check of image quality may be achieved using a step wedge or a commercially available phantom. This should be imaged using the same X-ray set each time, at a normal clinical exposure setting (such as that for an adult mandibular molar). The resultant image should be inspected and compared to the baseline result (e.g., 9 out of 10 steps visible) or the phantom manufacturer's specification. The findings should be recorded.

5.3.2 Panoramic and cephalometric image receptors

5.3.2.1 Visual inspection

The phosphor plate or sensor should be visually inspected as described for intra oral image receptors, and the findings recorded.

5.3.2.2 Image uniformity

A test image should be obtained by carrying out an exposure using the standard child panoramic setting with a 1 mm copper filter positioned over the beam port at the tube exit, without a patient present and with the AEC (if any) turned off. The image should then be viewed on a suitable display screen. This should show a uniform density over the exposed portion of the plate or sensor with no artefacts or signs of damage, usually with a darker vertical band in the centre of the image where the spinal compensation has increased the exposure of that portion of the image receptor to compensate for the extra attenuation due to the spine. This is illustrated in Figure 5.2.

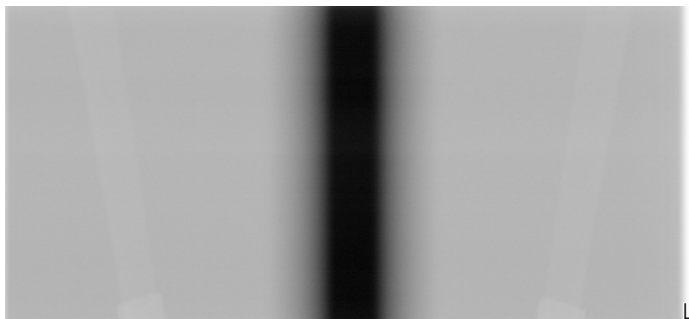


Figure 5.2 Typical panoramic image taken with a digital sensor in the absence of a patient, showing the central region of spinal compensation

The image should be assessed in accordance with the guidance provided above in section 5.3.1.2 and the additional comments in this section. The findings should be recorded.

The panoramic image capture process involves the tubehead rotating around the patient's head, accompanied by the side-to-side scanning action of the image receptor. Any irregularities in these motions will therefore produce non-uniformities in the resultant image, usually as additional dark vertical bands in positions corresponding to the irregularity of the motion of the tubehead or image receptor. Similar vertical bands will appear, usually at the left or right-hand edges of the image, if these rotating and scanning motions are poorly synchronised with the start and end of X-ray emission.

5.3.2.3 Check of image quality

Subjective image quality should be assessed using the manufacturer's QA phantom (if available), in accordance with the manufacturer's instructions. Alternatively, a step wedge may be attached to the centre of the detector, taking care to ensure the steps lie horizontally (it may also be necessary to employ a 1 mm copper filter as in the uniformity test). An exposure setting for a standard adult panoramic radiograph should be used, the resultant image inspected and the number of distinct steps in the image determined. The result should be compared (where relevant) to a baseline image and recorded.

If the unit has cephalometric capabilities, the above tests should be repeated in this mode, using a 1 mm copper filter and a step wedge and exposures settings as for a child lateral cephalometric radiograph. Alternatively, the manufacturer's QA test object should be used in accordance with the accompanying instructions.

5.3.3 Display screens and viewing conditions

Display screens will deteriorate over time and may need replacing within the lifetime of the X-ray equipment. They should be regularly checked and if necessary adjusted, using a suitable test pattern such as those available from the Society of Motion Picture

and Television Engineers (SMPTE) or the TG-18 QC test patterns which are available from the American Association of Physicists in Medicine (AAPM) website in DICOM and 16 bit TIF format, along with guidance on their use.¹ Checks should be carried out as detailed in Appendix I and the results recorded.

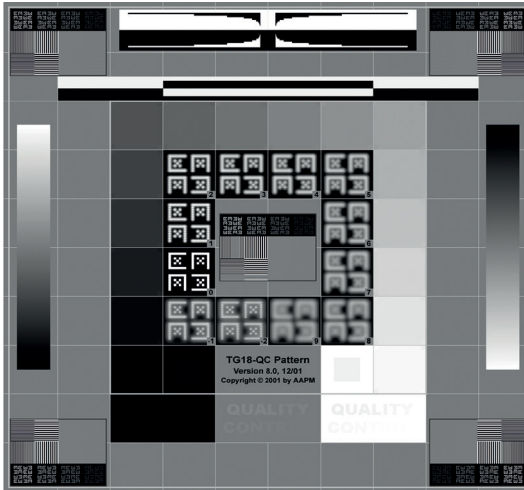


Figure 5.3 The AAPM TG-18 test pattern

5.3.4 Film-based imaging systems

Strict attention should be paid to correct and consistent film processing so as to produce good quality radiographs and avoid the necessity for examinations to be repeated. QA standards specified by the suppliers of the films, intensifying screens (if used), processing solutions and processing equipment should include the following:

- Film speed, expiry date and recommended storage conditions
- Processing conditions (times and temperatures)
- Changing frequency for processing solutions
- Cleaning instructions for automatic processors

The employer's QA programme should ensure that these standards are strictly adhered to by means of the following:

- Records and/or procedures to control film stock (this may not be necessary for practices with a high overall radiographic workload)
- Records to control and validate the chemical changes
- Cleaning records for automatic processors
- Records of checks made on the condition of film cassettes and intensifying screens and confirmation that they are used with spectrally matched film (every six months or when new screens are obtained)

5.3.4.1 Manual film processing

In the case of manual processing (e.g., using a desktop processing unit or a darkroom), checks should be made to ensure that processing units or darkrooms remain light tight and that safelights do not produce fogging of films.

A simple method is to place an unused, unwrapped dental film for 10 minutes on a working surface below the illuminated safelight(s), with a coin placed on the film. If the processed film shows an image of the coin, a further investigation should be made. This procedure can be repeated with the safelight(s) switched off to check the general light-tightness of the room. A similar procedure can also be used with desktop processing units.

In addition, a simple, routine, check for darkrooms is for a person with dark-adapted eyes (e.g. at the end of a processing session) to switch off the safelights and make a careful visual check for any signs of light entering.

These checks should be made at intervals not exceeding 12 months, and immediately following any alteration or maintenance to the safelights or to the light proofing of the room. All results should be recorded in a log.

5.3.4.2 QA of film processing

The overall performance of the processing also needs to be monitored. This may be achieved using a test-object such as a step-wedge. This test-object should be routinely radiographed, always using the same standard exposure parameters. Visual inspection of the resultant image (with comparison against a reference film if considered necessary) can detect variations in processing quality before they affect patient films. A check should be made after every change of processing solutions to ensure that conditions are satisfactory before patients' films are processed. More frequent checks, in some cases daily, may be appropriate where there is a need to closely monitor film processing (e.g. when the image quality procedures described in section 5.4 have identified deficiencies).

For large practices with a very high radiographic workload, more elaborate procedures (involving the use of sensitometry and densitometry equipment) may be appropriate, based on the advice of the MPE.

5.3.4.3 QA checks on light-boxes and viewing conditions

Routine checks are recommended, at intervals not exceeding six months, to ensure that the performance of each light-box (e.g., bulbs, light-box surface, magnifier etc.) and the viewing conditions (i.e. low ambient light) remain satisfactory.

5.4 QA of clinical image quality

5.4.1 Image quality rating

A principal objective of the employer's QA programme is to ensure the consistent production of radiographs of adequate quality for diagnostic purposes, while minimising patient doses so far as possible. It is therefore important to monitor image quality performance on a regular basis and a simple subjective image quality rating system is proposed for this.

The first edition of this guidance recommended a three-point scale for the subjective quality rating of dental radiographs. However, with the widespread use

of digital imaging systems replacing film-based imaging, one major source of reduced image quality (wet chemical processing) has been effectively removed. With regard to dental CBCT, metallic restorations in the teeth will inevitably cause artefacts in clinical images that will often be of adequate diagnostic value although not of 'excellent' quality. Consequently, the use of a two-point scale is now recommended for all forms of dental radiography and dental CBCT imaging, where the images are rated either 'diagnostically acceptable' ('A') or 'not acceptable' ('N') in accordance with Table 5.2. These recommended performance targets represent what is observed to be achievable in the majority of well-managed dental practices.

It is recognised that some practices which serve particular patient groups (for instance those with additional needs) will not be able to achieve the performance targets below. In such cases, the practice should consult its MPE and set its own performance targets and document the reasons for this in their *employer's procedures* (see section 3.5).

When viewing digitally produced images a suitable grey scale (window level and window width) should be chosen to allow optimum visualisation of the bone, teeth and other tissues. An SMPTE or AAPM TG-18QC test pattern should be used to configure the display screen if required. When viewing film-based images a suitable light-box should always be used. In both cases, the ambient viewing conditions should be optimised as described in section 5.3.

TABLE 5.2 Subjective image quality ratings of dental radiographs and CBCT images

Quality rating	Basis	Target (percentage of radiographs or CBCT images in sample)	
		Digital imaging	Film imaging
Diagnostically acceptable ('A')	No errors or minimal errors in either patient preparation, exposure, positioning, image (receptor) processing or image reconstruction and of sufficient image quality to answer the clinical question	Not less than 95%	Not less than 90%
Diagnostically not acceptable ('N')	Errors in either patient preparation, exposure, positioning, image (receptor) processing or image reconstruction which render the image diagnostically unacceptable	Not greater than 5%	Not greater than 10%

5.4.2 Image quality analysis

The employer's QA programme should incorporate a clearly defined regime to ensure that image quality is rated and the results analysed so as to permit comparison with the agreed performance targets. The image quality rating and analysis should be undertaken by an operator who is adequately trained and experienced in taking dental radiographs (or dental CBCT images) of the types being rated or audited. Two alternative approaches are suggested:

- a** A prospective evaluation whereby image quality ratings are assigned and recorded for all radiographs as they are being viewed
- b** A retrospective evaluation whereby a suitably representative sample of radiographs is drawn from clinical records at regular intervals, the image quality ratings are assigned and recorded, and the results analysed

In both cases, the analysis should be undertaken at least once every six months and the sample size should not be less than 100 images, unless the radiographic workload is too low to support this number. Where there is more than one imaging modality in use (e.g., intra oral and panoramic radiography), the results should be reported separately for each modality.

A record of each analysis of the results of image quality should be kept together with a record of any actions taken in response to the analysis. For instance, if a pattern of consistently lower image quality performance appears to be associated with a particular radiographic procedure, item of equipment or member of staff, then further investigation may indicate the underlying cause and hence a solution (modification of the procedure, repair or replacement of equipment or further training of staff). It will be particularly important to identify and take appropriate corrective action in cases where the agreed performance targets are not being achieved.

5.4.3 Reject image recording and analysis

Whenever a radiograph (or dental CBCT image) is rated to be of unacceptable diagnostic quality (image quality category 'N'), a record should be made of the underlying reason. This record should include the following details:

- a** The date
- b** Nature of the deficiency
- c** Known or suspected cause of this deficiency
- d** Number of repeat radiographs/images (if taken)

It is recommended that an analysis of the records of reject images is undertaken at the same time as the image quality analysis referred to above, i.e. every six months. As before, any emergent trends should be investigated and appropriate corrective actions identified, implemented and recorded.

Common faults that are seen in conventional dental radiographs and dental CBCT images are summarised in Appendix J.

5.5 QA audits

Each procedure within the overall QA programme will include a requirement for records to be made by the responsible person at certain intervals. The person with

overall responsibility for the QA programme should check the full programme at intervals not exceeding three years to verify that the programme is being implemented effectively. The corrective action taken in response to any shortcomings should be recorded.

Clinical audits and/or peer reviews of radiography must be provided for, as appropriate, and should include:

- The QA programme and associated records
- The justification and authorisation of radiographs (see section 3.2.2)
- The clinical evaluation of radiographs

Any such clinical audit or peer review should be carried out in accordance with the appropriate national arrangements. As above, the corrective action taken in response to any shortcomings should be recorded.

5.6 References

- 1 Samei E, Badano A, Chakraborty D, et al. Assessment of Display Performance for Medical Imaging Systems, Report of the American Association of Physicists in Medicine Task Group 18 [online]. Madison, WI: Medical Physics Publishing; 2005 Apr. Available at http://deckard.mc.duke.edu/~samei/aapm_tg18.html

6

MISCELLANEOUS REQUIREMENTS

6.1 Dental X-ray equipment engineers

Dental X-ray equipment engineers often undertake work with dental X-ray equipment, and employers at dental practices should know what is expected of engineers in terms of their arrangements for radiation protection and compliance with the requirements of IRR17.

Typical work undertaken by dental X-ray equipment engineers that is subject to IRR17 includes the following:

- Assisting the dental practice by providing the necessary information (such as adequate room plans, technical details of X-ray equipment) to enable the practice to consult its RPA regarding the planned installation or relocation of dental X-ray equipment
- Carrying out the installation of dental X-ray equipment, in which case they are responsible for ensuring the critical examination is completed satisfactorily
- The engineer carrying out the installation may also undertake test exposures as part of the critical examination
- As the supplier of dental X-ray equipment, they also have a duty to pass on the user adequate information regarding the safe use, testing and maintenance of the equipment

In order to comply with IRR17, employers of dental X-ray equipment engineers who carry out the above tasks must do the following:

- Register their work with radiation generators with HSE
- Appoint a suitable RPA (who will advise on the following matters)
- Draft a radiation risk assessment conforming to paragraphs 70 and 71 of the ACoP (which must identify the conditions under which the engineer will need to designate controlled areas when working on clients' sites, how these will be demarcated and how access will be restricted and the key working instructions needed to restrict exposure and co-operation with other employers, including hand-over arrangements)
- Draft local rules and contingency plans
- Appoint suitable staff as RPSs, provide training for them, and take steps to ensure that they are able to adequately supervise the work of the engineers

- Consult the RPA regarding the conduct of critical examinations of dental X-ray equipment they install and treatment of the results of the examinations (this is likely to require a detailed protocol to be drawn up which engineers follow, with the RPA having significant input into preparation of any report containing the results of the examination and any recommendations arising out of it, that may be passed on to the user, and further training of engineers)
- Consult the RPA regarding arrangements for the co-operation between employers (including the transfer of responsibility for compliance with IRR17 between the dental practice's employer and the engineer's employer)
- Ensure that engineers receive further training regarding how to conduct critical examinations in accordance with the protocol, as advised by the RPA

Furthermore, dental X-ray equipment engineers often carry out acceptance tests and routine tests on behalf of dental practices. The implications of this in terms of IRMER17 are as follows:

Employers of dental X-ray equipment engineers will need to:

- Make arrangements with an MPE to draw up protocols for the adequate testing of dental X-ray equipment that will meet the requirements of this guidance, and the requirements of IRMER17 (it is likely that the MPE will need to have significant input into preparation of the report containing the test results and any recommendations arising out of it, that may be passed on to the user)
- Purchase suitable instrumentation and other articles and arrange for this to be tested and maintained as appropriate, unless this is supplied and maintained by the MPE
- Put in place arrangements for the appropriate hand-over of dental X-ray equipment between the engineer and dental practice
- Ensure that dental X-ray equipment engineers are trained to an equivalent extent to RPSs, with additional training covering those subjects in Table 2, Schedule 3 of IRMER17 as relevant to dental radiography (but excluding clinical content), the testing protocols drawn up by the MPE and the correct use of any instrumentation

Employers of dental X-ray equipment engineers who undertake adequate testing should provide documentation giving an undertaking that the arrangements for the drafting of testing protocols and the training of engineers, as described above, have been met. Copies should be provided to employers at dental practices where this work takes place.

6.2 Disposal or selling-on of X-ray equipment

6.2.1 Safe disposal of X-ray equipment

When X-ray equipment has reached the end of its useful working life, the employer must ensure that it is disposed of with due regard to radiation safety. This is easily achieved by cutting the electrical power cable (once it has been switched off and disconnected from the mains supply) to render the X-ray unit inoperable. Before disposal, the employer is also advised to remove or obscure any trefoil symbols or other indications of an ionising radiation hazard that might cause unnecessary alarm, should these be noticed by any individual after disposal.

Employers disposing of X-ray equipment must also consider their duties under the Waste Electrical and Electronic Equipment Regulations 2013 (as amended)¹ and, due to the X-ray tubehead containing potentially hazardous materials such as lead, beryllium and mineral oil, the Special Waste Regulations 1996 (as amended).² Because of this, it is recommended that any contractor providing a disposal service for redundant X-ray equipment is asked to provide documentary evidence of its eventual safe and appropriate disposal.

6.2.2 Selling-on or transfer of X-ray equipment

An employer who intends to sell or transfer an item of dental X-ray equipment to another person has the same obligations to pass on adequate information to the new user regarding the safe use, testing and maintenance of the equipment as would the original supplier (see section 2.9.1 for more details).

6.3 Retention of records

IRR17 requires that some records are retained for specified timescales. Other records, while required to be kept by IRR17, do not have a specified retention timescale. In such cases, an appropriate timescale has been recommended. Table 6.1 summarises both the required and recommended timescales for retention. Both hard copy and electronic forms of records are acceptable as long as they are kept safely and easily located when required. However, please note that no account has been taken of retention times specified for non-radiological purposes in other legislation or guidance.

TABLE 6.1 Records required by IRR17 and their retention periods

Record	Retention period specified in IRR17	Retention period recommended (not specified in IRR17)
Record of registering with HSE		Until registration is changed or cancelled
Radiation risk assessment		Until superseded by updated version
Record of critical examination		Working life of the X-ray equipment
Personal dose monitoring (non-classified employees)		At least two years
Local rules		Until superseded by updated version
Investigation of contingency plans being used	At least two years	

Table continued on next page

Table continued

Record	Retention period specified in IRR17	Retention period recommended (not specified in IRR17)
Report of dose investigation level (but not dose limit) exceeded	At least two years	
Monitoring of controlled areas	At least two years	Three years recommended to match monitoring interval
Maintenance and examination of engineering controls	At least two years after subsequent test	
Checks of safety and warning features	At least two years after subsequent test	
Examination of PPE		At least two years after date of test
Records of staff training in radiation safety		At least five years
Controlled area hand-over forms		At least three years

IRMER17 requires the employer to keep numerous records and to draft numerous documents, and to ensure these are available for inspection when required by the regulators. However, retention periods are not specified in the legislation, or in guidance drafted by the enforcing authorities available at the time of publication. Until such guidance becomes available, employers at dental practices are advised to retain copies of records (including results of QA checks and audits etc.) and *employer's procedures*, for at least five years. Records of the professional qualifications of staff should be retained throughout their employment and records of staff training in radiology and radiation protection should be kept for at least five years after the end of the CPD cycle to which they relate. Copies of any reports prepared in connection with a SAUE investigation should also be retained for at least five years; however, where the exposure is confirmed to be clinically significant, a copy of the report should be retained for at least 30 years (see section 3.5.10).

NHS guidance³ recommends that general dental service records, including image data (e.g., dental radiographs or dental CBCT images) should be retained for at least 10 years from when the patient was discharged or last seen, or in the case of children, until their 25th birthday (or 26th birthday if they were aged 17 when discharged).

6.4 References

- 1 The Waste Electrical and Electronic Equipment Regulations 2013. Department for Business, Energy, Innovation and Skills.
Available at <http://www.legislation.gov.uk/ukxi/2013/3113/contents>.
- 2 The Special Waste Regulations 1996. Department for the Environment.
Available at <http://www.legislation.gov.uk/ukxi/1996/972/contents/made>.
- 3 Department of Health. Records Management Code of Practice for Health and Social Care 2016 [Online]. London, UK: Information Governance Alliance for the Department of Health; 2016.
Available at <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/codes-of-practice-for-handling-information-in-health-and-care/records-management-code-of-practice-for-health-and-social-care-2016>.

Appendix

A

Guidance for dental practices on completing an application for registration with HSE

Suggested responses to selected questions during applications for HSE registration are provided below. If in doubt as to the correct response, the employer should seek advice from their RPA.

Question	Suggested answer	Relevant sections of this guidance
Type of work with ionising radiation	Select “work with a radiation generator” only (unless you are working in an atmosphere containing radon above a certain level)	2.2 (and 2.2.1 if relevant)
How many classified radiation employees do you have?	Dental practice employees should not normally need to be designated as classified persons so this should be zero Check your radiation risk assessment which should be drafted in consultation with your RPA	2.13, 2.10
Do you transport radioactive substances?	Answer ‘No’ – this does not apply to X-ray devices	N/A
Does your employer carry out work with portable ionising radiation sources at sites belonging to other employers?	If you visit care homes or other establishments and operate your own X-ray equipment there you should answer ‘Yes’ here	N/A

Table continued on next page

Table continued

Question	Suggested answer	Relevant sections of this guidance
How many fixed sites (in Great Britain) is your employer responsible for where they carry out work with ionising radiation?	Enter the total number of premises	N/A
Please provide details of the most recent radon concentration assessment	You will only be asked this if you have selected 'working in an atmosphere containing radon above an annual concentration of 300 Bq/m³' as one of your categories of work with ionising radiation	2.2.1
Questions specific to all registrations	The application process will require you to confirm, on behalf of the employer, that the following have been put in place: <ul style="list-style-type: none"> • A risk assessment has been completed • Estimates have been made of doses to employees and appropriate steps taken • Any actions identified in the risk assessment to restrict exposures have been taken • Contingency plans have been drawn up for all reasonably foreseeable radiation accidents • A suitable RPA has been appointed and consulted • Training, information and instruction has been provided to employees and other persons • Controlled and/or supervised areas have been correctly designated and demarcated • Local rules have been drawn up and radiation protection supervisors appointed (where required) 	2.10 2.13 2.4 2.17 2.3 2.21 2.11, 2.12 2.16, 2.18

Appendix

B**Proforma radiation risk assessment conforming to paragraphs 70 and 71 of the ACoP to IRR17**

Regulation 8 of the IRR17 requires the employer to carry out a risk assessment for any source of radiation under their control, to determine what steps are necessary to restrict the exposure of his employees and other persons, for both normal working conditions and accidents/incidents.

This constitutes the radiation risk assessment for the use of dental radiography equipment and specifically considers the items listed in paragraphs 70 and 71 of the Approved Code of Practice to the Regulations, as relevant to dental radiography. Work carried out on site by employees of other organisations should be subject to their own risk assessment and is not covered here.

B1 RISK ASSESSMENT INPUTS

Paragraph 70 of the Approved Code of Practice states that the following matters should be considered:

70 a Nature of sources of ionising radiation to be used, or likely to be present, including accumulation of radon in the working environment

State the X-ray equipment's operating parameters (e.g., kV and mA ranges). Refer to section 2.2.1 for guidance on radon. If the premises are not in a radon affected area this may be stated here; alternatively, if the premises are in a radon affected area it may be more appropriate to record a separate risk assessment for radon.

70 b Estimated radiation dose rates to which anyone can be exposed

Specify the typical radiation outputs and scattered radiation doses at a certain distance, for each type of X-ray equipment.

70 c The likelihood of contamination arising and being spread

This is not relevant to dental radiography.

70 d Results of previous personal dosimetry or area monitoring relevant to the proposed work

Summarise the results of any previous personal dosimetry in terms of the typical annual effective doses to individuals, or the RPA's estimated potential annual doses to staff and other persons.

70 e Advice from manufacturer or supplier about its safe use and maintenance

Use this section to note if the equipment's user manuals have been provided, together with details of any further information such as the manufacturer's recommended service programme and any practical training provided by the supplier (e.g., from the applications specialist for dental CBCT).

70 f Engineering control measures and design features already in place, or planned

Summarise the existing (or planned) control measures and design features for both the X-ray equipment and the rooms in which it is (or will be) used.

70 g Any planned systems of work

Summarise the planned systems of work (e.g., the key working instructions in the local rules) intended to protect operators and other persons.

70 h Estimated levels of airborne and surface contamination likely to be encountered

This is not relevant to dental radiography.

70 i Effectiveness and suitability of personal protective equipment to be provided

Use this section to state what, if any, PPE is required to protect employees and other persons (excepting patients).

70 j Extent of unrestricted access to working areas where dose rates or contamination levels are likely to be significant

State that either employees are not required to enter areas where dose rates may be significant, or identify the situations when they are. Contamination is not relevant to dental radiography.

70 k, l, m Possible accident situations, their likelihood and potential severity; the consequences of possible failure of control measures – such as electrical interlocks, ventilation systems and warning devices – or systems of work; and steps to prevent identified accidents or limit their consequences

Summarise the reasonably foreseeable accidents that could occur with the dental X-ray equipment used at the practice, who could be affected, the likelihood and severity of the accidents and how they could be avoided and their consequences minimised.

B2 RISK ASSESSMENT OUTPUTS

Paragraph 71 of the Approved Code of Practice states that the radiation risk assessment will help the employer to decide:

71 a What action is needed to ensure that radiation exposure of all persons is kept ALARP

Summarise what, if any, action is needed to improve radiation protection, taking into account all the measures described in sections 70 a) to 70 m).

71 b What steps are necessary to achieve this control of exposure by the use of engineering controls, design features, safety and warning devices; and by the development of systems of work

List any additional engineering controls, safety and warning features or administrative controls that have been identified as necessary.

71 c Whether it is appropriate to provide personal protective equipment and if so, what type is adequate and suitable

Review the work with dental X-ray equipment and either confirm that no PPE is required, or identify the situations in which it is required and specify what PPE is necessary.

71 d Whether it is appropriate to establish dose constraints for planning or design purposes and if so, what values will be used

Use this section to state any dose constraints advised by the RPA for any new X-ray facilities.

71 e The need to alter the working conditions of any employee who declares they are pregnant or breastfeeding

Identify if there is a need to place any restrictions on pregnant employees working with dental X-ray equipment (breastfeeding does not have any radiological implications for dental radiography) and, consequently, if it is necessary for employees to declare their pregnancy to their employer for radiation protection purposes.

71 f An appropriate investigation level to check that exposures are ALARP

State the dose investigation level set for employees and the basis on which this was selected.

71 g Maintenance and testing schedules required for the control measures selected

Summarise the routine checks on the radiation safety features of dental X-ray equipment and rooms undertaken by employees and/or service engineers to comply with IRR17.

71 h What contingency plans are necessary to address reasonably foreseeable accidents

Summarise the actions identified in 70 k, l, m that should be included in the contingency plans.

71 i The training needs of classified and non-classified employees

Summarise, for all members of staff, the appropriate level of training to enable them to work safely and comply with IRR17. This should include formal training and in-house briefings as appropriate, and both initial training and refresher training.

71 j The need to designate specific areas as controlled or supervised and to specify local rules

Describe the extent of any controlled areas that have been designated and the conditions under which they exist, and where the local rules applying to these controlled areas are to be found.

71 k The actions needed to make sure access is restricted and other specific measures are put in place, for controlled or supervised areas

Describe how access to the controlled areas is restricted and what written arrangements are necessary to adequately restrict the exposure of non-classified persons. Describe the arrangements for monitoring radiation levels in and around the controlled area.

71 l The need to designate certain employees as classified persons

Summarise the circumstances (if any) under which employees need to be designated as classified persons, or state that this is not required.

71 m The content of a suitable programme of dose assessment for employees designated as classified persons and for others who enter controlled areas

Summarise the circumstances under which the practice provides staff with personal dosimetry or other forms of dose assessment.

71 n The requirements for the leak testing of radioactive sources

This is not relevant to dental radiography.

71 o The responsibilities of managers and workers (including outside workers) for ensuring compliance with IRR17

Identify managerial responsibilities for radiation protection within the practice and specify the individual responsibilities of employees so far as they contribute to radiation safety.

71 p An appropriate programme of monitoring or auditing of arrangements to check that the requirements of IRR17 are being met

Summarise the programme of internal auditing together with the arrangements made for the RPA to carry out inspections, reviews or audits. Specify an appropriate frequency of routine reviews of the risk assessment and other circumstances when reviews would be appropriate.

Appendix

C

Template handover form for transfer of responsibility for compliance with IRR17

Practice name and address:	
Equipment (manufacturer/model):	
Serial number/location:	
INITIAL CONDITION OF EQUIPMENT	
(To be completed by the engineer and a representative of the practice before work commences)	
1 Record of settings found at commencement of work/when switching on X-ray equipment	
Type of X-ray set/Imaging mode(s):	Intra oral / panoramic / cephalometric / dental CBCT*
Operating potential (kV):	
Tube current (mA):	
Exposure time(s):	
Patient selection:	Child / Adult / Other:
Collimation:	
Overall working condition:	Fully operational / Not working / Working but some faults (specify): *
2 Correct operation of warning signals and exposure controls	
'Power on' light:	YES / NO / Not provided*
'X-rays on' light:	YES / NO / Not provided*

*delete as appropriate

Table continued on next page

Table continued

‘X-rays on’ audible signal:	YES / NO / Not provided*
‘Deadman’ exposure control/emergency stop:	YES / NO / Not provided*
*delete as appropriate	
<p>Responsibility for compliance with IRR17 in the working area(s) detailed below is transferred from the practice to [insert name of engineer’s employer] at the time and date indicated. From this point until responsibility is transferred back to the practice, the following shall apply:</p> <p>a [insert name of engineer’s employer] shall be responsible for the designation of any controlled areas, for their demarcation (e.g. with suitable warning signs) and for the appropriate restriction of entry into these areas</p> <p>b [insert name of engineer’s employer’s] local rules will apply – not the dental practice’s</p> <p>c [insert name of engineer’s employer’s] RPS will be responsible for ensuring the above local rules are followed by all persons</p> <p>The DENTAL PRACTICE must make all relevant staff aware of the above, and co-operate with the [engineer’s employer’s] representatives so that the work can be conducted safely and in accordance with IRR17</p>	
Description of work:	
Description of controlled area(s), if any, to be designated by [engineer’s employer]:	
Signed (for engineer’s employer):	
Signed (for the practice):	
Time and date:	
<p>On completion of the work carried out by the engineer, the above X-ray equipment has been returned to its original operating condition as recorded above. Responsibility for compliance with IRR17 in the working area(s) detailed above is transferred from [engineer’s employer] to the practice at the date and time indicated below.</p>	
Signed (for engineer’s employer):	
Signed (for the practice):	
Time and date:	
<p>A COPY OF THIS FORM SHOULD BE RETAINED BY BOTH THE PRACTICE AND [ENGINEER’S EMPLOYER]</p>	

Appendix

D

Examples of template employer's procedures required by IRMER17

The following template procedures are intended to assist employers in their duty under regulation 6 (1) of IRMER17 to provide written procedures in respect of those matters described in Schedule 2, and other matters for which IRMER17 mandates the establishment of procedures. The 'other matters' are; referral criteria guidelines which are required under regulation 6(5) and the justification and authorisation of exposures required under regulations 11(1)(b) and 11(1)(c).

D1 ENTITLEMENT AND TRAINING OF DUTY HOLDERS

Objective

To ensure that structures are in place for entitlement of IRMER17 duty holders, and that records will be kept and maintained of agreed qualifications, experience and training required for individuals to perform the roles of duty holders for all types of dental exposures undertaken at '██████████' Dental Practice.

Process of entitlement

Entitlement is demonstrated by '██████████' (the entitler) recording an individual's permitted duties on behalf of the employer. The entitler must decide whether the evidence of adequate training presented is sufficient for each individual to be deemed competent and to be entitled in the role of IRMER practitioner, operator, and/or referrer for dental exposures. For each duty holder, the permitted duties should be specified.

Duty holders will be informed by '██████████' of their entitlement and of the need to maintain their competency in line with the recommendations of the GDC, and for dental CBCT exposures, section 3.10 of the Dental Guidance Notes Second Edition.

When referrals are made from other practices, '██████████' will entitle the dentists at the other practices as referrers and, if necessary, as operators for clinical evaluation depending on who will be undertaking the clinical evaluation. This may be established by means of a service-level agreement between the two practices.

The medical physics expert (MPE) will be considered to be entitled as an operator on appointment. This appointment will be made in writing.

Training and education requirements

'[redacted]' will maintain an up-to-date record of qualifications, evidence of training and continuing professional development, for each entitled person.

OR

Each duty holder is responsible for maintaining their own personal training record containing an up-to-date record of qualifications, evidence of training and continuing professional development. This will be assessed by '[redacted]' on an annual basis.

On induction of new staff and with the implementation of any new dental X-ray equipment, ancillary equipment or equipment software, there must be associated training which must be documented within each duty holder's training records. Their duties should be reassessed by '[redacted]'.

Practitioners and operators shall satisfy themselves that they have appropriate training and experience to undertake duties that they are entitled to perform. They must not carry out any duty for which they have not been trained and entitled.

Any students or other trainees may undertake any aspect of the duty for which they are being trained provided this is done under the supervision of a person who is themselves adequately trained and entitled for that duty (e.g., nurses undergoing training to become competent in dental radiography being supervised in the positioning of the image receptor, patient and X-ray tube, and selecting exposure settings). This must be 'direct' supervision and the supervisor shall take responsibility for the activity as if they had carried it out themselves.

Where the employer enters into a contract with another to engage a practitioner or operator (e.g., agency staff or MPE), the latter (e.g., MPE) shall be responsible for keeping their training records.

Agreed qualifications, experience and training required for individuals to perform each duty holder role

Registrant group	IRMER17 duty holder	Qualifications/training/ experience required
Dentist	Referrer	Registration with GDC with additional training if requesting dental CBCT
	Practitioner	Registration with GDC and undergraduate dental degree, with additional training if justifying dental CBCT
	Operator	Registration with GDC, undergraduate dental degree and local equipment training, with additional training if clinically evaluating dental CBCT

Table continued on next page

Table continued

Registrant group	IRMER17 duty holder	Qualifications/training/ experience required
Dental nurse	Operator (including radiography)	Registration with GDC, diploma or certificate in dental nursing, certificate in dental radiography and local equipment training
	Operator (not including radiography)	Registration with GDC, diploma or certificate in dental nursing or suitable in-house training
Clinical dental technician	Referrer	Registration with GDC and appropriate qualification e.g., diploma in clinical dental technology, with additional training
	Practitioner	Registration with GDC and appropriate qualification e.g., diploma in clinical dental technology, with additional training
	Operator	Appropriate qualification e.g., diploma in clinical dental technology and local equipment training
Dental hygienist	Referrer	Registration with GDC and appropriate qualification e.g., diploma in dental hygiene and dental therapy with additional skills development
	Operator	Appropriate qualification and local equipment training
Dental therapist	Referrer	Registration with GDC and appropriate qualification e.g., diploma in dental hygiene and dental therapy with additional skills development
	Operator	Appropriate qualification and local equipment training
Medical physics expert	Operator	Science degree or equivalent. Experience in the application of physics, within dental uses of ionising radiation. Recognised as an MPE by the Secretary of State and named in the list of MPEs maintained by RPA2000. Written appointment to this role

Example tasks for entitlement as a duty holder under IRMER17 at [redacted] Dental Practice	
Name of duty holder:	
Job title:	
Qualification(s):	Date obtained:
GDC registration number:	Date last checked:
Training records held by:	
REFERRER tasks at [redacted] Dental Practice	ASSIGNED AS COMPETENT Date and signature/initials of duty holder and assessor
Refer for all dental examinations	
Refer for intra oral examinations	
Refer for panoramic/cephalometric examinations	
Refer for Cone Beam CT dental examinations	
PRACTITIONER tasks at [redacted] Dental Practice	ASSIGNED AS COMPETENT Date and signature/initials of duty holder and assessor
Competent to justify requests for all dental examinations	
Competent to justify requests for intra oral examinations	
Competent to justify requests for panoramic/cephalometric examinations	
Competent to justify requests for cone beam CT dental examinations	

Table continued on next page

D2 REFERRALS FOR DENTAL RADIOGRAPHY

Objective

To outline how a referral may be made for a dental radiograph.

Responsibilities

The employer must establish referral guidelines for dental radiography, including radiation doses, and shall ensure that these are available to all referrers.

Process of referral

A clinical history and examination of every patient is performed prior to requesting any dental radiograph or dental CBCT imaging.

1 When the referrer is also the IRMER practitioner and operator

Where the referrer also acts as the IRMER practitioner and operator for a dental exposure, they must ensure that the request for the exposure is documented within the patient's dental record. Within this record, the clinical indications for the X-ray should be clear, fit with the referral criteria, the referrer must be identifiable and authorisation of the exposure as justified must be completed.

2 When the referrer is not the IRMER practitioner or operator

2.1 Accepting external referrals

The referrer will be supplied with a copy of the referral guidelines (see part 3).

When accepting referrals for X-ray examinations from other dental practices, the IRMER practitioner will ensure that the referring practice has provided the following information on a suitably completed **request card/referral form/letter**:

- Patient's full name, date of birth and address
- Dental examination requested
- Type of imaging requested
- Sufficient clinical information to justify the radiographic exposure requested
- Information required from the radiographic exposure
- Signature of referrer
- Name of referrer (printed) and GDC registration number
- Date of referral

Each request for a radiographic examination will be justified and authorised prior to an exposure and this will be recorded on the **request card/referral form/letter**.

2.2 Referring to another dental practice

The referrer requesting the radiograph must be provided with a copy of the referral guidelines by the employer at the practice that will be carrying out the exposure. The referrer will ensure that the request is in line with these guidelines. If it is likely that multiple referrals will be made to another dental practice then a service level agreement should be established between the two practices.

A **request card/referral form/letter/note within the patient's dental record** will be completed by the referrer and be sent to the operator before the dental exposure is carried out.

The essential information required on each request card/referral form/letter is listed in 2.1 above.

3 Referral guidelines

The referral guidelines used at this practice are:

Faculty of General Dental Practice (UK) 'Selection Criteria for Dental Radiography', 3rd edition, FGDP (UK), 2013 (updated 2018).
<https://www.fgdp.org.uk/guidance-standards/selection-criteria-dental-radiography>

Guidelines for the use of radiographs in clinical orthodontics. London: British Orthodontic Society, 2015. <https://www.bos.org.uk/Public-Patients/News-Publications/Orthodontic-Radiographs-Guidelines>

Radiation Protection No 172. Cone beam CT for dental and maxillofacial radiology (Evidence-based guidelines). Chapter 4 (for dental CBCT only). Available from: <https://ec.europa.eu/energy/sites/ener/files/documents/172.pdf>

Other document (specify):

Copies of this/these document(s) are made available to the referrers in each room/on the intranet/by personal copy.

Version number: _____

Date of issue: _____

The text (especially the highlighted fields) should be edited as required

D3 JUSTIFICATION AND AUTHORISATION OF DENTAL RADIOGRAPHS AND DENTAL CBCT IMAGING

Objective

To ensure that every dental exposure (e.g., dental radiograph or dental CBCT examination) is justified and authorised.

Responsibilities

It is the responsibility of an entitled dentist/hygienist/therapist to justify each individual dental exposure taking the following into account:

- Specific objectives of the exposure and the characteristics of the individual involved
- Total potential diagnostic or therapeutic benefits, including the direct health benefits to the individual and the benefits to society, of the exposure
- Individual detriment that the radiation exposure associated with the exposure may cause
- Efficacy, benefits and risk of available alternative techniques having the same objective but involving no or less exposure to ionising radiation

If the practitioner is aware, at the time of authorisation, that a recorded clinical evaluation shall not result from the exposure, then the exposure must not be authorised and cannot take place.

Process for Justification and Authorisation – ‘in-house’ radiography or dental CBCT imaging

When the referrer, who is a **dentist/hygienist/therapist** and also an entitled IRMER17 practitioner, deems it in the patient's best interests to have a dental exposure, then the referral signature in the clinical notes indicates that it is also deemed to be a justified exposure. **[(For dental CBCT imaging the IRMER17 practitioner must be a dentist)].**

Process for Justification and Authorisation – referrals from other dental practices

If referrals for dental exposures are accepted from other practices enter here the procedure to be followed for the justification and authorisation of the exposures. Refer to sections 3.2.2, 3.5.6, 3.6.1 and 3.6.2 for guidance.

Special Circumstances Regarding Authorisation

It has been recognised that, in some specific circumstances, it may not be feasible for authorisation to be carried out in advance of an exposure. Should this situation arise then the person justifying the exposure should be present in the room while the X-ray is carried out and authorisation of the exposure must occur as soon as possible within the same episode of care.

Circumstances where this may occur are during treatments where it is not in the best interests of the patient for the dentist to leave them to document authorisation in the patient's dental record.

At all other times authorisation will be carried out in advance of the dental exposure.

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The text (especially the highlighted fields) should be edited as required

D4 PATIENT IDENTIFICATION

Objective

To ensure that each justified dental exposure is delivered by an entitled operator to the intended patient.

Responsibilities

The operator who undertakes the exposure is responsible for ensuring that the correct patient receives the correct exposure.

The process for patient identification

To ensure that the dental records are accurate, every patient's identity is confirmed when the patient enters the dental room, prior to the dental assessment starting. If

an operator, other than the dentist, e.g. dental nurse, carries out this identification there should be a verbal handover confirming ID to the dentist prior to the clinical examination starting.

For patients who are not referred from another practice, where possible, the operator must ask the patient to give three identifiers. The procedure must be positive and active e.g.:

- "What is your name?"
- "What is your address?"
- "What is your date of birth?"

Where patients are referred from another dental practice, three additional questions should be asked to verify the patient's identity, such as:

- "What area or tooth is this X-ray for?"
- "Who sent you for this X-ray?"
- "Why are you having this X-ray?"

These details should be checked against the patients' dental records. For follow up patients, the patient's dental chart would also be available which can be compared to a visual examination of the patient's teeth. This can act as an additional check to ensure that the person being examined is the correct patient **and the tooth/teeth to be imaged are still present.**

If the patient is deaf these questions can be asked using written cards. If the patient through illness, physical or mental disability, or language barrier is not able to confirm their identity:

- Always treat them with dignity and respect
- A carer or relative may be asked to identify the patient if they are escorted
- Examine any personal photographic identification they may have such as a passport or photocard driving licence
- For patients with language difficulties, the operator may identify the patient through an interpreter or relative if one is available

When the patient is unable to identify themselves, the method used to confirm patient identity should be recorded **in the patient's dental record/on the referral.**

Differences between patient identifiers

If one aspect of the patient identifiers does not correspond between the **patient's** record and the information obtained, e.g. one digit different in date of birth or different address (old address), but the operator is able to positively confirm the patient's identity, then the operator may use their professional judgement and the details may be changed. Clerical staff should be informed of the change to allow this to be changed on the patient's dental record.

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The text (especially the **highlighted fields**) should be edited as required

D5 PREGNANCY ENQUIRY

Objective

To outline the requirements for pregnancy enquiries prior to a dental exposure.

Scope

The ionising radiation dose involved with dental radiography or dental CBCT imaging is low and consequently, no formal pregnancy enquiries are required to be made.

If a pregnant patient is concerned about the potential for the radiograph to damage their unborn child, and is not reassured by the dentist, or medical physics expert, then the dentist may consider delaying the radiograph if it is in the best interests of the patient.

This decision should be documented in the patient's dental record.

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Date of issue: _____

The text (especially the highlighted fields) should be edited as required

D6 INFORMATION ON BENEFITS AND RISKS OF EXPOSURE

Objective

To ensure that wherever practicable, and prior to a radiograph or dental CBCT image being taken, the patient or the patient's representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the procedure.

Responsibilities

The IRMER practitioner/operator who undertakes an exposure is responsible for ensuring that the patient is informed about the benefits and risks associated with the radiograph prior to it taking place.

Procedure

Describe the benefits to the patient in terms of the expected positive outcome from the examination, for example diagnosis informing or monitoring treatment and explain that the risk from the radiation exposure is low.

The following wording could be considered:

"The risks associated with dental radiography are extremely small under normal conditions and the radiograph will help inform your treatment."

To help put the risk into perspective, dental radiography can be compared to other exposure situations. For example:

"The radiation dose from two bitewing radiographs or one panoramic radiograph is roughly equivalent to that received during a one-hour plane flight."

Reference may also be made to the poster developed by the Clinical Imaging Board (see <https://www.rcr.ac.uk/posts/new-patient-information->

posters-benefits-and-risks-imaging) / developed by Scottish Dental Clinical Effectiveness Programme (see <http://www.sdcep.org.uk/published-guidance/practice-support-manual/additional-resources-for-radiation-protection/>) that is displayed in a convenient location.

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Date of issue: _____

The text (especially the **highlighted fields**) should be edited as required

D7 DOSE CONSTRAINTS AND GUIDANCE FOR CARERS AND COMFORTERS

Objective

To identify when carers or comforters should be used to provide support to patients during an exposure and how doses to carers and comforters can be minimised.

To establish appropriate dose constraints and guidance for the exposure of carers and comforters.

Scope

This practice does not permit carers/comforters to support patients during radiography [in which case the rest of this procedure should be deleted].

OR

Carers or comforters should only provide support where the patient is unable to keep the image receptor still; or where the patient requires reassurance during a radiograph. Examples include the support and comfort of young children; and the support and comfort of patients with additional needs.

Dose constraints

Where a carer or comforter remains in the room with the patient during dental radiography, a dose constraint must be applied to the carer or comforter's exposure, based on the advice of the MPE. This should normally apply to exposures occurring within a specific episode of care, e.g.; a single visit to a dental practice. The dose constraint would not normally be expected to exceed an effective dose of 0.1 mSv per visit.

Responsibilities

The employer must undertake a risk assessment (with the advice of the MPE) to estimate the potential dose to the carer or comforter and to set a suitable dose constraint, and it should be ensured that the dose likely to be received by the carer/comforter is less than the dose constraint.

The IRMER practitioner is responsible for justifying and authorising the exposure of the carer/comforter. This must be considered separately to the justification and authorisation of the exposure of the individual undergoing the dental radiograph/dental CBCT imaging.

The operator who undertakes the exposure is responsible for ensuring that the carer or comforter is informed about the potential radiation exposure and for obtaining consent to proceed.

Procedure

The instructions below must be followed.

- 1 If a carer or comforter has to remain in the controlled area during an X-ray exposure they must stand as far away as possible from the X-ray tube head and out of the path of the main X-ray beam and not hold or support the X-ray tubehead, collimator or image receptor with their hand
- 2 The operator must record the dental X-ray exposure factors (to enable an estimate of the dose)
- 3 In exceptional cases, where the patient is unable to hold an image receptor in position or requires other assistance, a carer or comforter may assist provided that they adhere to the following procedure:
 - Do not hold the X-ray tubehead, collimator or image receptor with their hand
 - If practicable, use artery forceps to position and hold the image receptor
 - Wear a protective apron, if available

Such assistance should not be provided by any person who is pregnant.

Carers and comforters will be made aware of the low risk associated with a dental X-ray examination and will be asked whether they are willing to receive the small dose. The procedure 'Information on benefits and risks of exposure' will be used to explain the risk.

A note will be made in the **patient record** whenever a carer or comforter has been involved in an exposure, detailing the relationship of the of the carer or comforter to the patient, the type of support given and the number and type of exposures.

The note must also include the signature of an IRMER practitioner who justified the exposure of the carer or comforter.

Version number:	_____
Date of issue:	_____

The text (especially the highlighted fields) should be edited as required

D8 CLINICAL EVALUATION

Objective

To ensure every dental exposure undertaken has a corresponding recorded clinical evaluation. The aim of this is to document the findings from reporting on the dental radiograph or dental CBCT image.

Responsibilities

The dentist, as an entitled operator, is responsible for ensuring that an accurate and

timely clinical evaluation is recorded in **the patient's dental record or electronic record.**

Process of recording a clinical evaluation

Following a dental exposure each image must be clinically evaluated by the dentist (or suitably trained and entitled operator), and the findings documented in the **patient's dental record or electronic record.**

This evaluation of the whole image shall include:

- a** The identity, either signature or initials, of the operator undertaking the evaluation
- b** Details of all the radiological findings, for example:
 - Charting of caries
 - Findings relevant to the patient's management or prognosis
 - In the case of a pre-extraction radiograph, it may be sufficient to record either 'root form simple' or 'hooked roots'
 - Any unexpected or potentially serious incidental findings

Version number:

Date of issue:

The text (especially the highlighted fields) should be edited as required

D9 ASSESSMENT OF PATIENT DOSE

Objective

To enable assessment of patient dose for any dental exposure to be undertaken by recording the exposure settings used.

Responsibilities

The medical physics expert (MPE) will ensure that representative measurements of patient dose are made as part of the X-ray equipment quality assurance programme; and recommend appropriate exposure settings based on these measurements.

The MPE will compare representative measurements of patient dose with relevant national or local diagnostic reference levels and recommend any necessary action to address any deficiencies.

The operator undertaking the exposure will ensure that data required to assess patient dose is recorded, as outlined below.

The process for recording factors relevant to dose

When practicable, all operators initiating a dental radiographic exposure will adhere to the standard settings as laid out in the dental practice's guideline exposure protocols.

If the standard settings are not used, then the actual exposure settings used will be recorded.

These 'off-protocol' settings, along with the total number of exposures will be **recorded in the patient's notes/ within the radiographic image quality log/ electronic record.** This will include the reason for carrying out any repeat exposures.

If the standard settings are not used and the dental X-ray equipment provides a read-out of the dose or dose area product (DAP) delivered then the operator will record the DAP value or other dose indicator **within the patient's dental record/radiographic log/electronic record.**

Version number:	/ /
Date of issue:	/ /

The text (especially the highlighted fields) should be edited as required

D10 USE AND REVIEW OF DIAGNOSTIC REFERENCE LEVELS

Objective

To establish suitable local diagnostic reference levels (DRLs) for each type of dental X-ray equipment used by the employer, and to ensure these are reviewed at appropriate intervals.

Responsibilities

The medical physics expert (MPE) will:

- a** Ensure that representative measurements of patient dose are made as part of the X-ray equipment quality assurance programme
- b** Use the representative measurements of patient dose to recommend appropriate local DRLs, or to review and if appropriate, update existing local DRLs and recommend any changes to radiography practices
- c** Where there is evidence that patient doses consistently exceed one or more local DRLs, assist the employer to undertake a thorough review of radiographic practices, and recommend any changes that are necessary

The employer will:

- d** In consultation with the MPE, establish local DRLs for each type of dental X-ray set that is in clinical use, having due regard to European and national DRLs where available
- e** Make the local DRLs available to the operators
- f** Where patient doses consistently exceed one or more local DRLs, take action to improve the current techniques or justify their continued use, in accordance with the advice of the MPE
- g** Where patient doses consistently exceed twice the national DRL, immediately withdraw the equipment from clinical use until improvements can be made, or replace it, in accordance with the advice of the MPE
- h** Communicate any corrective action that may be required, to staff

The operator will:

- i** When possible, ensure that after each exposure for which a local DRL is set, any available dose information (e.g., the DAP value displayed on the equipment) is

considered in relation to the local DRL

- j** When it is suspected that a local DRL has been exceeded, record the exposure settings used, along with any extenuating circumstances, in **a designated book or electronic record**
- k** As soon as it is suspected that a local DRL is being consistently exceeded, inform the employer/line manager/RPS/MPE so that the reasons may be investigated immediately

Version number: ' _____ '

Date of issue: ' _____ '

The text (especially the **highlighted fields**) should be edited as required

D11 NON-MEDICAL IMAGING EXPOSURES (USING MEDICAL RADIOLOGICAL EQUIPMENT)

Objectives

To ensure that non-medical imaging exposures restrict any dose of ionising radiation to the minimum required to achieve the intended result and that special attention is given to the justification and optimisation of these exposures.

No non-medical exposures are undertaken at this practice. [The rest of this template should be deleted].

Responsibilities

The referrer must indicate within the dental records that the request is for a non-medical imaging exposure.

The IRMER practitioner will pay special attention to the justification of non-medical imaging exposures.

The IRMER practitioner and operator must ensure that these exposures are fully optimised.

Process

Non-medical imaging exposures are those which do not confer a health benefit to the individual exposed, for example:

- Health assessment for employment purposes
- Health assessment for immigration purposes
- Health assessment for insurance purposes

Referrals for non-medical imaging exposures must be clearly identified and must be justified by a dentist.

No person shall carry out a non-medical imaging exposure unless it complies with the *employer's procedure* for such exposures.

Health assessments for employment purposes include the following examples, where the individual may be asymptomatic at the time of the exposure:

- Dental X-ray examinations prior to working on an oil rig where there are no dental provisions
- Dental X-ray examinations for military personnel/flight crew
- Dental X-ray examinations for deep sea divers
- Delete or add any other types of occupational health surveillance exposure here as appropriate

The dental radiographic history of each patient attending for non-medical exposures should be checked by the dentist and recent similar examinations should be taken into account. For instance, it may not be necessary to complete a whole series of X-rays if some have been taken recently.

The justification will be recorded in the dental records.

In the absence of a clinical justification for the examination, a suitable form of written consent should be requested from the patient which acknowledges that there is no clinical justification for the examination.

Version number: _____

Date of issue: _____

The text (especially the highlighted fields) should be edited as required

D12 PROCEDURES FOR MEDICAL RESEARCH PROGRAMMES, INCLUDING DOSE CONSTRAINTS

Objective

To ensure that all research undertaken restricts any dose of ionising radiation to the minimum required to achieve the intended clinical result and that each study complies with regulatory requirements.

Scope

This practice does not undertake research exposures [in which case the rest of this procedure should be deleted].

OR

No research exposures will be justified or authorised unless the provisions set out below have been fully implemented.

Responsibilities

It will first be ensured that all research has received approval from an ethics committee and that there is sufficient net benefit to allow research exposures to go ahead.

Every request for a research exposure will be justified and authorised and a clinical evaluation of the outcome performed.

The referrer will indicate in the patient's dental record that the request is for a research examination.

The medical physics expert (MPE) will be involved with the dose and risk assess-

ment, as agreed within their contract, and will identify

- A dose constraint when no direct medical benefit is expected to the individual from the exposure, or
- An individual target level of dose for patients which are expected to receive a diagnostic or therapeutic benefit from the exposure

Process

It is the responsibility of the individual IRMER practitioner for a research study to ensure that every request is justified. Special attention is required for the justification of exposures that have no direct benefit for the individuals undergoing the exposure.

A protocol for each research project will be written by the research practitioner and made available to all operators **in the research folder/ electronically.**

Patient consent

All potential participants will receive an information sheet about the research programme and its risks and have the opportunity to discuss these with a responsible person before agreeing to take part. The explanation must make clear that treatment will not be prejudiced by failure to take part.

All individuals taking part in a research programme do so voluntarily. Each participant will sign a consent form indicating that the whole procedure has been properly explained, that they voluntarily undertake the procedure and are aware of the risks, including those from the radiation exposure.

Version number: _____

Date of issue: _____

The text (especially the **highlighted fields**) should be edited as required

D13 REDUCING THE PROBABILITY AND MAGNITUDE OF ACCIDENTAL OR UNINTENDED EXPOSURES

Objective

To ensure that the probability and magnitude of unintentional exposures is kept as low as reasonably practicable.

Responsibilities

The employer will ensure that all staff involved with dental radiography or dental CBCT imaging are adequately trained, competent and entitled, and that an equipment inventory is kept on all radiation equipment and that the equipment is maintained in accordance with the manufacturer's instructions.

All duty holders shall comply with the *employer's procedures*.

IRMER practitioners and operators shall ensure that the doses arising from an exposure are kept as low as reasonably practicable consistent with the intended purpose.

Process

The dental practice will reduce the risk of unintended exposures by adopting the following, records of which can be found in the radiation protection file:

- *Employer's procedures* and protocols will be in place and regularly reviewed to ensure they match local practice
- All equipment will regularly undergo quality assurance to ensure it is functioning correctly
- Additional equipment QA checks will be carried out if over 10% of images are deemed unacceptable
- Feedback will be given to dental professionals following any incident
- Training and competency assessments will be undertaken including when new equipment and procedures are introduced
- Induction programmes will be put in place for new staff
- The quality of dental images will be graded and reviewed
- Clinical audit will be carried out as appropriate
- Audit of procedures will be carried out at regular intervals
- Good practice and technique will be applied
- Near-miss incidents will be investigated

Version number: _____

Date of issue: _____

The text should be edited as required

D14 SIGNIFICANT, OR CLINICALLY SIGNIFICANT, ACCIDENTAL OR UNINTENDED EXPOSURES**Objectives**

To ensure that any unintended or accidental exposures are appropriately investigated.

To ensure that the referrer, the IRMER practitioner, and the patient or the patient's representative are informed of the occurrence of any clinically significant unintended or accidental exposure, and of the outcome of the analysis of this exposure.

Process for informing

If the operator suspects the patient may have received a significant accidental or unintended exposure, it should be reported to '_____' as soon as possible.

Take note of all display or control settings, save all images including rejects. If the incident was due to an equipment malfunction, the equipment should be removed from service pending an investigation. The MPE will advise whether instances of equipment failure should be reported to the manufacturer and/or the MHRA.

'_____' should discuss the exposure with the appointed medical physics expert (MPE) to determine an estimate of the patient dose.

If the MPE advises that the exposure is significant, '_____' will, on the advice of the MPE:

- Notify the Care Quality Commission (CQC)/Healthcare Inspectorate Wales (HIW)/The Regulation and Quality Improvement Authority (RQIA)/Healthcare Improvement Scotland (HIS) (as appropriate) within two weeks of the incident occurring
- Arrange for a detailed investigation of the circumstances of the event and if necessary a more detailed assessment of the dose received
- Notify the CQC/HIW/RQIA/HIS of the outcome of the investigation and any corrective measures adopted, within twelve weeks of the incident occurring

If the MPE advises that the exposure is clinically significant, ' ' should, in addition to notifying the relevant enforcing authority, ensure that the referrer and IRMER practitioner are informed of the exposure and estimated dose as soon as possible. The referrer or IRMER practitioner should then discuss the exposure with the patient, or the patient's representative.

Recording

The investigation into the exposure should be documented together with the outcomes of the analysis, including estimated patient dose. This should be done in consultation with the MPE. The report should be retained in the radiation protection file/patient notes for at least five years. If the exposure is clinically significant, copies must be provided to the referrer, IRMER practitioner and the patient or the patient's representative, and a copy retained for at least 30 years.

Version number: ' ' /

Date of issue: ' ' /

The text (especially the highlighted fields) should be edited as required

D15 QUALITY ASSURANCE PROGRAMMES FOR WRITTEN PROCEDURES, WRITTEN PROTOCOLS AND EQUIPMENT

Objective

To ensure that the quality assurance programme with respect to written procedures, written protocols and equipment is followed.

Responsibilities

The employer will ensure that all staff involved with dental radiography and/or dental CBCT imaging are adequately trained with respect to the quality assurance procedures.

All duty holders shall comply with the employer's procedures.

Process

The dental practice will:

- Train the relevant members of staff in the quality assurance programme contained in the radiation protection file

The employer has assigned responsibility to:

- (Insert name) for reviewing the written procedures and protocols whenever there is a change in practice, equipment or service delivery or at least every three years
- (Insert name) for undertaking and recording the X-ray and ancillary equipment quality assurance checks
- (Insert name) for undertaking and recording the imaging system quality assurance checks
- (Insert name) for undertaking and recording audits of radiographic and/or dental CBCT image quality at least once every six months
- (Insert name) for undertaking the annual audit of the records kept in support of the QA programmes
- (Insert name) for reviewing the annual audit of the records kept in support of the QA programmes and for taking any necessary improvement actions

Records of all reviews/revisions to documentation and quality assurance checks will be kept.

Version number: _____

Date of issue: _____

The text should be edited as required

Appendix

E

Template
service-level
agreement

For the referral of patients for **specify type** examinations

REFERRING practice	RECEIVING practice
Address:	Address:
Tel:	Tel:
Email:	Email:
Name of employer:*	Name of employer:*
Referral criteria	
<p>The document(s) specified here will be used by both parties as the basis for the referral of patients and the justification/authorisation of dental radiographic examinations:</p>	
<p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>	
<p>*The person who signs here should be the employer or, in the case of a body corporate or other situation where the “employer” may not be available, a suitable representative (e.g., a dentist at the practice who is involved with the referrals) who is able to sign on the employer’s behalf.</p>	

Table continued on next page

Table continued

Entitlement of people

Enter below the details of all people at the referring practice who will refer patients for radiographic examinations and/or report on dental images. Evidence of suitable training must be provided.

For completion by REFERRING practice			For completion by RECEIVING practice		
Names	GDC/GMC Registration Number	IRMER17 roles (tick)		Training OK?	Registration OK?
		Referrer	Operator (reporting)		

Signatures of agreement

We the undersigned agree: (1) to use the referral criteria above; (2) that evidence of adequate training has been provided for each of the people named above appropriate to their IRMER17 roles; (3) that adequate information will accompany each referred patient to allow the justification process to proceed, as set out in the standard imaging referral form attached.

For the REFERRING practice	For completion by RECEIVING practice
Name:*	Name:*
Signature:	Signature:
Date:	Date:

*The person who signs here should be the employer or, in the case of a body corporate or other situation where the "employer" may not be available, a suitable representative (e.g., a dentist at the practice who is involved with the referrals) who is able to sign on the employer's behalf.

Appendix

F

Template
imaging referral
form

PATIENT details	
Name:	
Date of birth:	
Address:	
Contact tel:	H: W: M:
REFERRER details	
Name:	
Address:	
Signature:	
Date of referral:	
Referrer contact tel:	
Type of radiograph requested:	Panoramic / cephalometric / dental CBCT* *delete as appropriate
Clinical context for requesting the above examination:	
Relevant results of history, clinical examination and other imaging:	

Table continued on next page

Table continued

What information do you want the radiographic examination to provide?	
Define the anatomical area that the radiograph should cover:	
Justification	
Name of IRMER practitioner:	
Signature:	
Date:	
Details of radiograph authorised:	
Radiograph information	
Name of operator:	
Signature:	
Date of radiograph:	
Exposure factors used:	
Clinical evaluation (reporting)*	
Name of operator (reporting):	
Signature:	
Date:	
Outcome:	
<p>*If, under the service level agreement 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 places and is properly recorded.</p> <p>On completion, retain this form and return a copy to the referring practice</p>	

Appendix



Template guideline exposure protocols

G1 INTRA ORAL RADIOGRAPHY

The practice should complete the relevant sections, following consultation with their medical physics expert (MPE).

Manufacturer and model:

Serial number/identifier:

Details of image receptors:

'Anatomical selection' exposure control: for each radiograph, operators should select the appropriate anatomical view, the appropriate patient type and the film type/density/coefficient setting recommended by the MPE.

The recommended film type/density/coefficient setting is:

'Set time' exposure control: the recommended exposure times for 'standard' adults are as follows (NB, do not complete for 'anatomical selection' exposure controls):

	Incisors	Pre-molars	Molars	Bitewings
Maxillary				
Mandibular				

NB: for the radiography of children, exposure times should be reduced by %

Radiographic technique and other comments (include kV and mA setting if these can be altered):

Date of preparation:

G2 PANORAMIC RADIOGRAPHY

The practice should complete the relevant sections, following consultation with their medical physics expert (MPE).

Manufacturer and model:			
Serial number/identifier:			
Details of image receptors:			
For "standard" panoramic exposures, the following settings are recommended:			
Patient size/ age range	Voltage (kV)	Current (mA)	Exposure time(s)
Radiographic technique and other comments:			
Date of preparation:			

G3 CEPHALOMETRIC RADIOGRAPHY

The practice should complete the relevant sections, following consultation with their medical physics expert (MPE).

Manufacturer and model:

Serial number/identifier:

Details of image receptors:

For "standard" cephalometric exposures, the following settings are recommended:

Patient size/ age range	View	Voltage (kV)	Current (mA)	Exposure time(s)
	Lateral			
	Postero-anterior			
	Lateral			
	Postero-anterior			
	Lateral			
	Postero-anterior			
	Lateral			
	Postero-anterior			
	Lateral			
	Postero-anterior			
	Lateral			
	Postero-anterior			

Radiographic technique and other comments:

Date of preparation:

G4 DENTAL CBCT IMAGING

The practice should complete the relevant sections, following consultation with their medical physics expert (MPE).

Manufacturer and model:						
Serial number/identifier:						
Details of image receptors:						
Radiographic technique	Voltage (kV)	Current (mA)	Exposure time(s)	Field of view (cm x cm)	Voxel size (mm ³)	Rotation angle (°)
EXAMPLE Placement of a single maxillary implant, standard adult male	90	5	10	5 x 5	0.2	360
Radiographic technique and other comments:						
Date of preparation:						

Appendix

H

Adequate training for work with dental cone-beam CT equipment

H1 LEVEL 1 ('CORE') TRAINING IN DENTAL CBCT

Intended recipients

All personnel involved with dental CBCT imaging (dentists, dental nurses with the CDR, dental hygienists and dental therapists).

Content

- The fundamentals of 3D imaging and dental CBCT radiography
- The principles of radiological imaging
- Radiation hazards and radiation protection
- Referral criteria for 3D imaging
- Regulations relating to dental CBCT imaging
- Appreciation of the different diagnostic yield but increased hazards presented by dental CBCT imaging in comparison with conventional 2D imaging
- Understanding how to optimise patient doses from dental CBCT for the specific imaging task and how to avoid unnecessary exposure
- Recognition of 3D anatomy sufficiently to correctly localise both small and large volume CBCT scans and to make an initial assessment of the image to confirm correct positioning and diagnostic value (e.g., freedom from artefacts etc.).
Limited to imaging of the dento-alveolar region only

Presentation

A formal course, 12 hours total (of which 5 hours may be provided by verifiable CPD in radiography and radiation protection as recommended by the GDC for all dentists and dental care professionals whose work involves dental radiography).

H2 LEVEL 2 ('FURTHER') TRAINING FOR OPERATORS PERFORMING DENTAL CBCT IMAGING

Intended recipients

All personnel who may be entitled to act as operators undertaking dental CBCT examinations (dentists, dental nurses with the CDR, dental hygienists and dental therapists).

Content

The practical aspects of dental CBCT radiography, including: exposure protocols, patient positioning, dose optimisation, QA test exposures and fault identification. This should be provided in tandem with core training.

Presentation

Hands-on training, ideally delivered at the place of work immediately following commissioning. An initial 6 hours to allow the operator to become familiar with the equipment and to begin imaging patients safely and confidently. A second 6-hour period should be undertaken after a short period of initial usage to provide further detailed training on patient positioning, dose and image optimisation, further machine options, to answer queries and problem-solve.

H3 LEVEL 2 ('FURTHER') TRAINING IN DENTAL CBCT JUSTIFICATION AND IMAGE INTERPRETATION

Intended recipients

All personnel who may be entitled to act as IRMER practitioners and operators undertaking the justification and clinical evaluation (radiological reporting) of CBCT images that are confined to the dento-alveolar region. (At the time of writing the clinical evaluation of dental CBCT images is restricted to appropriately trained and indemnified dentists and radiologists.) Successful completion of Level 1 training should be a prerequisite for attending this training.

Content

- The development of dental CBCT imaging knowledge, enabling appropriate justification, accurate dose and image optimisation and quality control
- Understanding of the regulatory requirements if offering a CBCT imaging and/or reporting service
- Reporting of normal anatomy, normal variants, dento-alveolar pathology and abnormalities, and pre-surgical planning as seen on dental CBCT images

Delivery

A mixture of theoretical and practical training in dental CBCT reporting, including hands-on training in use of imaging software and case-based interpretation exercises. Formal training should last at least 6 hours with a further 6 hours for self-study and small group study, including case-based discussions, interpretation exercises and mentoring.

H4 SUMMARY OF TRAINING IN DENTAL CBCT

H4.1 Learning outcomes

The required learning outcomes summarised in the table are adapted from the EADMFR Guidelines document 'Basic training requirements for the use of dental CBCT by dentists: a position paper prepared by the European Academy of Dentomaxillofacial Radiology' (2013).

Level	Outcome	Detailed requirement
Core (Level 1) knowledge and training	Knowledge and understanding	<p>Knowledge of:</p> <ul style="list-style-type: none"> • The concept of the imaging "chain" from initiating the X-ray exposure to displaying of the image • How X-rays interact with matter • Biological effects of radiation • Radiation dose and risk • Radiation protection in relation to CBCT equipment, including relevant aspects of optimisation of exposures and dose reduction • Background radiation and its origin • The principles of image detectors and their influence on image quality • Justification and referral criteria for 2D and 3D dental radiography and its influence on radiation protection • IRR17 and IRMER17 requirements and responsibilities, and responsibilities for data protection, and how these direct the use of dental CBCT • The factors controlling X-ray quantity, quality and geometry and its influence on image quality • The construction and function of dental CBCT equipment • Dental CBCT image acquisition, digital imaging and communications in medicine (DICOM) standards and processing <p>Understanding of:</p> <ul style="list-style-type: none"> • The difference between two-dimensional and 3D imaging • The importance of gaining new knowledge by following scientific developments and improvements in diagnostic imaging and technology

Table continued on next page

Table continued

Level	Outcome	Detailed requirement
		<ul style="list-style-type: none"> • The principles of dental CBCT radiographic technique • The principles of reformatting image data • CBCT artefacts, their production and reduction • The interpretation of a received radiological report
	<p>Skills and ability</p>	<p>Ability to:</p> <ul style="list-style-type: none"> • Describe and implement the regulations that direct the use of dental CBCT • Describe the function of dental CBCT equipment and its operation to create optimised imaging of the dento-alveolar region • Support staff development in the use of dental CBCT • Recognise dental and radiographic anatomy in the dento-alveolar and facial region in order to position the CBCT imaging volume correctly and understand the image created • Recognise the presence of disease of the teeth and their supporting structures in dental CBCT images • Search and identify relevant scientific literature • Recognise malfunctioning of dental CBCT devices • Describe a quality control programme for dental CBCT devices <p>Skills in practical use of software and other measures for radiation protection</p>
	<p>Judgement and stance</p>	<p>Judgement to:</p> <ul style="list-style-type: none"> • Apply the use of dental CBCT imaging for the net benefit of the patient • Strive to minimise radiation dosage to patients and staff in compliance with IRR17 and IRMER17 • Recognise when to seek assistance and support <p>Responsibility for own competence development in the field of dento-alveolar CBCT radiology</p>

Table continued on next page

Table continued

Level	Outcome	Detailed requirement
<p>Further (Level 2) knowledge and training for IRMER practitioners and dentists offering a CBCT imaging referral service and/or reporting on CBCT imaging</p>	<p>Knowledge and understanding</p>	<p>Knowledge of:</p> <ul style="list-style-type: none"> • The application of referral criteria in dental CBCT • Principles of diagnostics and how diagnostic radiology relates to other diagnostic methods • Preparation of a structured interpretation report • Principles and practice of interpretation of dento-alveolar CBCT images of the teeth, their supporting structures, the mandible and maxilla up to the floor of nasal fossa (e.g., smaller fields of view) and of the adjacent facial skeleton (e.g., larger fields of view) • Use of alternative and supplementary imaging modalities • Normal radiological anatomy on dental CBCT images and their variants • Radiological interpretation of abnormalities and disease affecting the teeth and jaws and facial skeleton on dental CBCT images and CBCT applications in various pathological conditions • Use of CBCT in pre-surgical planning • Recognise signs of malignancy • Interpretation of anatomy and disease in adjacent structures to the teeth and their supporting structures and of the facial skeleton • How to write a structured radiological report • Understanding of own limitations in knowledge and experience, and understanding when to refer for an expert opinion • Regulatory responsibilities if leading a CBCT imaging service • Staff training and continuing development

Table continued on next page

Table continued

Level	Outcome	Detailed requirement
	Skills and ability	<p>Ability to:</p> <ul style="list-style-type: none"> • Differentiate between findings indicative of normal anatomical structures and artefacts from those of diseased teeth, jaws and the adjacent facial skeleton • Recognise signs of malignancy • Understand and analyse disease and create a radiological report of dental CBCT images • Identify and critically review relevant scientific literature
	Judgement and stance	<p>Responsibility for self and staff development in the field of dento-alveolar CBCT radiology</p> <p>Judgement to identify when to refer for a second opinion or further radiological report</p>
Further (Level 2) knowledge and training for operators undertaking dental CBCT examinations	Knowledge and understanding	<p>Knowledge of:</p> <ul style="list-style-type: none"> • Practical instruction in principles of dental CBCT imaging • Use of different dental CBCT equipment • Dental CBCT imaging techniques and measures for dose reduction and image quality improvement • Optimisation of radiation dose and image quality • Recognition of normal dental and radiological anatomy relevant to patient positioning • Care of patients undergoing dental CBCT • Practical application of QA techniques
	Skills and ability	<p>Ability to:</p> <ul style="list-style-type: none"> • Use dental CBCT equipment to create the intended image • Use equipment and software to optimise patient dose and appropriate image quality • Correctly identify the patient and understand the role of the examination

Table continued on next page

Table continued

Level	Outcome	Detailed requirement
		<ul style="list-style-type: none"> • Correctly position the patient for CBCT examination using knowledge of dental and radiological anatomy • Evaluation of the image for quality and to ensure appropriate diagnostic information is obtained • Care for the patient under examination • Infection control • Post-process and store resultant images in compliance with the current regulatory framework for radiation protection and information governance • Perform a quality control programme for dental CBCT devices
	<p>Judgement and stance</p>	<p>Responsibility for own continued professional development in the field of dento-alveolar CBCT radiology</p>

Appendix



Adequate testing requirements for X-ray equipment and ancillary equipment

11 GENERAL TESTS FOR X-RAY EQUIPMENT

Test no.	Description	Frequency	Action Level	Suspension Level
1	Radiation output repeatability	3-yearly	Mean \pm 10%	Mean \pm 20%
2	Radiation output reproducibility	3-yearly	Mean \pm 20%	Mean \pm 50%
3	Operating potential	3-yearly	$> \pm$ 10% of intended or $<$ 50 kV (intra-oral) $<$ 60 kV (other)	$> \pm$ 20% of intended or $<$ 45 kV (intra oral)
4	Total beam filtration	Commissioning and after any tube modification	Max nominal kV up to 70 kV: $<$ 1.5 mmAl or does not meet manufacturer's spec Max nominal kV over 70 kV: $<$ 2.5 mmAl or does not meet manufacturer's spec	
5	X-ray tube leakage	Commissioning and after any tube modification	Intra-oral: $>$ 0.25 mGy/h (see explanatory notes for hand-held equipment) Other: $>$ 1 mGy/h	
6	Exposure timer	3-yearly	\pm 10% of set time	\pm 20% of set time

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Table continued

Test no.	Description	Frequency	Action Level	Suspension Level
7	Focus to skin distance	Commissioning and after any tube modification	Intra-oral: < 200 mm Extra-oral: < 150 mm	
8	Radiation field size	3-yearly	Intra-oral: Rectangular collimation: ≥40 mm x ≥50 mm Any circular collimation Other: > 10 mm or 10% of expected field size or detector (whichever is smaller)	Circular collimation: ≥ 70 mm > size of the solid detector housing

12 ADDITIONAL TESTS FOR DENTAL CBCT

Ref	Description	Frequency	Action Level
9	Image noise	Monthly and 3-yearly	Does not meet the manufacturer's specification or baseline $> \pm 40\%$
10	Mean pixel values (MPVs)	Monthly and 3-yearly	HU scale used: Does not meet the manufacturer's specification HU scale not used: Does not meet the manufacturer's specification or $R2 < 0.9$ when MPVs are plotted against material densities
11	Image uniformity	Monthly and 3-yearly	Does not meet the manufacturer's specification or maximum difference between mean pixel values at the centre and periphery > 200 units
12	Reconstructed image measurement	3-yearly	$> \pm 0.5$ mm
13	High contrast spatial resolution	3-yearly	Does not meet manufacturer's specification or < 1 lp/mm
14	Contrast to noise ratio (CNR)	3-yearly	Does not meet manufacturer's specification or baseline $> \pm 40\%$

13 TESTS FOR COMPUTER SCREENS

Ref	Description	Frequency	Action Level
15	Image display monitor condition	Monthly	See explanatory paragraph
16	Image display monitor distance calibration	3 Monthly	$> \pm 5$ mm
17	Image display monitor resolution	3 Monthly	see explanatory paragraph

14 PATIENT DOSE ASSESSMENT

Ref	Description	Dose measurement	Frequency	Action Level	Suspension Level
18	Intra-oral	Patient entrance dose (PED)	3-yearly	> National Diagnostic Reference Level (NDRL)*	> 2 x NDRL
19	Panoramic	Dose area product (DAP)			
20	Cephalometric	Dose area product (DAP)			
21	Dental CBCT	Dose area product (DAP)			

*Current NDRLs can be found at <https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls>

15 EXPLANATORY PARAGRAPHS

15.1 General tests (see I1)

1 Radiation output repeatability

Suggested method

Radiation dosimeter or other suitable device.

References

IPEM (2005)¹

Comments

Carry out at least 3 measurements at a typical clinical setting. It is normally easier to make measurements at the detector rather than at the isocentre for panoramic and dental CBCT equipment, or at the end of the spacer cone for intra-oral.

2 Radiation output reproducibility

Suggested method

Radiation dosimeter or other suitable device.

References

IPEM (2005)¹

Comments

Carry out measurements at a range of kV and mAs settings, covering the range of settings that may be clinically used.

3 Operating potential

Suggested method

Digital kV meter or other suitable device.

References

IPEM (2005); IEC (2012a; 2012b)^{2,3}

Comments

A 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.

4 Total filtration

Suggested method

Suitable total filtration or HVL meter, aluminium filters or other suitable device.

References

IEC (2008)⁴

Comments

Measure equivalent aluminium HVL and determine the total beam filtration or measure the total beam filtration directly using a suitable meter or other suitable device.

5 X-ray tube leakage

Suggested method

Suitable leakage detector.

References

IEC (2008, 2012a)^{2,4}, PHE (2016)⁵

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/h (or 0.25 mGy/h for fixed intra oral equipment).

For hand-held intra-oral X-ray equipment there is an additional recommendation that the total annual effective dose to the operator should not exceed 0.25 mSv and the total annual equivalent dose to the operator's hands should not exceed 10 mSv.

6 Exposure timer

Suggested method

Digital timer or other suitable device.

References

IPEM (2005)¹

Comments

The timer linearity can be checked with a dosimeter or film/digital image receptor over a typical range of clinical settings.

7 Focus to skin/image receptor distance

Suggested method

Tape measure/inspection of documents.

References

—

8 Radiation field size

Suggested method

Film or suitable CR or DR detector.

References

—

Comments

Intra-oral: place the film or CR/DR detector in contact with the end of the spacer cone and make a normal exposure. Measure the size of the resultant image.

Other

Place the film or CR/DR detector across the X-ray detector. If possible, mark the bounds of the detector and perform a normal scan. The size of the resultant image should be no greater than the bounds of the active area of the detector or expected field size (where smaller) 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 minimum and maximum field sizes.

Some equipment is provided with a service function which can initiate an exposure without rotation of the X-ray unit. This may assist with carrying out this test providing the radiation beam size is not altered from that in normal clinical use.

15.2 Additional tests for dental CBCT (see I2)

To ensure consistent image quality measurements can be made, an image quality phantom must always be placed in an identical position on the X-ray set and any ROIs drawn on the reconstructed image must also be in the same position. Care must also be taken to ensure exposure and reconstruction settings are kept the same and match those specified by the manufacturer.

For tests 9 to 14, a specification and QA test object provided by the manufacturer should be used in preference to the action levels specified in I2.

9 Image noise

Suggested method

System manufacturer's quality control phantom.

References

IPEM (2005)¹; EFOMP (2017)⁶

Comments

Measure the standard deviation for a central ROI (or alternative ROI location if specified by the manufacturer) for the phantom. The size of the ROI should be 40% of the phantom or field of view diameter, whichever is smaller, to improve the statistical accuracy of the measurement.

Measurements should be made in an axial slice at the centre of the phantom.

10 Mean pixel values

Suggested method

System manufacturer's quality control phantom or suitable commercial CBCT phantom.

References

IPEM (2005)¹; EFOMP (2017)⁶

Comments

Measure the mean pixel values for at least three materials, ideally covering the range of material densities that will be clinically imaged (e.g. air, water and bone). 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 an axial slice.

If the equipment manufacturer claims conformance to the Hounsfield Unit (HU) scale then the manufacturer's specification must be met.

If conformance is not claimed, and if there is not a specification provided by the manufacturer, a plot of physical density versus mean pixel value should be made and a simple linear regression plotted. A linear relationship would normally be expected and the action level is based on the coefficient of determination (R^2) value.

11 Image uniformity

Suggested method

System manufacturer's quality control phantom or suitable commercial CBCT phantom.

References

IPEM (2005)¹; EFOMP (2017)⁶

Comments

Measure mean pixel values for a ROI at the centre and at 50% along the axes around the periphery of the image (unless alternative ROI locations are specified by the manufacturer). A ROI with a diameter of 5 mm is recommended.

If there is not a specification provided by the manufacturer, the action level is based on the maximum difference between any two pixel values. The action level is more than 20% of the difference between the values for water and air. For example, if the density value of air was -1000 and the value for water was 0, the applicable action level would be greater than ± 200 .

Measurements should be made in an axial slice.

12 Reconstructed image measurement

Suggested method

System manufacturer's quality control phantom or suitable commercial CBCT phantom containing at least two high contrast objects of known separation.

References

IPEM (2005)¹; EFOMP (2017)⁶

Comments

Measure the distance between at least two points of known distance on the image. Measurements should be made in an axial slice. Additional measurements should be made for a number of fields of view that are used clinically, unless otherwise specified by the manufacturer. At commissioning, measurements could also be made in coronal and sagittal planes.

Where possible the measurement should be for a distance of at least 5 cm.

13 High contrast spatial resolution

Suggested method

System manufacturer's quality control phantom or suitable commercial CBCT phantom containing a high contrast edge, pin, bead or bar test insert.

References

IPEM (2005)¹; EFOMP (2017)⁶

Comments

Measurement should be made near the centre of the image.

The action level is for a bar test insert or a calculated MTF10 value.

Where possible, additional measurement should be made in all three planes using a range of voxel size settings that are clinically used.

14 Contrast to noise ratio (CNR)**Suggested method**

System manufacturer's quality control phantom or suitable commercial CBCT phantom.

References

EFOMP (2017)⁶

Comments

Two materials should be chosen, one that represents soft tissue (e.g. PMMA) and one that represents bone (e.g. PVC). CNR is defined as:

$$\text{CNR} = \frac{|MPV_1 - MPV_2|}{\sqrt{\sigma_1^2 + \sigma_2^2}}$$

where MPV_1 and MPV_2 are the mean pixel values of two materials and σ_1 and σ_2 are the standard deviations of pixel values in the two materials.

15.3 Tests for computer screens (see I3)**15 Image display monitor condition****Suggested method**

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

References

IPEM (2005)¹

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. Ensure that the 5% and 95% details superimposed on the 0% and 100% squares, respectively, are visible. The TG18-QC test pattern can be downloaded from http://deckard.mc.duke.edu/~samei/aapm_tg18.html

16 Image display monitor distance calibration

Suggested method

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

References

IPEM (2005)¹

Comments

This test is intended for those applications where measurements of distance and angle are performed using the image display monitor and diagnostic workstation.

17 Image display monitor resolution

Suggested method

Visual inspection of test pattern image, such as SMPTE or TG18-QC.

References

IPEM (2005)¹

Comments

Review both the low contrast and high contrast resolution patterns. Check resolution at centre and periphery is consistent. The TG18-QC test pattern can be downloaded from http://deckard.mc.duke.edu/~samei/aapm_tg18.html

15.4 Patient dose assessment (see I4)

18 Intra-oral: PED

Suggested method

Suitable dosimeter or other suitable device to measure dose at the end of the spacer cone.

References

IPEM (2005)¹; PHE (2019)⁷

Comments

PED measurements should be made for a mandibular molar radiograph of an adult and a child patient. The dosimeter or other device should have a calibration traceable to an appropriate primary standard.

Comparison should be made with the current NDRs (PHE, 2019) or any future NDRs that supersede these.

19 Panoramic: DAP

Suggested method

Suitable dosimeter or other suitable device to measure dose together with a beam area measurement or a suitable DAP meter.

References

IPEM (2005)¹; PHE (2019)⁷

Comments

Measurements should be made for a complete radiographic cycle without a patient or phantom in the beam, at the clinical exposure settings for a standard panoramic radiograph of an average-sized adult and a 12 year-old male child. The dosimeter should have a calibration traceable to an appropriate primary standard.

Comparison should be made with the current NDRLs (PHE, 2019) or any future NDRLs that supersede these.

20 Cephalometric: DAP

Suggested method

Suitable dosimeter or other suitable device to measure dose together with a beam area measurement or a suitable DAP meter.

References

Holroyd, J R (2011)⁸

Comments

Measurements should be made for a complete radiographic cycle without a patient or phantom in the beam, at the clinical exposure settings for a lateral cephalometric radiograph of an average-sized adult and a 12 year-old male child. The dosimeter should have a calibration traceable to an appropriate primary standard.

Comparison should be made with the current NDRLs (PHE, 2019) or any future NDRLs that supersede these.

21 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)^{6,9}; EFOMP (2017)¹⁰

Comments

DAP measurements should be made for commonly used adult and child procedures.

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

If children are imaged, then a 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 or shifts across the detector during the scan, multiple rotations are included in a single scan or there is a non-uniform dose distribution across the detector. 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. The dosimeter should have a calibration traceable to an appropriate primary standard.

Comparison should be made with the current NDRLs⁷ or any future NDRLs that supersede these.

16 REFERENCES

- 1 Institute of Physics and Engineering and Medicine (IPEM). Recommended Standards for the Routine Performance Testing of Diagnostic X-ray Equipment, IPEM Report 91. IPEM: York; 2005.
- 2 International Electrotechnical Commission (IEC). Medical electrical equipment – Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment Medical electrical equipment. London: ICE; 2012.
- 3 International Electrotechnical Commission (IEC). Medical electrical equipment – Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment Medical electrical equipment. London: ICE; 2012.
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Appendix

J

Common image quality faults
in dental radiographs and
dental CBCT imaging

The following tables are intended to assist a person when assessing the diagnostic quality of images and are based on the *Essentials of Dental Radiography and Radiology, Sixth Edition*.¹ The reader is advised to consult this or similar texts for further information on this subject.

J1 INTRA ORAL RADIOGRAPHY

Category of error	Cause	Effect
Preparation	Rectangular collimator inappropriately orientated	Region of interest only partially imaged; cone cut
	Incorrect placement of image receptor	Wrong tooth/area imaged
	Excessive bending of image receptor	Damage to receptor and/or geometrical distortion evident in processed image. White lines on image (phosphor plate) or black lines (film)
	Right/Left (R/L) marker placed incorrectly (for occlusal)	Region of interest obscured, and/or R/L markers on wrong side of image
	Inappropriate use of patient contact shielding	Region of interest obscured
	Denture or appliance not removed	White artefacts (foreign body) obscures region of interest

Table continued on next page

Table continued

Category of error	Cause	Effect
Positioning	Incorrect positioning of the spacer cone	Region of interest only partially imaged cone cut
	Wrong beam angle (horizontal)	Overlapping contact points and distortion
	Wrong beam angle (vertical)	Elongated or foreshortened image
	Incorrect positioning of image receptor	Wrong tooth/area or root apices not shown
Patient motion	Inadequate instruction to patient, or distraction etc.	Blurred image

J2 PANORAMIC RADIOGRAPHY

Category of error	Cause	Effect
Preparation	Wrong field limitation chosen	Wrong or inappropriate region imaged
	Patient failed to remove earrings/piercings/specs/dentures etc.	White artefacts on the image
	Inappropriate use of patient contact shielding	White artefacts on image
Positioning	Patient's head turned to one side	Teeth appear wider on one side and narrower on the other
	Chin tilted too high (Frankfort plane not horizontal)	Blurred upper anterior teeth and flat/inverted occlusal plane with hard palate superimposed on roots of maxillary teeth
	Chin tilted too low (Frankfort plane not horizontal)	Blurred lower anterior teeth, apices of lower incisors 'cut off' and exaggerated curve to the occlusal plane
	Patient not biting on peg – too far forward	Anterior teeth narrowed

Table continued on next page

Table continued

Category of error	Cause	Effect
	Patient not biting on peg – too far back	Anterior teeth widened
	Patient's tongue not touching palate	Air shadow obscuring apices of maxillary teeth
	Patient not standing up straight in the machine	Exaggerated ghost shadow of the cervical spine superimposed on anterior teeth
Patient motion	Inadequate instructions to patient, inadequate immobilisation, patient distracted during exposure or inappropriate referral for a patient who is unable to comply	Blurred or distorted image

J3 CEPHALOMETRIC RADIOGRAPHY

Category of error	Cause	Effect
Preparation	Wrong field limitation chosen	Wrong or inappropriate region imaged. Cephalometric landmarks not included
Positioning	Patient failed to remove earrings/jewellery/piercings/spectacles/dentures etc	White artefacts on image
	Inappropriate use of patient contact shielding	White artefacts on image
	Lips not relaxed	Error in soft tissue profile
	Patient not biting together correctly	Errors in the cephalometric analysis
	One or both ear rods not positioned correctly in respective side external auditory meatus	Tilted midline plane, will result in errors in the cephalometric analysis

Table continued on next page

Table continued

Category of error	Cause	Effect
Patient motion	Inadequate instructions to patient, inadequate immobilisation, patient distracted during exposure or inappropriate referral for a patient who is unable to comply	Blurred or distorted image

J4 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	Air gap between stent and alveolus Radiographic markers are not accurately related to the alveolus leading to errors in planning
	Metal objects not removed from hair, ears, face or mouth	Artefacts consisting of dark and pale streaks
Exposure	Exposure factors used too high	Image may be dark and lack contrast Unnecessary dose delivered to the patient
	Exposure factors used too low	Image may be noisy, pale and lack contrast
	Image protocol inappropriate for imaging task	Inappropriate image resolution or field size achieved for diagnostic task
Positioning	Inadequate immobilisation used leading to movement of the patient	Blurred image
	Patient swallowed during scan	Blurred image of lower jaw +/- blurred upper jaw
	Patient incorrectly positioned within the machine	Region of interest not included in scan volume

Table continued on next page

Table continued

Category of error	Cause	Effect
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
	Lack of familiarity with software and/or not understand how to reconstruct	Mis-diagnosis, over- or under-detection of abnormalities
<p>*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</p>		

J5 DIGITAL IMAGE ACQUISITION AND PROCESSING

Category of error	Cause	Effect
Exposure	Exposure factors used too high	Image may lack contrast DR images may show 'blooming' Unnecessary dose delivered to the patient
	Exposure factors used too low	Image may be noisy, show areas of image depletion and lack contrast
	Double exposure (CR) (operator error)	Superimposed images Unnecessary dose delivered to the patient
	Image receptor not exposed (operator error)	No image captured (may occur in tandem with double exposure of another image receptor)
DR image receptors (sensors)	Cracked sensor	Visible artefact on image
	Image receptor used back to front	Read out circuitry of the sensor visible on the image. Image incorrectly orientated

Table continued on next page

Table continued

Category of error	Cause	Effect
CR image receptors (phosphor plates)	Bend in phosphor plate	White linear artefact
	Debris on surface of phosphor plate	White artefacts corresponding to the debris on the image
	Phosphor plate used back to front	The outline of the magnet on the back of the phosphor plate visible (some models). Image incorrectly orientated, with markers either back-to-front or in incorrect corner of image
	Phosphor plate exposed to light before processing	Image erased/partially erased, pale and grainy
Image processing	Partial image clearing (CR reader error)	Current and previously captured image superimposed
	Stitching error (DR cephalometric imaging or large FOV CBCT)	Artefact visible at site of 'stitching'
	Image data "lost" (software, image receptor or reader error)	Image not captured or corrupted, repeat required
	Image assigned to wrong patient (operator or software error)	Risk of needing to repeat the exposure if image cannot be found
	Image mounted incorrectly (flipped)	Tooth appears in wrong orientation; and may appear as in another quadrant

J6 FILM-BASED IMAGE ACQUISITION AND PROCESSING

Category of error	Cause	Effect
Exposure	Exposure factors used too high	Image dark and lacks contrast Unnecessary dose delivered to the patient
	Exposure factors used too low	Image pale and lacks contrast

Table continued on next page

Table continued

Category of error	Cause	Effect
	Double exposure (operator error)	Superimposed images Unnecessary dose delivered to the patient
Developer error	Developer solution exhausted Developer time too short Developer temperature too low	Pale image and lack of contrast
	Developer solution overconcentrated Developer time too long Developer temperature too high	Dark image and lack of contrast
	Developer splashes onto film before processing	Black splash marks on image
Fixer error	Fixer exhausted Fixing time too short Fixer temperature too low	Green, opaque tinge to image
	Fixer splashes onto film before processing	White splash marks on image
Washing error	Inadequate washing after processing	Image turns brown over time

J7 REFERENCES

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Appendix

K

Glossary

K1 TERMINOLOGY USED IN DENTAL RADIOLOGY AND RADIATION PROTECTION

Absorbed dose (D)

Quantity of energy imparted by ionising radiation to unit mass of matter such as tissue. Unit gray, Symbol Gy. 1 Gy = 1 joule per kilogram.

Absorption

The reduction in intensity of a beam of radiation incident in the medium through which it is propagated.

Acceptance test

A regime of tests that must be carried out on X-ray equipment before it can be clinically used. The testing is designed to ensure the equipment meets an acceptable performance standard and to set baseline values to compare future routine tests against.

Air-kerma

Quantity of energy imparted by ionising radiation to unit mass of air. Unit gray, Symbol Gy. Gy = 1 joule per kilogram

ALARP (as low as reasonably practicable)

The ALARP principle is that the risk of radiation exposure shall be kept as low as reasonably practicable. In practice, this means that the risk arising from the radiation exposure should be weighed against the trouble, time and money needed to control it.

Alternating current ('AC')

An electric current that reverses direction in a circuit at regular intervals.

Anatomical timer

Where the exposure time is determined by the selection of an anatomical feature (a tooth or region of the jaw) and a particular size of patient to radiograph.

Anterior

The front (of the head or jaw).

Approved Code of Practice (ACoP)

HSE document providing guidance on achieving compliance with IRR17.

Approved dosimetry service (ADS)

A laboratory specialising in the assessment of personal dosimeters and/or the keeping of personal dose records on behalf of employers, that has been approved for those purposes by HSE.

Artefact

In relation to a radiograph, a defect in, or distortion of, the image produced by artificial means and resulting in a potentially misleading appearance.

Automatic exposure control (AEC)

A mechanism for automatically regulating the exposure parameters for individual patients, often achieved by means of an initial 'scout view' on dental CBCT equipment.

Background radiation

Ionising radiation in the environment to which we are all exposed. Examples include radon gas and cosmic rays.

Beam-aiming device

A device used to ensure an intra-oral X-ray tube is correctly aligned with the region of the teeth and jaws being investigated and the image receptor.

Bicuspid

A premolar tooth having two cusps (usually American terminology).

Bitewing

A radiograph of the crowns of teeth on both the upper and lower jaw.

Bremsstrahlung radiation

X-rays covering a continuous energy range generated when high energy electrons (such as those generated in an X-ray tube) are slowed down in a medium. Also known as continuous or braking radiation.

Canine

One of the pointed, conical teeth located between the incisors and the first bicuspids. Also called cuspid.

Caries

Tooth decay.

Cephalometric radiograph

Imaging of the bony structure of the head using reproducible lateral and antero-posterior (AP) or postero-anterior (PA) radiographs.

Certificate in dental radiography (CDR)

A nationally-recognised qualification that provides the adequate training requirement for dental nurses to be able to take dental radiographs (other than dental CBCT images).

Characteristic radiation

The generation of X-rays by the movement of an electron from a higher to lower energy state within an atom.

Classified person

An employee designated as classified under the Ionising Radiations Regulations, 2017, on the basis of the annual dose they are likely to receive. Must have their dose properly assessed, e.g. by personal dosimetry, annual health reviews and dose record keeping.

Collimator

A device used to limit the size of an X-ray field.

Computed digital radiography (CR)

Radiography using a image receptor device (usually a photostimulable phosphor plate) which is read in an automatic processor and the radiographic image then displayed on a computer monitor.

Computed tomography (CT)

Imaging whereby computer analysis of a series of cross-sectional scans is made using a fan-shaped X-ray beam rotating around and along a single axis of a bodily structure or tissue is used to construct a three-dimensional image of that structure.

Cone-beam computed tomography (CBCT)

A CT method where a series of images are acquired

with a cone-shaped X-ray beam during a single rotation of the X-ray tubehead. Specialised CBCT systems have been developed for dental applications.

Contingency plans

A set of written instructions specifying the actions to be taken following an incident to rectify the situation and make it safe. See **local rules**.

Continuing professional development (CPD)

A formal system of lifelong learning employed in a wide range of professions, including dentistry.

Controlled area

An area designated in accordance with the Ionising Radiations Regulations 2017 where special procedures are followed to restrict exposure, or to prevent or minimise the effects of a radiation accident. Must be physically demarcated, have access to it restricted and be described in the local rules. Entry into the controlled area is allowed for classified persons or non-classified persons who enter under written arrangements. See **classified person**.

Cosmic rays

High energy ionising radiations from space.

Critical examination

A regime of tests that must be carried out on X-ray equipment before it can be clinically used. The testing is designed to ensure the equipment and location provide sufficient protection from radiation for all persons. Must be carried out in consultation with an RPA.

Cusp

A pointed or rounded projection on the chewing surface of a tooth.

Cuspid

See **canine** (usually American terminology).

Dentate

Having teeth.

Diagnostic reference level (DRL)

A level of patient dose that the employer must set for standard diagnostic examinations on average-sized patients, which should not normally be exceeded. Also called a 'local DRL' and should not normally exceed any current 'National DRL' or 'National Reference Dose'. (See also '**National DRL**').

DICOM (digital imaging and communications in medicine)

An international standard related to the exchange, storage and communication of digital medical images and other related digital data.

Direct current ('DC')

An electric current flowing in one direction only.

Direct digital radiography (DR)

Radiography using a device which directly captures radiographs and instantly display them on a computer monitor.

Dose area product (DAP)

The product of the absorbed dose and the area of the X-ray field measured at the same point (usually the image receptor) and perpendicular to the axis of the useful beam.

Dose

General term for quantity of radiation. See **absorbed dose**, **equivalent dose**, **effective dose**. Frequently used in place of effective dose.

Dose constraint

An upper level of individual dose set out at the planning stage of work. Dose constraints may be applied to outside workers, carers and comforters and members of the public.

Dose investigation level (DIL)

A level of total effective dose to employees in a calendar year above which an investigation must be carried out, in consultation with an RPA, to determine the cause of the exposure.

Dose limit

A level of total dose within a calendar year (or occasionally 5 year period) that is defined in legislation, above which no person should be exposed.

Dose rate

Rate at which a dose is received, usually measured in micro Sv per hour, ($\mu\text{Sv/h}$).

Effective dose (E)

The quantity obtained by multiplying the equivalent doses to exposed tissues and organs by the tissue weighting factor appropriate to each and summing the products. Unit Sievert, symbol Sv. A measure of whole-body dose, frequently abbreviated to dose.

Electromagnetic spectrum

Electromagnetic radiations shown graphically in order of frequency or wavelength. The spectrum includes short wavelength radiations such as X-rays, visible radiation and longer wavelength radiations of microwaves, television and radio waves.

Electromagnetic radiation

Radiation with both electric and magnetic field components which can be described as waves propagating at the speed of light. Examples are X-rays, gamma rays, ultraviolet radiation, light, infrared radiation, and radio-frequency radiation.

Employer

The person or body legally responsible for the dental practice or company.

Endodontics

The study and treatment of tooth root, pulp and periapical tissues.

Equivalent dose (HT)

The quantity obtained by multiplying the absorbed dose by a radiation weighting factor to allow for the different effectiveness of the various ionising radiations in causing harm to tissue. A measure of dose to a single organ or tissue. Unit Sievert, symbol Sv. The radiation weighting factor for X-rays is 1.0.

Erythema

Reddening of the skin caused by dilation of blood vessels. A tissue reaction following radiation exposures exceeding about 2-3 Sv.

Extra oral radiograph

Radiograph produced by placing an image receptor outside the oral cavity (e.g., such as during panoramic or cephalometric radiography or dental CBCT imaging).

Field of view (FOV)

A term used to describe the extent of the imaged region of the patient, most often used with dental CBCT imaging.

Film speed

An indication of the amount of X-radiation needed to create an image of adequate diagnostic quality for a particular film. The faster the film the less radiation is required.

Filtration

The use of absorbers (usually aluminium) for the selective attenuation of lower energy radiation from a useful primary beam of X-radiation. If aluminium is used, the filtration is reported in 'mm Al equivalent'.

Focal spot

The specific area of the face of the target material in the X-ray tube that is bombarded by the focused electron stream when an X-ray tube is in action. It is usually an insert of tungsten.

Focus to film distance (FFD)

The distance from the X-ray source to the image receptor.

Focus to skin distance (FSD)

The distance from the X-ray source to the patient.

Frequency

The number of complete cycles of an electromagnetic wave in a second. Unit hertz, symbol Hz. 1Hz = 1 cycle per second.

Full-wave rectification

Rectification in which output current flows in the same direction during both half cycles of the alternating input voltage.

Genes

The biological units of heredity. They are arranged along the length of chromosomes.

Gonads

Ovaries and testes.

Gray

See **Absorbed dose**.

Half-wave rectification

Rectification of the power supply to an X-ray machine so that the forward phase of the cycle can be utilized and in the reverse phase no current flows across the tube.

Hounsfield unit (HU)

The Hounsfield unit is named after Sir Godfrey Hounsfield, is a dimensionless quantity used for describing radiodensity, most usually in CT scans, where it is also referred to as the CT number. Dental CBCT images may not use the HU scale.

Inherent filtration

An amount of filtration present in the X-ray beam due to the construction of the X-ray tube (e.g. glass, beryllium).

Intensity

The amount of X-rays per unit area or volume.

Intra oral radiograph

Radiograph produced by placing a radiographic image receptor within the oral cavity.

Ion

Electrically charged atom or group of atoms.

Ionisation

The process by which a neutral atom or molecule acquires or loses an electric charge. The production of ions.

Ionising radiation

Radiation that produces ionisation in matter. Examples are alpha, beta, gamma and X-radiation and neutrons. When these radiations pass through the tissues of the body, they have sufficient energy to disrupt molecular structures via the ionisation process.

IRMER17

The Ionising Radiation (Medical Exposure) Regulations 2017.

IRR17

The Ionising Radiations Regulations 2017.

Justification

As defined in IRMER17, the explanation (clinical reason) for carrying out a radiograph. This must take into account the benefit to the exposed individual or to society and the decision must be recorded for future reference.

Late radiation effects

Biological effects such as radiation-induced cancer which may occur sometime after a radiation exposure.

Lateral

The side (e.g., of the head).

Leakage radiation

Radiation that is transmitted through the X-ray tube housing assembly other than in the main beam.

Local rules

Set of working procedures written in accordance with the Ionising Radiations Regulations, 2017, to enable work with ionising radiations to proceed safely, providing a good standard of protection for workers. Required for every **Controlled area**.

Mandible

The lower jaw.

Maxilla

The upper jaw.

Mean pixel value (MPV)

The average of the pixel values in a region of an image displayed on a computer screen.

Medical physics expert (MPE)

A person who holds a science degree or its equivalent, is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation, and has been formally recognised as competent (e.g., by being included in the list of MPEs maintained by RPA2000). The MPE provides advice on, among other issues, patient dosimetry and quality assurance.

Molecule

The smallest portion of a substance composed of more than one atom that can exist by itself and retain the properties of the substance.

Molar

A tooth with a broad crown used to grind food, located behind the premolars.

Mutation

A chemical change in the DNA in the nucleus of a cell. Mutations in sperm or egg cells or their precursors may lead to inherited effects in children. Mutations in body cells may lead to effects in the individual.

National Diagnostic Reference Level

A level of patient dose for standard diagnostic examination on average-sized patients that has been formally announced by PHE on the gov.uk website, usually on the basis of national surveys of patient dose data (see also 'Diagnostic reference level').

Non-ionising radiation

Radiation that does not cause ionisation. Examples are ultraviolet radiation, light, infrared radiation, and radiofrequency radiation.

Non-medical exposure

An exposure where the benefit to the individual being examined may be financial rather than medical in nature, or may be to a third party.

Nucleus

The core of an atom, occupying little of the volume, containing most of the mass, and having positive electric charge.

Nucleus of cell

The controlling centre of the basic unit of tissue. Contains the important material DNA.

Occlusal

Contact of the lower and upper jaws.

Operating potential

See **Peak Operating Potential**.

Operator

A person undertaking any practical aspect of a radiographic exposure (e.g. pressing the exposure button, developing X-ray films or identifying patients prior to radiography).

Optimisation

The process whereby radiation dose is minimised, but radiographic quality is not compromised.

Orthodontics

The study and treatment of craniofacial development.

Overexposure

Where a dose limit set under IRR17 has been exceeded.

Panoramic

A tomogram of the jaws, taken with a specialised machine designed to present a panoramic view of the full circumferential length of the jaws on a single image.

Patient entrance dose

The measure of radiation dose at the surface of the patient during intra oral radiography.

Peak operating potential

The X-ray tube peak voltage during an exposure. Also commonly referred to as just 'Operating Potential' or 'kilovoltage' (kVp).

Periapical

Teeth plus surrounding bone and tissues.

Photostimulable phosphor plate (PSP)

A type of Computed Digital Radiography (CR) image receptor.

Posterior

The back (of the head or jaw).

Practitioner

In the IRR17 definition this is a person who can justify and authorise a radiographic exposure.

Pre-molar

One of eight bicuspid teeth located in pairs on each side of the upper and lower jaws behind the canines and in front of the molars.

Primary beam

The useful part of the X-ray beam that is directed from the X-ray source towards the patient and image receptor.

Radiation protection adviser (RPA)

Person or corporate body consulted in accordance with the Ionising Radiations Regulations, 2017, to give advice on radiation protection and compliance with IRR17.

Radiation protection supervisor (RPS)

Person appointed in accordance with the Ionising Radiations Regulations, 2017 who is responsible for day-to-day supervision of work with ionising radiation (e.g. ensuring that local rules are followed).

Radiation risk assessment

Defined in the Ionising Radiations Regulations 2017, an assessment made by the employer to determine whether any further steps should be taken to restrict radiation exposures.

Radiograph

The image obtained by using an X-ray machine.

Radiography

The process by which radiographs are made.

Radiology

The profession of medical diagnosis or treatment planning using radiographs.

Referrer

A registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for medical exposure to a practitioner.

Routine test

A test carried out at least every 3 years (or every year for hand held X-ray units) to ensure the X-ray equipment still meets an acceptable performance standard.

Scattered radiation

Radiation that is produced when the primary X-ray beam interacts with matter (e.g. the patient and image receptor, or the surgery wall).

Sievert

See **Effective dose**.

Set-time timer

A timer, typically used for some intra-oral and cephalometric equipment, where the exposure time is manually selected.

Stochastic effect

Biological effects whose probability of occurrence depends on the dose received, e.g. radiation induced cancer.

Supervised area

An area designated in accordance with the Ionising Radiations Regulations, 2017 where working conditions are kept under review. Supervised areas must be described in the local rules and routine radiation monitoring must be carried out.

Temporomandibular joints (TMJ)

The 'hinges' of the jaw bone.

Tissue reactions

Biological effect of acute, and high radiation exposure. Tissue reactions only occur when the dose exceeds a known threshold. Examples include radiation induced skin burn, hair loss and radiation sickness. Typically seen hours, days or weeks after the exposure.

Tomography

An X-ray technique that shows a single plane (slice) of the object under examination.

Tube current

The current flowing in the X-ray tube. It is directly proportional to the number of X rays produced and reported as mA (milliamperes).

Wavelength

The distance between successive crests of an electromagnetic wave passing through a given material. An indicator of radiation energy (higher wavelength = higher energy) Unit metre, symbol m.

Wisdom teeth

The third molar teeth which generally appear during the ages of 17-25.

Workload

The number of radiographs that the X-ray set will take over a specific period of time.

X-ray

A discrete quantity of electromagnetic energy, without mass or charge. Generated in an X-ray tube (see **X-ray tube**) or resulting from changes in the position of the orbiting electrons around an atomic nucleus – also known as characteristic X-rays.

X-ray tube

Device that produces X-rays by accelerating electrons through an evacuated tube onto a dense metallic target.

K2 ABBREVIATIONS USED IN THIS GUIDANCE

The abbreviations used in this guidance are given below, in alphabetical order, unless they already appear in the 'Terminology' section, or are fully explained elsewhere in this document.

A

AXREM (the Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care, formerly the Association of X-ray Equipment Manufacturers)
AAPM (the American Association of Physicists in Medicine)

B

BSDMFR (the British Society of Dental and Maxillofacial Radiology)
BDA (the British Dental Association)
BIR (the British Institute of Radiology)

C

CQC (the Care Quality Commission)
CIB (the Clinical Imaging Board)
CRE (clinical radiation expert)
CSAUE (clinically significant accidental or unintended exposures)
CNR (contrast to noise ratio)

D

DCP (dental care professional)
2D (meaning "two-dimensional" and used in this guidance to refer to any form of dental radiograph other than dental CBCT)
3D (meaning "three-dimensional" and used in this guidance to refer to dental CBCT imaging)

E

EADMFR (the European Academy of Dental and Maxillofacial Radiology)
ENT (ear, nose and throat)
EFOMP (European Federation of Organisations for Medical Physics)

F

FGDP(UK) (Faculty of General Dental Practitioners (UK))

G

GDC (General Dental Council)

H

HSE (the Health and Safety Executive)
HRA (the Health Research Authority)
HSENI (the Health and Safety Executive for Northern Ireland)
HIW (Healthcare Inspectorate Wales)
HIS (Healthcare Inspectorate Scotland)

I

IPEM (Institute of Physics and Engineering in Medicine)
IRAS (Integrated Research Application System)
IEC (International Electrotechnical Commission)

J, K, L, M

MHRA (Medicines and Healthcare products Regulatory Agency)
mAs (the product of the tube current and exposure time, which is proportional to the dose delivered to the patient as long as no other exposure factors change)

N, O, P, Q

NHS (National Health Service)
PPE (personal protective equipment)
PED (patient entrance dose)
PHE (Public Health England)
PMMA (polymethyl methacrylate)
PVC (polyvinyl chloride)
QA (quality assurance)
QC (quality control)

R

RQIA (Regulation and Quality Improvement Authority)
REC (research ethics committee)
ROI (region of interest)
RCR (Royal College of Radiologists)

S

SCoR (Society and College of Radiographers)
SLA (service-level agreement)
SDCEP (Scottish Dental Clinical Effectiveness Programme)
SAUE (significant accidental or unintended exposures)
SSD (source to skin distance)
SMPTE (Society of Motion Picture and Television Engineers)

T, U, V, W, X, Y, Z

TLD (thermo-luminescent dosimeter)
TIF (tagged image file format, also known as TIFF)

**Guidance Notes for
Dental Practitioners on the
Safe Use of X-ray Equipment**
2nd Edition

Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment sets standards for the safe use of X-ray equipment within dental practice.

Since the publication of the first edition in 2001, technological advances have been made in dental X-ray equipment and imaging techniques, radiation protection legislation has been revised and professional best practice guidelines updated. To reflect this, the second edition of the *Guidance Notes* has been completely revised and updated.

Presenting definitive, detailed and comprehensive recommendations in a logically ordered and intelligible format, the new edition is designed as a reference for the whole primary care dental team.

The guidance was produced by a working party led by Public Health England, and consisting of regulatory bodies, professional bodies representing dentistry and radiation protection, consultant dental radiologists and general dental practitioners.

Endorsed by

