

**Ionising Radiation (Medical Exposure) Regulations 2000,
(as amended)**

(IR(ME)R)

An Explanation Guide for Dental Practices

December 2011

IR(ME)R Explanation Guide as applied to dental practice

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1. Introduction

The Ionising Radiation (Medical Exposure) Regulations 2000¹, (as amended²) (IR(ME)R) governs the use of ionising radiation, including x-rays, in healthcare. They apply to any facility that carries out medical exposures involving the use of ionising radiation, whether in the NHS or independent sector. This includes therefore any dental practice that undertakes radiographic examinations.

The purpose of IR(ME)R is to minimize the risk to patients undergoing medical exposures. The legal requirements for the protection of employees who are involved in the use of ionising radiation are addressed by the Ionising Radiations Regulations (IRR 99)³ however these are not covered in this document.

The requirements of IR(ME)R apply regardless of the size of the dental practice, number of dentists employed or number of dental exposures carried out, and the aim of this document is to assist Dental Practices with their compliance with IR(ME)R through explanation and advice.

The use of ionising radiation within dental practices falls largely into 2 categories:

1. Where only dentists undertake their own radiographs
2. Where, as well as dentists undertaking their own radiographs, other staff groups such as dental nurses or hygienists may also take radiographs

With this in mind, two sets of example Employer's Written Procedures to accompany this explanation guide have been developed, to correspond with each scenario. These procedures and their appendices are intended as a guide only, and, whilst attempts have been made to ensure they are comprehensive, there will always be local variations which must be taken into account. Therefore, all the suggested text and examples must be carefully adapted to ensure they match local practice. Any text displayed in red will need to be carefully considered to demonstrate local ownership and practice.

It is important to note that, as definitive interpretation of law can only be established in the courts, the advice given here should be regarded as an expression of professional opinion rather than an absolute statement on the legal position.

IR(ME)R is regulated and enforced by different organisations within each country. These are known within the regulations as the 'appropriate authorities'. For Scotland the appropriate authority is the Scottish Ministers.

Further guidance on IR(ME)R can be found within IPeM's Medical and Dental Guidance notes⁴, the NRPB's Guidance Notes for Dental Practitioners on the safe use of x-ray equipment⁵, HPA Guidance on the Safe Use of Dental Cone Beam CT⁶ and the Department of Health guidance and good practice notes for IR(ME)R⁷.

2. Duty Holders and their responsibilities

There are 4 classes of 'duty holder' defined within IR(ME)R, and the legal obligation associated with each role is detailed below. These responsibilities apply even when the same person is acting as the employer, referrer, practitioner and operator.

2.1 Employer

As defined within IR(ME)R Regulation 2, the employer is 'any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation'.

The employer is sometimes known as the 'legal person' as described in 2.2 of the NRPB's Guidance Notes for Dental Practitioners on the safe use of radiographic equipment. The employer as defined within IR(ME)R is not necessarily the same as that defined in employment law. It should be the most appropriate person to take the responsibilities of this role. The employer is required to provide a framework under which duty holders carry out their functions.

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It may not be practicable for the employer to personally carry out all the duties required of the employer by IR(ME)R. Whilst the task of carrying out these duties may be delegated to others, the legal responsibility will always remain with the employer. Therefore, any such delegation should be properly documented, along with arrangements by the employer to oversee implementation of these duties by the delegated person.

The duties of the employer are –

- a) To ensure that appropriate written procedures are in place (Regulation 4(1)) and are subject to a quality assurance programme for document maintenance (Regulation 4(3)b). These written procedures shall include those defined in Schedule 1 of IR(ME)R, for example, procedures for entitlement of all duty holders, clinical evaluation and audit. A comprehensive list of Schedule 1 procedures may be found in Appendix 2
- b) To ensure that the procedures are complied with by entitled practitioners and operators (Regulation 4(1)a)
- c) To ensure that the training needs of entitled practitioners and operators are met and that there is continuing education for these duty holders (Regulation 4(4)).
- d) To ensure there is an up to date training record for all entitled practitioners and operators, including where the employer is concurrently the practitioner or operator (Regulation 11(4))
- e) To establish recommendations on referral criteria for dental exposures and make these available to all entitled referrers (Regulation 4(3)a).
- f) To ensure that appropriate written protocols are in place for every type of standard radiological practice and each piece of equipment (Regulation 4(2)).
- g) To establish diagnostic reference levels (DRLs) for standard radio-diagnostic examinations and ensure that there is a mechanism for assessment of compliance with these DRLs. If it is known that the DRLs are consistently exceeded, the employer shall set up a review and shall ensure that corrective action is taken (Regulation 4(3)c and (Regulation 4(6)).
- h) If research is carried out at the practice, to establish ‘dose constraints’ for biomedical and medical research programmes where there is no direct medical benefit to the individual (Regulation 4(3)d).
- i) To establish a process for the investigation of incidents resulting in exposures much greater than intended and for reporting such incidents to the appropriate authority (Regulation 4(5)).
- j) To ensure that a medical physics expert is retained and provides advice on matters relating to radiation protection concerning dental exposures (Regulation 9(1)).
- k) To keep an inventory of equipment and ensure that this equipment is limited to the amount necessary (Regulation 10(1) and Regulation 10(3)).

2.2 Referrer

A referrer is defined within IR(ME)R Regulation 2 as a registered healthcare professional who is entitled in accordance with the employer's procedures to refer individuals to a practitioner for dental exposure.

The referrer is responsible for supplying the practitioner with sufficient medical data (such as previous diagnostic information or medical/dental records) relevant to the dental exposure to enable the practitioner to decide on whether there is a sufficient net benefit (Regulation 5(5)). The referrer should take a history and perform a relevant assessment through the charting of the patients dental anatomy prior to requesting the radiograph, and document this information in the patient's dental record.

The referrer is expected to consider the specific ‘Referral Criteria’ provided by the employer when making a referral. Referral criteria should include the clinical problem or diagnosis, the type of radiograph required, an indication of the radiation dose to the patient, and any additional relevant comments such as the recommended interval between radiographs. The Faculty of General Dental Practitioners “Selection Criteria for Dental Radiography”⁸, British Orthodontic Society’s – Orthodontic Guidelines⁹ or other European criteria may be adopted. For cone beam CT (CBCT) referral criteria based on the recommendations of SEDENTEXCT could be utilised¹⁰.

The referrer is usually a dentist, but potentially could also be a GDC dental hygienist or dental therapist¹¹.

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Where it is necessary for a dentist to refer a patient for a medical exposure (such as an OPG or CBCT) that cannot be undertaken within the dental practice itself, and where it is not anticipated that any additional examination of the patient will take place, then the dentist remains as the referrer, and must be so entitled by the employer at the site where the exposure is undertaken (see Section 3).

It is for the employer where the radiograph is taken to ensure that all such 'external' referrers are properly entitled.

2.3 Practitioner

IR(ME)R Regulation 2 defines a practitioner as 'a registered healthcare professional who is entitled, in accordance with the employer's procedures, to take responsibility for an individual dental exposure'. This is a different definition to that of a 'dental practitioner' and care should be taken not to confuse the two.

Whilst the main duty of the IR(ME)R practitioner is the justification of individual dental exposures; the practitioner must also:

- a) Comply with the employer's procedures (Regulation 5(1))
- b) Cooperate with the operator regarding practical aspects, with other specialists and staff involved in a dental exposure, as appropriate (Regulation 5(6))
- c) Provide guidelines if they require entitled operators to authorise against them (Regulation 6(5)). See Section 5
- d) Ensure, to the extent of their involvement with the exposure, that the dose arising from the exposure is kept as low as reasonably practicable (Regulation 7(1))
- e) Only carry out a duty if they are trained to do so (Regulation 11(1))

Normally the role of the practitioner is carried out by a dentist.

2.4 Operator

Under IR(ME)R Regulation 2 an operator is 'any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects of dental exposures, except where they do so as a trainee under the direct supervision of a person who is adequately trained'.

The operator's duties are to take responsibility for each and every practical aspect which he/she undertakes. These duties may be carried out by a dentist, other dental professional or any other person involved in the process of taking a radiograph.

Examples of practical aspects might be:

- Identification of the patient
- Carry out OPG and cephalometric exposures
- Carry out intra oral exposures
- Carry out Cone Beam CT exposure
- Process dental film or CDR plates
- Clinical evaluation of dental exposures
- Undertake QA of equipment

The range of duties for some operators may be fairly limited e.g. process dental film, but still must be specified. For this, it is recommended that employers establish a list of competences against which each operator may be entitled. (See Dental Employer's Written Procedure EP1 Appendix 2)

Consideration should be given to the training requirements appropriate to each of the operator's defined competences. (See Dental Employer's Written Procedure EP1 Appendix 1)

Whilst the primary role of the operator is to carry out the practical aspects of an exposure, operator must also

- a) Comply with the employer's procedures (Regulation 5(1))
- b) Cooperate with the practitioner, regarding practical aspects, with other specialists and staff involved in a dental exposure, as appropriate (Regulation 5(6))

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- c) Ensure, to the extent of their involvement with the exposure, that the dose to the patient arising from the exposure is kept as low as reasonably practicable (Regulation 7(1))
- d) Only carry out a duty if they are trained to do so (Regulation 11(1))

2.4.1 Medical Physics Expert

The medical physics expert (MPE) should not be confused with the radiation protection adviser (RPA) which is identified in IRR 1999. The functions are different although, in practice, the same person may undertake both roles if suitably qualified.

The MPE must hold a science degree or its equivalent which is relevant to the use of ionising radiation as applied to dental exposures. The MPE is required to have been adequately trained for their involvement in dental exposures under the Regulation 11(1) as this role is considered to be an operator function.

The MPE must be entitled by the employer as an operator, on appointment, and their roles and functions (their 'scope of entitlement' (SoE)) defined. Evidence of this appointment and definition of SoE might be included in the Radiation Protection File (see section 17).

For a dental practice, the MPE would be expected to undertake tasks such as giving advice on patient dose, development and use of new and/or complex techniques, as well as other matters related to radiation protection concerning dental exposures, when necessary (Regulation 9(2)c).

3. Entitlement

3.1 General requirements

All duty holders identified in Section 2 of this document (referrers, practitioners, and operators (including MPEs)) must be entitled by the employer, or by the person to whom the task of entitlement has been delegated. If entitlement of duty holders is delegated, then the allocation of this duty should be clearly documented by the employer.

A prerequisite for entitlement as a referrer or practitioner for dental professionals is registration with the General Dental Council.

There is no requirement for operators to be registered. So, for example, an employer could, if they so wish, entitle an appropriately trained Receptionist or Practice Manager for the operator function of film processing (see Section 3.3).

Practitioners and operators must be adequately trained for the tasks they are entitled to perform (Regulation 11(1)), and the Regulations require that the employer shall keep an up-to-date record of such training which shall be available for inspection (Regulation 11(4)). More information on adequate training is covered in Section 4 of this guidance, and within Dental Employer's procedures EP1 and EP9.

The Regulations do not require that employers keep training records for their entitled referrers.

Each duty holder should have an associated scope of entitlement (Section 3.3) which outlines the duties they are entitled to undertake. This scope of entitlement might change over time for a number of reasons; a person might develop further skills, undertake additional training, or the practice might install new equipment. If the needs of a dental practice change, then competences might need to be added or removed as appropriate.

3.2 Specific requirements for different categories of employment

Since responsibility for entitlement of duty holders rests with the employer, the first question that arises is 'who is the employer?'

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For dentists, there are three categories of employment. These are

- i. Salaried dentists employed by the NHS Health Board
- ii. Self employed dentists treating NHS patients
- iii. Independent (private) dentists with no NHS patients

For the first of these categories, the employer is the Chief Executive of the NHS Health Board, and the salaried dentist is subject to all applicable provisions of the NHS Health Board's Employer's Written Procedures, including those for entitlement of duty holders. In this case, the 'entitler' shall be the Chief Executive of the NHS Health Board, or (normally) the person delegated by the Chief Executive for this function.

For the second of these categories, the employer would normally be the person who is recognised as the practice owner, and that person is responsible for providing the relevant Employer's Written Procedures, including those for entitlement of duty holders. Any such practice is subject to NHS Health Board practice inspection provisions, and this shall include an overview that the relevant Employer's Written Procedures and protocols for compliance with IR(ME)R are in place. Neither the practice owner nor any staff operating from within the practice is subject to the NHS Health Board's Employer's Written Procedures for any functions undertaken within the practice.

Independent dentists with no NHS patients are not subject to the provisions of the NHS Health Board's Employer's Written Procedures. Such practices must define clearly who is the employer (normally the practice owner) for the purposes of IR(ME)R, and this person is responsible for providing the relevant Employer's Written Procedures and protocols, and for entitlement of all duty holders.

A dentist in any of these categories who refers a patient to an NHS Health Board for a dental exposure (such as an OPG) must be entitled by the NHS Health Board as a 'referrer', and shall then be subject to the 'referral criteria' issued by the NHS Health Board (in their Employer's Written Procedures), and any relevant additional provisions for clinical evaluation of the resulting image (see Section 3.3).

Associate dentists must be entitled by the employer for the tasks they undertake within the dental practice and comply with the practice Employer's Procedures.

3.3 Scope of entitlement

Entitlement as a practitioner or operator must be restricted to those functions for which the duty holder is properly trained and experienced. To achieve this, employers should define a set of 'competences' which are applicable for the various staff groups (registered dentists, dental nurses etc.), then, for each staff member, assess and assign the appropriate range of duties according to training and competence. The General Dental Council have provided a Scope of Practice for its members which should also be considered¹¹.

Appropriate assessment of competence might include:

- | | |
|--------------------|--|
| For referrers: | Competent to refer for all dental exposures within the practice |
| For practitioners: | Competent to justify all dental exposures within the practice |
| For operators: | i Competent to identify the patient prior to a dental exposure in accordance with Employer's Written Procedure EP4 |
| | ii Competent to carry out all dental exposures within the practice |
| | iii Competent for clinical evaluation of all dental exposures carried out within the practice |
| | iv Competent for clinical evaluation of all dental exposures carried out by the NHS Health Board for patients referred by the practice |
| | v Competent to process films |
| | vi Competent to change chemicals in a dental processor |
| | vii Competent to carry out quality assurance on equipment |

The employer may nominate specific individuals as competence assessors where it is impractical for them to personally assess all duty holders. A competence assessor must be entitled and experienced in the duties they are assessing.

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For staff members that have been working within a practice for some time and are known by the competence assessor to be competent to undertake certain duties, it is not expected that they be reassessed and asked to demonstrate competence. They may be deemed competent by their experience. A competence assessor may assess their own competence.

For referral to the NHS Health Board (e.g. for OPG) entitlement as a referrer will be conferred by the NHS Health Board in accordance with their own Employer's Written Procedure for entitlement of duty-holders. This might be a generic entitlement in the NHS Health Board's Employer's Written Procedure (for example a statement that all registered dentists are deemed to be entitled to refer patients to the NHS Health Board for all dental exposure procedures), or by a separate letter of entitlement to each dentist from the NHS Health Board.

In conferring this referral entitlement, the NHS Health Board should take due account of the need to ensure that such referrals will only be accepted and justified by an NHS Health Board practitioner on the understanding that a competent clinical evaluation will be made and recorded. With regard to the previous paragraph, this should be stated by the NHS Health Board either in the letter of entitlement or, where generic entitlement applies, in the NHS Health Boards relevant Employer's Written Procedure.

For completeness, the dental practice should indicate to the NHS Health Board, the arrangements for ensuring that a competent clinical evaluation shall be made and recorded by an operator who has been so entitled by the practice employer, either by name or generically, (e.g. confirmation that all registered dentists at the practice are competent and have been entitled by the practice employer to carry out clinical evaluation on all dental images including OPGs). In this regard, while the NHS Health Board can take no responsibility for the competence of the clinical evaluation of these images, the Health Board might retain the right to include a check on whether these images are being properly evaluated in their provisions for clinical audit under the Regulations.

Each practice owner must also appoint a Medical Physics Expert, the scope of entitlement for whom should be to provide any necessary expert advice for all types of dental exposure carried out within the practice.

3.4 Employer's Written Procedure for entitlement of duty holders

The provisions described above are reflected in the sample Dental Employer's Written Procedure EP1 and its appendices, which accompany this explanation guide. This also includes examples of required qualifications, training, and experience.

4. Training

Under IR(ME)R Regulation 11(1), no operator or practitioner shall carry out a dental exposure or any practical aspect without first having been adequately trained. Under IR(ME)R referrers do not need additional training on radiation protection, but will be expected to have up to date training on new techniques and technologies e.g. specific training on CBCT (as recommended within HPA-CRCE-010⁹).

IR(ME)R also requires (Regulation 4(4)a) that the employer take steps to ensure that every practitioner or operator engaged by them is adequately trained to undertake all of their duties. This includes undertaking continuing education and training after qualification (Regulation 4(4)b). For example, in the case of clinical use of new techniques, this might include training related to these techniques and the relevant radiation protection requirements.

It is important that practitioners and operators maintain their competence for each duty for which they are entitled. If competence cannot be maintained for any reason, then consideration should be given to either undertaking further training or removing the task from their scope of entitlement. Where appropriate, a review of scope of entitlement should form part of an appraisal process.

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The employer is responsible for ensuring an up to date record is kept of training and must make it available to an inspector if requested (Regulation 11(4)). The training record should contain any relevant dates on which training was completed and the nature of the training. Whilst the employer is responsible for this record, it is often the duty holder themselves who maintains their own personal continuing professional development folder which contains a more detailed record. For clarity this could be laid out within an Employer's Written Procedure, though this is not required by the legislation. (See Dental Employers procedures EP9). For an example of a training record, see Appendix 6.

When the employer is concurrently the practitioner and operator, he/she is required keep a record of their own training.

Regulation 11(5) says that when the employer enters into a contract with another to engage a practitioner or operator otherwise employed by that other, e.g. agency staff or MPE, the latter (agency or medical physics service) shall be responsible for keeping the duty holders training records. If requested, the third party employer must supply these records to the dental practice employer. This requirement should be specified in the contract between the employer and third party.

Where a duty holder is 'in training' for a particular competence, that function may only be carried out under the supervision of a duty holder who is 'assigned as competent' for that function. The level of supervision shall be appropriate to the function in question, and the supervisor shall be responsible for carrying out that function in accordance with Employer's Written Procedures and protocols.

5. Justification and Authorisation

Justification is the intellectual process of weighing up the expected benefit of an exposure against the possible detriment of the associated radiation dose. Authorisation is the record that this justification has been carried out, and must occur prior to the exposure. This record is usually a signature or unique electronic entry in the patient's dental record.

Justification is the primary role of the practitioner. However, if it is not practicable for a practitioner to justify a dental exposure, then an appropriately entitled operator may authorise an exposure using guidelines issued by a practitioner (Regulation 6(5)).

These are sometimes known as justification or authorisation guidelines. It should be noted that these guidelines are not required if dental exposures are always justified and authorised by a practitioner, which in dentistry is normally the case.

An example is provided for explanation purposes.

An example of the use of guidelines issued by a practitioner:-

A dental hygienist may be entitled as a referrer (following additional skills development) and as an operator for carrying out a dental radiograph. However, the GDC does not currently recognize a role for dental hygienists as practitioners to undertake justification of a dental exposure. So, instead of asking a dentist who is entitled as an IR(ME)R practitioner to justify the exposure every time they need to take a dental radiograph, guidelines can be issued by the practitioner for the dental hygienist to use and authorise against.

These guidelines must be comprehensive and written by a dentist who is entitled as a practitioner for all the dental exposures it contains. They should be explicit as to the age of patient they refer to e.g. adult or child. The guidelines must be authorised by the practitioner to display ownership and demonstrate suitable document control. For an example of a guideline, see Appendix 3.

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When justifying an exposure appropriate weight must be given to the following

IR(ME)R - Regulation 6(2)		Consider
a	The specific objectives of the exposure	What is to be gained by carrying out the exposure? How will it change the management of the patient?
b	The characteristics of the individual involved	Such as age or individual dental history of the patient
c	The potential diagnostic benefits to the individual from the exposure	What is the expected benefit of the dental exposure? Have they already had an radiograph which could provide the required information?
d	The detriment the exposure may cause	What is the possible detriment from the associated radiation dose?
e	The efficacy, benefits and risk of available alternative techniques having the same object but involving no or less exposure to radiation	What other examinations are available that could answer the diagnostic question but involve no or less exposure to radiation?

IR(ME)R requires special attention to be given during the justification of any dental exposure that is undertaken for either medico-legal reasons (Regulation 6(3)a) or for research when there is no direct benefit to the patient (Regulation 6(3)b).

For dental treatments where it is known in advance that a series of radiographs will be required e.g. for root canal treatment, a protocol may be written that describes when the radiographs will be taken. Therefore documenting 'root canal' within the patient's dental notes prior to the treatment will demonstrate authorisation for the series of exposures.

Where specific circumstances, such as the need for an unplanned radiograph due to a complication mid-procedure, dictate that it might not be in the best interests of the patient for a practitioner to carry out authorisation in advance of an exposure, authorisation of the exposure must occur as soon as practicable thereafter. A note detailing the deviation from accepted practice should be included in the patient's notes.

Suggested dental practice provisions for justification and authorisation have been outlined in dental Employer's Written Procedure EP3.

6. Optimisation

Every dental exposure must be optimised to ensure that the radiation dose arising from the exposure is kept as low as reasonably practicable (Regulation 7(1)). This is the responsibility of both the practitioner and operator in their respective roles. Even though the radiation doses associated with dental images are usually very low, these exposures still need to be optimised.

Matters which may help ensure optimisation include the following; however this list is not exhaustive:

- a) When purchasing new equipment or introducing new techniques, consideration should be given to the resultant dose to the patient
- b) If using film, ensure that a fast film or film screen combination is utilised e.g. E-speed or faster for I/O film; effective speed ≥ 400 for any extra-oral film/screen combination
- c) All practitioners and operators are adequately trained to perform the tasks for which they are entitled
- d) Practitioners and operators undertake regular and relevant CPD and training after qualification
- e) Protocols are written to ensure that the minimum number of exposures are taken to answer the clinical question
- f) The correct settings are used to ensure that the dose is as low as reasonably practicable
- g) The correct collimation used to ensure that the dose is as low as reasonably practicable
- h) Images should be scored using the 1, 2, 3 system or for CBCT the 1, 2 system to monitor image quality. This may highlight any issues

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- i) Audit of image quality
- j) Implementing dental DRLs where possible

Critical examination of newly installed equipment, acceptance testing and regular equipment quality assurance are also ways to ensure that examinations are optimised, these are covered under IRR99.

IR(ME)R also calls for special attention for optimisation to be given to any medico-legal exposure (Regulation 7(7)a) and to exposures to children (Regulation 7(7)b). Although not defined in law, an example of special attention may be having specific protocols in place for paediatric and medico-legal dental exposures.

7. Research

Although not common within dental practices, IR(ME)R places additional obligations relating to research exposures. These are listed below and, if research is undertaken within a dental practice, must be addressed within the employer's procedures. (See Dental Employers procedures EP14)

- a) All research must have been approved by an ethics committee (Regulation 6(1)c)
- b) All individuals must participate voluntarily (Regulation 7(4)a)
- c) Individuals must be informed of the risks of the radiation exposure in advance (Regulation 7(4)b)
- d) Dose constraints must be set down in the employers procedures for individuals whom no direct medical benefit is expected (Regulation 7(4)c)
- e) Individual dose targets are planned when the individual is expected to receive a diagnostic benefit (Regulation 7(4)d)

A dose constraint is a restriction on the total dose of a research study that is not expected to be exceeded. The constraint is based on the total dose from all radiodiagnostic procedures included in the research protocol. A dose target is target level of dose set before research exposures begin, in this way, excessive doses should be avoided.

8. Medico-Legal

Medico-legal exposures are defined in Regulation 2 as an examination performed for insurance or legal purposes without a medical indication. An example of this may be a dental radiograph following an assault where compensation is being claimed and the radiograph is not required as part of the persons diagnosis or treatment.

IR(ME)R has additional obligations associated with medico-legal exposures which are listed below. If medico-legal exposures are undertaken within a dental practice an employer's procedure is required (See Dental Employer's Written Procedure EP15).

- a) The practitioner when justifying the exposure shall pay special attention to medico legal exposures (Regulation 6(3)a)
- b) The practitioner and operator shall pay special attention to the need to keep doses arising from medico legal exposures as low as reasonably practicable. (Regulation 7(7)a)

9. Occupational Health Surveillance

Occupational health surveillance exposures as defined in Regulation 2 are those associated with the medical surveillance exposure for workers. An example might be a dental radiograph prior to working on an oil rig where there are no dental provisions although the patient may be asymptomatic at the time. If these types of exposure are undertaken then for clarity and completeness they could be reflected within a written procedure. (See Dental Employer's Written Procedure EP15)

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10. Diagnostic Reference Levels

Regulation 4(3)(c) states that the employer must 'establish Diagnostic Reference Levels' (DRLs). These DRLs are the dose levels for each type of dental radiography (such as an Intra Oral (mandibular molar)) that would not be expected to be exceeded when good and normal technique is used for a 'standard-sized' patient.

For some types of medical and dental radiography, National and European DRLs are available, and these should be considered by the employer when setting the actual ('local') DRLs for the practice. The chosen DRLs should reflect local practice, and could, for example be calculated and provided to the employer by the MPE following a dose survey for the practice. Where the employer sets local DRLs that are higher than the national ones, this would need to be explained. Further information on DRLs can be found on the Department of Health website¹³.

Currently the only formally adopted National DRL for dental exposures is for an adult intra oral radiograph and is shown below. This is from a survey in 1998.

Radiograph	Patient entrance dose (PED) per radiograph (mGy)
Intra Oral (mandibular molar)	4

A more recent review of patient doses which included dental radiography was carried out by the HPA in the 2005 Review¹⁴ and the following are reference levels which reflect practice at that time. A recommendation of an achievable dose for CBCT has been made by an HPA Working Party¹⁵ and is also listed below. The cephalometric figures are from a recent HPA report¹⁶. Whilst these are not formally adopted national DRLs, it is strongly recommended that these, and any other subsequent recommendations from the HPA, are considered.

Radiograph	Patient entrance dose (PED) per radiograph (mGy)
Intra-oral (adult)	2.3
Intra-oral (child)	1.5
Dose Width Product (DWP) per radiograph (mGy mm)	
Panoramic (adult and child)	60
Dose Area Product (DAP) per radiograph (mGy cm ²)	
Panoramic (adult and child)	82
Cephalometric (adult)	40
Cephalometric (child)	25
Cone Beam CT (adult)	250

Regulation 4(6) requires that the employer must undertake an appropriate review whenever the defined DRLs are consistently exceeded. To establish whether this is the case, the employer must therefore, in accordance with Schedule 1(g), have a written procedure 'for the assessment of patient dose'.

If a dose value, e.g. a 'Dose Area Product (DAP) for a panoramic view, is displayed by the x-ray equipment, a routine review of such data will give an indication of whether the corresponding local DRL is being exceeded.

However, where the equipment does not provide a dose value after an exposure, then the only practical means of assessing patient dose is to record the machine settings (the 'exposure factors ') and assess the dose on the basis of prior knowledge of how these exposure factors relate to the dose being delivered by the x-ray machine. In practice, this 'prior knowledge' will normally arise from the equipment assessment and calibration

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carried out by the RPA on a 3 yearly basis. An example of how exposure factors and related doses might be recorded and compared with DRLs is in Appendix 5.

In Table A5.1, (Appendix 5), Columns 3, 4, 5 and 6 are the exposure factors, and Column 7 the 'Focus to Skin Distance (FSD)' or 'Focus to Film Distance (FFD)' set and recorded by the RPA at the 3 yearly equipment assessment for each of the listed 'examinations'. Column 8, the 'Reference dose' is the dose measured by the RPA for these settings.

If these standard exposure factors are then used by the operator for the examination in question, and the film is acceptable, then there should be reasonable confidence that the 'reference dose' is the dose being delivered to the patient, and hence, by comparison with Column 9, the DRL is not being exceeded. However, if, during the period between machine assessments, it is found necessary to alter exposure factors to achieve acceptable image quality, then a reassessment of the doses to the patient will be necessary.

As a further check, if a stepwedge is carried out regularly and is within tolerance then it can be assumed that the x-ray machine and processor are both working correctly. If the stepwedge is out of tolerance and the chemistry is proven to be correct, then consideration should be given to carrying out further tests on the radiographic equipment.

For CR/DR the resultant image may include a Sensitivity/Exposure Index or graph. This information can be compared with the manufacturer's recommendations which will give an indication of how much radiation has reached the detector. If the information displayed on the image is higher or lower than recommended, too much or too little radiation is being used. If too little radiation is being given then the resultant image may also be grainy in appearance.

Care must be taken when using CR/DR as the image will appear diagnostic even when too much radiation is used. This is especially true if no exposure index/graph is displayed.

If it can be demonstrated that a DRL has been unexpectedly exceeded, it should be documented along with any extenuating circumstances. Where DRLs are consistently exceeded it should be reported to the employer for investigation. Once an investigation has taken place any necessary corrective action must be implemented. (An occasional exceedance due to a change in exposure factors to accommodate special circumstances such as unusual patient anatomy should be recorded but does not require investigation.)

The procedure for establishing and using DRLs, along with the process of investigation needs to be documented (See Dental Employers procedures EP7).

11. Clinical Evaluation

Every dental exposure must have a documented report or clinical evaluation. If it is known prior to the exposure that no clinical evaluation will occur, the exposure cannot be justified and cannot lawfully take place (IR(ME)R Notes for Guidance Regulation 7(8)).

Clinical evaluation is considered to be one of the practical aspects of an exposure, and is therefore an operator function. The Employer's Written Procedures must make it clear where this evaluation is to be recorded e.g. in the patients dental record, and how the entitled operator undertaking this task can be identified. (See Dental Employer's Written Procedure EP8). In most cases the dentist will be the operator for clinical evaluation.

12. Incidents and near misses involving ionising radiation

It is a requirement of the legislation that when an employer knows or has reason to believe that the radiation dose given to a patient is 'much greater than intended' (MGTI), it must be investigated and if necessary be reported to the appropriate authority (Regulation 4(5)). For conventional dental radiographs, an exposure MGTI is defined in HSE Guidance document PM 77 'Equipment used in medical exposure 'as one where the

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dose is at least 20 times that intended. For other procedures such as CBCT see HPA-CRCE-010 or consult your RPA and/or MPE.

Incidents involving dental radiation exposures can occur for several reasons. They may be due to an equipment fault, human error or a procedural failure. Incidents should be internally reported and investigated. Following a preliminary investigation, if it is found that a given exposure was MGTI then this would require external reporting to the appropriate authority. The authority will vary depending on the cause of the incident. External reporting could be to either-

- SM for all incidents, excluding those due by equipment malfunctions. These include when the wrong patient is x-rayed or there has been a failure to follow Employer's Written Procedures. (IR(ME)R)
- HSE, for incidents caused by equipment malfunctions (IRR 99)

Ideally all near miss incidents should follow the same pathway, as any lessons learnt can be applied and have the potential to prevent an actual incident from occurring. The process of investigation of incidents and near misses, including responsibilities and timescales may be laid out within Employer's Written Procedure, although this is not required under legislation. Then should a radiation incident occur the process of investigation will be standardised. (See Dental Employer's Written Procedure EP10)

13. Clinical Audit

Clinical audit is a requirement under IR(ME)R Regulation 8. It includes a review of dental radiological practices which seeks to improve the quality and outcome of patient care. This can be done through a structured review which might lead to a modification of practice or the application of new practices where necessary. The Employer's Written Procedures should include provision for carrying out clinical audit as appropriate. (See Dental Employer's Written Procedure EP13)

Clinical audit might include:

- a) Review of image quality monitoring (1, 2, 3 or for CBCT 1, 2 scorings). These should be reviewed to see if there are any issues which may highlight training requirements
- b) Review of images, by multiple persons where possible, to agree levels of quality
- c) Dose audit
- d) An audit of dental records to ensure that each dental exposure has been referred, authorised and clinically evaluated in line with the written procedures and that the duty holders are identifiable
- e) An audit to check that entitlement of staff has taken place and that it is supported by appropriate training and CPD when necessary
- f) Audit of the patient identification process to ensure that each operator is following the correct procedure

14. Quality Assurance

Quality assurance (QA) as defined in IR(ME)R Regulation 2 refers to the provision and maintenance of the Employer's Written Procedures and protocols (see Dental Employer's Written Procedure EP12). It does not refer to equipment QA which is covered by IRR 99 or IRR (NI) 2000.

Document QA entails ensuring that the Employer's Written Procedures and protocols comply with a document control system where the document author, version number, issue date, review date etc are clearly identified, and that the documents are reviewed by the review date.

IR(ME)R (Schedule 1(e)) requires that there shall be an Employer's Written Procedure outlining what QA under IR(ME)R is to take place, who is responsible for carrying it out, how often documentation is reviewed and, importantly, how the employer knows this has taken place.

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15. Employer's Written Protocols

The employer must ensure that written protocols are in place for every type of standard radiological practice for each piece of equipment (Regulation 4(2)).

Employer's written protocols describe which exposures/projections should be done in most circumstances and should include matters such as whether it is an adult or paediatric exposure, the area of the mouth, the machine settings or exposure factors, whether they are film or digital exposure factors and the expected dose or DRL if available. Protocols may be displayed next to the each x-ray machine. For an example of a written protocol and exposure chart see Appendix 4 and 5.

Employer's written protocols are subject to the document quality assurance provisions referred to in Section 14 of this Guidance (and see Employer's Written Procedure EP12).

16. Equipment

The employer is responsible for keeping an up-to date inventory of equipment and ensuring it is available to an IR(ME)R inspector if requested (Regulation 10(1)). The inventory must contain the following information (Regulation 10(2)):

- a) Name of manufacturer
- b) Model number
- c) Serial number or other unique identifier
- d) Year of manufacturer
- e) Year of installation

The inventory must include all equipment that has the potential to impact patient dose e.g. processor, CR reader and each digital detector. It could also include information such as location and servicing arrangements if not covered elsewhere.

The employer must also ensure that the amount of equipment at an installation is limited to the amount necessary (Regulation 10(3)). This implies that any superseded equipment must be decommissioned.

17. IR(ME)R within the existing Radiation Protection File

Most dental practices will already have a (paper or electronic) Radiation Protection File, and this could contain a number of statements which outline the key requirements of IR(ME)R (See Appendix 1).

These might include:

- Clarification over who is the IR(ME)R 'employer' for the organisation
- Radiation doses to patients are kept as low as reasonably practicable consistent with the clinical purpose
- Clear framework of delegation if persons are to carry out duties on the employers behalf (if appropriate)
- That the required IR(ME)R procedures are in place
- A statement that all duty holders must comply with IR(ME)R procedures
- Appointment and entitlement of a Medical Physics Expert

This file might also include copies of the Employer's Written Procedures and protocols, and records to demonstrate that they have been read by the appropriate staff members.

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References

1. Ionising Radiation (Medical Exposure) Regulations 2000
http://www.opsi.gov.uk/si/si2000/uksi_20001059_en.pdf
2. Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006 and 2011
http://www.opsi.gov.uk/si/si2006/uksi_20062523_en.pdf
<http://www.legislation.gov.uk/uksi/2011/1567/regulation/2/made>
3. Ionising Radiations Regulations 1999
<http://www.england-legislation.hmso.gov.uk/si/si1999/19993232.htm>
4. Medical and Dental Guidance Notes
http://www.ipem.org.uk/ipem_public/article.asp?id=0&did=49&aid=628&st=&oaid=-1
5. Guidance notes for dental practitioners on the safe use of x-ray equipment
http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947310610
6. Guidance on the Safe Use of Dental Cone Beam CT
<http://www.hpa.org.uk/Publications/Radiation/CRCEScientificAndTechnicalReportSeries/HPACRCE010/>
7. Guidance and good practice notes for IR(ME)R
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_064707.pdf
8. Faculty of General Dental Practitioners “Selection Criteria for Dental Radiography”
<http://www.fgdp.org.uk/content/publications/selection-criteria-for-dental-radiography.ashx>
9. British Orthodontic Society’s – Orthodontic Guidelines
<http://www.bos.org.uk/index/booksguides/radiographyguidelinespp>
10. SEDENTEXCT Cone Beam CT for Dental and Maxillofacial radiology : evidence based guidelines
http://www.sedentexct.eu/files/guidelines_final.pdf
11. General Dental Council Scope of Practice
<http://www.gdc-uk.org/Newsandpublications/Publications/Publications/ScopeofpracticeApril2009%5B1%5D.pdf>
12. IPEM - Guidance in the Establishment and Use of Diagnostic Reference Levels for Medical X-ray Examinations Report 88
<http://www.ipem.ac.uk/publications/ipemreports/Pages/GuidanceontheEstablishmentandUseofDiagnosticReferenceLevelsforMedicalX-RayExaminations.aspx>
13. Guidance on the establishment and use of “Diagnostic Reference Levels” (DRLs) as the term is applied in the Ionising Radiation (Medical Exposure) Regulations 2000
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_074099.pdf
14. Doses to Patients from Radiographic and Fluoroscopic X-ray Imaging Procedures in the UK -2005 Review
<http://www.hpa.org.uk/Publications/Radiation/HPARPDSeriesReports/HpaRpd029/>
15. Recommendations for the Design of x-ray facilities and the Quality Assurance of Dental cone Beam CT Systems
<http://www.hpa.org.uk/Publications/Radiation/HPARPDSeriesReports/HPARPD065/>
16. National Reference doses for dental cephalometric radiography
<http://bjr.birjournals.org/cgi/gca?sendit=Get+All+Checked+Abstract%28s%29&gca=84%2F1008%2F1121>

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Appendix 1

The following statements describe some key requirements of IR(ME)R that could be considered for inclusion in the Radiation Protection File, if they are relevant and reflect local practice.

IR(ME)R statements
For the XXXXX Dental Practice , <i>(named person)</i> is the employer for the purposes of IR(ME)R
The employer will ensure that all of the Employer's Written Procedures and protocols required for compliance with IR(ME)R are provided and are authorised by <i>(named person)</i> on behalf of the employer, and are subject to a written procedure for document quality control.
Entitlement of duty holders at XXXXX Dental Practice , will be carried out by <i>(named person)</i> , on behalf of the employer <i>(if a different person)</i>
The employer will ensure that all referrers to the XXXXX Dental Practice are provided with appropriate referral criteria
Responsibility for the task of maintaining a record of training of duty holders under IR(ME)R (including other staff carrying out procedures within the dental practice's premises) will lie with <i>(named person(s))</i>
A Medical Physics Expert shall be appointed and entitled to be involved as required for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning dental exposures
The employer shall establish 'diagnostic reference levels' (DRLs) for dental examinations and ensure that there is a mechanism for assessment of compliance with these DRLs. Where it is known that DRLs are consistently exceeded, the employer shall set up a review, and shall ensure the corrective action is taken
The employer shall establish a procedure for the investigation of incidents which may have resulted in an overexposure of patients and for reporting such incidents to the appropriate authority (either Scottish Ministers (for IR(ME)R) or for incidents due to equipment malfunction, the HSE (for IRR 99)
Entitled practitioners and operators must comply with the employer's procedures. For the avoidance of doubt, where a person acts as employer, referrer, practitioner and operator concurrently (or in any combination of these roles) he shall comply with all the duties placed on employers, referrers, practitioners or operators under these Regulations accordingly
All practitioners and operators, to the extent of their respective involvement in a dental exposure, shall ensure that doses arising from the exposure are kept as low as reasonably practicable consistent with the intended purpose
Responsibility for maintaining an inventory of all radiation equipment used at the XXXXX Dental Practice lies with <i>(named person)</i>
The document authoriser is responsible for ensuring that the document is reviewed within the required period and for recording completion of each review (irrespective of whether the document is amended or not)

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Appendix 2

IR(ME)R Schedule 1

The whole of Schedule 1 is included below for completeness. However Procedure (f) '...and administered activity' and all of Procedure (i) refers to nuclear medicine examinations so are not applicable to dentistry.

Schedule 1

The written procedures for medical exposures shall include –

- a) procedures to identify correctly the individual to be exposed to ionising radiation;
- b) procedures to identify individuals entitled to act as referrer or practitioner or operator;
- c) procedures to be observed in the case of medico-legal exposures;
- d) procedures for making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding;
- e) procedures to ensure that quality assurance programmes are followed;
- f) procedures for the assessment of patient dose and administered activity;
- g) procedures for the use of diagnostic reference levels established by the employer for radiodiagnostic examinations falling within regulation 3(a), (b), (c) and (e), specifying that these are expected not to be exceeded for standard procedures when good and normal practice regarding diagnostic and technical performance is applied;
- h) procedures for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 7(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(d) where no direct medical benefit for the individual is expected from the exposure;
- i) procedures for the giving of information and written instructions as referred to in regulation 7(5);
- j) procedures for the carrying out and recording of an evaluation for each dental exposure including, where appropriate, factors relevant to patient dose;
- k) procedures to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable.

Appendix 3 – Example of a Guideline issued by a practitioner

JUS 1	Example Guidelines for the authorisation of dental radiographs	XXXXXX Dental Practice
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Adults (over 16 years of age)

Type of dental exposure	Clinical indication	Individual characteristics	Alternative techniques involving less or no radiation	Effective dose (mSv)
Intra oral radiograph (bitewing/periapical)	<ul style="list-style-type: none"> • Assessment of Caries • Clinical suspicion of retained root • Clinical suspicion of unusual anatomy 	<p><u>Minimum</u> frequency for radiograph to assess caries following a clinical assessment</p> <ul style="list-style-type: none"> – High risk – 6 months – Moderate risk – 12 months – Low risk – approximately 2 year intervals <p>– For indications other than caries, no dental radiograph within the last 3 years</p>	N/A	<0.01

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Appendix 4 – Example of Dental Written Protocols

PRO1	Example Protocols for dental radiographs	XXXXX Dental Practice
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Adults (over 16 years of age)

Type of dental exposure	Clinical indication	Comments
OPG	Unusual eruption patterns Unusual morphology Extensive and general periodontal breakdown	Whole mouth is required
	Impacted teeth on one side	Select setting that includes the side required only
	Delayed eruption Unexplained missing teeth	Limit the area of the jaw imaged to the minimum area required
	Assessment of wisdom teeth prior to planned surgical intervention	Select setting to cover the wisdom teeth and not the whole mouth, unless specifically requested

Children (up to the age of 16 years)

Type of dental exposure	Clinical indication	Comments
OPG	Unusual eruption patterns Unusual morphology	Limit the area of the jaw imaged to the minimum area required
	Delayed eruption Unexplained missing teeth	Limit the area of the jaw imaged to the minimum area required
	Prior to orthodontic treatment for assessment of developing dentition when patient is aged 12-13 years	Image dentition image only – no condyles

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Appendix 5 – Example of Dental Exposure Settings

PRO2	Example Exposure Settings for dental radiographs	XXXXX Dental Practice
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With regard to Section 10 of this document, Tables A5.1 and A5.2 are examples of exposure charts that should be completed each time that the machine in question is calibrated by the RPA, and provided to the practice.

For most machines in common use, however, the information within most of the columns with red headings might not be provided by the RPA for all types of exposure. The RPA service typically will confine the information provided to those exposure factors that might be adjustable for the machine in question (for example time of exposure (Column 6) only), in addition to the ‘setting’ in Column 2.

It is recommended that the completed exposure chart be displayed alongside the relevant X-ray set

Table A5.1: An example of an adult exposure chart that should be completed each time that the machine in question is calibrated by the RPA service.

Film speed setting (or equivalent) _____

Examintion	X-ray Machine Settings	kV	mAs	mA	sec	FSD or FFD cms	Ref. Dose	Local DRL	Specific Comments
Upper	1-3 Adult and incisor	70	1.4	7	0.2	20	1.4 mGy	2.1 mGy	Rectangular collimation should be used whenever clinically possible
	4-5 Adult and premolar		1.75		0.25		1.9 mGy		
	6-8 Adult and molar		2.8		0.4		2.0 mGy		
Lower	1-3 Adult and incisor	70	1.12	7	0.16	20	1.1 mGy	1.7 mGy	Rectangular collimation should be used whenever clinically possible
	4-5 Adult and premolar		1.4		0.2		1.4 mGy		
	6-8 Adult and molar		2.24		0.32		1.6 mGy		
Bitewing	Adult and appropriate tooth	70	2.24	7	0.32	20	1.6 mGy		Rectangular collimation should be used whenever clinically possible
Occlusals	Adult and occlusal	70	2.24	7	0.32	20	1.6 mGy		Rectangular collimation should be used if clinically possible
Lat Ceph	Standard	90	-	20	0.3	150	40mGy cm ²	40mGy cm ²	If possible, limit field to area of interest
Panoramic	Standard jaw	73	-	8	10	-	80mGy cm ²	82mGy cm ²	If possible, limit field to area of interest in line with written protocols

Table A5.2: An example of a paediatric exposure chart that should be completed each time that the machine in question is calibrated by the RPA service. NB. Columns 5 and 7 of the paediatric exposure chart have been removed for clarity but could be included in practice if this information is available.

Film speed setting (or equivalent) _____

Paediatric Exposures for film

The information within the columns with red headings may not be available for all types of exposure or machine. They are all shown here for demonstration purposes to provide examples of the type of information that may be available.

This protocol information may be displayed in a different format and limited to the exposure settings available.

Examination	X-ray Machine Setting	kV	mAs	sec	Ref. Dose	Local DRL	Specific Comments
Upper 1-3 4-5 6-8	Child and Incisor Child and premolar Child and molar	60	1.12 1.4 2.24	0.16 0.2 0.32	1.0 mGy 1.1 mGy 1.3 mGy	1.4 mGy	Rectangular collimation should be used whenever clinically possible
Lower 1-3 4-5 6-8	Child and Incisor Child and premolar Child and molar	60	0.84 1.12 1.75	0.12 0.16 0.25	0.9mGy 1.2 mGy 1.4 mGy	1.4 mGy	Rectangular collimation should be used whenever clinically possible
Bitewing	Child and appropriate tooth	60	1.75	0.25	1.0 mGy		Rectangular collimation should be used whenever clinically possible
Occlusals	Child and occlusal	60	1.75	1.25	1.0 mGy		Rectangular collimation should be used whenever clinically possible
Lat Ceph	Child	80	-	0.25	25mGyc m ²	25mGy cm ²	If possible, limit field to area of interest
Panoramic	Child	60	-	10	60mGyc m ²	60mGy cm ²	If possible, limit field to area of interest in line with written protocols

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Appendix 6 – Examples of Training records

Name			
Job title	e.g. Dentist, Dental Nurse etc		
Site/Room/Equipment	e.g. Glasgow Dental Practice, Exam room 2, Intra oral machine		
Task	✓	Trainer initials	Date
Switch radiographic equipment on and off			
Aware of exposure charts and protocols			
Can select appropriate exposure factors			
Undertake an intra oral dental exposure			
Use rectangular collimation			
Complete room log including exposure factors/dose when appropriate			
This person has received training on the above tasks			Date
Signature of trainer			
Name of Trainer			
Signature of duty holder			

Name			
Job title	e.g. Dentist, Dental Nurse etc		
Site/Room/Equipment	e.g. Glasgow Dental Practice, Exam room 2, Desktop processor		
Task	✓	Trainer initials	Date
Switch radiographic equipment on and off			
Process a film			
Clean processor			
Change chemicals in processor			
Processor QA			
This person has received training on the above tasks			Date
Signature of trainer			
Name of Trainer			
Signature of duty holder			

Name			
Job title	e.g. Dentist		
Site/Room/Equipment	e.g. Glasgow Dental Practice, Exam room 2, Intra oral machine + desktop processor		
Task	✓	Trainer initials	Date
Use of intra-oral radiographic machines			
How to process a film			
This person has received training on the above tasks			Date
Signature of trainer			
Name of Trainer			
Signature of duty holder			