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This article counts towards one of the five core subjects introduced in 2007 by the GDC.

# Ionizing Radiation Regulations and the Dental Practitioner: 2. Regulations for the Use of X-rays in Dentistry

**Abstract:** The first article in this series covered radiation hazards and protection. To minimize the potential harmful effects of X-rays, legislation has been introduced by a number of countries including the European Union.

**Clinical Relevance:** This article describes some of the aspects of the regulations governing the use of ionizing radiation in the United Kingdom as it affects dental radiography and is not intended to be a comprehensive account of the legislation.

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Since the early part of the 20th century, X-rays have been recognized as potentially harmful. The International Commission on Radiation Protection (ICRP) was set up to give guidance on how people who use and receive radiation might do so safely.

There are three basic principles of good radiation protection practice:

- Justification;
- Dose Optimization;
- Dose Limitation.

In 1999, legislation regarding the use of radiation and radiation protection changed, with the introduction of *The Ionizing Radiation*

*Regulations (IRR) 1999* and also, a year later, with *The Ionizing Radiation (Medical Exposure) Regulations 2000*, which replaced IRR 1985 regulations, and IR(POPUMET)R 1988 regulations, respectively.<sup>1,2</sup> This article reviews the aims and essential requirements of these two pieces of legislation as they affect dentists and the use of X-radiation in a general dental practice setting in the United Kingdom.

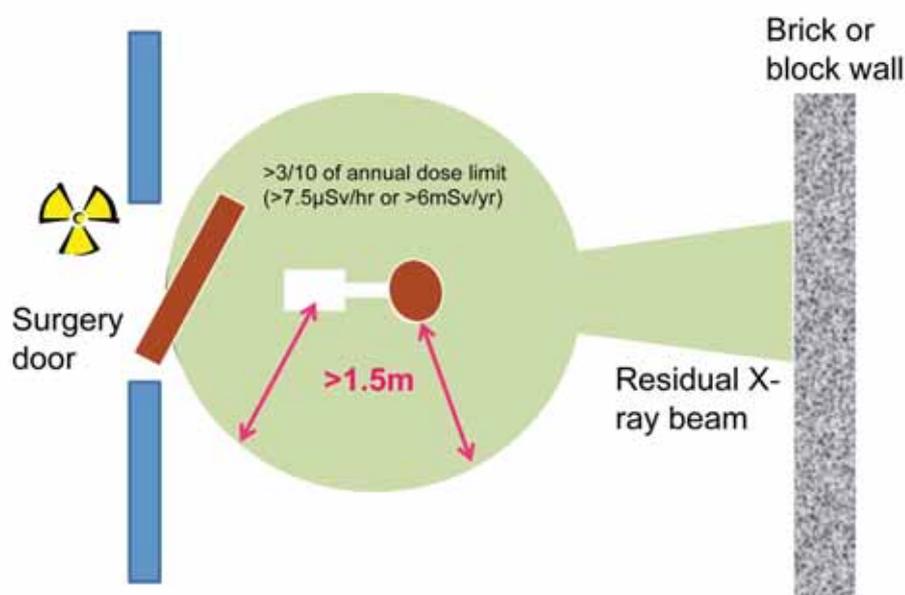
The two Acts, although showing some common themes, approach the subject of radiation protection from differing standpoints; IRR 1999 primarily implements radiation protection for workers exposed to radiation, while the IR(ME)R 2000 legislation is designed to protect patients from excess exposure to radiation during treatment. The two sets of legislation are monitored by two different bodies: IRR 1999 by the Health and Safety Executive (HSE) and IR(ME)R 2000 by the Care Quality Commission (CQC). A useful summary of how the legislation affects dentists can be found in guidance

published by the former National Radiological Protection Board (NRPB) which is now part of the Health Protection Agency (HPA) and Department of Health, in June 2001, entitled *Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment*.<sup>3</sup> This was sent to all dentists on the GDC register at that time, and is freely available on the HPA website under [http://www.hpa.org.uk/web/HPAwebFile/HPAweb\\_C/1194947310610](http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1194947310610). It is recommended that each dental practice has a copy of this guidance available for reference. It is an invaluable reference for help with implementing both sets of regulations.

## Ionizing Radiation Regulations 1999 (IRR 1999)

IRR 1999 came into effect on 1st January 2000, and forms part of the *Health and Safety at Work Act 1974*.<sup>4</sup> Its principal function is to protect workers who may be occupationally exposed to ionizing radiation. The essential elements of this legislation can be considered under

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**Figure 1.** The controlled area around an intra-oral dental X-ray set.

matters relating to X-ray equipment, staff and their training and methods in which X-ray exposure may be restricted.

## X-ray equipment

When you first begin work with X-ray generating equipment you must inform the Health and Safety Executive, providing information on the installation date, location and type of equipment. An annual radiation safety check is recommended for all X-ray sets but must be performed at least once every three years. The Radiation Protection Advisor (RPA) will advise and undertake this test. In addition, an X-ray set should be serviced in accordance with the manufacturer's instructions, normally once a year.

## Staff and training

Any staff who are involved with any part of the radiographic process should be appropriately trained to do this safely. For dentists, this is initially covered by the undergraduate dental curriculum, and similarly for Dental Care Professionals (DCP) during their training. Subsequently, the GDC recommends that all dentists and DCPs update their knowledge within every

5-year cycle by attending a relevant radiation protection course.

The Legal Person (normally the owner of the dental practice) must make two appointments:

- Radiation Protection Advisor (RPA);
- Radiation Protection Supervisor (RPS).

The RPA should be a qualified medical physicist with suitable experience in radiation protection. His/her task is to monitor X-ray equipment, give advice on radiation protection (such as safe installation of an X-ray set) and give crucial input to allow the dental practitioner to comply with the regulations over matters such as implementing dose reference levels, and estimating predicted dose rates for a risk assessment. The HPA Radiation Protection Division offers such a service, as might the Medical Physics Department of your local district general hospital.

By contrast, an RPS is a member of the dental team, usually a dentist within the practice, who takes day-to-day responsibility for ensuring radiation protection is implemented.

## Restricting exposure

Just as with the Control of Substances Hazardous to Health

(COSHH), IRR 1999 require a *risk assessment* to evaluate the nature and size of the hazard and identify the steps in place to reduce risk. You may be asked to produce a Risk Assessment document which would start by identifying the X-ray equipment, who may be at risk of exposure, the size of the risk (the predicted dose rate and risk level calculated by your RPA) and the steps you would normally put in place to reduce exposure and prevent accidents, such as local rules and systems of work.

An *accident*, for the purposes of dental X-ray protection, is considered as any unintended X-ray exposure which results in an individual receiving more than 20 times the anticipated dose. For cone beam CT this figure is 10 times the intended dose. This could result from a serious X-ray set or timer malfunction. If this happens, ensure the X-ray set is immediately taken out of service pending investigation and always ask advice from your RPA. Taking a radiograph of the wrong patient or the wrong tooth may also, under certain circumstances, be deemed an 'accident', so having steps in place to ensure that you irradiate the correct person is essential. In confirmed accidents, the HPA must be informed and records of the event kept for 50 years.

The annual dose limit for any worker is set at 20 mSv per year, having been reduced from 50 mSv per year under IRR 1985. It recognizes that some people are exposed to relatively high levels of radiation at work, and those receiving over 6 mSv per year, one third of the annual dose, are termed as 'classified workers', requiring an annual health check. Dentists, and indeed most diagnostic radiographers and healthcare workers, do not normally exceed the 6 mSv dose level and so are referred to as 'non-classified' workers. In general, dose levels received during routine dental radiography are well below this figure and so constant radiation monitoring is normally not necessary. However, monitoring is advised if the work load is high, for instance, taking over 50 panoramic exposures or 100 intra-oral views per week.

The dose limit for the 'general public', is set at 1 mSv per year. In this

context, the general public refers to any person who may work near, visit or pass by a dental surgery where radiographs are being taken, and is designed such that the practice receptionist or person sitting in the waiting room is not exposed to an excessive level of radiation as a result of the dentist's use of radiation. Thus the room where the X-rays are taken may need appropriate protection. The term 'general public' does not refer to the patient who is undergoing the radiographic examination. There are no dose limits as such for the patient, the exposure being governed by the principles of 'justification' in which the benefit to the patient from the radiographic exposure should outweigh the risk. There are further dose constraints for people undergoing radiographs for medico-legal reasons and for research purposes.

A member of staff who takes radiographs and who becomes pregnant should write to inform her employer (or Legal Person) as soon as the pregnancy is confirmed. From this point it is recommended that they do not receive more than 1 mSv of radiation to the abdomen during the pregnancy, and this may be determined by personal monitoring. The employer should inform the employee of the level and nature of risks from radiation in writing if they continue to take radiographs after this point, and it is wise to consult the RPA, particularly if the member of staff is taking more than 100 radiographs per week.

The *controlled area* is an exclusion zone, around the patient's head and X-ray tube that exists only when the X-ray exposure is being made and into which only the patient may normally enter. Its main purpose is to prevent or restrict routine or potential exposures. It extends for a minimum of 1.5 m around a conventional dental intra-oral set (up to 70kV), 1.5 m from the patient and for any distance down the main X-ray beam until this reaches, and is attenuated by, a solid wall (such as a brick-and-plaster, or breezeblock wall), shown diagrammatically in Figure 1. These dimensions are considered adequate provided the work load does not exceed 100 intra-oral films or 50

panoramic films per week, however, you must seek confirmation from your RPA. An ordinary fibreboard partition, if close by, will not stop X-rays! If another person needs to enter the controlled area (eg a mother helping support a small child during a radiograph), consult your RPA on how he/she should be protected (normally with a lead apron). Note that the controlled area around a *panoramic* machine is a circle of minimum diameter 1.5 m.

Be particularly careful if a nearby door could allow anyone to enter the room, and thus the controlled area, accidentally. Signs outside the X-ray room/surgery should warn other people that an exposure is taking place and should prevent anyone from inadvertently entering the controlled area during the radiograph.

### Local Rules

*Local Rules* contain the fundamental working instructions and responsibilities in order to restrict radiation exposure. They name the key people: the 'legal person' or employer responsible for the X-ray installation, the RPA and the RPS. They identify the location of the 'controlled area' and X-ray machine, working instructions for this area, the policy for maintenance of the equipment, for monitoring staff doses, for pregnant staff and the contingency arrangements for a radiation accident. These should be displayed near the X-ray tube, with a copy kept in the Radiation Protection File and updated annually.

### Ionizing Radiation (Medical Exposure) Regulations 2000 IR(ME)R 2000

The IR(ME)R 2000 legislation is designed to protect patients from receiving excessive or incorrect exposure to radiation. It requires systems of work to ensure that equipment is properly maintained, functioning correctly and exposing within designated dose boundaries, that staff are appropriately trained, patients are correctly identified before exposure, doses for any given examination are monitored and dose

reference levels applied, that resultant radiographs are evaluated and the quality of the process monitored in a quality assessment programme. In all it ensures that the patient is examined appropriately and as safely as possible.

One key part of this process is the allocation of roles to the staff involved in a radiographic exposure. The chain of events in the radiographic investigation of a patient is divided, within this legislation, into roles for which individual responsibilities are identified. In the dental practice setting, the dentist may find that he/she occupies one or several of these roles in law.

### The referrer

This is a medically or dentally qualified individual who begins the chain of events by deciding that a radiographic examination of his/her patient is necessary to aid diagnosis or treatment, thus 'prescribing' the radiograph. Other healthcare workers, under certain circumstances, may also act in this capacity in accordance with the Legal Persons instructions. The referrer has one important responsibility under the IR(ME)R legislation; to supply sufficient clinical and personal information about the patient, including previous relevant radiographs, and why the radiograph is needed, in order to allow the 'IR(ME)R practitioner' to be able to 'justify' the exposure and for the patient to be accurately identified.

### The IR(ME)R practitioner

The IR(ME)R practitioner may be a medically or dentally qualified individual, and will normally be a radiologist in a hospital setting or a dentist in the dental surgery setting. This is the central role in the radiographic process since it is this individual who, under the IR(ME)R law, carries responsibility for the 'justification' of the radiographic exposure. The current UK dental degree should contain a mandatory 'Core Curriculum' in radiation protection (as specified in Schedule 2 of IR(ME)R)<sup>2</sup> that ensures that, by the time of graduation, the dentist is adequately

trained to fulfil this role, and similarly any dentist taking up practice in the UK should be equally trained. This individual 'justifies' the exposure; that is, he/she considers the aims of the radiographic exposure, weighs up the benefit against the potential harm to the patient from exposure to X-rays and determines whether there is any other way of achieving the same information yet with less risk, or without radiation exposure, to the patient.

### The operator

This person undertakes some or all of the practical aspects of a radiographic exposure. This includes responsibilities for taking the radiograph, processing and archiving the image, quality assurance of the radiographic process and ensuring that a clinical evaluation and radiographic report is undertaken. The operator must be adequately trained for whichever part he/she plays. If undertaking radiography, the operator must be properly trained to take radiographs; suitable training is included within the undergraduate dental degree and as outlined by the British Society of Dental and Maxillofacial Radiology core curriculum and most hygienist and therapist training courses. Other DCPs must obtain further recognized training after qualification, ensuring that this leads to a Certificate in Dental Radiography, as issued by the National Examining Board for Dental Nurses (NEBDN).

The GDC recommend that registrants that act as practitioners and operators update in radiation protection and the relevant topics listed in Schedule 2 of IR(ME)R 2000 at least once in every 5 years with at least 5 hours of verifiable CPD. For practitioners, this must include an update on selection criteria; the indications, benefits and relative risks from their commonly used radiographic examinations, and may usefully include an update on radiological interpretation.

### The 'legal person'

The terminology here refers to the person with natural or legal responsibility for the X-ray installation.

This will most commonly be the owner or principal of the practice, the Chief Executive of a hospital Trust, PCT or local authority. It falls to this person or body corporate to comply with the law – the essential requirements under IR(ME)R 2000 relate to:

- Equipment – to keep an inventory of X-ray equipment and its maintenance;
- Staff – to name and allocate responsibilities of the Referrers, IR(ME)R Practitioners and Operators:
  - to keep a register and training record of Referrers, IR(ME)R Practitioners and Operators, ensuring training and updating occurs;
  - to appoint an RPA with dental radiation physics expertise to act as advisor to the dental surgery and its staff;
- Providing 'Written procedures' (see below);
- Ensuring good practice – to 'justify' all radiographic exposures:
  - to 'optimize' radiographic exposures;
  - to carry out a Quality Assurance programme;
  - to conduct Clinical Audit.

### Written procedures

The 'legal person' must provide written procedures that set out the details of how radiation protection is put into effect. These need to cover:

- Staff – an up-to-date register of all those acting as Referrers, IR(ME)R Practitioners and Operators;
- Patients – how you correctly identify patients undergoing a radiographic examination (to ensure that the wrong person is not mistakenly irradiated, which would constitute an accident):
  - acceptable criteria for medico-legal exposures of patients;
  - identification of pregnant patients;
- The Quality Assurance programme for radiographic image quality;
- Optimizing radiation doses:
  - a. assessing and monitoring patient doses for given x-ray examinations;
  - b. employing diagnostic reference levels (DRL) (see below);
- The 'clinical evaluation' of every

radiograph – an evaluation of both the quality of the image and the diagnostic information (report); the former recorded in a QA log, the latter in the patient's records;

- Avoiding accidents and over-exposure of patients – protocols from your risk assessment document;
- Referral criteria for radiographs – what are considered reasonable indications for any given radiograph (eg you may refer to published selection criteria such as the *Selection Criteria for Dental Radiography* published by the Faculty of General Dental Practitioners of the Royal College of Surgeons (Eng));<sup>5</sup>
- Written protocols – guidelines on positioning and exposure factors for the commonly taken views (exposure factors may be taken from your X-ray machine manufacturer's handbook, or agreed with your RPA);
- Clinical audit.

### Assessment of patient radiation dose and Diagnostic Reference Levels (DRLs)

In 2000, the concept of a nationally-applied maximum recommended radiation dose for any given examination (a Diagnostic Reference Level or DRL) was implemented as part of the IR(ME)R 2000 legislation. A Diagnostic Reference Level (DRL) is normally obtained by calculating the third quartile of a dose distribution from a large survey of a specific radiographic examination. Those X-ray units delivering the highest 25% dose, for whatever reason, are regarded as unacceptable, requiring measures taken to reduce the patient dose such that it falls below the third quartile.

Implementation of DRLs ensured that the staff of all X-ray installations throughout the UK were aware of the typical doses that they delivered for the radiographs which they commonly took. It applied to both general radiology departments, to CT and radiotherapy units, as well as to smaller installations such as dental practices. The benefit of this was to make staff aware of equipment that was

delivering unnecessarily high exposures so that remedial action could be taken, or for reassurance that doses were within acceptable limits.

The introduction of Diagnostic Reference Levels has had the huge benefit of making every employer aware of how his/her particular X-ray equipment performs, and has encouraged those giving the highest doses to reduce exposures. For the patient, it has given peace-of-mind and confidence that, wherever they are examined, they will not receive an unreasonably high X-ray dose. The need to comply with DRLs has put the onus on all owners of X-ray equipment to keep seeking measures to reduce patient doses.

Initially, the NRPB in 1999, now the Health Protection Agency HPA, set a DRL for two typical dental radiographs – the lower molar periapical and the full panoramic radiograph – as benchmarks for the performance of dental X-ray equipment. They based their DRLs on a survey by Napier in 1999<sup>6</sup> of doses from 6,344 dental intra-oral X-ray sets and 387 panoramic units – these machines having been surveyed by the then NRPB as part

of their postal-pack X-ray equipment survey service. They derived a DRL for the entrance dose for a lower molar periapical as 4 mGy, and a dose-width product of 66.7 mGy mm for the panoramic radiograph.

Improvements in X-ray set design and the pressure to maintain dose reduction has continued and, in 2007, these two DRLs were revised downwards, based on a more recent survey, to 2.3 mGy (2.4 mGy) and 60 mGy mm, respectively.<sup>7,8</sup> The dose set for paediatric exposure set by the HPA is 1.5 mGy and was accepted by the Department of Health in 2007.

The final act in preparing for possible inspection by either the Health and Safety Executive or the Care Quality Commission (CQC) is to ensure that the information that has been gathered, as described above, is compiled and collated in a *Radiation Protection File* that should be lodged within the dental practice and available for all staff to consult and use for reference.

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## Technique Tips - A 'Get Out of Jail' Material

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