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An Update on Radiation Protection and the Ionizing Radiation Regulations

Abstract: In this article, the risks associated with dental X-ray examinations, the doses from different types of dental x-ray examinations, the principles of radiation protection and the key points set out in the IRR 17 and IRMER 17 legislation, with emphasis on the relevant changes between these new sets of legislation and the preceding IRR 99 and IRMER 2000 legislation, are considered.

CPD/Clinical Relevance: An update and overview for the dental team on radiation protection and the relevant legislation.

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Radiographs are an essential part of dentistry. It is important to remember that although there are risks associated with radiation exposure, the risks from individual dental radiographs are extremely low. Patients should be reassured that this is a safe technique. However, as a profession, in any given year, we undertake a very high volume of radiographs. In 2008, it was estimated that 20.5 million dental radiographs were taken per year in general dental practice in the UK. This is almost a quarter of all X-ray examinations taken per year in the UK.[1] The cumulative risk is therefore potentially significant. As a profession, it is essential that we take measures to protect ourselves and our patients. We have a legal obligation to do this as set out in the Ionising Radiation Regulations 2017 (IRR 17)[2] and the Ionising Radiation Medical Exposure Regulations 2017 (IRMER 17).[3]

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In this article, the following are considered:

- The risks associated with dental X-ray examinations;
- The doses from different types of dental X-ray examinations;
- The principles of radiation protection;
- The key points set out in the IRR 17[2] and IRMER 17[3] legislation, with emphasis on the relevant changes between these new sets of legislation and the preceding IRR 99 and IRMER 2000 legislation.

The risks associated with dental X-ray examinations

X-rays are a type of electromagnetic radiation. There are different types of electromagnetic radiation that make up the electromagnetic spectrum (Figure 1). How these waves interact with matter depends on their frequency and wavelength. Higher-frequency, shorter-wavelength radiation, such as X-rays, gamma rays and the upper part of the ultraviolet spectrum, are types of ionizing radiation. They can ionize the atoms they interact with and have the potential to cause harm. The lower part of the ultraviolet spectrum, visible light, infrared and radiowaves, are also types of electromagnetic radiation, but do not have the ability to ionize the atoms they interact with, and therefore, cannot cause harm in the same way.

When X-rays interact with an atom, energy is transferred to the atom causing a negatively charged electron to be ejected, resulting in the atom becoming ionized with a net positive charge. DNA molecules can become directly ionized, but most of the harm is caused from the ionization of water molecules causing them to become unstable, break down and form free radicals. Most of the damage to DNA is caused by the interactions with these free radicals.

When DNA becomes damaged there are two possible outcomes: cell death; or cell mutation. Cell death results in what are known as deterministic effects. These will only occur above a threshold dose, but once they do occur, the severity is dose

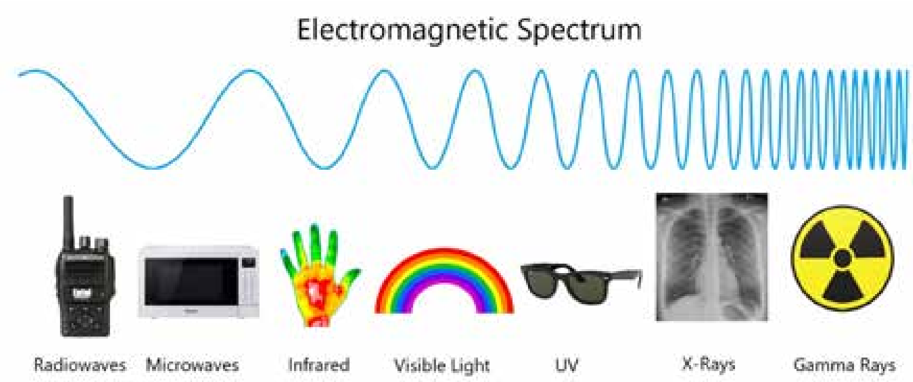

Figure 1. An illustration of the electromagnetic spectrum. The types of radiation that have a higher frequency than visible light are all types of ionizing radiation and cause harm when they interact with human tissue.

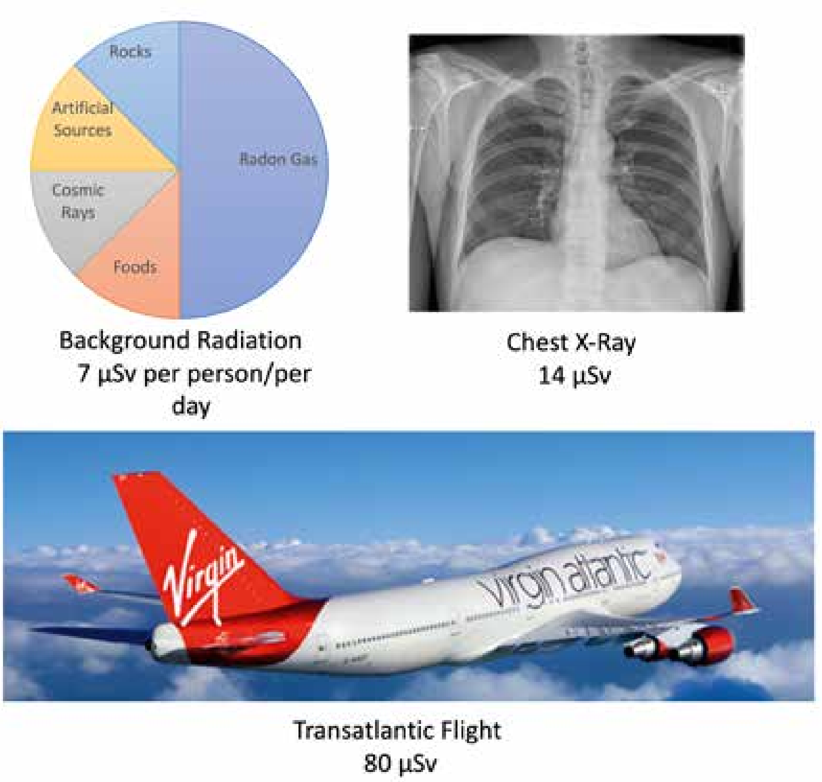

Figure 2. An illustration to show the effective doses from background radiation and commonly encountered sources.

dependent. In dental imaging, we should never reach this threshold and therefore, we would not expect deterministic effects to occur. An example of when these do occur is following radiotherapy, where we would expect certain deterministic effects such as skin reddening, mucositis, xerostomia and hair loss if a patient has had irradiation of the head and neck region. Cell mutations can result in the patient developing a malignancy in the damaged tissues, this is a type of stochastic effect. Cell mutations and, therefore, stochastic effects, can occur from any radiation dose. It is these stochastic effects that dentists need to protect themselves and their patients from. There is no safe dose, and the severity of the outcome (a malignancy) is independent of dose. However, the likelihood of a stochastic effect occurring is dose dependent. The higher the dose, the more likely the patient will be to develop a malignancy. Doses from individual dental radiographs are very low and therefore carry a minimal risk.

The doses from dental X-ray examinations

As X-rays pass through tissue, they deposit energy in that tissue by ionizing atoms. The greater the energy that is deposited, the greater the biological damage. Dose is a way of quantifying this. The simplest measure of dose is the absorbed dose, which is the mean energy imparted per unit mass of tissue. It can be measured as Joules per kilogram, which is commonly expressed in Grays (1 Gy = 1 J/Kg). This is a useful quantity to measure, but the amount of biological harm caused is also dependent on other factors. Some types of ionizing radiation are more damaging to tissues than others. Weighting of the absorbed dose depending on the type of ionizing radiation is performed to account for this factor, and an equivalent dose is achieved. The radiation weighting factor for X-rays is a factor of one, and therefore the numerical value of absorbed and equivalent doses is unchanged. The unit used is the Sievert, not the Gray. Different tissues in the body have different susceptibilities to ionizing radiation, and the harm inflicted by a given exposure depends on the types of tissues irradiated, as well as the equivalent dose. The effective dose overcomes this by considering the types of tissues irradiated. The effective dose allows a direct comparison between X-ray examinations of different body parts to be made and can be directly correlated to the risk of cancer induction. Effective dose is also measured in Sieverts. The risk of cancer induction from dental radiography is 1 in 15 000/mSv for men and 1 in 18 000/mSv for women.[4]

To contextualize the effective doses from dental radiography it is useful to compare them to the effective doses from other sources (Figure 2). The first thing to understand is that we are constantly exposed to background radiation from sources in our environment. The largest single source of background radiation is from inhalation of radon gas in the air. Other sources include cosmic rays from the sun, foods, rocks and artificial sources. The average person in the UK is exposed to 2700 μSv of background radiation per year, which equates to roughly 7 μSv per person/ per day. A chest X-ray is about 2-days' background radiation (14 μSv) and a CT scan of the brain about 200 (1400 μSv). A transatlantic flight is equivalent to around 10 days' background radiation (80 μSv).[5]

The effective dose from a bitewing or peri-apical radiograph should be less than 2 μSv if F-speed film or digital radiography are used, along with rectangular collimation (Figure 3). It is essential that rectangular collimation is used as it reduces the effective dose by about 50% compared to round collimation.[6] The dose of a lateral cephalometric radiograph should be less than 6 μSv, and the dose of a panoramic radiograph in the range of 14–24 μSv.[6] Cone beam CT (CBCT) technology is now becoming increasingly popular as a dental imaging modality. Doses of CBCT examinations are very variable. Generally speaking, CBCT exposes patients to higher doses than intra-oral or panoramic radiographs would, but the doses from CBCT should be significantly lower than from conventional, 'medical' CT. The key thing to understand with CBCT imaging is that the field of view scanned affects the dose that the patient receives. The larger the field of view scanned, the more anatomy that is imaged, and the greater the dose the patient will receive. The average effective dose from a CBCT scan where the height of the field of view is greater than 15 cm is 212 μSv. The average dose is 177 μSv when the height of the field of view is between 10 and 15 cm. When the height of the field of view is less than 10 cm the average dose is 84 μSv. When the field of view is kept to a maximum of 5 x 5 cm the average dose is much smaller at 39 μSv, which is similar in dose to just a couple of panoramic radiographs.[7] Some manufacturers will claim that their machines can achieve considerably lower doses than these stated. It will be technically possible to perform scans whereby the patient dose is considerably lower, but the image quality will also be significantly reduced. A balance needs to be achieved between reducing patient dose and diagnostically acceptable images.

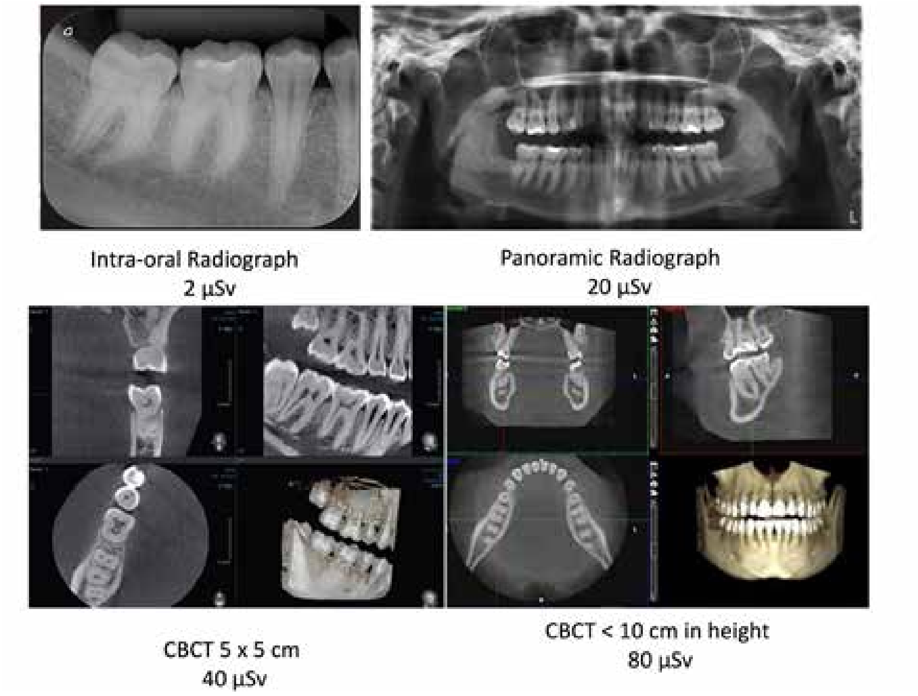

Figure 3. An illustration to show the effective doses from dental radiographs and CBCT.

The principles of radiation protection

The International Commission on Radiological Protection (ICRP) defines three key principles of radiation protection that are carried forward into local legislation in different countries including the UK. The three principles are:

- Justification;
- Optimization;
- Limitation.[8]

Justification is the idea that a patient should only be exposed to ionizing radiation if the benefit outweighs the risk of harm. Every X-ray exposure must be justified prior to being carried out. The Royal College of Radiologists (RCR) state that 'a useful investigation is one in which the result – positive or negative – will inform clinical management and/or add confidence to the clinician's diagnosis'.[9] This test should be applied before any patient is exposed to ionizing radiation. It must also be remembered that a history and clinical examination of the patient are essential prior to any radiographs being taken, and that there can be no possible justification for the routine radiography of 'new' patients prior to clinical examination.[10] Various professional bodies produce selection criteria guidelines to help clinicians decide whether an X-ray is justified. All general dentists should be familiar with the 'Selection criteria for dental radiography' document published by the Faculty of General Dental Practice (FGDP). This document is freely available online.[4] When considering taking radiographs of pregnant women, these radiographs must be justified like any other radiograph. It is not contraindicated to take dental X-rays if a woman is pregnant, because it is highly unlikely that the pelvic area will be irradiated, and the risk to the unborn child is negligible. However, due to the emotive nature of radiography during pregnancy, it is reasonable to give the option of delaying the examination if this is felt to be in the patient's best interest.[10]

Optimization is the idea that every reasonable attempt is made to reduce unnecessary dose to patients, staff and the public. Doses of ionizing radiation should

Quality rating	Basis	Target for digital imaging	Target for digital imaging
Diagnostically acceptable (A)	No or minimal errors with sufficient image quality to answer the clinical question	Not less than 95%	Not less than 90%
Diagnostically not acceptable (N)	Errors that render the image diagnostically unacceptable	Not greater than 5%	Not greater than 10%

Table 1. The newly updated image quality rating system and targets for dental radiography and CBCT.

be 'as low as reasonably practicable' (ALARP) with economic and social factors being taken into account.[8] What this means in practice is that we should use the lowest necessary exposure factors that produce a diagnostic image, we must use rectangular collimation, digital imaging systems or F-speed film. When taking panoramic radiographs, we should consider using field limiting settings, such as a sectional panoramic (eg 'a half OPG') or collimating out the TMJs to reduce the exposure to the parotid salivary glands. When using CBCT, we must use the smallest possible field of view that we can to get the information required. It is also essential to ensure that staff are well trained and have good technique to avoid patients being exposed to unnecessarily high doses, or repeated doses if poor technique necessitates the image to be repeated. The routine use of lead aprons and thyroid collars is not necessary when undertaking dental radiography. Thyroid shields should be used if the thyroid gland will be in the primary X-ray beam, but this situation is uncommon. An example would be an upper standard occlusal radiograph taken with the bisecting angle technique.[10,11]

Doses to the general public, or from occupational exposure, should not exceed the appropriate limits that are set out in UK law. The dose limit for occupational exposure for an adult is an effective dose of 20 mSv per year. If an individual is expected to receive an annual effective dose greater than 6 mSv then they must be registered as a classified worker and should be subjected to more thorough dose monitoring and medical surveillance. Employees in a well-managed dental practice should not receive an effective dose greater than 1 mSv per year. The use of personal dosimetry devices has historically been uncommon in dental practice. Previous guidance advised that personal dosimetry should be used if the risk assessment indicated that individual doses could exceed 1 mSv per year and that this could occur if the weekly workload exceeded either 100 intra-oral or 50 panoramic radiographs.[12] The updated guidance is less prescriptive, but states that it should be based upon a risk assessment process in consultation with a radiation protection adviser (RPA).[10] Dose limits apply to the general public and staff, but do not apply to patients. There are no dose limits for patients, but the potential benefit even from a high-dose examination must outweigh the risk. All doses to patients must be justified.

The key points set out in the IRR 17 and IRMER 17 legislation

There are two sets of UK legislation that are relevant to those involved with dental radiography and the use of ionizing radiation. The Ionising Radiation Regulations 2017 (IRR 17)[2] are concerned with the safety of workers and the general public. They are enforced by the Health and Safety Executive (HSE). The Ionising Radiation Medical Exposure Regulations 2017 (IRMER 17)[3] are concerned with patient safety. They are enforced by the Care Quality Commission (CQC) in England, the Healthcare Inspectorate Wales, Healthcare Improvement Scotland and the Regulation and Quality Improvement Authority in Northern Ireland.

The IRR 17 legislation sets out the role of the employer as the person who takes legal responsibility for implementing the regulations. It is the responsibility of the employer (practice owner, or CEO of a corporate body or NHS Trust) to provide a safe working environment for staff and the public. Some of the responsibilities of the employer are summarized below:

- Register with the HSE before undertaking practices involving ionizing radiation;
- Appoint a radiation protection advisor (RPA) to act as a safety consultant;
- Perform a risk assessment prior to starting any new procedure involving ionizing radiation, and have contingency plans for adverse accidents;
- Designate certain areas as being 'controlled areas';
- Provide 'local rules' for all controlled areas, and appoint radiation protection supervisors (RPS) to ensure compliance with them.

Under the IRR 99 legislation the employer was required to notify the HSE at least 28 days prior to their intention to commence work using ionizing radiation for the first time, or if there was a material change, such as the practice changing ownership. Under the IRR 17 legislation a 'graded approach' based on perceived risk has been introduced. Dental radiography falls into the intermediate risk category, and therefore, employers are required to register with the HSE and pay a fee. Only the employer needs to register, and they only need to register once, no matter how many sites they have.

Dentists have always been required to appoint an RPA; this is someone with specific qualifications in radiation protection who can act as a radiation consultant to a dental practice. They will be involved with new installations, designation of controlled areas, drawing up local rules and performing risk assessments and the periodic examination of existing installations among other things.

The dose limits that were discussed earlier are set out in the IRR 17 legislation.[2] The whole-body dose limit of 20 mSv per year for an adult is unchanged between the IRR 99 and IRR 17 legislation.[2] There are some organ-specific dose limits set out in the legislation. A significant change for some, is the reduction in the dose limit to the eye, but this is not something that will have any significance for dental practice.

The objective of the IRMER 17[3] legislation is to protect patients exposed to ionizing radiation not only as part of diagnostic imaging, but also for therapeutic reasons, as part of medical research or a medico-legal process. There are no dose limits for patients, but all exposures must be justified and the ALARP principle should be observed.

The IRMER legislation defines five separate individuals:

- The employer;
- The referrer;
- The practitioner;
- The operator;
- The medical physics expert (MPE).

The employer is responsible for setting up a framework for the protection of patients. They must ensure staff are adequately trained, and they must appoint an MPE. The MPE is a state-registered clinical scientist who advises on optimization of patient dose. Under IRMER 2000, an MPE had to be involved with medical exposures, but under IRMER 17,[3] an MPE must be formally appointed. The RPA is also often able to act as the MPE, and therefore, this change in the legislation is unlikely to have significant practical implications. The employer must adopt diagnostic reference levels (DRLs) in consultation with the MPE. A DRL is a reference dose for common X-ray examinations, and it would not be expected for patient dose to exceed the DRL without good reason. National DRLs are available for dental radiography,[13] but practices can also set their own local DRLs.

The employer should identify who is entitled to act as a referrer, practitioner and operator, and must ensure they have adequate training. The referrer provides sufficient clinical information to allow the exposure to be justified. The practitioner justifies the exposure, and the operator is responsible for all practical aspects associated with performing the exposure. Reporting of the radiographs is also defined as an operator role under IRMER. In the hospital setting, these roles are often performed by different individuals. In the dental setting, the dentist may be the referrer, practitioner and operator. Depending on local arrangements and training that staff have received, some of these tasks may also be performed by other members of the dental team.

Under IRMER 17,[3] there is a requirement to give patients adequate information relating to the benefits and risks associated with the radiation dose of the exposure. NHS Scotland[14] and the Clinical Imaging Board[15] have both produced posters that can be displayed in dental practices to fulfil this requirement. The message of these posters is that the risks associated with dental X-rays are extremely low and that it is a safe investigation. There is also a new requirement under IRMER 17[3] that any exposures to 'carers and comforters' must be justified. This is an individual who is exposed when supporting another individual undergoing an X-ray exposure. This may be while supporting a child, or an adult with a disability. Both the IRR 17[2] and the IRMER 17[3] legislation place responsibility on the employer to establish and maintain an effective quality assurance (QA) programme. There should be QA programmes for the employer's procedures, X-ray equipment, image processing and viewing facilities, clinical image quality and audits.[10]

There is now updated guidance regarding the rating of clinical image quality. Previously, a three-tier system was used, rating images as excellent, diagnostically acceptable or unacceptable.[12] It is now advised that a simplified two-tier system is used (Table 1), rating both dental radiographs and CBCT examinations as diagnostically acceptable or not acceptable.[10] Legislation also requires there to be a QA programme for equipment testing. The IRMER legislation requires the employer to keep an equipment inventory and under the 2017 legislation, equipment testing has been moved from IRR into IRMER.

It is also a requirement of both sets of legislation that the employer ensures staff involved in dental radiography have adequate training. All IRMER practitioners and operators must undergo continuing professional development (CPD), and it is recommended by the General Dental Council (GDC) that any dentist or dental care profession involved in radiography does at least 5 hours of CPD in radiography and radiation protection in each CPD cycle.[16] Undergraduate dental programmes do not currently allow for dentists to be considered adequately trained to refer, justify, perform or interpret dental CBCT examinations, and the area is also largely absent from the professional qualifications of other dental care professionals. Further training is therefore required for all dental practice staff undertaking dental CBCT examinations.[10]

Compliance with Ethical Standards

Conflict of Interest: The authors declare that they have no conflict of interest.
Informed Consent: Informed consent was obtained from all individual participants included in the article.

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