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Guidance on the Safe Use of Hand-held Dental X-ray Equipment

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Guidance on the Safe Use of Hand-Held Dental X-ray Equipment

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

Executive Summary

Intra-oral radiography is a long established and essential aspect of dentistry, with the first instance of its use dating from 1896. Traditional intra-oral X-ray equipment is designed to be fixed to the wall or ceiling of a dental surgery, or mounted on a mobile stand, with the exposure initiated using a hand switch connected to the control panel by a long cable. The operator then stands some distance away, thereby reducing their radiation exposure. Hand-held X-ray sets have been used for some years in the field of forensics and disaster recovery, where their portability has proven valuable for use in the field to obtain post-mortem dental radiographs to aid in the identification of victims. Instances include the Asian Tsunami of 2004 and Hurricane Katrina in 2005. Since that time, Public Health England's Dental X-ray Protection Services (DXPS) have noted a steady increase in both the numbers of hand-held X-ray sets used in UK general dental practice for routine intra-oral radiography and the number of models of hand-held X-ray sets available to dentists. Previous guidance on the safe use of dental X-ray equipment does not address hand-held X-ray sets and, as described in this document, the radiation protection measures needed for these extend beyond those set down in the previous guidance.

Investigations undertaken by PHE in recent years have revealed a wide variation in the standard of radiation protection afforded by the different designs. Doses to operators of hand-held X-ray equipment that is well designed and constructed are comparable to doses received by operators of wall-mounted X-ray units, provided certain additional precautions are observed; while poorly designed and constructed equipment may place the operator at risk of exceeding statutory dose limits and incurring potential radiation injuries. Investigations by PHE also indicate that it is clinically practicable to use hand-held dental X-ray equipment for the majority of the radiographic examinations commonly undertaken with wall-mounted X-ray equipment, albeit with some adjustments to procedural aspects of radiography such as patient positioning.

With the portability of hand-held dental X-ray equipment, it is also necessary to consider safeguards for people who might be exposed as a result of the equipment being used in locations remote from the dental practice, such as care homes.

The main aims of this publication are as follows:

- a** To propose a safety standard for the design and construction of dental X-ray equipment that is intended to be used in a hand-held fashion
- b** To provide guidance to assist all people involved with hand-held dental X-ray equipment to work with it safely and in accordance with UK radiation protection legislation

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1 Introduction

The aims of this publication are two-fold: firstly, to propose a safety standard for the design and construction of hand-held dental X-ray equipment; and, secondly, to provide guidance for dentists regarding the practical application of the Ionising Radiations Regulations 1999 (IRR99) to use of the equipment for intra-oral radiography. The advice supplements and updates that already provided in the Guidance Notes for Dental Practitioners on the Safe Use of X-ray Equipment (the Dental GNs), published by the National Radiological Protection Board (NRPB, 2001)*, and the Medical and Dental Guidance Notes (MDGNs), published by the Institute of Physics and Engineering in Medicine (IPEM, 2002). Much of the advice on radiation protection will also be applicable to non-dental sectors such as forensic or veterinary uses.

References to other radiation protection legislation are also made, where appropriate. In particular, the Ionising Radiation (Medical Exposure) Regulations 2000 and subsequent amendments (IRMER) impose requirements on employers using diagnostic X-ray equipment that have areas of overlap with IRR99. Guidance on the application of IRMER to dental radiography is provided in the Dental GNs[†].

Both IRR99 and IRMER impose responsibility for compliance on either the 'employer' or 'radiation employer'. Throughout this guidance, the person or body corporate that takes legal responsibility for implementing the requirements of IRR99 and IRMER is referred to as the 'legal person' unless the context requires otherwise.

Attention is also drawn to the requirements of more general health and safety legislation, eg the Management of Health and Safety at Work Regulations 1999, which require employers to consider workplace hazards other than those from ionising radiation. Employers will need to consider any non-radiological hazards to employees, patients and other people associated with the use of hand-held X-ray equipment for dental radiography (such as manual handling) and undertake a suitable and sufficient risk assessment. However, a detailed discussion of these issues is outside the scope of this publication.

2 Clinical Efficacy of Hand-held Dental X-ray Equipment

2.1 Discussion

A dentist considering buying a hand-held dental X-ray device needs to be confident that it will be suitable for all the diagnostic tasks for which it is likely to be used. The factors which might conceivably distinguish between traditional and hand-held dental X-ray equipment in terms of

* The NRPB was subsequently incorporated into the Health Protection Agency (HPA). On 1 April 2013 the HPA was abolished and its functions transferred to Public Health England.

† European Directive 2013/59/Euratom, which was published on 17 January 2014 (EC, 2014), provides a revised basis for ionising radiation protection legislation throughout the EU and, as a result, IRR99 and IRMER will be replaced by new legislation by 6 February 2018. It is anticipated that the Dental GNs and MDGNs will be revised as a result. This guidance has been drafted with due regard to the new Directive, with the intention that its advice will remain relevant following the introduction of the new legislation in 2018.

clinical efficacy or suitability for use in dental practices were initially considered by PHE to be as follows:

- a** Degree to which image quality might be adversely affected by movement of the operator during exposure
- b** Restrictions in terms of the radiographic views that can be used, given the need to maintain the X-ray beam in the horizontal plane (and any other ergonomic factors)
- c** Practicality of use with rectangular collimation, image receptor holders and beam aiming devices (recommended as standard practice for intra-oral radiography in the Dental GNs)

Position statements issued recently by the European Academy of DentoMaxillofacial Radiology (EADMFR) (Berkhout et al, 2015) and the Heads of the European Radiological Protection Competent Authorities (HERCA, 2014), which is based largely on the EADMFR document, raise the following potential issues with hand-held dental X-ray equipment, in addition to those above:

- d** Need for longer exposure times, potentially affecting image quality and increasing exposure of the patient and operator
- e** Potential for image quality to be affected by reduced or inconsistent radiation output as the battery charge reduces, or is affected by environmental conditions
- f** Potential for significantly increased exposure of the operator compared to traditional dental X-ray equipment
- g** Use of X-ray equipment in 'uncontrolled environments'

The EADMFR statement concludes that, given the lack of definitive information or experience regarding many of the above issues, hand-held dental X-ray equipment should only be used in exceptional circumstances, when an intra-oral radiograph is indicated in a specific case, but use of traditional X-ray equipment is impracticable. The examples given include use for anaesthetised or sedated patients, and use in residential care homes, on remote military operations, or for forensic odontology. However, the present situation in the UK is that more than 350 dental practices (Beal, 2015) already routinely use hand-held X-ray equipment for intra-oral radiography. While expressing reservations concerning the situation, none of the UK regulatory bodies has taken action to prohibit this. Clarification and guidance regarding the safe and appropriate use of hand-held X-ray equipment for dental radiography is therefore urgently required.

PHE's investigations into the use of hand-held dental X-ray equipment are able to provide more detailed information on issues **b**, **c**, **d**, **f** and **g**, as set out in the various sections of this guidance. Although not investigated by PHE, studies (Bailey et al, 2009) suggest that there is no significant adverse effect on image quality due to the use of an X-ray set when held in the operator's hands compared to a traditional wall-mounted unit (issue **a**). It is also pertinent to note that, to PHE's knowledge, no adverse effects on image quality have been reported by the many dentists who regularly use hand-held X-ray equipment. PHE nevertheless considers that it would be appropriate for further detailed studies to be made to determine whether or not any systematic difference in image quality exists between hand-held dental X-ray equipment and traditional equipment, and the extent or otherwise of its impact on diagnostic performance (issues **a** and **e**).

To address items **b** and **c** in the list above, PHE convened a workshop of consultant dental radiologists, dentists and operators experienced in the use of hand-held dental X-ray equipment, to undertake a practical trial of intra-oral and extra-oral dental radiography procedures. Two models of hand-held X-ray set were used, representing the two basic design types available on the UK market. An Aribex Nomad Pro represented the ‘pistol’ style design, while a Dexcowin DX-4000 represented the ‘camera’ style design. Both these models are fitted as standard with a lead-acrylic shield at the end of the spacer cone to protect the operator against X-rays backscattered from the patient (see Figure 1). It should be noted that, for the backscatter shield to offer maximum protection for the operator, the X-ray beam must be confined to the horizontal plane. (The area protected by the backscatter shield is commonly referred to as the ‘protected zone’.)

The workshop took place in a dental surgery setting, with a volunteer acting as the ‘patient’ being seated in a dental chair. All commonly used intra-oral radiographic views, and oblique lateral views, were trialled. In each case, an image receptor was prepared as normal and positioned in the patient’s mouth as appropriate for each radiographic view. The patient was then positioned so that the spacer cones of the X-ray devices could be positioned properly with regard to the beam aiming device, with the added restrictions that the X-ray beam must remain in the horizontal plane so that the operator remained within the protected zone, and the beam must not be directed towards the abdomen or torso of the patient. The hand-held X-ray devices were used exactly as they would be during normal radiography procedures, with the exception that no actual X-ray exposures took place.



Figure 1: Hand-held dental X-ray units: Aribex Nomad Pro (left) and Dexcowin DX-4000 (right)

2.2 Findings of the workshop

2.2.1 Radiographic views

The majority of the views investigated (bitewings, periapicals, occlusals and oblique lateral views) were clinically practicable using hand-held equipment, though sometimes with some added discomfort or difficulty for the patient resulting from the positioning necessary to confine the X-ray beam to the horizontal plane. The views most likely to cause positioning problems

were the lower 90 degree occlusal, the upper standard occlusal (see Figure 2) and both upper and lower anterior periapicals (see Figure 3), particularly for patients with restricted neck movement or with short necks.

The views which caused fewest problems were bitewings (see Figure 4), lower posterior periapicals and oblique lateral views.



Figure 2: Upper standard occlusal radiograph, showing tipping of the patient's head is required to retain the X-ray beam in the horizontal plane (copyright © Cardiff University)

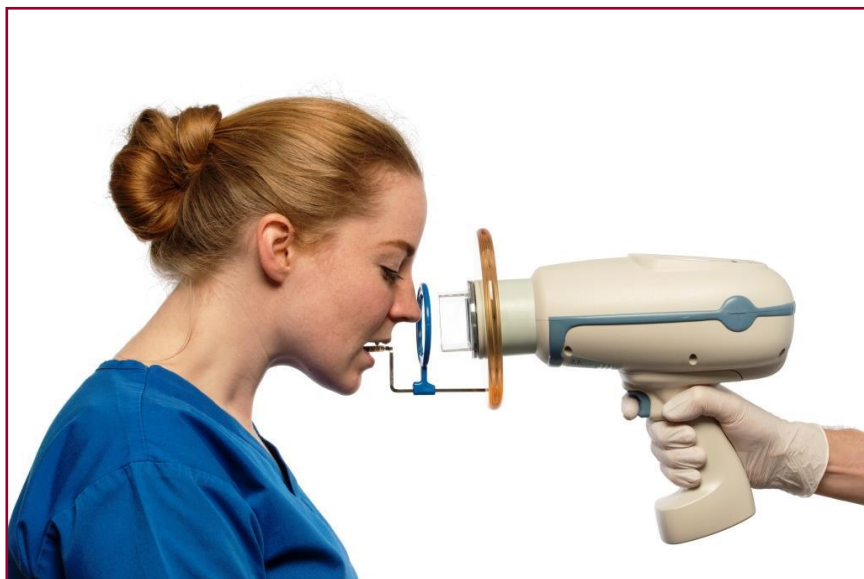


Figure 3: Upper anterior periapical radiograph, showing tipping of the patient's head is required to retain the X-ray beam in the horizontal plane (copyright © Cardiff University)

For periapical views the operator will need to think carefully about how to position the patient before commencing radiography. In the dental practice setting, the height and inclination of the dental chair should be adjusted to bring the patient to the position of the X-ray tube, and so maintain the X-ray beam in the horizontal plane (see Figure 5). It is undesirable for the operator to adjust their position to suit the patient, as this may result in part of the operator's body (head or feet) not being in the protected zone.

In a care home (or other) setting without the benefit of a dental chair, ideal positioning as described above may prove problematic for some views.

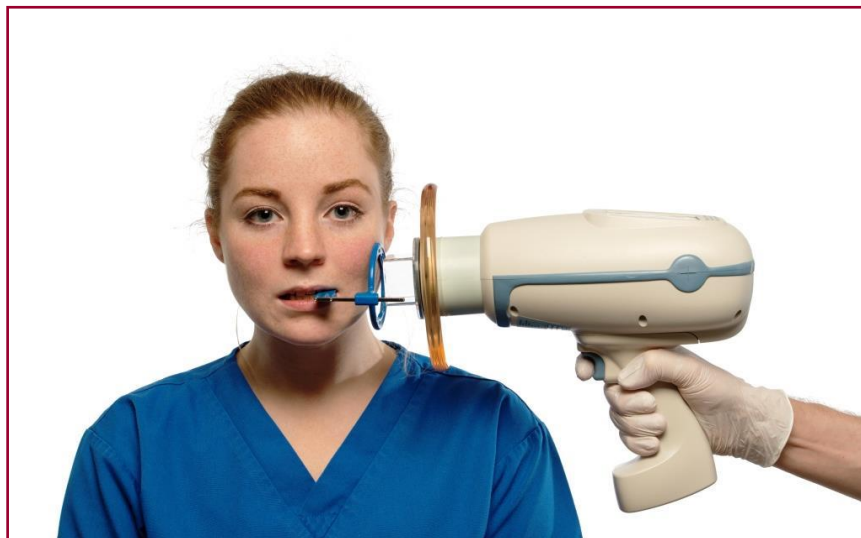


Figure 4: Bitewing radiograph, showing use of image receptor holder, beam aiming device and rectangular collimation. No changes to patient position required (copyright © Cardiff University)



Figure 5: Upper posterior periapical radiograph, showing tilting of the patient's head is required to retain the X-ray beam in the horizontal plane (copyright © Cardiff University)

2.2.2 Equipment factors

Use of an image receptor holder and beam aiming device enabled easy visual alignment of the spacer cone (fitted with rectangular collimation on both units) with the patient. However, the projecting arm of the device used in the workshop abutted the backscatter shield such that it was necessary to hold the end of the spacer cone 5–10 cm further away from the patient than would otherwise be the case. In real radiography procedures this would increase both the size of the X-ray beam incident on the patient and the exposure time required, resulting in an overall increase in patient dose of 50%–100% (in terms of dose area product) compared to radiographs taken with the cone very close to the patient's skin. In addition, there may be an increased risk of improper alignment of the spacer cone with the image receptor leading to 'cone cutting', which could increase patient dose due to the need for repeat exposures. The size of the operator's protected zone would also be reduced. To avoid these effects, beam aiming devices allowing the spacer cone to be placed as close to the patient as possible need to be used with hand-held equipment, and should be provided as standard with the equipment.

There was no reason in principle why rectangular collimation could not be used with either hand-held model, subject to a suitable beam aiming device being available, as discussed above.

There was no obvious advantage in using one or other of the two designs (the 'pistol' style or the 'camera' style), in terms of ease of positioning.

3 Design Standards for Hand-held Dental X-ray Equipment

3.1 Restriction of dose to the patient

Hand-held dental X-ray equipment should perform to the same standard as traditional dental intra-oral X-ray equipment with regard to diagnostic imaging and the capability to adequately control patient exposure; it should comply with the Medical Devices Regulations 2002 (MDR2002)*, IPEM Report 91 (IPEM, 2005), the Dental GNs and MDGNs in this regard. In particular, patient doses should conform to the latest national diagnostic reference levels (NDRLs) for dental radiography (Hart et al, 2012). Information regarding typical patient entrance doses for the models tested by PHE appears in Appendix A. It is apparent that compliance with the NDRLs will usually restrict the user to employing speed group F film, or a digital imaging system; however, this observation applies equally to those wall-mounted X-ray sets that have a fixed operating potential of 60 kV.

* The Medical Devices Regulations 2002 (and subsequent amendments) enact Council Directive 93/42/EEC (EC, 1993), which was published on 14 June 1993 and is commonly known as the Medical Devices Directive (MDD). The MDD requires that medical devices sold in the EU are CE marked to signify that the following essential requirements are met: "Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes" (Annexe I, paragraph 11.1.1), and "Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible" (Annexe I, paragraph 1.3.1).

3.2 Restriction of dose to the operator

The publications cited in Section 3.1 also make recommendations with respect to X-ray equipment design features and working methods with the aim of protecting the operator, in order that doses are restricted to levels that are as low as reasonably practicable (ALARP). This is a fundamental requirement of IRR99. However, the current guidance does not take any account of X-ray devices that are intended to be held in the hands, where the operator is clearly much closer to the source of both leakage radiation transmitted through the X-ray tube head, and radiation backscattered from the patient. An operator of hand-held dental X-ray equipment cannot be confident that following the existing guidance will provide adequate restriction of their exposure. Indeed, using a dental X-ray set held in the hands is of itself a contravention of some aspects of existing guidance; for instance, paragraph 3.21 of the Dental GNs.

3.2.1 Discussion

British Standard BS EN 60601-2-65:2013 sets a limit on tube head leakage of 0.25 mGy an hour averaged over 100 cm² at a distance of 1 m, with an added note that, for hand-held equipment, the protection of the operator is subject to the manufacturer's risk assessment process (BSI, 2013). The national foreword to BS EN 60601-2-65: 2013 states: "BSI as a member of CENELEC is obliged to publish EN 60601-2-65 as a British Standard. However, attention is drawn to the fact that the UK national committee voted against the UK implementation of EN 60601-2-65, as it feels that provisions are not quite fit for purpose for those hand-held devices that are new to the market with regards to assessing leakage radiation at the surface of the units". Simple calculations using pessimistic, but realistic assumptions* indicate that a hand-held X-ray set meeting this numerical limit on tube head leakage could deliver annual doses to the operator's torso of more than the statutory dose limit of 20 mSv, while the annual dose to the hands could easily exceed 150 mSv, and perhaps even 500 mSv. This clearly illustrates that the internal tube head shielding of hand-held dental equipment must be designed and constructed to much higher standards than currently permitted. Tests conducted by PHE indicate that backscattered radiation also makes a significant contribution to both effective and equivalent doses received by the operator and, in practical terms, manufacturers will need to ensure that both leakage and backscattered radiation are considered when determining the shielding requirements.

It is important to propose a definitive standard of tube head construction to provide guidance to manufacturers, suppliers, regulators and not least to dentists considering buying a hand-held device; this is set out in Section 3.3 of this guidance.

3.2.2 Effective doses

The Dental GNs recommend that, during radiography with static intra-oral X-ray equipment, a controlled area is designated that (other than the main beam) extends not less than 1.5 m

* Radiographic workload: 100 exposures a week, 50 weeks a year. The operator's torso is 50 cm from the anode of the X-ray set (eg the unit is held with the operator's arm bent at the elbow) and the operator's hands are 5 cm away from the anode. The loading factor of the X-ray device is 1 : 60.

from the X-ray tube head and patient. The basis of this approach is that the annual effective dose to the operator would then be unlikely to exceed 1 mSv, assuming a workload for a single operator of 100 radiographs a week for 50 weeks a year.

Owing to technological improvements since the Dental GNs were published, the annual effective dose to an operator making the best use of modern dental X-ray equipment and imaging techniques (but otherwise under the same workload assumptions) would now be rather less than 1 mSv. Based on measurements of scattered dose made during simulated radiography using an anatomical phantom, PHE calculates that the annual effective dose received by an operator of a modern wall-mounted intra-oral X-ray set, who stands between 1.5 m and 2.5 m away from the X-ray tube head and patient and personally undertakes the workload described above, would range from 0.01 mSv to about 0.25 mSv. Differences in the features of different models of X-ray set, together with the choice of collimation and the imaging system used, together account for a factor of five separating the highest and lowest figures for the annual dose to the operator at any given distance. It should be pointed out that if the operator stands a greater distance away, or behind a shielded screen to initiate exposures, the lower end of the range of annual doses effectively becomes zero. However, it is not obligatory for operators of fixed dental X-ray equipment to stand further than 1.5 m away from the equipment, behind a shielded panel, or indeed use the fastest available imaging system or rectangular collimation, in order to satisfy IRR99 regulation 8(1), which requires exposures to ionising radiation to be restricted to levels which are as low as reasonably practicable (ALARP).

A constraint on annual effective dose of 0.25 mSv is therefore considered appropriate as an indicator of whether a particular model of hand-held X-ray equipment is acceptable on radiation protection grounds for use in general dental practice, as it provides a reasonable basis for comparing exposures resulting from the use of a hand-held device compared to a fixed unit. The results of PHE's tests (as shown in Appendix A) suggest that annual effective doses to operators of hand-held models fitted with backscatter shields may be lower in some circumstances than doses to operators of wall-mounted units. This finding has been reported elsewhere in the literature (Gray et al, 2012).

3.2.3 Equivalent dose

Fixed X-ray equipment will not involve any localised exposure of the operator during normal use, whereas even the best designed hand-held models will necessarily involve some potential for increased exposure to the operator's hands. Dentists considering buying hand-held equipment need to be aware of this fact and take account of the guidance below in their purchasing decision.

It is recommended that the maximum likely annual equivalent dose should not exceed 10 mSv, which would represent a contribution to the operator's annual effective dose* of less than 1 μ Sv. Most of the hand-held models tested by PHE comply with this constraint, as detailed in Appendix A.

* Assuming that exposure of the skin dominates the contribution made to the effective dose from exposure of the hand, that the exposed area of skin is 28 cm², that the total surface area of skin is 19,000 cm² (ICRP, 2002) and that the tissue weighting factor for exposure of the skin is 0.01 (EC, 2014).

A dentist wishing to buy a hand-held X-ray set should aim to select a model that provides a level of protection for the operator that is comparable to that provided by fixed X-ray equipment, and so should purchase equipment that is capable of restricting annual effective doses to less than 0.25 mSv, and annual equivalent doses to well below 10 mSv. Failure to do so may leave the dentist at risk of contravening IRR99 regulation 8(1).

3.3 Recommended design features for hand-held dental X-ray equipment

Testing by PHE on a variety of hand-held dental X-ray devices currently available for purchase by dentists in the UK indicates a very wide variation in the degree of protection afforded to the operator. In the case of the worst example tested, estimated annual doses to the operator's torso and hands exceeded the statutory dose limits set out in schedule 8 of IRR99, with the dose to the hands being so high that deterministic effects (eg radiation burns) would be a real possibility. As a result of these and other failings in the design and performance of the unit, including the lack of CE marking, the then Health Protection Agency notified the Medicines and Healthcare Products Regulatory Agency (MHRA) of the situation, with the result that a medical devices alert was issued (MHRA, 2012). Further action taken by the MHRA included the seizure of a number of similar items from a wholesaler located in the UK. However, similar units continue to be available for dentists to buy online from overseas sources, at very low prices. Dentists considering purchasing hand-held dental X-ray equipment should be particularly cautious of using suppliers of this kind, and are strongly advised to consult their radiation protection adviser (RPA)*.

In contrast, the best examples tested complied with all the standards and guidance for fixed X-ray equipment, and estimated annual doses to the operator's whole body and hands from these devices, when used correctly, were well below 0.25 mSv and 10 mSv, respectively. Potential annual effective doses were comparable to those expected from wall-mounted units. In these cases attention had clearly been paid at the design stage to the need to provide adequate protection to the operator.

Legal persons are required by IRR99 regulation 32(1) to consider the restriction of patient doses when purchasing equipment, and are also required by regulation 8(1) to restrict doses to their employees and other people arising from their work with ionising radiation.

Regulation 8(2) expands on this by establishing a hierarchy of control measures for restricting doses, whereby the first priority should be to restrict doses by the use of engineering controls and design features. Only once these have been applied should consideration be given to the use of systems of work, with the use of personal protective equipment (PPE) being the last consideration. Traditional intra-oral dental X-ray equipment is usually manufactured with the X-ray tube head, control panel and exposure switch as physically separate units, thereby allowing the equipment to be installed in such a way that the operator can be positioned at an appropriate distance from the X-ray tube head and not within the range of X-ray beam

* Attention is also drawn to the duties of people who import an article for use at work under section 6 of the Health and Safety at Work etc Act 1974. These include a duty to ensure that any such article is safe for use (including by testing where appropriate) and to provide adequate information to others regarding its safe use. A dentist purchasing a hand-held dental X-ray unit directly from a source outside the European Economic Area would be considered an importer and so subject to this regulation.

directions that would be used during radiography. A wall-mounted intra-oral X-ray set installed in this way would therefore be making appropriate use of engineering controls and design features as the primary means to restrict exposure, with important measures to further restrict exposure being set out in systems of work, namely the local rules drafted by the dental practice in consultation with its RPA (see Section 4.10).

With hand-held dental X-ray equipment, annual effective doses to operators can be restricted to levels comparable to wall-mounted equipment by means of engineering controls and design features, eg shielding of the tube head against leakage radiation and providing further shielding against radiation backscattered from the patient. As with wall-mounted X-ray equipment, additional measures necessary to further restrict exposures (including the correct positioning of the device) should be set out in the local rules.

PHE recommends that hand-held X-ray equipment intended for routine dental radiography purposes should only be obtained and used if it meets the following requirements:

- a** Chapter 4 of the Dental GNs, and chapter 9 of IPEM Report 91 (excepting those aspects superseded by this guidance), as relevant to intra-oral X-ray equipment. This includes bespoke rectangular collimation (either built-in or as an accessory), image receptor holders and bespoke beam aiming devices to allow the spacer cone to be held as close to the patient as possible (see Section 2.2)
- b** In addition to those specified in **a**, the safety and warning features should incorporate safeguards against unauthorised operation, or unintentional initiation of exposures. Examples might include some or all of the following: use of a PIN or key to enable the control panel; a need to initiate exposures within a few seconds of enabling the exposure switch; and an automatic 'power off' after a certain elapsed time with no use of the control panel. The exposure switch should function in the manner described in paragraphs 4.19 and 4.20 of the Dental GNs. The control panel should also display the exposure time (see Section 4.3)
- c** Sufficient internal shielding of the tube head, including (if necessary) additional permanent shielding against radiation backscattered from the patient*, to restrict the annual effective dose to the operator to no more than 0.25 mSv, and the annual equivalent dose to the operator's hands to no more than 10 mSv (calculated using the same workload assumptions as described in Section 3.2.1)
- d** Hand-held equipment not meeting condition **c** should be provided with a suitable means of remotely initiating exposures, ie a tripod and exposure switch on a cable long enough to enable the operator to stand at least 1.5 m away from the tube head and patient
- e** Means of quickly and easily switching off the power or removing the battery without exposing the operator's hands to the X-ray beam, in the event of an accident

PHE recommends that manufacturers take note of the above in their design and construction of hand-held dental X-ray equipment.

* Any backscatter shield should be of a design which produces a protected zone of sufficient size to include the operator's entire body when the hand-held X-ray unit is used in an appropriate fashion (eg operator holding the unit at forearm's length from the body while standing, and maintaining the X-ray beam in the horizontal plane).

4 Application of IRR99 to Work with Hand-held Dental X-ray Sets

This section of the guidance deals with the requirements of IRR99 as relevant to work with hand-held dental X-ray equipment. Each regulation is discussed in detail below, and a summary of the key requirements is provided in Appendix B.

4.1 Notification to the HSE

The Health and Safety Executive (HSE) must be notified when it is intended to use ionising radiation for the first time, or a 'material change' is going to be made to an existing use. With respect to the latter, provided that the legal person has already informed the HSE of the existing use of dental X-ray equipment on the practice premises, the addition of hand-held dental X-ray equipment that will only be used at the practice does not constitute a 'material change' and further notification is not required. However, if it is intended that the X-ray equipment will be used at other premises such as care homes, this does constitute a material change and the HSE must be informed in advance.

When required, notification of work with ionising radiation should be made to the HSE, in writing, at least 28 days in advance of its commencement. This can be done on the HSE website using form IRR6. For further information on notifications see <http://www.hse.gov.uk/radiation/ionising/notification.htm>.

4.2 Radiation protection adviser (RPA)

According to IRR99 regulation 13(1), legal persons must consult one or more suitable RPAs as necessary for advice regarding compliance with IRR99. As hand-held X-ray equipment has only recently started to be used in dental practices, it is important that the advice of a suitable RPA is obtained at the appropriate time, particularly on the matters listed below. Consultation with an RPA for advice on any of the matters set out in schedule 5 of IRR99 (indicated in bold type) is specifically required under regulation 13(1):

- a** Equipment selection (ie choice of a model that is suitable for the intended tasks and which complies with this guidance)
- b** **Prior examination of plans (eg of dental surgeries where hand-held equipment may be used)**
- c** Review of risk assessment, local rules and contingency plans
- d** **Designation of areas and subsequent requirements**
- e** Personal dosimetry
- f** Quality assurance programme, including adequate acceptance, commissioning and routine testing
- g** **Periodic testing of engineering controls, design features, safety and warning devices**
- h** Where appropriate, the selection and use of personal protective equipment

A suitable RPA would be an individual, or RPA body, able to demonstrate compliance with the HSE's current criteria of competence and having specific knowledge and adequate experience of radiation protection as applied to diagnostic radiology in the medical/dental sector, including an understanding of the issues arising from the use of hand-held dental X-ray devices.

4.3 Equipment selection

The legal person in a dental practice is required by IRR99 regulation 32(1) to consider the restriction of patient doses when purchasing equipment. As with other types of X-ray imaging equipment, hand-held dental X-ray equipment should be capable of providing images of adequate diagnostic quality while restricting patient exposures so far as reasonably practicable. The practicalities of using X-ray equipment that is held in position by the operator's hands during radiography means that it cannot be considered an equivalent replacement for fixed X-ray equipment in all circumstances, due to the additional complications in patient positioning for some commonly used views (eg the lower 90 degree occlusal). This is discussed in detail in Section 2. Legal persons considering purchasing hand-held dental X-ray equipment must ensure that it will be appropriate for their intended clinical purposes.

Legal persons also have a general duty under regulation 8(1) to restrict the exposure of people to ionising radiation, so far as reasonably practicable. With regard to hand-held dental X-ray equipment, the shielding provided to protect the operator from backscattered X-rays and leakage radiation is of crucial importance.

New hand-held dental X-ray equipment should only be considered acceptable for clinical use if it is supplied with the following features:

- a** Shielding, designed to protect the operator from backscattered and leakage radiation when used in a hand-held manner, that meets the proposed standard set out in Section 3.3
- b** Safety and warning features described in Section 3.3
- c** Rectangular collimation, beam aiming devices and image receptor holders as described in Section 3.3
- d** For each X-ray exposure, the exposure time should be displayed, to meet the requirement under IRR99 regulation 32(2) that an indication of the quantity of radiation produced by the equipment is provided, where practicable
- e** CE marking in accordance with the Medical Devices Directive (although this alone cannot be taken as an assurance that a model of hand-held X-ray set is suitable for routine use in dental radiography)
- f** Details of typical doses or dose rates from tube head leakage and scattered radiation

Legal persons are obliged under IRMER to consult a medical physics expert (MPE) for advice on the measurement and optimisation of patient dose, and quality assurance. An MPE or RPA should be able to offer useful advice on the suitability or otherwise of different equipment for its intended clinical use. Further guidance is provided in Section 2.

4.4 Critical examination and acceptance testing

IRR99 regulation 31(2) requires a person who 'erects or installs' an article that will be used in work with ionising radiation, to carry out a critical examination to ensure that the safety features and warning devices operate correctly, and that there is adequate protection for people from exposure to ionising radiation. HSE Guidance Note PM77 Edition 3 (HSE, 2006) states that mobile equipment that arrives on site fully assembled will not formally require a critical examination if it has already been tested by the manufacturer; however, the HSE has indicated that, in the case of hand-held dental X-ray equipment, it is considered appropriate for a critical examination to be carried out, before the unit enters clinical use (HSE, 2014). IPEM Report 107 contains further guidance on critical examinations for diagnostic X-ray equipment (IPEM, 2012).

The radiation protection afforded to the operator by the tube head shielding and other design features is crucially important with hand-held equipment. For this reason, the following aspects should be critically examined for each individual device:

- a** Tube head shielding, designed to protect the operator from leakage radiation and backscattered radiation when used in a hand-held manner, that meets the proposed standard set out in Section 3.3
- b** Safety and warning features described in Section 3.3

Suppliers of hand-held dental X-ray equipment should ensure that both the critical examination and adequate testing ('acceptance testing') of hand-held dental X-ray equipment is carried out, either immediately prior to, or immediately following, supply.

Dental practices, which do not have ready access to the services of a hospital medical physics department, may neglect to arrange the testing if left to do it themselves, and this could have serious consequences in terms of the exposure of both staff and patients if the model of hand-held X-ray equipment purchased is of poor quality design or construction (see Section 3). Legal persons are encouraged to confirm with the equipment supplier that both the critical examination and acceptance test will be carried out, and a report of the results provided, or else make their own arrangements, in consultation with their RPA or MPE, for this to be done before clinical use commences.

Details of the adequate testing recommended by PHE for hand-held dental X-ray equipment are given in Section 4.14 of this report.

4.5 Prior risk assessment

Before using hand-held dental X-ray equipment for the first time, it is important that a specific risk assessment for the work is produced and reviewed thoroughly against paragraphs 44 and 45 of the Approved Code of Practice to IRR99 (ACoP) (HSE, 2000), in consultation with a suitable RPA, and the outcome documented. The aspects that will require careful consideration (with the RPA's assistance) are listed below:

- a** Likely annual effective dose and annual equivalent dose to the operator and other people arising from use of the model concerned (see Section 4.5.1)

- b** Likely effective and equivalent doses to the operator and any other affected people arising from reasonably foreseeable accidents involving the model concerned (see Section 4.5.2)
- c** Based on the above, a decision regarding whether or not the model selected meets the standard proposed in Section 3 of this guidance and, consequently, under what circumstances it is appropriate for use as a hand-held device
- d** Suitability of the device's safety and warning features
- e** Suitability of the intended location for use of a hand-held X-ray set, or if it is to be used at remote locations, a description of how the suitability of each location will be assessed on a case-by-case basis
- f** Arrangements for preventing accidental damage of the device during use, and for ensuring its security when not in use and when being transported (if applicable)
- g** Working methods needed to restrict the dose to the operator, ie maintaining the X-ray beam in the horizontal plane, avoiding placing hands in the X-ray beam, holding the unit at forearm's length from the body, and the practicality of applying these in the working environment in question
- h** Whether there are likely to be special circumstances where the working methods given above will not be practicable; for instance, radiography on patients with restricted head movement, or under sedation or general anaesthesia, or in a care home setting (see Section 2.2)
- i** Based on consideration of items **g** and **h** above, if use of a lead apron, lead gauntlets or any other personal protective equipment will be required
- j** Based on consideration of items **c**, **g** and **h** above, whether a means of remotely initiating exposures is required (see Section 3.3, paragraph **e**)
- k** Decisions regarding the need (or otherwise) to designate operators as classified persons, and the need (or otherwise) for personal dosimetry

The completed risk assessment will identify any further actions necessary to restrict exposure, including the working methods that will be necessary to ensure the radiation safety of all people and compliance with IRR99 during the work. These working methods should be included in the local rules (see Section 4.10).

4.5.1 Potential for radiation exposure from routine work

Effective doses to operators and other people arising from routine work with a hand-held dental X-ray set that is designed, constructed and used in accordance with this guidance, should be less than 0.25 mSv a year, and equivalent doses to the operator's hands should be much less than 10 mSv a year.

Appendix A includes estimates of the likely annual effective and equivalent doses to operators from a number of models tested by PHE. More accurate information on the likely annual effective and equivalent doses received by the operator should be available from the supplier.

4.5.2 Potential for radiation exposure from reasonably foreseeable accidents

Accidents that should be considered to be reasonably foreseeable for hand-held dental X-ray equipment include the following:

- a** Damage to the equipment affecting the shielding
- b** Accidental exposure of a person (other than the patient) to the X-ray beam
- c** Failure of the timer to terminate the exposure after the pre-set time has elapsed
- d** Loss or theft of the equipment

This list is not exhaustive. In common with other forms of dental X-ray diagnostic equipment, it is not usually considered reasonably foreseeable that accidents could give rise to effective doses exceeding 6 mSv, or equivalent doses exceeding 3/10th of the relevant dose limit. However, it should be recognised that accidental doses to the operator from the use of hand-held X-ray equipment could be higher than from traditional equipment under equivalent conditions, due to the proximity of the operator's body and hands to the X-ray beam. For instance, if the operator's hands were accidentally exposed to the main beam at the end of the director cone for 10 seconds in the event of the failure of the timer to terminate the exposure, the equivalent dose to the hands could exceed 30 mSv. Assuming the X-ray beam was not directed towards the operator's body, the effective dose from scattered X-rays under the same conditions should not be more than a few microsieverts.

The findings of the risk assessment with regard to reasonably foreseeable accidents should be incorporated into the contingency plans (see Section 4.11).

4.6 Personal protective equipment (PPE)

If operators use hand-held X-ray equipment designed and constructed to appropriate standards, and following the working procedures recommended in this guidance, the use of PPE should not normally be necessary. Effective doses to employees would be expected to be very low, certainly less than 0.25 mSv a year. Equivalent doses to the hands should similarly be restricted to a small fraction of the statutory dose limit. Where the use of lead aprons is required (for instance, by people supporting or reassuring patients, or where it is necessary for the X-ray beam to depart from the horizontal plane), these must be stored appropriately when not in use. Lead aprons should be hung on rails of sufficiently large diameter to avoid creasing, and should never be folded. Lead gauntlets would only be appropriate in circumstances where there was a risk of the hands being exposed to the X-ray beam, which should only be considered acceptable if the information provided by the radiograph was essential for directing the care of a patient, eg during surgical procedures. It would be necessary to weigh the advantages of the protection provided against any disadvantages; for instance, reduced dexterity. Alternative methods of avoiding exposure of the hands should also be considered; for instance, by the use of long-handled forceps. As far as possible, all these factors should be identified and considered in advance, during the risk assessment process. Each item of PPE should be visually examined at frequent intervals. Thorough examinations for cracks in the protective material should be made annually and the results recorded to assess when PPE should be replaced.

4.7 Designation of areas

Once a hand-held dental X-ray unit is switched on, pressing an 'enable' key followed by pressing the exposure button are often the only actions required to initiate X-rays. In some cases, pressing the exposure button alone is sufficient to trigger an exposure. Therefore, operators are required to follow special procedures to restrict their own exposure and those of anyone else who might be in the vicinity. It follows that, as required by IRR99 regulation 16, a controlled area should always be designated and should be considered to exist whenever the unit's power is switched on. Within the dental practice setting there are two options for designating the controlled area, as follows.

4.7.1 Option A

The whole room is designated as a controlled area during radiography where this is reasonably practicable. This is the preferred approach for hand-held X-ray equipment as the walls of the room physically demarcate the controlled area, access to which can then be more easily restricted.

The following points should be noted:

- a** Access to the controlled area should be restricted by either locking doors or positioning another member of staff outside the door
- b** Use of room warning lights (ie outside each of the surgery entrances) is only practicable for hand-held equipment where the operator can switch the warning lights on and off between periods of radiography

4.7.2 Option B

Where it is impracticable to follow option A, a controlled area could be designated that extends to not less than 1.5 m from the X-ray tube head and patient, and includes the primary beam until suitably attenuated. The operator should restrict access to the area by continuous supervision, be able to see the boundaries of the controlled area and be able to terminate the exposure if someone tries to enter.

Whether option A or B is chosen, no person other than the operator and the patient should remain in the controlled area during an exposure, unless this is necessary to assist or support the patient. In either case the operator's work in the controlled area should be under suitable written arrangements (as part of the local rules) similar to those used for traditional dental X-ray equipment, unless the operator is a classified person (see Section 4.8).

4.7.3 Special cases

Where a hand-held X-ray set will be used at other premises, such as at a care home or patient's private residence, some flexibility of approach will be necessary to take account of the circumstances in each case, while still complying with the requirements of IRR99 with regard to the designation and demarcation of a controlled area, and restriction of access. This is discussed further in Section 4.18 dealing with co-operation between employers. Appendix C provides a form for risk assessments for work on remote sites.

It should not normally be necessary to designate any other areas as either controlled or supervised, outside a controlled area that has been designated in accordance with the guidance above.

4.8 Classified persons

Decisions regarding the designation of persons as classified and the provision of personal dosimetry should be made during the risk assessment process. It is unusual for dental practice staff to be classified, and this should not normally be necessary when hand-held dental X-ray equipment is used, as annual effective doses and doses likely to be received during reasonably foreseeable accidents should be well below 6 mSv, or 3/10th of any relevant equivalent dose limit*.

4.9 Personal dosimetry

Personal dosimetry in the form of whole body dosimeters is appropriate for operators of equipment meeting the recommended design standard (including service engineers and physicists testing the equipment), to ensure that the written arrangements are effective in restricting exposures (IRR99 regulation 18(3)). Owing to the anticipated low annual doses if proper procedures are followed, dosimetry could, if preferred, be provided for an initial trial period. The dosimetry method and wear period should be selected based on the advice of the RPA, and should be capable of determining compliance with the dose investigation level (see Section 4.9.2). If the trial period can establish that doses are adequately restricted, the RPA may advise that continuous monitoring is unnecessary. Any significant changes to workload, equipment or techniques should, however, trigger a review of the risk assessment, including whether a further fixed period or continuous personal monitoring is required.

Work with hand-held dental X-ray equipment that is designed, constructed and used in accordance with this guidance should not require the use of extremity dosimetry. In other circumstances, however, where the use of such equipment while being held in the hands is considered justified (see Section 3.3), extremity dosimetry should be considered as part of the risk assessment in consultation with an RPA. In such cases the RPA may advise that either whole body, extremity or both forms of dosimetry, should be provided on a continuing basis.

4.9.1 Pregnant employees

The effective dose received by an employee working with a model of hand-held equipment that complies with the recommended design standards in Section 3, and used in accordance with this guidance, is expected to be significantly lower than 1 mSv a year. This should be identified as part of the risk assessment process, in which case it can be concluded that the dose to the fetus should also be lower than this level and therefore no special protection measures are necessary. However, the legal person may consider a change of duties, or opt

* European Directive 2013/59/Euratom comes into legal force in the UK on 6 February 2018. Classification of workers will be required if effective doses are likely to exceed 6 mSv a year, or equivalent doses to the lens of the eye exceed 15 mSv a year, or equivalent doses to the skin and extremities exceed 150 mSv a year.

to provide personal dosimetry (and/or the use of a lead apron) for female employees for reassurance purposes, should they wish.

4.9.2 Dose investigation level

The annual effective dose to employees arising from work with a hand-held dental X-ray set meeting the conditions referred to in Section 3.3 should be well below 1 mSv a year. A dose of 1 mSv would therefore be an appropriate value for the dose investigation level required by IRR99 regulation 8(7), as above this level doses are unlikely to be ALARP.

4.10 Local rules

In consultation with the RPA, local rules specifically for the use of hand-held X-ray equipment should be produced. These local rules should describe, for the specific model of X-ray set, the clinical situations for which it would be appropriate to use it in a hand-held fashion, and when (if relevant) it should be used mounted on a tripod or a conventional fixed dental X-ray set be used instead.

The local rules should also include the following items, those highlighted in **bold type** will require special consideration for hand-held dental X-ray equipment:

- a** Description of the extent of the controlled area, and the exact conditions under which it exists
- b** Means of restricting access to the controlled area
- c** Name(s) of the radiation protection supervisor(s) for the dental team (RPSs)
- d** Means of preventing operation of the equipment by unauthorised people (see Sections 3.3 and 4.12)
- e** 'Key working instructions' setting out the safety precautions that the operator must follow to restrict exposures to themselves and other people (these will constitute written arrangements as the operator, who will not usually be a classified person, stands in the controlled area)
- f** Arrangements for ensuring the security of the equipment when not in use, when in transit and when used at other premises (if relevant)
- g** Dose investigation level
- h** Use of personal dosimetry
- i** Circumstances (if any) under which PPE should be used, and what this should comprise
- j** Contingency plans to be followed in the event of accidents, including notifications to be made in the event of high doses to people, and **loss or theft of the unit**

4.11 Contingency plans

Incidents for hand-held dental X-ray equipment that are considered reasonably foreseeable are listed in Section 4.5.2. Items **a** (damage to the equipment affecting the shielding) and **b** (accidental exposure of a person to the X-ray beam) apply to both traditional dental X-ray

equipment and hand-held units and should therefore be included as standard in any local rules.

However, item **c** (failure of the timer to terminate the exposure after the pre-set time has elapsed) requires special consideration of exactly what actions the operator will need to take to remove the power supply as quickly and safely as possible, given the specific design features of the model concerned. Item **d** (loss or theft of the equipment) is not an issue for traditional dental X-ray equipment and will require a new section to be added to the contingency plans of a dental practice obtaining hand-held dental X-ray equipment for the first time.

It should be noted that IRR99 regulation 12(2)(c) states that, where appropriate, the contingency plans should be rehearsed at suitable intervals. This is particularly important for hand-held dental X-ray equipment where the actions required in the contingency plans to deal with cases **c** and **d** differ markedly from those for traditional X-ray equipment. These two cases are discussed in more detail below.

4.11.1 Failure of timer

The contingency plans should address how to quickly prevent any further generation of X-rays, once the incident has occurred. The operator should immediately direct the X-ray beam away from the patient (or any other people) to avoid them receiving excessive radiation doses. With the beam directed safely towards a solid wall or other suitable surface, the operator should attempt to switch off the unit with the power switch. If this does not work, the operator should quickly remove the battery without exposing their hands to the X-ray beam. The prior risk assessment should identify whether or not this is practicable for the model concerned and, if not, identify an alternative method. One possible alternative would be to place the unit on a flat surface with the end of the spacer cone directly against a wall that provides adequate attenuation of the beam, and leave it there until either the X-ray tube fails, or the battery is exhausted, preventing anyone from approaching it in the meantime. Whatever method is identified, any necessary arrangements must be put in place before use of the equipment commences. After dealing with the initial stages of the incident, the operator should immediately inform the legal person who will then (together with the RPS and the RPA) prohibit further use of the device until the cause of the fault has been identified and corrective action taken.

It will then be necessary to consider what, if any, doses were received by the operator and other people as a result of the incident. The likely doses to the operator are discussed in Section 4.5.2. (It is also necessary to consider whether the patient received a dose much greater than intended as a result of equipment failure. This is covered in Section 4.19.) A note should be made of all relevant circumstances of the exposure to assist with estimating the doses actually received by the people concerned. This would normally be done in consultation with the RPA.

In any such cases, it is generally desirable to provide reassurance to the people concerned that the effects of any excessive exposure on their health are likely to be negligible, at an early stage.

4.11.2 Loss or theft of unit

If a device has been lost or stolen, any subsequent exposures are beyond the legal person's control. The only effective means of limiting any subsequent exposure is to prevent loss or theft in the first place, by putting in place the measures described in Section 4.12 to ensure the security of the unit at all times, whether while in use, in transit or in storage.

However, if the device can be recovered quickly, the opportunity for accidental exposure is reduced. Therefore, once the loss or theft of a hand-held device is suspected, a search of the premises should be conducted immediately. If at a remote location such as a care home, the host should be informed immediately and asked to assist in this.

In all cases, if the search is unsuccessful, the legal person should then immediately inform the RPA and the police.

4.12 Security of hand-held dental X-ray equipment

At any time when it is not being used, or under the operator's direct supervision, hand-held dental X-ray equipment should be placed in a secure, locked area to prevent its reasonably foreseeable loss, theft or unauthorised use. While the practice is closed the unit should be stored out of sight in a locked metal or theft-proof cabinet. The battery should also be removed from the main unit if possible and stored separately from it, particularly if the control panel lacks features protecting it against unauthorised operation, such as a PIN.

If the X-ray unit is to be used at other premises, such as a care home, the person transporting the unit will be responsible for ensuring its security en route. The unit must be transported in a way that would not allow an unauthorised person to easily gain access to it, or operate it in the event that it, or any vehicle in which it is transported, is stolen (eg by transporting the unit in a locked metal case). It should only be kept in an unattended vehicle for short times if unavoidable and only if it is out of sight within the vehicle, and the vehicle locked.

4.13 Quality assurance (QA) programme for equipment

As with any equipment used for medical exposures, legal persons are required by IRR99 regulation 32(3) to establish a QA programme, in consultation with a suitable RPA, to ensure that equipment remains capable of the adequate restriction of patient dose. (It should be noted that IRMER also contains extensive QA requirements regarding documentation, details of which are set out in the Dental GNs.)

The QA programme under IRR99 should include the following:

- a** Adequate testing before the first clinical use (commonly known as 'acceptance testing')
- b** Further adequate testing (including in-house checks) at appropriate intervals and following any major maintenance
- c** Representative measurements of patient dose
- d** Remedial and suspension levels for action

- e Preventive maintenance and inspections in accordance with the supplier's recommendations, and simple in-house checks as set out in Section 4.15

4.14 Adequate testing

The tests and performance standards for the adequate testing of traditional intra-oral X-ray equipment are well established and widely understood. As a diagnostic X-ray device there is little to distinguish hand-held X-ray equipment from static X-ray equipment and so all the usual tests and standards that apply to static X-ray equipment apply also to hand-held equipment.

4.14.1 Routine annual testing and tests after repairs or modifications

Hand-held X-ray equipment should be subject to routine testing at suitable intervals. Additional tests should also be carried out following any significant repairs or modifications that may have affected the equipment's performance or radiation output. All the tests carried out at the initial acceptance test should be repeated at the time of all subsequent annual tests, including those aspects of the critical examination listed in Section 4.4.

While it is sufficient to carry out routine tests once every 3 years for traditional dental X-ray equipment, hand-held dental X-ray units should be subject to an annual routine test, due to the greater potential for damage that might impair the shielding of the device, and the higher potential doses to the operator that might result from such damage.

4.15 Maintenance and examination of engineering controls

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

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

- a Equipment warning lights indicating 'power on' and 'X-rays'
- b Equipment audible warning of X-ray exposure
- c Physical condition of the device, especially the backscatter shield (if fitted)
- d Correct functioning of the exposure controls, including any providing protection against unauthorised use

Observing whether or not these features are operating correctly should be a matter of habit for all operators, so that any problems are brought to the immediate attention of the legal person and any necessary action taken. However, it is advisable for routine functional checks to be made, and the results recorded, at intervals not exceeding once every 6 months.

4.16 Information, instruction and training

Dental practice staff (eg dentists, nurses, hygienists and therapists) will need to have their radiation safety training updated following the introduction of hand-held dental X-ray equipment so they have a good understanding of the requirements of the local rules, particularly the acceptable beam directions that provide adequate operator protection, and other actions required to minimise their exposure. Staff not directly involved in radiography should be provided with information sufficient to ensure their continued safety; for instance, the means of restricting access to the rooms where the equipment will be used.

The appointed RPS must be aware of the differences in radiation hazard presented by hand-held dental X-ray units compared to traditional dental X-ray sets, and the reasons underlying the different working arrangements set out in the local rules for use of the equipment.

Details of any in-house training provided in respect of the above should be recorded, as should any formal training; for example, that provided by the supplier.

4.17 Manufacturers and suppliers

Manufacturers and suppliers also have a duty to pass adequate information to the user to enable them to comply with IRR99 and, in particular, regulation 31 in respect of the proper use, testing and maintenance of the equipment.

This information should include the following specific aspects of IRR99 compliance:

- a** Need for testing prior to use (and whether this will be arranged by the supplier)
- b** Need for subsequent annual adequate testing
- c** Recommendation that the client should consult a suitable RPA
- d** Need for routine surveillance checks of the condition of the device (particularly evidence of damage to any backscatter shield or other signs that might indicate the tube head shielding might have been disturbed) and the functioning of the safety and warning features
- e** Advice regarding the safe use of the equipment, particularly with regard to minimising doses to the operator
- f** Indication of the likely annual effective and equivalent doses to the operator, and the basis upon which these were calculated
- g** Schedule for the recommended maintenance and inspection of the equipment

The above information should be provided in writing and included either in the operator's manual for the equipment or in accompanying documentation*. As mentioned earlier, it would be highly desirable for suppliers to provide hand-held equipment that has already passed a suitable test consisting of the elements set out in Section 4.4 of this guidance. Should this information not be available from the supplier, the user should consult their RPA for advice, and make arrangements for the necessary testing.

* Paragraph 11.4.1 of Annexe I of the Medical Devices Directive states that "The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation".

4.18 Co-operation between employers

Where employees undertake work with ionising radiation on another employer's premises, IRR99 require that the different employers co-operate through the exchange of information and in other ways, to ensure that all employees are adequately protected and to enable all the employers involved to comply with the relevant requirements of IRR99. This is important where hand-held dental X-ray equipment is used in locations remote from the dental practice, such as a care home or private dwelling, where the host is unlikely to be a radiation employer.

The dentist visiting the remote location will need to explain to the host that X-ray equipment will be involved, and state the likely doses to staff and other people, and the essential radiation safety precautions to be followed. Ideally this should be done in advance, to enable the host to identify a suitable room for the work, and warn staff of the need to avoid entering the room. The best means of preventing access to the chosen room should be discussed and agreed on a case-by-case basis. If it will not be possible to prevent the host's employees from entering the controlled area, the RPA should be consulted regarding how the work should be managed.

Work with hand-held dental X-ray equipment at other premises should be conducted as follows:

- a** The visiting dentist should make their arrival known to the host and re-iterate the above information
- b** The dentist should then view the proposed room to check it is suitable (eg that it is possible to control access and to avoid directing the X-ray beam at unsuitable barriers such as doors). This is best performed using a template risk assessment which addresses all the pertinent points and provides a record of the assessment. A suggested template risk assessment for this purpose is provided as Appendix C
- c** A copy of the risk assessment and local rules should accompany the equipment at all times when being used off-site

On completion of the work, the dentist should make their departure known to the host so that normal use of the room can recommence.

4.19 Doses to patients much greater than intended

Immediately after an incident in which a patient is suspected of receiving an excessive dose, a note should be made of all relevant circumstances of the exposure to assist with estimating the dose actually received by the patient. As for most other dental X-radiography examinations, a factor of 20 times the intended dose should be used as a guideline for determining whether the exposure was 'much greater than intended', and therefore required to be notified to the HSE in accordance with IRR99 regulation 32(6). The best indicator of the dose delivered is likely to be the exposure time (considered together with other relevant factors such as the patient's position and distance in relation to the X-ray tube). If the patient dose is confirmed as being 'much greater than intended' as a result of the equipment failure, the HSE must be notified forthwith. This can be done by email, to irrnot@hse.gsi.gov.uk. The HSE provides further guidance on 'doses much greater than intended' in Guidance Note PM77, Version 3 (HSE, 2006). In such cases the employer is also encouraged to make use of

the MHRA's online reporting system for adverse incidents involving medical devices known as the 'Yellow Card Scheme'*.

It should be noted that if the exposure is confirmed as much greater than intended but as a result of human factors rather than equipment failure, the notification should be made under the provisions of IRMER regulation 4(5), to the Care Quality Commission (CQC) in England – either by telephone to 020 7448 9025, or by completing the form on the CQC website. Guidance on notifications made to the CQC is currently under review and is expected to be published as a separate document to PM77. Interim guidance is available at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/329842/Medical_exposures.pdf.

The enforcing authorities for IRMER in other parts of the UK are as follows:

Wales – the Healthcare Inspectorate Wales – telephone 0300 062 8163

Scotland – the Scottish Government – telephone 0131 244 2779

Northern Ireland – the Regulation and Quality Improvement Authority – telephone 028 9051 7500

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* See <https://yellowcard.mhra.gov.uk/>.

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Appendix A Results of Tests on Hand-held Dental X-ray Equipment conducted by PHE

A1 Summary of models tested by PHE

Table A1 lists the models of hand-held X-ray equipment that have been tested by PHE and summarises their main features. The tests were either conducted on behalf of suppliers prior to sale or for type testing purposes, or were annual routine tests undertaken on behalf of dental practices. The models have been anonymised for the purposes of this report.

The test results for the Tianjie Dental 'Falcon' are not included here as they were published in summary form in an MHRA medical device alert*. Furthermore, the device is not CE marked, so is not considered to be legitimately available in the UK.

Table A1: Main features of hand-held models tested by PHE

Specification/description	(Nomad) Model A	Model B	Model C	Model D	(Rextar X) Model E
Operating potential (kV)	60	60	60	60	70
Tube current (mA)	2.5	2.0	2.0	2.0	2.0
Exposure time range (seconds)	0.02–1.00	0.01–2.00	0.03–2.00	0.05–1.35	0.01–1.30
Dose rate at end of cone (mGy/s)	3.41	2.38	Not specified	4.90	3.37
Backscatter shield provided?	Yes	No	No	Yes	Yes
Focus to skin distance (mm)	200	200	100	120	205
Beam size: diameter (mm) or width (mm) x height (mm)	34 x 46	60	65	60	35 x 43
Total filtration (mm Al)	1.5	1.8	2.0	1.5	1.5
'Power on' light provided?	Yes	Yes	Yes	Yes	Yes
'X-rays on' light provided?	Yes	Yes	Yes	Yes	Yes
'X-rays on' audible signal provided?	Yes	Yes	Yes	Yes	Yes
Automatic power down/control timeout?	Yes	No	Yes	Yes	Yes

* MHRA (2012). Medical Device Alert: Non CE-marked portable dental X-ray units including the Tianjie Dental 'Falcon' (MDA/2012/046). London, Medicines and Healthcare Products Regulatory Agency. Available at <http://webarchive.nationalarchives.gov.uk/20141205150130/http://mhra.gov.uk/publications/safetywarnings/medicaldevicealerts/con173752> (accessed 18/06/2015).

A2 Results of tests conducted by PHE

Table A2 summarises the estimated annual absorbed doses to the operator's body and hands arising from use of the models in Table A1. The estimated doses are based on measurements of absorbed doses taken at positions in a vertical plane 0.50 m behind the hand-held unit, and at positions representative of the operator's hands, and an assumed workload of 100 radiographs a week for 50 weeks a year. Again, the models have been anonymised for the purposes of this report, and the test results for the Tianjie Dental 'Falcon' are not included.

Table A2: Results of tests on hand-held models conducted by PHE

Feature	(Nomad) Model A	Model B	Model C	Model D	(RextarX) Model E
PHE recommended exposure time for adult mandibular molar radiograph using speed group F film (s)	0.40	0.61	0.29	0.40	0.26
Patient entrance dose corresponding to above exposure time (mGy)	1.17	1.45	1.10	1.93	0.86
Absorbed dose per 0.50 s exposure at operator's body position (nGy)	73	122	461	73	27
Absorbed dose per 0.50 s exposure at operator's hand position (nGy)	160	1,800	10,800	1,700	70
Estimated annual dose at operator's body position (mGy)*	0.10	0.70	1.3	0.30	0.07
Estimated annual dose at operator's hand position (mGy)*	0.62	10.9	31.0	6.80	0.20

* For comparison with the dose constraints recommended in Section 3.2, measurements reported using the quantity air kerma (in units of mGy) are unlikely to underestimate the effective or equivalent dose (in units of mSv).

A2.1 Summary of test results

Models A, D and E complied with the dose constraints recommended in Section 3.3 of the main text. These models were provided with a backscatter shield. It is likely that model B would also have complied if it were fitted with a backscatter shield.

However, models C and D had a focus-to-skin distance (fsd) which was less than the minimum value of 200 mm recommended for equipment operating at 60 kV or above. Use of a longer spacer cone providing an fsd of 200 mm would reduce the patient entrance dose necessary for a radiograph of adequate diagnostic quality, with a proportionate reduction in the annual doses to the operator's body and hands.

In the case of model C this would not be sufficient to meet the recommended constraints on effective and equivalent dose. Model C was supplied with a circular collimator of stated diameter 65 mm, which exceeds the maximum recommended value of 63 mm. However, the X-ray beam at the end of the spacer cone was measured to be 57 mm in diameter.

In the case of model D, provision of an fsd of 200 mm would also have the desirable effect of reducing the patient entrance dose to below the current national diagnostic reference level of 1.7 mGy and increasing the size of the protected zone.

Appendix B Summary of Essential Actions when acquiring a Hand-held Dental X-ray Set

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

The legal person at the dental practice (see Section 1 of the main text) is responsible for making sure that all the following are carried out.

'Done' (✓)	Action/task	Relevant section of this guidance
<input type="checkbox"/>	If starting work with X-ray equipment for the first time, or starting work with X-ray equipment at other premises for the first time, notify the HSE at least 28 days in advance	4.1
<input type="checkbox"/>	Consult a suitable radiation protection adviser (RPA) and medical physics expert (MPE) about the decision to use hand-held dental X-ray equipment, the choice of model and the situations and locations in which it is to be used	2.3, 3.3, 4.2, 4.3, 4.17
<input type="checkbox"/>	Confirm with the equipment supplier, if possible, that the X-ray set will be subject to tests meeting the standards in this guidance, prior to delivery. Alternatively, make arrangements with your RPA and MPE for this to be done before clinical use commences	4.4, 4.14
<input type="checkbox"/>	Draft or revise the radiation prior risk assessment, taking advice from your RPA	4.5 to 4.9 inclusive
<input type="checkbox"/>	Draft or revise the local rules, taking advice from your RPA. Ensure that suitable key working instructions, written arrangements and contingency plans are included	4.10, 4.11
<input type="checkbox"/>	Make suitable arrangements for the security of the unit when not in use and (if applicable) when being transported	4.12
<input type="checkbox"/>	Include the hand-held X-ray equipment in the in-house QA programme, making provision for adequate testing at annual intervals and routine surveillance of the equipment's safety and warning features and general condition	4.13 to 4.15 inclusive
<input type="checkbox"/>	Ensure relevant staff are adequately trained to use hand-held X-ray equipment, including the requirements of the local rules and practical aspects of radiation safety and radiography. Record details of training	4.16
<input type="checkbox"/>	Where the equipment is to be used at other premises, discuss and agree the radiation safety arrangements with the host, as far as possible in advance	4.18, Appendix C

Appendix C Dynamic Risk Assessment for Work with a Hand-held Dental X-ray Set on Remote Premises

Address where hand-held X-ray set is to be used:	
.....	
Date(s) of the work:	
Has the HSE been notified that the equipment is being used at different premises to the dental practice?	YES / NO
If YES , date notification sent to the HSE:
Sketch plan of the room(s) in which X-ray set will be used (<i>include the floor level, dimensions and construction of walls, positions of doors and windows, beam directions, and positions of the operator, patient and any other people during radiography</i>)	<i>[See attached sheet]</i>
Restriction of radiation exposure to the operator	
1 Does the position of the exposure switch allow the operator to keep their hands outside the primary beam at all times?	YES / NO
2 Is the main X-ray beam always directed away from the operator?	YES / NO
3 Does each X-ray set have warning lights that indicate both when power is supplied and when an exposure is taking place?	YES / NO
4 Can the operator see the patient and the equipment warning lights during an exposure?	YES / NO
5 In the event of an incident, can the operator quickly remove the battery without having to position their hands in the primary beam?	YES / NO
6 Is a backscatter shield provided and attached at the far end of the director cone for all radiographic views?	YES / NO
7 Is the X-ray set always used such that the operator is stood directly behind the backscatter shield?	YES / NO
If the answer to any question above is NO, stop and consult your radiation protection adviser (RPA) before commencing radiography	
Restriction of radiation exposure to other people	
8 Describe the arrangements at this location for the safe storage of the hand-held X-ray set when not being used:	
9 When in use, is the X-ray tube head always at least 1.5 m from any unshielded doors, unshielded partition walls and ground floor windows?	YES / NO
10 Is the primary X-ray beam always directed towards a solid or adequately shielded wall or shielded locked door?	YES / NO
11 Can the operator restrict access to the area within 1.5 m of the X-ray set, and within the primary beam until attenuated by a solid or adequately shielded wall or shielded locked door?	YES / NO
If the answer to any question above is NO, stop and consult your RPA before commencing radiography	